

ORGANIZATIONAL STRATEGY DEVELOPMENT FOR THE PHARMACEUTICAL  
INDUSTRY: EVENT STRUCTURE ANALYSIS, COMPARATIVE BOOLEAN  
ANALYSIS, AND ANALOGICAL REASONING MODEL

by

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## ABSTRACT OF THE DISSERTATION

Organizational Strategy Development for the Pharmaceutical Industry: Event Structure

Analysis, Comparative Boolean Analysis, and Analogical Reasoning Model

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This dissertation aims to develop a new direction, in stakeholder management terms, for the pharmaceutical industry to deal with its risks/challenges, particularly in relation to the access to essential, life-saving medicines, posed by its various stakeholders. The organizational strategy development framework of this dissertation is comprised of five phases. The first phase investigates the implications of the stakeholder management perspective for the organizational strategy development in terms of the pharmaceutical industry, examining the concepts, theories, and empirical evidences of extant studies.

The second and third phases present a new analytical approach in stakeholder analysis terms, linking stakeholder analysis with organizational strategy development. The stakeholder analysis of this dissertation is performed by adopting two different types of the formal qualitative analysis - an event structure analysis and a qualitative comparative Boolean analysis – examining 48 major global public health-related cases (which consist of 146 events) from 1987 to 2007. The stakeholder analysis examines: the key stakeholders of the pharmaceutical industry; the circumstances/conditions under which

the pharmaceutical industry has put measures of stakeholder management into practice; and the types of the measures that have been adopted by the pharmaceutical industry to deal with its stakeholders in conjunction with the ability to gain access to essential, life-saving medicines.

The fourth phase constructs an analogical reasoning model for the pharmaceutical industry in comparison with the food and beverage industry. In the last phase, a specific stakeholder management strategy for the pharmaceutical industry is suggested: i.e., the comprehensive, proactive, multi-stakeholder public-private partnership. This strategic option is developed based on the outcomes of the stakeholder analysis combined with those of the analogical reasoning model.

The new strategic direction for the pharmaceutical industry suggested in this dissertation provides an integrated approach to the industry's strategic decision making to satisfy the multiple types of stakeholders simultaneously. It is expected that this new organizational strategy for the pharmaceutical industry can be a useful tool to realize a comprehensive win-win situation: i.e., for the pharmaceutical industry in the stakeholder management terms and for its stakeholders in the access to essential, life-saving medicine terms.

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## Chapter1: Introduction

### 1.1 The Stakeholder Management Perspective and the Pharmaceutical Industry

Many scholars (e.g. Donaldson & Preston [1995]<sup>1</sup>, Quinn & Jones [1995]<sup>2</sup>, Phillips [1997]<sup>3</sup>, Phillips & Reichart [2000]<sup>4</sup>, Reed [2002]<sup>5</sup>, Bailur [2006]<sup>6</sup>) in the fields of business ethics and business and society have added to greatly the understanding of how morality and ethics should play a role in the world of business and the normative stakeholder theory has played a very significant role in this progress. However, it is argued that a stakeholder approach still remains, as Freeman and McVea (2001)<sup>7</sup> contend, a powerful but under-exploited theory of business particularly in connection with a strategy development process. Although “a stakeholder approach is intended to provide a single strategic framework” (Freeman et al, 2001, p. 11)<sup>8</sup>, the review of extant studies reveals that a study which relates a stakeholder approach to an analysis of a strategy development process has been scant. In this respect, the primary purpose of this dissertation is to relate a stakeholder approach to an analysis of a strategy development process. In particular, this dissertation elaborates a new framework to conduct a stakeholder analysis, adopting two different types of formal qualitative analysis, i.e.,

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<sup>1</sup> Donaldson, T., & Preston, L. E. (1995). The Stakeholder Theory of the Corporation: Concepts, Evidence, and Implications. *Academy of Management Review*, 20, 65-91.

<sup>2</sup> Quinn, D. P., Jones, T. M. (1995). An Agent Morality View of Business Policy. *Academy of Management Review*, 20, 22-42.

<sup>3</sup> Phillips, R. (1997). Stakeholder theory and a Principle of fairness. *Business Ethics Quarterly*, 7, 51-66.

<sup>4</sup> Phillips, R. & Reichart, J. (2000). The Environment as a Stakeholder: A Fairness-based Approach. *Journal of Business Ethics*, 23, 185-197.

<sup>5</sup> Reed, D (2002). Employing Normative Stakeholder Theory in Developing Countries. *Business & Society*, 166-207.

<sup>6</sup> Bailur, S. (2006). Using Stakeholder Theory to Analyze Telecenter Projects. *Information Technologies and International Development*, 3, 61-80.

<sup>7</sup> Freeman, R. E. & McVea, J. (2001). A Stakeholder Approach to Strategic Management [Electronic Version]. Darden Graduate School of Business Administration. Retrieved December 10, 2007, from [http://papers.ssrn.com/paper.taf?abstract\\_id=263511](http://papers.ssrn.com/paper.taf?abstract_id=263511)

<sup>8</sup> Ibid.

event structure analysis (ESA) and qualitative comparative Boolean analysis. These two analytical methods are especially appropriate for developing causal interpretations of the historical narrative of events of this dissertation.

It is noted that the stakeholder analysis of this dissertation is conducted in the case of the pharmaceutical industry, since a stakeholder analysis in conjunction with the pharmaceutical industry can prove the usefulness of a stakeholder approach as a tool for an analysis of a strategy development process. In comparison with other industry sectors, the pharmaceutical industry, as several scholars confirms (e.g. Danzon [1997]<sup>9</sup>, Ashcroft [2001]<sup>10</sup>, Danzon & Towse [2003]<sup>11</sup>, Kremer [2004]<sup>12</sup>, Vachani & Smith [2004]<sup>13</sup>, Rosen et al. [2003]<sup>14</sup>, Kennedy et al. [2004]<sup>15</sup>, Mascarenhas et al. [2005]<sup>16</sup>) has been confronted with more social, regulatory, legislative, and judicial challenges for the last two decades. Nevertheless, it is argued that the responses of the pharmaceutical industry to these challenges have not been strategic and innovative, because, today, the industry is still heavily criticized by its various stakeholders, such as NGOs, activist groups, and national governments. The opponents of the pharmaceutical industry argue that the industry has

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<sup>9</sup> Danzon, P. M. (1997). Price discrimination for pharmaceuticals: Welfare effects in the US and the EU. *International Journal of the Economics of Business*, 4, 301-321.

<sup>10</sup> Ashcroft, R. E. (2001). Affordable access to essential medication in developing countries: Conflicts between ethical and economic imperatives. *Journal of Medicine and Philosophy*, 27, 179-195.

<sup>11</sup> Danzon, P. M., & Towse, A. (2003). Differential pricing for pharmaceuticals: Reconciling access, R&D and patents. *International Journal of Healthcare Finance and Economics*, 3, 183-205.

<sup>12</sup> Kremer, M. (2002). Pharmaceuticals and the developing world. *Journal of Economic Perspectives*, 16, 67-90.

<sup>13</sup> Vachani, S., & Smith, C. N. (2004). Socially responsible pricing: Lessons from the pricing of the AIDS drugs in developing countries. *California Management Review*, 47, 117-145.

<sup>14</sup> Rosen, S., Vincent, J. R., MacLeod, W., Fox, M., & Thea, D.M. (2003). AIDS is your business. *Harvard Business Review*, February, 81-87.

<sup>15</sup> Kennedy, C. R., Harris, F. H., & Lord, M. (2004). Integrating public policy and public affairs in a pharmaceutical marketing program: The AIDS pandemic. *Journal of Public Policy and Marketing*, 23, 128-139.

<sup>16</sup> Mascarenhas, O. A., Kesavan, R., & Bernacchi, M. (2005). Global marketing of lifesaving drugs: an analogical model. *Journal of Consumer Marketing*, 22, 404-411.

mainly tried to manage the challenges with symbolic tactics, not with substantial measures, emphasizing the importance of the stringent patent protection of pharmaceutical products to recover the massive R&D investment. With regard to the expected profits for HIV medicines, the former chief executive officer of Merck, Roy Vagelos comments that “world opinion would force the company to waive its patents, write off its research costs, and let anyone sell the magic pills at their production costs” (Washington Post, 2003, p. E1)<sup>17</sup>. Nevertheless, virtually, no extant study which conducts a stakeholder analysis relating it to an analysis of a strategy development process in the case of the pharmaceutical industry exists. Mascarenhas et al. [2005]<sup>18</sup> indicate that several conventional solutions which have been proposed to solve the issues related to the stakeholders of the pharmaceutical industry are “ideological, very general and fraught with a bevy of other problems” (p. 404). Therefore, if this dissertation suggests a new direction, more realizable and workable than the conventional solutions, for the pharmaceutical industry, it can be considered that the stakeholder analysis of this dissertation proves the usefulness of a stakeholder approach as a tool for an analysis of a strategy development process.

It is argued that the pharmaceutical industry should better appreciate the severity of the risks that can have a bad effect upon its business in the long-term. Since the risks which have been posed by the stakeholders of the pharmaceutical industry are, in essence, in conjunction with the global public health, the industry’s adversarial and defensive approaches to the risks (from the stakeholders’ point of view) have created resentment

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<sup>17</sup> Washington Post (2003, July 4). Politics Slows Agreement on Lifesaving Medicines. July 4, E1.

<sup>18</sup> Mascarenhas, O. A., Kesavan, R., & Bernacchi, M. (2005). Global marketing of lifesaving drugs: an analogical model. *Journal of Consumer Marketing*, 22, 404-411.

and distrust of the public against the industry, and, at the same time, have stimulated a negative public affairs reaction against the industry. In addition, the industry's inappropriate responses to the risks and, in some cases, noncompliance, have led to the new industry regulations, raising the industry's total costs of compliance as well as the financial and reputational damages. According to the research conducted by PriceWaterhouseCoopers (2007)<sup>19</sup>, the large multinational pharmaceutical companies have paid a total of more than \$3 billion in regulatory settlements and criminal fines between 2000 and 2006.

The criticisms against the pharmaceutical companies have centered on the issues connected with the global public health, especially in the developing world, such as high drug prices, stringent intellectual property rights protection (i.e. patents) of pharmaceutical products, inappropriate/irrational use of medicines, insufficient research and development into the tropical diseases particularly common in the developing world, and inadequate access to essential, life-saving medicines. Besides, the controversy over the pharmaceutical companies has recently extended to the price and affordability of essential, life-saving medicines in the developed world, particularly in the U.S., caused mainly by the differential pricing policy of the companies. For instance, in the case of the HIV/AIDS medicines, a nation/state specific pricing policies of the pharmaceutical companies have resulted in about ten-fold differential between the highest-prices market

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<sup>19</sup> PriceWaterhouseCoopers (2007). Recapturing the Vision: Integrity driven Performance in the Pharmaceutical Industry [Electronic Version]. Retrieved March 14, 2007, from <http://www.pwc.com/extweb/pwcpublications.nsf/docid/ee74bacb6de454768525702a00630cff>

(i.e. the U.S.) and the price charged in the poorest countries (Kennedy et al., 2004)<sup>20</sup>. In addition, although the criticisms against the pharmaceutical companies have mainly focused on the global HIV/AIDS epidemic, the concerns, today, are becoming more problematic for a wide range of other diseases, affecting both developed and developing countries, such as tuberculosis, heart disease, cancer, and diabetes.

In regard of the access to essential, life-saving medicines, the challenges posed by the stakeholders of the pharmaceutical companies have been increasingly systematic, broad-based, multi-dimensional, and intense. Moreover, the on-going debates over the pharmaceutical companies have been severely intensified by: (1) the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement of the WTO (1994) which revolutionized the international IPRs regime, ensuring the strong patents on pharmaceutical products; (2) the subsequent international agreements which supplement the TRIPS agreement<sup>21</sup>; and (3) the bilateral and regional free trade agreements (FTAs)<sup>22</sup> which secure the more stringent patents on pharmaceutical products with the so-called TRIPS-plus provisions. Today, in both the developing and the developed world, the pharmaceutical industry as a whole is confronted with acute resistance against its traditional business model such as the strong patents on pharmaceutical products and the differential pricing policy, on diverse dimensions (i.e. social, regulatory, legislative, and

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<sup>20</sup> Kennedy, C. R., Harris, F. H., & Lord, M. (2004). Integrating public policy and public affairs in a pharmaceutical marketing program: The AIDS pandemic. *Journal of Public Policy and Marketing*, 23, 128-139.

<sup>21</sup> Namely, the Doha Declaration on the TRIPS Agreement and Public Health – Access to Medicine for All (2001), the proposed Substantive Patent Law Treaty (SPLT) of the World Intellectual Property Organization (WIPO) (2001), and the WTO Decision on Implementation of the Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (2003).

<sup>22</sup> For example, the US-Chile FTA, the US-Peru FTA, the US-Colombia FTA, the US-Australia FTA, the North American Free Trade Agreement (NAFTA), the CAFTA between the US and Central American countries, and the US-South African Customs Union Free Trade Negotiations.



judicial), from its various internal and external stakeholders. In this respect, the former chief executive officer of Merck, Roy Vagelos, comments the following: “world opinion would force the company to waive its patents, write off its research costs, and let anyone sell the magic pills at their production costs....AIDS drugs would put the industry in the middle of a political firestorm” (Washington Post, 2003, p. E1)<sup>23</sup>. It is noted that the risks faced by the pharmaceutical companies are becoming more systematic, collaborative, and broad-based in the global scale.

Although the pharmaceutical industry argues that the expectation of the stakeholders exceeds, in many cases, what is reasonable, it is noted that the pharmaceutical industry cannot carry on any sustainable and profitable business without the trust of its stakeholders such as consumers, non-governmental organizations/activist groups, inter-governmental organizations (IGOs), national governments, investors, and creditors. As Kennedy et al. (2004)<sup>24</sup> point out, the pharmaceutical industry is “heavily dependent on favorable public relations to sustain patent, health care cost reimbursement, and international trade policies that undergird its business model” (p.136). Moreover, although there is no extant empirical study which specifically investigates the relationship between the social and financial performance of the pharmaceutical companies, there is a general evidence to suggest that becoming socially responsible can lead to higher profits for companies. Waddock and Graves (1997)<sup>25</sup> argue that both the

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<sup>23</sup> Washington Post (2003, July 4). Politics Slows Agreement on Lifesaving Medicines. July 4, E1.

<sup>24</sup> Kennedy, C. R., Harris, F. H., & Lord, M. (2004). Integrating public policy and public affairs in a pharmaceutical marketing program: The AIDS pandemic. *Journal of Public Policy and Marketing*, 23, 128-139.

<sup>25</sup> Waddock, S. A., & Graves, S. B. (1997). The Corporate Social Performance – Financial Performance Link. *Strategic Management Journal*, 18, 303-319.

slack resource theory (i.e. financially successful companies simply have more resources to spend on social performance and therefore attain a higher standard) and the good management theory (i.e. better performance along various dimensions of corporate social performance itself results in better financial performance) may be operating simultaneously. Fryxell and Wang (1994)<sup>26</sup> also contend that the social performance of a company is highly correlated with the overall corporate reputation and a halo effect may exist. Since inappropriate actions (from the stakeholders' view point) of a company tend to be more widely reported in the media than good actions, the stakeholders of a company are likely to be heavily influenced by the negative outcomes. Hence, the financial success of a particular company may be attributed to the social factors whether or not such a relationship between the social and financial performance exists. With regard to the pharmaceutical companies, the financial success may also be attributed to the social factors of the companies. Without strategic, effective stakeholder management, the public backlash against the pharmaceutical companies will be growing worse and, thus, the financial damages to the companies can also be growing worse.

Therefore, without question, the pharmaceutical companies should develop strategies through which they can balance their expensive, R&D-intensive business with their global corporate social responsibility. The report produced by Ernest & Young (2002)<sup>27</sup> highlights the importance of a new strategic direction for the pharmaceutical industry, that is: "at no other time in history has it been more important for the pharmaceutical

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<sup>26</sup> Fryxell, G. E., & Wang, J. (1994). The *Fortune* "Reputation" Index: Reputation for What? *Journal of Management*, 20, 1-14.

<sup>27</sup> Pharma Market Letter (2002, December, 23). Ernst & Young's First Ever Global Pharma Report Highlights Key Issues for the Future. December, 23.

industry to shape the public's perceptions and provide a vision for its myriad partners" (Pharma Market Letter, 2002)<sup>28</sup>.

This dissertation aims primarily to develop organizational strategies, in the stakeholder management terms, for the pharmaceutical companies to cope with the risks, essentially in connection with the access to essential, life-saving medicines, posed by their various stakeholders. The concern over the global public health, particularly over the global HIV/AIDS pandemic, has been one of the most controversial agenda in the international arena and the pharmaceutical companies have always been on the center of the concern. Numerous scholars and practitioners have emphasized the crucial role of the pharmaceutical industry in the middle of the global public health crisis, suggesting strategic options for the pharmaceutical companies as well as policy options for the stakeholders of the companies (particularly for the national governments, NGOs, and IGOs such as the WTO and WHO) to resolve the issues related to the global public health. However, it seems that little progress has been accomplished in practice. Both the pharmaceutical industry and its stakeholders have not performed well in terms of the global public health. It is argued that not only the pharmaceutical industry but also its stakeholders should do more to improve the global public health. It is highly noted that the pharmaceutical industry alone, without making a great deal of united effort with its stakeholders, cannot improve the global public health. Nevertheless, the stakeholders of the pharmaceutical industry, in most cases, have just criticized the industry on the global public health crisis. This explains why the pharmaceutical industry needs to develop a

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<sup>28</sup> Pharma Market Letter (2002, December, 23). Ernst & Young's First Ever Global Pharma Report Highlights Key Issues for the Future. December, 23.

new strategic direction in the stakeholder management terms. Now, it is the time for the pharmaceutical industry to give a more careful consideration to the risks it faces. The industry needs to develop strategies that can lead to achieving sustainable and profitable business as well as fulfilling the enlarged, global social responsibility.

It is noted that developing strategies for organizations is necessarily influenced by how the term strategy is defined. In this respect, the strategy concept of Mintzberg (1978)<sup>29</sup> has important implications for this dissertation. Mintzberg defines the term strategy as “a pattern in a stream of decisions” (Mintzberg, 1978, p. 934)<sup>30</sup> and has studied the process of strategy formation<sup>31</sup>. Mintzberg, first, identifies two different strategy types, i.e., ‘intended’ and ‘realized’ strategy, and, then, elaborates further three specific strategy types, i.e., ‘deliberate’, ‘unrealized’, and ‘emergent’ strategy, combining two different strategy types. The strategy concept of Mintzberg enables a researcher to consider two different sides of the organizational strategy development, that is: (1) strategies realized as intended (i.e. deliberate); and (2) strategies realized despite, or in the absence of, intentions (i.e. emergent). In essence, according to Mintzberg (1987)<sup>32</sup>, strategies can form as evolved, a posteriori consistencies, as well as be formulated as intended, a priori guide-lines in decisional behavior. Mintzberg’s definition and classification of strategy operationalize the strategy concept of this dissertation, providing a basis of how strategies can be developed for the pharmaceutical companies. In specific, it is argued that to

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<sup>29</sup>Mintzberg, H. (1978). Patterns in Strategy Formation. *Management Science*, 24, 934-948.

<sup>30</sup> Ibid.

<sup>31</sup> In terms of the organizational strategy development, Mintzberg employs the term ‘formation’, not ‘formulation’, distinguishing the concept of ‘strategy formation’ from that of ‘strategy formulation’ or ‘strategy planning’.

<sup>32</sup> Mintzberg, H. (1987). Crafting strategy. *Harvard Business Review*, July 1, 66-75.

develop strategies for the pharmaceutical companies in the stakeholder management terms, both sides of the strategy development process (i.e. deliberate and emerged strategy) should be examined, because the strategies of the pharmaceutical companies not only have been formulated through a conscious process before specific decisions have been made, but also have formed incrementally, perhaps unintentionally, as decisions have been made one by one.

The strategy concept of Mintzberg also has a close connection with the research methodology of this dissertation. As Mintzberg (1987)<sup>33</sup> maintains, strategies are both plans for the future and patterns from the past and, moreover, strategies need not be deliberate – they can also emerge. For this dissertation, Mintzberg's strategy concept necessitates the study of 'decision streams', in the stakeholder management terms, within the pharmaceutical industry over time periods in order to develop more effective strategies in conjunction with its stakeholders. That is, the empirical studies of data analysis, using two different types of formal qualitative analysis (i.e. the event structure analysis [ESA] and the qualitative comparative Boolean analysis), examine: first, how some strategies of the pharmaceutical industry, in the stakeholder management terms, have formed, perhaps unintentionally, as decisions have been made one by one (i.e. emergent strategy) as well as how other strategies have been formulated (i.e. deliberated); and, second, how the different types of strategies have interplayed. In essence, as Mintzberg (1987)<sup>34</sup> suggests, the strategies for the pharmaceutical companies are 'crafted', not planned, in this dissertation as a new direction for the companies.

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<sup>33</sup> Mintzberg, H. (1987). Crafting strategy. Harvard Business Review, July 1, 66-75.

<sup>34</sup> Ibid.

## **1.2 Research Purpose and the Framework of the Dissertation**

With regard to the stakeholder management perspective, what we need is, as Freeman (1999)<sup>35</sup> emphasizes, not more theory that converges, but more narratives that are divergent that show us different but useful ways to understand organizations in the stakeholder management terms. This Freeman's indication has an important implication for this dissertation. That is, this dissertation aims at, not constructing a new theory in relation to the stakeholder management perspective, but developing a new framework for the organizational strategy development in conjunction with the stakeholder management perspective, particularly in connection with the strategic stakeholder management approach. In other words, the primary purpose of this dissertation is developing strategies, in the stakeholder management terms, for the large multinational pharmaceutical companies that can lead to achieving sustainable and profitable business as well as fulfilling the enlarged, global social responsibility.

For this dissertation, the framework for the strategy development is composed of five phases and each phase has its own specific objective. The objective of the first phase is, above all, examining critically the concepts, theories, and empirical evidences of the stakeholder management perspective through a review of the extant literature in order to figure out the important implications of the stakeholder management perspective for the pharmaceutical companies in terms of the strategy development.

The objective of the second and third phase is performing an empirical stakeholder analysis which can facilitate the actual practice of the stakeholder management

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<sup>35</sup> Freeman, R. E. (1999). Divergent Stakeholder Theory. *Academy of Management Review*, 24, 233-236.

perspective for the companies within the pharmaceutical industry. It is noted that the stakeholder analysis of this dissertation is performed by two different types of the formal qualitative analysis, that is, the ESA and the qualitative comparative Boolean analysis. In specific, the stakeholder analysis examines: (1) to whom (or to what) the pharmaceutical companies have ‘actually’ paid attention, in other words, to the risks posed by whom (or what) the pharmaceutical companies have actually responded, putting the specific measures, such as donations and price reductions, into practice; and (2) the conditions under which the pharmaceutical companies have considered certain entities/institutions as stakeholders, in other words, the circumstances under which the pharmaceutical companies have been forced to employ the specific measures to deal with the risks posed by their stakeholders. In addition, the stakeholder analysis reveals the types of the measures, in the stakeholder management terms, which have been adopted by the pharmaceutical companies to deal with the risks posed by their stakeholders. It is argued that a stakeholder analysis can be used as a best practice template for the pharmaceutical companies to assess what has been done with the stakeholders on the part of the companies and, also, as an analytical tool for the companies to understand who the stakeholders are, their behaviors, and the ways in which they are managed. The stakeholder analysis of this dissertation performed by two different types of the formal qualitative analysis corresponds to the first stage of a stakeholder analysis defined by Freeman. According to Freeman (1984)<sup>36</sup>, the first stage of a stakeholder analysis is to investigate who the stakeholders affected by a project are, their interest, how they behave and why, and what their history is and, then, to undertake a coalition analysis, i.e., how

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<sup>36</sup> Freeman, R. E. (1984). *Strategic management: A stakeholder approach*. Englewood Cliffs, NJ: Prentice-Hall.

they interact with other groups. The stakeholder analysis of this dissertation, first, aims at identifying and examining the (key) stakeholders of the pharmaceutical companies, and, then, assessing what has been done with the stakeholders, namely, the ways in which the stakeholders have been managed on the part of the pharmaceutical companies. If the stakeholder analysis reveals that the stakeholders matter to the pharmaceutical companies in terms of not only fulfilling the enlarged, global social responsibility but also achieving sustainable and profitable business, new, effective strategies should be developed, in the stakeholder management terms, for the companies to deal with their stakeholders.

The objective of the fourth phase is constructing the analogical reasoning model (ARM) in the stakeholder management terms. The outcomes of the ARM combine with those of the stakeholder analysis performed in the second and third phase to develop strategies for the pharmaceutical companies. It is noted that, here, the term ‘combine’ does not mean any simple mixing of the outcomes resulting from different analytical methods. In essence, the stakeholder analysis of this dissertation is tested by the ARM. The ARM is also expected to compensate for some of the weaknesses of the ESA and the qualitative comparative Boolean analysis. An ARM solves “a ‘target problem’ by seeking and evaluating ‘candidate solutions’ from a ‘source industry’ that bears close resemblance to the target industry” (Mascarenhas et al, 2005, p. 404)<sup>37</sup>. In this respect, the ARM developed by Gavetti et al. (2005)<sup>38</sup> is particularly useful for the strategy development for the pharmaceutical industry. Although the pharmaceutical industry has been heavily

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<sup>37</sup> Mascarenhas, O. A., Kesavan, R., & Bernacchi, M. (2005). Global marketing of lifesaving drugs: an analogical model. *Journal of Consumer Marketing*, 22, 404-411.

<sup>38</sup> Gavetti, G., & Rivkin, J. W. (2005, April). How strategies really think: Tapping the power of analogy [Electronic Version]. *Harvard Business Review*. Retrieved March, 2008, from <http://www.eleganthack.com/homepage/archives/How%20Strategists%20Really%20Think.pdf>.



criticized in connection with its traditional business strategies, it has not developed any practical, effective strategies in the stakeholder management terms. It is argued that the ARM of this dissertation can facilitate the pharmaceutical industry to develop any practical, effective strategies, in the stakeholder management terms by examining the strategies of other industry sectors that have been under similar circumstances. The ARM of this dissertation is performed, not only for the purpose of gaining access to the essential, life-saving medicines by those who need them most, but also for the purpose of developing strategies for the pharmaceutical companies in the stakeholder management terms. Therefore, the ARM helps to develop any practicable, effective strategies that can realize a win-win situation for both the pharmaceutical industry and its stakeholders.

The ultimate purpose of this dissertation is to develop new, effective organizational strategies, in the stakeholder management terms, for the pharmaceutical companies to deal with the risks, in connection with the access to essential, life-saving medicines, posed by their stakeholders. In other words, this dissertation aims primarily at suggesting a new strategic direction for the pharmaceutical companies in the stakeholder management terms. Accordingly, the objective of the last phase of the organizational strategy development is developing and suggesting specific stakeholder management strategies for the pharmaceutical companies with which the companies can deal with the risks posed by their various stakeholders. The strategies are developed based on the outcomes of the stakeholder analysis combined with those of the ARM. That is, this dissertation tries to develop strategies for the pharmaceutical companies, seeking to

understand what organizational strategies are needed to manage the stakeholders implicitly or explicitly.

Developing organizational strategies in the stakeholder management terms concerns the strategic stakeholder management approach, an instrumental theory of the stakeholder management perspective, demonstrating that firms that consider their stakeholders can devise successful strategies. The strategic stakeholder management approach has important implications for this dissertation in the strategy development terms. It is argued that the idea of stakeholders or the stakeholder management perspective is useful in providing a tool for an understanding of the contemporary new business environment. However, it is also argued that developing the theory of stakeholder identification and salience or identifying the relationship between the social and financial performance of corporations cannot be the ultimate goal in studying the stakeholder management perspective. The stakeholder management perspective should be put into practice within the actual business environment. In this respect, the stakeholder approach to the strategic management has important implications for firms. This notion corresponds to the second stage of a stakeholder analysis defined by Freeman. According to Freeman (1984)<sup>39</sup>, beyond stakeholder identification will be a second stage of stakeholder analysis - seeking to understand what organizational strategies are needed to manage these stakeholders implicitly and explicitly. Firms need to develop strategies to cope with the pressure from both internal and external stakeholders. The strategies developed in conjunction with the strategic stakeholder management approach can foster friendly relationships with

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<sup>39</sup> Freeman, R. E. (1984). *Strategic management: A stakeholder approach*. Englewood Cliffs, NJ: Prentice-Hall.

stakeholders avoiding the risks to the reputation of firms and, thus, can benefit the firms by working with their stakeholders.

In regard of developing strategies in terms of the strategic stakeholder management approach, Freeman and McVea (2001)<sup>40</sup> argue that the stakeholder management perspective calls for an integrated approach to the strategic decision making and, thus, rather than set strategy stakeholder by stakeholder, managers must find ways to satisfy multiple stakeholders simultaneously. It is noted that the new strategic direction for the pharmaceutical industry suggested in this dissertation is, as Freeman et al. (2001)<sup>41</sup> suggest, an integrated approach to the strategic decision making of the industry to satisfy the multiple types of stakeholders simultaneously rather than set strategy stakeholder by stakeholder. It is also noted that the strategies for the pharmaceutical companies are developed, not from a single region or single country point of view, but from a global perspective, that is, from a pharmaceutical industry-wide, cross-region/cross-country, comparative point of view.

In conclusion, the pharmaceutical companies should consider the stakeholder management perspective in general and the strategic stakeholder management approach in specific in their decision-making processes systematically and strategically, since they can help the companies to develop, select, and implement more effective strategies to deal with the risks posed by their stakeholders. It is argued that the strategic use of the

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<sup>40</sup> Freeman, R. E. & McVea, J. (2001). A Stakeholder Approach to Strategic Management [Electronic Version]. Darden Graduate School of Business Administration. Retrieved December 10, 2007, from [http://papers.ssrn.com/paper.taf?abstract\\_id=263511](http://papers.ssrn.com/paper.taf?abstract_id=263511)

<sup>41</sup> Ibid.

stakeholder management perspective can help the pharmaceutical companies to renew the reputation and the public trust, and to reverse the damages such as the heightened regulation and patent litigation.

## **Chapter 2: Background of the Intense Controversy over the Pharmaceutical Companies**

### **2.1 Globalization, Global Trade, International Trade Agreements, and the Global Public Health**

Globalization is a complex and multidimensional process which can be defined in a variety of ways. However, as Bhagwati (2004)<sup>42</sup> indicates, there is lack of clear, coherent, and comprehensive sense of how globalization works and how it can do better. To understand the nature of globalization more clearly, Langhorne's definition of globalization should be noted. Langhorne (2001)<sup>43</sup> defines globalization as follows:

Globalization is the latest stage in a long accumulation of technological advance which has given human beings the ability to conduct their affairs across the world without reference to nationality, government, time of day or physical environment. These activities may be commercial, financial, religious, cultural, social or political; nothing is barred. Technological advances in global communications have made globalization possible; while the fact of globalization itself is to be seen in the contemporary surge in human activities conducted globally. The effects of these activities on the whole range of humanity's expectations, systems and structures have been and are a heady mixture...They present both opportunities and threats. (p. 2)

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<sup>42</sup> Bhagwati, J. (2004). In defense of globalization. New York, NY: Oxford University Press.

<sup>43</sup> Langhorne, R. (2001). The coming of globalization: Its evolution and contemporary consequences. New York, NY: Plagrave.

The term globalization has become so popular and has been used on a diverse level of meanings. As a result, it is difficult to define globalization with a definite term. However, it is clear that the process of globalization has changed and will change our social, political, economic, and cultural environment both at global and at national level. Here, there is the reason why we should make a special effort to understand globalization. That is, does globalization present new opportunities, or new tensions and anxieties, or both? In general, as Langhorne (2001)<sup>44</sup> points out, it can be argued that globalization has presented both opportunities and threats. However, the process of globalization has been severely criticized by the anti-globalization activists. Especially, many critics have condemned the economic side of globalization, which constitutes integration of national economies into the international economy through trade, long-term direct foreign investments, short-term capital flows, and the international flows of workers and technology. Bhagwati (2004)<sup>45</sup> argues that “globalization is good but not good enough...occasionally, globalization will do harm that requires attention” (p. 32). In this respect, the author further contends that “we must create institutions and policies that either reduce the probability of such downsides or can be triggered so as to cope with them, preferably doing both” (Bhagwati, 2004, p. 32)<sup>46</sup>. Bhagwati’s (2004)<sup>47</sup> argument is very persuasive:

...in these different ways, globalization must be managed so that its fundamentally benign effects are ensured and reinforced. Without this wise management, it is imperiled. I shall also argue that this management will be

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<sup>44</sup> Langhorne, R. (2001). *The coming of globalization: Its evolution and contemporary consequences*. New York, NY: Plagrave.

<sup>45</sup> Bhagwati, J. (2004). *In defense of globalization*. New York, NY: Oxford University Press.

<sup>46</sup> Ibid.

<sup>47</sup> Ibid.

better and more effective if the governments, international institutions, corporations, and intellectuals who celebrate and reinforce globalization joined hands with the non-governmental organizations that generally discount and oppose it, creating what UN Secretary General Kofi Annan calls a partnership, achieving what I call a shared success. (p. 35)

As described above, globalization, particularly its economic side, has been criticized by numerous anti-globalization activists and such criticisms on globalization are in deep connection with this dissertation. That is, the criticisms against globalization have been extended to the issues connected with the global public health, such as the international trade agreements and the global intellectual property rights (IPRs) regime, that have influence on the access to essential, life-saving medicines particularly in the developing world. This dissertation concerns the effects of economic globalization in the global public health terms, specifically in the access to essential, life-saving medicines terms.

It is argued that economic globalization has a complex influence on the global public health. Its effects on the public health in a country are mediated by several factors such as income growth and distribution, political and economic stability (or instability), and the availability of health and other social services. The public health in a country is also affected by the initial conditions of the country such as the size and international specialization of its economy, the availability and distribution of assets, its human capital and infrastructure, and the quality of its domestic policies. Theoretically, as Bhagwati (2004)<sup>48</sup> argues, if properly managed, economic globalization can lead to important gains in connection with the global public health. However, the public health in the developing word, especially in the least developed world, has not been improved much for the last

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<sup>48</sup> Bhagwati, J. (2004). In defense of globalization. New York, NY: Oxford University Press.

two decades, particularly with relation to HIV/AIDS. Therefore, today, there is greater tension than ever before between promoting economic globalization, global trade, and international trade agreements and protecting the global public health. It should be noted that two major aspects of economic globalization, namely, various (i.e. bilateral, regional, and multilateral) international trade agreements and the global IPRs regime which has been introduced and developed through the international trade agreements have been the focal points of the tension, because these two aspects of economic globalization have huge influence on the global public health.

Regardless of supporting or opposing economic globalization, it is hard to deny the fact that global trade and international trade agreements have transformed the capacity of individual nation states to monitor and protect the public health, particularly in terms of the access to essential, life-saving medicines. In other words, economic globalization has reduced the capacity of individual nation states to influence the determinants, status, and outcomes of the public health. Today, the public health of a country cannot be assured by the actions of the country. In this respect, many critics argue that economic globalization is reducing the capacity of national governments to provide the necessities of the public health such as essential, life-saving medicines for their domestic populations. The critics also argue that the cooperation among national governments in relation to the public health has been limited because of economic globalization. Dodgson et al. (2002)<sup>49</sup> illustrate the impacts of globalization on the capacity of individual nation states in the public health terms. First, globalization has introduced or intensified ‘trans-border health

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<sup>49</sup> Dodgson, R., Lee., K., & Drager, N. (2002, February). Global health governance: A conceptual review [Electronic Version]. World Health Organization. Retrieved January 2, 2007 from [http://whqlibdoc.who.int/publications/2002/a85727\\_eng.pdf](http://whqlibdoc.who.int/publications/2002/a85727_eng.pdf)

risks' defined as the "risks to human health that transcend national borders in their origin or impact" (Dodgson et al., 2002, p.7)<sup>50</sup>. Second, the relative authority and capacity of national governments to protect and promote the public health of their domestic populations has declined because of the growth in the number, and in the degree of influence, of the non-state actors in the public health governance. The growth of the non-state actors in terms of power and influence is one of the important characteristics of globalization. Third, "the current forms of globalization appear to be problematic for sustaining, even worsening, existing socioeconomic, political, and environmental problems" (Dodgson et al., 2002, p.8)<sup>51</sup>. The authors argue that the current forms of globalization, based on the neo-liberalism, have widened the gap between the rich and the poor across the globe. Fourth, globalization "has contributed to a decline in both the political and practical capacity of the national governments, acting alone or in cooperation with other states, to deal with global health challenges" (Dodgson et al., 2002, p.8)<sup>52</sup>. The acceleration and intensification of economic globalization, particularly since the late twentieth century, coupled with the initiatives to further liberalize global trade of goods and services have led individual nation states to the situation in which they cannot address, by themselves, many of the public health risks they are facing.

Historically, the global public health has been one of the major concerns in the international arena. Nevertheless, in reality, the measures which have been taken by the powerful actors in the international scene to promote economic globalization have been

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<sup>50</sup> Dodgson, R., Lee, K., & Drager, N. (2002, February). Global health governance: A conceptual review [Electronic Version]. World Health Organization. Retrieved January 2, 2007 from [http://whqlibdoc.who.int/publications/2002/a85727\\_eng.pdf](http://whqlibdoc.who.int/publications/2002/a85727_eng.pdf)

<sup>51</sup> Ibid.

<sup>52</sup> Ibid.



criticized on the ground that these measures have tried to minimize the interference by the global public health matters in global trade. For instance, recently, several multilateral, regional, and bilateral trade agreements have been formed mostly by the leadership of the developed country governments. It is noted that many of these international trade agreements cover a wide range of the global public health-related issues. The critics argue that these international trade agreements impose a particular set of rules which favor business concerns not only over the social and environmental priorities but also over the public health priorities. The critics also argue that these international trade agreements increasingly curtail the right and ability of nation states to determine whether they wish to abide by these trade agreements. Shaffer and Brenner (2004)<sup>53</sup> contend that “trade agreements supersede democratic decision-making by local, regional, and national governments, shifting the power to anonymous trade tribunals to decide which regulations may be permitted to stand” (p. 472). Shaffer et al. (2004)<sup>54</sup> further argue that “at issue is the role that democratically elected public officials and civil society will and should play in determining the rules of trade, and their own policy priorities” (p. 472). Shaffer et al. (2004)<sup>55</sup> point out that the public health professionals and organizations rarely participate in trade negotiations or in the resolution of trade disputes that have implications for the public health. The public health community argues that “trade has raced ahead of corresponding measures to protect health” and, thus, “efforts to ensure that there is an appropriate balance between the two policy areas has

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<sup>53</sup> Shaffer, E. R., & Brenner, J. E. (2004). International trade agreements: Hazards to health? *International Journal of Health Services*, 34, 467-481.

<sup>54</sup> Ibid.

<sup>55</sup> Ibid.

become a difficult challenge” (Lee & Koivusalo, 2005, p.12)<sup>56</sup>. It is argued that the implications of economic globalization for the global public health or the relationships among global trade, international trade agreements, and the global public health deserve more attention among scholars. In this respect, more efforts should be made, on the part of both the public and the private sector, to develop measures which can balance these two policy areas.

In terms of the global public health, international trade agreements have been criticized in that they enforce, extend, and progressively strengthen the intellectual property rules, developing the stringent global IPRs regime. The critics argue that the patents on pharmaceutical products ensured by international trade agreements offer monopoly marketing rights to large, multinational pharmaceutical companies and, thus, the companies exert a tremendous influence over the price of pharmaceutical products excluding the poor patients in the developing world from accessing to essential, life-saving medicines. Since the patents on pharmaceutical products have been one of the focal points of the concerns over the global public health, how the global IPRs regime that has implications for the global public health was introduced and how it has been developed are investigated below.

## **2.2 The Global Intellectual Property Rights (IPRs) Regime represented in Multilateral Trade Agreements and its Implications for the Global Public Health**

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<sup>56</sup> Lee, K., & Koivusalo, M. (2005, January). Trade and health: Is the health community ready for action? [Electronic version]. PLoS Medicine. Retrieved February 15, 2007, from <http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0020008>

Prior to the Uruguay Round, the international governance in the area of the intellectual property rights (IPRs) was weak, because IPRs were not considered as ‘trade-related’ (Schadlen, 2004)<sup>57</sup>. Thus, IPRs were not regulated by the multilateral trade organization such as GATT. However, since the 1980s, the developed world, led mainly by the U.S., began to emphasize the stronger enforcement of a less flexible set of regulations in relation to the IPRs protection. In addition, as Shadlen (2004) comments, the U.S. started to insist on integrating IPRs into the Uruguay Round negotiations to establish a new set of global standards to guide individual countries’ IPRs regimes. That is, IPRs regimes have been harmonized rapidly, on a global scale, driven largely by the developed world. Alsegard (2004)<sup>58</sup> illustrates that “when the Uruguay Round concluded and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) was put into force in 1994 many believed that, although it may have been a step towards reaching a global solution, the TRIPS Agreement was created by a few for the benefit of a few” (p. 13). It should be noted that the patents on pharmaceutical products have been one of the most controversial issues in terms of the global IPRs regime. For the last two decades, there has been a widespread, bitter debate over the access to essential, life-saving medicines, particularly in the developing world, in connection with the stringent patent protection of pharmaceutical products.

In sum, the pharmaceutical industry considers the strong IPRs protection as indispensable to its R&D-intensive, expensive business. Both the pharmaceutical industry and the

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<sup>57</sup> Shadlen, K.C. (2004). Challenges to treatment: The price-infrastructure trap and access to HIV/AIDS drugs. *Journal of International Development*, 16, 1169-1180.

<sup>58</sup> Alsegard, E. (2004). Global pharmaceutical patents after the Doha Declaration – What lies in the future [Electronic version]. *SCRIPT-ed Open License (SOL)*. Retrieved December 25, 2007, from <http://www.law.ed.ac.uk/ahrc/script-ed/docs/doha.asp>

developed world argue that the patent protection facilitates innovation and R&D, and, thereby, improves the overall global health (Anderson, 2006)<sup>59</sup>. In contrast, the developing world has viewed the patent law quite differently. Barton (2004)<sup>60</sup> illustrates that a number of developing countries “deliberately decided to deny patent protection to pharmaceutical products and to grant protection only to processes for producing pharmaceuticals” (p. 147). Barton (2004)<sup>61</sup> further explains that “these countries believe that access to pharmaceutical products is so important that the products themselves should not be patented” (p. 147). It is argued that the fundamental issue in relation to the patents on pharmaceutical products is the imbalance between the rights of the pharmaceutical companies in terms of the IPRs protection and the lack of obligation on the part of the companies in terms of the access to essential, life-saving medicines. Below, how the global IPRs regime that has important implications for the global public health has been developed through multilateral trade agreements is discussed.

### **2.2.1 The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement of the WTO (1994)**

The Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement was adopted by the WTO at the end of the Uruguay Round in 1994 and it came into effect on January 1, 1995. The TRIPS Agreement, which can be considered as one pillar of the WTO, requires all member countries to adhere to the minimum standards of intellectual

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<sup>59</sup> Anderson, A. J. (2006, March). Global pharmaceutical patent law in developing countries – Amending TRIPS to promote access for all [Electronic version]. ExpressO Reprint Series, Working Paper 1052. Retrieved December 24, 2006, <http://law.bepress.com/cgi/viewcontent.cgi?article=5237&context=expresso>

<sup>60</sup> Barton, J. H. (2004). Trips and the global pharmaceutical market. Can the pharmaceutical industry make drugs available to developing countries without compromising its research incentive? *Health Affairs*, 23, 146-154.

<sup>61</sup> Ibid.

property protection including pharmaceuticals as innovative inventions. Based on the TRIPS Agreement, the potential competitors are prohibited from producing and marketing the cheap generic versions of the patented medicines for a twenty-year period, giving the pharmaceutical patent holder a monopoly (i.e. the exclusive marketing rights) on its patented product. Although the TRIPS Agreement was signed in 1994, developing countries were in position to utilize a transitional period until January 2005. In other words, developing countries could benefit of a waiver for applying the TRIPS Agreement. However, as Cicco (2004)<sup>62</sup> argues, the TRIPS Agreement, since its birth, has suffered adverse criticism in connection with its implications for the global public health. For instance, Anderson (2006)<sup>63</sup> argues that “by restricting the right of governments to allow the production, marketing, and import of low-cost copies of patented medicines (called generic drugs), the WTO’s rules will restrict competition, increase prices, and further reduced the already limited access of poor people to vital medicines” (p. 7). Anderson (2006)<sup>64</sup> further argues that “in reality, the twenty-year global patent protection system has created an extremely profitable and powerful group of multinational pharmaceutical companies that by law are allowed to deny access to life-saving medicines” (p. 7).

The TRIPS Agreement can be considered as “the most comprehensive legal regime ever concluded at the multilateral level in the area of intellectual property rights” (Lanoszka,

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<sup>62</sup> Cicco, L. (2004). Patenting drugs from 1st January 2005: Implications and problems. *Health Policy and Development*, 2, 136-143.

<sup>63</sup> Anderson, A. J. (2006, March). Global pharmaceutical patent law in developing countries – Amending TRIPS to promote access for all [Electronic version]. *ExpressO Reprint Series, Working Paper 1052*. Retrieved December 24, 2006, <http://law.bepress.com/cgi/viewcontent.cgi?article=5237&context=expresso>

<sup>64</sup> Ibid.

2003, p. 183)<sup>65</sup>. The TRIPS Agreement establishes the minimum global standards of the IPRs protection and rules for their enforcement. The Agreement covers seven areas of IPRs (i.e. copyrights, trademarks, geographical indications, industrial designs, layout designs for integrated circuits, trade secrets, and patents) and, among these areas, patents have been the most controversial. The critics have argued that “the TRIPS Agreement helps to create the powerful monopolies that control the market for often essential knowledge-based products such as life-saving medicines” (Lanoszka, 2003, p. 182)<sup>66</sup>. In essence, the patents on pharmaceutical products represented in the TRIPS Agreement have been one of the key issues between the North and the South. Lanoszka (2003)<sup>67</sup> maintains that “patents, by design, increase the price of medicines to consumers because they enable pharmaceutical firms to keep prices much higher than their managerial costs of production by discouraging the emergence of competitors” (p. 182).

Although the overall TRIPS Agreement presents the stringent patent protection of pharmaceutical products, it also describes exceptions, implicit and explicit, providing the developing world with the measures to deal with the problem of the inadequate access to essential, life-saving medicines. The World Health Organization (WHO) recommends to developing countries to fully exploit the flexibilities provided by the TRIPS Agreement (Ciccio, 2004)<sup>68</sup>. In particular, Article 31 of the TRIPS Agreement allows for compulsory licensing. By authorizing a compulsory license, a developing country government can

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<sup>65</sup> Lanoszka, A. (2003). The global politics of intellectual property rights and pharmaceutical drug policies in developing countries. *International Political Science Review*, 24, 181-197.

<sup>66</sup> Ibid.

<sup>67</sup> Ibid.

<sup>68</sup> Ciccio, L. (2004). Patenting drugs from 1st January 2005: Implications and problems. *Health Policy and Development*, 2, 136-143.

override the patents on pharmaceutical products. In other words, a compulsory license can be “granted by the competent national authority to allow a third party to manufacture a patented product without the authorization of the right holder” (Matthews, 2004)<sup>69</sup>.

Theoretically, it can be argued that compulsory licensing permits countries to produce generic drugs which are more affordable than the patented medicines. However, the Article 31 also sets out the conditions that must be satisfied before a compulsory license can be granted. In specific, the Article 31(b) requires that “a reasonable period of time is allowed to negotiate a voluntary license with the right holder on the basis of commercial terms” (Ciccio, 2004, p. 137)<sup>70</sup>. In addition, “whenever a compulsory license is awarded, an adequate remuneration for the patent holder is expected to be paid by the government” (Ciccio, 2004, p. 137)<sup>71</sup>. However, the requirements of prior negotiation and adequate remuneration can be waived in the event of national emergencies or other circumstances of extreme urgency. Thus, “compulsory licenses could be granted by a developing country without prior negotiation with the holder of rights to key pharmaceutical patents in the case of a public health crisis of epidemic proportions” (Matthews, 2004, p. 4)<sup>72</sup>. It should be noted that the true limitation which reduces the scope of compulsory licensing is the Article 31(f) of the TRIPS Agreement. According to the Article 31(f), the generic

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<sup>69</sup> Matthews, D. (2004). Is history repeating itself? The outcome of negotiations on access to medicines, the HIV/AIDS pandemic and intellectual property rights in the World Trade Organization. *Law, Social Justice & Global Development Journal (LGD)*, 2004(1), Retrieved March 14, 2007, from [http://www.2.warwick.ac.uk/fac/soc/law/elj/lgd/2004\\_1/Matthews/](http://www.2.warwick.ac.uk/fac/soc/law/elj/lgd/2004_1/Matthews/)

<sup>70</sup> Ciccio, L. (2004). Patenting drugs from 1st January 2005: Implications and problems. *Health Policy and Development*, 2, 136-143.

<sup>71</sup> Ibid.

<sup>72</sup> Matthews, D. (2004). Is history repeating itself? The outcome of negotiations on access to medicines, the HIV/AIDS pandemic and intellectual property rights in the World Trade Organization. *Law, Social Justice & Global Development Journal (LGD)*, 2004(1), Retrieved March 14, 2007, from [http://www.2.warwick.ac.uk/fac/soc/law/elj/lgd/2004\\_1/Matthews/](http://www.2.warwick.ac.uk/fac/soc/law/elj/lgd/2004_1/Matthews/)

version of a patented medicine produced under a compulsory license must be ‘predominantly’ for the domestic market of the country authorizing such use. The term ‘predominantly’ implies that, at least, 51% of the production must be used in the producing country (Ciccio, 2004)<sup>73</sup>. Many critics argued that this limitation had the practical effect of preventing the exports of generic medicines to the countries that do not have sufficient manufacturing capacity to produce essential, life-saving medicines, although the countries with insufficient manufacturing capacity had no choice but to import the medicines. Therefore, during the late 1990s, NGOs and activist groups had criticized the requirements of the TRIPS Agreement, especially the conditions to issue a compulsory license.

### **2.2.2 The Doha Declaration on the TRIPS Agreement and Public Health – Access to Medicine for All (2001)**

Before the 4th Ministerial Conference of the WTO was held in Doha, Qatar in November 2001, two particular cases intensified the disputes over the TRIPS Agreement. In March 2001, the 39 leading multinational pharmaceutical companies, led by the Pharmaceutical Research and Manufacturers of America (PhRMA), challenged the South African patent law (i.e. the Medicines and Related Substances Act) that allowed the South African government to produce or import cheap, generic medicines for HIV/AIDS and other diseases. The lawsuit became public affairs disaster to the pharmaceutical industry and, thus, through an out of court settlement, the pharmaceutical companies, in April 2001, dropped the lawsuit against South Africa. The other case is in connection with Brazil.

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<sup>73</sup> Ciccio, L. (2004). Patenting drugs from 1st January 2005: Implications and problems. *Health Policy and Development*, 2, 136-143.



Namely, the Brazilian patent law, specifically Article 68, Section 689 of the Industrial Patent Law, passed in 1996, proposes the local production of patented medicines within three years of the patent approval. The patent law also proposes that in case the patent holder does not comply, the Brazilian government is entitled to override the patent and allow third-party manufacturing of the product. In addition, for many years, the state-run factories in Brazil had been producing the generic versions of the HIV/AIDS medicines patented before 1996. Thus, finally, in February 2001, the U.S. initiated a complaint to the WTO against Brazil. However, again, the criticism against the U.S. became too much and, thus, in June 2001, on the eve of the U.N. Special Session on HIV/AIDS, the U.S. and Brazil announced a decision to resolve the dispute at the WTO through bilateral negotiations.

Barton (2004)<sup>74</sup> points out that these two disputes “led to international agreements that are based on a compromise that prices should be lower in developing than in developed countries, permitting drug firms to recover their research spending through high prices in the developed world while making products available at lower prices that are near actual production cost to the poor in developing countries” (p. 148). That is, in November 2001, at the 4th Ministerial Conference of the WTO in Doha, Qatar, the WTO member states adopted a ‘Declaration on the TRIPS Agreement and Public Health’. The Doha Declaration acknowledged the concerns of developing countries and, thus, sought to alleviate developing country dissatisfaction with the TRIPS regime. The Doha Declaration delayed the implementation of the patent system provisions for

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<sup>74</sup> Barton, J. H. (2004). Trips and the global pharmaceutical market. Can the pharmaceutical industry make drugs available to developing countries without compromising its research incentive? *Health Affairs*, 23, 146-154.

pharmaceutical products for the least developed countries until 2016 (Fergusson, 2007)<sup>75</sup>. Among other things, the Doha Declaration states that “...TRIPS Agreement does not and should not prevent Members from taking measures to protect public health...the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all” (Ciccio, 2004, p. 138)<sup>76</sup>. The Declaration also affirmed the right of the WTO members to use the flexibilities in the TRIPS Agreement to promote the public health and the access to medicines. Particularly, the Doha Declaration is noted in connection with compulsory licensing. That is: “...paragraph 5 of the Declaration employs the expression “compulsory license” – which is not mentioned in the TRIPS Agreement itself – as an opportunity for any WTO Member, not even limiting the ground to grant it, therefore, each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency where compulsory license can be utilized” (Ciccio, 2004, p. 138)<sup>77</sup>.

Nevertheless, unfortunately, the Doha Declaration failed to resolve whether further exceptions could be made to supply medicines to the countries which lack sufficient manufacturing capacity to make effective use of the compulsory licensing provisions in the TRIPS Agreement. “The basic problem underlying paragraph 6 of the Doha Declaration is that many developing countries lack or have an insufficient capacity to

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<sup>75</sup> Fergusson, I. F. (2007, November). The WTO, intellectual property rights, and the access to medicines controversy. Congressional Research Service [Electronic Version]. Retrieved December 1, 2008, from <http://italy.usembassy.gov/pdf/other/RL33750.pdf>

<sup>76</sup> Ciccio, L. (2004). Patenting drugs from 1st January 2005: Implications and problems. *Health Policy and Development*, 2, 136-143.

<sup>77</sup> Ibid.

manufacture medicines on their own” (Correa, 2002, p. 19)<sup>78</sup>. Thus, many critics argued that once the TRIPS Agreement would become fully operative, many developing countries might face difficulties in acquiring medicines at affordable prices. As Barton (2004)<sup>79</sup> points out, the Doha Declaration left a technical legal problem unsolved. Thus, in an attempt to resolve the issues identified in paragraph 6 of the Doha Declaration, negotiations started immediately among the WTO members, culminating in the WTO Decision in 2003.

### **2.2.3 The WTO Decision on Implementation of the Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (2003)**

Before the 5th Ministerial Conference of the WTO in Cancun, Mexico in September 2003, finding an acceptable ‘expeditious solution’ to the paragraph 6 of the Doha Declaration became a priority. New consultations started again trying to reach a satisfactory solution and, finally, in August 2003, the WTO General Council adopted a Decision entitled ‘Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health’, which was designed to make it easier for poor developing countries that lack domestic manufacturing capacity to import cheaper generic drugs produced under compulsory licenses (Anderson, 2006)<sup>80</sup>. That is, “the Decision provides for a temporary waiver of Members’ obligations under Article 31(f) of the TRIPS

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<sup>78</sup> Correa, C. M. (2002, June). Implications of the Doha Declaration on the TRIPS Agreement and public health [Electronic version]. The World Health Organization (WHO). Retrieved November 15, 2006, from [http://www.who.int/medicines/areas/policy/WHO\\_EDM\\_PAR\\_2002.3.pdf](http://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf)

<sup>79</sup> Barton, J. H. (2004). Trips and the global pharmaceutical market. Can the pharmaceutical industry make drugs available to developing countries without compromising its research incentive? *Health Affairs*, 23, 146-154.

<sup>80</sup> Anderson, A. J. (2006, March). Global pharmaceutical patent law in developing countries – Amending TRIPS to promote access for all [Electronic version]. *ExpressO Reprint Series*, Working Paper 1052. Retrieved December 24, 2006, <http://law.bepress.com/cgi/viewcontent.cgi?article=5237&context=expresso>

Agreement, of the type originally proposed by the US during the paragraph 6 negotiations, until such time as that article is amended” (Matthews, 2004, p. 11)<sup>81</sup>. In other words, the Decision waived Article 31(f) for the exports of pharmaceutical products to the least developed countries and the countries with insufficient manufacturing capacity (Fergusson, 2007)<sup>82</sup>. The pharmaceutical products covered by the Decision include any patented products, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized by paragraph 1 of the Doha declaration (Matthews, 2004)<sup>83</sup>. The Decision was intended to supplement the Doha Declaration by providing clarification of the steps necessary to improve the access to essential, life-saving medicines. However, as Ciccio (2004)<sup>84</sup> contends, the whole procedure represented in the Decision is far from being simple and straightforward, because it requires a number of pre-conditions to be fulfilled. In this respect, the Decision, designed to allow the production and export of generic medicines, has long been criticized by NGOs and activists groups as overly cumbersome and inefficient.

Nevertheless, compulsory licensing has been advanced, particularly after the Decision, as a way for developing countries to improve the access to essential, life-saving medicines.

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<sup>81</sup> Matthews, D. (2004). Is history repeating itself? The outcome of negotiations on access to medicines, the HIV/AIDS pandemic and intellectual property rights in the World Trade Organization. *Law, Social Justice & Global Development Journal (LGD)*, 2004(1), Retrieved March 14, 2007, from [http://www.2.warwick.ac.uk/fac/soc/law/elj/lgd/2004\\_1/Matthews/](http://www.2.warwick.ac.uk/fac/soc/law/elj/lgd/2004_1/Matthews/)

<sup>82</sup> Fergusson, I. F. (2007, November). The WTO, intellectual property rights, and the access to medicines controversy. Congressional Research Service [Electronic Version]. Retrieved December 1, 2008, from <http://italy.usembassy.gov/pdf/other/RL33750.pdf>

<sup>83</sup> Matthews, D. (2004). Is history repeating itself? The outcome of negotiations on access to medicines, the HIV/AIDS pandemic and intellectual property rights in the World Trade Organization. *Law, Social Justice & Global Development Journal (LGD)*, 2004(1), Retrieved March 14, 2007, from [http://www.2.warwick.ac.uk/fac/soc/law/elj/lgd/2004\\_1/Matthews/](http://www.2.warwick.ac.uk/fac/soc/law/elj/lgd/2004_1/Matthews/)

<sup>84</sup> Ciccio, L. (2004). Patenting drugs from 1st January 2005: Implications and problems. *Health Policy and Development*, 2, 136-143.

As described in detail below (in Chapter 5), several developing countries have announced their intention to issue compulsory licenses. However, compulsory licensing has not helped developing countries much in terms of the access to essential, life-saving medicines. Fergusson (2007)<sup>85</sup> argues that “a system of compulsory licensing may have a relatively modest effect on the availability of medicines in the developing world” (p. 6) on the ground that about 10% of the problem of the access to medicines in developing countries has been solved by the actions of the WTO. Although the issues such as the inadequate distribution system of medicines and the lack of trained personnel to administer medicines in the developing world hinder the effective use of compulsory licensing, the restrictions represented in the Decision such as special packaging and notification requirements also create an obstacle to issuing compulsory licenses on the part of developing countries.

In conclusion, there is a great need to clarify the global IPRs regime to achieve not only to protect the patents on pharmaceutical products but also to promote the global public health in terms of the access to essential, life-saving medicines. In other words, the framework of the TRIPS Agreement needs to be amended to create clearer global IPRs regime that can balance the patents on pharmaceuticals with the public health. However, it is argued that in addition to multilateral trade agreements such as the TRIPS Agreement, the IPRs provisions represented in bilateral and regional free trade agreements (FTAs) are considered as another challenge in connection with the access to essential, life-saving medicines. Thus, the implications of the TRIPS-plus provisions

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<sup>85</sup> Fergusson, I. F. (2007, November). The WTO, intellectual property rights, and the access to medicines controversy. Congressional Research Service [Electronic Version]. Retrieved December 1, 2008, from <http://italy.usembassy.gov/pdf/other/RL33750.pdf>

represented in bilateral and regional FTAs for the global public health are discussed below.

### **2.3 The IPRs Provisions represented in Bilateral and Regional Free Trade Agreements (FTAs) and their Implications for the Global Public Health**

With regard to the impacts of the patents on pharmaceutical products upon the global public health, particularly in the access to essential, life-saving medicines terms, it is argued that the focus of the controversy has been shifted from multilateral trade agreements to bilateral and regional free trade agreements (FTAs). NGOs and activist groups argue that these FTAs have added to the traditional patent rights another form of protection which has influence on the access to essential, life-saving medicines. Roffe and Spennemann (2006)<sup>86</sup> describe that “prominent actors have voiced the concern that provisions on intellectual property rights (IPRs) in FTAs that go beyond the TRIPS minimum standards (‘TRIPS-plus’) have serious impact on countries’ public health policies” (p. 76). Thus, Roffe et al. (2006)<sup>87</sup> argue that “the widely-shared concern is that developing countries by signing the TRIPS-plus FTAs risk losing the very flexibilities they are granted through the TRIPS Agreement, the Doha Declaration and its implementing decision” (p. 77).

The developed world, which is represented by the U.S., Japan, the E.U. and the countries of the European Free Trade Association (EFTA), has been active in the negotiation of FTAs. These FTAs have been negotiated outside the WTO and, in general, require higher

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<sup>86</sup> Roffe, P., & Spennemann, C. (2006). The impact of FTAs on public health policies and TRIPS flexibilities. *International Journal of Intellectual Property Management*, 1, 75-93.

<sup>87</sup> Ibid.

levels of IPRs protection for medicines than those mandated by the TRIPS Agreement. It is noted that some FTAs require even higher levels of IPRs protection than those required in developed countries, emphasizing the stringent IPRs protection for pharmaceutical products. In other words, the additional standards of IPRs protection represented in the TRIPS-plus rules in these FTAs have significant implications for the access to medicines.

That is, first, the FTAs, especially promoted by the U.S., try to extend the patent monopolies in connection with the administrative delays by patent offices and drug regulatory authorities (Oxfam International, 2006)<sup>88</sup>. Correa (2006)<sup>89</sup> criticizes that the extension of the patent term under FTAs (i.e. the term longer than 20 years required by the TRIPS Agreement) would have the effect of making the public pay for any administrative delays while generating an increased flow of payments to the pharmaceutical companies that can hardly be justified by any additional benefits to the patients in developing countries.

Second, the FTAs enhance the protections for the clinical trial data by providing at least five years of marketing exclusivity for the data (Oxfam International, 2006)<sup>90</sup>. Namely, the FTAs oblige the parties to grant the exclusive rights for at least five years counted

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<sup>88</sup> Oxfam International (2006, November). Patents versus patients: Five years after the Doha Declaration [Electronic version]. Retrieved April 13, 2007, from [http://www.oxfamamerica.org/newsandpublications/publications/briefing\\_papers/patents\\_patients/Doha5\\_Final\\_paper\\_101106\\_2.pdf](http://www.oxfamamerica.org/newsandpublications/publications/briefing_papers/patents_patients/Doha5_Final_paper_101106_2.pdf)

<sup>89</sup> Correa, C. M. (2006, May). Implications of bilateral free trade agreements on access to medicines [Electronic version]. Bulletin of the World Health Organization. Retrieved March 15, 2007, from <http://www.scielosp.org/scielo.php?script=arttext&pid=S0042-96862006000500021>

<sup>90</sup> Oxfam International (2006, November). Patents versus patients: Five years after the Doha Declaration [Electronic version]. Retrieved April 13, 2007, from [http://www.oxfamamerica.org/newsandpublications/publications/briefing\\_papers/patents\\_patients/Doha5\\_Final\\_paper\\_101106\\_2.pdf](http://www.oxfamamerica.org/newsandpublications/publications/briefing_papers/patents_patients/Doha5_Final_paper_101106_2.pdf)

from the date of approval of the product, irrespective of whether it is patented or not and, in most cases, of whether the data are undisclosed or not. In addition, such exclusivity would apply irrespective of whether the national health authority requires the submission of the data or not and covers chemical entities that are not ‘new’ as they might have been previously approved in other territories (Correa, 2006)<sup>91</sup>.

Third, the U.S. FTAs link drug registration to patent status, thereby preventing registration and the sale of generic medicines during the patent term (Oxfam International, 2006)<sup>92</sup>. This linkage between drug registration and patent protection is absent in the TRIPS Agreement. Correa (2006)<sup>93</sup> argues that “the patent-registration linkage goes beyond the standards applied in the USA and the EU” (p. 8).

Fourth, in some FTAs, the possibility of parallel importing of medicines has been limited by permitting the patent owner to prevent parallel imports through the use of contract or other means (Correa, 2006)<sup>94</sup>. For instance, “the U.S.-Singapore FTA ‘enhances the ability of patent owners to prohibit international exhaustion’ by requiring the U.S. and Singapore to institute measures that enable patent holders to block parallel importation into these two markets” (p. 19). This provision can be considered as the case of TRIPS-

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<sup>91</sup> Correa, C. M. (2006, May). Implications of bilateral free trade agreements on access to medicines [Electric version]. Bulletin of the World Health Organization. Retrieved March 15, 2007, from <http://www.scielo.org/scielo.php?script=arttext&pid=S0042-96862006000500021>

<sup>92</sup> Oxfam International (2006, November). Patents versus patients: Five years after the Doha Declaration [Electronic version]. Retrieved April 13, 2007, from [http://www.oxfamamerica.org/newsandpublications/publications/briefing\\_papers/patents\\_patients/Doha5\\_Final\\_paper\\_101106\\_2.pdf](http://www.oxfamamerica.org/newsandpublications/publications/briefing_papers/patents_patients/Doha5_Final_paper_101106_2.pdf)

<sup>93</sup> Correa, C. M. (2006, May). Implications of bilateral free trade agreements on access to medicines [Electric version]. Bulletin of the World Health Organization. Retrieved March 15, 2007, from <http://www.scielo.org/scielo.php?script=arttext&pid=S0042-96862006000500021>

<sup>94</sup> Ibid.



plus, because the TRIPS Agreement leaves it to countries to regulate parallel importation under their national laws. The U.S. FTAs with Australia and Morocco also limit parallel importing by authorizing the patent owner to prevent parallel importing through the use of contract or other means (Roffe et al., 2006)<sup>95</sup>.

Lastly, with regard to FTAs, compulsory licensing should be discussed. It is argued that compulsory licensing is a crucial way of introducing the generic competition and, thus, reducing drug prices. The TRIPS Agreement gives governments complete freedom to determine the grounds for using compulsory licensing including the need to address the public health problems (Oxfam International, 2003)<sup>96</sup>. A compulsory license allows the production or importation of a generic medicine without the consent of the patent holder, although the patent holder receives adequate compensation. It is noted that compulsory licenses may be issued by governments for various reasons including, but not limited to, addressing the public health or other types of emergencies (MSF, 2004)<sup>97</sup>. That is, compulsory licenses are explicitly permitted under the TRIPS Agreement and there is no restriction on the conditions for the use of compulsory licensing. “The Doha Declaration on TRIPS and Public Health, adopted by all WTO Members in 2001, confirmed that countries have the freedom to determine the grounds upon which such licenses are

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<sup>95</sup> Roffe, P., & Spennemann, C. (2006). The impact of FTAs on public health policies and TRIPS flexibilities. *International Journal of Intellectual Property Management*, 1, 75-93.

<sup>96</sup> Oxfam International (2003, November). Robbing the poor to pay the rich? How the United States keeps medicines from the world's poorest [Electronic Version]. Retrieved December 1, 2008, from [http://www.oxfam.org.uk/resources/policy/health/downloads/bp56\\_medicines.pdf](http://www.oxfam.org.uk/resources/policy/health/downloads/bp56_medicines.pdf)

<sup>97</sup> Médecins Sans Frontières (2004, May). Access to medicines at risk: What to watch out for in free trade agreements with the United States [Electronic Version]. Retrieved November 1, 2008, from [http://www.twinside.org.sg/title2/FTAs/Intellectual\\_Property/IP\\_and\\_Access\\_to\\_Medicines/AccessToMedicinesAtRiskAcrossTheGlobe-WhatToWatchOutForMSF.pdf](http://www.twinside.org.sg/title2/FTAs/Intellectual_Property/IP_and_Access_to_Medicines/AccessToMedicinesAtRiskAcrossTheGlobe-WhatToWatchOutForMSF.pdf)

granted” (MSF, 2004, p. 8)<sup>98</sup>. However, as opposed to the TRIPS Agreement, the U.S. FTAs with Australia, Jordan, Singapore, and Vietnam limit the grounds for the use of compulsory licenses to the cases of anti-competitive practices, public non-commercial use, national emergency or other circumstances of extreme urgency (Roffe et al., 2006)<sup>99</sup>. NGOs and activist groups argue that the limitations on the use of compulsory licensing would restrict the access to essential, life-saving medicines.

## **2.4 Trade versus the Global Public Health: The Implications for the Pharmaceutical Companies**

As discussed above, globalization, global trade, international trade agreements, and the public health are linked. Global trade and international trade agreements have transformed the ability of national governments to protect the public health and to ensure the access to essential, life-saving medicines. That is, as Lee et al. (2005)<sup>100</sup> maintain, it is argued that although protecting the public health has been a clear aim, in reality, the primary task has been to minimize the interference by the public health matters in international trade. Today, there is intense debate on international trade agreements in conjunction with the global public health and the debate focuses on the value of the stringent patent protection of pharmaceutical products, represented in international trade

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<sup>98</sup> Médecins Sans Frontières (2004, May). Access to medicines at risk: What to watch out for in free trade agreements with the United States [Electronic Version]. Retrieved November 1, 2008, from [http://www.twinside.org.sg/title2/FTAs/Intellectual\\_Property/IP\\_and\\_Access\\_to\\_Medicines/AccessToMedicinesAtRiskAcrossTheGlobe-WhatToWatchOutForMSF.pdf](http://www.twinside.org.sg/title2/FTAs/Intellectual_Property/IP_and_Access_to_Medicines/AccessToMedicinesAtRiskAcrossTheGlobe-WhatToWatchOutForMSF.pdf)

<sup>99</sup> Roffe, P., & Spennemann, C. (2006). The impact of FTAs on public health policies and TRIPS flexibilities. *International Journal of Intellectual Property Management*, 1, 75-93.

<sup>100</sup> Lee, K., & Koivusalo, M. (2005, January). Trade and health: Is the health community ready for action? [Electronic version]. *PLoS Medicine*. Retrieved February 15, 2007, from <http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0020008>

agreements, amid the global public health crises. Shaffer et al. (2005)<sup>101</sup> argue that “trade agreements enforce, extend, and progressively strengthen intellectual property rules internationally, such as patents that offer monopoly marketing rights to pharmaceutical companies which therefore exert tremendous influence over prices” (p. 7). The authors further argue that “trade rules, including intellectual property rules, can discourage the production of generic equivalents and the distribution of essential medicines in developing countries” (Shaffer et al., 2005, p. 7)<sup>102</sup>. It is clear that international trade agreements, in terms of the global IPRs regime, raised fundamental questions for policy makers and the public about how the public health can be improved attaining sustainable economic development.

In particular, the recent bilateral and regional FTAs which ensure the strong IPRs protection through the TRIPS-plus provisions have intensified the debate over international trade agreements. Shadlen (2004)<sup>103</sup> contends that “developing countries often found themselves subject to penalties not for violating TRIPS, or for being too slow in making their IPR regimes TRIPS-compliant, but rather for using the flexibilities that TRIPS formally preserves - for not adapting ‘TRIPS-Plus’ regimes” (p. 87). Namely, it is argued that the FTAs have strengthened the position of the pharmaceutical companies risking the flexibilities represented in the TRIPS Agreement confirmed by the Doha Declaration and the Decision of the WTO. Roffe et al. (2006)<sup>104</sup> comment that “one

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<sup>101</sup> Shaffer, E. R., Waitzkin, H., Brennier, J., & Jasso-Aguilar, R. (2005). Global trade and public health. *American Journal of Public Health*, 95, 23-34.

<sup>102</sup> Ibid.

<sup>103</sup> Shadlen, K.C. (2004). Challenges to treatment: The price-infrastructure trap and access to HIV/AIDS drugs. *Journal of International Development*, 16, 1169-1180.

<sup>104</sup> Roffe, P., & Spennemann, C. (2006). The impact of FTAs on public health policies and TRIPS flexibilities. *International Journal of Intellectual Property Management*, 1, 75-93.

worrisome recent development has been the shift of the discussion away from the multilateral level to the regional and bilateral arena, where a number of post-TRIPS Free Trade Agreements (FTAs) have been signed” (p. 86). Numerous NGOs and activist groups have criticized FTAs arguing that FTAs would have severe consequences on the public health in the developing world, because the enforcement of FTAs in the developing world would increase the price of new medicines and the higher price would remain over time restricting the access to essential, life-saving medicines. In addition, the critics have argued that FTAs would severely restrict the issuance of compulsory licensing on the part of developing countries and would also restrict the generic competition reducing the access to medicines.

In this respect, the pharmaceutical industry has been severely pressed by its stakeholders. It is noted that although the pharmaceutical industry itself is not a party of international trade agreements, it has been under the pressure of its stakeholders because it has exercised its influence over the developed country governments, particularly over the U.S., in relation to international trade agreements. NGOs, activist groups, the developing country governments, and the civil society have argued that the intellectual property provisions should be excluded from bilateral and regional trade agreements to protect the public health and to guarantee the access to essential, life-saving medicines. On the contrary, for the pharmaceutical industry, it is also noted that the support for the strong patent protection of pharmaceutical products by the developed country governments is not all clear. As illustrated in detail below, when the anthrax (Cipro) incident occurred in

2001, in other words, when the national security interests were at stake, the U.S. government turned quickly on the pharmaceutical industry.

Therefore, the pharmaceutical industry should develop strategies to deal with the challenges posed by its stakeholders. In other words, the pharmaceutical industry should find a new direction to balance its expensive, R&D-intensive business with its global social responsibility in connection with the access to essential, life-saving medicines. It is argued that the pharmaceutical companies should incorporate the stakeholder management perspective into its marketing strategies.

### **Chapter 3: The Stakeholder Management Perspective and its Implications for the Organizational Strategy Development for the Pharmaceutical Companies**

#### **3.1 The Historical Background of the Stakeholder Management Perspective**

The stakeholder management perspective has its origins in management literature (Bailur, 2006)<sup>105</sup>. Preston et al. (1990)<sup>106</sup> trace the notion of stakeholder back to the time when E. M. Dodd quoted the views of General Electric executives and others in his statement in 1932 that identified four major stakeholder groups, i.e., shareholders, employees, customers, and the general public. On the other hand, Freeman (1984)<sup>107</sup> traces the term stakeholder back to the research conducted by the Stanford Research Institute (SRI) in

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<sup>105</sup> Bailur, S. (2006). Using Stakeholder Theory to Analyze Telecenter Projects. *Information Technologies and International Development*, 3, 61-80.

<sup>106</sup> Preston, L. E., & Sapienza, H. J. (1990). Stakeholder Management and Corporate Performance. *Journal of Behavioral Economics*, 19, 361-375.

<sup>107</sup> Freeman, R. E. (1984). *Strategic management: A stakeholder approach*. Englewood Cliffs, NJ: Prentice-Hall.

1963. The SRI defines stakeholders as “those groups without whose support the organization would cease to exist” (Freeman, 1984, p. 31)<sup>108</sup>. The concept of stakeholder approach was popularized by R. E. Freeman. That is, the stakeholder management perspective started to gain widespread acceptance from the academia with the publication of Freeman’s ‘Strategic Management: A Stakeholder Approach’ in 1984. The book brought the stakeholder theory into the mainstream of management literature. It is noted that Freeman (1984)<sup>109</sup> widened the definition of stakeholder to include “any group or individual who can affect or is affected by the achievement of the organization’s objectives” (p. 46). Freeman (1984)<sup>110</sup> argues that the traditional view of a firm is a perspective based on process and this perspective cannot explain the complex interaction between different interest groups in a firm. Freeman (1984)<sup>111</sup>, instead, suggests a managerial perspective identifying four key stakeholder groups of a firm such as owners, customers, employees, and suppliers. A further set of stakeholder groups are added to these key stakeholder groups and it includes governments, competitors, consumers, advocates, environmentalists, special interest groups, and the media. Freeman’s early work already exhibited how the notion of stakeholder management is broad and complicated. Nevertheless, Stoney et al. (2001)<sup>112</sup> comment that, by Freeman (1984)<sup>113</sup>, “a clear and fundamental juxtaposition was made between serving the needs of shareholders through dividend maximization, and serving the needs of a wider

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<sup>108</sup> Freeman, R. E. (1984). *Strategic management: A stakeholder approach*. Englewood Cliffs, NJ: Prentice-Hall.

<sup>109</sup> Ibid.

<sup>110</sup> Ibid.

<sup>111</sup> Ibid.

<sup>112</sup> Stoney, C., & Winstanley, D. (2001). Stakeholding: Confusion or Utopia? Mapping the Conceptual Terrain. *Journal of Management studies*, 38, 603-626.

<sup>113</sup> Freeman, R. E. (1984). *Strategic management: A stakeholder approach*. Englewood Cliffs, NJ: Prentice-Hall.

constituency of stakeholders” (p. 604). The authors further indicate that “Freeman’s work has been a catalyst for economists and business strategists to discuss the academic validity of the stakeholding concept...and it has also provided a focal point for business ethics to debate its moral and epistemological significance” (Stoney et al., 2001, p. 604)<sup>114</sup>.

Freeman’s landmark book (1984)<sup>115</sup> induced numerous conceptual and theoretical studies of the stakeholder management perspective. Namely, since Freeman’s early work, many scholars have explored the stakeholder management perspective, and their investigations into the stakeholder management perspective can be classified into the following five major categories: (1) how to define and identify stakeholders; (2) how to define and use the stakeholder related variables; (3) how to balance the competing demands of various stakeholders; (4) how to measure the business performance with the stakeholder related variables; and (5) how to relate the stakeholder management perspective to the organizational strategy development. In addition, since Freeman’s early work, there has been much contention over the theoretical underpinnings of the stakeholder management perspective. In specific, three theories of the stakeholder management perspective (i.e. empirical/descriptive, normative/moral, and instrumental theory) have been identified.

However, it is noted that little empirical study, except for investigating the relationship between corporate social performance (CSP) and corporate financial performance (CFP),

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<sup>114</sup> Stoney, C., & Winstanley, D. (2001). Stakeholding: Confusion or Utopia? Mapping the Conceptual Terrain. *Journal of Management studies*, 38, 603-626.

<sup>115</sup> Freeman, R. E. (1984). *Strategic management: A stakeholder approach*. Englewood Cliffs, NJ: Prentice-Hall.

which can facilitate the actual practice of the stakeholder management perspective for firms, has been conducted. In particular, for the pharmaceutical companies, virtually no empirical study has been done in conjunction with the stakeholder management perspective. Consequently, an empirical study which develops organizational strategies for the pharmaceutical companies in the stakeholder management terms does not exist. As seen from the recent debate between Kennedy et al. (2004)<sup>116</sup> and Calfee et al. (2004)<sup>117</sup>, for the pharmaceutical companies, apart from the actual implementation of the stakeholder management perspective, even the fundamental question of whether or not the stakeholder management perspective is applicable to the pharmaceutical industry is highly controversial. In this respect, the review of the extant studies is crucial to achieve the primary purpose of this dissertation (i.e. developing strategies for the pharmaceutical companies in the stakeholder management terms), providing important theoretical bases for this dissertation.

### **3.2 The Development of the Stakeholder Management Perspective**

#### **3.2.1 Defining and Identifying the Stakeholders of Firms**

One of the fundamental and key issues in the stakeholder management perspective has been how to identify the stakeholders of a firm, i.e., who are the relevant stakeholders of a corporation? Basically, the identification of stakeholders is based upon how to define

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<sup>116</sup> Kennedy, C. R., Harris, F. H., & Lord, M. (2004). Integrating public policy and public affairs in a pharmaceutical marketing program: The AIDS pandemic. *Journal of Public Policy and Marketing*, 23, 128-139.

<sup>117</sup> Calfee, J. E., & Bate, R. (2004). Pharmaceuticals and the Worldwide HIV Epidemic: Can a Stakeholder Model Work? *Journal of Public Policy & Marketing*, 23, 140-152.



stakeholders. As described earlier, Freeman (1984)<sup>118</sup> defines a stakeholder as “any group or individual who can affect or is affected by the achievement of the organization’s objectives” (p. 46), and identifies four key stakeholder groups of a firm, adding a further set of stakeholder groups to them. It is noted that Freeman’s definition of stakeholders, as Berman et al. (1999)<sup>119</sup> indicate, suggests “a two-way relationship between a firm (that is, its management) and its stakeholders” (p. 491). That is, based on Freeman’s definition of stakeholders, the stakeholder management perspective can be seen in two ways: first, if stakeholders can affect the achievement of a firm’s objectives, the firm’s decisions and financial performance are affected by the activities of its stakeholders and, thus, the stakeholders should be managed instrumentally on the part of the firm to maximize its profits; and, second, if stakeholders are affected by the achievement of a firm’s objectives, the firm’s decisions affect the well-being of its stakeholders and, thus, the managers of the firm may feel moral obligation to its stakeholders that grounds the firm’s decisions. In essence, Freeman’s definition of stakeholders may be construed as suggesting the validity of both the instrumental and normative/moral approach of the stakeholder management perspective.

Clarkson (1995)<sup>120</sup> defines stakeholders as “persons or groups that have, or claim, ownership, rights, or interests in a corporation and its activities, past, present, or future”

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<sup>118</sup> Freeman, R. E. (1984). *Strategic management: A stakeholder approach*. Englewood Cliffs, NJ: Prentice-Hall.

<sup>119</sup> Berman, S. L., Wicks, A. C., Kotha, S., & Jones, T.M. (1999). Does stakeholder orientation matter? The relationship between stakeholder management models and firm financial performance. *Academy of Management Journal*, 42, 488-506.

<sup>120</sup> Clarkson, M. B. E. (1995). A Stakeholder Framework for Analyzing and Evaluating Corporate Social Performance. *Academy of Management Review*, 92-117.

(p.106). Clarkson (1995)<sup>121</sup> further explains that “such claimed rights or interests are the results of the transactions with, or actions taken by, the corporation, and may be legal or moral, individual or collective”. (p. 106). It is noted that Clarkson identifies two different types of stakeholders, i.e., primary and secondary. The primary stakeholder group is defined as “one without whose continuing participation the corporation cannot survive as a going concern” (Clarkson, 1995, p. 106)<sup>122</sup>. The primary stakeholder groups typically include shareholders and investors, employees, customers, and suppliers together with the public stakeholder groups such as the government and communities. Clarkson (1995)<sup>123</sup> argues that there is a high level of interdependence between a firm and its primary stakeholder groups. In contrast, the secondary stakeholder groups are defined as “those who influence or affect, or are influenced or affected by, the corporation, but they are not engaged in transactions with the corporation and are not essential for its survival” (Clarkson, 1995, p. 107)<sup>124</sup>. The secondary stakeholder groups include the media and a wide range of special interest groups. Clarkson (1995)<sup>125</sup> maintains that although a firm is not dependent for its survival on the secondary stakeholder groups, they can cause significant damage to the firm because they have the capacity to mobilize public opinion in opposition to the firm’s performance. While the typology suggested by Clarkson must be instructive to defining and identifying the stakeholders of a firm, it should be noted that, as Preble (2005)<sup>126</sup> points out, the actual stakeholder groups that can be identified by

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<sup>121</sup> Clarkson, M. B. E. (1995). A Stakeholder Framework for Analyzing and Evaluating Corporate Social Performance. *Academy of Management Review*, 92-117.

<sup>122</sup> Ibid.

<sup>123</sup> Ibid.

<sup>124</sup> Ibid.

<sup>125</sup> Ibid.

<sup>126</sup> Preble, J. F. (2005). Toward a comprehensive model of stakeholder management. *Business and Society*, 110, 407-431.

an empirical study may be dependent on a firm's size, industry, and the location of its headquarters and operations.

Mitchell et al. (1997)<sup>127</sup> present a theory of the stakeholder identification and salience in an attempt to improve the collective understanding of what Freeman (1994)<sup>128</sup> calls "The Principle of Who and What Really Count" (p. 411). Mitchell et al. (1997)<sup>129</sup> emphasize the need to develop not only a theory of the stakeholder identification which can reliably separate stakeholders from non-stakeholders but also a theory of the stakeholder salience which can explain to whom and to what managers actually pay attention. Mitchell et al. (1997)<sup>130</sup> explain why the notion of the stakeholder identification should be distinguished from that of the stakeholder salience, suggesting that "the question of stakeholder salience – the degree to which managers give priority to competing stakeholder claims – goes beyond the question of stakeholder identification, because the dynamics inherent in each relationship involve complex considerations that are not readily explained by the stakeholder framework as it currently stands" (p. 854). Mitchell et al. (1997)<sup>131</sup> propose that the "stakeholder salience will be positively related to the cumulative number of stakeholder attributes – power, legitimacy, and urgency – perceived by managers to be present" (p. 873). Based on the possession, or the attributed possession, of these three key stakeholder attributes, the authors identify seven classes of stakeholders such as dormant,

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<sup>127</sup> Mitchell, R. K., Agle, B. R., & Wood, D. J. (1997). Toward a Theory of Stakeholder Identification and Salience: Defining the Principle of Who and What really Counts. *Academy of Management Review*, 22, 853-886.

<sup>128</sup> Freeman, R. E. (1984). *Strategic management: A stakeholder approach*. Englewood Cliffs, NJ: Prentice-Hall.

<sup>129</sup> Mitchell, R. K., Agle, B. R., & Wood, D. J. (1997). Toward a Theory of Stakeholder Identification and Salience: Defining the Principle of Who and What really Counts. *Academy of Management Review*, 22, 853-886.

<sup>130</sup> Ibid.

<sup>131</sup> Ibid.

discretionary, demanding, dominant, dangerous, dependent, definitive, and non-stakeholder. In sum, Mitchell et al. (1997)<sup>132</sup> suggest that managers' perception of three key stakeholder attributes affects the stakeholder salience, i.e., the degree to which managers give priority to the competing stakeholder claims. The theory developed by Mitchell et al. can be a useful tool for a firm to figure out a stakeholder group which needs the most attention at particular points in time.

Gavin et al. (1998)<sup>133</sup> identify the key stakeholders, based on two attributes of stakeholders (i.e. influence and importance). Namely, Gavin et al. (1998)<sup>134</sup> define the key stakeholders as "those which can significantly influence, or are important, to the success of the project" (p. 7). Here, the term influence refers to "how powerful a stakeholder is" and the term importance refers to "those stakeholders whose problems, needs, and interests are the priority of DFID's intervention" (Gavin et al., 1998, p.7)<sup>135</sup>. By combining two attributes of influence and importance, Gavin et al. classify stakeholders into three different groups (i.e. primary, secondary, and external) and each group is composed of two or three different stakeholders.

Based on a review of literature, Sirgy (2002)<sup>136</sup> develops an extensive list of organizational stakeholders and, then, identifies three different types of stakeholder

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<sup>132</sup> Mitchell, R. K., Agle, B. R., & Wood, D. J. (1997). Toward a Theory of Stakeholder Identification and Salience: Defining the Principle of Who and What really Counts. *Academy of Management Review*, 22, 853-886.

<sup>133</sup> Gavin, T., & Pinder, C. (1998). *Impact Assessment & Stakeholder Analysis*. Manchester, EDIAIS, University of Manchester.

<sup>134</sup> Ibid.

<sup>135</sup> Ibid.

<sup>136</sup> Sirgy, M. J. (2002). Measuring corporate performance by building on the stakeholders model of business ethics. *Journal of Business Ethics*, 35, 143-162.

groups, i.e., internal, external, and distal. According to Sirgy (2002)<sup>137</sup>, a firm can exchange the vital resources with the external stakeholders (e.g. customers, share/bondholders, distributors, suppliers, creditors, employees, local community, the mass media, and the environment) and the survival and growth of the firm depend on the extent to which the firm effectively exchanges the value with the external stakeholders. In order for a firm to engage in effective exchange with the external stakeholders, the firm should organize itself through the division of labor such as the CEO, board of directors, strategic business units, R&D, engineering, production, logistics, sales, financing, marketing, human resources, public relations, accounting, and risk management. Sirgy (2002)<sup>138</sup> defines these departments, divisions, and functional units as the internal stakeholders. Lastly, Sirgy (2002)<sup>139</sup> defines the distal stakeholders as “indirectly influence the survival and growth of the business firm through influence exerted on the firm’s external groups” (p. 145). Consumer and environmental advocacy groups, government agencies, labor unions, auditors, industry leaders, professional and trade associations, and higher education can be considered as the distal stakeholders.

### **3.2.2 Defining and Identifying the Nature of Stakeholders**

Once the stakeholders of a firm have been identified, it must be essential to examine the nature of the stakeholders. This examination can help a firm to define how a stakeholder group can have influence on the firm and how the firm can respond to the stakeholder group effectively. Several scholars have distinguished the notion of the stakeholder

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<sup>137</sup> Sirgy, M. J. (2002). Measuring corporate performance by building on the stakeholders model of business ethics. *Journal of Business Ethics*, 35, 143-162.

<sup>138</sup> Ibid.

<sup>139</sup> Ibid.

attributes from that of the stakeholder relationships. As illustrated above, Mitchell et al. (1997)<sup>140</sup> performed the most comprehensive study of defining and identifying the stakeholders of firms and, then, used the stakeholder-related variables for the study. Lim, Lee, and Kim (2005)<sup>141</sup> summarize the stakeholder attributes defined by Mitchell et al. (1997)<sup>142</sup> as follows:

Power is defined as a capability of one stakeholder to get another stakeholder to do something. Legitimacy is a generalized perception or assumption that the actions of a stakeholder are desirable, or appropriate within some socially constructed norms and beliefs. Urgency is the degree to which stakeholder claims call for immediate attention. Another stakeholders' variable, stakeholders' salience, is the degree to which managers give priority to competing stakeholders' claims. (p. 544)

Agle et al. (1999)<sup>143</sup> develop further the concept of the stakeholder attributes identified by Mitchell et al. (1997)<sup>144</sup> using unique data provided by the CEOs of 80 large U.S. firms. Specifically, the authors examine the relationships among the stakeholder attributes (i.e. power, legitimacy, urgency, and salience), CEO values, and corporate performance. The authors test the model presented by Mitchell et al., applying it to the specific decisions made by the CEOs. The study results confirm the validity of the model

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<sup>140</sup> Mitchell, R. K., Agle, B. R., & Wood, D. J. (1997). Toward a Theory of Stakeholder Identification and Salience: Defining the Principle of Who and What really Counts. *Academy of Management Review*, 22, 853-886.

<sup>141</sup> Lim, G., Lee, H., & Kim, T. (2005). Formulating Business Strategies from a Stakeholder's Perspective: Korean Healthcare IT Business Case. *International Journal of Information Technology & Decision Making*, 4, 541-566.

<sup>142</sup> Mitchell, R. K., Agle, B. R., & Wood, D. J. (1997). Toward a Theory of Stakeholder Identification and Salience: Defining the Principle of Who and What really Counts. *Academy of Management Review*, 22, 853-886.

<sup>143</sup> Agle, B. R., Mitchell, R. K., & Sonnenfeld, J. A. (1999). Who matters to CEOs? An Investigation of Stakeholder Attributes and Salience, Corporate Performance, and CEO Values. *Academy of Management Journal*, 42, 507-525.

<sup>144</sup> Mitchell, R. K., Agle, B. R., & Wood, D. J. (1997). Toward a Theory of Stakeholder Identification and Salience: Defining the Principle of Who and What really Counts. *Academy of Management Review*, 22, 853-886.

presented by Mitchell et al. (1997). To be concrete, the findings of Agle et al. (1999)<sup>145</sup> reveal that: there is a strong relationship between the stakeholder attributes and the stakeholder salience; there are some significant relationships among CEO values, the stakeholder salience, and corporate social performance; and, there is no relationship between the stakeholder salience and corporate financial performance. Based on these findings, Agle et al. (1999)<sup>146</sup> argue that there is a need for continued emphasis on the development of the normative stakeholder theory.

Freeman et al. (1997)<sup>147</sup> try to develop a method to specify the stakeholder relationships that can be sustained over time. The authors begin by laying out the road map of the concept of stakeholder capitalism in conjunction with key principles (i.e. the principles of stakeholder cooperation, complexity, continuous creation, and emergent competition). Then, Freeman et al. review the concept of the value chain as it has evolved in the strategy literature. The authors show how the new perspectives of the value chain and the principles of the stakeholder capitalism reinforce each other. Lastly, Freeman et al. present how it is possible to operationalize the concept of the stakeholder value chain in a transactional mode identifying how particular discrete relationships can be managed. Freeman et al. (1997)<sup>148</sup> assume that “how value actually gets created is a function of the behavior of particular stakeholders and, of course, the consequences of the behavior” (p.

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<sup>145</sup> Agle, B. R., Mitchell, R. K., & Sonnenfeld, J. A. (1999). Who matters to CEOs? An Investigation of Stakeholder Attributes and Salience, Corporate Performance, and CEO Values. *Academy of Management Journal*, 42, 507-525.

<sup>146</sup> Ibid.

<sup>147</sup> Freeman, R. E., & Liedtka, J. (1997). Stakeholder capitalism and value chain. *European Management Journal*, 15, 286-296.

<sup>148</sup> Ibid.

292). In conclusion, Freeman et al. (1997)<sup>149</sup> suggest that “by paying attention to particular stakeholder profiles, managers can undertake a process of reasonably sophisticated analysis to understand where, from a behavior view, value is created, and where there is potential for more cooperation, and where there is the need to sustain the value that has been created” (p. 293). It is noted that Freeman et al. (1997)<sup>150</sup> adopt the concepts of the stakeholder capitalism and the value chain to define (or identify) the stakeholder related variables. Further, the authors propose some general rules for managers to manage stakeholders in the context of the stakeholder relationships. The perspective presented by the authors is new in terms of the stakeholder management perspective as well as the organizational strategy development. The ideas suggested by the authors are enough to encourage scholars to rethink the stakeholder management perspective in general and the organizational strategy development in specific from a new direction.

### **3.2.3 Balancing or Prioritizing the competing Demands of various Stakeholders**

Although it must be an ideal strategy for a firm to consider all the demands of its various stakeholders, it must be practically impossible because firms not only have limited resources but also have limited information processing capabilities. As explained above, Mitchell et al. (1997)<sup>151</sup> suggest a theory of the stakeholder identification and salience, identifying seven classes of stakeholders based on whether they possess one, two, or three

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<sup>149</sup> Freeman, R. E., & Liedtka, J. (1997). Stakeholder capitalism and value chain. *European Management Journal*, 15, 286-296.

<sup>150</sup> Ibid.

<sup>151</sup> Mitchell, R. K., Agle, B. R., & Wood, D. J. (1997). Toward a Theory of Stakeholder Identification and Salience: Defining the Principle of Who and What really Counts. *Academy of Management Review*, 22, 853-886.



of the stakeholder attributes in various combination. The authors propose that the stakeholder salience will be high where all three of the stakeholder attributes are perceived by managers to be present, defining this kind of stakeholders as definitive stakeholders. In other words, a stakeholder exhibiting both power and legitimacy is already a member of a firm's dominant coalition and, thus, when such a stakeholder's claim is urgent, managers have a clear and immediate mandate to attend to and give priority to that stakeholder's claim. The theory developed by Mitchell et al. (1997)<sup>152</sup> can be a useful tool for a firm to balance or to prioritize the competing demands of its various stakeholders.

On the other hand, Harrison et al. (1996)<sup>153</sup> provide a framework to determine which stakeholders are the most important at a given point in time and, thus, deserve priority status by management. The authors suggest that there is an increased need to manage stakeholders more strategically in terms of partnering in connection with the recent changes in environments in which firms operate. The authors contend that stakeholders are considered to be strategically important, or to be prior, to the extent that they can influence the amount of environmental uncertainty faced by firms, classifying stakeholders as having either high or low strategic importance. Harrison et al. (1996)<sup>154</sup> recommend managers to adopt the strategic partnering tactics in connection with the stakeholders that have high strategic importance. Specifically, the authors suggest a wide

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<sup>152</sup> Mitchell, R. K., Agle, B. R., & Wood, D. J. (1997). Toward a Theory of Stakeholder Identification and Salience: Defining the Principle of Who and What really Counts. *Academy of Management Review*, 22, 853-886.

<sup>153</sup> Harrison, J. S., & St. John, C. H. (1996). Managing and partnering with external stakeholders. *Academy of Management Executive*, 10, 46-60.

<sup>154</sup> Ibid.

range of the stakeholder partnering tactics such as joint ventures, cooperative product development efforts with suppliers, and collective lobbying campaigns with critical stakeholders. It is argued that the ideas presented by Harrison et al. (1996)<sup>155</sup> can be applied to the process of the organizational strategy development, managing the interactions between a firm and its stakeholders.

Rowley (1997)<sup>156</sup> argues that “a comprehensive theory of the firm requires not only an explanation of stakeholder influences but also how firms respond to these influences” (Rowley, 1997 p. 887)<sup>157</sup>. That is, Rowley (1997) tries to develop a theory of stakeholder influences, which accommodates multiple, interdependent stakeholder demands, and also tries to predict how firms respond to the simultaneous influences of multiple stakeholders. It is noted that the model of stakeholder influences presented by Rowley (1997) incorporates the social network constructs (i.e. density and centrality) and moves beyond the traditional analysis of stakeholders. The author also extends Oliver’s approach, i.e., the convergent institutional and resource dependence theory, to develop a theory that explains how firms respond to the simultaneous influences of multiple stakeholders. That is, Rowley (1997)<sup>158</sup> examines how the aspects of an organization’s stakeholder network, i.e., the network density and the focal organization’s centrality, impact the focal organization’s degree of resistance to the stakeholder pressures. Based on the interaction between the two social network constructs (i.e. the network density and

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<sup>155</sup> Harrison, J. S., & St. John, C. H. (1996). Managing and partnering with external stakeholders. *Academy of Management Executive*, 10, 46-60.

<sup>156</sup> Rowley, T. J. (1997). Moving beyond dyadic ties: A network theory of stakeholder influences. *Academy of Management Review*, 22, 887-910.

<sup>157</sup> Ibid.

<sup>158</sup> Ibid.

the focal organization's centrality), the author identifies four different types of network structures (i.e. compromiser, commander, subordinate, and solitarian) which influence the relative power balance between a focal firm and its stakeholders. Rowley (1997)<sup>159</sup> concludes that "other things being equal, under conditions of high density and high centrality, the focal organization will adopt a compromiser role, attempting to negotiate with its stakeholders" (p. 902). In contrast, "other things being equal, under conditions of low density and low centrality, the focal organization will adopt a solitarian role, attempting to avoid stakeholder pressures" (p. 904). Rowley's approach to the stakeholder management has important implications for this dissertation. The pharmaceutical companies have been under severe pressure posed by their various external (in most cases) stakeholders. The companies have dealt with the external pressure through both the passive compliance and the active manipulation and control. Therefore, it can be useful for this dissertation to investigate how the aspects of the stakeholder network (i.e. the network density and the companies' centrality) impact the pharmaceutical companies' degree of resistance to their stakeholder pressure.

### **3.3 The Theories within the Stakeholder Management Perspective**

Although, since Freeman's early work, the stakeholder management perspective has been developed on a variety of subjects, from theory developments to empirical studies, there has been much contention over the theoretical underpinnings of the stakeholder management perspective. The controversy over the stakeholder management perspective can be attributed to the conceptual confusion with the term stakeholders as well as with

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<sup>159</sup> Rowley, T. J. (1997). Moving beyond dyadic ties: A network theory of stakeholder influences. *Academy of Management Review*, 22, 887-910.

the term stakeholder management. Although numerous interpretations and definitions on two terms have been presented, defining the stakeholders of a firm and conceptualizing the process of the stakeholder management of a firm are still challenging tasks on the part of a firm. In this respect, Stoney et al. (2001)<sup>160</sup> maintain that “major factors contributing to the vagueness of the stakeholder concept include the failure to clarify its theoretical underpinnings and the ambiguity surrounding overall aims and objectives” (p. 605).

In brief, although many scholars have attempted to clarify the nature, scope, and practical implications of the stakeholder management perspective, there has been considerable confusion on the perspective because of the multitude of conflicting views and approaches to the stakeholder management. In a sense, this diversity has weakened the legitimacy of the stakeholder management perspective. That is, the diverse interpretations on and approaches to the stakeholder management perspective have induced criticism on the perspective. The critics argue that the stakeholder management perspective can be viewed as the aggregation of ideas and practices which presents naïve, unrealistic, and superficial aspirations rather than a specific concept. Therefore, the similarities and differences among the diverse approaches to the stakeholder management perspective should be clearly understood to develop a comprehensive model of the stakeholder management perspective, a more sophisticated in terms of theory as well as a more realizable in terms of practice.

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<sup>160</sup> Stoney, C., & Winstanley, D. (2001). Stakeholding: Confusion or Utopia? Mapping the Conceptual Terrain. *Journal of Management studies*, 38, 603-626.

As Donaldson et al. (1995)<sup>161</sup> describe, three main theories/approaches have been identified within the stakeholder management perspective, that is: (1) the empirical/descriptive; (2) the normative/moral; and (3) the instrumental theory of the stakeholder management. Although these three theories share common themes in some aspects and they are not mutually exclusive, each theory is based on the very different motive for adopting and promoting the stakeholder management perspective. Consequently, each theory provides different managerial implications of the stakeholder management perspective for firms. Thus, the confusion on the stakeholder management perspective has deepened by the differences among these theories. Below, these three theories are examined, focusing on the implications of each theory for the pharmaceutical companies in the stakeholder management terms.

### **3.3.1 Descriptive/Empirical Theory of the Stakeholder Management Perspective**

The descriptive/empirical stakeholder theory appears to be rooted in the organizational behavior literature, and describes the characteristics and behavior of the stakeholders involved in a system and how an organization interacts with its stakeholders (Bailur, 2006)<sup>162</sup>. In brief, the descriptive stakeholder theory aims at understanding the relationship between an organization and its stakeholders. In other words, the descriptive stakeholder theory concerns how managers actually deal with stakeholders. The work of Brenner et al. (1991)<sup>163</sup> is viewed as an early effort to provide and develop the descriptive

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<sup>161</sup> Donaldson, T., & Preston, L. E. (1995). The Stakeholder Theory of the Corporation: Concepts, Evidence, and Implications. *Academy of Management Review*, 20, 65-91.

<sup>162</sup> Bailur, S. (2006). Using Stakeholder Theory to Analyze Telecenter Projects. *Information Technologies and International Development*, 3, 61-80.

<sup>163</sup> Brenner, S. N., & Cochran, P. L. (1991). The stakeholder theory of the firm: Implications for business and society theory and research. In Mahon, J. F. (Eds.), *Proceedings of the Second Annual Meeting of International Association for Business and Society* (pp. 449-467). Sundance, UT.

stakeholder theory. According to the authors, “the stakeholder theory of the firm posits that the nature of an organization’s stakeholders, their values, their relative influence on decisions and the nature of the situation are all relevant information for predicting organizational behavior” (Brenner, 1991, p. 462)<sup>164</sup>.

Donaldson et al. (1995)<sup>165</sup> point out that the descriptive stakeholder theory is used “to describe, and sometimes to explain, specific corporate characteristics and behaviors” (p. 70). Specifically, the authors identify what the stakeholder theory has tried to describe: i.e., the nature of a firm; the way managers think about managing; how board members think about the interests of corporate constituencies; and, how some corporations are actually managed. Donaldson et al. (1995)<sup>166</sup> summarize the central thesis of the descriptive stakeholder theory as follows:

The stakeholder theory is unarguably descriptive. It presents a model describing what the corporation is. It describes the corporation as a constellation of cooperative and competitive interests possessing intrinsic value. Aspects of this mode may be tested for descriptive accuracy: Is this model more descriptively accurate than rival models? Moreover, do observers and participants, in fact, see the corporation this way? The model can also serve as a framework for testing any empirical claims, including instrumental predictions, relevant to the stakeholder concept (but not for testing the concept’s normative base) (p. 66)

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<sup>164</sup> Brenner, S. N., & Cochran, P. L. (1991). The stakeholder theory of the firm: Implications for business and society theory and research. In Mahon, J. F. (Eds.), *Proceedings of the Second Annual Meeting of International Association for Business and Society* (pp. 449-467). Sundance, UT.

<sup>165</sup> Donaldson, T., & Preston, L. E. (1995). The Stakeholder Theory of the Corporation: Concepts, Evidence, and Implications. *Academy of Management Review*, 20, 65-91.

<sup>166</sup> Ibid.

Jawahar et al. (2001)<sup>167</sup> discuss how the descriptive stakeholder theory can be used and developed in connection with other theories of organization in a pragmatic way. The authors integrate the organizational life cycle theory, the resource dependence theory, the prospect theory, and the stakeholder management strategies to present a descriptive stakeholder theory, which can be viewed as a comprehensive stakeholder theory. The descriptive stakeholder theory presented by Jawahar et al. (2001)<sup>168</sup> posits that organizations are likely not only to use different strategies to deal with different stakeholders at a given time but also to use different strategies to deal with the same stakeholder over time. In other words, the strategy an organization uses to deal with a stakeholder will vary with the life cycle stage of the organization. Jawahar et al. (2001)<sup>169</sup> argue that the descriptive stakeholder theory developed in connection with other theories of organization is descriptive and contains many testable propositions. Thus, the descriptive stakeholder theory has the potential to conduct future empirical research in the stakeholder management perspective. It is argued that the descriptive stakeholder theory presented by Jawahar et al. (2001)<sup>170</sup> is more comprehensive than the theories developed earlier such as a model proposed by Brenner et al. (1991)<sup>171</sup>.

However, the descriptive stakeholder theory has been criticized in that it is just simply descriptive and lacking a clear objective. In other words, the descriptive stakeholder theory has been criticized on the grounds that it is unfocused and its aims are not clear.

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<sup>167</sup> Jawahar, I. M., & Mclaughlin, G. (2001). Toward a Descriptive Stakeholder Theory: An Organizational Life Cycle Approach. *Academy of Management Review*, 26, 397-414.

<sup>168</sup> Ibid.

<sup>169</sup> Ibid.

<sup>170</sup> Ibid.

<sup>171</sup> Brenner, S. N., & Cochran, P. L. (1991). The stakeholder theory of the firm: Implications for business and society theory and research. In Mahon, J. F. (Eds.), *Proceedings of the Second Annual Meeting of International Association for Business and Society* (pp. 449-467). Sundance, UT.

For instance, Donaldson et al. (1995)<sup>172</sup> argue that the descriptive justification for the stakeholder theory has “the problem of so-called “naturalistic fallacy”, moving from is to ought or from describe to evaluate, without the necessary intervening analysis and explanation” (p. 77) and, also, has “the simple problem of hasty generalization” (p. 77). In these respects, Donaldson et al. (1995)<sup>173</sup> conclude that the descriptive justification for the stakeholder theory is of limited significance and that the most important issues for the stakeholder theory lie elsewhere. Similarly, Jones et al. (1999)<sup>174</sup> argue that although the descriptive stakeholder theory would create a wealth of research possibilities and would probably catapult the stakeholder theory into the ranks of the major theories of organization, the formulation suggested by the descriptive stakeholder theory to investigate the relationship between the various stakeholder traits and situational characteristics, and the decisions that firms actually make is empirically less tractable because the propositions presented by the descriptive theory are general claims that cannot be disproved. Therefore, Jones et al. (1999)<sup>175</sup> conclude that although some possibilities exist for the development of the descriptive stakeholder theory, the theory needs to be developed more fully before any testing can take place. In this respect, the authors concentrate their attention on the instrumental stakeholder theory, which they feel holds greater promise.

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<sup>172</sup> Donaldson, T., & Preston, L. E. (1995). The Stakeholder Theory of the Corporation: Concepts, Evidence, and Implications. *Academy of Management Review*, 20, 65-91.

<sup>173</sup> Ibid.

<sup>174</sup> Jones, T. M., & Wicks, A. C. (1999). Convergent Stakeholder Theory. *Academy of Management Review*, 24, 206-221.

<sup>175</sup> Ibid.



Regardless of whether the claims of Jones et al. (1999)<sup>176</sup> are right or wrong, the authors contribute to the attempts to expand the stakeholder theory into a central paradigm that could link together the theories (or concepts) such as agency theory, transactions costs, human relationships, contracts theory, and ethics into a coherent whole. In addition, the authors try to pull together the diverging research streams of the stakeholder theory, developing a convergent stakeholder theory that moves the stakeholder research towards theoretical integration. Jones et al. (1999)<sup>177</sup> propose a new way of theorizing about organizations, namely, a convergent stakeholder theory that can be viewed as a development of normatively and instrumentally sound stakeholder theory. Although some scholars (e.g. Treviño et al. [1999]<sup>178</sup> and Freeman [1999]<sup>179</sup>) criticize the idea of the convergent stakeholder theory proposed by Jones et al., it is noted that their work has sparked a useful dialogue that contributes to the development within the research tradition of the stakeholder approach.

### **3.3.2 Normative/Moral Theory of the Stakeholder Management Perspective**

The normative/moral theory of the stakeholder management perspective appears to be grounded in the business ethics (or the corporate social responsibility [CSR]) literature (Bailur, 2006)<sup>180</sup>, and in comparison with the descriptive and the instrumental stakeholder theory, there has been considerable discussion on the normative stakeholder theory. In essence, the normative stakeholder theory concerns the notion that stakeholders

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<sup>176</sup> Jones, T. M., & Wicks, A. C. (1999). Convergent Stakeholder Theory. *Academy of Management Review*, 24, 206-221.

<sup>177</sup> Ibid.

<sup>178</sup> Treviño, L. K., & Weaver, G. R. (1999). The Stakeholder Research Tradition: Converging Theorists – Not Convergent Theory. *Academy of Management Review*, 24, 222-227.

<sup>179</sup> Freeman, R. E. (1999). Divergent Stakeholder Theory. *Academy of Management Review*, 24, 233-236.

<sup>180</sup> Bailur, S. (2006). Using Stakeholder Theory to Analyze Telecenter Projects. *Information Technologies and International Development*, 3, 61-80.

themselves are an end for a corporation. According to Berman et al. (1999)<sup>181</sup>, the normative stakeholder theory proposes that managerial relationships with stakeholders are based on normative, moral commitments rather than on a desire to use those stakeholders solely to maximize profits. That is, “a firm establishes certain fundamental moral principles that guide how it does business – particularly with respect to how it treats stakeholders – and uses those principles to drive decision-making” (Berman et al., 1999, p. 492)<sup>182</sup>. The normative stakeholder theory is based on the principle of fairness, a feminist perspective, a fair contract approach, and the Kantian theory of common good in that “all human beings are ultimately affected by any decision and, because we all have an equal and legitimate interest in a safe and stable life, we should all have equality of opportunity and consideration” (Bailur, 2006, p. 65)<sup>183</sup>.

In general, the studies on the normative stakeholder theory have involved specifying what moral obligations the stakeholder theory places on managers, particularly the relative importance of obligations to shareholders and those to other stakeholder groups (Jones et al. 1999)<sup>184</sup>. That is, the normative stakeholder theory involves the specification of what firms ought to do or should do, from an ethical and moral standpoint, in the treatment of shareholders and stakeholders. As Evan et al. (1993)<sup>185</sup> points out, the common theme in the normative stakeholder theory is the interests of stakeholders have intrinsic value and,

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<sup>181</sup> Berman, S. L., Wicks, A. C., Kotha, S., & Jones, T.M. (1999). Does stakeholder orientation matter? The relationship between stakeholder management models and firm financial performance. *Academy of Management Journal*, 42, 488-506.

<sup>182</sup> Ibid.

<sup>183</sup> Bailur, S. (2006). Using Stakeholder Theory to Analyze Telecenter Projects. *Information Technologies and International Development*, 3, 61-80.

<sup>184</sup> Jones, T. M., & Wicks, A. C. (1999). Convergent Stakeholder Theory. *Academy of Management Review*, 24, 206-221.

<sup>185</sup> Evan, W. & Freeman, R. E. (1993). *A Stakeholder Theory of the Modern Corporation: Kantian Capitalism*. Ethical Theory and Business, 5th edition. Englewood Cliffs, NJ: Prentice Hall.

as such, ought to be treated as ends in themselves and not just as means to an end. In this respect, the normative theorists criticize the instrumental stakeholder theory arguing that strategically applying the ethical principles is (i.e. acting according to the moral principles only when doing so is to the advantage of a firm), by definition, not following the ethical principles at all, thus, cannot lead to the strategic outcomes desired (Berman et al, 1999)<sup>186</sup>. The normative stakeholder theorists assert that the interests of stakeholders enter a firm's decision-making processes prior to the strategic considerations and form a moral foundation for a firm's strategy itself.

Phillips (1997)<sup>187</sup> assumes that the stakeholder model has problems, that is: it cannot provide the standards for assigning the relative weights to the interests of various constituencies; and it fails to be contained within, or to make reference to, a normative, justificatory foundation. The author maintains that a possible source of obligations to stakeholders is the principle of fairness (or fair play) as discussed in the political philosophic literature. That is, Phillips (1997)<sup>188</sup> argues that a superior normative model of the stakeholder relations can be found in the idea of what has been called fair play or fairness and the gaps in the current stakeholder literature can be filled by the principle of fairness. Phillips (1997)<sup>189</sup> defines the principle of fairness as “whenever persons or groups of persons voluntarily accept the benefits of a mutually beneficial scheme of co-operation requiring sacrifice or contribution on the parts of the participants and there

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<sup>186</sup> Berman, S. L., Wicks, A. C., Kotha, S., & Jones, T.M. (1999). Does stakeholder orientation matter? The relationship between stakeholder management models and firm financial performance. *Academy of Management Journal*, 42, 488-506.

<sup>187</sup> Phillips, R. (1997). Stakeholder theory and a Principle of fairness. *Business Ethics Quarterly*, 7, 51-66.

<sup>188</sup> Ibid.

<sup>189</sup> Ibid.

exists the possibility of free-riding, there exist obligations of fairness on the part of these persons or groups to co-operate in proportion to the benefits accepted” (p.51). Phillips (1997)<sup>190</sup> ties the principle of fairness and the stakeholder theory and, then, shows how the former may strengthen the latter, by giving a more discerning basis for deciding which groups are and which are not stakeholders. It is noted that Phillips et al. (2000)<sup>191</sup> further argue that although the natural environment is not and cannot be a stakeholder, it may, nonetheless, be considered as a legitimate organizational stakeholder on a fairness-based approach.

Reed (2002)<sup>192</sup> investigates how the corporate responsibilities may change firms with operations in developing countries. The author contends that the normative stakeholder theory is of more concern in developing countries, as firms have a moral obligation and increased responsibilities in the context of unregulated financial markets, an uninformed consumer society, and a possibly unreliable state government. The author argues that, in the context of developing countries, firms have an obligation to provide employment and to be ethically right, for instance, by not dumping products that have been deemed defective, expired, or illegal in industrialized countries. Reed (2002)<sup>193</sup> maintains that two broad factors tend to increase the responsibilities of firms operating in developing countries to a full range of stakeholder groups. The first of these factors is constituted by the different (economic, political, and socio-cultural) circumstances under which

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<sup>190</sup> Phillips, R. (1997). Stakeholder theory and a Principle of fairness. *Business Ethics Quarterly*, 7, 51-66.

<sup>191</sup> Phillips, R. & Reichart, J. (2000). The Environment as a Stakeholder: A Fairness-based Approach. *Journal of Business Ethics*, 23, 185-197.

<sup>192</sup> Reed, D. (2002). Employing Normative Stakeholder Theory in Developing Countries. *Business & Society*, 166-207.

<sup>193</sup> Ibid.

corporations have to operate in developing countries. The second is a group of normative principles that are not generally incorporated into the analysis of corporate responsibilities to stakeholders, partly because of the emerging nature of stakeholder analysis and partly because they are not always (as) practically relevant in the context of developed countries. Reed (2002)<sup>194</sup> concludes that due to the different circumstances under which they operate and the existence of some basic normative principles that do not always come into play in determining corporate responsibilities in developed countries, firms active in developing countries may have increased responsibilities to their stakeholder groups.

Although the work of Quinn et al. (1995)<sup>195</sup> does not deal with the normative stakeholder theory directly, it has important implications for the normative theory. The authors, based on the non-instrumental ethics, develop a philosophical perspective on the moral obligation of managers (i.e. agent morality) by examining the moral implications of agency theory. That is, the authors offer an agent morality view of business policy, extending the logic of managerial agency. Quinn et al. (1995)<sup>196</sup> emphasize that an agent morality view of business policy is grounded in the non-instrumental ethics, which is logically superior to the instrumental ethics. The authors explain the non-instrumental ethics as follows: “...managers act according to moral principle in business as well as in all other aspects of life” and “businesses have no special rules or states that waive the

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<sup>194</sup> Reed, D. (2002). Employing Normative Stakeholder Theory in Developing Countries. *Business & Society*, 166-207.

<sup>195</sup> Quinn, D. P., & Jones, T. M. (1995). An Agent Morality View of Business Policy. *Academy of Management Review*, 20, 22-42.

<sup>196</sup> Ibid.

moral obligations that managers have as humans” (Quinn et al., 1995, p. 30)<sup>197</sup>. In essence, Quinn et al. (1995)<sup>198</sup> define an agent morality view of business policy as “...agents must first attend to the basic moral duties...agents have no special destination from moral obligations, theirs or principals...once these obligations have been met, shareholder wealth considerations can have priority” (p. 38). The agent morality view of business policy has much in common with the normative stakeholder theory.

Donaldson et al. (1995)<sup>199</sup> capture the implications of the normative stakeholder theory quite well and comment on the theory as follows:

The theory is used to interpret the function of the corporation, including the identification of moral or philosophical guidelines for the operation and management of corporations. Normative concerns dominated the classic stakeholder theory statements from the beginning (Dodd, 1932), and this tradition has been continued in the most recent versions (Carroll, 1989; Kuhn & Shriver, 1991; Marcus, 1993). Even Friedman’s (1970) famous attack on the concept of corporate social responsibility was cast in normative terms. (p.71)

Further, Donaldson et al. (1995)<sup>200</sup> present the normative propositions of the stakeholder theory, that is: (a) stakeholders are persons or groups with legitimate interests in procedural and/or substantive aspects of corporate activity; and (b) the interests of all stakeholders are intrinsic value. Donaldson et al. (1995)<sup>201</sup> admit that three aspects of the stakeholder theory (i.e. the descriptive, instrumental, and normative) are interrelated and

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<sup>197</sup> Quinn, D. P., & Jones, T. M. (1995). An Agent Morality View of Business Policy. *Academy of Management Review*, 20, 22-42.

<sup>198</sup> Ibid.

<sup>199</sup> Donaldson, T., & Preston, L. E. (1995). The Stakeholder Theory of the Corporation: Concepts, Evidence, and Implications. *Academy of Management Review*, 20, 65-91.

<sup>200</sup> Ibid.

<sup>201</sup> Ibid.

mutually supportive and both of the descriptive and the instrumental theory are significant aspects of the stakeholder management perspective. Nevertheless, the authors argue that three aspects of the stakeholder theory are quite distinct and the normative base of the theory, which includes the modern theory of property rights, is fundamental. In specific, the authors assert that the stakeholder theory goes beyond the purely descriptive observation that provides no direct managerial implication. The authors also argue that the notion of the instrumental theory (i.e. the stakeholder management contributes to the successful economic performance of a firm) is insufficient to stand alone as a basis for the stakeholder theory. Donaldson et al. (1995)<sup>202</sup> conclude that “the most thoughtful analyses of why stakeholder management might be causally related to corporate performance ultimately resort to normative arguments” (p. 87) and, thus, “the ultimate justification for the stakeholder theory is to be found in its normative base” (p. 87). It should be understood that why the authors emphasize the intrinsic worth of the stakeholder interests. According to the authors, certain claims of stakeholders are based on the fundamental moral principles unrelated to the stakeholders’ instrumental value to a firm. A firm cannot ignore these claims simply because they do not serve for the strategic interests of the firm. That is, stakeholder interests are thought to form the foundation of corporate strategy itself.

In general, Donaldson et al. (1995)<sup>203</sup> make very persuasive arguments for the normative stakeholder theory. However, whether or not the propositions presented by the authors are acceptable on the part of private sector companies is unclear. Can we expect a firm to

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<sup>202</sup> Donaldson, T., & Preston, L. E. (1995). The Stakeholder Theory of the Corporation: Concepts, Evidence, and Implications. *Academy of Management Review*, 20, 65-91.

<sup>203</sup> Ibid.

prioritize the interests of stakeholders sacrificing its profits? Can we enforce a firm to do that? As Bailur (2006)<sup>204</sup> indicates, the criticism on the normative stakeholder theory, from both the private and the non-profit sector, is that the theory can be regarded as artificially altruistic, where the key concern of those consulting stakeholders is to get their initiative to succeed. But, the normative stakeholder theory has been the target of criticism particularly from the private sector. As Treviño and Weaver (1999)<sup>205</sup> ask, wouldn't the normative stakeholder theory's concern for the intrinsic interests of all the legitimate stakeholders sometimes dictate that a firm should go out of business? In this respect, the work of Jones et al. (1999)<sup>206</sup> is worth reviewing. The authors emphasize that the ethical theory ought to be practical, that is, a theory based on utopian ideals or unfeasible expectations is of little use. That is, Jones et al. (1999)<sup>207</sup> maintain that an impractical normative core seriously compromises the well-being of those with an interest in a firm's success (e.g. shareholders) and, thus, certainly fails the test of a morally sound normative core. (p. 214)

### **3.3.3 Instrumental Theory of the Stakeholder Management Perspective**

As discussed above, although the historical roots of the stakeholder concept date back to the 1960s or earlier<sup>208</sup>, the concept has been widely accepted among scholars and

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<sup>204</sup> Bailur, S. (2006). Using Stakeholder Theory to Analyze Telecenter Projects. *Information Technologies and International Development*, 3, 61-80.

<sup>205</sup> Treviño, L. K., & Weaver, G. R. (1999). The Stakeholder Research Tradition: Converging Theorists – Not Convergent Theory. *Academy of Management Review*, 24, 222-227.

<sup>206</sup> Jones, T. M., & Wicks, A. C. (1999). Convergent Stakeholder Theory. *Academy of Management Review*, 24, 206-221.

<sup>207</sup> Ibid.

<sup>208</sup> The use of the term stakeholder grew out of the pioneering work at Stanford Research Institute in 1960s.



practitioners after the publication of Freeman's book (1984)<sup>209</sup>. Freeman emphasizes the importance of stakeholders as well as the historical dimension of the stakeholder approach. Freeman's particular interest in the notion of voluntarism is his own stakeholder philosophy. Freeman extensively discusses the formulation and implementation of the stakeholder strategies and then illustrates the specific implications of the stakeholder approach for the board of directors, functional disciplines, and the role of the executive. Through his book, Freeman tries to clarify what managers exactly should do with stakeholders and tries to give the impression that it is possible for managers to deal with stakeholders successfully. Freeman elaborates the ways to deal with stakeholders in a pragmatic fashion, using specific empirical evidences. It is noted that, as Freeman (1999)<sup>210</sup> himself addresses, his stakeholder theory is built on the premises of the instrumental theory. That is, Freeman (1999)<sup>211</sup> suggests that:

...if organizations want to be effective, they will pay attention to all and only those relationships that can affect or be affected by the achievement of the organization's purposes. That is, stakeholder management is fundamentally a pragmatic concept. Regardless of the content of the purpose of a firm, the effective firm will manage the relationships that are important. (p. 234)

Contrary to the arguments of both Donaldson et al. (1995)<sup>212</sup> and Jones et al. (1999)<sup>213</sup>, Freeman (1999)<sup>214</sup> asserts that the normative cores of the stakeholder theory are always dependent on the instrumentality built into the idea of the stakeholder management.

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<sup>209</sup> Freeman, R. E. (1984). *Strategic management: A stakeholder approach*. Englewood Cliffs, NJ: Prentice-Hall.

<sup>210</sup> Freeman, R. E. (1999). Divergent Stakeholder Theory. *Academy of Management Review*, 24, 233-236.

<sup>211</sup> Ibid.

<sup>212</sup> Donaldson, T., & Preston, L. E. (1995). The Stakeholder Theory of the Corporation: Concepts, Evidence, and Implications. *Academy of Management Review*, 20, 65-91.

<sup>213</sup> Jones, T. M., & Wicks, A. C. (1999). Convergent Stakeholder Theory. *Academy of Management Review*, 24, 206-221.

It should be noted that the notion of the stakeholder management suggested by Freeman is in close connection with the concept of the strategic management. In other words, the stakeholder management suggested by Freeman can be viewed as a stakeholder approach to the strategic management. After the publication of Freeman's book (1984)<sup>215</sup>, one central purpose of the stakeholder management perspective has been to enable managers to understand and to strategically manage stakeholders. The strategic stakeholder management approach suggested by Freeman emphasizes that managing external and internal stakeholders has to be an integrated element of any promising strategy. However, Freeman fails to present any specific details regarding how to implement the 'generic' stakeholder strategies. For instance, Freeman's strategies, such as change the rules of the game, might be extremely difficult for managers to follow in many cases.

In essence, the instrumental stakeholder theory posits that organizations that take care of their stakeholders will gain competitive advantage over those that do not (Bailur, 2006). The instrumental theory has investigated the relationship between the stakeholder management and the achievement of corporate objectives such as financial performance and growth. Donaldson et al. (1995)<sup>216</sup> also acknowledge the instrumental stakeholder theory, indicating that it establishes a framework for examining the connections, if any, between the practice of stakeholder management and the achievement of various corporate performance goals. The principal focus of the instrumental stakeholder theory has been the proposition that corporations practicing stakeholder management will, other

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<sup>214</sup> Freeman, R. E. (1999). Divergent Stakeholder Theory. *Academy of Management Review*, 24, 233-236.

<sup>215</sup> Ibid.

<sup>216</sup> Donaldson, T., & Preston, L. E. (1995). The Stakeholder Theory of the Corporation: Concepts, Evidence, and Implications. *Academy of Management Review*, 20, 65-91.

things being equal, be relatively successful in conventional performance terms (i.e. profitability, stability, growth, etc.)

The instrumental stakeholder theory also posits that certain outcomes will obtain if certain behaviors are adopted. Jones et al. (1999)<sup>217</sup> indicate that the instrumental stakeholder theory is contingent theory in that the predicted outcomes are contingent on the behavior of a certain type. In this respect, Jones (1995)<sup>218</sup> advances a form of the instrumental stakeholder theory. Jones (1995)<sup>219</sup> proposes that if firms contract with their stakeholders on the basis of mutual trust and cooperation, they will have a competitive advantage over firms that do not. In specific, the author states that “trusting, trustworthy, and cooperative behavior will get better results than opportunistic and selfish behavior because it improves trust, lowers transaction costs and therefore increases revenue” (Jones, 1995, p. 432)<sup>220</sup>. That is, the instrumental stakeholder theory argues that if managers develop trusting and cooperative relationships with stakeholders, a competitive advantage would result. The claims of the instrumental stakeholder theory are relatively straightforward and methodologically tractable as long as the conventional financial measures of the corporate performance are employed.

The notion of the instrumental stakeholder theory is aligned with that of the resource dependence theory. One of the main arguments of the resource dependence theory is that

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<sup>217</sup> Jones, T. M., & Wicks, A. C. (1999). Convergent Stakeholder Theory. *Academy of Management Review*, 24, 206-221.

<sup>218</sup> Jones, T. M. (1995). Instrumental stakeholder theory: A synthesis of ethics and economics. *Academy of Management Review*, 20, 404-437.

<sup>219</sup> Ibid.

<sup>220</sup> Ibid.

without interactions and transactions with critical groups, an organization will fail (Pfeffer et al., 1978)<sup>221</sup>. In addition to the resource dependence theory, the idea of Porter and Kramer (2002)<sup>222</sup> is also in connection with the instrumental stakeholder theory. Porter et al. (2002)<sup>223</sup> argue that the strategic corporate philanthropy, attending to the external stakeholders of a firm, is beneficial for a firm because social and economic goals are connected. The authors demonstrate that how each element of competitive advantages (i.e. factor conditions, demand conditions, context for strategy and rivalry, and related and supporting industries) can be influenced positively by the strategic corporate philanthropy.

In discussing the instrumental stakeholder theory, the study of Berman et al. (1999)<sup>224</sup> should be considered. Berman et al. (1999)<sup>225</sup> attempt an empirical study by comparing the descriptive accuracy of two most commonly held views of the stakeholder theory (i.e. the implicit models of the normative and the instrumental stakeholder theory) on the efficacy of the stakeholder management practices. The authors refer the normative approach as the intrinsic stakeholder commitment model and refer the instrumental approach as the strategic stakeholder management model. Berman et al. (1999)<sup>226</sup> define that, in the former model, firms are viewed as having a normative/moral commitment to treating stakeholders in a positive way, and this commitment is, in turn, seen as shaping

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<sup>221</sup> Pfeffer, J. & Salancik, G. (1978). *The external control of organizations: A resource dependence perspective*. New York, NY: Harper and Row.

<sup>222</sup> Porter, M. & Kramer, M. (2002, December). The competitive advantage of corporate philanthropy. *Harvard Business Review*, 57-68.

<sup>223</sup> Ibid.

<sup>224</sup> Berman, S. L., Wicks, A. C., Kotha, S., & Jones, T.M. (1999). Does stakeholder orientation matter? The relationship between stakeholder management models and firm financial performance. *Academy of Management Journal*, 42, 488-506.

<sup>225</sup> Ibid.

<sup>226</sup> Ibid.

their strategy and impacting their financial performance. In contrast, in the latter model, the nature and extent of managerial concern for a stakeholder group is viewed as determined solely by the perceived ability of such concern to improve firm financial performance. To compare the accuracy of two models in explaining the relationship between the stakeholder management practice and the firm financial performance, the authors develop propositions for each model and test them using the KLD data base. It is noted that the authors examine the relationship between a firm and its stakeholders, for both models, from a firm-centered perspective. The study results provide support for the strategic stakeholder management model, but no support for the intrinsic stakeholder commitment model.

As discussed above, Freeman' stakeholder approach is built on the premises of the instrumental stakeholder theory. Yet, Berman et al. (1999)<sup>227</sup> maintain that Freeman's (1984)<sup>228</sup> definition of stakeholders suggests a two-way relationship between a firm and its stakeholders. That is, Freeman's (1984)<sup>229</sup> definition of stakeholders suggests an instrumental posture toward stakeholders on the part of a firm and also suggests a normative obligation to stakeholders on the firm's part. Berman et al. (1999)<sup>230</sup> indicate that each element of these two relationships represents the foundation for a model of the

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<sup>227</sup> Berman, S. L., Wicks, A. C., Kotha, S., & Jones, T.M. (1999). Does stakeholder orientation matter? The relationship between stakeholder management models and firm financial performance. *Academy of Management Journal*, 42, 488-506.

<sup>228</sup> Freeman, R. E. (1984). *Strategic management: A stakeholder approach*. Englewood Cliffs, NJ: Prentice-Hall.

<sup>229</sup> Ibid.

<sup>230</sup> Berman, S. L., Wicks, A. C., Kotha, S., & Jones, T.M. (1999). Does stakeholder orientation matter? The relationship between stakeholder management models and firm financial performance. *Academy of Management Journal*, 42, 488-506.

stakeholder management. However, Berman et al. (1999)<sup>231</sup> assert that a fundamental assumption of the strategic stakeholder management model is that “the ultimate objective of corporate decisions is marketplace success” (p. 491). That is, the authors argue that the stakeholder management is a means to an end. In other words, the end, or the ultimate result, may have nothing to do with the welfare of stakeholders in general. Instead, the firm’s goal is the advancement of the interests of only one stakeholder group – its shareholders.

The notion presented by Berman et al. (1999)<sup>232</sup> is contrary to that of the normative stakeholder theorists and, thus, there has been much contention over it. Yet, it is noted that Berman et al. (1999)<sup>233</sup> make a persuasive proposition on firms’ perspective. That is, in the strategic stakeholder management model, the stakeholder management is part of a company’s strategy. A company’s relationships with its stakeholders enter into its strategic calculus, and the types of relationships that produce the best prospective outcomes for the firm are pursued. Namely, in the strategic stakeholder management model, although the objective of managers is not to advance the morally legitimate claims of stakeholders but to maximize profits, managers will and should attend to the interests of stakeholders to the extent that the stakeholders affect the firm financial performance. In short, managers will and should consider the concerns of stakeholders in the process of decision-making, if they have strategic value to the firm. This explains why firms should deal with their stakeholders in a more practical way.

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<sup>231</sup> Berman, S. L., Wicks, A. C., Kotha, S., & Jones, T.M. (1999). Does stakeholder orientation matter? The relationship between stakeholder management models and firm financial performance. *Academy of Management Journal*, 42, 488-506.

<sup>232</sup> Ibid.

<sup>233</sup> Ibid.

It is noted that Friedman's (1970)<sup>234</sup> idea presented in "The Social Responsibility of Business is to Increase its Profits" is in connection with that of the instrumental stakeholder theory, although the author does not use the term stakeholder or stakeholder management. There are businessmen who believe that business has a 'social conscience' and takes seriously its responsibilities for providing employment, eliminating discrimination, avoiding pollution and whatever else may be the catchwords of the contemporary crop of reformers. Friedman (1970)<sup>235</sup> argues that "in fact, they are – or would be if they or anyone else took them seriously, preaching pure and unadulterated socialism" (p. 32). He further argues that the doctrine of social responsibility involves the acceptance of the socialist view because the political mechanisms, not the market mechanisms, are the appropriate way to determine the allocation of scarce resources to alternative uses. Friedman (1970)<sup>236</sup> emphasizes that "whether blameworthy or not, the use of the cloak of social responsibility, and the nonsense spoken in its name by influential and prestigious businessmen, does clearly harm the foundations of a free society" (p. 33). Namely, Friedman (1970)<sup>237</sup> warns us that the doctrine of social responsibility taken seriously would extend the scope of the political mechanism to every human activity. The author's concluding remark is very impressive: that is, in a free society, "there is one and only one social responsibility of business – to use its resources and engage in activities designed to increase its profits so long as it stays within the rules of the game, which is to say, engages in open and free competition without deception or

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<sup>234</sup> Friedman, M. (1970, September, 13). The social responsibility of business to increase its profits. New York Times Magazine. 32-33.

<sup>235</sup> Ibid.

<sup>236</sup> Ibid.

<sup>237</sup> Ibid.

fraud” (p.33). Friedman’s (1970)<sup>238</sup> perspective implies that, as the instrumental theory does, the modes of dealing with stakeholders proved to be unproductive on the part of a firm will be discontinued and managers will attend to the interests of stakeholders to the extent that the stakeholders can affect the firm’s financial performance.

The instrumental stakeholder theory has also its critics. The normative stakeholder theorists, such as Donaldson et al. (1995)<sup>239</sup>, argue that the interests of stakeholders have intrinsic value and, thus, certain claims of stakeholders are based on the fundamental moral principles unrelated to the stakeholders’ instrumental value to a firm. Therefore, the firm cannot ignore these claims simply because they do not serve for its strategic interests. Namely, the normative theory contends that “stakeholder interests are thought to form the foundation of corporate strategy itself, representing ‘what we are’ and ‘what we stand for’ as a company” (Berman et al., 1999, p. 493)<sup>240</sup>. Moreover, the normative theorists argue that making a strategic commitment to morality is not only conceptually flawed but also ineffective. That is, Quinn et al. (1995)<sup>241</sup> contend that the instrumental ethics is problematic because first, the ethics policies that are justified in the instrumental terms are less likely to elicit support from firm employees and other corporate constituencies, and second, the ethics policies that are justified in the instrumental terms are less likely benefit a firm economically in the long term. In addition, the authors

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<sup>238</sup> Friedman, M. (1970, September, 13). The social responsibility of business to increase its profits. *New York Times Magazine*. 32-33.

<sup>239</sup> Donaldson, T., & Preston, L. E. (1995). The Stakeholder Theory of the Corporation: Concepts, Evidence, and Implications. *Academy of Management Review*, 20, 65-91.

<sup>240</sup> Berman, S. L., Wicks, A. C., Kotha, S., & Jones, T.M. (1999). Does stakeholder orientation matter? The relationship between stakeholder management models and firm financial performance. *Academy of Management Journal*, 42, 488-506.

<sup>241</sup> Quinn, D. P., & Jones, T. M. (1995). An Agent Morality View of Business Policy. *Academy of Management Review*, 20, 22-42.



emphasize that the consequences of the instrumental ethics revealed as an opportunistic venture are severe. Quinn et al. (1995)<sup>242</sup> question that if the purpose of acting ethically is to acquire a good reputation that, in turn, will provide a firm with economic benefits, why not pursue the good reputation directly without the intellectual excursion into moral philosophy? Furthermore, Jones (1995)<sup>243</sup> maintains that the instrumental benefits of the stakeholder management paradoxically result only from a genuine commitment to the ethical principles. The author argues that firms which create and sustain the stakeholder relationships based on mutual trust and cooperation will have a competitive advantage over those which do not. In essence, the normative stakeholder theorists emphasize that a firm's commitment to trust and cooperation with its stakeholders should be intrinsic rather than strategic (or instrumental) to maintain the sincere manner and reputation.

### **3.4 The Implications of the Stakeholder Management Perspective for the Pharmaceutical Companies**

#### **3.4.1 The Instrumental Stakeholder Theory, the Strategic Stakeholder Management Approach, and the Organizational Strategy Development**

The notion of the strategic stakeholder management approach is derived from the instrumental stakeholder theory. A stakeholder approach to the strategic management emerged in the mid-1980s and one focal point in this movement was the publication of

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<sup>242</sup> Quinn, D. P., & Jones, T. M. (1995). An Agent Morality View of Business Policy. *Academy of Management Review*, 20, 22-42.

<sup>243</sup> Jones, T. M. (1995). Instrumental stakeholder theory: A synthesis of ethics and economics. *Academy of Management Review*, 20, 404-437.

Freeman's book in 1984. Freeman (1984)<sup>244</sup> explains that a "stakeholder approach is about groups and individuals who can affect the organization, and is about managerial behavior taken in response to those groups and individuals" (p.46). The author suggests that the strategic managerial attention to the stakeholder interests is indispensable for the successful performance of a firm, establishing a useful framework for the investigation of the stakeholder management practice of a firm. It is noted that, initially, the stakeholder management perspective was introduced to provide a framework for firms with which they can develop new strategic directions. According to Freeman et al. (2001)<sup>245</sup>, the impetus behind stakeholder management was to try and build a framework that was responsive to the concerns of managers who were being buffeted by unprecedented levels of environmental turbulence and change, because traditional strategy frameworks were neither helping managers develop new strategic directions nor were they helping them understand how to create new opportunities in the midst of so much change.

After the publication of Freeman's book, many scholars have studied and developed the instrumental stakeholder theory or the strategic stakeholder management approach in connection with the organizational strategy development. Donaldson et al. (1995)<sup>246</sup> develop, conceptually, three aspects of the stakeholder management perspective and clarify the critical differences among them. In particular, the authors define precisely the instrumental approach of the stakeholder management perspective: i.e., the instrumental

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<sup>244</sup> Freeman, R. E. (1984). *Strategic management: A stakeholder approach*. Englewood Cliffs, NJ: Prentice-Hall.

<sup>245</sup> Freeman, R. E. & McVea, J. (2001). *A Stakeholder Approach to Strategic Management* [Electronic Version]. Darden Graduate School of Business Administration. Retrieved December 10, 2007, from [http://papers.ssrn.com/paper.taf?abstract\\_id=263511](http://papers.ssrn.com/paper.taf?abstract_id=263511)

<sup>246</sup> Donaldson, T., & Preston, L. E. (1995). The Stakeholder Theory of the Corporation: Concepts, Evidence, and Implications. *Academy of Management Review*, 20, 65-91.

stakeholder theory “is used to identify the connections, or lack of connections, between the stakeholder management and the achievement of traditional corporate objectives (e.g. profitability, growth)” (Donaldson et al., 1995, p. 71)<sup>247</sup>. Although Donaldson et al. (1995)<sup>248</sup> emphasize the importance of the normative stakeholder theory, the authors clarify the nature of the instrumental approach of the stakeholder management perspective. That is, the instrumental stakeholder theory concerns the relationships among CSR, CSP, stakeholder strategies, and CFP. Many of the recent studies on the relationship between CSP and CFP make reference to the stakeholder management, explicitly or implicitly, especially in terms of the instrumental stakeholder theory. Although the results are mixed and inconclusive, numerous studies have been conducted to test the instrumental claim of firms that practice the stakeholder management would outperform firms that do not.

Berman et al. (1999)<sup>249</sup> derive the strategic stakeholder management model from the instrumental approach of the stakeholder management perspective. In the strategic stakeholder management model, “the nature and extent of managerial concern for a stakeholder group is viewed as determined solely by the perceived ability of such concern to improve firm financial performance” (Berman et al., 1999, p. 488)<sup>250</sup>. In contrast, in the intrinsic stakeholder commitment model, “firms are viewed as having a normative (moral) commitment to treating stakeholders in a positive way, and this commitment is,

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<sup>247</sup> Donaldson, T., & Preston, L. E. (1995). The Stakeholder Theory of the Corporation: Concepts, Evidence, and Implications. *Academy of Management Review*, 20, 65-91.

<sup>248</sup> Ibid.

<sup>249</sup> Berman, S. L., Wicks, A. C., Kotha, S., & Jones, T.M. (1999). Does stakeholder orientation matter? The relationship between stakeholder management models and firm financial performance. *Academy of Management Journal*, 42, 488-506.

<sup>250</sup> Ibid.

in turn, seen as shaping their strategy and impacting their financial performance” (Berman et al., 1999, p. 488)<sup>251</sup>. Based on an empirical study of the effect of the stakeholder management on CFP, Berman et al. (1999)<sup>252</sup> find that the strategic stakeholder management model is supported but the intrinsic stakeholder commitment model is not supported. Therefore, Berman et al. (1999)<sup>253</sup> support the strategic stakeholder management model arguing that “firms address stakeholder concerns when they believe doing so will enhance firm financial performance” (p. 502). That is, the authors refer to a firm’s interest in the stakeholder relationships as instrumental and contingent on the value of those relationships to the financial success of the firm.

Harrison et al. (2007)<sup>254</sup> present some distinctive views of the strategic stakeholder management perspective in connection with the organizational strategy development. The authors contend that the stakeholder management is built on a partnering mentality that involves communicating, negotiating, contracting, managing relationships, and motivating. These different aspects of the stakeholder management are held together by the enterprise strategy which defines what the firm stands for. In particular, Harrison et al. (2007)<sup>255</sup> introduce the concept of ‘bridging’, which involves forming strategic partnership to manage stakeholders, and, then, propose a framework which determines the importance of developing partnering tactics with stakeholders. With this framework,

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<sup>251</sup> Berman, S. L., Wicks, A. C., Kotha, S., & Jones, T.M. (1999). Does stakeholder orientation matter? The relationship between stakeholder management models and firm financial performance. *Academy of Management Journal*, 42, 488-506.

<sup>252</sup> Ibid.

<sup>253</sup> Ibid.

<sup>254</sup> Harrison, J. S., & St. John, C. H. (2007). *Foundations in Strategic Management* (4th ed.). Mason, OH: Thomson South-Western.

<sup>255</sup> Ibid.

the authors identify a wide range of partnering tactics that can be adopted to manage critical stakeholders as well as to develop organizational strategies.

The stakeholder management perspective, particularly the strategic stakeholder management approach, suggests that a firm should form and implement strategies in relation to its stakeholders to ensure the long-term success. As Freeman et al. (2001)<sup>256</sup> argue, the interests of the key stakeholders of a firm must be integrated into the very purpose of the firm, and the stakeholder relationships must be managed in a coherent and strategic fashion. The strategic stakeholder approach “encourages management to develop strategies by looking out from the firm and identifying, and investing in, all the relationships that will ensure long-term success” (Freeman et al., 2001, p. 8)<sup>257</sup>. It is noted that the strategic stakeholder management approach intend to provide a strategic framework flexible enough to deal with fast changing business environment. That is, the strategic stakeholder management approach “actively plots a new direction for the firm and considers how the firm can affect the environment as well as how the environment may affect the firm” (Freeman et al., 2001, p. 8). Therefore, the notion of the strategic stakeholder management approach is different form that of the strategic planning process in that the strategic planning process focuses on trying to predict the future business environment and then developing plans which can adapt a firm to the future environment to maximize its position.

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<sup>256</sup> Freeman, R. E. & McVea, J. (2001). A Stakeholder Approach to Strategic Management [Electronic Version]. Darden Graduate School of Business Administration. Retrieved December 10, 2007, from [http://papers.ssrn.com/paper.taf?abstract\\_id=263511](http://papers.ssrn.com/paper.taf?abstract_id=263511)

<sup>257</sup> Ibid.

In this respect, when the stakeholder management perspective is discussed in connection with the organizational strategy development, the strategy concept of Mintzberg<sup>258</sup> has important implications. Mintzberg (1978)<sup>259</sup> (1985)<sup>260</sup> has distinguished the ‘deliberate’ strategy from the ‘emergent’ strategy (1987a)<sup>261</sup> and adopts the term ‘crafting’ rather than ‘planning’ in conjunction with the organizational strategy development. In essence, Mintzberg (1987a)<sup>262</sup> maintains that strategies are both plans for the future and patterns from the past and, thus, strategies are not needed to be deliberated, i.e., they can also be emerged. Mintzberg (1987a)<sup>263</sup> emphasizes this point as follows:

Strategies can form as well as formulated. A realized strategy can emerge in response to an evolving situation, or it can be brought about deliberately, through a process of formulation followed by implementation. But when these planned intentions do not produce the desired actions, organizations are left with unrealized strategies... Sometimes they can be smarter by allowing their strategies to develop gradually, through the organization’s actions and experiences. Smart strategists appreciate that they cannot always be smart enough to think through everything in advance. (p. 69)

It is argued that although Mintzberg does not use the term ‘strategic management’ through his works, his strategy concept reflects the most important aspect of the strategic management approach in terms of the strategy development. As described above, the strategy concept of Mintzberg operationalizes the strategy concept of this dissertation, providing a basis of how strategies can be developed for the pharmaceutical companies.

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<sup>258</sup> As illustrated earlier, it is noted that the strategy concept of Mintzberg has been the basis for the organizational strategy development for the pharmaceutical companies in this dissertation.

<sup>259</sup> Mintzberg, H. (1978). Patterns in Strategy Formation. *Management Science*, 24, 934-948.

<sup>260</sup> Mintzberg, H. (1985). Of Strategies, Deliberate and Emergent. *Strategic Management Journal*, 6, 257-272.

<sup>261</sup> Mintzberg, H. (1987a, July). Crafting strategy. *Harvard Business Review*, 66-75.

<sup>262</sup> Ibid.

<sup>263</sup> Ibid.

As Freeman (1984)<sup>264</sup> defines, the “stakeholder approach is about groups and individuals who can affect the organization, and is about managerial behavior taken in response to those groups and individuals”. To develop such response strategies, it is argued that although the stakeholder theory is managerial in orientation, knowing how stakeholders may influence a firm must be critical for managers who want to respond strategically to the stakeholders. This can be considered as a counterintuitive approach to the strategic stakeholder approach. For instance, Frooman (1999)<sup>265</sup> puts the focus on the influence strategies of stakeholders instead of on the response strategies of firms. The author argues that building a model of the stakeholder influence strategies would address the missing part of the stakeholder theory and, ultimately, enables managers to better understand and manage the stakeholder behavior. It should be noted that, for this dissertation, both the influence strategies of stakeholders and the response strategies of the pharmaceutical companies are considered simultaneously, adopting two different types of the formal qualitative analysis and the ARM, to develop strategies for the pharmaceutical companies in the stakeholder management terms.

### **3.4.2 The Implications of the Strategic Stakeholder Management Approach for the Pharmaceutical Companies in terms of the Organizational Strategy Development**

Although numerous studies of the stakeholder management perspective have been conducted, studies which deal specifically with the pharmaceutical companies in the stakeholder management terms have been scant. It is noted that even the usefulness of the stakeholder management perspective for the pharmaceutical industry is controversial.

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<sup>264</sup> Freeman, R. E. (1984). *Strategic management: A stakeholder approach*. Englewood Cliffs, NJ: Prentice-Hall.

<sup>265</sup> Frooman, J. (1999). Stakeholder Influence Strategy. *Academy of Management Review*, 24, 191-205.

Two recent studies (i.e. Kennedy et al. [2004]<sup>266</sup> and Calfee et al. [2004]<sup>267</sup>) are truly descriptive of the opposite positions among scholars with regard to the usefulness of the stakeholder management perspective for the pharmaceutical industry in relation to the organizational strategy development.

Kennedy et al. (2004)<sup>268</sup> contend that the traditional business model of the pharmaceutical industry is under severe strain as a result of the differential pricing policy and the global threats to the intellectual property protection of pharmaceutical products. The authors suggest that an integrative marketing program of the public relations and the public policy initiatives in connection with the key stakeholders can motivate the creation of necessary incentives for the discovery of the new HIV/AIDS drugs and for their delivery to the global markets. In this respect, Kennedy et al. (2004)<sup>269</sup> propose several specific initiatives and policies. In essence, to address properly today's critical marketing management questions, the pharmaceutical industry must understand clearly the interests and behaviors of the key stakeholders. The authors assert that only such an understanding can help the pharmaceutical industry craft a broad consensus for the new public policy initiatives towards the global HIV/AIDS crisis and other similar diseases. The authors emphasize that the challenges faced by the pharmaceutical industry can be addressed through a mixture of corporate and governmental policies that incorporate the legitimate

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<sup>266</sup> Kennedy, C. R., Harris, F. H., & Lord, M. (2004). Integrating public policy and public affairs in a pharmaceutical marketing program: The AIDS pandemic. *Journal of Public Policy and Marketing*, 23, 128-139.

<sup>267</sup> Calfee, J. E., & Bate, R. (2004). Pharmaceuticals and the Worldwide HIV Epidemic: Can a Stakeholder Model Work? *Journal of Public Policy & Marketing*, 23, 140-152.

<sup>268</sup> Kennedy, C. R., Harris, F. H., & Lord, M. (2004). Integrating public policy and public affairs in a pharmaceutical marketing program: The AIDS pandemic. *Journal of Public Policy and Marketing*, 23, 128-139.

<sup>269</sup> Ibid.



stakeholder claims, while preserving the industry's ability to sustain a continuing program of needed R&D that will advance the global health products. The key strength of the authors' proposal is that it collectively addresses and facilitates the core interests and competences of the key stakeholders, thus, it is inherently more stable and sustainable. The authors conclude that, without the industry-wide collaboration and the effective stakeholder management, the realization of the comprehensive win-win policies – for both the pharmaceutical industry and its stakeholders - cannot be realized.

It is highly noted that Kennedy et al. (2004)<sup>270</sup> apply the stakeholder management perspective to the pharmaceutical industry, trying to show empirically the usefulness of the strategic stakeholder management approach for the industry in terms of the strategy development. Thus, it is argued that the work of Kennedy et al. (2004)<sup>271</sup> contribute to the extant literature by relating the strategic stakeholder management approach to the pharmaceutical industry. However, although the authors explain why the pharmaceutical industry should employ the stakeholder management perspective and, also, identify the key stakeholders of the industry, they fail to present any specific measures to facilitate the integration of the stakeholder management approach into its marketing program or its strategy development process on the part of the pharmaceutical industry. In this respect, a stakeholder analysis model that leads to the strategy development for the pharmaceutical industry is expected to be developed.

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<sup>270</sup> Kennedy, C. R., Harris, F. H., & Lord, M. (2004). Integrating public policy and public affairs in a pharmaceutical marketing program: The AIDS pandemic. *Journal of Public Policy and Marketing*, 23, 128-139.

<sup>271</sup> Ibid.

In response to Kennedy et al. (2004)<sup>272</sup>, Calfee et al. (2004)<sup>273</sup> argue that “the rapid drop in HIV drug prices, combined with generic entry and de facto abandonment of patent rights, has revealed the extremely limited role of drug prices and access in the face of fundamental problems in infrastructure, prevention, and other essential elements in battling HIV/AIDS” (p. 140). The authors further contend that the adoption of a stakeholder approach is likely to undermine the essential R&D, while doing little to curtail the HIV/AIDS epidemic. The main point of Calfee et al. (2004)<sup>274</sup> is that the drug prices, at the center of so much controversy, can play a relatively limited role in the battle against HIV/AIDS and progress will be determined largely by the factors other than the drug prices. Calfee et al. (2004)<sup>275</sup> assert the following:

Although the stakeholder model is hardly well-defined, its essential elements raise serious problems, including an inability to forge a lasting and predictable consensus on such basic matters as R&D and pricing, unnecessary costs and inefficiencies, and a near-certain undermining of R&D incentives. These difficulties gain force and concreteness when the stakeholder model is arrayed against the specifics of the HIV/AIDS crisis in what are often referred to as “resource-limited” economies of sub-Saharan Africa. It is difficult to imagine what the terms of a stakeholder approach might be, how that approach could help solve the problems facing poor nations, or how it could help generate the new medical technology – especially an HIV vaccine – that is desperately needed and is least likely to emerge from the government or non-profit sectors. (p. 149)

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<sup>272</sup> Kennedy, C. R., Harris, F. H., & Lord, M. (2004). Integrating public policy and public affairs in a pharmaceutical marketing program: The AIDS pandemic. *Journal of Public Policy and Marketing*, 23, 128-139.

<sup>273</sup> Calfee, J. E., & Bate, R. (2004). Pharmaceuticals and the Worldwide HIV Epidemic: Can a Stakeholder Model Work? *Journal of Public Policy & Marketing*, 23, 140-152.

<sup>274</sup> Ibid.

<sup>275</sup> Ibid.

Calfee et al. (2004)<sup>276</sup> conclude that stakeholders will be left with little to show for abandoning the traditional drug development model. However, the authors fail to present any alternative that can be taken by the pharmaceutical companies to deal with the challenges posed by their stakeholders. Will the traditional business model of the pharmaceutical industry continue to work under the increasing pressure from its various stakeholders? The stakeholder management perspective may not be a panacea for the pharmaceutical industry. However, it is argued that at least the effective stakeholder dialogue can help create more sustainable strategies on the part of the pharmaceutical industry for both the industry and its stakeholders.

As discussed earlier, the stakeholder management perspective can be represented in a variety of ways and the notion of the strategic stakeholder management approach is closely related to the process of the organizational strategy development. The instrumental stakeholder theory does not appeal to the CSR or the moral obligation rooted in the concept of the global corporate citizenship. Rather, the instrumental stakeholder theory argues that “the nature and extent of managerial concern for a stakeholder group is viewed as determined solely by the perceived ability of such concern to improve firm financial performance” (Berman et al., 1999, p. 488)<sup>277</sup>. That is, with the instrumental theory, firms address the stakeholder concerns when they believe doing so will enhance the firm financial performance.

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<sup>276</sup> Calfee, J. E., & Bate, R. (2004). Pharmaceuticals and the Worldwide HIV Epidemic: Can a Stakeholder Model Work? *Journal of Public Policy & Marketing*, 23, 140-152.

<sup>277</sup> Berman, S. L., Wicks, A. C., Kotha, S., & Jones, T.M. (1999). Does stakeholder orientation matter? The relationship between stakeholder management models and firm financial performance. *Academy of Management Journal*, 42, 488-506.

This dissertation develops strategies for the pharmaceutical companies in terms of the stakeholder management perspective, specifically in the strategic stakeholder management approach terms. Since the pressure posed by its stakeholders against the pharmaceutical industry has been severely intensified, without considering the interests of the stakeholders in its decision-making process, the successful long-term performance of the industry cannot be guaranteed. In other words, the pharmaceutical industry should consider the stakeholder management perspective in its strategy development process to balance the expensive, R&D-intensive business with enlarged, global social responsibility. In essence, considering the stakeholder management perspective in connection with its strategy development can help the pharmaceutical industry craft comprehensive win-win strategies not only for the pharmaceutical industry in the financial performance terms but also for its stakeholders in the access to essential, life-saving medicines terms.

In the next two chapters, to craft strategies for the pharmaceutical industry, first, two different types of formal qualitative analysis is conducted and, then, the ARM is performed. These different types of methodology are incorporated into the strategy development for the pharmaceutical industry. It is expected that these different methodologies can complement for each other to develop more effective strategies for the industry, attaining a win-win situation.

#### **Chapter 4: Formal Qualitative Analysis on the Responses of the Pharmaceutical Companies to the Issues related to the Global Public Health**

#### 4.1 Formal Qualitative Analysis: Event Structure Analysis (ESA) and Qualitative Comparative Boolean Analysis

ESA is an approach to the formal qualitative analysis of narrative sequences and actions. Griffin (1993)<sup>278</sup> points out that for the formal qualitative analysis, three approaches have been developed including ESA. Before introducing ESA, it might be useful to examine the other two approaches. Griffin (1993)<sup>279</sup> explains two approaches as follows:

Peter Abell's (1987) "comparative narrative analysis" traces the sequences in individual narratives with algebra of intentional action and intended and unintended consequences. The structure of the logic in the narrative is then generalized and systematically compared with the logical structures of other narratives. Andrew Abbott's (1992) procedures categorize narratives through the use of unidimensional and multidimensional scaling. Abbott's concern in analyzing repeated events is also with the "generic" or typical narrative (1991, 1992). (p. 1105)

Although Griffin (1993)<sup>280</sup> admits that these two approaches to the formal qualitative analysis of narrative sequences and actions have much to commend them, the author argues that if the purpose of an analysis is to construct a causal interpretation, then, both approaches are inappropriate. Griffin (1993)<sup>281</sup> contends that:

Neither Abell nor Abbott appears much interested in constructing Weberian-type causal interpretations. Abell (1987), for example, places great, perhaps even indiscriminating, weight on sequence per se, while, Abott (1991, p. 228) finds "abstracting 'causes' out of their narrative environments" seemingly impossible in principle. Given narrative's configurational, conjunctural character, Abott's demurral has force. But not analyzing narrative from a causal perspective sanctions by default the defects, discussed

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<sup>278</sup> Griffin, L. J. (1993). Narrative, Event-Structure Analysis, and Causal Interpretation in Historical Sociology. *American Journal of Sociology*, 98, 1094-1133.

<sup>279</sup> Ibid.

<sup>280</sup> Ibid.

<sup>281</sup> Ibid.

above, of accepting temporal flow as the basis of explanation and the narrator's construction of the event as the happening. (p. 1105)

Thus, Griffin (1993)<sup>282</sup> maintains that the third approach to the formal qualitative analysis, i.e., ESA, is acceptable, if the purpose of an analysis is to construct interpretation. ESA was originally developed to study the cultural routines (e.g. Stevenson et al., 1998)<sup>283</sup> and "the subjective representations of reality" (Griffin, 1993, p. 1105)<sup>284</sup>. Also, ESA "was influenced by developments in cognitive anthropology as well as by rational choice theory" (Griffin, 1993, p. 1105). ESA enables a researcher to develop "a dynamic, causal interpretation of the original narrative that can be replicated and generalized" (Stevenson et al., 1998, p. 744)<sup>285</sup> and several scholars have elaborated the methodology (e.g. Heise [1989]<sup>286</sup>; Griffin [1993]<sup>287</sup>; Isaac et al., [1994]<sup>288</sup>; Griffin et al., [1994]<sup>289</sup>). In particular, Heise (1989)<sup>290</sup> explicitly advances ESA and its associated computer program, ETHNO, for both causal and interpretive purposes. It is noted that ESA and ETHNO have features that render them especially appropriate for developing the causal interpretations of historical events. The term causality used in ESA and ETHNO can be defined as "the interdependency between two events in the narrative"

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<sup>282</sup> Griffin, L. J. (1993). Narrative, Event-Structure Analysis, and Causal Interpretation in Historical Sociology. *American Journal of Sociology*, 98, 1094-1133.

<sup>283</sup> Stevenson, W. B., & Greenberg, D. N. (1998). The Formal Analysis of Narratives of Organizational Change. *Journal of Management*, 24, 741-762.

<sup>284</sup> Griffin, L. J. (1993). Narrative, Event-Structure Analysis, and Casual Interpretation in Historical Sociology. *American Journal of Sociology*, 98, 1094-1133.

<sup>285</sup> Stevenson, W. B., & Greenberg, D. N. (1998). The Formal Analysis of Narratives of Organizational Change. *Journal of Management*, 24, 741-762.

<sup>286</sup> Heise, D. R. (1989). Modeling Event Structures. *Journal of Mathematical Sociology*, 14, 139-169.

<sup>287</sup> Griffin, L. J. (1993). Narrative, Event-Structure Analysis, and Casual Interpretation in Historical Sociology. *American Journal of Sociology*, 98, 1094-1133.

<sup>288</sup> Isaac, L. W., Street, D. A., & Knapp, S. J. (1994). Analyzing Historical Contingency with Formal Methods. *Sociological Methods and Research*, 23, 114-141.

<sup>289</sup> Griffin, L. J., & Ragin, C. C. (1994). Some Observations on Formal Methods of Qualitative Analysis. *Sociological Methods and Research*, 23, 4-21.

<sup>290</sup> Heise, D. R. (1989). Modeling Event Structures. *Journal of Mathematical Sociology*, 14, 139-169.

(Stevenson et al., 1998, p. 745)<sup>291</sup>. Griffin (1993)<sup>292</sup> explains that by locating an event in a particular sequence and by linking it to prior events, a researcher can identify what previous event(s) caused the subsequent event to occur. However, it should be noted that performing ESA itself using ETHNO does not reveal the causal relationships between particular events. As Griffin (1993)<sup>293</sup> illustrates, through the process of interrogation in executing ETHNO, a researcher can determine causal connections between particular events based on the researcher's 'expert judgments'. That is, "the analyst, not the computer program, possesses the knowledge to structure and interpret the narrative events" (Stevenson et al., 1998, p. 745)<sup>294</sup>.

Particularly, ETHNO, a software program designed by Heise (1989)<sup>295</sup> to execute ESA, enables a researcher to specify "causal linkages between each pair of consecutive events and tells the researcher when a causal claim is contradictory with previous specified relationships" (Trullen et al., 2006, p. 184)<sup>296</sup>. Griffin (1993)<sup>297</sup> delineates how ETHNO works. That is, a researcher first prepares a chronology of actions, which define the event. Although ETHNO does not offer a direct assistance in preparing a chronology of actions, a preliminary event structure analysis can help the researcher to detect weaknesses in the chronology and to refine it. The chronology of actions is then entered as input into

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<sup>291</sup> Stevenson, W. B., & Greenberg, D. N. (1998). The Formal Analysis of Narratives of Organizational Change. *Journal of Management*, 24, 741-762.

<sup>292</sup> Griffin, L. J. (1993). Narrative, Event-Structure Analysis, and Casual Interpretation in Historical Sociology. *American Journal of Sociology*, 98, 1094-1133.

<sup>293</sup> Ibid.

<sup>294</sup> Stevenson, W. B., & Greenberg, D. N. (1998). The Formal Analysis of Narratives of Organizational Change. *Journal of Management*, 24, 741-762.

<sup>295</sup> Heise, D. R. (1989). Modeling Event Structures. *Journal of Mathematical Sociology*, 14, 139-169.

<sup>296</sup> Trullen, J., & Stevenson, W. B. (2006). Strategy and Legitimacy: Pharmaceutical Companies' Reaction to HIV Crisis. *Business & Society*, 45, 178-210.

<sup>297</sup> Griffin, L. J. (1993). Narrative, Event-Structure Analysis, and Causal Interpretation in Historical Sociology. *American Journal of Sociology*, 98, 1094-1133.

ETHNO, where it is reformulated as a series of questions about the causal connections among actions constituting the chronology. The responses to the questions of ETHNO are displayed as a directed or causal diagram of the logical structure of action underlying the event's narrative or chronology. The diagram, finally, is the event structure and represents the researcher's interpretation of the causal connections among sequences constituting the chronology. The causal logic reflected by the diagram is, then, tested for consistency with a set of logical constraints or rules about how action can proceed that is built in ETHNO. Stevenson et al. (1998)<sup>298</sup> explain that the diagram that ETHNO produces enables a researcher to sharpen his/her insight into the causal relationships between the different events. Thus, the researcher can determine which events have no consequences and how certain events may not lead to anything in the present, but have implications for the future. In addition, with regard to the ETHNO diagram, Trullen et al. (2006)<sup>299</sup> illustrate that "by inspecting the Ethno diagram, one can see what events are pivotal to unleash others, see what events are key turning points in the narrative, and understand how parallel streams of action interact to create certain outcomes" (p. 184).

However, as discussed above, causality is not discovered through the use of ETHNO itself. Griffin (1993)<sup>300</sup> points out the following:

The analyst, not the software, possesses the knowledge needed to structure and interpret the event. What ETHNO does – and, at root, all that it really

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<sup>298</sup> Stevenson, W. B., & Greenberg, D. N. (1998). The Formal Analysis of Narratives of Organizational Change. *Journal of Management*, 24, 741-762.

<sup>299</sup> Trullen, J., & Stevenson, W. B. (2006). Strategy and Legitimacy: Pharmaceutical Companies' Reaction to HIV Crisis. *Business & Society*, 45, 178-210.

<sup>300</sup> Griffin, L. J. (1993). Narrative, Event-Structure Analysis, and Casual Interpretation in Historical Sociology. *American Journal of Sociology*, 98, 1094-1133.



does – is relentlessly probe the analyst’s construction and comprehension of the event. By forcing the user to be precise and meticulous about the construction of historical narratives, to reason causally about their sequences, and to be clear about the bases of causal judgments, ESA and ETHNO lay bare the investigator’s understanding so lucidly – indeed, starkly, as a diagram of the logic of action – that insights into causal significance are intensely sharpened, and problems of causal interpretation are prominently displayed. (p. 1108)

As Stevenson et al. (1998)<sup>301</sup> describe, ESA is grounded in the narrative interpretation and is based on the formal mathematical logic. Also, as Griffin et al. (1994)<sup>302</sup> explain, ESA is both explanatory and interpretive and can be classified as a form of formal qualitative analysis. Heise (1989)<sup>303</sup> explains ESA as follows: that is, ESA is

directed toward developing some methodology for studying subjective representations of reality – commonly called knowledge...However, computer-based procedures are presented which extend methods in cognitive anthropology directed at focusing field work and systematizing collection and analysis of qualitative data. The extended methodology permits systematic analysis of qualitative data, yields qualitative models, and allows qualitative formulations to be tested empirically. The computer technology does not make qualitative research quantitative, though...one of the long-range consequences of the integration of computers and qualitative data may be to break down the polarization of qualitative and quantitative research. (p. 139)

As indicated above, ESA performed by ETHNO is especially appropriate for developing the causal interpretations of historical events. Therefore, for this dissertation, the ESA performed by ETHNO help to explain how and why the pharmaceutical companies have responded to the issues related to the global public health and help to identify the events pivotal in shaping the responses of the companies.

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<sup>301</sup> Stevenson, W. B., & Greenberg, D. N. (1998). The Formal Analysis of Narratives of Organizational Change. *Journal of Management*, 24, 741-762.

<sup>302</sup> Griffin, L. J., & Ragin, C. C. (1994). Some Observations on Formal Methods of Qualitative Analysis. *Sociological Methods and Research*, 23, 4-21.

<sup>303</sup> Heise, D. R. (1989). Modeling Event Structures. *Journal of Mathematical Sociology*, 14, 139-169.

In connection with the ESA of this dissertation, another method of the formal qualitative analysis - i.e. the qualitative comparative Boolean analysis - is adopted to aid the ESA in developing causal interpretations of historical events. In other words, this dissertation performs a comparative Boolean analysis to help the ESA investigate how and why the pharmaceutical companies have responded to the issues related to the global public health and also to help the ESA identify the events pivotal in shaping the responses of the companies. Romme (1995)<sup>304</sup> explains the comparative Boolean analysis in connection with case study research. That is, Romme (1995)<sup>305</sup> argues that a ‘comparative Boolean analysis’<sup>306</sup> can compensate for the weaknesses of the conventional approach to comparative case studies by systematically addressing a larger number of cases without forsaking complexity too much. A comparative Boolean analysis can also systematically structure the kind of dialogue between theory and evidence typically found in case study research. In these respects, for this dissertation, it is expected that the adoption of the comparative Boolean analysis can complement the possible weaknesses of the comparative case study (i.e. the ESA). Romme’s (1995)<sup>307</sup> comment on the comparative Boolean analysis has important implications for the dissertation. That is:

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In common with case study research, the Boolean method allows assessment of complex patterns of causation, involving combinations of conditions for other outcomes that in turn can be conditions for other outcomes. Strictly speaking, Boolean comparison does not provide maximum attention to historical details, as case studies do, but it may alleviate some of the weaknesses of case studies, especially in terms of reliability and external

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<sup>304</sup> Romme, A. G. L. (1995). Self-organizing process in top management teams: A Boolean Comparative approach. *Journal of Business Research*, 34, 11-34.

<sup>305</sup> Ibid.

<sup>306</sup> Comparative Boolean analysis can also be termed as Boolean comparison as is used by Romme (1995).

<sup>307</sup> Romme, A. G. L. (1995). Self-organizing process in top management teams: A Boolean Comparative approach. *Journal of Business Research*, 34, 11-34.

validity. In this respect, Boolean comparison has a strong inductive element because it proceeds from the bottom up, by simplifying the complexity of the data in a systemic stepwise manner. In addition, by assessing cases to different sets of conditions, key cases and key combinations of conditions are simultaneously identified. These cases and conditions can then be examined in more detail by returning to the original case reports...or by more focused follow-up studies. (pp. 29-30)

In essence, the dialogue between theory and evidence typically found in a case study can be benefited from the comparative Boolean analysis which is a means to structure the dialogue in a systemic manner.

Nevertheless, as Ragin (1987)<sup>308</sup> points out, a comparative Boolean analysis should not be used mechanically. In other words, a comparative Boolean analysis should be used as an aid to an interpretive analysis such as an ESA. Romme (1995)<sup>309</sup> also emphasizes that the application of a comparative Boolean analysis is an effective analytical technique as long as it is not used mechanically but as an aid to interpretive analysis. In this respect, the application of the comparative Boolean analysis can be an effective analytical technique for this dissertation, because the comparative Boolean analysis is adopted as an aid to the interpretive analysis of the ESA. Namely, for this dissertation, the comparative Boolean analysis is used as a means to carefully structure the large amounts of qualitative data produced by the ESA. The results of the comparative Boolean analysis do not take the place of the interpretive analysis of the ESA.

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<sup>308</sup> Ragin, C. C. (1987). *The comparative methods*. Berkeley, California: University of California Press.

<sup>309</sup> Romme, A. G. L. (1995). Self-organizing process in top management teams: A Boolean Comparative approach. *Journal of Business Research*, 34, 11-34.

## **4.2 Formal Qualitative Analysis on the Responses of the Pharmaceutical Companies to the Issues related to the Global Public Health**

### **4.2.1 Research Objectives**

As illustrated earlier, the objective of the second and third phase of the organizational strategy development is performing an empirical stakeholder analysis to facilitate the actual practice of the stakeholder management perspective for the companies within the pharmaceutical industry. That is, in terms of the responses of the pharmaceutical companies to the risks posed by their stakeholders, who (or what) are the stakeholders of the pharmaceutical companies and why the companies should consider certain entities/institutions as stakeholders are investigated. In specific, the stakeholder analysis examines: (1) to whom (or to what) the pharmaceutical companies have ‘actually’ paid attention, namely, to the risks posed by whom (or what) the pharmaceutical companies have actually responded, putting the specific measures, such as donations and price reductions, into practice; (2) the conditions under which the pharmaceutical companies have considered certain entities/institutions as stakeholders, namely, the circumstances under which the pharmaceutical companies have been forced to put the specific measures into practice to deal with the risks posed by their stakeholders; and (3) the types of the specific measures that have been taken by the pharmaceutical companies to deal with the risks posed by their various stakeholders, identifying the most frequently adopted measures by the companies.

The normative theory of the ‘stakeholder identification’ is an important theoretical basis for the stakeholder analysis of this dissertation in that it helps to describe who (or what) are the stakeholders of the pharmaceutical companies and also helps to explain why the pharmaceutical companies should give consideration to these stakeholders. In addition, the descriptive theory of the ‘stakeholder salience’ is another important theoretical basis for the stakeholder analysis in that it helps to identify the circumstances (or conditions) under which managers should respond to the challenges they face in the stakeholder management terms. As illustrated earlier, the stakeholder analysis of this dissertation is performed through the method of the formal qualitative analysis adopting two different types of the method (i.e. the ESA and the comparative Boolean Analysis).

It is noted that the stakeholder analysis model developed through this dissertation reflects two most critical variables for the pharmaceutical companies in terms of the stakeholder management perspective, that is: (1) the risks, in the stakeholder management terms, faced by the pharmaceutical companies in connection with the global public health; and (2) the responses of the pharmaceutical companies, in the stakeholder management terms, to these risks. It is argued that, without considering the specific situations of the pharmaceutical companies in terms of the stakeholder management perspective, there is a possibility that a stakeholder analysis cannot facilitate the actual practice of the stakeholder management perspective for the companies. That is, a stakeholder analysis framework for the pharmaceutical companies should be an instrument to investigate the risks that have been faced by the companies and to examine the measures that have been adopted by the companies to deal with them.

In fact, there is little extant study which provides a suggestion on how to analyze, empirically, the stakeholders of the companies within the pharmaceutical industry. In other words, there is little extant study which applies the stakeholder management perspective specifically to the pharmaceutical companies, conducting an empirical stakeholder analysis. Moreover, there is no extant study which develops organizational strategies specifically for the pharmaceutical companies in conjunction with the stakeholder management perspective, performing an empirical stakeholder analysis. Therefore, considering the existing theories of the stakeholder management perspective, the stakeholder analysis of this dissertation is performed by analyzing the empirical evidence, i.e., the historical narrative of events under which the pharmaceutical companies have put the specific measures, such as donations and price cuts, into practice. In essence, the ESA and the comparative Boolean analysis can help to conduct more reliable stakeholder analysis for the pharmaceutical companies, combining the theories of the stakeholder management perspective with the empirical evidence of the historical narrative of events.

Specifically, the stakeholder analysis of this dissertation investigates the major global public health-related cases, from 1987 to 2007, considered to be the major risks to the pharmaceutical companies. The stakeholder analysis examines a total of 48 cases (composed of 146 events) and most major multinational pharmaceutical (and bio-tech) companies are involved in these cases. Also, several countries in different regions (e.g. Brazil, India, the U.S., Sub-Saharan African countries, and South Africa, etc.) are involved in these cases. Thus, the stakeholder analysis of the dissertation is a

pharmaceutical industry-wide, cross-region/cross-country, comparative analysis. Lastly, although most of the extant studies which deal with the pharmaceutical companies in relation to the global public health have focused on the HIV/AIDS epidemic, the cases for the ESA and the comparative Boolean analysis of this dissertation are not limited to the cases of HIV/AIDS.

#### **4.2.2 Research Questions**

1. To which entities/institutions, have the pharmaceutical companies actually paid attention in terms of the stakeholder management perspective? That is, which entities/institutions can be considered as the key stakeholders of the pharmaceutical companies in the light of the actual implementation of the specific measures such as donations and price reductions? In detail, to the risks/challenges posed by which entities/institutions, have the pharmaceutical companies actually responded putting the specific measures? Are the key stakeholders of the pharmaceutical companies in the developing world the same as or different from those in the developed world?
  
2. What types of measures, in the stakeholder management terms, have the pharmaceutical companies adopted to deal with the risks posed by their stakeholders? Which one, among the measures identified, has been taken most frequently by the pharmaceutical companies?
  
3. Among the key stakeholders identified in the research question 1, which one can be considered as the most influential and salient stakeholder of the pharmaceutical

companies in the light of the actual implementation of the specific measures? In detail, which entity/institution has exerted the greatest influence on the pharmaceutical companies in terms of forcing the companies to respond to the risks, putting the specific measures into practice, posed by the entity/institution? Is the most influential and salient stakeholder of the pharmaceutical companies in the developing world the same as or different from that in the developed world?

4. Under what circumstances, have the pharmaceutical companies put the specific measures into practice? In other words, under what conditions, do the pharmaceutical companies actually consider certain entities/institutions as their stakeholders and put the specific measures into practice to deal with the risks posed by the entities/institutions? Are the circumstances/conditions in the developing world under which the pharmaceutical companies have put the specific measures into practice the same as or different from those in the developed world?

5. Have the pharmaceutical companies given special consideration to specific countries (or regions) and/or to specific diseases in terms of putting the specific measures into practice? If so, why have the pharmaceutical companies given special consideration to the specific countries (or regions) and/or to the specific diseases in terms of implementing the specific measures such as donations and price cuts?

#### **4.2.3 Research Design/Methodology**



#### 4.2.3.1 Sources and Collection of Data

In the research context of this dissertation, which analyzes very sensitive issues for the pharmaceutical companies, to avoid distortions of data, the secondary sources of data are more appropriate than personal or telephone interviews with the managers of the companies. In the case of personal or telephone interviews, there is a risk that the impression management claims of managers rather than the real decision-making processes would be analyzed. Elsbach (1994)<sup>310</sup> maintains that this kind of distortions of data can occur especially when managers have to cope with negative events that threaten an organization's public image, and hence, its social legitimacy. This rationale is also confirmed by Trullen et al. (2006)<sup>311</sup>. The authors point out that "research on the management of organizational legitimacy and work done on corporate reputation indicates that organizations, as individuals, consciously manage their external images in self-serving ways" (Trullen, 2006, p. 183)<sup>312</sup>. Thus, Trullen et al. (2006)<sup>313</sup> suggest that "a researcher who wants to understand the decision-making processes of companies dealing with a public image crisis will need to do so indirectly, by paying attention to external records of events and statements of other stakeholders such as NGOs and the media" (p. 183). On the same rationale, a self-administered survey is also inappropriate to the data collection method for this dissertation. The extant studies show that the poor level of response to a self-administered survey, especially in conjunction with the pharmaceutical companies, can be an obstacle to a comparative, systematic data analysis.

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<sup>310</sup> Elsbach, K. D. (1994). Managing Organizational Legitimacy in the California Cattle Industry: The Construction and Effectiveness of Verbal Accounts. *American Sociological Review*, 48, 147-160.

<sup>311</sup> Trullen, J., & Stevenson, W. B. (2006). Strategy and Legitimacy: Pharmaceutical Companies' Reaction to HIV Crisis. *Business & Society*, 45, 178-210.

<sup>312</sup> Ibid.

<sup>313</sup> Ibid.

For instance, when the ‘Oxfam, VSO, and Save the Children’ (2002)<sup>314</sup> administered a questionnaire to the 11 pharmaceutical companies with regard to CSR, only 3 of the 11 companies responded directly to the questionnaire providing detailed, considered responses. In this respect, the data for the formal qualitative analysis of this dissertation have been collected, in most cases, from the secondary sources.

However, although the data for the ESA and the comparative Boolean analysis of this dissertation have been mainly collected from the secondary sources, this doesn’t mean that the outcomes of interviews with managers (or the results of a self-administered questionnaire to managers) cannot be the source of data for a study which aims at developing strategies for the pharmaceutical companies. The sources of data for a study which develops strategies for companies may depend on the ways in which the strategies are developed. This dissertation aims at developing strategies for the pharmaceutical companies in the stakeholder management terms based on the empirical studies of data analysis, adopting the formal qualitative analysis methods. Also, these empirical studies are longitudinal in that they examine the data over time periods (from 1987 to 2007). Thus, for this dissertation, it is argued that the secondary sources of data are more appropriate than interviews or a self-administered questionnaire. Nevertheless, further researches on the strategy development for the pharmaceutical companies which incorporate interviews and/or a self-administered questionnaire into the secondary sources of data are expected. The secondary sources of data for the ESA and the qualitative comparative Boolean analysis include a wide variety of sources such as the

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<sup>314</sup> Oxfam/Save the Children/VSO (2002). *Beyond Philanthropy: The Pharmaceutical Industry, Corporate Social Responsibility and the Developing World* [Electronic Version]. Retrieved January 2, 2007, from [http://www.oxfam.org.uk/what\\_we\\_do/issues/health/downloads/beyondphilanthropy.pdf](http://www.oxfam.org.uk/what_we_do/issues/health/downloads/beyondphilanthropy.pdf)

articles from newspapers and periodicals, the press releases, papers, and reports from NGOs/activist groups, and the reports from national governments and IGOs. It is argued that the diverse sources help to avoid the potentially biased interpretations on the outcomes of the stakeholder analysis of this dissertation.

The formal qualitative analysis of this dissertation deals with the major global public health-related cases, from 1987 to 2007, which can be considered as the major risks to the pharmaceutical companies. The narrative of events for the ESA begins with the case of ‘Retrovir’, i.e., the introduction of the first antiretroviral drug in 1987. In 1987, Burroughs Wellcome (now, GlaxoSmithKline [GSK]) developed and introduced the first antiretroviral drug, known as Retrovir, that can suppress HIV/AIDS, and it was the only approved therapy available to treat HIV/AIDS until 1991. After Retrovir was introduced, not only several large pharmaceutical companies but also small biotech companies have developed new antiretrovirals. According to Kennedy et al (2004)<sup>315</sup>, as a result of these antiretroviral drugs, the rate of increase in HIV/AIDS-related diseases in the U.S. has slowed dramatically from the early 1990s and, actually, the rate started to decrease from 1996. Consequently, the HIV/AIDS-related deaths in the U.S. have also decreased dramatically from the early 1990s. Similar trends have been witnessed in much of Western Europe. However, as Kennedy et al. (2004)<sup>316</sup> indicate, during the late 1980s, in the early days of antiretroviral drug development, the drug pricing of Retrovir (AZT) was a serious and contentious issue.

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<sup>315</sup> Kennedy, C. R., Harris, F. H., & Lord, M. (2004). Integrating public policy and public affairs in a pharmaceutical marketing program: The AIDS pandemic. *Journal of Public Policy and Marketing*, 23, 128-139.

<sup>316</sup> Ibid.

Although the narrative of events for the ESA and the comparative Boolean analysis begins with the introduction of the first antiretroviral drug, Retroviral, in 1987, the appearance of the so-called ‘drug cocktail’ in 1996 can be considered as the most significant incident for the pharmaceutical companies in the stakeholder management terms. The so-called ‘drug cocktail’, which can reduce enormously the spread of the HIV/AIDS virus, appeared in 1996 and the appearance of the drug cocktail was considered to be a breakthrough in the fight against HIV/AIDS. However, the problem of this new medicine was its expensive price, particularly to the AIDS patients in poor countries. Thus, since then, the pharmaceutical companies have been in the spotlight for not caring enough about the issues related to the global public health and being too concerned with protecting their patent rights. That is, the controversy against the pharmaceutical companies became worse and has been intensified since 1996.

In sum, the ESA and the comparative Boolean analysis of this dissertation deal with 48 cases which comprise 146 events and the data have been collected from various secondary sources to build the history (from 1987 to 2007) of the responses (e.g. donations, price cuts, patent waivers) to the issues related to the global public health on the part of the pharmaceutical companies. The outcomes of the ESA and the comparative Boolean analysis give answers to the research questions illustrated above. It is argued that since the formal qualitative analysis of this dissertation is a longitudinal study, the outcomes of the ESA and the comparative Boolean analysis are more reliable than those of cross-sectional studies.

Lastly, how 48 cases for the formal qualitative analysis were selected is explained. First, the initial cases for the historical narrative of events were selected reviewing the following five websites which provide the historical data of global public health-related incidents: (1) Consumer Project on Technology (CPTech); (2) Médecins Sans Frontières (Doctors Without Borders); (3) Oxfam; (4) Act Up; and (5) AIDS Education Global Information System (AEGIS). The incidents included in more than three of these five sources were chosen, a total of 63 cases, as the major global public health-related cases. Second, each of these 63 cases was cross-checked through the second sources to confirm the appropriateness as a case for the historical narrative of events of this dissertation. Among 63 cases, 48 cases were confirmed by the second sources and, thus, included in the historical narrative of events. In specific, the second sources include: (1) newspaper articles from the Wall Street Journal, New York Times, and Washington Post (e.g. “Politics Slows Agreement on Lifesaving Medicines” 2003, July 4, E1); (2) press releases, papers, and reports from NGOs/activist groups and private sector companies (e.g. Oxfam/Save the Children/VSO joint report (2004)<sup>317</sup>, Harris Interactive Survey (2004)<sup>318</sup>, Annual Global CEO Survey produced by the PriceWaterhouseCoopers (2005)<sup>319</sup>, a report produced by the Interfaith Center on Corporate Responsibility

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<sup>317</sup> Oxfam/Save the Children/VSO (2002). Beyond Philanthropy: The Pharmaceutical Industry, Corporate Social Responsibility and the Developing World [Electronic Version]. Retrieved January 2, 2007, from [http://www.oxfam.org.uk/what\\_we\\_do/issues/health/downloads/beyondphilanthropy.pdf](http://www.oxfam.org.uk/what_we_do/issues/health/downloads/beyondphilanthropy.pdf)

<sup>318</sup> Harris Interactive (July, 2004). Reputations of Pharmaceutical and Health Insurance Companies Continue Their Downward Slide [Electronic Version]. Retrieved February 15, 2007, from [http://www.harrisinteractive.com/news/newsletters/healthnews/HI\\_HealthCareNews2004Vol4\\_Iss11.pdf](http://www.harrisinteractive.com/news/newsletters/healthnews/HI_HealthCareNews2004Vol4_Iss11.pdf)

<sup>319</sup> PricewaterhouseCoopers (2005). 8<sup>th</sup> Annual Global CEO Survey: Bold Ambitions Careful Choices [Electronic Version]. Retrieved March 14, 2007, from <http://www.globalcompliance.com/pdf/8thAnnualGlobalCEOSurvey.pdf>

(2006)<sup>320</sup>, the access to medicine index presented by the Innovest Strategic Value Advisor (2007)<sup>321</sup>, diverse papers/reports produced by the Global Treatment Access Campaign and the Bill and Melinda Gates Foundation); and (3) reports from national governments and inter-governmental organizations (e.g. DFID policy report produced by the U.K. government (2005)<sup>322</sup>, the report of the WHO Commission on Intellectual Property Rights, Innovation, and Public Health (2006)<sup>323</sup>, the U.N. Millennium Development Goals Report [2006]<sup>324</sup>). It is argued that the diverse sources help avoid the potentially biased interpretations of the formal qualitative analysis of this dissertation.

#### **4.2.3.2 Analysis and Presentation of Data**

To examine the research questions analyzing the collected data, two different types of the formal qualitative analysis are adopted. First, the event structure analysis (ESA), using the ETHNO software program designed for doing ESA, is performed to establish the causal links between the events and to find out the variables important to the pharmaceutical companies in putting the specific measures into practice. Second, the

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<sup>320</sup> Interfaith Center on Corporate Responsibility (2006, August). Benchmarking AIDS: Evaluating Pharmaceutical Company Responses to the Public Health Crisis in Emerging Markets [Electronic Version]. Retrieved March 15, 2007, from [http://www.iccr.org/news/press\\_releases/pdf%20files/CEvol34no6-7AIDS](http://www.iccr.org/news/press_releases/pdf%20files/CEvol34no6-7AIDS)

<sup>321</sup> Innovest Strategic Value Advisor (2007, July). Access to Medicine Index: Scoping Report & Stakeholder Review [Electronic Version]. Retrieved April 2, 2007, from [http://www.atmindex.org/doc/atmindex\\_scoping\\_report.pdf](http://www.atmindex.org/doc/atmindex_scoping_report.pdf)

<sup>322</sup> Department for International Development (2005, March). Increasing People's Access to Essential Medicines in Developing Countries: A Framework for Good Practice in the Pharmaceutical Industry [Electronic Version]. Retrieved January 2, 2007 from <http://www.dfid.gov.uk/pubs/files/pharm-framework.pdf>

<sup>323</sup> World Health Organization (2006, April). WHO Report of the Commission on Intellectual Property Rights, Innovation and Public Health [Electronic version]. Retrieved March 15, 2007, from <http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf>

<sup>324</sup> United Nations (2006, June). The Millennium Development Goals Report [Electronic Version]. Retrieved March 15, 2007, from <http://mdgs.un.org/unsd/mdg/Resources/Static/Products/Progress2006/MDGReport2006.pdf>

qualitative comparative analysis (QCA), using the specific formal logic of Boolean approach, is conducted.

Both ESA and QCA are the methods of formal qualitative analysis and “they rely heavily on the interpretations that the researcher makes of the idea” (Trullen et al., 2006, p. 184)<sup>325</sup>. Griffin et al. (1994)<sup>326</sup> explain that both ESA and QCA “analyze nominal data of the yes/no or present/absent variety, offer deterministic rather than probabilistic explanations, rely on specific formal logic (Boolean algebra) rather than on quantitative counts or statistical procedures of any sort, and generally express causal relations as complex conjunctures of factors, conditions, and actions” (p. 8). In other words, both ESA and QCA “try to capture the complexity and interpretive thickness of case-oriented research while at the same time using formal logic in a way that allows the replicability of the analysis and comparison across contexts” (Trullen, et al., 2006, p. 184)<sup>327</sup>.

Stevenson et al. (1998)<sup>328</sup> point out that ESA is “both explanatory and descriptive and can be classified as a form of formal qualitative analysis” (p. 744). The authors also indicate that applying insights from cognitive anthropology and rational choice theory, ESA enables a researcher to develop causal, interpretive-based explanations of narratives.

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<sup>325</sup> Trullen, J., & Stevenson, W. B. (2006). Strategy and Legitimacy: Pharmaceutical Companies’ Reaction to HIV Crisis. *Business & Society*, 45, 178-210.

<sup>326</sup> Griffin, L. J., & Ragin, C. C. (1994). Some Observations on Formal Methods of Qualitative Analysis. *Sociological Methods and Research*, 23, 4-21.

<sup>327</sup> Trullen, J., & Stevenson, W. B. (2006). Strategy and Legitimacy: Pharmaceutical Companies’ Reaction to HIV Crisis. *Business & Society*, 45, 178-210.

<sup>328</sup> Stevenson, W. B., & Greenberg, D. N. (1998). The Formal Analysis of Narratives of Organizational Change. *Journal of Management*, 24, 741-762.

Since ESA is based on a formal mathematical logic, as Griffin et al. (1994)<sup>329</sup> comment, a researcher can develop a dynamic, causal interpretation of the original narrative of events that can be replicated and generalized. Specifically, Stevenson et al. (1998) illustrate that to conduct an ESA using its associated computer program ETHNO, a researcher can begin an analysis process by developing the chronology of events that constitute a particular (change) process. Then, the researcher can enter these events into the ETHNO program in the chronological order. As new events are entered into the ETHNO program, it poses a series of yes/no questions to the researcher that ask for clarification about whether a previously entered event is required for the occurrence of this new event. Stevenson et al. (1998)<sup>330</sup> argue that “through this process of interrogation, the analyst is able to dissect the running chronology of the narrative and reconstruct it with causal connections that are based upon the analyst’s expert judgments” (p. 745). In other words, the ETHNO software “forces the researcher to specify causal linkages between each pair of consecutive events and tells the researcher when a causal claim is contradictory with previous specified relationships” (Trullen et al., 2006, p. 184)<sup>331</sup>. In particular, the ETHNO diagram, produced by using the ETHNO software, is to help the researcher focus on “the analyst’s interpretation of the causal relationships, the path dependencies, and the critical points” (Trullen et al., 2006, p. 184)<sup>332</sup> in the narrative of events that would be difficult to identify just from the chronological of events.

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<sup>329</sup> Griffin, L. J., & Ragin, C. C. (1994). Some Observations on Formal Methods of Qualitative Analysis. *Sociological Methods and Research*, 23, 4-21.

<sup>330</sup> Stevenson, W. B., & Greenberg, D. N. (1998). The Formal Analysis of Narratives of Organizational Change. *Journal of Management*, 24, 741-762.

<sup>331</sup> Trullen, J., & Stevenson, W. B. (2006). Strategy and Legitimacy: Pharmaceutical Companies’ Reaction to HIV Crisis. *Business & Society*, 45, 178-210.

<sup>332</sup> Ibid.



The term causality in ESA refers to “the interdependency between two events in the narrative” and “by locating an event in a particular sequence and by linking it to prior events, the researcher is able to identify what previous event(s) ‘caused’ the subsequent event to occur” (Stevenson et al., 1998, p. 745)<sup>333</sup>. Stevenson et al. (1998)<sup>334</sup> explain how ETHNO can help a researcher who conducts ESA in relation to the causality. That is, “the diagram that ETHNO produces enables the researcher to sharpen his/her insight into the causal relationships between the different events. The researcher can determine which events have no consequences and how certain events may not lead to anything in the present, but have implications for the future.” (p. 746). It is important to understand the formal logic used in ESA and its associated software program, ETHNO. Heise (1989)<sup>335</sup> clarifies the formal logic used in ESA and its associated ETHNO program. That is, the causal links between events are identified based upon the production systems, if-then rules of action, which underlie the logic of ESA and ETHNO. If a configuration of prerequisite events arises, then, a certain event occurs. An event may have multiple prerequisites, and each event may be a prerequisite for multiple ensuing events. If two events are linked by this if-then logic, then the prerequisite event is seen as being causally linked to the subsequent event.

However, it is noted that, as Trullen et al. (2006)<sup>336</sup> emphasize, for ESA, a researcher is the one who decides what events are included in the narrative and how they are actually

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<sup>333</sup> Stevenson, W. B., & Greenberg, D. N. (1998). The Formal Analysis of Narratives of Organizational Change. *Journal of Management*, 24, 741-762.

<sup>334</sup> Ibid.

<sup>335</sup> Heise, D. R. (1989). Modeling Event Structures. *Journal of Mathematical Sociology*, 14, 139-169.

<sup>336</sup> Trullen, J., & Stevenson, W. B. (2006). Strategy and Legitimacy: Pharmaceutical Companies' Reaction to HIV Crisis. *Business & Society*, 45, 178-210.

linked. In other words, the ETHNO program itself cannot discover the causality. Griffin (1993)<sup>337</sup> indicates that the ETHNO program has not been built in algorithms or inherent logic to determine the causal connections between events. The analyst, not the computer program possesses the knowledge to structure and interpret the narrative of events. Stevenson et al. (1998)<sup>338</sup> point out that “through the use of probes, ETHNO forces the analyst to be precise and meticulous in his/her judgments about the relationship between particular events and to reason about these events causally, rather than chronologically” (p. 746).

For this dissertation, the ESA combined with the ETHNO program helps to establish the causal links among the events in the narrative. In other words, the ESA helps to establish the causal links between the risks posed by the stakeholders of the pharmaceutical companies in connection with the global public health and the responses (i.e. the specific measures) that have been adopted by the companies. In particular, ETHNO shows a diagram with all the linkages among the events and, thus, by examining the ETHNO diagram, both the events that are pivotal to unleash others and the events that are the key turning points in the narrative can be found. Also, by inspecting the ETHNO diagram, how the parallel streams of action interact to create certain outcomes can be understood. That is, first, the ESA helps to investigate the variables that have been important to the pharmaceutical companies in putting the specific measures into practice and, also, to examine whether or not these variables in the developing world are different from those

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<sup>337</sup> Griffin, L. J. (1993). Narrative, Event-Structure Analysis, and Casual Interpretation in Historical Sociology. *American Journal of Sociology*, 98, 1094-1133.

<sup>338</sup> Stevenson, W. B., & Greenberg, D. N. (1998). The Formal Analysis of Narratives of Organizational Change. *Journal of Management*, 24, 741-762.

in the developed world. Second, the ESA helps to identify the key stakeholders, including the most influential and salient stakeholder, of the pharmaceutical companies and to examine whether or not the key stakeholders of the companies in the developing world are different from those in the developed world. Lastly, the ESA reveals the types of the measures that have been taken by the pharmaceutical companies, in the stakeholder management terms, to deal with the risks posed by their stakeholders.

The cases examined in the narrative of events on which the ESA and the comparative Boolean analysis are based are concerned with the actual specific measures which have been adopted by the pharmaceutical companies towards the major global public health-related issues from 1987 to 2007. That is, the narrative of events reveals how the pharmaceutical companies have responded to the major risks posed by their stakeholders for the last two decades. Most influential, large multinational pharmaceutical (and biotech) companies are related to these global public health-related cases and, thus, they are investigated through the ESA and the comparative Boolean analysis. The pharmaceutical companies examined through the formal qualitative analysis include Abbott Laboratories, Bayer, Bristol-Myers Squibb, Boehringer Ingelheim, GlaxoSmithKline-Beckham, Hoffmann-La Roche, Merck & Co., Novartis, Pharmacia, and Pfizer. In addition, Cipla has connection with several cases in the narrative of events, although it is an Indian generic drug manufacture. Except Cipla, the companies investigated through the formal qualitative analysis have two similarities. First, the companies can be considered as leading, multinational, research-based pharmaceutical companies in terms of the global public health. Second, although the individual companies have pursued different

approaches, in terms of timing and intensity, in practicing the specific measures, all the companies have employed the specific measures for the last two decades to deal with the risks posed by their various stakeholders.

The formal qualitative analysis of this dissertation is divided into four parts. In the first part, the historical narrative of events<sup>339</sup> on which the ESA and the comparative Boolean analysis are based is described, providing a complete chronology of all the events in the narrative. Also, an abbreviation code (i.e. the ETHNO code) which represents each event is provided for all the events in the historical narrative. The second part is coding the narrative described in the first part into single events and introducing the data into the ETHNO program. Then, all the events in the narrative are systematically, causally linked with the help of ETHNO. Once, all the events are connected, ETHNO shows a diagram with all the linkages. It is noted that each event in the ETHNO diagram is represented by the ETHNO code provided in the previous part. The ETHNO diagram helps to identify the events pivotal in shaping the responses (i.e. the specific measures such as price cuts and donations) of the pharmaceutical companies. That is, by inspecting the ETHNO diagram, the antecedent and the consequent events are identified and, then, these events are categorized in the third part.

In the third part of the formal qualitative analysis, a comparative analysis of the potential measures, in the stakeholder management terms, on the part of the pharmaceutical companies is conducted. Based on the second part of the formal qualitative analysis, the

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<sup>339</sup> The full description of the historical narrative of events is available in the Appendix section of this dissertation.

events (i.e. the antecedent and the consequent events) in the narrative are categorized in the third part. The ETHNO diagram helps to categorize the events in the narrative. These event categories are used for a comparative analysis of the potential measures on the part of the pharmaceutical companies to establish the connections between the antecedent and the consequent events (i.e. between the risks posed by the stakeholders of the pharmaceutical companies that either directly or indirectly have influenced the responses of the companies as the ‘antecedent events’ and the specific measures that have been taken by the pharmaceutical companies as the ‘consequent events’). In other words, for each of the specific measures that has been adopted by the pharmaceutical companies, the comparative analysis codes what key factors, identified in the ETHNO diagram, are present or absent.

Lastly, in the fourth part of the formal qualitative analysis, how the antecedent events interact to affect the consequent events is investigated. That is, for a consequent event (e.g. donations or price reductions), what antecedent events have to be present independently or simultaneously are examined. Especially, this analysis is conducted by QCA using the Boolean logic, i.e., the qualitative comparative Boolean analysis. In essence, using the Boolean logic, the last part of the formal qualitative analysis compares the different occasions in which the pharmaceutical companies were faced with the risks posed by their stakeholders to put the specific measures into practice. In each of these occasions, the pharmaceutical companies could put the measures into practice or not. In sum, in the last part, the Boolean approach is used to identify what antecedent events

have to be present independently or simultaneously for the pharmaceutical companies to put the specific measures into practice.

#### **4.2.4 Historical Narrative of Events on which the ESA and the Qualitative Comparative Boolean Analysis are based**

For the first part of the formal qualitative analysis that follows, the historical narrative of events on which the ESA and the comparative Boolean analysis are based must be described. The historical narrative of events exhibits the history of the major events which have affected the pharmaceutical companies in the stakeholder management terms, that is: (1) the antecedent events (i.e. the risks posed by the stakeholders of the pharmaceutical companies that either directly or indirectly have influenced the responses of the companies); and (2) the consequent events (i.e. the responses taken by the pharmaceutical companies to the risks, such as drug price cuts, patent waivers, and donations). The full description of the historical narrative of events is presented in the Appendix section of this dissertation.

The formal qualitative analysis of this dissertation deals with the major global public health-related cases, from 1987 to 2007, which can be considered as the major risks to the pharmaceutical companies. A total of 48 global public health-related cases, comprised of 146 events, are investigated through the formal qualitative analysis. Since this dissertation tries to perform the formal qualitative analysis in perspective of the pharmaceutical industry-wide, cross-region/cross-country, comparative analysis, the historical narrative of events is composed of the events that reflect this comprehensive

perspective of analysis. The completed chronology of all the events in the narrative is provided in Table 1. Each event in the narrative is represented by an abbreviation code (i.e. the ETHNO code) which appears, in parenthesis, right next to the each event. Also, the same abbreviation code appears in Table 1.

**Table 1**

**The Chronology of Events on which the ESA is based and the ETHNO Codes**

ETHNO Codes	Year of Action	Description of Action
BWarv	March 1987	The first ARV was introduced by Burroughs Wellcome.
Arv	1987	Pharmaceutical (and bio-tech) companies developed new ARVs.
PubMedArv	Late 1987	The drug pricing of ARVs was a serious issue.
ACTngoAct	Late 1987	ACT UP led the protests against Burroughs Wellcome.
PolicyPress	Late 1987	Policy makers pressed Burroughs Wellcome.
EmPressDon	1987	Merck employees called for the donation of ivermectin.
MerDon	October 1987	Merck decided to donate Mectizan.
BWcut1	December 1987	Burroughs Wellcome cut the price of Retrovir by 20%.
MerPPP	1988	The Merck's Mectizan Donation Program was initiated.
ActPressBW	1989	AIDS activists (and ACT UP) staged protests against the pricing of AIDS medicines and Burroughs Wellcome.
ConMon	June 1989	The 5th International Conference on AIDS was held in Montreal.
ActConMon	June 1989	The voice of activists reached the delegates at

		the Montreal conference.
PubMedMon	June 1989	The Montreal conference triggered public opinion and the media pressure.
BWcut2	September 1989	Burroughs Wellcome cut the price of Retrovir by a further 20%.
HAART	1996	The drug cocktail (HAART) was appeared.
PubMedCockt	1996	Pharmaceutical industry was criticized on the price of the drug cocktail.
ConVan	July 1996	The 11th International AIDS Conference was held in Vancouver.
PubMedVan	July 1996	At the Vancouver conference, the high price of the drug cocktail was criticized explicitly by the AIDS Community.
UNAIDS	1996	The Joint United Nations Programme on HIV/AIDS was created.
UNAIDSpress	1996	The UNAIDS pressed pharmaceutical companies to join a pilot project.
GskBmsRpilot	1996	GSK, Bristol Meyers Squibb (BMS), Roche joined the UNAIDS pilot project.
BrazCL	1996	The Brazilian patent law authorized the use of compulsory licensing.
BrazNap	1996	Brazil announced the policy of free access to ARVs through the NAP.
BrazGen	1996	Brazil provided the cheap generic AIDS medicines for the NAP.
NapPharCut	1996	Pharmaceutical companies cut the prices of AIDS drugs in response to the NAP.
PharUS	1996	Pharmaceutical industry pushed the U.S. to take sanctions against Brazil.
US-Braz	1996	The U.S. cited Brazil as a potential target of trade sanctions in Super 301 case.

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SaCLpara	1997	The South Africa's Medicines Act authorized the use of compulsory licensing and parallel importing.
PhRMAUS	1997	PhRMA influenced the U.S. to press the South African government.
US-SA	1997	USTR put South Africa under its Watch List.
UApressGW	1998	UNAIDS urged Glaxo Wellcome to cut the price of AZT.
GWcut	March 1998	Glaxo Wellcome cut the price of AZT BY UP TP 75%.
ConGene	July 1998	The 12th International AIDS Conference was held in Geneva.
NgoActGene	July 1998	NGOs and activist groups put pressure on the pharmaceutical industry at the Geneva Conference.
GskUAcut	1998	GSK cut the prices of AIDS medicines in connection UNAIDS pilot project.
GskUApaten	1998	GSK cut the price of AZT because of the patent expiration.
BmsRoUAcut	1998	BMS and Roche cut the AIDS drug prices joining the UNAIDS Pilot project.
UAdona	1998	Pharmaceutical companies made donations through the UNAIDS pilot project.
HGap	January 1999	Health Gap was created by a coalition of several NGOs and activist groups.
UNpressBms	1999	U.N. requested BMS to perform a new program in connection with the HIV/AIDS pandemic.
BmsSF	May 1999	BMS announced the Secure the Future Initiative.

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BmsPPP	1999	A public private partnership (PPP) was formed through the BMS's Secure the Future program.
NgoActpressUS	June 1999	NGOs and activists put pressure over the U.S. policy towards South Africa.
MedPubSA	1999	The rallies against the U.S. policy towards South Africa attracted media and public attention.
USdropSA	December 1999	The U.S. dropped South Africa from the Watch List.
SApriceCut	1999	Pharmaceutical companies cut the AIDS drug prices in South Africa.
NgoPressPf	March 2000	NGOs launched a campaign against Pfizer in connection with Diflucan.
ActGenPressPf	2000	Activists pressed Pfizer to cut the price of Diflucan, pointing out the cheap generic medicines.
PfDona1	April 2000	Pfizer decided to donate Diflucan for South Africa.
PfPPP	2000	The Diflucan donation was coupled with a PPP.
UNpressPharma	2000	U.N. requested pharmaceutical companies to perform an initiative in connection with HIV/AIDS pandemic.
AAIpriceCut	May 2000	The Five pharmaceutical companies announced the Accelerated Access Initiative (AAI), a PPP, and also announced the preferential pricing policy.
MSFpress	July 2000	MSF pressed pharmaceutical companies releasing a report.

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ConDur	July 2000	The 13th International AIDS Conference was held in Durban, South Africa.
PubMedDur	July 2000	The Durban Conference heightened the awareness of the global AIDS pandemic.
UaDurPress	July 2000	At the Durban conference, UNAIDS helped developing countries to press pharmaceutical industry.
DurCut	July 2000	At the Durban conference, pharmaceutical companies announced their intention to cut the AIDS drug prices.
OxPressGsk	January 2001	Oxfam criticized pharmaceutical companies, especially GSK, publishing a report.
GenCipla	February 2001	Cipla started to offer the generic HIV/AIDS medicines to African countries.
MsfPressGsk	February 2001	MSF pressed pharmaceutical companies, particularly GSK, announcing the agreement with Cipla.
HdlGenPress	2001	Generic producer Hetero Drugs Ltd offered cheap generic drug cocktail.
ExtCut	February 2001	Pharmaceutical companies announced the extensive price cuts of the AIDS drugs.
CiplaPressDur	2001	Pharmaceutical companies started to implement the price cut announced in Durban after Cipla's offer to African countries.
AbAAI	2001	Abbott joined AAI.
AbAAIcut	2001	Abbott cut the AIDS drug prices in response to AAI.

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USwtoBraz	February 2001	The U.S. took Brazil to the WTO for the patent infringement encouraged by the pharmaceutical companies.
BrazOppUS	February 2001	Brazil criticized the U.S.'s complaint to the WTO.
PhRMA-SA	March 2001	Pharmaceutical companies challenged the South African patent law.
NgoActSA	2001	The South African court case became a public affairs disaster to the pharmaceutical industry encountering international petition calling led by MSF.
UNsupSA	April 2001	U.N. pressed the pharmaceutical companies to drop the South African case.
UsEuSupSA	April 2001	The U.S. and E.U. gave their public support to South Africa urging the pharmaceutical companies to drop the case.
PubMedSA	April 2001	The public opinion and media pressed the pharmaceutical companies to drop the case against South Africa.
PharDropSA	April 2001	Pharmaceutical companies drop the lawsuit against South Africa.
UNpressUS-Braz	June 2001	The U.S. was pressed by the U.N. Special Secession on HIV/AIDS in relation to the dispute settlement at the WTO against Brazil.
NgoActPubMedBraz	June 2001	The U.S. was pressed by the global campaigns led by NGOs, activist groups, civil society organizations, and

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		the public opinion and media to drop the case against Brazil at the WTO.
USnegoBraz	June 2001	The U.S. and Brazil decided to resolve the dispute at the WTO through bilateral negotiations.
USsupGF	2001	The U.S. supported the creation of the Global Fund.
UnSaGF	2001	The U.N. created the Global Fund (a PPP) taking advantage of the controversy created by the South African lawsuit.
GFvIPress	2001	NGOs and activists argued that pharmaceutical companies should issue voluntary licenses to the WTO through the Global Fund.
GFpressPf	2001	The Global Fund pushed Pfizer to extend its Diflucan donation program.
OxPressPf	2001	Oxfam pressed Pfizer to extend its Diflucan donation program releasing a report.
NgoActPressPf	2001	The South African HIV/AIDS groups called for the global action against Pfizer.
PfDona2	Mid-2001	Pfizer's Diflucan donation program was extended to other developing countries.
CipOffSA	2001	Cipla asked South Africa to issue a compulsory license offering cheap generic drug cocktail.
NgoActSupCL	2001	NGOs and activist groups supported the issuance of a compulsory license by South Africa.
SAPubPress	2001	In South Africa, there was dispute over

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		the access to HIV/AIDS drugs.
BmsVL	2001	BMS granted a voluntary license to Aspen Pharmacare, South Africa, and the voluntary licensing by BMS put pressure on GSK.
GskVL	2001	GSK granted a voluntary license to Aspen Pharmacare.
USpressBay	2001	The U.S. threatened Bayer with compulsory licensing to cut the price of Cipro.
CApressBay	2001	Canada overrode the patent for Cipro.
ComptPressBay	2001	Other pharmaceutical companies offered free or cheap antibiotics to the U.S.
BayCut	October 2001	Bayer cut the price of Cipro in the U.S. by 95%.
LegPressBay	2001	A class action suit against Bayer was filed.
CampPressGsk	2002	GSK faced a corporate campaign against its pricing policies.
LegPressGsk1	2002	GSK faced a legal action regarding Zidovudine (or Retrovir) by AHF.
MSFpressRoch	2002	In 2002, MSF started to campaign Roche to reduce the price of Viracept.
WTOpress	December 2002	At the WTO meeting, the pharmaceutical industry was prepared to permit the production of generic AIDS drugs.
Pepf	January 2003	The Bush administration announced the Emergency Plan for AIDS Relief (PEPFAR).
PhaVL	January 2003	Pharmacia announced its voluntary licensing of Delavirdine to a nonprofit organization in the Netherlands.

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ActPressRoch	2003	Humanitarian groups pressed Roche to cut the price of HIV/AIDS medicines.
RochCut1	February 2003	Roche cut the price of Viracept for the least developed countries.
RochCut2	February 2003	Roche cut the price of Invirase.
AHFmiss	March 2003	The lawsuit filed by AHF against GSK was dismissed.
AHFpressShare	2003	AHF strongly encouraged CalPERS (the major shareholder of GSK) to take an aggressive stance against GSK.
SharePressGsk	April 2003	CalPERS expressed strong concern to the GSK's approach to the AIDS pandemic.
LegPressGsk2	May 2003	AHF reopened its patent challenge and antitrust complaint against GSK.
InstPressGsk	May 2003	The institutional investors for GSK rejected the retirement package for the CEO of GSK.
GskShareCut	May 2003	GSK cut the price of its AIDS drugs for the poorest countries.
PepfLegist	May 2003	PEPFAR was legislated into law.
AHFdrop	May 2003	AHF dropped the lawsuit against GSK.
PhRMAchan	June 2003	PhRMA announced its increased focus on patients.
2003Decision	August 2003	The WTO General Council adopted 'The WTO Decision on Implementation of the Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health'.
MalaCL	October 2003	Malaysia issued a compulsory license to import generic AIDS drugs from Cipla.

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MalaGskBmsCut	2003	GSK and BMS cut the prices of their HIV/AIDS drugs in Malaysia by more than 50%.
TACpress	2003	The AIDS activists, led by TAC, filed a complaint against pharmaceutical companies, mainly against GSK, in South Africa.
SApressPharma	2003	The South African Competition Commission ruled against the pharmaceutical makers.
CApressPharma	2003	Canada decided to override the patent law for the essential drugs for Africa.
GskBIpress	December 2003	GSK and Boehringer Ingelheim (BI) waived the patents on their AIDS drugs, through a deal with TAC, for up to four generic manufacturers.
GsAAI	2004	Gilead Science Joined AAI.
GsAAIcut	2004	Gilead Science cut the AIDS drug prices in response to AAI.
IndoCL1	October 2004	Indonesia issued a compulsory license to manufacture the generic AIDS drugs.
IndoPriceCut	2004	Pharmaceutical companies cut the HIV/AIDS drug prices in Indonesia.
ActPressIndi	2005	Civil society pressed India to include the crucial safeguards in the new patent law.
IndiLaw	March 2005	The Patents (Amendment) Bill was passed in India.
BrazAbtCL	June 2005	Brazil threatened Abbott with issuing a compulsory license.
NgoActSupBraz	2005	NGOs and activist groups supported

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		Brazil's action against Abbott.
AbtCutBraz	October 2005	Abbott lowered the price of Kaletra in Brazil.
PepfGene	Late 2005	PEPFAR began to distribute generic drugs through its programs.
CPAoppNov	2006	The Cancer Patients Association filed an opposition to the patent application of Novartis for Gleevec.
NovChallIndi	May 2006	Novartis filed two sets of cases in India challenging the new Indian patent law.
NgoActPressNov	2006	NGOs and activists protested and launched a petition against Novartis.
NovOffer	2006	Novartis announced its intention to offer Gleevec free to the patients in India who could not afford it.
NgoActSupThai	2006	In Thailand, the civil society organizations campaigned for the introduction of compulsory licensing for the AIDS drugs.
ThaiCL1	November 2006	Thailand issued a compulsory license for Efavirenz.
GeneThai	November 2006	Through the compulsory licensing, the Thai government allowed either producing or importing (from India) the generic version of Efavirenz.
MkCutThai	2006	Merck announced its intention to negotiate with Thailand for voluntary license or price reduction for Efavirenz.
ThaiCL2	January 2007	Thai issued a compulsory license for Kaletra.

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AbtCutThai	February 2007	Abbott cut the price of Kaletra in Thailand.
PubMedThai	2007	The compulsory licenses of Thailand brought international media spotlight.
AbtRetThai	2007	Abbott decided not to seek the licenses for the new drugs in Thailand.
USoppThai	2007	USTR put Thailand on the Watch List.
UNpressAbt	2007	Abbott and the WHO agreed to cut the price of Kaletra.
NgoActPressAbt	2007	NGOs and activist groups called on Abbott to provide Kaletra at one low price to the developing world.
IndoCL2	March 2007	Indonesia renewed the 2004 Presidential decree to issue a compulsory license for Efavirenz.
AbtCutKal	April 2007	Abbott cut the price of Kaletra, by 55%, in the low and lower-middle income countries.
NgoActSupGene	2007	NGOs and activists pushed Brazil to cut the AIDS drug prices by producing the generic copies of the patented medicines.
BrazCLef	May 2007	Brazil issued a compulsory license for Efavirenz.
IndiPressNov	August 2007	The high court in India dismissed the cases filed by Novartis.

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#### **4.2.5 Ethno Diagrams: Coding the Narrative of Events and Introducing the Data into the Ethno Program**

The second part of the formal qualitative analysis is coding the narrative of events into single events and introducing the data into the ETHNO software program. Then, using the ETHNO software, all the events in the narrative are linked systematically and causally. As shown in the previous part, each event in the narrative is represented by an abbreviation code (i.e. the ETHNO code). The same abbreviation code appears in Table 1. For this second part of the formal qualitative analysis, each event in the ETHNO diagrams (from Figure 1 to Figure 6 in the Appendix) is also represented by the same ETHNO code appeared in the previous part of the analysis. It is noted that, based on this second part, the antecedent and the consequent events in the narrative are categorized in the third part of the formal qualitative analysis. That is, the ETHNO diagrams helps to categorize the events in the narrative. These event categories are used to conduct a comparative analysis of the potential measures, in the stakeholder management terms, on the part of the pharmaceutical companies.

In linking all the events in the narrative using the ETHNO software, two specific mechanisms are used. First, a causal link between the events in the narrative can be inferred by the occurrence of a previous event(s). In other words, a previous event(s) can lead to infer a causal link between the events in the narrative. That is, a casual link between the events can be inferred. Second, if a causal link between the events in the narrative cannot be inferred, the secondary sources that link the events, explicitly, can be found. Namely, a causal link between the events in the narrative, initially considered as reasonable and included in the Ethno diagrams, can be found and confirmed through the secondary sources (e.g. documents from NGOs and news paper articles).

To link casually all the events in the narrative in the ETHNO diagram, a ‘counterfactual logic’ is adopted. Trullen et al. (2006)<sup>340</sup> point out that “using counterfactual logic allows the researcher to pose what-if questions that consider what would happen if the event had not occurred or if the outcome of the event had been different”, thus, “counterfactual logic enables the researcher to have more confidence in causal linkages” (p. 191).

With regard to the ‘causal linkages’, Stevenson et al. (1998)<sup>341</sup> contend that: “the term causality is used in ESA to refer to the interdependency between two events in the narrative...The causal links...are identified based on the production systems if-then rules of action that underlie the logic of ESA and ETHNO” (P. 745). As represented in the ETHNO diagrams of this dissertation, the causal linkages identified through the ETHNO software program are very complicated. Trullen et al. (2006)<sup>342</sup> point out that “the type of analysis that the ETHNO program forces the researcher to do is very detailed and often involves a rather complex analysis of causality” (p. 191). The ETHNO diagrams for the formal qualitative analysis of this dissertation are presented in the Appendix section of this dissertation (from Figure 1 to Figure 6).

#### **4.2.6 Analysis of the Ethno Diagrams: Categorizing the Antecedent and the Consequent Events**

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<sup>340</sup> Trullen, J., & Stevenson, W. B. (2006). Strategy and Legitimacy: Pharmaceutical Companies’ Reaction to HIV Crisis. *Business & Society*, 45, 178-210.

<sup>341</sup> Stevenson, W. B., & Greenberg, D. N. (1998). The Formal Analysis of Narratives of Organizational Change. *Journal of Management*, 24, 741-762.

<sup>342</sup> Trullen, J., & Stevenson, W. B. (2006). Strategy and Legitimacy: Pharmaceutical Companies’ Reaction to HIV Crisis. *Business & Society*, 45, 178-210.

Based on the second part of the formal qualitative analysis, the antecedent and the consequent events in the historical narrative are categorized in this third part. The ETHNO diagrams help to categorize the events in the narrative. The event categories identified are used for a comparative analysis of the specific measures that have been taken by the pharmaceutical companies, establishing the connections between the antecedent events (i.e., the risks posed by the stakeholders of the pharmaceutical companies that either directly or indirectly have influenced the responses the companies) and the consequent events (i.e. the specific measures that have been taken by the pharmaceutical companies to deal with the risks). That is, for each of the specific measures, the comparative analysis attempts to code what key events identified in the ETHNO diagrams are present or absent. In essence, the main objective of the comparative analysis is to identify the key antecedents that have influenced each of the consequent events identified in the ETHNO diagrams.

For the comparative analysis, first, the events in the ETHNO diagrams are distinguished into two categories, i.e., the antecedent and the consequent events. The antecedent events refer to the risks posed by the stakeholders of the pharmaceutical companies that have influenced, directly or indirectly, the responses of the companies. In contrast, the consequent events refer to the responses of the pharmaceutical companies to deal with the risks. The antecedent events are divided into ten different categories. The event categories of the antecedent events are shown in Table 2. The consequent events are classified into six different categories. The event categories of the consequent events are

shown in Table 3. In Table 2 and 3, both the antecedent and consequent event categories are coded together with the ETHNO code.

**Table 2**  
**Antecedent Event Categories**

Event Category	ETHNO Code
Public pressure and/or media attention (P)	PunMedArv, PubMedMon, PubMedCockt, PubMedVan, NgoActGene, MedPubSA, NgoPressPf, PubMedDur, OxPressGsk, PubMedSA, SApubPress, NgoActPubMedBraz, UnSaGF, NgoActPressPf, SApubPress, LegPressBay, CampPressGsk, ActPressRoch, TACpress, GskBIpress, NgoActSupBraz, NgoActPressNov, NgoActSupThai, PubMedThai, NgoActPressAbt.
NGO and/or activist group pressure (N)	ACTngoAct, ActPressBW, ActConMon, PubMedCockt, PubMedVan, NgoActGene, NgoActPressUS, NgoPressPf, (ActGenPressPf), MSFpress, OxPressGsk, MsfPressGsk, NgoActSA, NgoActPubMedBraz, UnSaGF, GFvIPress, OxPressPf, NgoActPressPf, NgoActSupCL, SapubPress, LegPressBay, CampPressGsk, LegPressGsk1, MSFpressRoch,

	ActPressRoch, AHFpressShare, LegPressGsk2, TACpress, GskBIpress, ActPressIndi, NgoActSupBraz, CPAoppNov, NgoActPressNov, NgoActSupThai, NgoActPressAbt, NgoActSupGene.
Developed country/policy maker pressure (D)	PolicyPress, USdropSA, UsEuSupSA, USnegoBraz, USsupGF, USpressBay, CApressBay, PhRMAchan, CApressPharma, PepfGene.
Employee pressure (E)	EmPressDon.
Shareholder/Investor pressure (S)	SharePressGsk, InstPressGsk.
International conference pressure (C)	ConMon, ConVan, ConGene, ConDur.
Inter-governmental organization pressure (U)	UNAIDSpress, UapressGW, GskUAcut, Uadona, UnpressBms, UnpressPharma, UaDurPress, AbAAI, UnsupSA, UnpressUS-Braz, UnSaGF, GfpressPf, WTOPress, 2003Dicision, GsAAI, UnpressAbt.
Developing country pressure (G)	BrazCL, BrazNap, BrazGen, SaCLpara, BrazOppoUS, PhRMA-SA, MalaCL, SapressPharma, IndoCL1, IndiLaw, BrazAbtCL, ThaiCL1, ThaiCL2, IndoCL2, BrazCLef, IndiPressNov.

Generic medicine pressure (M)	BrazGen, ActGenPressPf, GenCipla, MskPressGsk, HdlGenPress, CiplaPressDur, CipOffSA, MalaCL, PepfGene, GeneThai, NgoActSupGene.
Competitor manufacturer pressure (R)	ComptPressBay, PhaVL, BmsVL.

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Note. The event, 'ActGenPressPf', is denoted in parentheses next to the event, 'NgoPressPf', to indicate that these two events can be considered as the same event in terms of the antecedent event to the consequent event of 'PfDona1' (i.e., the Pfizer's Diflucan donation for South Africa). It is noted that the two events are denoted separately in the Table 1 in terms of the ETHNO code.

The first antecedent event category refers to 'public pressure and/or media attention (P)'. The 'public pressure and/or media attention (P)' category includes the events which created the public pressure and/or media attention against the pharmaceutical companies that could lead, eventually, the companies to make any kind of concessions such as price reduction and voluntary licensing. For example, in April 2001, the pharmaceutical companies dropped the lawsuit that challenged the South African patent law through an out of court settlement. This court case became a public affairs disaster to the pharmaceutical industry. It is noted that the public pressure, combined with the pressure from the U.S., the E.U., and the U.N., forced the pharmaceutical companies to drop the case unconditionally. In particular, the 'public pressure and/or media attention (P)' category includes the event (i.e., NgoActPubMedBraz) that refers to the pressure on the U.S. government by the public, media, NGOs, and the activist groups to drop the case against Brazil at the WTO. Although, in this event, the public and media did not put the pressure directly on the pharmaceutical industry, they indirectly influenced the responses/reactions of the industry. At first, in February 2001, the U.S. initiated a



complaint to the WTO against Brazil at the request of the pharmaceutical companies. However, at last, June 2001, the U.S. and Brazil decided to resolve the dispute at the WTO through bilateral negotiations. The U.S. was forced to drop the case against Brazil at the WTO by the pressure from the U.N., global campaigns led by NGOs and the activist groups, the public opinion, and the media. It is noted that the public and media, in this event, put the pressure indirectly on the pharmaceutical companies, and, thus, they indirectly influenced the responses/reactions of the companies.

The second antecedent event category refers to 'NGO and/or activist group pressure (N)'. The 'NGO and/or activist group pressure (N)' category includes the events which had in connection with the pressure from NGOs and/or activist groups against the pharmaceutical companies that could lead, eventually, the companies to make any kind of concessions. It may be argued that the other nine antecedent events, in a certain degree, are related to the pressure from NGOs and/or activist groups. Particularly, in categorizing the antecedent events, the category of the 'NGO and/or activist group pressure' is interrelated with that of the 'public pressure and/or media attention'. It may be also argued that all the six consequent events are related to the pressure from NGOs and/or activist groups, either directly or indirectly. For instance, in July 2000, the pharmaceutical companies, at the Durban International AIDS Conference, announced their intention to cut the prices of the HIV/AIDS medicines. This price reduction decision was made under the pressure of NGOs and activist groups (in particular, MSF pressed the pharmaceutical companies releasing a report) combined with the pressure from the public opinion and the media attention heightened by the Durban Conference. In other words, at

the Durban Conference, the pharmaceutical companies decided to cut the AIDS drug prices pressed by the combined pressure from NGOs/activist groups, the public opinion/media attention, inter-governmental organization (i.e. the UNAIDS), and the international conference (i.e. the Durban International AIDS Conference). Nevertheless, it can be argued that the pressure from a NGO, i.e., MSF, played a pivotal role in forcing the pharmaceutical companies to make the price cut decisions.

The third antecedent event category refers to ‘developed country/policy maker pressure (D)’. The category of the developed country/policy maker pressure can be classified into two different kinds of pressure. First, developed country (or the policy makers) pressed the pharmaceutical companies, directly, to lower the prices of the essential, life-saving medicines. The anthrax crisis and the reactions of the U.S. and Canada were the typical example. In 2001, the U.S. threatened Bayer with compulsory licensing to lower the price of Cipro, the anthrax antibiotic medicine. That is, the Bush administration threatened to override the Bayer’s patent for Cipro, if Bayer did not cut the price of the medicine. In addition, Canada overrode the Bayer’s patent for Cipro and ordered a million tablets of a generic version of it from a Canadian manufacturer. Although the competitor manufacturers’ offers of antibiotics to the U.S. government, for free or at cost, also pressed Bayer, Bayer decided to cut the price of Cipro in the U.S. by 95%, mainly, under the pressure of the U.S. government with compulsory licensing, combined with the compulsory licensing of Canada. Second, developed country (or the policy makers) pressed the pharmaceutical companies, indirectly, in terms of the access to essential, life-saving medicines, although the developed country government did not intend to press the

pharmaceutical companies. For example, in 2003, the U.S. President George W. Bush launched the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) and PEPFAR began to distribute generic medicines from late 2005 through its programs. Another example can be found in the events related to the tension between the U.S. and South Africa. In 1997, PhRMA influenced the U.S. government to put pressure on the South African government concerning its Medicines and Related Substances Act and the USTR put South Africa under its Super 301 Watch List. However, in December 1999, the U.S. government dropped South Africa from the Watch List under the pressure of NGOs, activists, and the public and media attention. Although the U.S. government dropped South Africa from the list not to press the pharmaceutical industry but to bow to the pressure against the U.S. policy towards South Africa, the pharmaceutical companies were forced to cut the AIDS drug prices in South Africa after the U.S. had dropped South Africa from the list.

The fourth antecedent event category refers to 'employee pressure (E)'. As illustrated in the table 2 above, there is only one event, through the narrative of events of the ESA, which can be included in this antecedent event category. In October 1987, Merck announced its intention to donate Mectizan (ivermectin), the medicine for river blindness, and the Merck's decision gave birth to a public-private partnership, i.e., the Mectizan Donation Program, in 1988. As discussed earlier, Merck could not find a way to price the medicine because the river blindness patients could not afford it. Nevertheless, the various ivermectin-based veterinary drugs were bringing in more than \$300 million per

year (Collins, 2004)<sup>343</sup>. Even if Merck donated Mectizan, the company would incur no net loss on ivermectin. It can be argued that that was the real reason for Merck to decide to donate Mectizan. However, it is also noted that although some Merck officials questioned whether the donation of Mectizan was a sound strategy, within the company, especially the Merck employees called for the donation of the medicines. It is clear that the support from its employees encouraged Merck to decide to donate Mectizan.

The fifth antecedent event category refers to ‘shareholder/investor pressure (S)’. It is noted that not only the stakeholders outside of the pharmaceutical companies but also those inside of the companies can press the companies in terms of the access to essential, life-saving medicines. In other words, the adverse reactions from the shareholders and/or investors, sometimes, put pressure on the pharmaceutical companies forcing the companies to conduct any kind of concessions. For instance, in April 2003, the California Public Employees’ Retirement System (CalPERS), a major shareholder of GSK, expressed strong concern in connection with the GSK’s policies towards the HIV/AIDS pandemic. In addition, in May 2003, the institutional investors for GSK, such as CalPERS, the Association of British Insurers, the National Association of Pension Funds, and the Trade Unions Congress, rejected the \$36 million retirement package for the then CEO of GSK. Consequently, GSK, in May 2003, announced a price cut of 40-50% on its HIV/AIDS medicines to the poorest countries. It should be noted that the reputational damage to the pharmaceutical industry (especially to GSK), particularly after the South African lawsuit in 2001, was severe, and, thus, the shareholders and investors

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<sup>343</sup> Collins, K. (2004). Profitable Gifts: a history of the Merck Mectizan donation program and its implications for international health. *Perspective in Biology and Medicine*, 47, 100-109.

of GSK worried that the GSK policies would undermine the value of its stock. Although the shareholders and investors pressed GSK on the different grounds from those of the stakeholders outside of the company, GSK was forced to reduce the price of its medicines.

The sixth antecedent event category refers to ‘international conference pressure (C)’. The ‘international conference pressure (C)’ category includes the events which had in connection with the pressure from the international conferences against the pharmaceutical companies that could lead, eventually, the companies to make any kind of concessions. The narrative of events of the ESA includes four different international conferences (i.e. ConMon, ConVan, ConGene, and ConDur) which had in connection with the access to essential, life-saving medicines, as the antecedent events. For example, in July 2000, the 13th International AIDS Conference was held in Durban, South Africa. It was the first International AIDS Conference held in a developing country and in the ‘epicenter’ of the HIV/AIDS pandemic. (“Break the silence”, 2001)<sup>344</sup>. The Durban Conference served as multidisciplinary forum, and, thus, could height the awareness of the global HIV/AIDS pandemic. In other words, the Durban Conference increased the visibility of the HIV/AIDS crisis for the public across the globe. At the Durban Conference, in July 2000, the pharmaceutical companies announced their intention to cut the prices of the AIDS medicines. Although, during the Durban Conference, NGOs (particularly MSF) and activists groups as well as UNAIDS also pressed the pharmaceutical companies to cut the AIDS drug prices, the conference itself put pressure

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<sup>344</sup> 13th International AIDS Conference (2001). Break the silence [Electronic Version]. Retrieved November 17, 2008, from <http://www.uff.br/dst/revista13-12001/Cap%201%20%20International%20aids%20society.pdf>

on the companies. Trullen et al. (2006)<sup>345</sup> comment that “this increased the pressure on pharmaceutical companies that were negotiating with UNAIDS during the conference on how to implement the price cuts that they had promised in May under the Accelerating Treatment Initiative” (p. 188).

The seventh antecedent event category refers to ‘inter-governmental organization pressure (U)’. The ‘inter-governmental organization pressure (U)’ category includes the events which had in connection with the pressure from the inter-governmental organizations, such as the U.N., UNAIDS, the WTO, the World Bank, and the WHO, against the pharmaceutical companies that could lead, eventually, the companies to make any kind of concessions. For instance, in May 2000, after having talked to Kofi Annan, the five pharmaceutical companies (Boehringer Ingelheim, Bristol Meyers Squibb, GSK, Hoffman-LaRoche, and Merck) announced their agreement on the preferential pricing policy for the least developed countries. That is, the Accelerated Access Initiative (AAI), a public-private partnership, was launched by the five pharmaceutical companies responding to the calls by the leaders of the several U.N. organizations with the intention of cutting the AIDS drug prices in the developing world. Abbott and Gilead Sciences joined AAI later (in 2001 and 2004 respectively) and they also cut their AIDS drug prices in response to AAI.

The eighth antecedent event category refers to ‘developing country pressure (G)’. Some developing countries have pressed the pharmaceutical companies effectively, in

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<sup>345</sup> Trullen, J., & Stevenson, W. B. (2006). Strategy and Legitimacy: Pharmaceutical Companies’ Reaction to HIV Crisis. *Business & Society*, 45, 178-210.

connection with the access to essential, life-saving medicines, with either issuing a compulsory license or threatening an issuance of a compulsory license. Brazil has been considered a model country in the fight against HIV/AIDS, and the success of Brazil has depended on the cheap ARV medicines that have been secured from the pharmaceutical companies through fierce struggle. In 1996, the Industrial Patent Law of Brazil authorized the use of compulsory licensing and Brazil has used the law as leverage to force price cuts from the major pharmaceutical companies. The Brazilian government announced, for the first time among developing countries, the National AIDS Program (NAP), i.e., the policy of free access to ARVs. The Brazilian government reduced the treatment costs of the NAP by negotiating lower prices with the pharmaceutical companies and by manufacturing the generic versions of the patented medicines. However, it is noted that, although the Brazilian government had repeatedly managed to get steep price cuts on the patented medicines from the pharmaceutical companies by threatening the patents, it actually issued, for the first time, a compulsory license for Efavirenz, an ARV medicine manufactured by Merck, in May 2007. In other words, after Brazil had failed to secure a deal with Merck through negotiations, since 2006, over the price of Efavirenz, it decided to bypass the patent on Efavirenz issuing a compulsory license and started to import the generic version of the medicine from India. It is important to note that, although they have been successful for Brazil in terms of the HIV/AIDS treatment, the strategies that have been taken by the Brazilian government to fight against HIV/AIDS have created conflict with the large, multinational pharmaceutical companies. India, a major source of the inexpensive HIV/AIDS medicines, amended its 1970 Patent Act in March 2005. Although the new Indian patent

law, the Patents (Amendment) Bill, 2005, included the crucial safeguards, allowing the Indian government to declare an emergency and cancel the patent for the medicine desperately needed, and narrowing the scope of patentability, many critics worried that the new Indian patent law would make it far more difficult for the poor patients in the developing and the least-developed world to access essential, life-saving medicines, particularly the new ones, at affordable prices. Nevertheless, Novartis, on May 2006, filed two sets of cases challenging the rejection of the Gleevec (a cancer medicine) patent application and the Indian patent law in a high court in India. In August 2007, the Indian court dismissed the Novartis's claims on the ground that it believed it did not have jurisdiction to rule on whether the Indian patent laws were in compliance with the WTO's intellectual property laws ("Novartis challenges", 2007)<sup>346</sup>. The court decision must have put pressure on the pharmaceutical industry in general, because the decision preserved India's ability to produce inexpensive, generic versions of the patented medicines for the developing world. MSF in India announced that "we absolutely welcome this court order...it basically means fewer patents will be granted by the Indian patent office, and that means more affordable drugs can be produced by Indian manufacturers" ("Indian court rejects", August 8, 2007)<sup>347</sup>.

The ninth antecedent event category refers to 'generic medicine pressure (M)'. The 'generic medicine pressure (M)' category includes the events that could force the

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<sup>346</sup> Novartis challenges Indian's patent office decision (2007, September 6). My Intellectual Property Rights [Electronic Version]. Retrieved November 11, 2008, from <http://www.myintellectualpropertyrights.com/news-ticker/2007/09/06/novartis-challenges-indias-patent-office-decision.php>

<sup>347</sup> Indian court rejects Novartis' challenge to country's patent law (2007, August 8). Medical News Today [Electronic Version]. Retrieved November 17, 2008, from <http://www.medicalnewstoday.com/articles/78906.php>



pharmaceutical companies to make any kind of concessions, such as donation, price reduction and voluntary licensing, in connection with generic drug manufacturing or generic competition. For example, the first manufacturer of the generic versions of the HIV/AIDS medicines, Cipla, an Indian manufacturer, started to offer, in February 2001, unauthorized, cheap generic AIDS drugs to African countries at much lower prices than those of the patented medicines produced by the pharmaceutical companies. The offer by Cipla put pressure on the pharmaceutical companies which produced the patented, expensive HIV/AIDS drugs. Trullen et al. (2006)<sup>348</sup> point out that the appearance of the generic competition, triggered by Cipla, increased the pressure on the pharmaceutical companies. Namely, although the pharmaceutical companies both neglected the implementation of price cuts and tried to postpone them as much as possible, they had to implement the price cuts announced in Durban, more than half a year later, when Cipla started to offer its products to the African countries at much lower prices. In February 2001, the pharmaceutical companies (i.e. GSK, Bristol Meyers Squibb, Merck, and Abbott) announced the extensive price cuts of their HIV/AIDS medicines, to varying degrees, that would have influence on the developing world. It is noted that, although the pharmaceutical companies had been severely pressed by NGOs, such as MSF and Oxfam, from the beginning of 2001, in conjunction with the AIDS drug prices, the extensive price reductions of the pharmaceutical companies could attribute to the generic manufacturers, such as Cipla and Hetero Drugs Ltd., because the generic producers offered a triple-therapy AIDS drug cocktail to the governments and MSF in Africa at much lower prices than those of the pharmaceutical companies.

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<sup>348</sup> Trullen, J., & Stevenson, W. B. (2006). Strategy and Legitimacy: Pharmaceutical Companies' Reaction to HIV Crisis. *Business & Society*, 45, 178-210.

The last antecedent event category refers to ‘competitor manufacturer pressure (R)’. As illustrated above, in October 2001, Bayer, the patent holder of Cipro, agreed with the U.S. government to reduce the price of Cipro in the U.S. by 95%. Bayer decided to cut the price of Cipro in the U.S., mainly, under the pressure of the U.S. government with compulsory licensing, combined with the compulsory licensing of Canada. Nevertheless, it is noted that the competitor manufacturers’ offers of antibiotics to the U.S. government, for free or at cost, also pressed Bayer to reduce the price of Cipro. Namely, GSK, Bristol Meyers Squibb, and Johnson and Johnson announced their intention to supply large quantities of their antibiotics free for the U.S. government to treat the anthrax crisis. In addition, Eli Lilly and Pfizer offered to provide their antibiotics at cost. Thus, it is argued that the competitor manufacturers’ offers of antibiotics to the U.S. government, in 2001, also pressed Bayer to reduce the price of Cipro in the U.S.

The consequent events refer to the responses/reactions of the pharmaceutical companies to the risks/challenges (i.e. the antecedent events) that have been posed by their stakeholders. In specific, the consequent events in the narrative of the ESA include the humanitarian projects/programs and the concessions performed by the pharmaceutical companies in response to the antecedent events, and they are divided into six different categories: donations; public-private initiatives; drug price cuts; patent waivers; dropping lawsuit or dispute; and voluntary licensing to generic producers. Table 3 below exhibits the event categories of the consequent events and corresponding ETHNO codes.

**Table 3**  
**Consequent Event Categories**

Event Category	ETHNO Code
Donation (O)	MerDon, UAdona, PfDona1, PfDona2, NovOffer.
Price reduction (I)	BWcut1, BWcut2, NapPharCut, GWcut, GskUAcut, BmsRoUAcut, SApriceCut, AAIpriceCut, DurCut, ExtCut, CiplaPressDur, AbAAIcut, BayCut, RochCut1, RochCut2, GskShareCut, MalaGskBmsCut, GsAAIcut, IndoPriceCut, AbtCutBraz, MkCutThai, AbtCutThai, AbtRetThai, UNpressAbt, IndoCL2, AbtCutKal, BrazCLef, IndiPressNov.
Public-private partnership (T)	MerPPP, GskBmsRpilot, BmsPPP, (BmsSF), PfPPP, AAIpriceCut, AbAAI, UnSaGF, Pepf, GsAAI.
Withdrawal of lawsuit or dispute (L)	PharDropSA, USnegoBraz.
Voluntary licensing (V)	BmsVL, GskVL, PhaVL, MkCutThai.
Patent waiver (W)	GskBIpress.

Note 1. The events, ‘AbtRetThai’, ‘IndoCL2’, ‘BrazCLef’, and ‘IndiPressNov’, are denoted in italic to distinguish them from the other cases in the Table3. These are the events in which the pharmaceutical companies did not put the specific measures of the stakeholder management (i.e. the consequent events) into practice, although the stakeholders put pressure (i.e. the antecedent events) on them. In other words, they represent the events in which the pharmaceutical companies

did not cut the drug prices, although the stakeholders put pressure on them in connection with the price reductions.

Note 2. The event, 'BmsSf', is denoted in parentheses next to the event, 'BmsPPP', to indicate that the two events refer to the same incident in terms of the consequent event. It is noted that although the two events refer to the same incident, they are denoted separately in the Table1 in terms of the ETHNO code.

Among the consequent event categories, two categories, 'public-private partnership' and 'withdrawal of lawsuit or dispute' are needed to be explained further. First, the category of 'public-private partnership' can be understood, in some cases, a more extensive stakeholder management approach on the part of the pharmaceutical industry than other measures such as donation and price cut, because it is in connection with multiple kinds of humanitarian projects and/or concessions coupled with multiple pharmaceutical companies. In addition, the public-private partnership is in connection with multiple stakeholders of the pharmaceutical industry such as inter-governmental organizations, NGOs/activist groups, and developing country governments. For example, the UNAIDS, the Joint United Nations Programme on HIV/AIDS, was created in 1996 and it pressed the pharmaceutical companies to join a pilot project (i.e. the HIV Drug Access Initiative). The pilot project was designed to develop a collaborative effort between the pharmaceutical companies and the developing country governments. The pharmaceutical companies, such as GSK, Bristol Meyers Squibb, and Roche joined the pilot project, and the participating companies in the pilot project provided financial support through various means, such as drug price cuts and investments in non-profit firms by cash or

drug donations (“Joint and co-sponsored United Nations Programme”, 2005)<sup>349</sup>. A plan called Accelerated Access Initiative (AAI) was a public-private partnership similar to the pilot project. AAI was launched in May 2000 with the intention of cutting the AIDS drug prices in the developing world and it was involved a dialogue between the U.N. organizations (and the World Bank) and the pharmaceutical companies. Five pharmaceutical companies (i.e. GSK, Roche, Boehringer Ingelheim, Merck, and Bristol Meyers Squibb), initially, joined AAI and, later, Abbott (in 2001) and Gilead Sciences (in 2004) were responded to AAI. In contrast, a public-private partnership can be performed on a single company basis. For instance, in October 1987, Merck announced its intention to donate Mectizan (a medicine for river blindness) and the Mectizan Donation Program was launched in 1988. That is, Merck sought to overcome the obstacles of a lack of infrastructure and cultural barriers in connection with the distribution of Mectizan by establishing a multi-sectoral public-private partnership, the Mectizan Donation Program. As Collins (2004)<sup>350</sup> describes, the Mectizan Donation Program has become one of the foremost examples of a public-private partnership in the global health. It is noted that to implement a public-private partnership, regardless of whether it is a pharmaceutical industry-wide, collaborative basis or a single company basis, the pharmaceutical industry (or a pharmaceutical company) should cooperate with multiple stakeholders, such as the developing country governments, inter-governmental organizations, and civil society organizations.

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<sup>349</sup> UNAIDS (1999). Joint and co-sponsored United Nations programme on human immunodeficiency virus/acquired immunodeficiency syndrome. [Electronic Version]. Retrieved January 15, 2008, from [http://data.unaids.org/publications/External-Documents-Restored/ecosoc\\_unaidsreport1999\\_en.pdf](http://data.unaids.org/publications/External-Documents-Restored/ecosoc_unaidsreport1999_en.pdf)

<sup>350</sup> Collins, K. (2004). Profitable Gifts: a history of the Merck Mectizan donation program and its implications for international health. *Perspective in Biology and Medicine*, 47, 100-109.

Second, the consequent event category of ‘withdrawal of lawsuit or dispute’ refers to two events in the narrative, i.e., PharDropSA, USnegoBraz. The first event is the withdrawal of the lawsuit against South Africa by the pharmaceutical companies. In March 2001, the 39 leading multinational pharmaceutical companies challenged the South African Medicines and Related Substances Act, amended in 1997, that allowed the South African government to produce or import cheap, generic drugs for HIV/AIDS and other diseases. The lawsuit against South Africa prompted the public outrage against the pharmaceutical industry worldwide, and, thus, became a public affairs disaster to the industry. Through an out of court settlement, the pharmaceutical companies, finally, dropped the lawsuit against South Africa. It is noted that the powerful combination of the public pressure (such as the international petition calling led by MSF), the pressure from the inter-governmental organization (i.e. the U.N.), legal arguments, and the supports for South Africa from the U.S. and the E.U. forced the pharmaceutical companies to drop the case unconditionally. This withdrawal of lawsuit can be considered as concession by the pharmaceutical companies, because the South African patent law authorizes the use of compulsory licensing and parallel importing. In other words, although the South African government, under the patent law, allowed to produce or import inexpensive, patent-violating, generic drugs for HIV/AIDS and other diseases to provide medicines to South African in need, the pharmaceutical companies drop the case against South Africa unconditionally.

The second event is the withdrawal of the complaint to the WTO against Brazil by the U.S. government. In February 2001, the U.S. government initiated a complaint to the

WTO against Brazil, at the request of the pharmaceutical companies (mainly led by PhRMA), to gain a ruling against the Brazilian Industrial Patent Law which authorizes compulsory licensing. However, the U.S. and Brazil announced, in June 2001, a decision to resolve the dispute at the WTO through bilateral negotiations using the newly created 'US-Brazil Consultative Mechanisms'. Before the U.S. withdrew the complaint at the WTO against Brazil, the U.S. had been pressed by the U.N. (through the U.N. Special Session on HIV/AIDS) and by the global campaigns led by NGOs (such as MSF, Oxfam, and the Third World Network), activist groups, civil society organizations, and the public opinion and the media to drop the case against Brazil. It is noted that although the complaint against Brazil at the WTO was initiated and dropped by the U.S. government, the withdrawal of the complaint by the U.S. government can be classified into a concession of the pharmaceutical industry, because the U.S. was backed by the pharmaceutical industry in initiating the complaint. In other words, since the U.S. government took Brazil to the disciplinary tribunal of the WTO for the patent infringement on behalf of the pharmaceutical industry, the withdrawal of the complaint by the U.S. government can be considered as a concession of the pharmaceutical industry.

The specifics of how ten antecedent event categories interacted to affect six consequent event categories are examined below to complete the formal qualitative analysis of this dissertation. That is, the event categories identified in this third part are used for the last part of the formal qualitative analysis, i.e., a comparative analysis using Boolean logic. The comparative Boolean analysis examines, for a consequent event, what antecedent

events have to be present independently or simultaneously, attempting to identify and establish the causal links between the antecedent and consequent events.

The pharmaceutical companies have had to deal with the risks posed by their various stakeholders. In some cases, the companies put a specific measure such as donations into practice, in contrast, in other cases, they did not. Therefore, the comparative Boolean analysis investigates, for a consequent event, what key antecedent events, identified and categorized in Table 2, are present or absent. It is noted that, to complete the comparative analysis of this dissertation, truth tables should be constructed in order to adopt Boolean logic. In this third part of the formal qualitative analysis, truth tables are developed. But, a further analysis of the truth tables (i.e. how the antecedent event categories interact each other to affect the consequent event categories) is conducted in the last part of the formal qualitative analysis.

To develop truth tables, whether or not the pharmaceutical companies put the specific measures, such as donation, into practice is considered as a type of dependent variable. This is also a type of dependent variable in the Boolean algebra equations. In other words, for both the truth tables and the Boolean algebra equations, the dependent variables are the responses of the pharmaceutical companies to cope with the pressures posed by their various stakeholders. As shown in Table 3, the dependent variables refer to donation, public-private initiative, price reduction, patent waiver, and voluntary licensing, which have been exercised by the pharmaceutical companies, i.e., the consequent events.



On the other hand, for both the truth tables and the Boolean algebra equations, there are two types of independent variable. Whether or not the pharmaceutical companies put the specific measures into practice is coded Yes or No in the truth tables. It is noted that the coding of dependent variables is dependent on the presence or absence of the key antecedent events identified and categorized in Table 2. Thus, first, these key antecedent events are considered as a type of independent variable for both the truth tables and the Boolean algebra equations. Second, a total of 48 cases are identified as another type of independent variable. These cases, certain combinations of the key antecedent events, lead the pharmaceutical companies to putting the specific measures into practice. Thus, these cases are independent variables and they correspond to the key antecedents events identified in Table 2. In essence, if an antecedent event was presented when a case happened, then, the case is coded as true (T). Otherwise, the case is coded as false (F).

The truth tables are presented below, from Table 4 to 9. It is noted that the truth tables are developed for each of six consequent event categories. In other words, each truth table corresponds to each of six categories of the consequent events in Table3. The consequent event categories are represented by the abbreviation code shown in Table 3. The cases in the truth tables are represented by the ETHNO code and the antecedent event categories are represented by the abbreviation code shown in Table 2.

**Table 4**  
**Truth Table of Donation (O)**

Case	P	N	D	E	S	C	U	G	M	R	O
(MerDon)	F	F	F	T	F	F	F	F	F	F	Yes



GskShareCut	T	T	F	F	T	F	F	F	F	T	Yes
MalaGskBmsCut	F	F	T	F	F	F	T	T	T	F	Yes
GsAAIcut	F	F	T	F	F	F	T	F	F	F	Yes
IndoPriceCut	F	F	F	F	F	F	F	T	F	F	Yes
AbtCutBraz	T	T	F	F	F	F	F	T	F	F	Yes
MkCutThai	T	T	F	F	F	F	F	T	F	F	Yes
AbtCutThai	F	F	F	F	F	F	F	T	F	F	Yes
AbtRetThai	T	T	F	F	F	F	F	F	F	F	No
UNpressAbt	T	F	F	F	F	F	T	T	F	F	Yes
IndoCL2	F	F	F	F	F	F	F	T	F	F	No
AbtCutKal	T	T	F	F	F	F	F	F	F	F	Yes
BrazCLef	F	T	F	F	F	F	F	T	T	F	No
IndiPressNov	T	T	F	F	F	F	F	T	F	F	No

Note 1. The case, ‘GskUApaten’, is denoted in parentheses to indicate that the case is the same case as ‘GskUAcut’. Namely, although the two cases refer to the same incident and are in connection with the same consequent event, the antecedent events in connection with each of the two cases are different. In other words, based on the secondary sources of literature, there exist two different explanations concerning the GSK’s AIDS drug price cut in 1998. It is noted that, for the Boolean Comparative Analysis (Boolean equation), the case ‘GskUApaten’ is not counted as a case for Table 5.

Note 2. The four cases, ‘AbtRetThai’, ‘IndoCL2’, ‘BrazCLef’, and ‘IndiPressNov’, are denoted in italic to distinguish them from the other cases in the Table5. These are the cases in which the pharmaceutical companies did not put the specific measures of the stakeholder management (i.e. the consequent events) into practice, although the stakeholders put pressure (i.e. the antecedent events) on them.

**Table 6**  
**Truth Table of Public-Private Partnership (T)**

Case	P	N	D	E	S	C	U	G	M	R	T
(MerPPP)	F	F	F	T	F	F	F	F	F	F	Yes
GskBmsRpilot	T	T	F	F	F	T	T	F	F	F	Yes

BmsPPP (BmsSF)	F	F	F	F	F	F	T	F	F	F	Yes
(PfPPP)	T	T	F	F	F	F	F	F	T	F	Yes
AAIpriceCut	F	F	F	F	F	F	T	F	F	F	Yes
AbAAI	F	F	F	F	F	F	T	F	F	F	Yes
UnSaGF	T	T	T	F	F	F	T	F	F	F	Yes
Pepf	T	T	F	F	F	F	T	F	F	F	Yes
GsAAI	F	F	T	F	F	F	T	F	F	F	Yes

Note 1. The case, ‘MerDon’, is denoted in parentheses to distinguish it from the other cases in the Table 6. Although the category, the employee pressure (E), of the antecedent events is in connection with the case, the pharmaceutical company, Merck, initiated the donation program almost voluntarily without any severe pressure from the stakeholders. In this respect, for the Boolean Comparative Analysis (Boolean equation), the case ‘MerDon’ is not counted as a case for Table 6.

Note 2. The case, ‘BmsSf’, is denoted in parentheses next to the case of ‘BmsPPP’ to indicate that the two cases refer to the same incident in terms of the consequent event. It is noted that although the two cases refer to the same incident, they are denoted separately in the Table1 in terms of the ETHNO code.

Note 3. The case, ‘PfPPP’ is denoted in parentheses to distinguish it from the other cases in the Table 6. Although the two cases, ‘PfDonal’ and ‘PfPPP’, are denoted separately in the Table1 in terms of the ETHNO code, the two cases refer to the same incident, i.e., the Pfizer’s Diflucan donation in 2000 for South Africa. In other words, the case ‘PfPPP’ represents that the Diflucan donation program of Pfizer was, later, coupled with a public-private partnership in South Africa. It is noted that, for the Boolean Comparative Analysis (Boolean equation), the case ‘PfPPP’ is not counted as a case for Table 6.

**Table 7**

**Truth Table of Withdrawal of Lawsuit or Dispute (L)**

Case	P	N	D	E	S	C	U	G	M	R	L
PharDropSA	T	T	T	F	F	F	T	T	F	F	Yes
USnegoBraz	T	T	F	F	F	F	T	T	F	F	Yes

**Table 8**  
**Truth Table of Voluntary Licensing (V)**

Case	P	N	D	E	S	C	U	G	M	R	V
BmsVL	T	T	F	F	F	F	F	F	T	F	Yes
GskVL	T	T	F	F	F	F	F	F	T	T	Yes
(PhaVL)	F	F	F	F	F	F	F	F	F	F	Yes
MkCutThai	T	T	F	F	F	F	F	T	T	F	Yes

Note. The case, 'PhaVL', is denoted in parentheses to distinguish it from the other cases in the Table 8. The pharmaceutical company, Pharmacia, licensed its AIDS drug to a non-profit organization voluntarily without any severe pressure from the stakeholders. In this respect, for the Boolean Comparative Analysis (Boolean equation), the case 'MerDon' is not counted as a case for Table 8.

**Table 9**  
**Truth Table of Patent Waiver (W)**

Case	P	N	D	E	S	C	U	G	M	R	W
GskBIpress	T	T	T	F	F	F	F	T	F	F	Yes

#### **4.2.7. Analysis of the Ethno Diagram: Qualitative Comparative Boolean Analysis**

Lastly, in the fourth part of the formal qualitative analysis, the comparative analysis is completed. That is, an analysis of the truth tables (i.e. how the antecedent event categories interact each other to affect the responses of the pharmaceutical companies, the consequent event categories) is conducted. In other words, for a consequent event, what antecedent events have to be present, independently or simultaneously, are

examined using ‘Boolean logic’. Trullen et al. (2006)<sup>351</sup> indicate that “Boolean algebra is a data reduction technique that allows us to decide what factors or variables have to be present so that the dependent variable holds true” (p. 195). Using Boolean approach, the fourth part of the formal qualitative analysis compares and analyzes the diverse instances in which the pharmaceutical companies put the specific measures into practice to deal with the risks posed by their various stakeholders.

Before conducting an analysis of the truth tables, the basic features of Boolean approach to the qualitative comparative analysis are examined. The principles of Boolean approach used in the qualitative comparative analysis are consistent with the logical principles common to many types of research in the social sciences, especially the case study research (Yin, 1984)<sup>352</sup>. Romme (1984)<sup>353</sup> explains the following:

Boolean comparison is especially useful for the qualitative analysis of a number of cases. It pays attention to patterns of multiple causations and produces explanations that account for every different combination of conditions. The results of comparative Boolean analysis are therefore affected by each logically different observation, and not so much by the frequency of their occurrence. In this respect, Boolean analysis fundamentally differs from multivariate analysis, which pays special attention to the variance between different observations as well as the frequency of their occurrence. (p. 19)

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<sup>351</sup> Trullen, J., & Stevenson, W. B. (2006). Strategy and Legitimacy: Pharmaceutical Companies’ Reaction to HIV Crisis. *Business & Society*, 45, 178-210.

<sup>352</sup> Yin, R. K. (1984). *Case study research: Design and methods*. Thousand Oaks, CA: SAGE Publications, Inc.

<sup>353</sup> Romme, A. G. L. (1995). Self-organizing process in top management teams: A Boolean Comparative approach. *Journal of Business Research*, 34, 11-34.

It is noted that Boolean approach produces explanations that account for every different piece of data equally. Ragin (1987)<sup>354</sup> presents a similar view to Romme (1984) on Boolean logic. That is, Boolean comparison can be used to address complex empirical phenomena, especially apparent in the patterns of multiple causations, where different conditions combine in different, and sometimes contradictory, ways to produce the same or similar outcomes. Romme (1984)<sup>355</sup> also maintains that “given certain theoretical categories, Boolean comparison has a strong inductive element because it proceeds from the bottom, simplifying complexity of the data in a systematic, stepwise manner” (p. 20).

Ragin (1987)<sup>356</sup> suggests the steps that can be taken to conduct a comparative Boolean analysis. These steps are also compatible with those taken by the formal qualitative analysis of this dissertation (specifically, the third and fourth part of the analysis). According to Ragin (1987)<sup>357</sup>, the first step is inferring the central categories from the hypotheses. It is noted that each hypothesis is described in terms as a set of conditions and outcomes. In the case of this dissertation, based on the second part of the formal qualitative analysis, the events in the narrative are categorized in the third part. The ETHNO diagram, developed in the second part, helps to categorize these events. These event categories are used for a comparative analysis of the specific measures of the pharmaceutical companies to establish the connections between the major events. The comparative analysis attempts to code what the key antecedent events identified in the ETHNO diagram are present or absent for each of the consequent events. As illustrated

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<sup>354</sup> Ragin, C. C. (1987). *The comparative methods*. Berkeley, California: University of California Press.

<sup>355</sup> Romme, A. G. L. (1995). Self-organizing process in top management teams: A Boolean Comparative approach. *Journal of Business Research*, 34, 11-34.

<sup>356</sup> Ragin, C. C. (1987). *The comparative methods*. Berkeley, California: University of California Press.

<sup>357</sup> Ibid.

above, for the comparative analysis, the events in the ETHNO diagram are distinguished into two categories - the antecedent and the consequent events. The antecedent events are also divided into ten different categories (Table 2) and the consequent events are divided into six different categories (Table 3).

The second step is transforming the qualitative data into a truth table arranged according to the categories resulting from the first step. In connection with transforming into a truth table, Romme (1995)<sup>358</sup> comments that the “transformation may be involve extensive coding work. A truth table shows primitive expressions using Boolean logic. There are two logical states of one single variable in Boolean logic: 1/T (presence or true) and 0/F (absence or fault)” (p. 20). In the case of this dissertation, the truth tables are developed in the third part of the formal qualitative analysis (from Table 4 to 9). It is noted that, to complete the comparative analysis, a truth table should be constructed in order to adopt Boolean logic. Once the event categories of the antecedent and the consequent events are identified, the comparative analysis attempts to identify and establish the causal links between these events using the event categories. Also, the comparative analysis attempts to code whether each of the key antecedent events is present or absent for each of the consequent events.

The third and fourth steps suggested by Ragin (1987)<sup>359</sup> are in conjunction with how a truth table is developed. The third step is the minimization of a truth table. It is noted that the minimization is the most fundamental technique (or procedure) in Boolean approach.

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<sup>358</sup> Romme, A. G. L. (1995). Self-organizing process in top management teams: A Boolean Comparative approach. *Journal of Business Research*, 34, 11-34.

<sup>359</sup> Ragin, C. C. (1987). *The comparative methods*. Berkeley, California: University of California Press.



Romme (1995)<sup>360</sup> comments that “Boolean minimization of a truth table produces a Boolean expression that reflects the minimum set of the “extent” combinations of conditions for the dependent variables in the table...It is a simple and straightforward method for simplifying the complexity of truth tables” (p. 20). For example, if two Boolean expressions differ in only one condition but produce the same outcome, then, the condition that differentiate two Boolean expressions can be considered as irrelevant and can be removed. This is the basic principle of the minimization of a truth table. Through the minimization procedure, the prime implicants of the dependent variable needed for the next step of developing a truth table can be obtained. Also, the minimization of a truth table produce a reduced truth table expression needed for the next step. The fourth step is related to the selection of the essential prime implicants of the dependent variable. According to Romme (1995)<sup>361</sup>, the essential prime implicants “constitute the logically minimal conditions of the dependent variable...they involve the sufficient and/or necessary conditions for this dependent variable” (p. 20). Romme (1995)<sup>362</sup> further explains that the selection of the essential prime implicants is important “when the reduced truth table expression ...includes so-called cyclic combinations, that is, a set of overlapping prime implicants that are not all needed to minimally cover the truth table...if the reduced expression obtained earlier does not include cyclic combinations, the combinations of conditions in this expression provide the essential prime implicants” (p. 20).

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<sup>360</sup> Romme, A. G. L. (1995). Self-organizing process in top management teams: A Boolean Comparative approach. *Journal of Business Research*, 34, 11-34.

<sup>361</sup> Ibid.

<sup>362</sup> Ibid.

For this dissertation, to develop truth tables, whether or not the pharmaceutical companies put the specific measures into practice is considered as dependent variable. This is also dependent variable in the Boolean algebra equations. In other words, the dependent variables are the responses of the pharmaceutical companies (i.e. six event categories of the consequent event) to cope with the pressures posed by their various stakeholders (i.e. ten event categories of the antecedent event). Whereas, there are two different types of independent variable for both the truth tables and the Boolean algebra equations. First, the dependent variables are coded Yes or No in the truth tables, and the coding is dependent on the presence or absence of the key antecedent events. Thus, the key antecedent events are considered as the independent variables. Second, as indicated above, a total of 48 cases are identified as another type of independent variable. These cases refer to certain combinations of the key antecedent events and lead to the dependent variables. If an antecedent event was presented when a case happened, then, the case is coded as true (T). Otherwise, the case is coded as false (F).

The fifth and sixth steps suggested by Ragin (1987)<sup>363</sup> are in connection with how a truth table is translated or analyzed, once it is completed. The fifth step refers to the evaluation of results: that is, the results obtained through the prior steps of the minimization of a truth table and the selection of essential prime implicants are compared with the initial hypotheses presented in the first step. If a hypothesis is falsified (partly or entirely), it is possible to restart with the first step by reforming the hypothesis. Romme (1995)<sup>364</sup> points out that the step of the minimization of a truth table serves as an attempt to falsify

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<sup>363</sup> Ragin, C. C. (1987). *The comparative methods*. Berkeley, California: University of California Press.

<sup>364</sup> Romme, A. G. L. (1995). Self-organizing process in top management teams: A Boolean Comparative approach. *Journal of Business Research*, 34, 11-34.

the initial hypotheses. The last step suggested by Ragin (1987)<sup>365</sup> refers to introducing and simplifying assumptions. Romme (1995)<sup>366</sup> explains that “Boolean comparison avoids making simplifying assumptions at the outset. After having allowed for maximum causal complexity in the preceding steps, simplifying assumptions can now be introduced...the step of simplifying assumptions involves an attempt to identify the hypothesized conditions in the expression obtained by minimization” (p. 20).

For this dissertation, a further analysis of the truth tables is conducted using Boolean logic, i.e., the qualitative comparative Boolean analysis. In essence, for a consequent event, what antecedent events have to be present, independently or simultaneously, are examined. Below, the comparative Boolean analysis is presented simplifying and solving the truth tables (from Table 4 to 9). In terms of Boolean logic, these truth tables can be summarized in the following Boolean algebra equations:

**Equation 1 (Table 4):  $O = PNdesCUgmr + PNdescugMr + PNdescUgmr + PNdescugmr$**

**Equation 2 (Table 5):  $I = PNDescugmr + PNdesCugmr + pndescuGMr + pndescUgmr + PNdesCUgmr + PNdesCUgmr + PNDescuGmr + pndescUgmr + PNdesCUgmr + PNdescugMr + pndescugMr + pndescUgmr + PNDescugmR + PNdescugmR + PNdeScugmR + pnDescUGMr + pnDescUgmr +$**

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<sup>365</sup> Ragin, C. C. (1987). *The comparative methods*. Berkeley, California: University of California Press.

<sup>366</sup> Romme, A. G. L. (1995). Self-organizing process in top management teams: A Boolean Comparative approach. *Journal of Business Research*, 34, 11-34.

$$\text{pndescuGmr} + \text{PNdescuGmr} + \text{PNdescuGmr} + \text{pndescuGmr} + \text{PndescUGmr} + \text{PNdescugmr}$$

$$\text{Equation 3 (Table 6): } T = \text{PNdesCUgmr} + \text{pndescUgmr} + \text{pndescUgmr} + \text{pndescUgmr} + \text{PNDescUgmr} + \text{PNdescUgmr} + \text{pnDescUgmr}$$

$$\text{Equation 4 (Table 7): } L = \text{PNDescUGmr} + \text{PNdescUGmr}$$

$$\text{Equation 5 (Table 8): } V = \text{PNdescugMr} + \text{PNdescugMR} + \text{PNdescuGMr}$$

$$\text{Equation 6 (Table 9): } W = \text{PNDescuGmr}$$

Each letter in the Boolean equations represents a variable in the truth tables. In other words, the letters on the left side of the equal signs in the Boolean equations, i.e., O, I, T, L, V, and W, represent the event categories of the consequent events in the Table 3. On the other hand, the letters on the right side of the equal signs in the Boolean equations, i.e., P, N, D, E, S, C, U, G, M, and R, represent the event categories of the antecedent events in the Table 2. In the Boolean equations, the lowercase letters refer to the instances where the variable takes a value of false (F), whereas the uppercase letters refer to the instances where the variable takes a value of true (T). For example, the Boolean equation 4 for the Table 7 can be translated into as follows: when the event category of the consequent events, L, occurs, either the event categories of the antecedent events, P, N, D, U, and G, are occurred (or presented), and, simultaneously, the event categories of

the antecedent events, e, s, c, m, and r, are not occurred (or absent) or the event categories of the antecedent events, P, N, U, and G, are occurred (or presented), and, simultaneously, the event categories of the antecedent events, d, e, s, c, m, and r, are not occurred (or absent). Therefore, the Boolean equation 4 summarizes the truth table (Table 7) by saying that the withdrawal of lawsuit or dispute by the pharmaceutical companies (L) occurs when either PNDescUGmr (which corresponds to the case, PharDropSA) or PNdescUGmr (which corresponds to the case, USnegoBraz) occurs. By the same token, the Boolean equation 5 summarizes the truth table (Table 8) by saying that the voluntary licensing of the pharmaceutical companies (V) occurs when either PNdescugMr (which corresponds to both of the cases, BmsVL and GskVL) or PNdescuGMr (which corresponds to the case, MkCutThai) occurs.

To develop more the Boolean comparative analysis, the distributive law of Boolean algebra should be considered. According to Trullen et al. (2006)<sup>367</sup>, the distributive law of Boolean algebra states that  $(A \times B) + (A \times C)$  equals  $A \times (B + C)$ . Although it must be a simple principle of Boolean logic, the Boolean equations can be further summarized by this distributive law of Boolean algebra. Following the distributive law of Boolean algebra, the Boolean equations above (equations 1, 2, 3, 4, and 5) are further summarized in the following expressions (as equations 1-1, 2-2, 3-3, 4-4, and 5-5):

**Equation 1-1 (Table 4):  $O = \text{PNdesgr} \times (\text{CUM} + \text{cuM} + \text{cUm} + \text{cum})$**

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<sup>367</sup> Trullen, J., & Stevenson, W. B. (2006). Strategy and Legitimacy: Pharmaceutical Companies' Reaction to HIV Crisis. *Business & Society*, 45, 178-210.

**Equation 2-2 (Table 5):**  $I = e \times (PNDscugmr + PNdsCugmr + pndscuGMr + pndscUgmr + PNdsCUgmr + PNdsCUgmr + PNDscuGmr + pndscUgmr + PNdsCUgmr + PNDscugMr + pndscugMr + pndscUgmr + PNDscugmR + PNdsugmR + PNDscugmR + PNdScugmR + pnDscUGMr + pnDscUgmr + pndscuGmr + PNdscuGmr + PNdscuGmr + pndscuGmr + PndscUGmr + PNdscugmr)$

**Equation 3-3 (Table 6):**  $T = esUgmr \times (PNdC + pndc + pndc + pndc + PNDc + PNDc + pnDc) \therefore T = esUgmr \times (PNdC + PNDc + PNDc + pnDc)$

**Equation 4-4 (Table 7):**  $L = PNescUGmr \times (D + d)$

**Equation 5-5 (Table 8):**  $V = PNdescuM \times (gr + gR + Gr)$

These Boolean equations summarize what conditions were present and absent in the data when the pharmaceutical companies put the specific measures of the stakeholder management into practice. For example, the Boolean equation 1-1 explains that when the pharmaceutical companies donated their medicines (O), the two antecedent events, such as the public pressure and/or media attention (P) and the NGO and/or activist group pressure (N), were always present. In contrast, the antecedent events, such as the developed country/policy maker pressure (D), the employee pressure (E), the shareholder/investor pressure (S), the developing country pressure (G), and the competitor manufacturer pressure (R), were absent for these donations to be made. In

addition, the equation 1-1 further explains that although ‘PNdesgr’ is a necessary condition to cause the pharmaceutical companies’ donations (O), it is not a sufficient condition. In other words, the antecedent events, such as the international conference pressure (C), the inter-governmental organization pressure (U), and the generic medicine pressure (M), should either be present or absent, in the form of ‘CUm, cuM, cUm, or cum’, to cause the pharmaceutical companies’ donations (O).

The Boolean equation 3-3 explains that when the pharmaceutical companies performed the public-private partnerships (T), only one antecedent event, the inter-governmental organization pressure (U), were always present. In contrast, the antecedent events, such as the employee pressure (E), the shareholder/investor pressure (S), the developing country pressure (G), the generic medicine pressure (M), and the competitor manufacturer pressure (R), were absent for these public-private initiatives to be performed. Also, the equation 3-3 further explains that although ‘esUgmr’ is a necessary condition to cause the public-private partnerships in connection with the pharmaceutical companies (T), it is not a sufficient condition. In other words, the antecedent events, such as the public pressure and/or media attention (P), the NGO and/or activist group pressure (N), the developed country/policy maker pressure (D), and the international conference pressure (C), should either be present or absent, in the form of ‘PNdC, PNDc, PNdc, or pnDc’, to cause the public-private partnership in connection with the pharmaceutical companies (T).

By the same token, the Boolean equation 4-4 explains that when the pharmaceutical companies withdrew a lawsuit or a dispute (L), the four antecedent events, such as the public pressure and/or media attention (P), the NGO and/or activist group pressure (N), the inter-governmental organization pressure (U), and the developing country pressure (G), were always present. In contrast, the antecedent events, such as the employee pressure (E), the shareholder/investor pressure (S), the international conference pressure (C), the generic medicine pressure (M), and the competitor manufacturer pressure (R), were absent for the withdrawal of a lawsuit or a dispute to be made. The equation 4-4 further explains that although 'PNescUGmr' is a necessary condition to cause the withdrawal of a lawsuit or a dispute in connection with the pharmaceutical companies (L), it is not a sufficient condition. Namely, the antecedent event, i.e., the developed country/policy maker pressure (D), should either be present or absent to cause the withdrawal of a lawsuit or a dispute on the part of the pharmaceutical companies (L).

The equation 5-5 explains that when the pharmaceutical companies issued the voluntary licenses (V), the three antecedent events, such as the public pressure and/or media attention (P), the NGO and/or activist group pressure (N), and the generic medicine pressure (M), were always present. In contrast, the antecedent events, such as the developed country/policy maker pressure (D), the employee pressure (E), the shareholder/investor pressure (S), the international conference pressure (C), and the inter-governmental organization pressure (U), were absent for these voluntary licenses to be issued. In addition, the equation 5-5 further explains that although 'PNdescuM' is a necessary condition to cause the pharmaceutical companies' voluntary licenses (V), it is



not a sufficient condition. In other words, the antecedent events, such as the developing country pressure (G) and the generic medicine pressure (R), should either be present or absent, in the form of 'gr, gR, or Gr', to cause the pharmaceutical companies' voluntary licenses (V).

Among the five further summarized Boolean equations, the equation 2-2, for the Table 5, is not summarized much in comparison with the original Boolean equation 2. For the consequent event category of the price reduction (I), the Table 5 deals with 24 cases (except five cases such as GskUApaten, AbtRetThai, IndoCL2, BrazCLef, and IndiPressNov) and only one antecedent event category, i.e., the employee pressure (e), is identified as a common category, in connection with the price reduction (I), for all the cases involved in Table 5. The equation 2-2 explains that when the pharmaceutical companies cut the prices of their medicines (I), the antecedent event, i.e., the employee pressure (E), was always absent (e). However, no antecedent event which was always present for these price cuts to be made is identified. Based on the equation 2-2, although the absence of the employee pressure (e) is a necessary condition to cause the pharmaceutical companies' price reductions (N), it is not a sufficient condition. In other words, the other antecedent events, such as the public pressure and/or media attention (P), the NGO and/or activist group pressure (N), the developed country/policy maker pressure (D), the shareholder/investor pressure (S), the international conference pressure (C), the inter-governmental organization pressure (U), the developing country pressure (G), the generic medicine pressure (M), and the competitor manufacturer pressure (R), should either be present or absent, in various forms, as illustrated in the equation 2-2, to cause

the pharmaceutical companies' price cuts (N). In particular, as illustrated in the Table 5 and the Boolean equation 2-2, the antecedent event categories of the public pressure and/or media attention (P) and the NGOs and/or activist group pressure (N) were present simultaneously in 14 cases (among the 24 cases involved in the Table 5) when the pharmaceutical companies cut the prices of their medicines (I). Therefore, it may be argued that the pressures from the public (or media attention), and the NGOs and activist groups have, mainly, forced the pharmaceutical companies to reduce the drug prices.

Lastly, it is noted that the Boolean equation 6, for the Table 9, cannot be further summarized by the distributive law of Boolean algebra. The equation 6 ( $W = PNDescuGmr$ ) is in connection with only one case (i.e. GskBIpress), because the data in the ESA, i.e., the narrative of events of the ESA, include just one case of the patent waiver by the pharmaceutical companies as a major case worth examining for the ESA. Thus, the Boolean equation 6 cannot be further summarized. Nevertheless, it is argued that the equation has still some implications for explaining the responses/reactions of the pharmaceutical companies in the stakeholder management terms, because the equation, although it deals with only one case, is in conjunction with, at least, two companies, GSK and Bristol Meyers Squibb. Therefore, based on the Boolean equation 6, it may be argued that when the pharmaceutical companies waived the patents on their medicines (W), the four antecedent events, i.e., the public pressure and/or media attention (P), the NGO and/or activist group pressure (N), the developed country/policy maker pressure (D), and the developing country pressure (G), were always present. In contrast, the antecedent events, such as the employee pressure (E), the shareholder/investor pressure (S), the

international conference pressure (C), the inter-governmental organization pressure (U), the generic medicine pressure (M), and the generic medicine pressure (R), were absent for these patents to be waived. However, there is a need for a further research, with more cases, with regard to the relationship between the ten antecedent events and the consequent event of the patent waiver. A further research may develop a more general theory concerning how the ten antecedent events interact to affect the patent waivers of the pharmaceutical companies.

#### **4.3 Discussion and Conclusion: Review of the Outcomes of the Formal Qualitative Analysis in terms of the Organizational Strategy Development for the Pharmaceutical Companies**

The primary purpose of conducting the formal qualitative analysis (i.e. the ESA and the qualitative comparative Boolean analysis) was to examine the research questions, presented above, to develop organizational strategies in the stakeholder management terms for the companies within the pharmaceutical industry. First, the ESA could identify the key stakeholders of the pharmaceutical companies. The antecedent event categories (Table 2) were developed, analyzing 48 major global public health-related cases, composed of 146 events, from 1987 to 2007. That is, the antecedent event categories were developed investigating the risks to the pharmaceutical companies that either directly or indirectly have influenced the responses of the companies in the stakeholder management terms. Since these risks have been posed by the stakeholders of the pharmaceutical companies, the antecedent event categories reveal the key stakeholders of the companies. It is argued that the key stakeholders of the pharmaceutical companies

are: the public and/or the media; NGOs and activist groups; the developed country governments and/or policy makers; employees; shareholders and/or investors; the inter-governmental organizations; the international conferences; the developing country governments; the generic medicine manufacturers; and the competitor manufacturers. These entities/institutions are considered to be the key stakeholders of the pharmaceutical companies because the companies have actually paid attention to them in terms of the stakeholder management perspective putting the specific measures, such as donations, price reductions, patent waivers and public-private partnerships, into practice.

Among the key stakeholders of the pharmaceutical industry identified above, the stakeholder type of the media needs further investigation to decide whether or not the media can be considered as a type of stakeholder groups. Freeman (1984)<sup>368</sup> defines a stakeholder as “any group or individual who can affect or is affected by the achievement of the organization’s objectives” (p. 46) and identifies four key stakeholder groups of a firm such as owners, customers, employees, and suppliers. Freeman (1984)<sup>369</sup> defines a further set of stakeholder groups such as governments, competitors, consumers, advocates, environmentalists, special interest groups, and the media. Clarkson (1995)<sup>370</sup> defines stakeholders as “persons or groups that have, or claim, ownership, rights, or interests in a corporation and its activities” (p.106) and identifies the media as a type of secondary stakeholder groups along with a wide range of special interest groups.

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<sup>368</sup> Freeman, R. E. (1984). *Strategic management: A stakeholder approach*. Englewood Cliffs, NJ: Prentice-Hall.

<sup>369</sup> Ibid.

<sup>370</sup> Clarkson, M. B. E. (1995). A Stakeholder Framework for Analyzing and Evaluating Corporate Social Performance. *Academy of Management Review*, 92-117.

Clarkson (1995)<sup>371</sup> maintains that although a firm is not dependent for its survival on the secondary stakeholder groups, they can cause significant damage to the firm because they have the capacity to mobilize public opinion in opposition to the firm's performance. Sirgy (2002)<sup>372</sup> develops an extensive list of organizational stakeholders and identifies the media as a type of vital external stakeholders along with customers, share/bondholders, distributors, suppliers, creditors, employees, local community, and the environment. Sirgy (2002)<sup>373</sup> further argues that the survival and growth of a firm depend on the extent to which the firm effectively exchanges the value with these external stakeholders.

As Phillips et al. (2000)<sup>374</sup> contend, one glaring shortcoming of the stakeholder theory is the problem of stakeholder identity. In other words, the stakeholder theory is often unable to distinguish those individuals and groups that are stakeholders from those that are not. This inability threatens the very meaningfulness of the theory. With regard to the media, it might not be considered as a type of stakeholder groups because it can be recognized as an agent of other stakeholder groups. However, as illustrated above, several scholars consider clearly the media as a type of stakeholder groups. The formal qualitative analysis of this dissertation reveals that the media has affected significantly the objectives of the pharmaceutical industry either independently of or simultaneously with other types

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<sup>371</sup> Clarkson, M. B. E. (1995). A Stakeholder Framework for Analyzing and Evaluating Corporate Social Performance. *Academy of Management Review*, 92-117.

<sup>372</sup> Sirgy, M. J. (2002). Measuring corporate performance by building on the stakeholders model of business ethics. *Journal of Business Ethics*, 35, 143-162.

<sup>373</sup> Ibid.

<sup>374</sup> Phillips, R. & Reichart, J. (2000). The Environment as a Stakeholder: A Fairness-based Approach. *Journal of Business Ethics*, 23, 185-197.

of stakeholder groups. Therefore, based on Freeman's (1984)<sup>375</sup> definition of a stakeholder, i.e., "any group or individual who can affect or is affected by the achievement of the organization's objectives" (p. 46), the media can be considered as a type of stakeholder groups in conjunction with the pharmaceutical industry particularly on the issue of the access to essential, life-saving medicines. It is argued that although some scholars might not consider the media as a type of stakeholder groups, it should be considered as a type of stakeholder groups at least in the case of the pharmaceutical industry.

The category of NGOs and/or activist groups should also be noted. Based on Table 2 (the antecedent event categories), it is argued that NGOs and/or activist groups are in connection with, in a certain degree, the other nine antecedent events. In particular, in categorizing the antecedent events, the category of 'NGO and/or activist group pressure' is interrelated with that of 'public pressure and/or media attention'. In Table 2, the 'public pressure and/or media attention (P)' category includes the events which created the public pressure and/or media attention against the pharmaceutical companies that could lead, eventually, the companies to make any kind of concessions such as price reduction and voluntary licensing. The 'NGO and/or activist group pressure (N)' category includes the events which created the pressure from NGOs and/or activist groups against the pharmaceutical companies that could lead, eventually, the companies to make any kind of concessions. Based on the analysis of the historical narrative of events, it is concluded that several cases in connection with the pressure from NGOs and/or activist groups

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<sup>375</sup> Freeman, R. E. (1984). *Strategic management: A stakeholder approach*. Englewood Cliffs, NJ: Prentice-Hall.

induced the public pressure and/or the media attention. Reversely, several cases in connection with the public pressure and/or the media attention also induced the pressure from NGOs and/or activist groups. However, the analysis of the historical narrative of events reveals that, in most cases, the pressure from NGOs and/or activist groups on the pharmaceutical companies used to induce the public pressure and/or the media attention. For example, in February 2007, Abbott Laboratories offered to cut the price it charges the Thai public health system for Kaletra. Abbott offered the price reduction of Kaletra in a bid to dissuade the Thai government from pursuing a compulsory license that would allow a generic version of the medicine to be imported from India. That is, this Abbott's offer was the development in an increasingly aggressive strategy of the cost containment pursued by the Thai government which began in November 2006 with the announcement of a compulsory license for Efavirenz manufactured by Merck. It is noted that, in Thailand, civil society organizations, such as MSF, Oxfam, and Global AIDS Alliance, had campaigned for the introduction of compulsory licensing of HIV/AIDS medicines in order to reduce the cost of ARV treatment. The Thailand's bold move to compulsory licensing also attracted international media spotlight. Thus, it is argued that Abbott reduced the price of Kaletra under the pressure of the Thai government combined with the media attention which had been induced from the pressure from NGOs and activist groups. In sum, based on the analysis of the historical narrative of events, two antecedent event categories (i.e. N and P) are interlinked in many cases. Therefore, it is possible to combine the two antecedent event categories into a single stakeholder group for a future research.

The second part of the first research question seeks to answer whether the key stakeholders of the pharmaceutical companies in the developing world are the same as or different from those in the developed world. In general, based on the analysis of the narrative of events, it is argued that the key stakeholders of the pharmaceutical companies in the developing world are the same as those in the developed world. The formal qualitative analysis of this dissertation does not present any ground for differentiating the types of the stakeholder group of the pharmaceutical companies in connection with the region where the specific measures are implemented. In other words, the types of the stakeholder group, in terms of the specific measures, of the pharmaceutical companies in the developing world are the same as those in the developed world.

Nevertheless, the difference between the developing and the developed country governments as the stakeholders of the pharmaceutical companies should be noted. The developed country governments and/or the policy makers have put pressure, either directly or indirectly, on the pharmaceutical companies to take the specific measures such as price cuts for both the developing and the developed world. For instance, when the 39 pharmaceutical companies challenged the South African patent law in 2001, the U.S. government and the E.U. gave their public support to the South African government forcing the companies to drop the lawsuit against South Africa. On the other hand, in 2001, when the anthrax incident occurred, Bayer decided to cut the price of Cipro in the U.S. by 95%, mainly, under the pressure of the U.S. government with compulsory licensing, combined with the compulsory licensing of Canada. These two examples show how the developed country governments and/or the policy makers have pressed directly



the pharmaceutical companies for both the developing and the developed world. In addition, the developed country governments (or the policy makers) pressed the pharmaceutical companies indirectly, in terms of the access to essential, life-saving medicines, for the developing world, although the developed country governments did not intend to press the pharmaceutical companies. For example, PEPFAR, launched by the U.S. President George W. Bush in 2003, began to distribute the generic medicines from late 2005 through its programs. Another example can be found in the events related to the tension between the U.S. and South Africa. In 1997, the USTR put South Africa under its Super 301 Watch List led by the PhRMA, however, the U.S. government dropped, in 1999, South Africa from the Watch List under the pressure of NGOs, activists, and the public and the media attention. Although the U.S. government dropped South Africa from the list not to press the pharmaceutical industry but to bow to the pressure against the U.S. policy towards South Africa, the pharmaceutical companies were forced to cut the HIV/AIDS drug prices in South Africa after the U.S. had dropped South Africa from the list. In contrast to the developed country governments, the developing country governments have put pressure on the pharmaceutical companies for the developing world only, by the help of NGOs, activist groups, the media attention, the international conferences, the inter-governmental organizations, and the generic drug manufacturers, particularly with the issuance of or threatening to issue compulsory licensing. If we consider the disparity in capacity between the two in terms of the access to essential, life-saving medicines, this difference between the developing and the developed country governments as the stakeholders of the pharmaceutical companies is understandable.

As a type of the key stakeholders of the pharmaceutical companies, lastly, the category of competitor manufacturer needs to be discussed further. The analysis of the historical narrative of events reveals that a pharmaceutical company or a group of pharmaceutical companies can put pressure on the other pharmaceutical companies in the stakeholder management terms. In other words, in some cases, a pharmaceutical company or a group of pharmaceutical companies forced the other pharmaceutical companies to take the specific measures such as price reduction. The pharmaceutical company or the group of pharmaceutical companies which forced the other pharmaceutical companies to take the specific measures can be considered as the key stakeholder(s) of the other pharmaceutical companies, because it or they affected the behaviors (i.e. the responses) of the other pharmaceutical companies. For example, in 2001, Bayer, the patent holder of Cipro, agreed with the U.S. government to reduce the price of Cipro in the U.S. by 95%. Bayer decided to cut the price of Cipro in the U.S., mainly, under the pressure of the U.S. government with compulsory licensing, combined with the compulsory licensing of Canada. Nevertheless, it is noted that the competitor manufacturers' offers of antibiotics to the U.S. government, for free or at cost, also pressed Bayer to reduce the price of Cipro. In specific, GSK, Bristol Meyers Squibb, and Johnson and Johnson announced their intention to supply large quantities of their antibiotics free for the U.S. government to treat the anthrax crisis. Eli Lilly and Pfizer also offered to provide their antibiotics at cost. Thus, it is argued that the competitor manufacturers' offers of antibiotics to the U.S. government pressed Bayer to reduce the price of Cipro in the U.S. market. Another example can be found in the case of the Pharmacia's voluntary licensing. In 2003, Pharmacia licensed its HIV/AIDS drug, Delavirdine, to a nonprofit organization (i.e. the

International Dispensary Association of the Netherlands). In turn, the nonprofit organization would line up generic manufacturers to produce the medicines for use in developing countries. However, it is noted that, although Pharmacia was one of the industry leaders at the time<sup>376</sup>, it was not heavily invested in HIV/AIDS research (Dawkins, 2005)<sup>377</sup>. In this respect, Love (2003)<sup>378</sup> argues that “the cost of this announcement to Pharmacia will be next to nothing, since the drug is not likely to be used in any case” (p. 1). Nevertheless, the voluntary licensing of Pharmacia put pressure on the other pharmaceutical companies in the stakeholder management terms. Love (2003)<sup>379</sup> points out that “Glaxo will have to respond, as will every company with an AIDS product” (p. 1).

Second, the ESA could identify the types of the measures, in the stakeholder management terms, which have been adopted by the pharmaceutical companies to deal with the risks posed by their stakeholders. That is, the consequent event categories (Table 3) constructed by analyzing the historical narrative of events reveal how the pharmaceutical companies have responded or reacted to the risks (i.e. the antecedent events) that have been posed by their various stakeholders. As Table 3 exhibits, the types of the measures which have been adopted by the pharmaceutical companies (i.e. the consequent events) are divided into six different categories. These measures include: donation; public-private

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<sup>376</sup> Pharmacia was ranked as 9th in the global therapeutic sales in 2001.

<sup>377</sup> Dawkins, C. E. (2005). First to Market: Issue Management Pacesetters and the Pharmaceutical Industry Response to AIDS in Africa. *Business & Society*, 44, 244-282.

<sup>378</sup> Love, J. (2003, January). CPTech statement on Pharmacia voluntary license for Delavirdine [Electronic Version]. Retrieved March, 2008, from <http://www.cptech.org/ip/health/aids/cptech01242003.html>

<sup>379</sup> Ibid.

partnership; drug price reduction; patent waiver; withdrawal of lawsuit or dispute; and voluntary licensing to generic producers.

It is noted that the pharmaceutical companies have not always responded to the pressure posed by their stakeholders. In other words, the pharmaceutical companies, in some cases, did not put the specific measures into practice, although stakeholders put pressure on them in connection with the access to essential, life-saving medicines. For example, in 2007, the Thai government announced its intention to issue a compulsory license for Kaletra and in response to this announcement, Abbott, the patent holder of Kaletra, offered the price cut of the medicine to the Thai government. Nevertheless, the Thai government issued a compulsory license for Kaletra and, after the compulsory licensing, the price of Kaletra has been dropped by half in many developing countries. It is noted that, after the compulsory licensing by the Thai government, Abbott took a retaliatory measures upon Thailand instead of adopting the specific measures such as price cuts. That is, after the compulsory licensing, Abbott announced that it would not seek the licenses for seven new products in Thailand. As Janssen (2008)<sup>380</sup> describes, the pharmaceutical industry feared that “Thailand’s initiative might be copied worldwide and would undermine the global patent protection system for new drugs” (p. 1). Another example is found in the case of Brazil in relation to Merck. In 2007, the Brazilian government issued a compulsory license to allow the import of the generic versions of Efavirenz from India, after the patent holder of the medicine, Merck, had failed to reduce, adequately, the price of Efavirenz. Although the Brazilian government has consistently

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<sup>380</sup> Janssen, P. (July, 2008). Compulsory licensing sets precedent. Bangkok Post [Electronic Version]. Retrieved November 2, 2008, from <http://www.bangkokpost.com/topstories/topstories.php?=129131>

sought the lower prices for the ARV medicines, that was the first time for the government to issue a compulsory license. Merck and other pharmaceutical companies criticized heavily the Brazilian government on its issuance of a compulsory license for Efavirenz. It is noted that the Brazilian government and Merck had negotiated over the price of Efavirenz since 2001, but they could not secure a deal because Merck had failed to cut, adequately, the price of the medicine. Namely, in spite of the pressure from its stakeholders, Merck did not put the specific measures into practice to deal with them.

Among the specific measures which have been adopted by the pharmaceutical companies, 'patent waiver' has not been taken by the companies frequently. As Table 3 exhibits, just one event in the historical narrative of events is in connection with the category of patent waiver. In contrast, 'price reduction' has been the most frequently adopted category by the pharmaceutical companies to deal with the risks that have been posed by their stakeholders. This is the answer for the second part of the second research question. However, unfortunately, it is unclear why the pharmaceutical companies have preferred 'price cut' to other measures in the stakeholder management terms. Investigating the answer for this question is beyond the scope of this dissertation and, thus, a further research which examines this question is expected.

Also, among the specific measures which have been adopted by the pharmaceutical companies, the category of 'public-private partnership' needs to be examined further. Although, as Table 3 exhibits, 'public-private partnership' is classified as a type of the specific measures based on the analysis of the historical narrative of events, it should be

considered as more extensive measures on the part of the pharmaceutical industry than other measures such as donation and price cut, because it is in connection with multiple kinds of humanitarian projects and/or concessions coupled with multiple pharmaceutical companies. In addition, the category of public-private partnership is in connection with multiple stakeholders of the pharmaceutical industry such as inter-governmental organizations, NGOs/activist groups, and developing country governments. For instance, the UNAIDS was created in 1996 and it pressed the pharmaceutical companies to join a pilot project (i.e. the HIV Drug Access Initiative). The pilot project was designed to develop a collaborative effort between the pharmaceutical companies and the developing country governments. GSK, Bristol Meyers Squibb, and Roche joined the pilot project, and the companies provided financial support through various means, such as drug price cuts and investments in non-profit firms by cash or drug donations (“Joint and co-sponsored United Nations Programme”, 2005)<sup>381</sup>. Another example is a plan called Accelerated Access Initiative (AAI). AAI was a public-private partnership similar to the pilot project. AAI was launched in May 2000 with the intention of cutting the AIDS drug prices in the developing world and it was involved a dialogue between the U.N. organizations and the pharmaceutical companies. Initially, five pharmaceutical companies (i.e. GSK, Roche, Boehringer Ingelheim, Merck, and Bristol Meyers Squibb) joined AAI and, later, Abbott (in 2001) and Gilead Sciences (in 2004) were responded to AAI. However, a public-private partnership can be performed on a single company basis. For instance, in October 1987, Merck announced its intention to donate Mectizan and the Mectizan Donation Program was launched in 1988. Merck sought to overcome the

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<sup>381</sup> UNAIDS (1999). Joint and co-sponsored United Nations programme on human immunodeficiency virus/acquired immunodeficiency syndrome. [Electronic Version]. Retrieved January 15, 2008, from [http://data.unaids.org/publications/External-Documents-Restored/ecosoc\\_unaidsreport1999\\_en.pdf](http://data.unaids.org/publications/External-Documents-Restored/ecosoc_unaidsreport1999_en.pdf)

obstacles of a lack of infrastructure and cultural barriers in connection with the distribution of Mectizan by establishing a multi-sectoral public-private partnership, the Mectizan Donation Program. It is noted that the public-private partnership, regardless of whether it is a pharmaceutical industry-wide, collaborative basis or a single company basis, it is in connection with the multiple stakeholders of the pharmaceutical industry such as the developing country governments, inter-governmental organizations, and civil society organizations. In this respect, 'public-private partnership' can be construed as a more comprehensive stakeholder management on the part of the pharmaceutical companies than other measures identified through the analysis of the narrative of events. Nevertheless, it is noted that although the pharmaceutical companies have engaged in several public-private partnerships in conjunction with the access to essential, life-saving medicines, there has been no comprehensive, industry-wide, multi-stakeholder public-private partnership. Moreover, except the Merck's Mectizan Donation Program, the public-private partnerships related to the pharmaceutical industry have been initiated by the public sector institutions, not by the private sector pharmaceutical companies.

Third, the formal qualitative analysis could identify, among the key stakeholders, the most influential and salient stakeholder(s) of the pharmaceutical companies in terms of the actual implementation of the specific measures. The comparative Boolean analysis, using Boolean logic, investigates the specifics of how ten antecedent event categories interacted to affect six consequent event categories. In specific, the comparative Boolean analysis examines, for a consequent event, what antecedent events have to be present independently or simultaneously. In other words, the comparative Boolean analysis

compares and analyzes the diverse instances in which the pharmaceutical companies put the specific measures into practice to deal with the risks posed by their various stakeholders. In essence, the comparative Boolean analysis attempts to identify and establish the causal links between the antecedent and the consequent events, using the event categories, and, thus, it helps to identify the most influential and salient stakeholder of the pharmaceutical companies in the light of the actual implementation of the specific measures in the stakeholder management terms.

Based on the truth tables (from Table 4 to 9), the Boolean algebra equations have been developed summarizing the truth tables. These Boolean equations summarize what conditions were present and absent in the data when the pharmaceutical companies put the specific measures into practice. The Boolean equations (i.e. 1-1, 4-4, 5-5, and 6) reveal that when the consequent event O, L, V, and W are occurred, two antecedent events, P and N, are always occurred (or presented) simultaneously. In other words, when the pharmaceutical companies adopt the measures of donation, withdrawal of lawsuit or dispute, voluntary licensing, and patent waiver in the stakeholder management terms, both the pressure from the public and/or the media (P) and from NGOs and/or activist groups (N), always, were presented simultaneously forcing the companies to adopt the specific measures. In addition, based on the Boolean equation 3-3 (i.e.  $T = esUgmr \times [PNdC + PNDc + PNdc + pndc]$ ), with regard to the consequent event category of public-private partnership, it is argued that both the pressure from the public and/or the media (P) and from NGOs and/or activist groups (N) have exerted significant influence on the pharmaceutical companies. Therefore, it is concluded that the public and/or the



media and NGOs and/or activist groups have exerted the greatest influence on the pharmaceutical companies in terms of forcing the companies to respond to the risks posed by them, putting the specific measures into practice. These two stakeholder types can be construed as the most influential, salient stakeholders of the pharmaceutical companies. This conclusion is also supported by the interpretation of the Boolean equation 2-2. The equation 2-2 explains that whenever the pharmaceutical companies cut the prices of their medicines, the antecedent event category of employee pressure was always absent. In contrast, no antecedent event category was always present for these price cuts to be made. That is, the antecedent events, except employee pressure, should either be present or absent, in various forms to cause the pharmaceutical companies' price reductions. However, it is noted that, as the Boolean equation 2-2 exhibits, the antecedent event categories of the public pressure and/or media attention (P) and the NGOs and/or activist group pressure (N) were present simultaneously in 14 cases (among the 24 cases involved in Table 5) of price reductions. Therefore, it is argued that the pressure from the public (or the media attention) and from the NGOs and activist groups have mainly forced the pharmaceutical companies to reduce drug prices.

Lastly, as discussed above, in categorizing the antecedent events, the category of 'NGO and/or activist group pressure' is interrelated with that of the 'public pressure and/or media attention'. Thus, in identifying the most influential, salient stakeholder group(s) of the pharmaceutical industry, further elaboration to distinguish these two stakeholder types does not seem to be necessary.

Fourth, the formal qualitative analysis could identify the circumstances (or conditions) under which the pharmaceutical companies have actually adopted the specific measures, considering certain entities/institutions as their stakeholders. However, as the comparative Boolean analysis reveals, there is no simple explanation that can account for the circumstances under which the pharmaceutical companies have actually put the specific measures into practice. For this dissertation, the comparative Boolean analysis compares and analyzes the diverse instances under which the pharmaceutical companies put the specific measures into practice to deal with the risks posed by their various stakeholders. The comparative Boolean analysis simplifies and solves the truth tables, and, further, the Boolean algebra equations summarize the conditions present and absent, for each of the consequent event categories, when the pharmaceutical companies put the specific measures into practice. Therefore, the Boolean equations help to explain the circumstances under which the pharmaceutical companies have actually put the specific measures into practice. However, the Boolean equations also reveal the complexity of this issue.

The circumstances are summarized as follows: (1) when the pharmaceutical companies donated their medicines, the two antecedent events, i.e., the public pressure and/or the media attention and the NGO and/or activist group pressure, were always present. In contrast, the antecedent events, such as the developed country/policy maker pressure, employee pressure, shareholder/investor pressure, developing country pressure, and competitor manufacturer pressure, were absent for these donations to be made. It is noted that although this circumstance is a necessary condition to cause the pharmaceutical

companies' donations, it is not a sufficient condition. Namely, the antecedent events, such as the international conference pressure, inter-governmental organization pressure, and generic medicine pressure, should either be present or absent in various forms to cause the pharmaceutical companies' donations; (2) when the pharmaceutical companies performed the public-private partnerships, only one antecedent event, the inter-governmental organization pressure, was always present. In contrast, the antecedent events, such as the employee pressure, shareholder/investor pressure, developing country pressure, generic medicine pressure, and competitor manufacturer pressure, were absent for these public-private partnerships to be implemented. Also, although this circumstance is a necessary condition to cause the public-private partnerships in connection with the pharmaceutical companies, it is not a sufficient condition. Namely, the antecedent events, such as the public pressure and/or the media attention, NGO and/or activist group pressure, developed country/policy maker pressure, and international conference pressure, should either be present or absent to cause the public-private partnership in connection with the pharmaceutical companies; (3) when the pharmaceutical companies withdrew a lawsuit or a dispute, four antecedent events, such as the public pressure and/or the media attention, NGO and/or activist group pressure, inter-governmental organization pressure, and developing country pressure, were always present. In contrast, the antecedent events, such as the employee pressure, shareholder/investor pressure, international conference pressure, generic medicine pressure, and competitor manufacturer pressure, were absent for the withdrawal of a lawsuit or a dispute to be made. In addition, although this circumstance is a necessary condition to cause the withdrawal of a lawsuit or a dispute by the pharmaceutical companies, it is not a

sufficient condition. Namely, the antecedent event, the developed country/policy maker pressure, should either be present or absent to cause the withdrawal of a lawsuit or a dispute on the part of the pharmaceutical companies; (4) when the pharmaceutical companies issued the voluntary licenses, the three antecedent events, such as the public pressure and/or the media attention, NGO and/or activist group pressure, and generic medicine pressure, were always present. In contrast, the antecedent events, such as the developed country/policy maker pressure, employee pressure, shareholder/investor pressure, international conference pressure, and inter-governmental organization pressure, were absent for these voluntary licenses to be issued. In addition, although this circumstance is a necessary condition to cause the pharmaceutical companies' voluntary licenses, it is not a sufficient condition. In other words, the antecedent events, such as the developing country pressure and the generic medicine pressure, should either be present or absent to cause the pharmaceutical companies' voluntary licenses; (5) when the pharmaceutical companies reduced the prices of their medicines, the antecedent event, i.e., the employee pressure, was always absent. However, no antecedent event always present for these price cuts to be made is identified. Also, although the absence of the employee pressure is a necessary condition to cause the pharmaceutical companies' price reductions, it is not a sufficient condition. That is, other antecedent events, such as the public pressure and/or the media attention, NGO and/or activist group pressure, developed country/policy maker pressure, shareholder/investor pressure, international conference pressure, inter-governmental organization pressure, developing country pressure, generic medicine pressure, and competitor manufacturer pressure, should either be present or absent in various forms to cause the pharmaceutical companies' price

reductions. Especially, as discussed above, two antecedent event categories, i.e., the public pressure and/or the media attention and the NGOs and/or activist group pressure, were present simultaneously in 14 cases (among 24 cases involved in the truth table for 'price reduction'), when the pharmaceutical companies cut the prices of their medicines. Thus, it is argued that the pressures from the public (or the media attention) and from the NGOs and activist groups have mainly forced the pharmaceutical companies to reduce the drug prices; and, (6) when the pharmaceutical companies waived the patents on their medicines, four antecedent events, i.e., the public pressure and/or the media attention, NGO and/or activist group pressure, developed country/policy maker pressure, and developing country pressure, were always present. In contrast, the antecedent events, such as the employee pressure, shareholder/investor pressure, international conference pressure, inter-governmental organization pressure, and generic medicine pressure, were absent for these patents to be waived. However, as discussed earlier, there is a need for a further research, with more cases, concerning the relationship between the antecedent events and the consequent event of the patent waiver, because, in the case of the patent waiver, the formal qualitative analysis of this dissertation deals with only a single case.

Lastly, the analysis of the historical narrative of events could identify whether or not the pharmaceutical companies have given special consideration to specific countries/regions and/or to specific diseases in putting the specific measures into practice. Among 48 global public health-related cases in the narrative of events, just one case is concerned with the developed world. The case refers to the anthrax crisis in 2001 (case 29). In 2001, Bayer, the patent holder of Cipro, reduced the price of Cipro in the U.S. by 95% after the

U.S. government had threatened Bayer with compulsory licensing combined with the issuance of a compulsory license for Cipro by the Canadian government. Although Pharmacia licensed its HIV/AIDS medicine (Delavirdine) to a nonprofit organization in the Netherlands (case 31), this voluntary licensing was issued for the use of developing countries. All the other cases in the narrative of events are concerned with the developing world. The developing countries examined in the narrative of events include India, Brazil, Thailand, Indonesia, Vietnam, Malaysia, Chile, South Africa, and several African countries such as Uganda, Ivory Coast, Botswana, Lesotho, Namibia, and Swaziland.

Among the cases in the narrative of events, only three cases are concerned with the diseases other than HIV/AIDS. These cases refer to the Merck's Mectizan (ivermectin) donation program, initiated in 1988, for river blindness (onchocerciasis) in Africa, Latin America, and the Middle East (case 2), the Bayer's price reduction of Cipro for anthrax crisis in the U.S. in 2001 (case 29), and the Novartis's challenges against the Indian patent law in connection with its cancer drug Gleevec from 2006 to 2007 (case 43 and 48). Except these three cases, the cases in the narrative of events which have relation to the issues other than HIV/AIDS also focus mainly on the HIV/AIDS pandemic. For instance, the cases which have relation to the issues such as the Brazilian patent law (case 9, 22, and 25), the South African patent law (case 10, 15, 23, and 24), the creation of the Global Fund (case 26), and the WTO Decision in 2003 (case 37) deal with the diseases other than HIV/AIDS, the controversy between the pharmaceutical companies and their stakeholders in these cases is, mainly, in connection with HIV/AIDS in terms of the access to essential, life-saving medicines.

Therefore, based on the analysis of the historical narrative of events, it is argued that the pharmaceutical companies have given special consideration to the developing world, in terms of putting the specific measures into practice, particularly in relation to HIV/AIDS. In this respect, it can be construed that the stakeholders have put the most severe pressure on the pharmaceutical companies, forcing the companies to take the specific measures, in connection with the HIV/AIDS epidemic in the developing world. However, it does not mean that the stakeholders of the pharmaceutical companies do not have a stake in diseases other than HIV/AIDS in the developing world or do not have a stake in HIV/AIDS in the developed world. For the last two decades, in terms of the access to essential, life-saving medicines, the HIV/AIDS pandemic in the developing world has been considered as the most serious threat to the global public health. It is argued that the historical narrative of events reflects this perception.

## **Chapter 5: Introduction of Analogical Reasoning Model (ARM) into the Organizational Strategy Development for the Pharmaceutical Industry**

### **5.1 Analogical Reasoning Model (ARM) in terms of the Organizational Strategy Development for the Pharmaceutical Industry**

To improve the access to essential, life-saving medicines, particularly in conjunction with the HIV/AIDS pandemic in the developing world, several strategic options have been proposed by scholars and practitioners. For instance, the strategic options that have been proposed include the drug pricing strategy using the stakeholder management model as a

guide (Kennedy et al., 2004)<sup>382</sup>, the differential pricing strategy (Danzon, 1997; Danzon & Towse, 2003)<sup>383 384</sup>, the socially responsible drug pricing strategy (Vachani & Smith, 2004)<sup>385</sup>, the compulsory licensing strategy (Ashcroft, 2001)<sup>386</sup>, the free market-driven pricing strategy (Calfee et al., 2004)<sup>387</sup>, and the strategic option of voluntary licensing. Nevertheless, Mascarenhas et al. (2005)<sup>388</sup> criticize that each of these strategic solutions for the pharmaceutical companies in the light of the desire to bring about an increase in the global distribution of essential, life-saving medicines at affordable prices is “ideological, very general and fraught with a bevy of other problems” (p. 404).

It is noted that if the strategies of this dissertation developed for the pharmaceutical companies, conducting two different types of the formal qualitative analysis, are not tested in conjunction with another analytical method of the organizational strategy development, the strategies of this dissertation can also be considered to be too ideological or general. In this respect, it is necessary for the strategies developed through the formal qualitative analysis to be tested in connection with another organizational strategy development perspective, such as an analogical reasoning model (ARM). Thus, the main objective of this chapter is developing organizational strategies, in the

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<sup>382</sup> Kennedy, C. R., Harris, F. H., & Lord, M. (2004). Integrating public policy and public affairs in a pharmaceutical marketing program: The AIDS pandemic. *Journal of Public Policy and Marketing*, 23, 128-139.

<sup>383</sup> Danzon, P. M. (1997). Price discrimination for pharmaceuticals: Welfare effects in the US and the EU. *International Journal of the Economics of Business*, 4, 301-321.

<sup>384</sup> Danzon, P. M., & Towse, A. (2003). Differential pricing for pharmaceuticals: Reconciling access, R&D and patents. *International Journal of Healthcare Finance and Economics*, 3, 183-205.

<sup>385</sup> Vachani, S., & Smith, C. N. (2004). Socially responsible pricing: Lessons from the pricing of the AIDS drugs in developing countries. *California Management Review*, 47, 117-145.

<sup>386</sup> Ashcroft, R. E. (2001). Affordable access to essential medication in developing countries: Conflicts between ethical and economic imperatives. *Journal of Medicine and Philosophy*, 27, 179-195.

<sup>387</sup> Calfee, J. E., & Bate, R. (2004). Pharmaceuticals and the Worldwide HIV Epidemic: Can a Stakeholder Model Work? *Journal of Public Policy & Marketing*, 23, 140-152.

<sup>388</sup> Mascarenhas, O. A., Kesavan, R., & Bernacchi, M. (2005). Global marketing of lifesaving drugs: an analogical mode. *Journal of Consumer Marketing*, 22, 404-411.



stakeholder management terms, for the pharmaceutical companies, adopting the ARM. It is noted that the outcomes of the ESA and the comparative Boolean analysis are tested by performing the ARM and, in addition, the ARM is expected to compensate for some of the weaknesses of the formal qualitative analysis.

Recently, Gavetti et al. (2005)<sup>389</sup> suggested the way in which cases or analogies can be used in framing and implementing business strategies, i.e., an ARM. An ARM “makes efficient use of information, but does not pretend to detail every market issue of the problem at hand” (Mascarenhas et al., 2005, p. 405)<sup>390</sup>. That is, an ARM “pays attention to select features of the information, sees patterns in it, and applies the patterns to the present market challenges” (Mascarenhas et al., 2005, p. 405)<sup>391</sup>. An ARM can be seen as an alternative analogical model independent of the approaches mentioned above through which strategies are developed for the pharmaceutical companies. In essence, an ARM solves “a ‘target problem’ by seeking and evaluating ‘candidate solutions’ from a ‘source industry’ that bears close resemblance to the target industry” (Mascarenhas et al., 2005, p. 404)<sup>392</sup>. In this respect, it is argued that an ARM developed by Gavetti et al. (2005)<sup>393</sup> is particularly useful for the strategy development for the pharmaceutical industry, because it can facilitate the pharmaceutical industry to develop any realizable, effective strategies of its own, in the stakeholder management terms, based on the strategies of

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<sup>389</sup> Gavetti, G., & Rivkin, J. W. (2005, April). How strategies really think: Tapping the power of analogy [Electronic Version]. Harvard Business Review. Retrieved March, 2008, from <http://www.eleganthack.com/homepage/archives/How%20Strategists%20Really%20Think.pdf>.

<sup>390</sup> Mascarenhas, O. A., Kesavan, R., & Bernacchi, M. (2005). Global marketing of lifesaving drugs: an analogical mode. *Journal of Consumer Marketing*, 22, 404-411.

<sup>391</sup> Ibid.

<sup>392</sup> Ibid.

<sup>393</sup> Gavetti, G., & Rivkin, J. W. (2005, April). How strategies really think: Tapping the power of analogy [Electronic Version]. Harvard Business Review. Retrieved March, 2008, from <http://www.eleganthack.com/homepage/archives/How%20Strategists%20Really%20Think.pdf>.

other industry sectors that have been under similar circumstances. For this dissertation, the ARM is applied for the purposes of improving the access to essential, life-saving medicines by those who need them most, as well as of developing strategies for the pharmaceutical companies in the stakeholder management terms. That is, the ARM helps to develop any practical strategies that can realize a win-win situation for both the pharmaceutical industry and its stakeholders.

Gavetti et al. (2005)<sup>394</sup> explain how an ARM can be used as a key implement in the toolbox of the typical real-world strategist as follows:

Analogical reasoning makes enormously efficient use of the information and the mental processing power that strategy makers have. When reasoning by analogy, managers need not understand every aspect of the problem at hand. Rather, they pay attention to select features of it and use them to apply the patterns of the past to the problems of the present...Analogical reasoning can also be a source of remarkable insight. Analogies lie at the root of some of the most compelling and creative thinking in business as a whole, not just in discussions in strategy...Reasoning by analogy is prevalent among strategy makers because of a series of close matches...Reflecting these matches, business schools typically teach strategy by means of case studies, which provide an abundance of analogies from which the students can draw...Similarly, some of the foremost strategy consultants are famed for their ability to draw lessons from one industry and apply them to another. (p. 3)

In essence, in an ARM, a previous solution may be transferred to solve a present problem. Mascarenhas et al. (2005)<sup>395</sup> assert that the value of applying the precedent to the present is fully recognized in an ARM.

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<sup>394</sup> Gavetti, G., & Rivkin, J. W. (2005, April). How strategies really think: Tapping the power of analogy [Electronic Version]. Harvard Business Review. Retrieved March, 2008, from <http://www.eleganthack.com/homepage/archives/How%20Strategists%20Really%20Think.pdf>.

It is noted that an ARM tries to find “a bilateral case-by-case solution” (Mascarenhas et al., 2005, p. 404)<sup>396</sup> to the target problems. In specific, an ARM is a bilateral, market-by-market, brand-by-brand, or even corporate-by-customer approach (Mascarenhas et al., 2005)<sup>397</sup>. In this respect, an ARM is a more appropriate approach for the pharmaceutical companies to develop strategies in the stakeholder management terms than those that have been adopted for the companies in the extent studies. In other words, the approaches that have been taken by the extent studies to address the issue of the access to essential, life-saving medicines are multilateral, general, and ideological models and, thus, they have been failed to solve the issue of the global public health. Mascarenhas et al. (2005) argue that “appeals to pharmaceutical company’s moral, responsibilities, ethical corporate citizenship and the application of the distributive justice principles to mandate the prevention of preventable deaths have led to an impasse” (pp. 404-405). It is argued that the approaches that have been taken to address the issue of the global public health do not produce any effective solution. Therefore, it is needed to explore and adopt an alternative model, such as an ARM, to generate any viable remedies for both the pharmaceutical companies and the people who need the essential, life-saving medicines.

An ARM, a simple adaptation of a familiar experience to a new setting, can be a powerful source for firms in terms of discovering effective and competitive positions, developing their business strategies. Gavetti et al. (2005)<sup>398</sup> argue that an ARM, a prevalent strategy-

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<sup>395</sup> Mascarenhas, O. A., Kesavan, R., & Bernacchi, M. (2005). Global marketing of lifesaving drugs: an analogical mode. *Journal of Consumer Marketing*, 22, 404-411.

<sup>396</sup> Ibid.

<sup>397</sup> Ibid.

<sup>398</sup> Gavetti, G., Levinthal, D. A., & Rivkin, J. W. (2005). Strategy making in novel and complex worlds: The power of analogy. *Strategic Management Journal*, 26, 691-712.

making process relatively untapped in research, can be a potentially important source of novel strategies for firms. The authors further contend that, in complex and novel contexts, an ARM may be superior to other strategy-making models.

However, there are also criticisms on an ARM. For instance, Farjoun (2008)<sup>399</sup> argues that “to be effective, the transfer of knowledge from a familiar to an unfamiliar domain needs to go beyond the cognitive undertaking emphasized in GLR<sup>400</sup> to address organizational and inter-organizational realities” (Farjoun, 2008, p. 1009)<sup>401</sup>. The author further contends that an ARM is not necessarily superior to other strategy-making models and, thus, an ARM and other approaches can play a larger role, particularly in developing effective strategies in novel and complex contexts. In other words, Farjoun (2008)<sup>402</sup> admits that the transfer of existing solutions and experience through an ARM to develop organizational strategies within a new setting can be an important source of new strategies. Nevertheless, alternative approaches “that highlight endogenous environments, strategy as constructing logic, less extreme forms of rational choice and local search, and alternative search models attenuate and bound the GLR’s claim” (Farjoun, 2008, p. 1011)<sup>403</sup>. Thus, Farjoun (2008)<sup>404</sup> argues that the relative value of an ARM against the

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<sup>399</sup> Farjoun, M. (2008). Research notes and commentaries. Strategy making, novelty and analogical reasoning – Commentary on Gavetti, Levinthal, and Rivkin (2005). *Strategic Management Journal*, 29, 1001-1016.

<sup>400</sup> In Farjoun (2008)’s article, GLR refers to the article written by Gavetti, G., Levinthal, D. A., & Rivkin, J. W. (2005).

<sup>401</sup> Farjoun, M. (2008). Research notes and commentaries. Strategy making, novelty and analogical reasoning – Commentary on Gavetti, Levinthal, and Rivkin (2005). *Strategic Management Journal*, 29, 1001-1016.

<sup>402</sup> Ibid.

<sup>403</sup> Ibid.

<sup>404</sup> Ibid.

alternative approaches should be reconsidered and other equally important sources of novel strategies should be underscored.

It is noted that the advocates of an ARM also discuss the danger in applying an ARM. Namely, Gavetti et al. (2005)<sup>405</sup> point out that, although an ARM is a powerful and prevalent tool, it is extremely easy to reason poorly through analogies and, thus, strategy makers rarely consider how to use them wisely. Especially, problems arise when the strategists draw an analogy on the basis of ‘superficial similarity’, not deep causal traits. In this respect, Gavetti et al. (2005)<sup>406</sup> illustrate a dilemma posed by reasoning by analogy. That is, on the one hand, reasoning by analogy is a powerful tool, well suited to the challenges of making strategy in novel, complex settings sparking breakthrough ideas, and, then, fuelling successful implementation of strategies. On the other hand, it raises the specter of superficiality. Gavetti et al. (2005)<sup>407</sup> emphasize that it is impossible to make analogies 100% safe. In general, since the strategists use an ARM under unfamiliar, ambiguous circumstances where other methods of strategy development are unavailable, it must be very hard for the strategists to distinguish the deep traits and the superficial similarity. Thus, Gavetti et al. (2005)<sup>408</sup> argue that it is often difficult to tell whether similarities between a familiar and an unfamiliar problem are deep or superficial. In this respect, for the strategists facing strategic choices, Gavetti et al. (2005)<sup>409</sup> propose four straightforward steps which can improve the strategists’ odds of using analogies

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<sup>405</sup> Gavetti, G., & Rivkin, J. W. (2005, April). How strategies really think: Tapping the power of analogy [Electronic Version]. Harvard Business Review. Retrieved March, 2008, from <http://www.eleganthack.com/homepage/archives/How%20Strategists%20Really%20Think.pdf>.

<sup>406</sup> Ibid.

<sup>407</sup> Ibid.

<sup>408</sup> Ibid.

<sup>409</sup> Ibid.

skillfully avoiding superficial analogies. In the next section, these four steps of an ARM are explained and applied to the strategy development for the pharmaceutical companies.

In sum, it is noted that an ARM has also some weaknesses as an analytical method. To compensate for the possible weaknesses of an ARM, it is better to combine other alternative approaches with an ARM. For this dissertation, the ARM is not adopted as a sole analytical tool to develop strategies for the pharmaceutical companies. The formal qualitative analysis has also been performed to develop strategies for the pharmaceutical companies. That is, in regard of this dissertation, although the ARM is expected to compensate for the possible weaknesses of the formal qualitative analysis, the latter can also compensate for the weaknesses of the former.

## **5.2 Four-Steps of the Analogical Reasoning Model (ARM)**

This dissertation follows four steps of the ARM presented by Gavetti et al. (2005)<sup>410</sup> to develop organizational strategies for the pharmaceutical companies in the stakeholder management terms. Gavetti et al. (2005)<sup>411</sup> acknowledge that these straightforward steps, which can improve the strategists' odds of using analogies skillfully avoiding superficial analogies, are rooted in the political science. The authors mention that "we must acknowledge our debt to political scientists, especially Harvard's Ernest May and Richard Neustadt, who found that analogical reasoning often leads policy makers astray"

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<sup>410</sup> Gavetti, G., & Rivkin, J. W. (2005, April). How strategies really think: Tapping the power of analogy [Electronic Version]. Harvard Business Review. Retrieved March, 2008, from <http://www.eleganthack.com/homepage/archives/How%20Strategists%20Really%20Think.pdf>.

<sup>411</sup> Ibid.

(Gavetti et al., 2005, p. 9)<sup>412</sup>. In their book, “Thinking in Time” (Neustadt & May, 1986)<sup>413</sup>, Neustadt and May present three assumptions: (1) particulars matter; (2) managerial improvement in performance is worth seeking; and (3) a little thought is helpful. Based on these assumptions, the authors propose that political scientists should separate the ‘known’ from the ‘unclear’ and both the known and unclear from the ‘presumed’. The authors also stress the need to pull apart analogies, identifying ‘likenesses’ and ‘differences’. The steps taken by Gavetti et al. (2005)<sup>414</sup> that help put an ARM into practice reflect the basic notions presented by Neustadt et al. (1986)<sup>415</sup>.

The first step of the ARM is to articulate the analogy, that is, to recognize the analogy and to identify its purpose. In other words, to defend against flawed analogies, a strategist, first, must recognize the analogies he or she is using. Sometimes, the analogies are obvious, however, in other cases, the influential analogies remain hidden. Gavetti et al. (2005)<sup>416</sup> point out that the analogies often come from executives’ backgrounds. It is also important to identify how a company is using any analogies it recognizes. For instance, in case of this dissertation, although the ARM is used as a tool for choosing among possible solutions to the strategic problems that the pharmaceutical companies face<sup>417</sup>, as Gavetti et al. (2005)<sup>418</sup> argue, the ARM can be used for a variety of other

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<sup>412</sup> Gavetti, G., & Rivkin, J. W. (2005, April). How strategies really think: Tapping the power of analogy [Electronic Version]. Harvard Business Review. Retrieved March, 2008, from <http://www.eleganthack.com/homepage/archives/How%20Strategists%20Really%20Think.pdf>.

<sup>413</sup> Neustadt, R., & May, E. (1986). Thinking in time. New York, NY: The Free Press.

<sup>414</sup> Gavetti, G., & Rivkin, J. W. (2005, April). How strategies really think: Tapping the power of analogy [Electronic Version]. Harvard Business Review. Retrieved March, 2008, from <http://www.eleganthack.com/homepage/archives/How%20Strategists%20Really%20Think.pdf>.

<sup>415</sup> Neustadt, R., & May, E. (1986). Thinking in time. New York, NY: The Free Press.

<sup>416</sup> Ibid.

<sup>417</sup> Gavetti et al. (2005) argue that “Most important, analogies can be catalysts for generating creative options” (p. 14).

purposes (e.g. brainstorming, communicating complexity, and motivating employees) in other cases. In the light of the purpose of using the ARM for this dissertation (i.e. developing organizational strategies for the pharmaceutical companies in the stakeholder management terms), as Gavetti et al. (2005)<sup>419</sup> suggest, it might be useful to break the process of analogical reasoning into three further steps to analyze the chains of cause and effect.

The second step of the ARM aims at identifying and understanding the source. Also, through the second step, how and why the source strategies worked in the source context. In other words, the ‘source industries’ and ‘source problems’ that might offer solutions to the target problems are explored. In essence, the second step of the ARM can be defined as a process in which the source is understood. This second step can be begun by examining why the strategies worked in the source industry from which the analogy is drawn. Gavetti et al. (2005)<sup>420</sup> suggest that the classic tools of strategy analysis are extremely useful at this stage. They maintain that “indeed, the key is to lay out in-depth analyses that are familiar to strategists, particularly analyses of the source environment, the solution or strategy that worked well (or that failed) in the original context, and the link between the source environment and the winning (or losing) strategy” (Gavetti et al., 2005, p. 9). In short, during the second step of the ARM, a strategist lay out a chain of cause and effect that explains why the original strategy worked in the source environment. Then, the strategist’s goal should be to figure out whether the causal logic

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<sup>418</sup> Gavetti, G., & Rivkin, J. W. (2005, April). How strategies really think: Tapping the power of analogy [Electronic Version]. Harvard Business Review. Retrieved March, 2008, from <http://www.eleganthack.com/homepage/archives/How%20Strategists%20Really%20Think.pdf>.

<sup>419</sup> Ibid.

<sup>420</sup> Ibid.



identified in the source environment is supported in the target environment. Gavetti et al. (2005)<sup>421</sup> argue that “in preparing to make that analysis, the strategy maker will find it useful to compile two lists of industry features: those that play a crucial role in the causal logic and those that don’t” (p. 9).

The third step of the ARM aims at assessing actively the similarities and differences between the source and the target setting, and, then, presenting feasible ‘candidate solutions’ to the target problems. In other words, Gavetti et al. (2005)<sup>422</sup> suggest that a strategist maps the similarities between the source and the target setting, and, then, determines whether the resemblance between the two settings is more than ‘superficial’. Gavetti et al. (2005)<sup>423</sup> argue that the understanding of the source that a strategist has built up through the second step is crucial in this third step. The authors further argue that rather than wrestling with the entire target problems, which are much less familiar with the source, the strategist can focus on the key features of the causal logic. That is, the basic question for the third step is whether the source and the target are similar or different along these key features. In addition, Gavetti et al. (2005)<sup>424</sup> emphasize that not only the similarities but also the differences between the source and the target setting should be considered. The strategist must search actively the differences between the source and target setting, seeking evidence that each essential feature of the source problem is absent in the target setting. The authors also emphasize that the list of industry

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<sup>421</sup> Gavetti, G., & Rivkin, J. W. (2005, April). How strategies really think: Tapping the power of analogy [Electronic Version]. Harvard Business Review. Retrieved March, 2008, from <http://www.eleganthack.com/homepage/archives/How%20Strategists%20Really%20Think.pdf>.

<sup>422</sup> Ibid.

<sup>423</sup> Ibid.

<sup>424</sup> Ibid.

features that are not crucial in the causal logic is very useful in this step. Namely, it should be noted that if many of the similarities between the source and the target are on this list of not crucial in the causal logic rather than crucial correspondences, the analogy may be based on superficial similarity.

The last step of the ARM aims at evaluating the ‘target solutions’. In other words, the last step aims at translating, deciding, and adapting the original strategies to the new setting. In essence, the final step is to decide whether the original strategies, properly translated, will work for the target industry. According to Gavetti et al. (2005)<sup>425</sup>, this step requires, first, that a strategist can say clearly what the strategy would look like in the new setting, and this requires some adjustment. The authors comment that even the best analogies involve some differences between the source and the target setting. Gavetti et al. (2005)<sup>426</sup> summarize the final step as follows:

By now, executives have a sense of the most important differences, and, in translating the strategy, they try to make adjustments that deal with them. After the translation comes a go-no-go decision on whether to pursue the analogy in the marketplace. This involves a clearheaded assessment of whether the translated strategy is likely to fare well in the new context. If executives opt to pursue the analogy, they face another round of adjustment – adapting in the marketplace in response to feedback from customers, rivals, suppliers, and others. It is here, in the market, that managers truly learn how good their analogies are. (p. 12)

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<sup>425</sup> Gavetti, G., & Rivkin, J. W. (2005, April). How strategies really think: Tapping the power of analogy [Electronic Version]. Harvard Business Review. Retrieved March, 2008, from <http://www.eleganthack.com/homepage/archives/How%20Strategists%20Really%20Think.pdf>.

<sup>426</sup> Ibid.

Gavetti et al. (2005)<sup>427</sup>, for this final step of an ARM, ask a critical question to strategists. Namely, how much should a company translate the candidate solution, based on the forethought alone, before launching it in the marketplace? The authors suggest that it makes sense to adjust a candidate solution beforehand to account for the glaring differences between the source and the target. However, the authors also stress that, in novel and uncertain environments, where strategists rely the most on analogies, it is often wise to hold off on fine-tuning the solution until the market can give its guidance.

In essence, although the majority of analogies are imperfect, they are useful in terms of strategy development. In this respect, Gavetti et al. (2005)<sup>428</sup> maintain that the analogies of an ARM lie on a spectrum. That is, at the one end of the spectrum, there are perfect analogies, where the source and target setting are truly alike on the dimensions that drive economic performance. In contrast, at the opposite end of the spectrum, there are profoundly problematic analogies that are based on superficial similarities yet plagued by underlying differences. Gavetti et al. (2005)<sup>429</sup> argue that the vast majority of the analogies of ARMs fall somewhere in between, thus, they are imperfect but useful. Gavetti et al. (2005)<sup>430</sup> emphasize that “the challenge is to get the most out of them” (p.13), and, to get the most out of them, “managers who wish to tap the great power of analogy and sidestep its pitfalls must master multiple modes of thoughts” (p. 13).

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<sup>427</sup> Gavetti, G., & Rivkin, J. W. (2005, April). How strategies really think: Tapping the power of analogy [Electronic Version]. Harvard Business Review. Retrieved March, 2008, from <http://www.eleganthack.com/homepage/archives/How%20Strategists%20Really%20Think.pdf>.

<sup>428</sup> Ibid.

<sup>429</sup> Ibid.

<sup>430</sup> Ibid.

### **5.3 Applying Four-Steps of the Analogical Reasoning Model (ARM) to the Pharmaceutical Industry in the Stakeholder Management Terms**

Four steps of the ARM are applied to the organizational strategy development, in the stakeholder management terms, for the pharmaceutical industry. As explained earlier, the first step of the ARM tries to recognize the analogy and identify its purpose. Thus, through the first step, the ‘target problems’ of the pharmaceutical industry in connection with its stakeholders are examined. The second step tries to identify how and why the source strategies worked. In other words, the ‘source industries’ and ‘source problems’ that might offer solutions for the pharmaceutical industry are examined. The third step tries to assess the similarities and the differences between the source and the target setting and, then, to present feasible ‘candidate solutions’ to the target problems of the pharmaceutical industry. The last step tries to evaluate the ‘candidate solutions’. In other words, the last step tries to translate, decide, and adapt the original strategies to the new setting (i.e. the pharmaceutical industry which is under severe pressure in connection with the access to essential, life-saving medicines). In essence, given the target problem of the pharmaceutical industry (i.e. improving the access to essential, life-saving medicines to deal with the risks posed by its stakeholders), the ARM examines other comparable industries that tackled similar problems that the pharmaceutical industry encounters. These source industries and source problems can offer candidate solutions to the target problem of the pharmaceutical industry. Then, the ‘target solutions’ (i.e. what the pharmaceutical industry can learn from the candidate solutions in relation to producing and marketing essential, life-saving medicines) for the pharmaceutical industry are developed and suggested.

### 5.3.1 Step One: Recognize the Analogy and Identify Its Purpose

Gavetti et al. (2005)<sup>431</sup> point out that to defend against flawed analogies, a strategist, first of all, must recognize the analogies he or she is using and identify how a company (or an industry) is using any analogies it recognizes. This dissertation adopts the ARM as a tool for choosing among possible solutions to the strategic problems, in the stakeholder management terms, encountered by the pharmaceutical industry. It is noted that the ARM, for this dissertation, is introduced to compensate for the weaknesses of the qualitative comparative analyses (i.e. the ESA and the Boolean comparative analysis) in terms of the organizational strategy development. Reversely, the qualitative comparative analyses can also compensate for the weaknesses of the ARM. The ARM, alone, may not be a perfect analytical tool for developing organizational strategies. However, it is argued that if the ARM is combined with or complemented by another analytical method, such as a qualitative comparative analysis, it can be a very useful analytical tool to generate strategic options. Therefore, the ARM of this dissertation can be considered as a safe analytical method as long as the model is tested carefully in connection with the formal qualitative analysis performed in the previous chapter.

For the first step of the ARM, it is important to identify the target problem of the pharmaceutical industry. In a broad sense, the target problem of the pharmaceutical industry is how to deal with the risks/challenges posed by its various stakeholders. More specifically, the target problem can be defined as how to improve the global public health through enhancing the access to essential, life-saving medicines on the part of the

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<sup>431</sup> Gavetti, G., & Rivkin, J. W. (2005, April). How strategies really think: Tapping the power of analogy [Electronic Version]. Harvard Business Review. Retrieved March, 2008, from <http://www.eleganthack.com/homepage/archives/How%20Strategists%20Really%20Think.pdf>.

pharmaceutical industry, balancing its R&D-intensive, expensive business, to cope with the risks/challenges posed by its various stakeholders. In the previous chapter of the formal qualitative analysis, specifically in the section of ‘the historical narrative of events on which the ESA is based’, the target problem of the pharmaceutical industry was explored in detail. The pharmaceutical industry has been under severe pressure posed by its stakeholders. The industry has been criticized in perspective of the global public health because the industry’s business model, particularly the stringent patent protection on the pharmaceutical products, is considered to be a huge impediment to improving the access to essential, life-saving medicines. As was described above, the access to essential, life-saving medicines is a critical issue not only for the developing world but also for the developed world, although the specific circumstances of each world are different. In addition, although the HIV/AIDS pandemic, especially in the least-developed countries, has been the major issue in connection with the access to essential, life-saving medicines, other diseases are also becoming more problematic. Under these circumstances, it is imperative for the pharmaceutical industry to develop strategies that can balance the issue of the access to essential, lifesaving medicines with its R&D-intensive, expensive business.

Although this dissertation deals with other diseases than HIV/AIDS in relation to the access to essential, life-saving medicines, it is noted that the HIV/AIDS pandemic, as Mascarenhas et al. (2005)<sup>432</sup> illustrate, has been the worst global public health crisis since the Black Plague in the fourteenth century. HIV/AIDS now kills more people worldwide

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<sup>432</sup> Mascarenhas, O. A., Kesavan, R., & Bernacchi, M. (2005). Global marketing of lifesaving drugs: an analogical mode. *Journal of Consumer Marketing*, 22, 404-411.

than any other infectious diseases. According to UNAIDS (2004)<sup>433</sup>, more than 22 million people, already, have died from HIV/AIDS since 1981. In addition, nearly all of the 40 million currently HIV/AIDS victims would die from the HIV/AIDS-related complications within the next two decades (International AIDS Vaccine Initiative, 2005)<sup>434</sup>. It is noted that although the HIV/AIDS pandemic has been predominant in the developing world, today, HIV/AIDS is everybody's business. According to Mascarenhas et al. (2005)<sup>435</sup>, "by 2010, unless the pandemic is drastically controlled, we may register more than 100 million HIV-infected people out side of Africa" (p. 405). Thus, an effective solution to the HIV/AIDS pandemic is in the interest of all including the developed world. Nevertheless, still, no cure or vaccine has been developed for HIV virus. The best that can be done at present is to temporarily suppress the virus in the HIV patient, therefore, delaying the progression of the infection. As illustrated earlier, the medicines that can suppress HIV/AIDS are called antiretrovirals (ARVs) and Burroughs Wellcome introduced Retrovir (i.e. AZT), the first ARV drug, in 1987. However, since Burroughs Wellcome introduced the first antiretroviral drug, there has been huge controversy over the prices of the HIV/AIDS medicines, and the pharmaceutical industry has been on the center of the controversy.

In sum, the target problem of the ARM is how to improve the state of the access to essential, life-saving medicines (i.e. how to rapidly produce and effectively distribute the

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<sup>433</sup> UNAIDS (2004). 2004 Report on the Global AIDS Epidemic. UNAIDS, Geneva.

<sup>434</sup> International AIDS Vaccine Initiative (2005). Scientific Blueprint 2004: Accelerating Global Efforts in AIDS Vaccine Research and Development [Electronic Version]. Retrieved April 2, 2008, from <http://www.iavi.org/pdf/IAVIScientificBlueprint2004.pdf>

<sup>435</sup> Mascarenhas, O. A., Kesavan, R., & Bernacchi, M. (2005). Global marketing of lifesaving drugs: an analogical mode. *Journal of Consumer Marketing*, 22, 404-411.

essential, life-saving medicines) on the part of the pharmaceutical industry to deal with the risks/challenges posed by its stakeholders. In particular, how the pharmaceutical industry can produce and market the essential, life-saving medicines in the developing world that need them most at affordable prices is the main point of the target problem, although the dissertation considers the developed world in connection with the access to essential, life-saving medicines.

### **5.3.2 Step Two: Understand the Source – The Food and Beverage Industry**

Since the target problem of the ARM of this dissertation is to improve the global public health through enhancing the access to medicines (i.e. the rapid and effective distribution of essential, life-saving medicines) on the part of the pharmaceutical industry, a source industry to examine source problems should be chosen among the industries which have effectively and profitably resolved the problems of marketing and distributing critically needed products or services, at affordable prices, especially in the developing world. In other words, the analysis of source problems should show how a comparable industry has marketed and distributed vitally needed products or services particularly to the developing world that has needed them most.

In this respect, as a source industry for the ARM of this dissertation, the food and beverage industry was chosen. For an ARM, a researcher borrows related choices from one industry (i.e. a source industry) and applies the system to a new industry (i.e. a target industry). In essence, a source industry should show similarities to some crucial dimensions of the representation of a target industry and the observable characteristics of



a target industry may constitute the crucial dimensions of the representation of the target setting (Gavetti et al., 2005)<sup>436</sup>. It is noted that there are innumerable dimensions along which a researcher can form a representation. Thus, Gavetti et al. (2005)<sup>437</sup> emphasize that a researcher should develop a crucial dimensions of the representation of a target problem in terms of capturing the salient characteristics of the situation. Then, the researcher can identify a setting that displays the similar salient characteristics. This setting serves as a source of a candidate solution.

The following crucial dimensions of the representation of the pharmaceutical industry were developed, reflecting the salient characteristics of the target setting. That is, to avoid a superficial analogy, a source industry must: (1) relate to marketing and distributing critically needed (i.e. life-saving) products or services; (2) relate to the developing world in terms of the production, distribution, prices, and access; (3) relate to the issues of economic growth, productivity, and poverty reduction especially in the developing world; (4) relate to lack of coherent leadership on the part of public sector that can help incentivize, monitor, and coordinate programs and policies in connection with private sector industry; (5) relate to political instability and social unrest; (6) relate to multiple stakeholders, such as consumers, national governments, NGOs, inter-governmental organizations, and shareholders; (7) relate to the uncertainty of the best practices to tackle problems; and (8) relate to R&D costs/IPRs protection. For this dissertation, the source industry (i.e. the food and beverage industry) was selected based on these crucial dimensions of the representation of the target setting. In the Step Three below, the

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<sup>436</sup> Gavetti, G., Levinthal, D. A., & Rivkin, J. W. (2005). Strategy making in novel and complex worlds: The power of analogy. *Strategic Management Journal*, 26, 691-712.

<sup>437</sup> Ibid.

similarities and differences between the source and target industry are examined in detail. In essence, the food and beverage industry satisfies seven dimensions of the target setting except the dimension of R&D costs/IPRs protection. It is noted that other industry sectors were also tested for a source industry. For instance, infrastructure industries such as energy/electricity, transportation, and high tech sectors (e.g. telecommunications) were examined for a source industry. As Gasmi et al. (2006)<sup>438</sup> indicate, the last two decades have witnessed a worldwide wave of reforms that have significantly affected the infrastructure industries to improve the functioning of the industries. However, on the dimensions of the target setting of the pharmaceutical industry, there is a significant difference between the target setting and the infrastructure industries. That is, the infrastructure industries relate to life-enhancing products or services, while the target industry is focused on life-saving products or services. It is noted that the food and beverage industry relates to life-saving products or services. In addition, the infrastructure industries have related to the issues of liberalization, privatization, and regulatory governance on performance (Cubbin et al., 2005)<sup>439</sup>, not to the issue of R&D costs/IPRs protection. However, these differences do not necessary bar an infrastructure industry from a source industry for the pharmaceutical industry. Since the energy/electricity and the transportation industry reveals significant similarities to the

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<sup>438</sup> Gasmi, F., Nomba, P., & Virto, L. R. (2006). Political accountability and regulatory performance in infrastructure industries: An Empirical Analysis [Electronic Version]. Retrieved September 10, 2010, from [http://www-wds.worldbank.org/external/default/WDSContentServer/IW3P/IB/2006/12/29/000016406\\_20061229104357/Rendered/PDF/wps4101.pdf](http://www-wds.worldbank.org/external/default/WDSContentServer/IW3P/IB/2006/12/29/000016406_20061229104357/Rendered/PDF/wps4101.pdf)

<sup>439</sup> Cubbin, J. & Stern, J. (2005). Regulatory effectiveness: The impact of regulation and regulatory governance arrangements on electricity industry outcomes. World Bank Policy Research Paper 3536.

dimensions of the target setting, a careful “adjustment” (Gavetti, 2005)<sup>440</sup> in the process of an ARM might produce useful solutions for the pharmaceutical industry.

It is clear that proper nutrition is a foundation for the overall health. However, global under-nutrition (or malnutrition)<sup>441</sup> persists at unacceptable levels. Under-nutrition remains one of the world’s most serious health problems. For example, malnutrition is the single, biggest contributor to child mortality, with over 50% of all the deaths of children under the age of five is attributed to underlying under-nutrition (Nelson, 2006)<sup>442</sup>. In addition, more than 2 billion people, about 30% of population in the developing world, suffer from the micronutrient deficiencies (Nelson, 2006)<sup>443</sup>. Under-nutrition can be defined as “a diet that does not provide adequate calories and/or micronutrients for growth and maintenance (Bradley, 2008, p. 171)<sup>444</sup>. It is estimated that 32% of the global burden of disease would be removed by eliminating malnutrition, including micronutrient deficiency (Nelson, 2006)<sup>445</sup>. It is important to note that, as Nelson (2006)<sup>446</sup> points out, under-nutrition is “linked to the HIV/AIDS pandemic in that it makes adults more susceptible to the virus, inadequate infant feeding aggravates its

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<sup>440</sup> Gavetti, G., Levinthal, D. A., & Rivkin, J. W. (2005). Strategy making in novel and complex worlds: The power of analogy. *Strategic Management Journal*, 26, 691-712.

<sup>441</sup> In specific, the term ‘malnutrition’ covers under-nutrition, micronutrient deficiencies, and overweight/obesity.

<sup>442</sup> Nelson, J. (2006). Business as a partner in overcoming malnutrition. An agenda for action. Harvard University Kennedy School of Government [Electronic Version]. Retrieved December 5, 2008, from [http://www.hks.harvard.edu/m-rcbg/CSRI/publications/report\\_14\\_NUTRITION%20FINAL.pdf](http://www.hks.harvard.edu/m-rcbg/CSRI/publications/report_14_NUTRITION%20FINAL.pdf)

<sup>443</sup> Ibid.

<sup>444</sup> Bradley, D. (2008). Beyond product: The private sectors drive to perform with the purpose of alleviating global under-nutrition. Global Forum Update on Research on Health Volume 5 [Electronic Version]. Retrieved December 4, 2008, from [http://www.globalforumhealth.org/filesupld/global\\_update5/art/Update5\\_BeyondProduct\\_Bradley.pdf](http://www.globalforumhealth.org/filesupld/global_update5/art/Update5_BeyondProduct_Bradley.pdf)

<sup>445</sup> Nelson, J. (2006). Business as a partner in overcoming malnutrition. An agenda for action. Harvard University Kennedy School of Government [Electronic Version]. Retrieved December 5, 2008, from [http://www.hks.harvard.edu/m-rcbg/CSRI/publications/report\\_14\\_NUTRITION%20FINAL.pdf](http://www.hks.harvard.edu/m-rcbg/CSRI/publications/report_14_NUTRITION%20FINAL.pdf)

<sup>446</sup> Ibid.

transmission from mother to child, and there is evidence to suggest that it makes antiretroviral drugs less effective” (p. 4). Under-nutrition is also a serious problem in terms of economy, costing the developing countries (especially, the least-developed countries) billions of dollars annually. That is, under-nutrition is an impediment to productivity, economic growth, and poverty reduction. Bekefi (2006)<sup>447</sup> describes the following:

Sustainable and equitable international development is predicated on individuals who are able to live long, healthy lives, be innovative, work, and contribute to society. These basic human traits are contingent on proper nutrition, particularly during childhood, to foster normal growth and healthy development. Micronutrient deficiency – the lack of proper vitamins and minerals in diet – is a hidden epidemic that leads to low birth weight, impaired cognitive development, impaired immunity, and compromised life expectancy. These problems have a disastrous effect on human capital, which is a key to improving both individual lives and to fostering the growth of national economies. (p. 5)

The scale of the under-nutrition problem, in the economic terms, is large and extensive. If the problem is not significantly reduced, the under-nutrition could cost the global economy about \$180-250 billion over the next ten years, and yet the total public investments to address the problem are estimated to be only about \$4-5 billion (Nelson, 2006)<sup>448</sup>.

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<sup>447</sup> Bekefi, T. (2006). Business as a partner in tackling micronutrient deficiency: Lessons in multisector partnership. Corporate Social Responsibility Initiative [Electronic Version]. Retrieved December 5, 2008, from [http://www.hks.harvard.edu/m-rcbg/CSRI/publications/report\\_7\\_Bekefi\\_micronutrient\\_2006FNL1-23-07.pdf](http://www.hks.harvard.edu/m-rcbg/CSRI/publications/report_7_Bekefi_micronutrient_2006FNL1-23-07.pdf)

<sup>448</sup> Nelson, J. (2006). Business as a partner in overcoming malnutrition. An agenda for action. Harvard University Kennedy School of Government [Electronic Version]. Retrieved December 5, 2008, from [http://www.hks.harvard.edu/m-rcbg/CSRI/publications/report\\_14\\_NUTRITION%20FINAL.pdf](http://www.hks.harvard.edu/m-rcbg/CSRI/publications/report_14_NUTRITION%20FINAL.pdf)

Today, with a challenge so significant, there is broad acceptance that the future success of the global public health depends, to a large extent, on sound nutrition. Nevertheless, as Bradley (2008)<sup>449</sup> comments, still “obtaining food for survival far outweighs obtaining optimal nutrition in countries where the economic reality is harsh...in an unstable financial atmosphere, making sound and affordable nutritional decisions is a luxury many cannot afford” (p. 171). The Center for Health and Aging of the National Bureau of Asian Research (NBR) addresses a few of the key challenges related to the global under-nutrition (“Food for Thought”)<sup>450</sup>. First, in the field of nutrition, there is lack of coherent leadership. The diversity of topics and corresponding organizations in the field of nutrition make it difficult to identify a clear leading body of organizations that can help incentivize, monitor, and coordinate the global nutrition programs and policies. Second, despite renewed momentum in the nutrition field, under-nutrition (or malnutrition) is not perceived to be an urgent issue in comparison with infectious diseases such as HIV/AIDS. Although nutrition is related to the major health issues, it seems that nutrition still remains abstract, low-priority issue for many decision makers. Third, in terms of nutrition, many developing countries face health inequities and a dual burden of disease. Economic growth with large economic disparities between the rural and urban populations in the countries such as Brazil, India, South Africa, and China under-nutrition and obesity coexists at relatively high rates. However, it is also noted that, in the least developed world such as sub-Saharan African countries, still, obtaining food for

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<sup>449</sup> Bradley, D. (2008). Beyond product: The private sectors drive to perform with the purpose of alleviating global under-nutrition. Global Forum Update on Research on Health Volume 5 [Electronic Version]. Retrieved December 4, 2008, from

[http://www.globalforumhealth.org/filesupld/global\\_update5/art/Update5\\_BeyondProduct\\_Bradley.pdf](http://www.globalforumhealth.org/filesupld/global_update5/art/Update5_BeyondProduct_Bradley.pdf)

<sup>450</sup> Food for Thought: Challenges for Global Nutrition (n.d.). The National Bureau of Asian Research, Center for Health and Aging [Electronic Version]. Retrieved December 5, 2008, from [http://pacifichealthsummit.org/downloads/nutrition/nutrition\\_challenges.pdf](http://pacifichealthsummit.org/downloads/nutrition/nutrition_challenges.pdf)

survival far outweighs obtaining optimal nutrition. Fourth, the prices for grains, sugars, and oils have doubled or tripled in recent years. This food crisis has caused political instability and social unrest. Fifth, although some significant, proven, cost-efficient global nutrition intervention strategies have been developed and implemented, they still remain fragmented and miss out the opportunities to reach more people. In other words, there exists uncertainty about the best practices in the nutrition interventions. Public policies that incentivize more positive private sector engagement in the nutrition field would motivate the private companies to tackle the issues related to nutrition, leveraging their distribution systems, and share their valuable knowledge about consumer behavior. Sixth, although many countries have put comprehensive nutrition strategies into practice in recent years, the implementation remains weak. Also, numerous governments, in terms of nutrition, still lack comprehensive strategies as well as specific policies. In other words, at the state level, there is lack of nutrition-related strategies and policies which are clear, enforceable, and flexible. Lastly, it is criticized that the private sector engagement in the nutrition field has been insufficient. The Center for Health and Aging of NBR (“Food for Thought”)<sup>451</sup> describes the following:

Although many food and beverage companies have made concerted efforts to emphasize wellness and healthy by producing more nutritious products, those efforts are still fragmented and largely directed at upper-income consumers. Additionally, while some companies have successfully developed and marketed fortified foods for lower-income groups, those initiatives have been limited and most have not yet been scaled up. More proactive industry approaches to tackling both under-nutrition and obesity, in full collaboration with the public and nonprofit sectors, would be of great help to efforts to improve nutrition worldwide. (p. 2)

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<sup>451</sup> Food for Thought: Challenges for Global Nutrition (n.d.). The National Bureau of Asian Research, Center for Health and Aging [Electronic Version]. Retrieved December 5, 2008, from [http://pacifichalthsummit.org/downloads/nutrition/nutrition\\_challenges.pdf](http://pacifichalthsummit.org/downloads/nutrition/nutrition_challenges.pdf)

The problem of global malnutrition is extensive and growing in many countries. However, Nelson (2006)<sup>452</sup> argues that “proven and cost-effective interventions exist – especially in the areas of under-nutrition and micronutrient deficiencies” (p. 4). A report produced by the World Bank (2006)<sup>453</sup> points out that there is now unequivocal evidence in connection with the workable solutions to the malnutrition problem, and they are the excellent economic investments. It is noted that the returns of investing in the micronutrient programs are the second only to the returns of the fighting HIV/AIDS among a lengthy list of ways to meet the world’s development challenges. In essence, the World Bank report (2006)<sup>454</sup> made a strong case that the investments in proven technologies and interventions to tackle under-nutrition (or malnutrition) offer potentially very high economic returns. The World Bank, UNICEF, WHO and others contend that the most critical ‘window of opportunity’ for addressing under-nutrition is from before pregnancy through to a child’s the first two years of life (Nelson, 2006)<sup>455</sup>. It is highly noted that, as Nelson (2006)<sup>456</sup> comments, the investments and interventions are likely to have their greatest impact in terms of both the improved health outcomes and the high economic returns during this short periods of time. The workable solutions to the under-

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<sup>452</sup> Nelson, J. (2006). Business as a partner in overcoming malnutrition. An agenda for action. Harvard University Kennedy School of Government [Electronic Version]. Retrieved December 5, 2008, from [http://www.hks.harvard.edu/m-rcbg/CSRI/publications/report\\_14\\_NUTRITION%20FINAL.pdf](http://www.hks.harvard.edu/m-rcbg/CSRI/publications/report_14_NUTRITION%20FINAL.pdf)

<sup>453</sup> Repositioning nutrition as central to development: A strategy for large-scale action (2006). The World Bank [Electronic Version]. Retrieved November 10, 2008 from <http://siteresources.worldbank.org/NUTRITION/Resources/281846-1131636806329/NutritionStrategy.pdf>.

<sup>454</sup> Ibid.

<sup>455</sup> Nelson, J. (2006). Business as a partner in overcoming malnutrition. An agenda for action. Harvard University Kennedy School of Government [Electronic Version]. Retrieved December 5, 2008, from [http://www.hks.harvard.edu/m-rcbg/CSRI/publications/report\\_14\\_NUTRITION%20FINAL.pdf](http://www.hks.harvard.edu/m-rcbg/CSRI/publications/report_14_NUTRITION%20FINAL.pdf)

<sup>456</sup> Ibid.

nutrition problem, considering the proven, cost-effective interventions, are needed to be dramatically scaled up.

At this point, it should be considered that how the workable solutions to the under-nutrition problem can be dramatically scaled up. The World Bank report (2006)<sup>457</sup> explains that why the proven, cost-effective solutions to under-nutrition (or malnutrition) problem have not been scaled up, although they are exit, as follows:

Nutrition problem have been low priority for both governments and development partners for three reasons. First, there is little demand for nutrition services communities because malnutrition is often invisible; families and communities are unaware that even moderate and mild malnutrition contributes substantially to death, disease, and low intelligence; and most malnourished families are poor and hence have little voice. Second, governments and development partners have been slow to recognize how malnutrition's economic costs are...or that there is now substantial experience with how to implement cost-effective, nutrition programs on a large scale. Third, there are multiple organizational stakeholders in nutrition, so malnutrition often falls between the cracks both in governments and in development assistance agencies – the partial responsibility of several sectoral ministries or agency departments, but the main responsibility of none. Country financing is usually allocated by sectors or ministries, so unless one sector takes the lead, no large-scale action can follow. (p. 13)

Individual state governments should take the lead in tackling the under-nutrition (or malnutrition) problem. However, the international development community can help the individual countries do more on the problem. The international community of the development partners “must use their combined resources of analysis, advocacy, and capacity-building to encourage and influence governments to move nutrition higher on the agenda...This role can be fulfilled only if the development partners share a common

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<sup>457</sup> Repositioning nutrition as central to development: A strategy for large-scale action (2006). The World Bank [Electronic Version]. Retrieved November 10, 2008 from <http://siteresources.worldbank.org/NUTRITION/Resources/281846-1131636806329/NutritionStrategy.pdf>



view of malnutrition problem and broad strategies to address it, and if they speak with common voice” (“Repositioning nutrition”, 2006, p.14)<sup>458</sup>. It is argued that without the coordinated and focused action between the individual governments and international development partners, no significant progress in the nutrition field can be expected.

In this respect, i.e., in terms of the coordinated and focused action between the individual governments and international development partners, how can the private sector, specifically the food and beverage industry, share their business resources and expertise in conjunction with the under-nutrition problem? In other words, how can the private and the public sector join forces to develop and implement programs that resolve the under-nutrition problem? As Nelson (2006)<sup>459</sup> illustrates, the ‘business case’ for companies to engage in hunger-reduction efforts varies by industry and by company. Nevertheless, it is noted that nearly every step in the food production and consumption process is related to some type of private sector involvement. A report produced by the World Economic Forum (2006)<sup>460</sup> identified the key components of the ‘business case’. They include: new market and product development that is commercially viable or has the prospect becoming profitable with market expansion and economies of scale; stimulating innovation with the company; reputation management and building positive brand value by being associated with the efforts to improve health and nutrition; strengthening the relations with government, community, NGOs, and international organizations

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<sup>458</sup> Repositioning nutrition as central to development: A strategy for large-scale action (2006). The World Bank [Electronic Version]. Retrieved November 10, 2008 from <http://siteresources.worldbank.org/NUTRITION/Resources/281846-1131636806329/NutritionStrategy.pdf>

<sup>459</sup> Nelson, J. (2006). Business as a partner in overcoming malnutrition. An agenda for action. Harvard University Kennedy School of Government [Electronic Version]. Retrieved December 5, 2008, from [http://www.hks.harvard.edu/m-rcbg/CSRI/publications/report\\_14\\_NUTRITION%20FINAL.pdf](http://www.hks.harvard.edu/m-rcbg/CSRI/publications/report_14_NUTRITION%20FINAL.pdf)

<sup>460</sup> Harnessing private sector capabilities to meet public needs: The potential of partnerships to advance progress on hunger, Malaria and basic education (January 2006). The World Economic Forum.

particularly in connection with the developing world; contributing to economic development and building long-term markets by improving physical and mental development of future generations of consumers and workers; enacting corporate values; developing healthy and productive local labor force in the developing world; and motivating employees through volunteering activities that address social issues.

The contribution that an industry (or a company) can make in overcoming the under-nutrition problem in connection with the public private partnership may vary depending on the kind of the industry sector and the type of intervention it pursues. Also, it would be influenced by the capacities and abilities of other actors related to the under-nutrition problem, such as national governments, NGOs, inter-governmental organizations, and the research institutions. It is noted that whether the companies act individually, or act on a collective industry-wide basis, or act in collaboration with other industry sectors can affect the results of the public private partnership to address the under-nutrition problem. Nevertheless, it is clear that the under-nutrition and other forms of malnutrition problems cannot be solved without the strong, effective partnerships, and the most powerful untapped opportunities for partnerships in connection with the under-nutrition problem involve the public private interaction.

### **5.3.3 Step Three: Access the Similarity between the Source and the Target**

In this step, the similarities between the food and beverage industry and the pharmaceutical industry are mapped, and whether the resemblance is more than

superficial is determined. As described earlier, Gavetti et al. (2005)<sup>461</sup> emphasize that a strategist must search actively not only the similarities but also the differences between the source and the target setting, seeking evidence that each essential feature of the source problem is absent in the target setting. Therefore, for this dissertation, whether the key features of the food and beverage industry are exit or absent in the pharmaceutical industry in conjunction with its target problem, i.e., how to improve the global public health through enhancing the access to essential, life-saving medicines on the part of the pharmaceutical industry, balancing its R&D-intensive, expensive business, to cope with the risks/challenges posed by its various stakeholders.

The similarities between the source and the target setting of the ARM are summarized as follows. That is, both the source (the food and beverage) and the target (the pharmaceutical) industry problems (1) relate to the issue of the global public health, i.e., they supply the essential products/services for the overall public health; (2) relate to the developing world (in particular, the least-developed world) in terms of the production, distribution, prices, and access; (3) relate to the issues of economic growth, productivity, and poverty reduction especially in the developing world; (4) relate to lack of coherent leadership that can help incentivize, monitor, and coordinate the global public health programs and policies in connection with the industries; (5) can relate to political instability and social unrest; (6) relate to multiple stakeholders, such as consumers/patients, national governments, NGOs, inter-governmental organizations, and the shareholders of the industries; and (7) relate to uncertainty in that the best practices to

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<sup>461</sup> Gavetti, G., & Rivkin, J. W. (2005, April). How strategies really think: Tapping the power of analogy [Electronic Version]. Harvard Business Review. Retrieved March, 2008, from <http://www.eleganthack.com/homepage/archives/How%20Strategists%20Really%20Think.pdf>.

tackle the problems are still unclear. Lastly, it is highly noted that, for both the source and the target problem, the proven, effective, workable solutions have been found and scaled up dramatically through the partnerships between the public and the private sectors.

In contrast, the differences between the source and the target setting of the ARM can be summarized as follows. First, while the access to essential, life-saving medicines has been perceived to be an urgent issue in terms of the global public health, the under-nutrition (or malnutrition) has not been perceived to be an urgent issue. Although the under-nutrition problem is related to other major health issues, infectious diseases such as HIV/AIDS have attracted the majority of policy attention and funding (as Nelson [2006]<sup>462</sup> points out, under-nutrition is linked to the HIV/AIDS pandemic). Second, thus, the food and beverage industry has not been pressed severely by its multiple stakeholders in comparison with the pharmaceutical industry. The under-nutrition (or malnutrition) problem still remains low-priority issue for many decision makers. Third, in the case of the access to essential, life-saving medicines, the R&D cost incurred by the pharmaceutical industry is one of the major issues in explaining the conflicts between the industry and its stakeholders. That is, the pharmaceutical companies have emphasized the stringent patent protection on the pharmaceutical products to recoup the expensive R&D cost (for the future R&D investment), and, in contrast, the critics have criticized the pharmaceutical companies on the ground that the strong patent protection impedes the access to essential, life-saving medicines, particularly, in the developing world. However, in the case of the under-nutrition problem, the R&D cost incurred by the food and

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<sup>462</sup> Nelson, J. (2006). Business as a partner in overcoming malnutrition. An agenda for action. Harvard University Kennedy School of Government [Electronic Version]. Retrieved December 5, 2008, from [http://www.hks.harvard.edu/m-rcbg/CSRI/publications/report\\_14\\_NUTRITION%20FINAL.pdf](http://www.hks.harvard.edu/m-rcbg/CSRI/publications/report_14_NUTRITION%20FINAL.pdf).

beverage industry (including the R&D cost-related patent protection) is not as important issue as in the case of the access to essential, life-saving medicines. Lastly, there has been lack of clear, enforceable, and flexible policies to address the under-nutrition problem at the state level. In contrast, as witnessed in Brazil, Thailand, and South Africa, there have been effective policies at the state level to address the issue of the access to essential, life-saving medicines forcing the pharmaceutical industry make concessions.

The original strategy of the food and beverage industry for the source problem of the under-nutrition (or malnutrition) is the public private partnership. Yach (2008)<sup>463</sup> argues as follows:

Food and beverage companies have the resources and the reach, not to mention a strong profit motive, to make products and conduct their business in ways that benefit their consumers. Leading food and beverage companies are increasingly being judged by investors and consumers on the basis of how they meet all the consumer needs, including health aspects, and not just on sales...When we look back a decade, the notion of private-public partnerships in health has not been broadly accepted...public-private partnerships have led to new pharmaceutical products being developed and priced in ways that allow for better control of many infectious diseases; and to new ways of working in communities...The magnitude of the changes required to slow down and reverse trends in all forms of malnutrition cannot be achieved without strong, new and effective partnerships. The most powerful untapped opportunities for partnerships involve public-corporate interaction...significant support for change will not come from traditional sources of health development finance such as government development agencies or the major private foundations. These partnerships needed to be embedded in new business models that promote better health and are profitable...We must learn to work together and responsibly. At the end of the day, consumers as citizens will hold us accountable for our actions or inactions. (p. 111)

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<sup>463</sup> Yach, D. (2008). Invited editorial: a personal view. Food and nutrition for better health. *Public Health Nutrition*, 11, 109-111.

In the last step of the ARM below, first, the original strategy that has been adopted by the food and beverage industry (i.e. the public private partnerships) to deal with the under-nutrition problem is described in detail. Then, second, whether the original strategy, properly translated, would work for the target problem of the pharmaceutical industry is examined.

#### **5.3.4 Step Four: Translate, Decide, and Adapt the Original Strategy**

The final step of the ARM is to evaluate whether the original strategy of the public private partnerships that has been adopted by the food and beverage industry to address the global under-nutrition problem would work, when it is translated properly, for the target problem (i.e. how to improve the global public health through enhancing the access to essential, life-saving medicines on the part of the pharmaceutical industry, balancing its R&D-intensive, expensive business, to cope with the risks/challenges posed by its various stakeholders) of the target industry, i.e., the pharmaceutical industry. Gavetti et al. (2005)<sup>464</sup> emphasize that since even the best analogies involve some differences between the source and the target setting, in translating the original strategy, some adjustments that deal with the differences should be made. In addition, if the analogy is chosen to be pursued for the target setting, another round of adjustment – adapting in the marketplace in response to the feedback from the customers, rivals, suppliers, and others – should be made (Gavetti et al., 2005)<sup>465</sup>. Therefore, to decide whether the public private partnership strategy that has been adopted by the food and beverage industry to deal with

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<sup>464</sup> Gavetti, G., & Rivkin, J. W. (2005, April). How strategies really think: Tapping the power of analogy [Electronic Version]. Harvard Business Review. Retrieved March, 2008, from <http://www.eleganthack.com/homepage/archives/How%20Strategists%20Really%20Think.pdf>

<sup>465</sup> Ibid.

the global under-nutrition problem would work for the pharmaceutical industry in terms of the access to essential, life-saving medicines, the original strategy of the food and beverage industry is tried to be translated properly as much as possible, adjusting the differences between the two industry settings.

Private sector (here, the food and beverage industry) can play a vital role in the systems that sustain healthy communities, reduce poverty, and prevent hunger. A report produced by the World Economic Forum (2006)<sup>466</sup> points out the following: “It is no coincidence that areas with widespread chronic hunger often have little private sector activity” (p. 11). The food and beverage companies can play innovative roles in tackling the global under-nutrition (or malnutrition) problem on the individual firm basis. Several food and beverage companies, such as Heinz, Nestlé, Group DANONE, The Coca-Cola Company, Unilever, and PepsiCo Inc., have undertaken initiatives that could harness their core competences, products, services, and business networks to help overcome under-nutrition (Nelson, 2006)<sup>467</sup>. However, one of the most important contributions to tackling the global under-nutrition problem by the food and beverage industry has been implemented on a collective basis particularly through the partnership with the public sector. A report produced by the World Bank (2006)<sup>468</sup> describes the following:

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<sup>466</sup> Harnessing private sector capabilities to meet public needs: The potential of partnerships to advance progress on hunger, Malaria and basic education (January 2006). The World Economic Forum.

<sup>467</sup> Nelson, J. (2006). Business as a partner in overcoming malnutrition. An agenda for action. Harvard University Kennedy School of Government [Electronic Version]. Retrieved December 5, 2008, from [http://www.hks.harvard.edu/m-rcbg/CSRI/publications/report\\_14\\_NUTRITION%20FINAL.pdf](http://www.hks.harvard.edu/m-rcbg/CSRI/publications/report_14_NUTRITION%20FINAL.pdf)

<sup>468</sup> Repositioning nutrition as central to development: A strategy for large-scale action (2006). The World Bank [Electronic Version]. Retrieved November 10, 2008 from <http://siteresources.worldbank.org/NUTRITION/Resources/281846-1131636806329/NutritionStrategy.pdf>.

Countries are increasingly using institutional resources outside government. Food fortification programs harness the institutional capacity of the commercial private sector for production and marketing, while the government's role is usually to build awareness, monitor, and regulate...In each country there is a need to identify ways in which the food industry can be involved in designing and supporting implementation of the national nutritional strategy. This means developing a multi-sectoral alliance in each country between industry, the national government, international agencies, the expert groups, and other players to work on specific issues relating to technology; food processing and marketing; standards; quality assurance; product certification; social communications and demand creation; and monitoring and evaluation. (p. 99)

It should also be noted that, in addition to working with the private sector, the national governments are increasingly working through the partnerships that use the institutional capacity of NGOs for growth promotion as well as micronutrient programs (“Repositioning nutrition”, 2006)<sup>469</sup>.

In essence, the public sector, normally, is responsible for addressing the essential underlying issues of the under-nutrition problem. Nevertheless, it often has neither the capacity nor the resources to do so effectively (“Harnessing private sector”, 2006)<sup>470</sup>. Thus, the private sector can take part in the public private partnerships to compensate for the weaknesses of the public sector applying its core competences to strengthen the public institutions. The public private partnerships are collaborative capacity building efforts among companies, national governments or public agencies, and/or NGOs to tackle the global under-nutrition problem. It is important to note that “the application of private sector technical and managerial skills to strengthen the capacity of public

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<sup>469</sup> Repositioning nutrition as central to development: A strategy for large-scale action (2006). The World Bank [Electronic Version]. Retrieved November 10, 2008 from <http://siteresources.worldbank.org/NUTRITION/Resources/281846-1131636806329/NutritionStrategy.pdf>.

<sup>470</sup> Harnessing private sector capabilities to meet public needs: The potential of partnerships to advance progress on hunger, Malaria and basic education (January 2006). The World Economic Forum.



agencies and NGOs can often bring greater long-term value than cash or in-kind donations” (“Harnessing private sector”, 2006, p. 19)<sup>471</sup>.

The Global Alliance for Improved Nutrition (GAIN) presents a proven, effective model of the public-private partnership for the under-nutrition problem. GAIN was founded in 2002 at the United Nations General Assembly’s Special Session on Children as a public-private network to reduce malnutrition through the use of food fortification and other strategies aimed at improving the health and nutrition of populations at risk (Ameringen et al., 2008)<sup>472</sup>. In specific, GAIN was launched as “a multi-sector alliance, grant-giving and technical assistance body, and advocacy network with a core purpose to tackle micronutrient deficiency primarily through food fortification” (Nelson, 2006, p. 11)<sup>473</sup>. That is, GAIN is a public-private partnership launched to help create cost-effective food fortification programs in a bid to improve health, cognitive development, and productivity in the developing world (“GAIN to improve”, 2002)<sup>474</sup>. GAIN has set clear, measurable targets for itself. The major targets of GAIN include: (1) Reduce the prevalence of vitamins and mineral deficiencies by 30% in the areas where GAIN supports projects; (2) Reach 1 billion people with food that has been fortified with vitamins and minerals; (3) Ensure that 500 million of the people most in need, such as

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<sup>471</sup> Harnessing private sector capabilities to meet public needs: The potential of partnerships to advance progress on hunger, Malaria and basic education (January 2006). The World Economic Forum.

<sup>472</sup> Ameringen, M. V., Magarinos, B., & Jarvis, M. (2008). Business and malnutrition: Opportunities and challenges for the food industry in reaching the poor. The World Bank Group [Electronic Version]. Retrieved December 8, 2008, from <http://www1.worldbank.org/devoutreach/june08/article.asp?id=494>

<sup>473</sup> Nelson, J. (2006). Business as a partner in overcoming malnutrition. An agenda for action. Harvard University Kennedy School of Government [Electronic Version]. Retrieved December 5, 2008, from [http://www.hks.harvard.edu/m-rcbg/CSRI/publications/report\\_14\\_NUTRITION%20FINAL.pdf](http://www.hks.harvard.edu/m-rcbg/CSRI/publications/report_14_NUTRITION%20FINAL.pdf)

<sup>474</sup> GAIN to improve global nutrition (2002, May 14). Foodnavigator.com [Electronic Version]. Retrieved July 1, 2008, from <http://www.foodnavigator.com/content/view/print/98759>

children and the pregnant women, regularly consume the fortified foods; and (4) Achieve these results at a cost of less than 25 U.S. cents per person, per year (Nelson, 2006)<sup>475</sup>.

Although GAIN is a Swiss Foundation funded by the Bill and Melinda Gates Foundation, the United States Agency for International Development (USAID) and the Canadian International Development Agency (CIDA), it builds the partnerships between the public and the private sector. In other words, GAIN is composed of diverse groups including foundations, the U.N., the developing country governments, the private sector companies, NGOs, and the academic institutions (“GAIN to improve”, 2002)<sup>476</sup>. The supporters of GAIN include UNICEF, THE World Bank, WHO, the World Food Programme, the Helen Keller International, the U.S. Center for Disease Control and Prevention, A2Z (the USAID Micronutrient Program), and the Micronutrient Initiative. It is particularly noted that GAIN is partner with the private sector companies such as Group DANONE, Unilever, and Cargill. GAIN delivers its funding and technical assistance through the multi-sector National Fortification Alliances in about 17 countries, and each has its own targets. At the global level, GAIN has a multi-sector Board of Directors and a multi-sector Reference Group (Nelson, 2006)<sup>477</sup>. GAIN advocates for better nutrition worldwide as a cost-effective way to make people and economies stronger, healthier, and

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<sup>475</sup> Nelson, J. (2006). Business as a partner in overcoming malnutrition. An agenda for action. Harvard University Kennedy School of Government [Electronic Version]. Retrieved December 5, 2008, from [http://www.hks.harvard.edu/m-rcbg/CSRI/publications/report\\_14\\_NUTRITION%20FINAL.pdf](http://www.hks.harvard.edu/m-rcbg/CSRI/publications/report_14_NUTRITION%20FINAL.pdf)

<sup>476</sup> GAIN to improve global nutrition (2002, May 14). Foodnavigator.com [Electronic Version]. Retrieved July 1, 2008, from <http://www.foodnavigator.com/content/view/print/98759>

<sup>477</sup> Nelson, J. (2006). Business as a partner in overcoming malnutrition. An agenda for action. Harvard University Kennedy School of Government [Electronic Version]. Retrieved December 5, 2008, from [http://www.hks.harvard.edu/m-rcbg/CSRI/publications/report\\_14\\_NUTRITION%20FINAL.pdf](http://www.hks.harvard.edu/m-rcbg/CSRI/publications/report_14_NUTRITION%20FINAL.pdf)

more productive (Ameringen et al., 2008)<sup>478</sup>. GAIN has tried to enable innovative solutions to improve nutrition at a large scale by providing financial and technical support. According to Ameringen et al. (2008)<sup>479</sup>, as described above, GAIN has set itself the target of reaching 1 billion people of whom 500 million are in target groups most vulnerable to under-nutrition (or malnutrition).

In sum, the most distinctive and essential feature of GAIN is its partnership with the private sector companies in order to use the companies' know-how in product development, marketing, and distribution. This distinctive and essential feature of GAIN, i.e., the partnership with the private sector, enabled it to launch a business alliance. That is, GAIN established the GAIN Business Alliance for Improved Nutrition in Beijing in 2005. In specific, the GAIN Business Alliance is a jointly funded initiative of GAIN and the World Bank Institute to bring together the global food companies committed to furthering food fortification around the world ("Business action")<sup>480</sup>. In other words, the GAIN Business Alliance was launched to support the GAIN's commitment to finding the market-based solutions through spearheading active business-led initiatives in a number of regions around the world (Ameringen et al., 2008)<sup>481</sup>. In addition, GAIN has made a strategic commitment to systematically increase its dialogue and engagement with the

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<sup>478</sup> Ameringen, M. V., Magarinos, B., & Jarvis, M. (2008). Business and malnutrition: Opportunities and challenges for the food industry in reaching the poor. The World Bank Group [Electronic Version]. Retrieved December 8, 2008, from <http://www1.worldbank.org/devoutreach/june08/article.asp?id=494>

<sup>479</sup> Ibid.

<sup>480</sup> Business action to combat malnutrition (n.d.). The World Bank Institution [Electronic Version]. Retrieved September 5, 2008, from <http://web.worldbank.org/WBSITE/EXTERNAL/WBI/WBIPROGRAMS/CGCSRLP/0,,contentMDK:20649737~pagePK:64156158~piPK:64152884~theSitePK:460861,00.html>

<sup>481</sup> Ameringen, M. V., Magarinos, B., & Jarvis, M. (2008). Business and malnutrition: Opportunities and challenges for the food industry in reaching the poor. The World Bank Group [Electronic Version]. Retrieved December 8, 2008, from <http://www1.worldbank.org/devoutreach/june08/article.asp?id=494>

business community, increasing the number of companies with which it has significant interaction (Nelson, 2006)<sup>482</sup>. The establishment of the GAIN Business Alliance has been central to this strategic commitment. The GAIN Business Alliance “operates globally, regionally, and nationally in countries such as China and India, as well as through regional networks in the Americas and in Africa” (Nelson, 2006, p. 11)<sup>483</sup>. The GAIN Business Alliance is chaired by Unilever and it focuses on: (1) Mobilizing companies in developing countries to promote the food fortification through providing technical assistance, recognition, and other support; (2) Creating media attention and visibility for the food fortification; and (3) Creating a clear and rigorous progress for engaging the private sector in a manner that makes clear business sense to the companies and offers clear development benefits in terms of results (Nelson, 2006)<sup>484</sup>. The private sector companies involved in the GAIN Business Alliance include Unilever, Heinz, Group DANONE, Cargill, DSM, BASF, Tetra Pak, and Coca-Cola.

In conclusion, the GAIN’s global partnership model is an innovative one, building programs with the private sector, and, thus, providing the partnerships between the public and the private sector. The GAIN Business Alliance is the key part of the GAIN’s strategy and it was launched “as a platform to extend the production and distribution of affordable fortified foods around the world, in particular to poor and at-risk populations”

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<sup>482</sup> Nelson, J. (2006). Business as a partner in overcoming malnutrition. An agenda for action. Harvard University Kennedy School of Government [Electronic Version]. Retrieved December 5, 2008, from [http://www.hks.harvard.edu/m-rcbg/CSRI/publications/report\\_14\\_NUTRITION%20FINAL.pdf](http://www.hks.harvard.edu/m-rcbg/CSRI/publications/report_14_NUTRITION%20FINAL.pdf)

<sup>483</sup> Ibid.

<sup>484</sup> Ibid.

(“Memorandum”, 2006)<sup>485</sup>. GAIN and the GAIN Business Alliance aim at effective regulatory change to improve diets, working with the national governments, consumers, and the private sector companies. In particular, it is noted that, as the World Bank Institution (“Business Action”)<sup>486</sup> points out, the GAIN Business Alliance’s mission is “to develop innovative and new approaches for dealing with the barriers that have traditionally kept affordable fortified products outside of the market place”. It is argued that the GAIN’s global partnership model is an innovative example of how to make markets work better for the poor people by facilitating a more active partnerships between the public and the private sector in the area of health and nutrition.

Another example of the public-private partnership, a business-led alliance, to tackle the under-nutrition problem is the Business Alliance Against Chronic Hunger (BAACH). “In 2006, the World Economic Forum and some of its member companies jointly launched an innovative new initiative with the mission to form a network of businesses committed to taking action to reduce chronic hunger in Africa, in cooperation with the public sector, civil society and community partners” (Nelson, 2006, p. 12)<sup>487</sup>. Namely, BAACH is a cross-industry, multi-stakeholder initiative working with a broad array of companies to promote business models that contribute to sustainable food production and raise incomes

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<sup>485</sup> Memorandum submitted by GAIN – THE Global Alliance for Improved Nutrition (2006). The United Kingdom Parliament [Electronic Version]. Retrieved September 1, 2008, from <http://www.parliament.the-stationery-office.co.uk/pa/cm200506/cmselect/cmintdev/921/921we16.htm>

<sup>486</sup> Business action to combat malnutrition (n.d.). The World Bank Institution [Electronic Version]. Retrieved September 5, 2008, from <http://web.worldbank.org/WBSITE/EXTERNAL/WBI/WBIPROGRAMS/CGCSRLP/0,,contentMDK:20649737~pagePK:64156158~piPK:64152884~theSitePK:460861,00.html>

<sup>487</sup> Nelson, J. (2006). Business as a partner in overcoming malnutrition. An agenda for action. Harvard University Kennedy School of Government [Electronic Version]. Retrieved December 5, 2008, from [http://www.hks.harvard.edu/m-rcbg/CSRI/publications/report\\_14\\_NUTRITION%20FINAL.pdf](http://www.hks.harvard.edu/m-rcbg/CSRI/publications/report_14_NUTRITION%20FINAL.pdf)

in poor regions (“Food sustainability”, 2008)<sup>488</sup>. BAACH enables businesses leverage their expertise and capabilities to improve value chains from production, processing, and packaging to retailing and marketing to increase food supply, nutrition, and incomes in hungry regions (“Food sustainability”, 2008)<sup>489</sup>. For example, BAACH works to reduce hunger in Africa by strengthening specific food value chains through the business development and the market linkages. The private sector companies implement the solutions in partnership with the national governments, NGOs, the inter-governmental organizations, and the communities (“Food sustainability”, 2008)<sup>490</sup>. It is noted that BAACH is looking at the partnership opportunities between the public and the private at the every stage of the value chain. In other words, the strategy of BAACH is “to take an integrated approach to solving hunger by focusing on using business expertise and market power to strengthen food value chains and build more sustainable and equitable market systems through multi-stakeholder partnership, testing these new approaches in a specific region, and disseminating lessons globally” (Nelson, 2006, p. 12)<sup>491</sup>. In essence, BAACH strengthens, globally, commitment to action on hunger by promoting effective business models to reduce hunger, facilitating dialogue and engaging in the global partnerships (“Food sustainability”, 2008)<sup>492</sup>.

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<sup>488</sup> Food sustainability: A guide to private sector action (2008). The United Nations Global Compact [Electronic Version]. Retrieved December 10, 2008, from [http://www.unglobalcompact.org/docs/news\\_events/9.1\\_news\\_archives/2008\\_09\\_24/foodsustainability.pdf](http://www.unglobalcompact.org/docs/news_events/9.1_news_archives/2008_09_24/foodsustainability.pdf)

<sup>489</sup> Ibid.

<sup>490</sup> Ibid.

<sup>491</sup> Nelson, J. (2006). Business as a partner in overcoming malnutrition. An agenda for action. Harvard University Kennedy School of Government [Electronic Version]. Retrieved December 5, 2008, from [http://www.hks.harvard.edu/m-rcbg/CSRI/publications/report\\_14\\_NUTRITION%20FINAL.pdf](http://www.hks.harvard.edu/m-rcbg/CSRI/publications/report_14_NUTRITION%20FINAL.pdf)

<sup>492</sup> Food sustainability: A guide to private sector action (2008). The United Nations Global Compact [Electronic Version]. Retrieved December 10, 2008, from [http://www.unglobalcompact.org/docs/news\\_events/9.1\\_news\\_archives/2008\\_09\\_24/foodsustainability.pdf](http://www.unglobalcompact.org/docs/news_events/9.1_news_archives/2008_09_24/foodsustainability.pdf)

As Bradley (2008)<sup>493</sup> describes, it can be argued that “creating trust and building relationships are at the heart of good business...Partnerships built on a foundation of trust, shared values and common aspirations seem to be the most productive way to reach realistic, measurable goals” (p. 171). Each of the possible partners in the public-private initiatives (i.e. the private sector companies, NGOs, the national governments, inter-governmental organizations, and the academia) can provide specific and unique expertise of its own, and working together to tackle the global issues, such as the under-nutrition and the access to essential, life-saving medicines, can be the most effective way to deal with the issues, providing the highest rate of success. Nevertheless, it should be noted that a successful public-private partnership is based on a strong understanding, among the partners, of the challenges to be overcome in the target community. Thus, facilitating dialogue, concerning the capabilities and the shared values, among the partners can maximize the potential of a public-private partnership, enabling a strong understanding to be formed. In terms of the public-private partnership, both the public and the private sector must discard the traditional way of thinking and try to invent strategies or programs that can effectively tackle the global issues such as the under-nutrition and the access to essential, life-saving medicines. It is suggested that to deal effectively with the pressure posed by their stakeholders, the private sector industries (such as the food and beverage industry, and the pharmaceutical industry) should actively incorporate the public-private partnership into their business model - preferably on a industry-wide, collective business basis – and should develop innovative strategies that utilize and share

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<sup>493</sup> Bradley, D. (2008). Beyond product: The private sectors drive to perform with the purpose of alleviating global under-nutrition. Global Forum Update on Research on Health Volume 5 [Electronic Version]. Retrieved December 4, 2008, from [http://www.globalforumhealth.org/filesupld/global\\_update5/art/Update5\\_BeyondProduct\\_Bradley.pdf](http://www.globalforumhealth.org/filesupld/global_update5/art/Update5_BeyondProduct_Bradley.pdf)

business know-how with their partners such as the national governments, NGOs, international agencies, and the academia.

#### **5.4 Discussion and Conclusion: The Analogical Target Solution for the Pharmaceutical Industry – The Public-Private Partnership**

In the third step of the ARM above, whether the key features of the food and beverage industry are exist or absent in the pharmaceutical industry in connection with its target problem (i.e. how to improve the global public health through enhancing the access to essential, life-saving medicines on the part of the pharmaceutical industry to deal with the risks posed by its various stakeholders) was examined. Before introducing the analogical target solution, the similarities and the differences between the source (the food industry) and the target (the pharmaceutical industry) setting are illustrated again to refresh the ARM.

The similarities between the food and the pharmaceutical industry can be summarized as follows. That is, the problems (the source and target problems) of both industries (1) relate to the issue of the global public health, (i.e. they both supply the essential products/services for the overall public health); (2) relate to the developing world in terms of production, distribution, price, and access; (3) relate to the issues of economic growth, productivity, and poverty reduction particularly in the developing world; (4) relate to the lack of coherent leadership that can help incentivize, monitor, and coordinate the global public health programs and policies in connection with the industries; (5) can relate to political instability and social unrest; (6) relate to multiple stakeholders, such as



consumers/patients, national governments, NGOs, inter-governmental organizations, and the shareholders; and (7) relate to uncertainty in that the best practices to tackle the problems are still unclear.

In contrast, the differences between the food and the pharmaceutical industry can be summarized as follows: (1) While the access to essential, life-saving medicines has been perceived to be an urgent issue in terms of the global public health, the under-nutrition (or malnutrition) has not been perceived to be an urgent issue as compared with the issue of the access to medicines; (2) The food industry has not been pressed severely by its multiple stakeholders in comparison with the pharmaceutical industry; (3) In the case of the access to essential, life-saving medicines, the R&D cost incurred by the pharmaceutical industry is one of the major issues in explaining the conflicts between the industry and its stakeholders. That is, the pharmaceutical industry has emphasized the stringent patent protection of pharmaceutical products to recoup the expensive R&D cost, but, in contrast, the industry has been criticized on the ground that the strong patent protection impedes the access to essential, life-saving medicines, particularly in the developing world. Moreover, some critics argue that there is no relationship between the strong patent protection and the R&D investment. However, in the case of the under-nutrition problem, the R&D cost incurred by the food industry (including the R&D cost-related patent protection) is not as important as in the case of the access to essential, life-saving medicines.

The similarities between two industries suggest the application of the proven, cost-effective candidate solution to the source problem of the food industry to the target problem of the pharmaceutical industry. In addition, the first two differences between two industries even reinforce the potential for applying the candidate solution to the target problem of the pharmaceutical industry. That is, although the under-nutrition (or malnutrition) has not been perceived to be an urgent issue in comparison with the issue of the access to essential, life-saving medicines in terms of the global public health and, thus, the food industry has not been pressed severely by its stakeholders as compared with the pharmaceutical industry, the food industry has developed a proven, cost-effective strategy to deal with the global under-nutrition (malnutrition) problem. This means that the pharmaceutical industry - which has been severely pressed by its stakeholders in connection with the access to essential, life-saving medicines, perceived to be an urgent issue in terms of the global public health – should also develop an effective strategy to improve the access to essential, life-saving medicines. Although it should be adjusted for the target setting, the proven, cost-effective solution to the source problem of the food industry can be an effective target solution to the target problem of the pharmaceutical industry.

However, before introducing and applying the candidate solution to the target problem, the third difference between two industries should be considered. This difference, regarding the stringent patent protection to recoup the R&D cost for the future investment, requires some adjustment in adapting the original strategy (i.e. the candidate solution) of the food industry to the target problem of the pharmaceutical industry. In the

case of the access to essential, life-saving medicines, the R&D cost incurred by the pharmaceutical industry is one of the major issues in explaining the conflicts between the industry and its stakeholders. In contrast, in the case of the under-nutrition problem, the R&D cost and patent protection are not as important as in the case of the access to essential, life-saving medicines. Therefore, the pharmaceutical industry needs to develop strategies which can balance the access to essential, life-saving medicines with its expensive, R&D-intensive business. However, it is highly noted that although the difference exists between two industries in terms of the patent protection, there is no need for the candidate solution of the food industry (i.e. the comprehensive, industry-wide, multi-stakeholder public-private partnership) to be significantly adjusted to the target setting/target problem of the pharmaceutical industry. That is, it is argued that, without making any significant adjustment, the candidate solution can be applied to the target problem of the pharmaceutical industry.

The suggested analogical target solution (i.e. target strategy) for the pharmaceutical industry in connection with the access to essential, life-saving medicines is implementing the candidate solution of the food industry, i.e., the comprehensive, industry-wide, multi-stakeholder public-private partnership. That is, this type of public-private partnership can help the pharmaceutical industry to deal with the pressure posed by various stakeholders in connection with the access to essential, life-saving medicines, balancing its R&D-intensive, expensive business with the enlarged corporate social responsibility. Although the pharmaceutical companies have engaged in several public-private initiatives in conjunction with the access to essential, life-saving medicines, there has been no

comprehensive, industry-wide, multi-stakeholder public-private partnership. Moreover, except the Merck's Mectizan Donation Program, the public-private initiatives which have a connection with the pharmaceutical industry have always been initiated by the public sector institutions, not by the private sector pharmaceutical companies. For instance, the UNAIDS pressed the pharmaceutical companies to join a pilot project, the HIV Drug Access Initiative, that would start to provide the cheaper HIV/AIDS medicines to Chile, Vietnam, Uganda, and the Ivory Coast (United Nations Information Service [UNIS], 2001)<sup>494</sup>. This pilot program intended a collaborative effort between the pharmaceutical companies and the developing country governments. Although the multinational pharmaceutical companies, initially, apposed the idea, the companies, such as GSK, Bristol Meyers Squibb, and Roche, later, joined the pilot project. Through the pilot project, in 1998, GSK decided to reduce its HIV/AIDS drug prices in the developing countries in connection with the UNAIDS pilot project. Bristol Myers Squibb and Roche also joined this UNAIDS pilot project and cut their HIV/AIDS drug prices. The participating pharmaceutical companies in the pilot project provided financial support through various means, such as drug price cuts and investments in non-profit firms by cash or drug donations (UNAIDS, 1999)<sup>495</sup>. However, as Trullen et al. (2006)<sup>496</sup> indicate, GSK was criticized on the ground that "Glaxo's patent on AZT was about to expire and that this was the real reason for the price reduction" (p. 187). In fact, the initiatives of the

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<sup>494</sup>United Nations Information Service (2001, April 6). Secretary General announces steps by leading drug companies to improve AIDS treatment access to developing countries [Electronic Version]. Retrieved January 15, 2008, from <http://www.unis.unvienna.org/unis/pressrels/2001/sgsm7764.html>

<sup>495</sup> UNAIDS (1999). Joint and co-sponsored United Nations programme on human immunodeficiency virus/acquired immunodeficiency syndrome. [Electronic Version]. Retrieved January 15, 2008, from [http://data.unaids.org/publications/External-Documents-Restored/ecosoc\\_unaidsreport1999\\_en.pdf](http://data.unaids.org/publications/External-Documents-Restored/ecosoc_unaidsreport1999_en.pdf)

<sup>496</sup> Trullen, J., & Stevenson, W. B. (2006). Strategy and Legitimacy: Pharmaceutical Companies' Reaction to HIV Crisis. *Business & Society*, 45, 178-210.

pharmaceutical companies for this UNAIDS pilot project were small and were not enough to affect all the developing countries that need the HIV/AIDS medicines most.

Another example of the public-private partnership in connection with the pharmaceutical companies is the Accelerated Access Initiative (AAI). In May 2000, five pharmaceutical companies (i.e. Boehringer Ingelheim, Bristol Myers Squibb, GSK, Hoffman-LaRoche, and Merck) announced their agreement on the preferential pricing for the least developed countries after having talked to Kofi Annan (Trullen et al., 2006)<sup>497</sup>. A plan called AAI involved a dialogue between the U.N. and five pharmaceutical companies with the intention of cutting the price of HIV/AIDS medicines in developing countries, particularly, in the least developed countries. Specifically, the AAI was launched, in May 2000, when five pharmaceutical companies responded to the calls by the leaders of the several U.N. organizations (the UNAIDS, WHO, UNICEF, and UNFPA) and the World Bank for a new public-private partnership to expand the global response to the HIV/AIDS epidemic, and Abbott Laboratories and Gilead Sciences joined the initiative later, in 2001 and in 2004, respectively (Sturchio, 2004)<sup>498</sup>.

The Secure the Future initiative is also an example of the public-private partnership in connection with the pharmaceutical companies. In May 1999, Bristol Myers Squibb announced a new program (i.e. the Secure the Future) at the request of Kofi Annan. Bristol Myers Squibb made clear that it would spend \$100 million to address HIV/AIDS

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<sup>497</sup> Trullen, J., & Stevenson, W. B. (2006). Strategy and Legitimacy: Pharmaceutical Companies' Reaction to HIV Crisis. *Business & Society*, 45, 178-210.

<sup>498</sup> Sturchio, J. L. (2004). Partnership for action: The experience of the Accelerating Access Initiative, 2000-04, and lessons learned. The WHO [Electronic Version]. Retrieved November 28, 2008, from [https://www.who.int/hiv/amds/AAI\\_chapter6.pdf](https://www.who.int/hiv/amds/AAI_chapter6.pdf)

treatment issues in five southern African countries (i.e. Botswana, Lesotho, Namibia, South Africa, and Swaziland) during the next five years (Trullen et al., 2006)<sup>499</sup>. According to the president of Bristol Myers Squibb Foundation, the Secure the Future program aimed at working with community partners, such as the community-based groups and individuals, in Africa to develop new approaches to respond to HIV/AIDS epidemic in hard-hit communities where resources are limited (“Bristol-Myers Squibb”, 2008)<sup>500</sup>. However, the initiative did not include price reductions (Trullen et al., 2006)<sup>501</sup>.

The last example of the public-private partnership in conjunction with the pharmaceutical companies is the Global Fund. The Global Fund to Fight AIDS, Tuberculosis, and Malaria is an independent public-private partnership that was first proposed by the then U.N. Secretary General Kofi Annan in 2001, and officially came into being, with the support of the U.S. government in January 2002 (“The Global Fund to Fight AIDS, Tuberculosis, and Malaria”)<sup>502</sup>. The U.N. created the Global Fund, taking the advantage of the controversy created by the South African lawsuit (Trullen et al., 2006)<sup>503</sup>. The objective of the Global Fund is to raise funds and pool money from governments, businesses, and individuals around the world, and channel them into the grant programs to fight AIDS, Tuberculosis, and Malaria. The Global Fund is managed by 23 board

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<sup>499</sup> Trullen, J., & Stevenson, W. B. (2006). Strategy and Legitimacy: Pharmaceutical Companies’ Reaction to HIV Crisis. *Business & Society*, 45, 178-210.

<sup>500</sup> Bristol-Meyers Squibb launches Secure the Future technical assistance program to optimize community services for comprehensive HIV management in sub-Saharan Africa. (2008, August 5). Reuters, Retrieved November 10, 2008, from <http://www.reuters.com/article/pressRelease/idUS190867+05-Aug-2008+BW20080805>

<sup>501</sup> Trullen, J., & Stevenson, W. B. (2006). Strategy and Legitimacy: Pharmaceutical Companies’ Reaction to HIV Crisis. *Business & Society*, 45, 178-210.

<sup>502</sup> AVERT (n.d.). The Global Fund to Fight AIDS, Tuberculosis, and Malaria [Electronic Version]. Retrieved October 10, 2008, from <http://www.avert.org/global-fund.htm>

<sup>503</sup> Trullen, J., & Stevenson, W. B. (2006). Strategy and Legitimacy: Pharmaceutical Companies’ Reaction to HIV Crisis. *Business & Society*, 45, 178-210.

members and they include the representatives from the G-8 governments, the WHO, the World Bank, the UNAIDS, and NGOs such as the Bill and Melinda Gates Foundation (Kennedy et al., 2004)<sup>504</sup>. It is noted that how the Global Fund would be governed and operated was one of the major concerns, particularly in connection with the pharmaceutical companies. NGOs and activists argued that the participation of the multinational pharmaceutical companies in the governing body of the Global Fund would create an irresolvable, structural conflict of interest (Mokhiber et al., 2001)<sup>505</sup>. In contrast, they pressed the pharmaceutical companies to issue licenses for their medicines to the WHO, which could then contract with the generic manufacturers to provide cheap medicines in the developing world through the Global Fund (Mokhiber et al., 2001)<sup>506</sup>.

As illustrated above, the comprehensive, industry-wide, multi-stakeholder public-private partnership is suggested as the target strategy (i.e. target solution) for the pharmaceutical industry. Therefore, the public-private partnerships which have been implemented between the public sector institutions and the pharmaceutical companies should be examined and evaluated in terms of the proven, cost-effective public-private partnerships, such as the GAIN Business Alliance and the Business Alliance Against Chronic Hunger, which have been implemented between the public sector institutions and the food companies, in order to develop the public-private partnership strategy for the pharmaceutical industry.

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<sup>504</sup> Kennedy, C. R., Harris, F. H., & Lord, M. (2004). Integrating public policy and public affairs in a pharmaceutical marketing program: The AIDS pandemic. *Journal of Public Policy and Marketing*, 23, 128-139.

<sup>505</sup> Mokhiber, R. & Weissman, R. (2001, May 11). Big pharma and global response to HIV/AIDS. CommonDreams.org [Electronic Version]. Retrieved November 11, 2008, from <http://www.commondreams.org/views01/0511-01.htm>

<sup>506</sup> Ibid.

As discussed above, the pharmaceutical companies have engaged in several public-private partnerships, there has been no comprehensive, industry-wide, multi-stakeholder public-private partnership. Furthermore, the public-private initiatives have always been initiated by the public sector institutions, not by the pharmaceutical companies. In this respect, the Merck's Mectizan Donation Program is worth considering. The Merck's Mectizan donation program, a public-private partnership, was initiated not by the public sector institutions but by the private sector company, Merck. That is, the Mectizan Donation Program was developed out of the Merck's decision to develop a drug without a market, donate the drug, and assemble the public organizations to aid in the distribution of the drug. Since the Mectizan Donation Program's inception, Merck has donated more than 2.0 billion tablets of Mectizan, with more than 600 million treatment approved since 1988 ("Merck Supports")<sup>507</sup>. The donation program currently reaches approximately 80 million people in Africa, Latin America, and the Middle East (Yemen) each year ("Merck Supports")<sup>508</sup>. Collins (2004)<sup>509</sup> states that "A unique public/private partnership situated around a pharmaceutical, Merck's Mectizan donation program stands out as an example of corporate philanthropy in the history of the pharmaceutical industry and provides insight into future public/private partnerships in public health" (p. 100). It is highly noted that Merck sought to overcome the obstacles of a lack of infrastructure and cultural barriers by establishing a multi-sectoral public-private partnership, involving the WHO, UNICEF, the World Bank, the ministries of health, non-governmental development organizations, and the local communities, to provide the medical, technical, and

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<sup>507</sup> Merck supports the worldwide fight against river blindness (n.d.). UNICEF [Electronic Version]. Retrieved December 10, 2008, from <http://www.unicefusa.org/news/news-from-the-field/merck-pia.html>

<sup>508</sup> Ibid.

<sup>509</sup> Collins, K. (2004). Profitable Gifts: a history of the Merck Mectizan donation program and its implications for international health. *Perspective in Biology and Medicine*, 47, 100-109.



administrative oversight of the Mectizan donation (“Merck supports”)<sup>510</sup>. The Mectizan Donation program proves the potential of the public-private partnership for the global public health in connection with the pharmaceutical industry and demonstrates how the private sector pharmaceutical companies can be a viable partner in improving the global public health in terms of the access to essential, life-saving medicines. Nevertheless, the Merck’s Mectizan Donation Program has also some limitations. First of all, the public-private partnership has focused only on one neglected tropical disease, the river blindness, with a single medicine, Mectizan. It was neither a comprehensive nor a pharmaceutical industry-wide public-private partnership. Second, whether or not the case of Mectizan public-private partnership can be applied to other essential, life-saving medicines, such as the HIV/AIDS medicines, is uncertain. In this respect, Collins (2004)<sup>511</sup> questions that, for the medicines that do not share the double identity of human therapeutic and profitable veterinary drug, where will the incentive to donate come from? In sum, although the Merck’s Mectizan Donation Program has showed the potential of the public-private partnership in connection with the pharmaceutical industry in terms of the access to essential, life-saving medicines, the more comprehensive, effective, industry-wide, multi-stakeholder public-private partnership model should be developed for the pharmaceutical industry.

As discussed earlier, the Global Alliance for Improved Nutrition (GAIN) presents a proven, effective model of the public-private partnership for the under-nutrition problem

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<sup>510</sup> Merck supports the worldwide fight against river blindness (n.d.). UNICEF [Electronic Version]. Retrieved December 10, 2008, from <http://www.unicefusa.org/news/news-from-the-field/merck-pia.html>

<sup>511</sup> Collins, K. (2004). Profitable Gifts: a history of the Merck Mectizan donation program and its implications for international health. *Perspective in Biology and Medicine*, 47, 100-109.

in connection with the food industry. GAIN was founded in 2002 as a public-private network to reduce malnutrition through the use of food fortification and other strategies aimed at improving the health and nutrition of populations at risk (Ameringen et al., 2008)<sup>512</sup>. That is, GAIN was launched as “a multi-sector alliance, grant-giving and technical assistance body, and advocacy network with a core purpose to tackle micronutrient deficiency primarily through food fortification” (Nelson, 2006, p. 11)<sup>513</sup>. As a public-private partnership, GAIN is composed of diverse groups including foundations, the U.N., the developing country governments, the private sector companies, NGOs, and the academic institutions (“GAIN to improve”, 2002)<sup>514</sup>. In particular, GAIN is partner with the private sector companies such as Group DANONE, Unilever, and Cargill. In essence, the most distinctive and essential feature of GAIN is its partnership with the private sector companies in order to use the companies’ know-how in product development, marketing, and distribution, and this distinctive feature enabled it to launch, in 2005, a business alliance, i.e., the GAIN Business Alliance for Improved Nutrition. The GAIN Business Alliance is a jointly funded initiative of GAIN and the World Bank Institute to bring together the global food companies committed to furthering food fortification around the world (“Business action”)<sup>515</sup>. It is noted that the GAIN Business Alliance was launched to support the GAIN’s commitment to finding the market-based

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<sup>512</sup> Ameringen, M. V., Magarinos, B., & Jarvis, M. (2008). Business and malnutrition: Opportunities and challenges for the food industry in reaching the poor. The World Bank Group [Electronic Version]. Retrieved December 8, 2008, from <http://www1.worldbank.org/devoutreach/june08/article.asp?id=494>

<sup>513</sup> Nelson, J. (2006). Business as a partner in overcoming malnutrition. An agenda for action. Harvard University Kennedy School of Government [Electronic Version]. Retrieved December 5, 2008, from [http://www.hks.harvard.edu/m-rcbg/CSRI/publications/report\\_14\\_NUTRITION%20FINAL.pdf](http://www.hks.harvard.edu/m-rcbg/CSRI/publications/report_14_NUTRITION%20FINAL.pdf)

<sup>514</sup> Ibid.

<sup>515</sup> Business action to combat malnutrition (n.d.). The World Bank Institution [Electronic Version]. Retrieved September 5, 2008, from <http://web.worldbank.org/WBSITE/EXTERNAL/WBI/WBIPROGRAMS/CGCSRLP/0,,contentMDK:20649737~pagePK:64156158~piPK:64152884~theSitePK:460861,00.html>

solutions through spearheading active business-led initiatives in a number of regions around the world (Ameringen et al., 2008)<sup>516</sup>. The establishment of the GAIN Business Alliance has been central to the strategic commitment of GAIN. The GAIN Business Alliance is chaired by Unilever and the private sector companies involved in the GAIN Business Alliance include Heinz, Group DANONE, Cargill, DSM, BASF, Tetra Pak, and Coca-Cola.

Another example of the proven, effective model of the public-private partnership, a business-led alliance, is the Business Alliance Against Chronic Hunger (BAACH), launched in 2006 to tackle the global under-nutrition problem. BAACH is a cross-industry, multi-stakeholder initiative working with a broad array of companies to promote business models that contribute to sustainable food production and raise incomes in poor regions in cooperation with the public sector, civil society and community partners (“Food sustainability”, 2008)<sup>517</sup>. BAACH enables businesses leverage their expertise and capabilities to improve value chains from production, processing, and packaging to retailing and marketing to increase food supply, nutrition, and incomes in hungry regions (“Food sustainability”, 2008)<sup>518</sup>. For instance, BAACH works to reduce hunger in Africa by strengthening specific food value chains through the business development and the market linkages, and the private sector companies implement the solutions in partnership with the national governments, NGOs, the inter-governmental organizations, and the

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<sup>516</sup> Ameringen, M. V., Magarinos, B., & Jarvis, M. (2008). Business and malnutrition: Opportunities and challenges for the food industry in reaching the poor. The World Bank Group [Electronic Version]. Retrieved December 8, 2008, from <http://www1.worldbank.org/devoutreach/june08/article.asp?id=494>

<sup>517</sup> Food sustainability: A guide to private sector action (2008). The United Nations Global Compact [Electronic Version]. Retrieved December 10, 2008, from [http://www.unglobalcompact.org/docs/news\\_events/9.1\\_news\\_archives/2008\\_09\\_24/foodsustainability.pdf](http://www.unglobalcompact.org/docs/news_events/9.1_news_archives/2008_09_24/foodsustainability.pdf)

<sup>518</sup> Ibid.

communities (“Food sustainability”, 2008)<sup>519</sup>. It is noted that the strategy of BAACH is “to take an integrated approach to solving hunger by focusing on using business expertise and market power to strengthen food value chains and build more sustainable and equitable market systems through multi-stakeholder partnership, testing these new approaches in a specific region, and disseminating lessons globally” (Nelson, 2006, p. 12)<sup>520</sup>. In essence, BAACH strengthens, globally, commitment to action on hunger by promoting effective business models to reduce hunger, facilitating dialogue and engaging in the global partnerships (“Food sustainability”, 2008)<sup>521</sup>.

GAIN (in particular, the GAIN Business Alliance) and BAACH have important implications for the pharmaceutical companies in terms of the public-private partnership. That is, the GAIN Business Alliance and BAACH present how the pharmaceutical industry can form the comprehensive, industry-wide, multi-stakeholder, cost-effective public-private partnership in relation to the access to essential, life-saving medicines. It is noted that GAIN’s global partnership model is an innovative example of how to make markets work better for the poor people by facilitating a more active partnership between the public and the private sector in the area of the global public health. Namely, GAIN’s global partnership model is an innovative one in that it builds programs with the private sector and, thus, provides partnership between the public and the private sector. In

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<sup>519</sup> Food sustainability: A guide to private sector action (2008). The United Nations Global Compact [Electronic Version]. Retrieved December 10, 2008, from [http://www.unglobalcompact.org/docs/news\\_events/9.1\\_news\\_archives/2008\\_09\\_24/foodsustainability.pdf](http://www.unglobalcompact.org/docs/news_events/9.1_news_archives/2008_09_24/foodsustainability.pdf)

<sup>520</sup> Nelson, J. (2006). Business as a partner in overcoming malnutrition. An agenda for action. Harvard University Kennedy School of Government [Electronic Version]. Retrieved December 5, 2008, from [http://www.hks.harvard.edu/m-rcbg/CSRI/publications/report\\_14\\_NUTRITION%20FINAL.pdf](http://www.hks.harvard.edu/m-rcbg/CSRI/publications/report_14_NUTRITION%20FINAL.pdf)

<sup>521</sup> Food sustainability: A guide to private sector action (2008). The United Nations Global Compact [Electronic Version]. Retrieved December 10, 2008, from [http://www.unglobalcompact.org/docs/news\\_events/9.1\\_news\\_archives/2008\\_09\\_24/foodsustainability.pdf](http://www.unglobalcompact.org/docs/news_events/9.1_news_archives/2008_09_24/foodsustainability.pdf)

particular, the GAIN Business Alliance is the key part of the GAIN's strategy and the business alliance has formed the business-led public-private partnerships. It is argued that GAIN's global partnership model can be applied to the strategy development for the pharmaceutical industry in terms of the access to essential, life-saving medicines. In essence, the GAIN Business Alliance presents how the public-private partnership can be led by the private sector companies, not by the public sector institutions, benefiting both the public and the private sector. BAACH is another proven, effective model of the public-private partnership, a business-led alliance, in the field of the global public health which takes an integrated approach to hunger through the multi-stakeholder partnership.

The pharmaceutical industry should do something to deal with the risks posed by its stakeholders. However, the pharmaceutical industry alone cannot resolve the problem of the access to essential, life-saving medicines, particularly in the long-term. That is, with regard to the access to essential, life-saving medicines, the pharmaceutical industry needs a comprehensive, industry-wide, multi-stakeholder public-private partnership to secure the cooperation from its various stakeholders. It should be noted that one of the most important contributions to tackling the global under-nutrition problem by the food industry has been implemented on a collective basis particularly through the partnership with the public sector. In this respect, the strategy of the public-private partnership must be a useful solution to improving the access to essential, life-saving medicines on the part of the pharmaceutical companies, particularly in overcoming the obstacle of a lack of infrastructure in connection with marketing and distributing medicines and related products particularly in the developing world. In addition, it is argued that the

pharmaceutical industry should initiate (or lead) the public-private partnership, promoting effective business models and facilitating the dialogue between the industry and its stakeholders. That is, the pharmaceutical industry should actively incorporate the public-private partnership into its business model - preferably on an industry-wide, collective business basis – and should develop innovative strategies that utilize and share business know-how with its partners such as the national governments, NGOs, international agencies, and the academia.

It should be noted that a successful public-private partnership is based on a strong understanding of the challenges to be overcome among the partners in the target community. In other words, without a strong understanding between the pharmaceutical industry and its various stakeholders (in addition to a strong understanding within the industry itself and a strong understanding among the stakeholders themselves) concerning the issues related to the access to essential, life-saving medicines, an effective public-private partnership cannot be expected. The strong understanding among the partners in relation to the global public health enables a comprehensive, cost-effective, multi-stakeholder public-private partnership in terms of the access to essential, life-saving medicines. Facilitating dialogue among the partners concerning the capabilities and the shared values can maximize the potential of a public-private partnership, enabling a strong understanding to be formed. In this respect, for an effective public-private partnership, both the public and the private sector must discard the traditional way of thinking and try to invent strategies or programs that can effectively tackle the issues in connection with the access to essential, life-saving medicines.

In general, the public-private partnerships are collaborative capacity building efforts among the private sector companies, national governments, inter-governmental agencies, NGOs, and the academia to tackle the global issues such as the problems related to the under-nutrition and the access to essential, life-saving medicines. It is noted that “the application of private sector technical and managerial skills to strengthen the capacity of public agencies and NGOs can often bring greater long-term value than cash or in-kind donations” (“Harnessing private sector”, 2006, p. 19)<sup>522</sup>. Each of the possible partners in the public-private initiatives can provide specific and unique expertise of its own, and working together to tackle the global issues can be the most effective way to deal with the issues, providing the highest rate of success. However, once again, it should be emphasized that a strong understanding of the problem or issue (such as the access to essential, life-saving medicines) among the partners is indispensable to be an effective public-private partnership. Bradley (2008)<sup>523</sup> describes that “creating trust and building relationships are at the heart of good business...Partnerships built on a foundation of trust, shared values and common aspirations seem to be the most productive way to reach realistic, measurable goals” (p. 171). Therefore, a comprehensive, industry-wide, multi-stakeholder public-private partnership, based on a strong understanding among the partners, can provide the most effective solutions to improving the access to essential, life-saving medicines.

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<sup>522</sup> Harnessing private sector capabilities to meet public needs: The potential of partnerships to advance progress on hunger, Malaria and basic education (January 2006). The World Economic Forum.

<sup>523</sup> Bradley, D. (2008). Beyond product: The private sectors drive to perform with the purpose of alleviating global under-nutrition. Global Forum Update on Research on Health Volume 5 [Electronic Version]. Retrieved December 4, 2008, from [http://www.globalforumhealth.org/filesupld/global\\_update5/art/Update5\\_BeyondProduct\\_Bradley.pdf](http://www.globalforumhealth.org/filesupld/global_update5/art/Update5_BeyondProduct_Bradley.pdf).

## **Chapter 6: Organizational Strategy Development for the Pharmaceutical Companies in the Stakeholder Management Terms**

### **6.1 Collaboration, Partnership, and Communication with the key Stakeholders**

The primary purpose of this dissertation is to develop organizational strategies for the pharmaceutical companies in the stakeholder management terms to deal with the risks posed by their various stakeholders. The strategies for the pharmaceutical companies are developed based on the outcomes of the stakeholder analysis performed by two different types of the formal qualitative analysis (i.e. the ESA and the qualitative comparative Boolean analysis), combined with those of the analogical reasoning model (ARM). That is, this dissertation develops the strategies for the pharmaceutical companies combining the outcomes of three analogical methods. In essence, this dissertation seeks to understand what organizational strategies are needed for the pharmaceutical companies not only to manage their stakeholders implicitly or explicitly but also to realize a win-win situation for both the pharmaceutical companies and their stakeholders.

It is noted that this dissertation develops strategies for the pharmaceutical industry based on the strategic stakeholder management approach, an instrumental theory of the stakeholder management perspective. In other words, as Freeman et al. (2001)<sup>524</sup> emphasize, a stakeholder approach is a strategic management process rather than a strategic planning process. Strategic planning focuses on trying to predict the future environment and then independently developing plans for the firm to exploit its position.

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<sup>524</sup> Freeman, R. E. & McVea, J. (2001). A Stakeholder Approach to Strategic Management [Electronic Version]. Darden Graduate School of Business Administration. Retrieved December 10, 2007, from [http://papers.ssrn.com/paper.taf?abstract\\_id=263511](http://papers.ssrn.com/paper.taf?abstract_id=263511)



In contrast, the strategic management actively plots a new direction for a firm and considers how the firm can affect the environment as well as how the environment may affect the firm. Therefore, a stakeholder approach encourages management to develop strategies by looking out from the firm and identifying, and investing in, all the relationships that will ensure long-term success. In essence, the strategic stakeholder management approach calls for an integrated approach to strategic decision making, finding ways to satisfy multiple stakeholders simultaneously rather than set strategy stakeholder by stakeholder.

In addition, the strategy concept of Mintzberg has also important implications for this dissertation in the strategy development terms. Mintzberg (1987)<sup>525</sup> argues that strategies can form as evolved as well as be formulated as intended. That is, strategies are both plans for the future and patterns from the past and, thus, strategies need not be deliberate because they can also emerge. The strategy concept of Mintzberg necessitate the study of ‘decision streams’ in the pharmaceutical industry over time periods in order to develop more effective organizational strategies for the industry and, thus, the empirical studies of the two different types of formal qualitative analysis have been conducted.

Based on the strategic stakeholder management approach as well as Mintzberg’s strategy concept and adopting the formal qualitative analysis as well as the ARM, this dissertation proposes a new direction for the pharmaceutical industry in the stakeholder management terms. It is noted that the new direction for the pharmaceutical industry is, as Freeman et

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<sup>525</sup> Mintzberg, H. (1987). Crafting strategy. Harvard Business Review, July 1, 66-75.

al. (2001)<sup>526</sup> suggest, an integrated approach to the strategic decision making to satisfy the multiple stakeholders of the industry simultaneously. Before suggesting the new direction, the stakeholder type of mixed blessing must be introduced in connection with the pharmaceutical industry.

Savage et al. (1991)<sup>527</sup> define stakeholders as “those individuals, groups, and organizations who have an interest in the actions of an organization and who have the ability to influence it” (p. 61). The authors develop a framework to identify four types of stakeholders and, then, specify four generic strategies on how to manage these stakeholders. In specific, by assessing each stakeholder’s potential to threaten or to cooperate with the organization, Savage et al. (1991)<sup>528</sup> classify stakeholders into four types such as supportive, mixed blessing, nonsupportive, and marginal, and, then, the authors specify the generic strategies for managing stakeholders with different levels of potential. Among the stakeholder types identified by Savage et al. (1991)<sup>529</sup>, the stakeholder type of mixed blessing is noted in terms of the strategy development for the pharmaceutical companies. The authors explain the mixed blessing type of stakeholders and the strategies for them as follows:

The mixed blessing stakeholder plays a major role. Here, the executive faces a stakeholder whose potential to threaten or to cooperative are equally high. Generally, in a well-managed organization, stakeholders of the mixed blessing type would include employees who are in short supply, clients or

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<sup>526</sup> Freeman, R. E. & McVea, J. (2001). A Stakeholder Approach to Strategic Management [Electronic Version]. Darden Graduate School of Business Administration. Retrieved December 10, 2007, from [http://papers.ssrn.com/paper.taf?abstract\\_id=263511](http://papers.ssrn.com/paper.taf?abstract_id=263511)

<sup>527</sup> Savage, G. T., Nix, T. W., Whitehead, C. J., & Blair, J. D. (1991). Strategies for assessing and managing organizational stakeholders. *Academy of Management Executive*, 5, 61-75.

<sup>528</sup> Ibid.

<sup>529</sup> Ibid.

customers, and organizations with complementary products or services...mixed blessing stakeholder could become either more or less supportive...The mixed blessing stakeholder, high on both the dimensions of potential threat and potential cooperation, may best be managed through collaboration. If business executives maximize the stakeholders' cooperation, potentially threatening stakeholders will find it more difficult to oppose the organization. A variety of joint ventures or other collaborative efforts, up to and including mergers, are possible. (p. 67)

The identification of the mixed blessing type of stakeholders and the strategies to manage them have important implications for the pharmaceutical companies in terms of the organizational strategy development. The analysis of the historical narrative of events of this dissertation identifies ten different stakeholder types in connection with the pharmaceutical companies and all these stakeholder types can be considered as the mixed blessing type of stakeholders. In other words, although the stakeholders of the pharmaceutical companies are classified into ten different types based on the formal qualitative analysis, all these stakeholder types are, intrinsically, high on both dimensions of the potential threat and cooperation. It is noted that although the stakeholder type of 'developed countries/policy makers' has been considered as a supportive stakeholder type (i.e. the ideal stakeholder type which supports the goals and actions of the pharmaceutical companies), in some cases, this stakeholder type turned against the pharmaceutical companies. Namely, as the anthrax incident demonstrates, developed country governments would turn against the pharmaceutical industry if the national security interests were at stake. It is not at all clear that the support for the pharmaceutical industry by the developed country governments would continue. Similarly, the stakeholder type of 'shareholders/investors' has been considered as a supportive stakeholder type, however, in some cases, this stakeholder type also put pressure on the

pharmaceutical industry. As discussed earlier, the shareholders and institutional investors of GSK turned against the company when the reputational damage to GSK became, eventually, a public relations disaster after the South African lawsuit. In contrast, although the stakeholder type of ‘NGOs/activist groups’ has been considered as a nonsupportive stakeholder type (i.e. the most distressing stakeholder type to the pharmaceutical companies high on the potential threat but low on the potential cooperation), in some cases, this stakeholder type supported the pharmaceutical industry. For example, with regard to the Merck’s Mectizan Donation Program, a number of NGOs and activist groups have appreciated the donation program as one of the foremost examples of a public-private partnership in the area of the global public health. They also have appreciated that the donation program demonstrates how the private sector companies can be a viable partner in improving the global public health.

Savage et al. (1991)<sup>530</sup> argue that the mixed blessing type of stakeholders could become either more or less supportive to an organization because they are high on both dimensions of the potential threat and cooperation. In this respect, the authors argue that the mixed blessing stakeholders may best be managed through ‘collaboration’. That is, if business executives maximize the mixed blessing stakeholders’ cooperation, potentially threatening stakeholders will find it more difficult to oppose the organization. Savage et al. (1991)<sup>531</sup> also maintain that transforming the stakeholder relationship from a less favorable to a more favorable one is the fundamental stakeholder management strategy. That is, “as an overarching strategy, managers should try to change their organizations’

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<sup>530</sup> Savage, G. T., Nix, T. W., Whitehead, C. J., & Blair, J. D. (1991). Strategies for assessing and managing organizational stakeholders. *Academy of Management Executive*, 5, 61-75.

<sup>531</sup> Ibid.

relationships with the stakeholder from a less favorable category to a more favorable one” (Savage et al., 1991, p. 72)<sup>532</sup>. It is argued that if an organization built a more positive relationship with its stakeholders, the organization could continue to manage them through a less intensive strategy of involvement. Then, how can the pharmaceutical industry secure the collaboration with the mixed blessing type of stakeholders, transforming the relationships with these stakeholders from a less favorable to a more favorable one? To answer this question, the work of Harrison et al. (1996)<sup>533</sup> is very suggestive.

Harrison et al. (1996)<sup>534</sup> argue that “increasingly, organizations moving beyond traditional stakeholder management techniques to partnering tactics that lead to the achievement of common goals” (p. 46). The authors also maintain that successful partnerships with stakeholders can reduce unfavorable litigation, levels of negative publicity, and unfavorable regulatory policies. It is noted that the partnering tactics suggested by Harrison et al. (1996)<sup>535</sup> have important implications for the pharmaceutical industry because the industry has suffered from unfavorable litigations, high levels of negative publicity, and unfavorable regulatory policies.

Harrison et al. (1996)<sup>536</sup> define stakeholders as “groups or individuals who can significantly affect or are significantly affected by an organization’s activities” (p. 47).

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<sup>532</sup> Savage, G. T., Nix, T. W., Whitehead, C. J., & Blair, J. D. (1991). Strategies for assessing and managing organizational stakeholders. *Academy of Management Executive*, 5, 61-75.

<sup>533</sup> Harrison, J. S., & St. John, C. H. (1996). Managing and partnering with external stakeholders. *Academy of Management Executive*, 10, 46-60.

<sup>534</sup> Ibid.

<sup>535</sup> Ibid.

<sup>536</sup> Ibid.

The authors maintain that firms should focus attention on the stakeholder management perspective on two grounds. First, the instrumental perspective is that the stakeholder management activities can lead to higher profitability or increased firm value. Although there is little conclusive empirical evidence that the ‘proactive’ stakeholder management leads to higher profitability than other management approaches, Harrison et al. (1996)<sup>537</sup> contend that “the most compelling instrumental argument for the benefits of proactive stakeholder management is that it creates and preserves organizational flexibility” (p. 49). In specific, the authors argue that “organizational flexibility reflects not only the speed of responses [to environmental change], but also an organization’s ability to reduce the impact of environmental change and the costs of responding to it” (p. 49)<sup>538</sup>. Second, the normative perspective is that the proactive stakeholder management simply the right thing to do. The authors argue that “the normative view is particularly important at present because of increasing public interest in corporations and an increasingly powerful media” (p. 49)<sup>539</sup>.

Harrison et al. (1996)<sup>540</sup> explain that the strategic importance of a stakeholder to a firm is determined by the contribution of the stakeholder to the environmental uncertainty facing the firm, the ability of the stakeholder to reduce the environmental uncertainty for the firm, and the strategic choices of managers within the firm. The authors argue that strategically important stakeholders should be managed as ‘partners’ and the proactive stakeholder management is to engage in effective strategic partnering. Harrison et al.

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<sup>537</sup> Harrison, J. S., & St. John, C. H. (1996). Managing and partnering with external stakeholders. *Academy of Management Executive*, 10, 46-60.

<sup>538</sup> Ibid.

<sup>539</sup> Ibid.

<sup>540</sup> Ibid.

(1996)<sup>541</sup> illustrate the way through which firms can create effective partners with strategically important stakeholders as follows:

When environments are more complex and uncertain, webs of interdependencies are created among stakeholders. In these environments, bridging (also called boundary-spanning) techniques are needed that built on interdependences rather than buffer them...partnering techniques that bring the firm into closer alliance with its critical stakeholders...Our thesis is that firms should consider proactive partnering techniques not only to increase control in the face of environmental uncertainty, but to create organizational flexibility. Partnering activities allow firms to build bridges with their stakeholders in the pursuit of common goals, whereas traditional stakeholder management techniques (buffering) simply facilitate the satisfaction of stakeholder needs and/or demands. (p. 52)

In particular, the authors' discussion about the tactics that can be used to partner with activist groups is noted in terms of the organizational strategy development for the pharmaceutical companies, because, as illustrated earlier, NGOs/activist groups combined with the public/the media has been identified as the most influential and salient stakeholder type of the pharmaceutical industry.

Activist groups are most often seen in an adversarial role relative to other organizational stakeholders. This adversarial stance, though common, can change...To adopt a win-win attitude with activist groups, executives should consider potential benefits from partnering activities, especially in situations in which an activist is strategically important. One of the best ways to reduce unfavorable regulation in an industry is to operate in a manner consistent with the values of society...Public interests groups are particularly important in helping organizations avoids conflicts with social values, which can result in unfavorable media and a damaged reputation...As a result, many companies invite public interest group members to participate in strategic planning processes either as advisors or board members. A benefit of such participation may be that there are fewer obstacles during strategy implementation. The groups involved would be less likely to protest or seek

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<sup>541</sup> Harrison, J. S., & St. John, C. H. (1996). Managing and partnering with external stakeholders. *Academy of Management Executive*, 10, 46-60.

government intervention. This may also result in good public relations and publicity. (p. 56)

For an effective, proactive, strategic partnership with key stakeholders, Harrison et al. (1996)<sup>542</sup> propose several approaches that should be adopted by firms and emphasize the importance of communication or dialogue with key stakeholders. Namely, the authors suggest that when forming a strategic partnership, firms should: communicate frequently and openly to foster the development of a shared interpretation of the situation; make a commitment; share information during the agreement stage and during the implementation of the partnership; clearly delineate what is expected from the partnership and develop a strategy for achieving it through partnership activities; and resolves conflicts through joint problem-solving techniques. As Preble (2005)<sup>543</sup> points out, the use of direct communication or open dialogue with key stakeholders is an approach likely to have wide applicability for organizations. It is argued that the communication or dialogue on key issues between firms and their strategically important stakeholders can allow each party to define more clearly their positions or situations leading to an increased mutual understanding. This understanding can reduce the gap between the parties and, thus, helps to avoid negative events such as stakeholder protests or boycotts.

In sum, to develop organizational strategies for the pharmaceutical companies in the stakeholder management terms, two important requisites, on the part of the companies,

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<sup>542</sup> Harrison, J. S., & St. John, C. H. (1996). Managing and partnering with external stakeholders. *Academy of Management Executive*, 10, 46-60.

<sup>543</sup> Preble, J. F. (2005). Toward a comprehensive model of stakeholder management. *Business and Society*, 110, 407-431.



has been examined: that is, first, collaboration with the mixed blessing type of stakeholders, transforming the pharmaceutical companies' relationships with the stakeholders from a less favorable category to a more favorable one; and second, effective, proactive, strategic partnerships with strategically important stakeholders, facilitating communication or dialogue with these stakeholders. Below, a new direction for the pharmaceutical industry in the stakeholder management terms is suggested. This new direction satisfies two requisites specifically for the organizational strategy development for the pharmaceutical industry described above as well as reflects the outcomes of the formal qualitative analysis (i.e. the ESA and the qualitative comparative Boolean analysis) combined with those of the ARM.

## **6.2 The Comprehensive, Industry-wide, Proactive, Multi-Stakeholder Public-Private Partnership**

The pharmaceutical companies have adopted several strategies to deal with the pressure posed by their stakeholders in connection with the access to essential, life-saving medicines. It is argued that none of the strategies that have been adopted by the pharmaceutical companies can be considered as a long-term effective solution to the global public health in terms of the access to essential, life-saving medicines as well as to the companies in terms of the stakeholder management. However, it does not mean that all the strategies are useless and ineffective. Each individual strategy has not only its own strengths but also its own weaknesses. Thus, if a strategy is implemented under the circumstances that can compensate for its weaknesses, reinforcing its strengths, each individual strategy has potential to be a long-term effective solution, realizing a win-win

situation. The main issue is how the pharmaceutical industry can attain or promote the circumstances which not only compensate for the weaknesses but also reinforce the strengths of its stakeholder management strategies, realizing a win-win-situation. In essence, the new strategic direction for the pharmaceutical industry in the stakeholder management terms concerns how to attain or promote these circumstances on the part of the industry.

According to Mascarenhas et al. (2005)<sup>544</sup>, even though the developed world represents less than 15% of the world's population, it consumes 85% of pharmaceutical products. However, it is noted that although the resources and infrastructure in the developing world necessary to create, purchase, and deliver pharmaceutical products are largely insufficient, the need for pharmaceuticals in the developing world is as great as (or greater than) that in the developed world. Therefore, the developing world has been characterized by very strong pharmaceutical need and very weak economic ability. In other words, the markets of the developing world have been underserved in terms of pharmaceuticals, and the conventional reasoning is that although these markets are large, they have a very low buying power and, thus, they cannot afford essential, life-saving medicines (Mascarenhas et al., 2005)<sup>545</sup>. In this respect, the pharmaceutical industry has been heavily criticized on the ground that the industry overcharges the consumers, particularly those in the developing world for essential, life-saving drugs such as HIV/AIDS medicines. On the contrary, the support for the pharmaceutical industry by the developed world, particularly by the U.S. government, is not at all clear. The anthrax

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<sup>544</sup> Mascarenhas, O. A., Kesavan, R., & Bernacchi, M. (2005). Global marketing of lifesaving drugs: an analogical mode. *Journal of Consumer Marketing*, 22, 404-411.

<sup>545</sup> Ibid.

incident demonstrated that the developed world can also turn on the pharmaceutical industry if the national security interests are at stake. On these grounds, to deal with the risks posed by its various stakeholders, the pharmaceutical industry needs to develop strategies which can balance its R&D-intensive, expensive business with the enlarged social responsibility, enhancing the access to essential, life-saving medicines.

The formal qualitative analysis of this dissertation reveals that the pharmaceutical industry, for the last two decades, has adopted various measures, in the stakeholder management terms, in response to the risks posed by their stakeholders. Nevertheless, the pharmaceutical industry has been severely criticized and pressed by their stakeholders in connection with the access to essential, life-saving medicines. Although the criticisms against the pharmaceutical industry have focused on the HIV/AIDS pandemic, the concerns, today, are becoming more problematic for other diseases such as tuberculosis, diabetes, heart disease, and cancer. The opponents of the pharmaceutical industry have emphasized the importance of the humanitarian priorities and have accused the pharmaceutical industry for exaggerating the R&D cost. The pharmaceutical industry, as a whole, has confronted a rising tide of political and legal risks that threaten its fundamental business model, such as the differential pricing policy and the IPRs protection, underpinning the industry's financial performance. That is, as Kennedy et al. (2004)<sup>546</sup> point out “a major strategic risk for pharmaceutical companies is that an environment of confrontational politics over the distribution of lifesaving drugs may endanger a broad-based public affairs and public policy backlash” (p. 131).

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<sup>546</sup> Kennedy, C. R., Harris, F. H., & Lord, M. (2004). Integrating public policy and public affairs in a pharmaceutical marketing program: The AIDS pandemic. *Journal of Public Policy and Marketing*, 23, 128-139.

Both the formal qualitative analysis and the ARM of this dissertation confirm that the pharmaceutical industry needs to develop new, effective stakeholder management strategies to deal with the risks, in connection with the access to essential, life-saving medicines, posed by their stakeholders. There is great uncertainty about the future changes in public policy towards the pharmaceutical industry. In particular, the challenges to the current strong patents on pharmaceutical products are very real. If the pharmaceutical industry cannot find a new direction, in the stakeholder management terms, particularly in connection with the access to essential, life-saving medicines, it may lose the market for HIV/AIDS (and, further, the markets for other global health-related diseases, such as cancer and diabetes) in the near future. Kennedy et al. (2004)<sup>547</sup> argue the following:

Major pharmaceutical companies now provide AIDS drugs to poor countries by donating medicines to select programs or selling drugs at prices that reflect manufacturing costs. To produce enough volume to meet future global demand and needs, major pharmaceutical companies would need to increase their current production capacity significantly. Such an investment is currently difficult to justify because of the low expected returns and high opportunity costs. Thus, when intellectual property rights, as defined by the original TRIPS agreement, are redefined for countries with declared healthcare emergencies, the major pharmaceutical companies may decide to abandon the global AIDS market to generic producers. Without a commitment to provide AIDS medicines on terms at least as favorable as those for the best generics, major pharmaceutical companies will witness global sales becoming dominated by generic producers. (p.135)

Without doubt, the pharmaceutical industry should find a new direction, in the stakeholder management terms, particularly in relation to the access to essential, life-

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<sup>547</sup> Kennedy, C. R., Harris, F. H., & Lord, M. (2004). Integrating public policy and public affairs in a pharmaceutical marketing program: The AIDS pandemic. *Journal of Public Policy and Marketing*, 23, 128-139.

saving medicines. In addition, the new direction should be the one which can balance the legitimate stakeholder claims with the needed R&D investments. Most of the measures in the stakeholder management terms which have been taken by the pharmaceutical industry, such as donations and price reductions, can be considered as a gradualist approach. It is argued that the gradualist approach of the pharmaceutical industry has been ineffective in the stakeholder management terms in that the public images of the industry have not been helped by the approach and it has attracted the greatest criticism over the patent policy of the pharmaceutical industry.

As the formal qualitative analysis of this dissertation reveals, the pharmaceutical industry has adopted six different types of measures, in the stakeholder management terms, to respond to the pressure posed by their ten different types of key stakeholders. However, it is argued that the pharmaceutical industry, in general, has not satisfied with the multiple types of stakeholders. Moreover, the pharmaceutical industry has not implemented the stakeholder management on an industry-wide, collective business basis. Although the pharmaceutical companies have performed several public-private partnerships, these partnerships were not the pharmaceutical industry-wide, collective business basis. In essence, these partnerships, except the Merck's Mectizan Donation Program, have been led by the public sector, not by the pharmaceutical companies.

This dissertation suggests a permanent, comprehensive, proactive, multi-stakeholder public-private partnership as a new direction, in the stakeholder management terms, for the pharmaceutical Industry. In specific, the public-private partnership must be on the

pharmaceutical industry-wide, collective business basis and should adopt an integrated approach to the strategic decision making of the pharmaceutical industry to satisfy multiple stakeholders simultaneously rather than stakeholder by stakeholder. In addition, the public-private partnership should be initiated by the pharmaceutical industry, not by the public sector such as the U.N., although a prior consultation between the pharmaceutical industry and the public sector is needed. In essence, the partnership should incorporate multiple stakeholders of the pharmaceutical industry and should deal with not only the HIV/AIDS pandemic but also other diseases, such as tuberculosis, diabetes, heart disease, and cancer. However, it should be noted that the public-private partnership suggested by this dissertation concerns not the development of new medicines but the distribution of medicines. In other words, the public-private partnership suggested by this dissertation is a new strategic direction through which essential, life-saving medicines are distributed effectively and rapidly at affordable prices.

The formal qualitative analysis and the ARM of this dissertation reveal that the specific measures that have been taken by the pharmaceutical industry have been ineffective in terms of the stakeholder management. This ineffectiveness results partly from the absence of the collaboration and partnership between the pharmaceutical industry and its stakeholders. It is noted that although the opponents of the pharmaceutical industry argue that the industry has not adopted any substantial measures to enhance the access to essential, life-saving medicines, it is clear that the access to essential, life-saving medicines, particularly in the developing world, cannot be improved by the single effort or contribution of the pharmaceutical industry. If the collaboration and partnership

between the pharmaceutical industry and its stakeholders had been sounder, the specific measures that have been taken by the pharmaceutical industry could have been more effective. Not only the pharmaceutical industry but also its stakeholders should do more to improve the access to essential, life-saving medicines. The type of the public-private partnership suggested by this dissertation can help to improve the collaboration and partnership between the pharmaceutical industry and its stakeholders, improving the access to essential, life-saving medicines.

In essence, as discussed above, to develop effective organizational strategies for the pharmaceutical industry in the stakeholder management terms, two important requisites, on the part of the industry, should be considered: that is, first, the collaboration with the mixed blessing type of stakeholders (whose potential to threaten or to cooperative are equally high), transforming the pharmaceutical industry's relationships with these stakeholders from a less favorable category to a more favorable one; and, second, the effective, proactive, strategic partnerships with the strategically important stakeholders, facilitating communication or dialogue with these stakeholders. In these respects, a comprehensive, industry-wide, proactive, multi-stakeholder public-private partnership is suggested as a new direction, in the stakeholder management terms, for the pharmaceutical industry. On the part of the pharmaceutical industry, this type of the public-private partnership should ground on the pharmaceutical industry-wide, collective business basis.

In other words, this dissertation suggests forming a 'permanent' public-private partnership between the pharmaceutical industry and its stakeholders. Through this type of the public-private partnership, it is argued that the pharmaceutical industry can attain not only the collaboration with its mixed blessing type of stakeholders but also the strategic partnerships with its strategically important stakeholders. It is noted that the public-private partnership suggested by this dissertation aims at benefiting both the pharmaceutical industry and its stakeholders. In consultation with its stakeholders, the pharmaceutical industry can find the most effective means to improve the access to essential, life-saving medicines, considering its expensive, R&D-intensive business. On the other hand, in consultation with the pharmaceutical industry, the stakeholders can also find the most effective means to improve the access to essential, life-saving medicines, considering the deficiencies on their sides particularly in the developing world, such as insufficient health-related infrastructure and personnel, ineffective distribution system for medicines, and high tax on imported medicines. That is, the public-private partnership suggested by this dissertation can increase the mutual understanding between the pharmaceutical industry and its stakeholders and, thus, help to devise the most effective means to improve the access to essential, life-saving medicines through a concerted effort between two parties. The key strength is that the means which would be produced by the public-private partnership to improve the access to essential, life-saving medicines can be inherently more stable and sustainable than the measures which have been taken by the pharmaceutical industry for the last two decades, because it would address and facilitate the interests of both the pharmaceutical industry and its stakeholders and, thus, it would be less likely to be challenged by either the industry or the stakeholders.



At this point, the importance of the effective communication or dialogue between the pharmaceutical industry and its stakeholders should be discussed. The public-private partnership suggested by this dissertation requires that, on the part of the pharmaceutical industry, the collaboration with the mixed blessing type of stakeholders and the strategic partnerships with the strategically important stakeholders. The mutual understanding between the pharmaceutical industry and its stakeholders is the basis for these collaboration and partnerships required by the public-private partnership of this dissertation. It is noted that this mutual understanding between the pharmaceutical industry and its stakeholders can be increased through the effective communication or dialogue between two parties. In other words, the effective communication or dialogue between the pharmaceutical industry and its key stakeholders is essential to facilitate the actual implementation of the suggested public-private partnership. Direct communication or open dialogue between two parties on the key issues where potential conflicts are perceived to exist can allow each party to more clearly examine not only its own position but also the other's situation leading to an increased mutual understanding. The pharmaceutical industry, then, is in a position to suggest any means to improve the access to essential, life-saving medicines and the stakeholders, based on the improved mutual understanding, are in a position to modify or refine their expectations. It is noted that in the suggested public-private partnership model, the reverse situation (i.e. the stakeholders suggest any means and the pharmaceutical industry modify or redefine its expectation) is also possible. In sum, the effective communication or dialogue between the pharmaceutical industry and its stakeholders helps two parties to move their positions based on the increased mutual understanding, reducing, substantially, the potential

conflicts and negative events between two parties. Kaptein et al. (2003)<sup>548</sup> argue that “a proper dialogue not only enhances a company’s sensitivity to its environment, but also increases the environment’s understanding of the dilemmas facing the organization” (p. 208).

The ARM of this dissertation reveals that the public-private partnerships, such as the GAIN Business Alliance and BAACH, have huge implications for the pharmaceutical industry. In other words, both the GAIN’s global partnership model and BAACH are innovative examples of how to make markets work better for the poor people by facilitating more active partnerships between the public and the private sector in the area of the global public health. That is, these public-private partnership models are innovative ones, building programs with the private sector and, thus, providing the partnerships between the public and the private sector. For the pharmaceutical industry, it is noted that a strong mutual understanding with its stakeholders enables a comprehensive, cost-effective, multi-stakeholder public-private partnership in terms of the access to essential, life-saving medicines. Moreover, only this type of the public-private partnership can help the pharmaceutical industry not only to deal with the pressure, in connection with the access to essential, life-saving medicines, posed by its various stakeholders but also to balance its R&D-intensive, expensive business with the increasing demand for the corporate social responsibility.

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<sup>548</sup> Kaptein, M. & Tulder, R. V. (2003). Toward Effective Stakeholder Dialogue. *Business and Society Review*, 108, 203-224.

Bradley (2008)<sup>549</sup> maintains that “creating trust and building relationships are at the heart of good business...Partnerships built on a foundation of trust, shared values and common aspirations seem to be the most productive way to reach realistic, measurable goals” (p. 171). As discussed above, increasing the mutual understanding, creating trust and building relationships, between the pharmaceutical industry and its stakeholders through the effective communication or dialogue, is essential for the suggested type of the public-private partnership. Then, specifically, what is the effective communication or dialogue which can improve the mutual understanding with its stakeholders on the part of the pharmaceutical industry? The recommendation of Szwajkowski (2000)<sup>550</sup> is suggestive. The author argues the following:

...stakeholder management does not inherently conflict with sound conventional economics and financial stewardship, how do we best manage stakeholder concerns in actual practice?.. A bit disingenuous, but I steadfastly believe that disclosure is to stakeholder management as location is to real estate: you can theoretically succeed without it, but it is so much harder that way. Why? The key phrase is one we have already mentioned, namely “all publicly available information.” Information is the currency in the stakeholder environment. Honest disclosure breeds control of information, control of behavior, empowerment on stakeholder issues, and perhaps most important, trust. (p. 388-389)

However, Szwajkowski (2000)<sup>551</sup> also points out that it is easy to say disclosure in the stakeholder management terms, but it is not that easy in the actual practice of the stakeholder management. The public-private partnership suggested by this dissertation

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<sup>549</sup> Bradley, D. (2008). Beyond product: The private sectors drive to perform with the purpose of alleviating global under-nutrition. Global Forum Update on Research on Health Volume 5 [Electronic Version]. Retrieved December 4, 2008, from

[http://www.globalforumhealth.org/filesupld/global\\_update5/art/Update5\\_BeyondProduct\\_Bradley.pdf](http://www.globalforumhealth.org/filesupld/global_update5/art/Update5_BeyondProduct_Bradley.pdf)

<sup>550</sup> Szwajkowski, E. (2000). Simplifying the Principles of Stakeholder Management: The Three most important Principles. *Business & Society*, 39, 379-396.

<sup>551</sup> Ibid.

also concerns the notion of disclosure. However, this dissertation leaves the question of disclosure unanswered, because it is beyond the scope of the dissertation. A further research is expected to examine the specifics of how the comprehensive, industry-wide, proactive, multi-stakeholder public-private partnership suggested by this dissertation can be formed between the pharmaceutical industry and its stakeholders.

This dissertation aims at, not constructing a new theory in relation to the stakeholder management perspective, but developing a new framework for the organizational strategy development in connection with the stakeholder management perspective. The stakeholder management perspective, as Freeman (1994)<sup>552</sup> argues, suggests that the relationships with stakeholders can be created and influenced, not just taken as given, on the part of firms. Therefore, it is suggested that the pharmaceutical industry should, not merely adapt itself to the current business environment, but try to create the future environment understanding its strategic options it can create. However, as emphasized earlier, a new strategic option for the pharmaceutical industry should be the one which can balance its enlarged, global social responsibility with the expensive, R&D-intensive business in order to achieve a win-win situation as much as possible for both the pharmaceutical industry and its stakeholders. Or, the risks posed by the stakeholders of the pharmaceutical industry against its business model will be growing worse. It is expected that the new strategic direction for the pharmaceutical industry presented in this dissertation, that is, a comprehensive, industry-wide, proactive, multi-stakeholder public-private partnership, can be a useful tool to realize a win-win situation for both the

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<sup>552</sup> Freeman, R. E. (1994). The Politics of Stakeholder Theory: Some Future Directions. *Business Ethics Quarterly*, 4, 409-421.

pharmaceutical industry in terms of the stakeholder management and its stakeholders in terms of the access to essential, life-saving medicines.

## **Chapter 7: Conclusion – Contributions to the Extant Studies and the Future Research Agenda**

The main purpose of this dissertation is to actively plot a new direction for the pharmaceutical industry in the stakeholder management terms. To achieve this primary purpose, this dissertation builds on concrete facts and analyses, but it goes beyond such description to suggest a new direction developing specific organizational strategies for the pharmaceutical industry. That is, although this dissertation is descriptive in that it builds on the facts and analyses, such as the formal qualitative analysis (i.e. ESA and the qualitative comparative Boolean analysis), it goes beyond such description to suggest a new direction for the pharmaceutical industry given its stakeholder environment. In addition, although the ARM of this dissertation is descriptive in that it builds on the facts and analysis, it is not purely descriptive. In other words, four steps of the ARM adopted by this dissertation facilitate the development of any realizable, effective strategy, in the stakeholder management terms, for the pharmaceutical industry in conjunction with the food industry that has been under similar circumstances to the pharmaceutical industry. Therefore, this dissertation can be characterized as prescriptive as well as descriptive rather than as purely empirical and descriptive.

It is argued that this dissertation makes contributions to the extant literature in four perspectives. First, this dissertation tries to develop a new framework to approach the

issues related to the global public health in connection with the pharmaceutical industry. The primary purpose of this dissertation is to develop new, effective strategies, in the stakeholder management terms, for the pharmaceutical companies to deal with the risks posed by their stakeholders. It is noted that the strategic option developed by this dissertation aims at not only achieving sustainable and profitable business for the pharmaceutical industry but also fulfilling the enlarged, global social responsibility on the part of the industry. It is argued that most of the extant studies which deal with the global public health have approached the subject from the view point of the external stakeholders of the pharmaceutical industry, such as the poor patients in the developing world, focusing on the issue of the access to essential, life-saving medicines. Although the extant studies have considered the position of the pharmaceutical industry as the private sector, they have considered it in a limited manner. In other words, the extant studies, in dealing with the global public health, have mainly focused on the consumers/patients, particularly in the least-developed world, in relation to the access to essential, life-saving medicines. However, it is argued that the global public health should also be examined from the view point of the pharmaceutical industry. If the pharmaceutical industry is truly on the center of the issues related to the global public health, the industry should be the focal point of a study that deals with the global public health. However, this does not mean that the interests of the stakeholders can be sacrificed for the sake of the pharmaceutical industry. It would be hard for the pharmaceutical industry to survive without favorable public relations, and the industry itself recognizes it. In essence, to realize, although not fully guaranteed, a comprehensive win-win situation for both the pharmaceutical industry and its stakeholders, it is argued

that a new framework which approaches the global public health from the view point of the pharmaceutical industry should be elaborated, because this type of framework can help the pharmaceutical industry to craft more practical and realizable strategies, balancing the expensive, R&D-intensive business with its enlarged, global social responsibility particularly in terms of the access to essential, life-saving medicines.

Second, to suggest a new direction, in the stakeholder management terms, for the pharmaceutical industry, this dissertation relates the stakeholder management perspective to an analysis of a strategy development process in the case of the pharmaceutical industry. Although numerous studies on the stakeholder management perspective have been conducted, a study which relates the stakeholder management perspective to an analysis of a strategy development process has been scant. This dissertation proves the usefulness of the stakeholder management perspective as a tool for an analysis of a strategy development process.

Third, this dissertation elaborates a new framework to conduct a stakeholder analysis, adopting two different types of the formal qualitative analysis, i.e., the ESA and the qualitative comparative Boolean analysis. As explained earlier, the objective of the second and third phase of the organizational strategy development of this dissertation is performing an ‘empirical’ stakeholder analysis which can facilitate the actual practice of the stakeholder management perspective for the companies within the pharmaceutical industry. This stakeholder analysis has been performed by these two different types of the formal qualitative analysis. It is noted that although there are several extant studies which

conduct the stakeholder analysis, a stakeholder analysis performed based on empirical data is scant. Furthermore, there is no extant study which performs a stakeholder analysis adopting the methods of the formal qualitative analysis. In fact, the extant studies provide no suggestion on how to analyze the stakeholders of the companies within the pharmaceutical industry in connection with developing strategies in the stakeholder management terms. In this respect, considering the existing theories of the stakeholder management perspective, this dissertation performs a stakeholder analysis by analyzing the empirical evidences of the historical narrative of events. Therefore, it is argued that the formal qualitative analysis of this dissertation helps to conduct more reliable stakeholder analysis for the pharmaceutical industry, combining the theories of the stakeholder management perspective with the empirical evidences. It is also argued that the methods of the formal qualitative analysis can be adopted for a stakeholder analysis in connection with any industry sector, if the stakeholder analysis is based upon an empirical data such as the historical narrative of events.

Fourth, both the formal qualitative analysis and the ARM of this dissertation can be considered as the pharmaceutical industry-wide, cross-region/cross-country, comparative analysis. That is, this dissertation develops strategies for the pharmaceutical companies in the ‘global perspective’, examining the global public health-related cases not only in the developing world but also in the developed world. The extant studies, which deal with the global public health in relation to the pharmaceutical industry, have mainly concentrated their attention on the global the HIV/AIDS epidemic particularly in the least-developed world. However, the risks to the pharmaceutical industry are becoming more systematic,



collaborative, and broad-based in the global scale. Today, the case of HIV/AIDS in the least-developed world is not the only issue in terms of the global public health and, also, is not the only challenge to the pharmaceutical industry. In this respect, to develop strategies for the pharmaceutical industry, this dissertation performs, not a single country (or single region) analysis which reflects a single disease such as the HIV/AIDS epidemic in sub-Saharan African countries, but a pharmaceutical industry-wide, cross-region/cross-country, comparative analysis. In sum, although the extant studies have mainly focused on the global HIV/AIDS pandemic, especially in the least-developed world, in relation to the global public health, the formal qualitative analysis of this dissertation is not limited to the global HIV/AIDS epidemic in the least-developed world, examining both HIV/AIDS and other diseases such as cancer, anthrax, and river blindness in both the developing and the developed world.

Although this dissertation makes contributions to the extant literature on the perspectives described above, it also presents two future research agenda. The first future research agenda is to investigate the relationship between CSP and CFP in relation to the companies within the pharmaceutical industry. In fact, as Harrison et al. (1999)<sup>553</sup> maintain, one of the original ideas behind the stakeholder management approach was trying to find a way to integrate the economic and the social. Nevertheless, based on the extant literature, separating the financial/economic performance from the social performance of companies is a widely accepted assumption among scholars. That is, many researchers have studied whether or not the companies that perform well on the

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<sup>553</sup> Harrison, J. S., & Freeman, R. E. (1999). Stakeholders, Social Responsibility, and Performance: Empirical Evidence and Theoretical Perspectives. *Academy of Management Journal*, 42, 479-485.

social measures also perform well on the financial measures. For the pharmaceutical companies, which should run expensive, R&D-intensive business and which should act under the severe pressure posed by their various stakeholders, it must be particularly meaningful to investigate the correlation between the social and financial performance. If a positive correlation exists between these two variables, the pharmaceutical companies should develop strategies with which they can deal with their stakeholders more effectively, achieving simultaneously better financial performance. It is noted that although lots of studies have been conducted to investigate the relationship between CSP and CFP in connection with diverse industry sectors, a study which examines the correlation between CSP and CFP in relation to the pharmaceutical companies is scant. In particular, there is no extant study which investigates the relationship between the social and financial performance of the pharmaceutical companies in the stakeholder management terms. The correlation analysis between the stakeholder management practice and the financial performance of the pharmaceutical companies can be a useful investigation for the companies to develop strategies for the future business. The instrumental stakeholder theory, as Donaldson et al. (1999)<sup>554</sup> explain, tries to establish a framework for examining the connections, if any, between the practice of stakeholder management and the achievement of various corporate performance goals. The instrumental proposition of firms that practice stakeholder management will outperform firms that do not or firms that practice stakeholder management will, other things being equal, be relatively successful in financial terms can be tested by the correlation analysis between CSP and CFP, in the stakeholder management terms, particularly in connection

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<sup>554</sup> Donaldson, T., & Dunfee, T. (1999). *Ties that Bind: A Social Contract Approach to Business Ethics*. Boston, MA: Harvard Business School Press.

with the pharmaceutical companies. Waddock et al. (1997)<sup>555</sup> argue that both the ‘slack resource theory’ (i.e. financially successful companies simply have more resources to spend on CSP and therefore attain a higher standard) and the ‘good management theory’ (i.e. better performance along various dimensions of CSP itself results in better financial performance) may be operating simultaneously. These propositions can also be tested by the correlation analysis in connection with the pharmaceutical companies.

Nevertheless, the outcomes of the correlation analysis between CSP and CFP, in the stakeholder management terms, of the pharmaceutical industry may put the industry into a dilemma. That is, if there is a positive correlation between these two variables, the pharmaceutical industry has no choice but to craft effective strategies in the stakeholder management terms to deal with their stakeholders, maintaining its profitable business. In contrast, if no or unclear correlation exists between these two variables, is there any reason for the pharmaceutical industry to craft and implement strategies in terms of the stakeholder management? It can be argued that this kind of dilemma occurs because the nature of the pharmaceutical industry is different from that of other industry sectors. This does not mean that the pharmaceutical industry is inherently special in that it assumes or takes more social responsibility than other industry sectors. However, it is noted that producing and marketing consumer electronic products and pharmaceutical products are different in the nature because the pharmaceutical products are in connection with the global public health. This is why the pharmaceutical industry has been severely pressed by its stakeholders particularly in terms of the access to essential, life-saving medicines.

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<sup>555</sup> Waddock, S. A., & Graves, S. B. (1997). The Corporate Social Performance – Financial Performance Link. *Strategic Management Journal*, 18, 303-319.

In this respect, a study which investigates the relationship between CSP and CFP of the pharmaceutical industry in the stakeholder management terms would have important implications for both the pharmaceutical industry and its stakeholders.

Second, although this dissertation suggests the comprehensive, industry-wide, proactive, multi-stakeholder public-private partnership as a new, effective direction for the pharmaceutical industry, it does not explain in detail concerning how the suggested public-private partnership can be formed between the pharmaceutical industry and its stakeholders, incorporating not only the various stakeholders but also the diverse pharmaceutical companies in the partnership. This dissertation leaves the question of how, in specific terms, the suggested public-private partnership can be formed unanswered, because it is beyond the scope of this dissertation. A further research is expected to examine the specifics of how the suggested public-private partnership of this dissertation can be formed between the pharmaceutical industry and its stakeholders. That is, the future study is expected to investigate the possible issues in forming the suggested public-private partnership, such as the issues which can be raised by the interrelation among the pharmaceutical companies, among the various stakeholders, and between the pharmaceutical industry and its stakeholders. In addition, the notion of 'disclosure' and the specifics of 'communication' (or dialogue) in connection with the suggested public-private partnership are also expected to be examined through the further research.

It is argued that developing a theory of the stakeholder identification and salience or identifying the relationship between the social and financial performance of corporations

cannot be the ultimate goal in studying the stakeholder management perspective as well as in studying the organizational strategy development in relation to the stakeholder management perspective. The stakeholder management perspective should be put into practice within the actual business environment. This is why the stakeholder approach to the strategic management (i.e. the strategic stakeholder management approach to the organizational strategy development) has important implications for firms. In this respect, it is argued that the stakeholder analysis performed by two different types of the formal qualitative analysis, the ARM, and the resultant new direction for the pharmaceutical industry in this dissertation can stimulate the individual pharmaceutical companies and, further, the pharmaceutical industry as a whole to actively incorporate the stakeholder management perspective into their decision-making process to deal with the risks they face.

In conclusion, as emphasized above, it should be noted that the pharmaceutical industry alone, without making a great deal of united effort with its stakeholders, cannot improve the global public health, enhancing the access to essential, life-saving medicines. In this respect, the argument of Archibugi and Bizzarri (2004)<sup>556</sup> is suggestive. The authors assert that neither the private nor the public entities are investing sufficiently for the development of a vaccine capable of eradicating the diseases such as HIV/AIDS, malaria, and tuberculosis (TB) because of the low priority that these diseases are given on the political agenda of the high income countries as well as a lack of market incentives (i.e. financial commitment) for both the private and the public sector. In particular, the authors

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<sup>556</sup> Archibugi, D. & Bizzarri, K. (2004). Committing to vaccine R&D: a global science policy priority. *Research Policy*, 33, 1657-1671.

indicate that business sources have limited interest to invest vaccine R&D for communicable diseases because of the lack of profitable markets. Therefore, to increase the resources devoted to vaccine R&D from both the private and public sector and to manage the R&D activity aimed at vaccine development, the authors emphasize the international coordination supporting the creation of a 'Global Health Research Fund'. The policy options suggested by Archibugi et al. (2004<sup>557</sup>, 2005<sup>558</sup>) imply that only the comprehensive coordination between the pharmaceutical industry and other parties in connection with the global public health can improve the global public health. Nevertheless, the stakeholders of the pharmaceutical industry have mainly criticized the industry as if only the pharmaceutical industry is responsible for the global public health. This explains why the pharmaceutical industry should develop strategies in the stakeholder management terms.

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<sup>557</sup> Archibugi, D. & Bizzarri, K. (2004). Committing to vaccine R&D: a global science policy priority. *Research Policy*, 33, 1657-1671.

<sup>558</sup> Archibugi, D. & Bizzarri, K. (2005). The global governance of communicable diseases: The case for vaccine R&D. *Law & Policy*, 27, 33-51.

## Appendix 1: Historical Narrative of Events

### (1) The appearance of the first antiretroviral drug, Retrovir (AZT)

The drugs that can suppress HIV/AIDS are called antiretrovirals (ARVs). In March 1987, Burroughs Wellcome (now, GlaxoSmithKline [GSK]) developed and introduced the first antiretroviral drug (BWArv), known as Retrovir (also known as, in its generic name, Zidovudine or AZT) and it was the only approved (by the U.S. Food and Drug Administration [FDA]) therapy available to treat HIV/AIDS until 1991 (Kennedy, Harris, & Lord, 2004)<sup>559</sup>. Since Retrovir was first introduced, not only several large pharmaceutical companies such as Abbott Laboratories, Bristol Myers Squibb, Merck, and Roche, but also small biotech companies such as Agouron, Gilead Sciences, Triangle Pharmaceuticals, and Trimeris, have developed new antiretrovirals (Arv). As a result of these antiretroviral drugs, in the U.S., the rate of increase in HIV/AIDS-related diseases has slowed dramatically from the early 1990s, and, actually, the rate started to decrease from 1996 (Kennedy et al., 2004)<sup>560</sup>. Consequently, the HIV/AIDS-related deaths in the U.S. have also decreased dramatically from the early 1990s. Similar trends have been witnessed in much of Western Europe. However, as Kennedy et al. (2004)<sup>561</sup> indicate, during the late 1980s, in the early days of antiretroviral drug development, the drug pricing of Retrovir (AZT) was a serious and contentious issue (PubMedArv). The cost of

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<sup>559</sup> Kennedy, C. R., Harris, F. H., & Lord, M. (2004). Integrating public policy and public affairs in a pharmaceutical marketing program: The AIDS pandemic. *Journal of Public Policy and Marketing*, 23, 128-139.

<sup>560</sup> Ibid.

<sup>561</sup> Ibid.

Retrovir (AZT) for a patient was about \$10,000 per year, and, thus, Retrovir became the most expensive medicine in history (“HIV/AIDS facts”)<sup>562</sup>.

## **(2) The Merck’s Mectizan (ivermectin) Donation Program**

On October 21, 1987, upon the demonstration of ivermectin’s dramatic efficacy against onchocerciasis, Merck announced that it would give the medicine, the brand name Mectizan, away for free to anyone who needed it for as long as it was needed (MerDon) (Collins, 2004)<sup>563</sup>. Onchocerciasis, more commonly known as ‘river blindness’, is a neglected tropical disease (“Merck Supports”)<sup>564</sup>. Merck’s decision gave birth to a drug donation program – the Mectizan Donation Program – that has become one of the foremost examples of a public-private partnership in the global health (MerPPP) (Collins, 2004)<sup>565</sup>. Since the Mectizan Donation Program’s inception, Merck has donated more than 2.0 billion tablets of Mectizan, with more than 600 million treatment approved since 1988 (“Merck Supports”)<sup>566</sup>. The donation program currently reaches approximately 80 million people in Africa, Latin America, and the Middle East (Yemen) each year (“Merck Supports”)<sup>567</sup>. Before the Mectizan Donation Program was launched, other public-private initiatives had been existed in connection with the pharmaceutical industry. Nevertheless, it is noted that these public-private partnerships were initiated by the public sector and

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<sup>562</sup> AIDS Project Los Angeles (APLA) (n.d.). HIV/AIDS facts & statistics. Retrieved November 17, 2008, from <http://www.apla.org/facts/timeline.html>

<sup>563</sup> Collins, K. (2004). Profitable Gifts: a history of the Merck Mectizan donation program and its implications for international health. *Perspective in Biology and Medicine*, 47, 100-109.

<sup>564</sup> Merck supports the worldwide fight against river blindness (n.d.). UNICEF [Electronic Version]. Retrieved December 10, 2008, from <http://www.unicefusa.org/news/news-from-the-field/merck-pia.html>

<sup>565</sup> Collins, K. (2004). Profitable Gifts: a history of the Merck Mectizan donation program and its implications for international health. *Perspective in Biology and Medicine*, 47, 100-109.

<sup>566</sup> Merck supports the worldwide fight against river blindness (n.d.). UNICEF [Electronic Version]. Retrieved December 10, 2008, from <http://www.unicefusa.org/news/news-from-the-field/merck-pia.html>

<sup>567</sup> Ibid.



then the private sector corporations were involved. In contrast, as Collins (2004)<sup>568</sup> point out, the Mectizan Donation Program was developed out of the Merck's decision to develop a drug without a market, donate the drug, and assemble the public organizations to aid in the distribution of the drug. However, under what circumstances, Merck decided to donate Mectizan should be considered. The development of ivermectin posed unusual problem to Merck concerning the marketing of the medicine. According to Collins (2004)<sup>569</sup>, Merck could not find a way to price Mectizan, because there was no way the river blindness patients could afford it (the normal price of an anti-parasitic medicine was about \$3 a dose, and those affected with the river blindness could afford less than \$1). Although Merck, initially, attempted to find the means of funding Mectizan's distribution rather than considering the donation of Mectizan, by late 1986, the prospects of covering the cost of distribution of the medicine, let alone recouping the costs of development, appeared unlikely (Collins, 2004)<sup>570</sup>. Under this circumstance, the possibility of donation began to be voiced within the company. Especially, the Merck employees called for the donation of ivermectin (EmPressDon) (Collins, 2004)<sup>571</sup>. Although some Merck officials questioned whether the donation of Mectizan was a sound strategy, it was the best option that the company could consider at the time. Collins (2004)<sup>572</sup> describes the following:

The various ivermectin-based veterinary drugs were bringing in more than \$300 million annually, with a 15% growth in sales per year. Even if the company donated Mectizan, it would incur no net loss on ivermectin, because sales on Ivomec alone would be likely to exceed the production and

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<sup>568</sup> Collins, K. (2004). Profitable Gifts: a history of the Merck Mectizan donation program and its implications for international health. *Perspectives in Biology and Medicine*, 47, 100-109.

<sup>569</sup> Ibid.

<sup>570</sup> Ibid.

<sup>571</sup> Ibid.

<sup>572</sup> Ibid.

distribution costs of Mectizan. The financial success of ivermectin added to the moral pressure to donate. However, even those more skeptical of pharmaceutical donations have argued that the donation of Mectizan was a minimal price to pay – compared to the profits brought in by Ivomec – for the benefits of good publicity, improved employee morale, and a tax write-off. (p. 105)

Merck sought to overcome the obstacles of a lack of infrastructure and cultural barriers in connection with the distribution of Mectizan by establishing the public-private partnerships. That is, Merck established the Mectizan Donation Program - a multi-sectoral public-private partnership, involving the WHO, UNICEF, the World Bank, the ministries of health, non-governmental development organizations, and the local communities – to provide the medical, technical, and administrative oversight of the donation of Mectizan (“Merck supports”)<sup>573</sup>. The Mectizan Donation program proves the potential of the public-private partnership for the global public health and demonstrates how the private sector companies can be a viable partner in improving the global public health. However, as Collins (2004)<sup>574</sup> questions, for the medicines that do not share the double identity of human therapeutic and profitable veterinary drug, where will the incentive to donate come from?

### **(3) The contention over the price of Retrovir (AZT) and the first price reduction by Burroughs Wellcome (GSK)**

During the late 1980s, Burroughs Wellcome had faced huge protests in the U.S. and Europe against its pricing of the first antiretroviral drug, Retrovir (AZT). Especially, the

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<sup>573</sup> Merck supports the worldwide fight against river blindness (n.d.). UNICEF [Electronic Version]. Retrieved December 10, 2008, from <http://www.unicefusa.org/news/news-from-the-field/merck-pia.html>

<sup>574</sup> Collins, K. (2004). Profitable Gifts: a history of the Merck Mectizan donation program and its implications for international health. *Perspective in Biology and Medicine*, 47, 100-109.

protests were led by the ACT UP coalition. It is noted that the ACT UP (the AIDS Coalition to Unleash Power) was established in New York in February 1987 in response to the proposed cost of Retrovir (AZT) (“The global HIV/AIDS” timeline”)<sup>575</sup>. It was founded to end the HIV/AIDS crisis through direct, confrontational political action (“HIV/AIDS facts”)<sup>576</sup>, and its demands included better access to medicines as well as cheaper prices, public education about HIV/AIDS, and the prohibition of AIDS-related discrimination (Kennedy et al., 2004)<sup>577</sup>. In March 1987, the protestors led by the ACT UP coalition held their first mass demonstration against FDA on Wall Street urging to shorten the drug approval process. Later in the same year, the protesters also marched against Burroughs Wellcome in front of the company facilities in the U.S. and elsewhere blocking the facility entrances (ACTngoAct). The protestors also pushed the public policymakers to take action against “homicidal price gouging” of the company (PolicyPress) (Kennedy et al., 2004, p. 129)<sup>578</sup>. To deal with the pressure from the protestors and the policymakers in the U.S. and Europe over the price of Retrovir, Burroughs Wellcome reduced the price of Retrovir by 20% in December 1987 (BWcut1) (Kennedy et al., 2004)<sup>579</sup>.

#### **(4) The 5th International Conference on AIDS in Montreal and the AIDS activists**

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<sup>575</sup> The Henry J. Keiser Family Foundation. (n.d.). The global HIV/AIDS timeline. Retrieved November 24, 2008, from <http://www.kff.org/hivaids/timeline/hivtimeline.cfm>

<sup>576</sup> AIDS Project Los Angeles (APLA) (n.d.). HIV/AIDS facts & statistics. Retrieved November 17, 2008, from <http://www.apla.org/facts/timeline.html>

<sup>577</sup> AVERT. (n.d.). History of AIDS. Retrieved November 24, 2008, from [http://www.avert.org/his87\\_92.htm](http://www.avert.org/his87_92.htm)

<sup>578</sup> Kennedy, C. R., Harris, F. H., & Lord, M. (2004). Integrating public policy and public affairs in a pharmaceutical marketing program: The AIDS pandemic. *Journal of Public Policy and Marketing*, 23, 128-139.

<sup>579</sup> Ibid.

In June 1989, the 5th International Conference on AIDS (the Scientific and Social Challenge of AIDS) was held in Montreal, Canada (ConMon). It is noted that, during the conference, the voice of activists reached the delegates: that is, it was reported that “activists occupied the podium and cried their claims” (“Break the silence”, 2001)<sup>580</sup> (ActConMon). In addition, in 1989, the AIDS activists staged major protests, in connection with the issue of the access to the HIV/AIDS medicines, at the several places including the Golden Gate Bridge, the New York Stock Exchange, and the U.S. headquarters of Burroughs Wellcome (“The global HIV/AIDS timeline”)<sup>581</sup> (ActpressBW). As a result of these AIDS activists’ protests, Burroughs Wellcome, in September 1989, decided to cut the price of its Retrovir by a further 20% (BWcut2). This second price cut of Retrovir by Burroughs Wellcome is described below.

#### **(5) The second price reduction of Retrovir (AZT) by Burroughs Wellcome (GSK)**

As illustrated above, Burroughs Wellcome had reduced the price of Retrovir by 20% in 1987. But the company lowered the price of Retrovir by a further 20% in September 1989. It is noted that the second price cut by Burroughs Wellcome was made under the pressure from the AIDS community (“HIV/AIDS facts”)<sup>582</sup>, such as the ACT UP coalition and the AIDS activists, through staging major protests as well as under the pressure from the public opinion and the media triggered by the international conference, the 5th International Conference on AIDS in Montreal, Canada (PubMedMon).

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<sup>580</sup> 13th International AIDS Conference (2001). Break the silence [Electronic Version]. Retrieved November 17, 2008, from <http://www.uff.br/dst/revista13-12001/Cap%201%20%20International%20aids%20society.pdf>

<sup>581</sup> The Henry J. Keiser Family Foundation. (n.d.). The global HIV/AIDS timeline. Retrieved November 24, 2008, from <http://www.kff.org/hiv/aids/timeline/hivtimeline.cfm>

<sup>582</sup> AIDS Project Los Angeles (APLA) (n.d.). HIV/AIDS facts & statistics. Retrieved November 17, 2008, from <http://www.apla.org/facts/timeline.html>

## **(6) The appearance of the first drug cocktail, the Highly Active Antiretroviral Therapy (HAART)**

In 1996, researchers found that the combination of the two types of the anti-HIV/AIDS drugs, taken at the same time, reduced the spread of HIV/AIDS virus enormously. That is, the HAART (the Highly Active Antiretroviral Therapy) regimen or the so-called ‘drug cocktail’ (HAART), which can reduce enormously the spread of the HIV/AIDS virus, was appeared in 1996 and the appearance of the drug cocktail was considered as a great breakthrough in the fight against HIV/AIDS. The HAART or the drug cocktail is “the combination of the two inhibitors of reverse transcriptase and one protease inhibitor” (“Break the silence”)<sup>583</sup>, and it became the gold standard of the therapy of the HIV infection. In fact, the drug cocktail made a huge difference for the HIV infected people. For example, “in the United States, deaths from AIDS sank by 44% from 1996-97, and hospitalizations declined as well” (The Biotechnology Institute)<sup>584</sup>. However, the problem of this new medicine was its expensive price, about \$12,000 to \$16,000 a year, particularly to the AIDS patients in poor countries (Waldholz, 1996)<sup>585</sup>. Thus, since then, the pharmaceutical companies have been in the spotlight for not caring enough about the issues related to the global public health and being too concerned with protecting their patent rights (PubMedCockt). That is, it seems that the controversy against the pharmaceutical companies has been intensified dramatically since the drug cocktail or the HAART was introduced in 1996.

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<sup>583</sup> 13th International AIDS Conference (2001). Break the silence [Electronic Version]. Retrieved November 17, 2008, from <http://www.uff.br/dst/revista13-12001/Cap%201%20%20International%20aids%20society.pdf>

<sup>584</sup> The Biotechnology Institute (n.d.). The combination drug cocktail. Retrieved November 25, 2008, from <http://www.biotechinstitute.org/resources/YWarticles/9.2/9.2.4.pdf>

<sup>585</sup> Waldholtz, M. (1996, July 3). Precious pills: New AIDS treatment raises tough question of who will get it; For the poor, high costs, rigid regimes dim drug cocktails’ promise a major issue for Medicaid. *The Wall Street Journal*, p. A1.

### **(7) The 11th International AIDS Conference in Vancouver**

In July 1996, the 11th International AIDS Conference (ConVan) was held in Vancouver, Canada. The International AIDS Conference is organized every other year and the HIV/AIDS experts from all around the world meet to discuss and share their ideas. At Vancouver, the official theme was “One World-One Hope” (Dunlap, 1996)<sup>586</sup>. Although the conference highlighted the effectiveness of the HAART and generated a new wave of optimism, the primary concern was how the HIV/AIDS patients in poor countries could afford the newly introduced drug cocktail (i.e. the HAART). Namely, at Vancouver, “the first voices were raised regarding how poor countries – where 90% of the people infected with HIV live – were going to afford these new drugs” (PubMedVan) (Trullen et al., 2006)<sup>587</sup>. The Health Minister of South Africa reminded the conference delegates that “most people infected with HIV live in Africa, where therapies involving combinations of expensive antiviral drugs are out of the question” (AVERT)<sup>588</sup>. Namely, the concern with the high price of HIV/AIDS medicines in the Third World countries was voiced more explicitly at Vancouver (Trullen et al., 2006)<sup>589</sup>. However, according to Dunlap (1996)<sup>590</sup>, many participants of the conference express ambivalence because the

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<sup>586</sup> Dunlap, D. W. (1996, July 15). From AIDS conference, talk of life, not death [Electronic Version]. The New York Times. Retrieved January 15, 2008, from <http://query.nytimes.com/gst/fullpage.html?res=9B01EED81E39F936A25754C0A960958260&sec=health&spon=&pagewanted=all>

<sup>587</sup> Trullen, J., & Stevenson, W. B. (2006). Strategy and Legitimacy: Pharmaceutical Companies' Reaction to HIV Crisis. *Business & Society*, 45, 178-210.

<sup>588</sup> AVERT. (n.d.). History of AIDS. Retrieved November 24, 2008, from [http://www.avert.org/his87\\_92.htm](http://www.avert.org/his87_92.htm)

<sup>589</sup> Trullen, J., & Stevenson, W. B. (2006). Strategy and Legitimacy: Pharmaceutical Companies' Reaction to HIV Crisis. *Business & Society*, 45, 178-210.

<sup>590</sup> Dunlap, D. W. (1996, July 15). From AIDS conference, talk of life, not death [Electronic Version]. The New York Times. Retrieved January 15, 2008, from <http://query.nytimes.com/gst/fullpage.html?res=9B01EED81E39F936A25754C0A960958260&sec=health&spon=&pagewanted=all>

conference just had made clear how wide a gap there was between those who could afford the new drug therapies and those who could not.

### **(8) The creation of UNAIDS and its proposal to the pharmaceutical companies**

Following the International AIDS conference in Vancouver (ConVan), the UNAIDS, the Joint United Nations Programme on HIV/AIDS (UNAIDS), was created in 1996. The primary goal of the UNAIDS is bringing together the efforts and resources of the ten U.N. system organizations (i.e. the UNHCR, WFP, WHO, UNODC, ILO, UNDP, UNICEF, UNFPA, UNESCO, and the World Bank) in the AIDS response to help the world to prevent new HIV infections, to care for people living with HIV, and to mitigate the impact of the HIV/AIDS epidemic. In other words, the UNAIDS was established to advocate the global HIV/AIDS pandemic and to coordinate the efforts on the pandemic across the U.N. system (The Henry J. Keiser Family Foundation)<sup>591</sup>. In specific, the UNAIDS pressed the pharmaceutical companies to join a pilot project (i.e. the HIV Drug Access Initiative) that would start to provide the cheaper HIV/AIDS medicines to Chile, Vietnam, Uganda, and the Ivory Coast (UNAIDSpress) (United Nations Information Service [UNIS], 2001)<sup>592</sup>. The pilot project was designed “to develop ways of making AIDS-related treatment more available to the 90% of people with HIV who live in developing countries and have little or no access to modern treatments today” (“Treatment in developing countries”)<sup>593</sup>. This pilot program intended a collaborative

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<sup>591</sup> The Henry J. Keiser Family Foundation. (n.d.). The global HIV/AIDS timeline. Retrieved November 24, 2008, from <http://www.kff.org/hivaids/timeline/hivtimeline.cfm>

<sup>592</sup> United Nations Information Service (2001, April 6). Secretary General announces steps by leading drug companies to improve AIDS treatment access to developing countries [Electronic Version]. Retrieved January 15, 2008, from <http://www.unis.unvienna.org/unis/pressrels/2001/sgsm7764.html>

<sup>593</sup> AIDS.ORG (n.d.). Treatment in developing countries: New UNAIDS pilot program. Retrieved November 18, 2008, from <http://www.aids.org/atn/a-283-05.html>

effort between the pharmaceutical companies and the developing country governments. Although the multinational pharmaceutical companies, initially, apposed the idea out of the fear that it would expand to the developed country markets, the companies such as GSK, Bristol Meyers Squibb, and Roche, later, joined the pilot project, as illustrated below (GskBmsRpilot).

### **(9) The Brazilian patent law and the National AIDS Program (NAP)**

Pursuant to the TRIPS Agreement, the Industrial Patent Law of Brazil was signed in 1996 and it came into force in May 1997. Cohen et al. (2005)<sup>594</sup> indicate that “the law provides a higher level of protection for pharmaceutical patents than that found in most other developing countries” (p.215). However, it is noted that the Industrial Patent Law, specifically, Article 68, Section 689 of the patent law proposes the local production of the patented products within three years of the patent approval. In other words, the Brazil’s patent law requires companies to produce the patented medicines locally within three years or face compulsory licensing. In case the patent holder does not comply, the Brazilian government is entitled to override the patent and allow third-party manufacturing of the product (“Brazil moves on”, 2007)<sup>595</sup> (BrazCL). Kennedy et al. (2004)<sup>596</sup> point out that “Brazil used the law as leverage to force price reductions from the major pharmaceutical companies, most recently in the fall of 2003” (p. 132). In addition to its patent law, the Brazilian government allowed, for many years, the state-run

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<sup>594</sup> Cohen, J. C., & Lybecker, K. M. (2005). AIDS policy and pharmaceutical patents: Brazil’s strategy to safeguard public health. *The World Economy*, 28, 211-230.

<sup>595</sup> Brazil moves on compulsory licenses after failed talks with drug company. (2007, May 3). Third World Network, Retrieved November 11, 2008, from <http://www.twinside.org.sg/title2/wto.info/twninfo05703.htm>

<sup>596</sup> Kennedy, C. R., Harris, F. H., & Lord, M. (2004). Integrating public policy and public affairs in a pharmaceutical marketing program: The AIDS pandemic. *Journal of Public Policy and Marketing*, 23, 128-139.



factories to produce the generic copies of the HIV/AIDS medicines patented before 1996. Government health centers, then, dispensed the HIV/AIDS medicines to the AIDS patients in Brazil for free. In 1996, the Brazilian government announced that it would guarantee all the citizens with HIV the free access to ARV medicines through the Brazilian National AIDS Program (NAP), that is, the policy of free access to ARVs (BrazNap). This was the first case within the developing world. The government reduced the treatment costs of the NAP by negotiating lower prices with the multinational pharmaceutical companies (NapPharCut) and by manufacturing the generic versions of the patented medicines (Global Health Council, 2003)<sup>597</sup> (BrazGen). As a result, since 1996, the incidence of HIV/AIDS in Brazil has been declined dramatically, and, as Kennedy et al. (2004)<sup>598</sup> indicate, many commentators have cited Brazil as a model for how to combat HIV/AIDS. However, as the 2001 release of the ‘U.S. Trade Representative (USTR) Section 301 Report’<sup>599</sup> shows, the U.S. government concerned about the Industrial Patent Law of Brazil (Cohen et al., 2005)<sup>600</sup>. In other words, the U.S. government has always resisted the liberal interpretations of the TRIPS Agreement. Particularly, concerning the exceptions, represented in the TRIPS Agreement, to the patent rights that authorize countries, facing a public health emergency, to import generic equivalents or to manufacture the cheap copies of the patented drugs, the U.S. has resisted liberal interpretations that would allow countries to abuse the exceptions. As a

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<sup>597</sup> Global Health Council (2003, May). Brazilian National AIDS Program receives 2003 Gates Award for global health [Electronic Version]. Retrieved November 24, 2008, from <http://www.globalhealth.org/news/article/3123>

<sup>598</sup> Kennedy, C. R., Harris, F. H., & Lord, M. (2004). Integrating public policy and public affairs in a pharmaceutical marketing program: The AIDS pandemic. *Journal of Public Policy and Marketing*, 23, 128-139.

<sup>599</sup> Consumer Project on Technology (n.d.). 2001 special 301 report [Electronic Version]. Retrieved November 24, 2008, from <http://www.cptech.org/ip/health/ustr/special301.pdf>

<sup>600</sup> Cohen, J. C., & Lybecker, K. M. (2005). AIDS policy and pharmaceutical patents: Brazil’s strategy to safeguard public health. *The World Economy*, 28, 211-230.

result, encouraged strongly by the pharmaceutical industry (PharUS), the U.S., finally, cited Brazil as a potential target of trade sanctions in Super 301 case (Kennedy et al., 2004)<sup>601</sup> (US-Braz).

#### **(10) The South African Medicines and Related Substances Act**

In 1997, South Africa amended its Medicines and Related Substances Act authorizing the use of compulsory licensing and parallel importing (SaCLPara). In other words, under the amended law, the South African government is allowed to produce or import inexpensive, patent-violating, generic drugs for HIV/AIDS and other diseases to provide medications to South Africans in need. However, as Trullen et al. (2006)<sup>602</sup> indicate, this South African law was never really implemented because of the opposition of the U.S. government. The pharmaceutical industry represented by the Pharmaceutical Research and Manufacturers of America (PhRMA) lobbied and exercised its influence (PhRMAUS) over the U.S. government to press the South African government (Trullen et al., 2006)<sup>603</sup>. In addition, the U.S. Trade Representative (USTR) put South Africa under its Super 301 Watch List (US-SA), a preliminary step leading to a further review of possible trade sanctions.

#### **(11) The price reduction of AZT by Glaxo Wellcome (GSK)**

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<sup>601</sup> Kennedy, C. R., Harris, F. H., & Lord, M. (2004). Integrating public policy and public affairs in a pharmaceutical marketing program: The AIDS pandemic. *Journal of Public Policy and Marketing*, 23, 128-139.

<sup>602</sup> Trullen, J., & Stevenson, W. B. (2006). Strategy and Legitimacy: Pharmaceutical Companies' Reaction to HIV Crisis. *Business & Society*, 45, 178-210.

<sup>603</sup> Ibid.

In March 1998, the manufacturer of AZT, Glaxo Wellcome<sup>604</sup> announced that it would cut the price of AZT (GWcut) by up to 75% to make it accessible, particularly for the pregnant HIV-positive women, in developing countries. This marked the first time one of the world's largest drug manufacturers agreed to cut the price of the HIV/AIDS medicine to get it to the regions particularly hard hit by the epidemic (Waldholtz, 1998)<sup>605</sup>. This announcement of the price reduction by Glaxo Wellcome came two weeks after a research in Thailand revealed that a small dose of AZT administered for three weeks before birth reduced the transmission of the AIDS virus from the infected mothers to their newborns by 50% ("Company to offer AZT", 1998)<sup>606</sup>. The research in Thailand was conducted by the Center for Disease Control and Prevention (CDC), an agency of the U.S. Public Health Service, and the UNAIDS ("Company to offer AZT", 1998)<sup>607</sup>. After the research results were revealed, the officials from the UNAIDS urged Glaxo Wellcome to offer such a discount to the developing world (UApresGW) ("Company to offer AZT", 1998)<sup>608</sup>. The UNAIDS issued a statement after Glaxo Wellcome's announcement of the price cut stating it an important step in efforts to reduce the mother-to-child transmission of HIV in the developing world ("Company to offer AZT", 1998)<sup>609</sup>. Concerning the price reduction of AZT by Glaxo Wellcome, most commentators expressed optimism, in contrast, others remained skeptical. They argued

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<sup>604</sup> Burroughs Wellcome and Glaxo Laboratories merged in 1995 to form Glaxo Wellcome. In 2001, Glaxo Wellcome and SmithKline Beecham merged to form GlaxoSmithKline.

<sup>605</sup> Waldholtz, M. (1998, March 5). AZT price cut for Third-World mothers-to-be. *The Wall Street Journal*, p. B1.

<sup>606</sup> CNN Interactive (1998, March 5). Company to offer AZT at steep discount to Third World [Electronic Version]. Retrieved November 27, 2008, from <http://www.cnn.com/HEALTH/9803/05/azt.discount/index.html>

<sup>607</sup> Ibid.

<sup>608</sup> Ibid.

<sup>609</sup> Ibid.

that the developed world would need to contribute more heavily to any program that could significantly reduce the number of infants born as HIV-infected (Baker, 1998)<sup>610</sup>

### **(12) The 12th International AIDS Conference in Geneva**

In July 1998, the 12th International AIDS Conference (“Bridging the Gap”)<sup>611</sup> was held in Geneva, Switzerland (ConGene). Several results from the clinical trials on the combination therapies were showed during the conference. However, the challenge of the conference was not only to discuss the advantages available for the treatment of HIV/AIDS but also to conquer the overwhelming pessimism (“History of AIDS”)<sup>612</sup>. It is noted that “the unquestionable progresses of the science in the fight against HIV (mortality was halved in the USA) produced a feeling of Aids defeat and that the epidemic is blocked but at the same time increased the sensation of a greater gap between the North and the South of the world” (Break the silence, 2001, p. 5)<sup>613</sup>. The international community was plunged into mourning and the activist groups and NGOs joined their efforts to put pressure on the pharmaceutical companies (NgoActGene). After the conference, a coalition of several activist groups and NGOs around the world (e.g. ACT UP chapters from New York, Philadelphia and Paris, the Treatment Action Campaign of South Africa [TAC], the International Gay and Lesbian Human Rights Commission

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<sup>610</sup> Baker, R. (1998, May 5). Glaxo opens broad expanded access program for Abacavir (Ziagen). San Francisco AIDS Foundation [Electronic Version]. Retrieved, November 27, 2008, from <http://www.sfaf.org/treatment/beta/b36/b36advocacy.html>

<sup>611</sup> The Henry J. Keiser Family Foundation. (n.d.). The global HIV/AIDS timeline. Retrieved November 24, 2008, from <http://www.kff.org/hivaids/timeline/hivtimeline.cfm>

<sup>612</sup> AVERT. (n.d.). History of AIDS. Retrieved November 24, 2008, from [http://www.avert.org/his87\\_92.htm](http://www.avert.org/his87_92.htm)

<sup>613</sup> 13th International AIDS Conference (2001). Break the silence [Electronic Version]. Retrieved November 17, 2008, from <http://www.uff.br/dst/revista13-12001/Cap%201%20%20International%20aids%20society.pdf>

[IGLHRC], Médecins Sans Frontières [MSF]) created Health Gap (HGap) in January 1999.

### **(13) The UNAIDS pilot project for Chile, Vietnam, Uganda, and the Ivory Coast**

As described above, UNAIDS pressed the pharmaceutical companies to join a pilot project (i.e. the HIV Drug Access Initiative) that would start to provide the cheaper HIV/AIDS medicines to Chile, Vietnam, Uganda and the Ivory Coast (UNAIDSPress). In 1998, GSK decided, for the first time, among the large multinational pharmaceutical companies that produce the patented HIV/AIDS medicines, to reduce its HIV/AIDS drug prices in the developing countries that are in connection with the UNAIDS pilot project (GskUAcut). Bristol Myers Squibb and Roche also joined this UNAIDS pilot project and cut their HIV/AIDS drug prices (BmsRoUAcut). In specific, the participating pharmaceutical companies in the pilot project provided financial support through various means, such as drug price cuts and investments in non-profit firms by cash or drug donations (UAdona) (“Joint and co-sponsored United Nations Programme”, 2005)<sup>614</sup>. However, as Trullen et al. (2006)<sup>615</sup> indicate, GSK was criticized on the ground that “Glaxo’s patent on AZT was about to expire (GskUApaten) and that this was the real reason for the price reduction” (p. 187). In fact, the initiatives of the pharmaceutical companies for this UNAIDS pilot project were small and were not enough to affect all the developing countries that need the HIV/AIDS medicines most.

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<sup>614</sup> UNAIDS (1999). Joint and co-sponsored United Nations programme on human immunodeficiency virus/acquired immunodeficiency syndrome. [Electronic Version]. Retrieved January 15, 2008, from [http://data.unaids.org/publications/External-Documents-Restored/ecosoc\\_unaidsreport1999\\_en.pdf](http://data.unaids.org/publications/External-Documents-Restored/ecosoc_unaidsreport1999_en.pdf)

<sup>615</sup> Trullen, J., & Stevenson, W. B. (2006). Strategy and Legitimacy: Pharmaceutical Companies’ Reaction to HIV Crisis. *Business & Society*, 45, 178-210.

#### **(14) The Secure the Future initiative of Bristol Myers Squibb**

In May 1999, following the UNAIDS pilot project for Chile, Vietnam, Uganda, and the Ivory Coast, Bristol Myers Squibb announced a new program, i.e., the Secure the Future (BmsSF), at the request of Kofi Annan (UNpressBms). Bristol Myers Squibb made clear that it would spend \$100 million to address HIV/AIDS treatment issues in five southern African countries (i.e. Botswana, Lesotho, Namibia, South Africa, and Swaziland) during the next five years (Trullen et al., 2006)<sup>616</sup>. According to the president of Bristol Myers Squibb Foundation, the Secure the Future program aimed at working with community partners (i.e. community-based groups and individuals) in Africa to develop new approaches to respond to HIV/AIDS epidemic in hard-hit communities where resources are limited (BmsPPP) (“Bristol-Myers Squibb”, 2008)<sup>617</sup>. However, the initiative did not include price reductions (Trullen et al., 2006)<sup>618</sup>.

#### **(15) The activists campaign against the U.S. policies towards South Africa**

During the second half of 1999, the activists, “members of a large coalition of organizations and individuals dedicated to helping people around the world get the medications they need to fight HIV/AIDS and related life-threatening illnesses” (ACT UP, 1999)<sup>619</sup>, prepared rallies against the U.S. policies towards South Africa which aimed

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<sup>616</sup> Trullen, J., & Stevenson, W. B. (2006). Strategy and Legitimacy: Pharmaceutical Companies’ Reaction to HIV Crisis. *Business & Society*, 45, 178-210.

<sup>617</sup> Bristol-Meyers Squibb launches Secure the Future technical assistance program to optimize community services for comprehensive HIV management in sub-Saharan Africa. (2008, August 5). Reuters, Retrieved November 10, 2008, from <http://www.reuters.com/article/pressRelease/idUS190867+05-Aug-2008+BW20080805>

<sup>618</sup> Trullen, J., & Stevenson, W. B. (2006). Strategy and Legitimacy: Pharmaceutical Companies’ Reaction to HIV Crisis. *Business & Society*, 45, 178-210.

<sup>619</sup> ACT UP (1999, June). AIDS activists hit Al Gore three times in two days [Electronic Version]. Global Treatment Access. Retrieved January 20, 2008, from [http://www.globaltreatmentaccess.org/content/press\\_releases/99/061899\\_AU\\_PR\\_GORE.html](http://www.globaltreatmentaccess.org/content/press_releases/99/061899_AU_PR_GORE.html)

at trade sanctions with the country (Trullen et al., 2004)<sup>620</sup>. Especially, these activists tried to disrupt the Al Gore's campaign, several times, in June 1999 (NgoActpressUS). On September 17, 1999, the USTR announced an agreement with South Africa that would lead to the removal of the country from the Super 301 Watch List, and, finally, on December 1, 1999, the U.S. government dropped South Africa from the list signaling a change of the U.S. policy (USdropSA). However, according to ACT UP (2000)<sup>621</sup>, the U.S. government dropped South Africa from the Watch List because of the pressure from the activists and the media (MedPubSA). In other words, they played important roles in achieving this victory for South Africa. Therefore, South Africa won the first round in its battle with the U.S. and the multinational pharmaceutical companies to force a cut in the prices of the HIV/AIDS medicines (SApriceCut) ("History of AIDS")<sup>622</sup>.

#### **(16) The Pfizer's decision to donate its Diflucan medicine: The NGOs and activists campaign against Pfizer**

In March 2000, the Médecins Sans Frontières (MSF), ACT UP (ACT UP in the U.S. and others), and the Treatment Action Campaign (TAC) launched a public relations and letter-writing campaign in 18 countries against Pfizer (NgoPressPf) to make it reduce the price of Diflucan, an essential medicine to treat HIV/AIDS-related diseases (AIDS Treatment News, 2000)<sup>623</sup>. The HIV/AIDS activists also broke into the headquarters of

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<sup>620</sup> Trullen, J., & Stevenson, W. B. (2006). Strategy and Legitimacy: Pharmaceutical Companies' Reaction to HIV Crisis. *Business & Society*, 45, 178-210.

<sup>621</sup> ACT UP (2000, July). Breaking the silence: Activists efforts to improve global access to AIDS medications [Electronic Version]. ACT UP New York. Retrieved January 20, 2008, from <http://www.actupny.org/reports/milano.html>

<sup>622</sup> AVERT. (n.d.). History of AIDS. Retrieved November 24, 2008, from [http://www.avert.org/his87\\_92.htm](http://www.avert.org/his87_92.htm)

<sup>623</sup> AIDS Treatment News (2000). Pfizer will donate Fluconazole to South Africa [Electronic Version]. AIDS.org. Retrieved January 20, 2008, from <http://www.aids.org/atn/a-340-03.html>

Pfizer in New York. In particular, the activists pointed out that the generic versions of Diflucan (ActGenPressPf), known as Fluconazole, were being sold about \$1.50 a day in Thailand, where the Pfizer's patent was not honored (Waldholtz, 2000)<sup>624</sup>. On April 3, 2000, in response to the pressure from the activists' campaign, Pfizer announced that it would donate its drug Diflucan to people with AIDS in South Africa (PfDona1). Diflucan was donated by Pfizer to the state facilities and NGOs without limit on time or value and the donation was coupled with training, ensuring correct diagnosis, treatment, and management of infections (PfPPP) (Pfizer, 2008)<sup>625</sup>. This unexpected announcement was another victory for South Africa. However, "the actual implementation of this offer would not take place through until the end of 2000" (Trullen et al., 2006, p. 188)<sup>626</sup>. Nevertheless, Pfizer insisted that "the overall program of support showed that the company was playing its part" (Pfizer targeted, July, 2001)<sup>627</sup>. As described below, in mid-2001, the Pfizer's Diflucan donation program was extended to other poor countries suffering from the HIV/AIDS pandemic around the world (PfDona2).

### **(17) The public-private partnership: The Accelerated Access Initiative (AAI)**

On May 10, 2000, one month after Pfizer made its announcement of giving away Diflucan to people with HIV/AIDS in South Africa, the five pharmaceutical companies (i.e. Boehringer Ingelheim, Bristol Myers Squibb, GSK, Hoffman-LaRoche, and Merck)

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<sup>624</sup> Waldholtz, M. (2000, April 30). Pfizer plans to provide Diflucan drug at no cost to South Africans with AIDS. The Wall Street Journal [Electronic Version]. Retrieved November 28, 2008, from <http://www.essentialdrugs.org/edrug/archive/200004/msg00005.php>

<sup>625</sup> Pfizer, (2008). Philanthropy [Electronic Version]. Retrieved November 17, 2008, from <http://www.pfizer.co.za/runtime/popcontentrun.aspx?Pageidref=1632>

<sup>626</sup> Trullen, J., & Stevenson, W. B. (2006). Strategy and Legitimacy: Pharmaceutical Companies' Reaction to HIV Crisis. *Business & Society*, 45, 178-210.

<sup>627</sup> Pfizer targeted on drugs pricing (2001, July 28). Mallenbaker.net [Electronic Version]. Retrieved November 17, 2008, from [http://www.mallenbaker.net/csr/CSRfiles/page.php?Story\\_ID=101](http://www.mallenbaker.net/csr/CSRfiles/page.php?Story_ID=101)



announced their agreement on the preferential pricing policy (AAIpriceCut) for the least developed countries after having talked to Kofi Annan (UNpressPharma) (Trullen et al., 2006)<sup>628</sup>. A plan called the Accelerated Access Initiative (AAI) involved a dialogue between the U.N. and the five pharmaceutical companies with the intention of cutting the price of HIV/AIDS medicines in developing countries (particularly, in the least developed countries). In specific, the AAI was launched, in May 2000, when the five pharmaceutical companies - Abbott Laboratories (AbAAI) and Gilead Sciences (GsAAI) joined later, in 2001 (AbAAIcut) and in 2004 (GsAAIcut), respectively - responded to the calls by the leaders of the several U.N. organizations for a new public-private partnership to expand the global response to the HIV/AIDS epidemic (Sturchio, 2004)<sup>629</sup>. The U.N. organizations in connection with the AAI are the UNAIDS, WHO, UNICEF, UNFPA, and the World Bank. However, Pfizer did not join this initiative stating that it was already donating Diflucan to South Africa, although, at the time, Pfizer had not implemented its announcement yet (Trullen et al., 2006)<sup>630</sup>.

### **(18) The 13th International AIDS Conference in Durban**

In July 2000, the 13th International AIDS Conference was held in Durban, South Africa (“Break the Silence”) (ConDur). It was the first International AIDS Conference held in a developing country and in the very epicenter of the pandemic (“Break the Silence”,

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<sup>628</sup> Trullen, J., & Stevenson, W. B. (2006). Strategy and Legitimacy: Pharmaceutical Companies’ Reaction to HIV Crisis. *Business & Society*, 45, 178-210.

<sup>629</sup> Sturchio, J. L. (2004). Partnership for action: The experience of the Accelerating Access Initiative, 2000-04, and lessons learned. The WHO [Electronic Version]. Retrieved November 28, 2008, from [https://www.who.int/hiv/amds/AAI\\_chapter6.pdf](https://www.who.int/hiv/amds/AAI_chapter6.pdf)

<sup>630</sup> Trullen, J., & Stevenson, W. B. (2006). Strategy and Legitimacy: Pharmaceutical Companies’ Reaction to HIV Crisis. *Business & Society*, 45, 178-210.

2001)<sup>631</sup>. The Durban Conference served as multidisciplinary forum at which issues could be discussed by all those affected by the HIV/AIDS epidemic, such as scientists, international agencies, NGOs, national governments, and the people living with HIV/AIDS (“Break the Silence”, 2001)<sup>632</sup>. Thus, the Durban Conference could heighten the awareness of the global pandemic (PubMedDur). In particular, on the eve of the conference, MSF released a report (“MSF calls for replication and expansion of successful efforts to reduce AIDS drug prices”, 2000)<sup>633</sup> (MSFpress) demonstrating how some developing countries had already significantly reduced the prices of HIV/AIDS medicines. In the report, MSF also suggested the steps to replicate and expand the success of these countries (Médecins Sans Frontières [MSF], 2000)<sup>634</sup>. During the conference, African countries discussed, with the help of the UNAIDS, how they could buy cheap generic HIV/AIDS medicines from countries such as India and Brazil (UaDurPress). The Durban Conference increased the visibility of the HIV/AIDS crisis for the public across the globe. The AIDS Project Los Angeles (“HIV/AIDS facts”)<sup>635</sup> reported the following: “The location of the conference leaves a huge impression on the 12,000 participants who travelled there. It is considered “ground zero” of the epidemic in the year 2000” (“HIV/AIDS facts”)<sup>636</sup>. Trullen et al. (2006)<sup>637</sup> comment that “this increased the pressure on pharmaceutical companies that were negotiating with UNAIDS

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<sup>631</sup> 13th International AIDS Conference (2001). Break the silence [Electronic Version]. Retrieved November 17, 2008, from <http://www.uff.br/dst/revista13-12001/Cap%201%20%20International%20aids%20society.pdf>

<sup>632</sup> Ibid.

<sup>633</sup> Médecins Sans Frontières (2000, July). MSF calls for replication and expansion of successful efforts to reduce AIDS drugs prices [Electronic Version]. Retrieved January 20, 2008, from [http://www.globaltreatmentaccess.org/content/press\\_releases/00/070900\\_MSF\\_PRICE\\_REDUCTION.html](http://www.globaltreatmentaccess.org/content/press_releases/00/070900_MSF_PRICE_REDUCTION.html)

<sup>634</sup> Ibid.

<sup>635</sup> AIDS Project Los Angeles (APLA) (n.d.). HIV/AIDS facts & statistics. Retrieved November 17, 2008, from <http://www.apla.org/facts/timeline.html>

<sup>636</sup> Ibid.

<sup>637</sup> Trullen, J., & Stevenson, W. B. (2006). Strategy and Legitimacy: Pharmaceutical Companies’ Reaction to HIV Crisis. *Business & Society*, 45, 178-210.

during the conference on how to implement the price cuts that they had promised in May under the Accelerating Treatment Initiative” (p. 188).

**(19) The tension between NGOs (Oxfam and MSF) and the multinational pharmaceutical companies (GSK)**

In January 2001, Oxfam published a report – “Dear to lead: Public health and company wealth” - criticizing the large multinational pharmaceutical companies. Especially, GSK was heavily criticized in the report as a market leader of the HIV/AIDS medicines (OxPressGsk) (Oxfam, 2001a)<sup>638</sup>. Furthermore, in February 2001, MSF announced that it reached an agreement with Cipla, and, thus, it would distribute the generic versions of the patented medicines (e.g. the generic version of GSK’s world-leading HIV/AIDS medicine, Combivir<sup>639</sup>) produced by Cipla to African countries at much lower prices than those of the patented medicines produced by the large multinational pharmaceutical companies (MSF, 2001)<sup>640</sup>. The details of the agreement between MSF and Cipla are illustrated in the next case below. The announcement of MSF increased the pressure on GSK and other pharmaceutical companies (MsfPressGsk). It is noted that, by January 2001, only four African countries had reached agreements with the large multinational pharmaceutical companies in conjunction with their offer made by AAI launched in May

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<sup>638</sup> Oxfam (2001a). Dear to lead: Public health and company wealth [Electronic Version]. Retrieved February 1, 2008, from <http://www.oxfam.org.uk/resources/policy/health/index.html>

<sup>639</sup> Among other reasons, Combivir is a world-leading HIV/AIDS drug because it provides a combination of medications in one form. This greatly simplifies the drug regimen of patients that could include 20 pills per day (Dawkins, 2005, p. 275).

<sup>640</sup> Médecins Sans Frontières (2001, February 23). Progress reported on implementation of offer for more affordable anti-AIDS drug [Electronic Version]. Retrieved February 1, 2008, from <http://www.accessmed-msf.org/media-room/press-releases/press-release-detail/article/progress-reported-on-implementation-of-offer-for-more-affordable-anti-aids-drug/>

2000 (Trullen et al., 2006)<sup>641</sup>. In this respect, it can be argued that Oxfam and MSF put more pressure on the pharmaceutical companies, particularly on GSK.

## **(20) The appearance of the generic competition: Cipla**

In February 2001, the first manufacturer of the generic versions of the HIV/AIDS medicines, i.e., Cipla<sup>642</sup>, an Indian generic manufacturer, started to offer unauthorized, generic versions of the HIV/AIDS medicines to African countries at much lower prices than those of the patented drugs produced by the large multinational pharmaceutical companies (GenCipla). In specific, Cipla offered a three-drug anti-AIDS cocktail of stavudrine, lamivudine, and nevirapine for just \$600 to governments and \$350 to MSF, the volunteer doctors who had set up AIDS clinics in sub-Saharan Africa (Harding, 2001)<sup>643</sup>. The offer by Cipla put pressure on the pharmaceutical companies which produced the patented, expensive HIV/AIDS drugs. According to Trullen et al. (2006)<sup>644</sup>, the appearance of the generic competition, triggered by Cipla, increased the pressure on the pharmaceutical companies. Trullen et al. (2006)<sup>645</sup> point out the following:

In our study, pharmaceutical companies both neglected the implementation of price cuts and tried to postpone them as much as possible. Price cuts announced in Durban (DurCut) were delayed and did not start to be implemented until the first generic manufacturer, Cipla, offered its products to these countries at much lower prices more than half a year later

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<sup>641</sup> Trullen, J., & Stevenson, W. B. (2006). Strategy and Legitimacy: Pharmaceutical Companies' Reaction to HIV Crisis. *Business & Society*, 45, 178-210.

<sup>642</sup> Cipla was officially opened in September 1937 when the first products were ready for the market. (<http://www.cipla.com/corporateprofile/history.htm>)

<sup>643</sup> Harding, L. (2001, February 14). Crusading Indian firm takes on might of Glaxo SmithKline. *The Guardian* [Electronic Version]. Retrieved November 28, 2008, from <http://www.guardian.co.uk/world/2001/feb/14/sarahboseley.lukeharding>

<sup>644</sup> Trullen, J., & Stevenson, W. B. (2006). Strategy and Legitimacy: Pharmaceutical Companies' Reaction to HIV Crisis. *Business & Society*, 45, 178-210.

<sup>645</sup> Ibid.

(CiplaPressDur). A similar situation happened with Pfizer. The company announced the giveaway program of Diflucan in South Africa early in April 2000 but did not start implementing it until the end of the year. This action allowed Pfizer to justify its exclusion from the Accelerating Treatment Initiative in May. (p. 203)

## **(21) The extensive price reductions by the pharmaceutical companies**

As described in the two previous cases (case 19 and 20), the multinational pharmaceutical companies, from the beginning of 2001, had been pressed by NGOs, such as Oxfam and MSF, and by the generic manufacturer, Cipla. Finally, in February 2001, the multinational pharmaceutical companies - GSK, Bristol Myers Squibb, Merck, and Abbott Laboratories - announced the extensive price reductions of their HIV/AIDS medicines (ExtCut), to varying degrees, that would have influence on developing countries, particularly on the least developed countries (Trullen et al., 2006<sup>646</sup>; Zimmerman, Waldholz, & Schoofs, 2001<sup>647</sup>). Among the factors that forced the pharmaceutical companies to cut the prices, the generic competition is worth reviewing in detail. As illustrated above, in February 2001, Cipla offered to supply a triple-therapy AIDS drug cocktail for \$350 per year to MSF. Another Indian generic drug producer, Hetero Drugs Ltd. (HdlGenPress), also offered the same cocktail for \$347 per year to MSF. Particularly, Cipla aggressively targeted the African market by offering medicines at much lower prices than those of the U.S. and European pharmaceutical companies. For instance, Cipla offered a triple-therapy AIDS drug cocktail to African countries for about

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<sup>646</sup> Trullen, J., & Stevenson, W. B. (2006). Strategy and Legitimacy: Pharmaceutical Companies' Reaction to HIV Crisis. *Business & Society*, 45, 178-210.

<sup>647</sup> Zimmerman, R., Waldholz, M., & Schoofs, M. (2001). Abbott to cut prices African AIDS drugs prices [Electronic Version]. *The Wall Street Journal*. Retrieved February 1, 2008, from <http://www.aegis.com/news/ads/2001/AD010460.html>

\$600 per year (Miller & Goldman, 2003)<sup>648</sup>. Although the pharmaceutical companies argued that the medicines offered by generic producers violated the patents on the original drugs (Miller & Goldman, 2003)<sup>649</sup>, the companies, such as Bristol Myers Squibb, Merck, Abbott Laboratories, and GSK, announced the extensive price reductions of their HIV/AIDS medicines.

## **(22) The U.S.'s complaint to the WTO against Brazil**

As illustrated earlier (in the case 9) encouraged strongly by the pharmaceutical industry (mainly led by the PhRMA), the U.S. cited Brazil as a potential target of trade sanctions in Super 301 case. The U.S. concerned that Brazil was abusing (or could abuse) the exceptions represented in the TRIPS Agreement. In specific, as described above, the patent law of Brazil, specifically, Article 68, Section 689 of the Industrial Patent Law, passed in 1996, proposes the local production of the patented medicines within three years of the patent approval. The patent law also proposes that in case the patent holder does not comply, the Brazilian government is entitled to override the patent and allow third-party manufacturing of the product. In addition, for many years, the state-run factories in Brazil were producing the generic versions of the HIV/AIDS medicines patented before 1996. Thus, finally, in February 2001, the U.S. initiated a complaint to the WTO against Brazil (USwtoBraz). It is noted that the complaint to the WTO was also initiated at the request of the pharmaceutical companies to gain a ruling against the

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<sup>648</sup> Miller, C., & Goldman, K. (2003). Merck, AIDS, and Africa. New York University [Electronic Version]. Retrieved September 25, 2008, from <http://pages.stern.nyu.edu/~lcabral/teaching/aids.pdf>

<sup>649</sup> Ibid.

Brazilian patent law<sup>650</sup>. As a result, the U.S. took Brazil to the disciplinary tribunal of the WTO for the patent infringement (USwtoBraz). The Brazil's ambassador to the WTO announced that the legislation of Brazil was fully consistent with the TRIPS agreement and the U.S.'s action amounted to a demand for commitments which went beyond the agreement through resorting to the dispute settlement procedures (BrazOppUS) (Zarocostas, 2001)<sup>651</sup>.

### **(23) The lawsuit against South Africa by the multinational pharmaceutical companies**

In March 2001, the 39 leading multinational pharmaceutical companies, led by the Pharmaceutical Research and Manufacturers of America (PhRMA), challenged (PhRMA-SA) the South African patent law (i.e. the Medicines and Related Substances Act) that allowed the South African government to produce or import cheap, generic medicines for HIV/AIDS and other diseases. The pharmaceutical companies objected to the several provisions included in the Act and filed a lawsuit to block the legislation. The companies claimed that the Act was unconstitutional and it violated the South Africa's commitments under the TRIPS Agreement<sup>652</sup>. It is noted that "GSK<sup>653</sup> was at the forefront of the

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<sup>650</sup> Trullen, J., & Stevenson, W. B. (2006). Strategy and Legitimacy: Pharmaceutical Companies' Reaction to HIV Crisis. *Business & Society*, 45, 178-210.

<sup>651</sup> Zarocostas, J. (2001, February 1). U.S., Brazil in dispute on AIDS drug patent at WTO. *UPI Science News* [Electronic Version]. Retrieved November 28, 2008, from <http://www.aegis.org/news/UPI/2001/UP010201.html>

<sup>652</sup> MSF Activity Report 2001 (2001). South Africa: Big pharma backs down [Electronic Version]. Retrieved November 29, 2008, from <http://www.doctorswithoutborders.org/publications/ar/i2001/bigpharma.cfm>

<sup>653</sup> Trullen et al (2006) describe that "A study by Attaran and Gillespie-White (2001) shows GSK to be far more aggressive in patenting its AIDS drugs in African countries than were competitors; GSK held 66% of all patents for AIDS drugs in 53 African countries" (p. 131).

controversial lawsuit” (Kennedy et al., 2004)<sup>654</sup>. The lawsuit against the South African government prompted public outrage against the pharmaceutical industry worldwide, and, in contrast, the support for the South African government poured in (MSF Activity Report 2001, 2001)<sup>655</sup>. The public protesters focused on the access to ARV treatment. When the case went to the court in Pretoria, South Africa, MSF launched an international petition calling on the companies to drop the case. Nearly 300,000 people from over 130 countries signed the petition, and other organizations joined in as well (MSF Activity Report 2001, 2001)<sup>656</sup>. This court case became a public affairs disaster to the pharmaceutical industry (NgoActSA). Trullen et al. (2006)<sup>657</sup> describe the whole affair as follows:

Activists, advocates, and labor federations demanded the pharmaceutical industry drop the lawsuit against the South African government over the Medicines Act and asked President Bush to publicly repudiate the lawsuit against South Africa’s Medicines Act and state support for South Africa’s right to use legal measures to ensure access to affordable medication. (p. 189)

#### **(24) The withdrawal of the lawsuit against South Africa**

During a meeting with CEOs of the major multinational pharmaceutical companies in April 2001, Kofi Annan backed the need of patent regulation claimed by the pharmaceutical companies, while, in return, the companies promised to make an effort to

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<sup>654</sup> Kennedy, C. R., Harris, F. H., & Lord, M. (2004). Integrating public policy and public affairs in a pharmaceutical marketing program: The AIDS pandemic. *Journal of Public Policy and Marketing*, 23, 128-139.

<sup>655</sup> MSF Activity Report 2001 (2001). South Africa: Big pharma backs down [Electronic Version]. Retrieved November 29, 2008, from

<http://www.doctorswithoutborders.org/publications/ar/i2001/bigpharma.cfm>

<sup>656</sup> Ibid.

<sup>657</sup> Trullen, J., & Stevenson, W. B. (2006). Strategy and Legitimacy: Pharmaceutical Companies’ Reaction to HIV Crisis. *Business & Society*, 45, 178-210.



help the countries suffering from HIV/AIDS (UNsupSA) (Freedman, 2001)<sup>658</sup>. Through an out of court settlement, the pharmaceutical companies dropped the lawsuit against South Africa (PharDropSA) and the South African government promised to apply the Medicines and Related Substances Act in ways that were consistent with the international agreements on intellectual property conventions (Kennedy et al., 2004)<sup>659</sup>. It is noted that, before the pharmaceutical industry dropped the court challenge, “the U.S. government and the European Union had given their public support to the South African government” (UsEuSupSA) (Trullen et al, 2006, P. 189). In the case of the European Union, the European Parliament passed a resolution urging the pharmaceutical companies to drop the case, a position backed by the ministers from a number of European governments (MSF Activity Report 2001, 2001)<sup>660</sup>. It is noted that the powerful combination of the public pressure (PubMedSA), the pressure from the international organization, legal arguments, and the supports for South Africa from the U.S. and the E.U. forced the pharmaceutical companies to drop the case unconditionally.

## **(25) The bilateral agreement between the U.S. and Brazil**

In June 2001, on the eve of the U.N. Special Session on HIV/AIDS (“Global Crisis - Global Action”)<sup>661</sup> (UNpressUS-Braz), the U.S. and Brazil announced a decision to resolve the dispute at the WTO through bilateral negotiations (USnegoBRAZ). In other

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<sup>658</sup> Freedman, A. M. (2001, April 6). Annan gains pledges from drug makers – Patent protection affirmed on AIDS medications for price cuts to poor. *The Wall Street Journal*, p. A2.

<sup>659</sup> Kennedy, C. R., Harris, F. H., & Lord, M. (2004). Integrating public policy and public affairs in a pharmaceutical marketing program: The AIDS pandemic. *Journal of Public Policy and Marketing*, 23, 128-139.

<sup>660</sup> MSF Activity Report 2001 (2001). South Africa: Big pharma backs down [Electronic Version]. Retrieved November 29, 2008, from

<http://www.doctorswithoutborders.org/publications/ar/i2001/bigpharma.cfm>

<sup>661</sup> United Nations Special Session on HIV/AIDS (2001, June). Global Crisis – Global Action [Electronic Version]. Retrieved November 20, 2008, from <http://www.un.org/ga/aids/conference.html>

words, the two countries announced that they decided to use the newly created ‘U.S.-Brazil Consultative Mechanism’ (Kennedy et al., 2004; Tren & Bate, 2006)<sup>662</sup>. As illustrated earlier, when the U.S. government took Brazil to the disciplinary tribunal of the WTO for the patent infringement, the Brazilian government argued that the legislation of Brazil was fully consistent with the TRIPS agreement, and, thus, the U.S. was demanding commitments which went beyond the TRIPS agreement (Zarocostas, 2001)<sup>663</sup>. Moreover, NGOs and activist groups started to criticize the U.S. government in connection with the dispute at the WTO against Brazil. For instance, MSF urged the U.S. government to drop its request, asserting that it threatened the Brazil’s policy in the fight against HIV/AIDS that could provide treatments to hundreds of thousands of people with HIV/AIDS (“US complaint against Brazil”, 2001)<sup>664</sup>. In a statement of support for Brazil, MSF further criticized the U.S. for opposing Brazil’s system for granting compulsory licenses, a government’s right to override patents in certain circumstances (Zarocostas, 2001)<sup>665</sup>. It is clear that the U.S. was under the severe public pressure. To deal with the public relations disaster, the U.S. had to bow the global campaigns against the costs of essential, life-saving medicines, such as an NGO signature campaign launched by MSF,

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<sup>662</sup> Kennedy, C. R., Harris, F. H., & Lord, M. (2004). Integrating public policy and public affairs in a pharmaceutical marketing program: The AIDS pandemic. *Journal of Public Policy and Marketing*, 23, 128-139.

<sup>663</sup> Zarocostas, J. (2001, February 1). U.S., Brazil in dispute on AIDS drug patent at WTO. UPI Science News [Electronic Version]. Retrieved November 28, 2008, from <http://www.aegis.org/news/UPI/2001/UP010201.html>

<sup>664</sup> WTO to examine US complaint against Brazil generic AIDS drugs (2001, February 1). Agence France Press [Electronic Version]. Retrieved October 10, 2008, from <http://www.aegis.com/news/ads/2001/AD010185.html>

<sup>665</sup> Zarocostas, J. (2001, February 1). U.S., Brazil in dispute on AIDS drug patent at WTO. UPI Science News [Electronic Version]. Retrieved November 28, 2008, from <http://www.aegis.org/news/UPI/2001/UP010201.html>

Oxfam, and the Third World Network (Raghavan, 2001)<sup>666</sup>. Leading civil society organizations that had been campaigning on the issue of the TRIPS Agreement, and the public health and the affordable, life-saving medicines increased the pressure against the U.S. government (NgoActPubMedBraz) (Raghavan, 2001)<sup>667</sup>. MSF welcomed the U.S.'s decision suggesting that other developing countries could follow the example of the successful Brazilian policy that had cut the prices of the HIV/AIDS medicines by about 80% (Raghavan, 2001)<sup>668</sup>. Oxfam also welcomed the U.S.'s decision commenting that this would help other developing countries to stand up against the U.S. government and the multinational pharmaceutical companies (Raghavan, 2001)<sup>669</sup>. It is interesting to note that, although Brazil agreed, through the bilateral negotiations, to consult with the U.S. before taking actions under the 1996 patent law, Brazil has continued to apply its patent law aggressively to force the major pharmaceutical companies to cut the prices of HIV/AIDS medicines.

## **(26) The creation of the Global Fund to Fight AIDS, Tuberculosis, and Malaria**

The Global Fund to Fight AIDS, Tuberculosis, and Malaria is an independent public-private partnership that was first proposed by the then U.N. Secretary General Kofi Annan in 2001, and officially came into being, with the support of the U.S. government in January 2002 (USsupGF) ("The Global Fund to Fight AIDS, Tuberculosis, and

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<sup>666</sup> Raghavan, C. (2001, June 25). US beats a (tactical) retreat over Brazil's patent law. Third World Network [Electronic Version]. Retrieved October 10, 2008, from <http://www.twinside.org.sg/title/tactical.htm>

<sup>667</sup> Ibid.

<sup>668</sup> Ibid.

<sup>669</sup> Ibid.

Malaria”)<sup>670</sup>. As Trullen et al. (2006)<sup>671</sup> comment, taking the advantage of the controversy created by the South African lawsuit, the U.N. created the Global Fund (UnSaGf). The objectives of the Global Fund is to raise funds and pool money from governments, businesses, and individuals around the world, and channel them into the grant programs to fight AIDS, Tuberculosis, and Malaria. The Global Fund is managed by 23 board members and they include the representatives from the G-8 governments, the WHO, the World Bank, the UNAIDS, and NGOs such as the Bill and Melinda Gates Foundation (Kennedy et al., 2004)<sup>672</sup>. It is noted that how the Global Fund would be government and operated was one of the major concerns, particularly in connection with the pharmaceutical companies. NGOs and activists argued that the participation of the multinational pharmaceutical companies in the governing body of the Global Fund would create an irresolvable, structural conflict of interest (Mokhiber et al., 2001)<sup>673</sup>. In contrast, they pressed the pharmaceutical companies to issue licenses for their medicines to the WHO, which could then contract with the generic manufacturers to provide cheap medicines in the developing world through the Global Fund (GFvIPress) (Mokhiber et al., 2001)<sup>674</sup>.

## **(27) The tension between NGOs and Pfizer**

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<sup>670</sup> AVERT (n.d.). The Global Fund to Fight AIDS, Tuberculosis, and Malaria [Electronic Version]. Retrieved October 10, 2008, from <http://www.avert.org/global-fund.htm>

<sup>671</sup> Trullen, J., & Stevenson, W. B. (2006). Strategy and Legitimacy: Pharmaceutical Companies' Reaction to HIV Crisis. *Business & Society*, 45, 178-210.

<sup>672</sup> Kennedy, C. R., Harris, F. H., & Lord, M. (2004). Integrating public policy and public affairs in a pharmaceutical marketing program: The AIDS pandemic. *Journal of Public Policy and Marketing*, 23, 128-139.

<sup>673</sup> Mokhiber, R. & Weissman, R. (2001, May 11). Big pharma and global response to HIV/AIDS. *CommonDreams.org* [Electronic Version]. Retrieved November 11, 2008, from <http://www.commondreams.org/views01/0511-01.htm>

<sup>674</sup> Ibid.

In 2001, Pfizer, pushed by the creation of the Global Fund (GFpressPf) as well as pressured by a report published by Oxfam (Oxfam, 2001b)<sup>675</sup> (OxpressPf), announced its intention to extend Diflucan donation program to 50 of the poorest countries encompassing all African countries (Trullen et al., 2006)<sup>676</sup>. Pfizer also announced that there was no time or money limit for the extended Diflucan donation program (“Pfizer statement”, 2001)<sup>677</sup>. Before Pfizer announced the extended Diflucan donation program, Oxfam and the South African HIV/AIDS groups had called for global action against Pfizer on the grounds of its pricing policies (NgoActPressPf). Oxfam, in particular, accused Pfizer of ‘moral bankruptcy’ for pricing medicines out of the reach of millions of poor patients (“Pfizer targeted”, July, 2001)<sup>678</sup>. In 2001, Oxfam released a report, “Formula for fairness: Patients before patent rights” (Oxfam, 2001b)<sup>679</sup>. In the report, Oxfam contended that Pfizer’s protection of its patent rights had been aggressive and had had the effect of forcing prices up. Oxfam also argued that, unlike some of its competitors, Pfizer had not cut the price of its branded medicines in the developing world. In particular, Oxfam criticized that the donation scheme that Pfizer had offered could be characterized as ad hoc, reversible, and limited (“Pfizer targeted”, July, 2001)<sup>680</sup>.

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<sup>675</sup> Oxfam (2001b). Formula for fairness: Patient rights before patent rights [Electronic Version]. Retrieved February 1, 2008, from

[http://www.oxfamamerica.org/newsandpublications/publications/briefing\\_papers/art793.html](http://www.oxfamamerica.org/newsandpublications/publications/briefing_papers/art793.html)

<sup>676</sup> Trullen, J., & Stevenson, W. B. (2006). Strategy and Legitimacy: Pharmaceutical Companies’ Reaction to HIV Crisis. *Business & Society*, 45, 178-210.

<sup>677</sup> Pfizer statement on Oxfam report (2001, July). Retrieved November 30, 2008 from <http://www.pfizer.ca/english/newsroom/press%20releases/default.asp?s=1&year=2001&releaseID=59>

<sup>678</sup> Pfizer targeted on drugs pricing (2001, July 28). *Mallenbaker.net* [Electronic Version]. Retrieved November 17, 2008, from [http://www.mallenbaker.net/csr/CSRfiles/page.php?Story\\_ID=101](http://www.mallenbaker.net/csr/CSRfiles/page.php?Story_ID=101)

<sup>679</sup> Oxfam (2001b). Formula for fairness: Patient rights before patent rights [Electronic Version]. Retrieved February 1, 2008, from

[http://www.oxfamamerica.org/newsandpublications/publications/briefing\\_papers/art793.html](http://www.oxfamamerica.org/newsandpublications/publications/briefing_papers/art793.html)

<sup>680</sup> Pfizer targeted on drugs pricing (2001, July 28). *Mallenbaker.net* [Electronic Version]. Retrieved November 17, 2008, from [http://www.mallenbaker.net/csr/CSRfiles/page.php?Story\\_ID=101](http://www.mallenbaker.net/csr/CSRfiles/page.php?Story_ID=101)

## **(28) Voluntary licensing: GSK and Bristol Meyers Squibb**

In 2001, both GSK and Bristol-Myers Squibb decided, for the first time, to allow a generic manufacture to use their patents, that is, the two companies granted voluntary licenses to a generic manufacturer in South Africa (Trullen et al., 2006)<sup>681</sup>. In specific, Bristol Meyers Squibb licensed a South African laboratory, Aspen Pharmacare, the largest generic producer in South Africa, to make the cheaper generic copies of its HIV/AIDS medicines for the sale in sub-Saharan Africa (BmsVL). The license to Aspen Pharmacare covered Bristol Meyers Squibb's Videx and Zerit drugs and was valid for the next five years. The company did not receive royalties from the deal ("Pfizer targeted", July, 2001)<sup>682</sup>. GSK also granted a voluntary license to Aspen Pharmacare (GskVL), allowing it to use the GSK's patents on two ARVs, AZT and 3TC, and a third pill, Combivir, which combines the two ARVs. GSK and another British company, the Shire Pharmaceuticals Group, which licensed 3TC to GSK decided to waive their rights to royalties on sale. Aspen Pharmacare, in turn, promised to pay 30% of net sales to NGOs fighting HIV/AIDS in Africa ("GlaxoSmithKline gives", 2001)<sup>683</sup>. It is highly noted that, before the two companies granted voluntary licenses to Aspen Pharmacare, Cipla had asked the South African government to issue a compulsory license, offering a triple-therapy drug cocktail for about \$600 (CiplaOffSA) (Swarns, 2001)<sup>684</sup>. In fact, NGOs and

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<sup>681</sup> Trullen, J., & Stevenson, W. B. (2006). Strategy and Legitimacy: Pharmaceutical Companies' Reaction to HIV Crisis. *Business & Society*, 45, 178-210.

<sup>682</sup> Pfizer targeted on drugs pricing (2001, July 28). *Mallenbaker.net* [Electronic Version]. Retrieved November 17, 2008, from [http://www.mallenbaker.net/csr/CSRfiles/page.php?Story\\_ID=101](http://www.mallenbaker.net/csr/CSRfiles/page.php?Story_ID=101)

<sup>683</sup> GlaxoSmithKline gives AIDS drug rights to generic maker (2001, October 9). *The New York Times* [Electronic Version]. Retrieved October 10, 2008, from <http://query.nytimes.com/gst/fullpage.html?res=9C03E3DF113CF93AA35753C1A9679C8B63>

<sup>684</sup> Swarns, R. (2001, March 8). AIDS drug battle defense in Africa. *The New York Times* [Electronic Version]. Retrieved September 15, 2008, from <http://query.nytimes.com/gst/fullpage.html?res=9B06E3DC163AF93BA35750C0A9679C8B63&sec=&spn=&pagewanted=all>

activist groups expected Aspen Pharmacare to cut the deals with the multinational pharmaceutical companies because they assumed that the big pharmaceutical companies would try to undermine Cipla's compulsory licensing offer or a parallel patient-led compulsory licensing effort that was in the works in South Africa (NgoActSupCL) (Swarns, 2001)<sup>685</sup>. Some critics also argued that GSK and Bristol Meyers Squibb had granted voluntary licenses to Aspen Pharmacare tactically. In other words, the companies chose the voluntary licensing rather than selling their own medicines at highly discounted prices to avoid the risk of parallel export which could spoil their profitable the U.S. and European market, while, at the same time, to avoid the issuance of a compulsory license by the South African government and the pressure from NGOs and activists ("GSK licenses", 2001)<sup>686</sup>. Although the two companies had licensed their HIV/AIDS medicines to a generic manufacture in South Africa in an attempt to defuse the dispute over the access to HIV/AIDS drugs (SApubPress), the companies were still criticized in the fact that the cost was still significantly higher than that of Cipla (Dawkins, 2005)<sup>687</sup>. Nevertheless, it is noted that "some companies, such as GlaxoSmithKline and Bristol-Myers-Squibb, have entered into the voluntary license agreements that allow generic drug companies to produce copies of their patented drugs" (Calfee et al, 2004, p. 147)<sup>688</sup>.

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<sup>685</sup> Swarns, R. (2001, March 8). AIDS drug battle defense in Africa. The New York Times [Electronic Version]. Retrieved September 15, 2008, from <http://query.nytimes.com/gst/fullpage.html?res=9B06E3DC163AF93BA35750C0A9679C8B63&sec=&spoon=&pagewanted=all>

<sup>686</sup> GSK licenses ARVs to South African generic manufacturer (2001, October, 8). ESSENTIALDRUGS.ORG. Retrieved November 30, 2008, from <http://www.essentialdrugs.org/edrug/archive/200110/msg00023.php>

<sup>687</sup> Dawkins, C. E. (2005). First to Market: Issue Management Pacesetters and the Pharmaceutical Industry Response to AIDS in Africa. *Business & Society*, 44, 244-282.

<sup>688</sup> Calfee, J. E., & Bate, R. (2004). Pharmaceuticals and the Worldwide HIV Epidemic: Can a Stakeholder Model Work? *Journal of Public Policy & Marketing*, 23, 140-152.

### **(29) The Anthrax crisis and the price reduction by Bayer**

In October 2001, the Bush administration announced that “it had won a major price concession from Bayer A. G. for its anthrax medicine, Cipro (BayCut), after the administration threatened to buy generic alternatives instead” (Bradsher & Andrews, October, 2001)<sup>689</sup> That is, in 2001, Bayer, the patent holder of Cipro (the anthrax antibiotic medicine) agreed with the U.S. government to reduce the price of Cipro in the U.S. by 95%. This price reduction applied only to the sales to the U.S. government, not to the sales to the public. Bayer also announced that no other companies in the U.S. would produce Cipro and, also, no other companies import Cipro into the U.S. (“2001 Anthrax attacks”, 2001)<sup>690</sup>. It is highly noted that the agreement, between the U.S. government and Bayer, was reached in conjunction with some important incidents. First, Bayer and the U.S. government reached the deal after the Secretary of Health and Human Services publicly demanded that Bayer should match the price of Cipro charged by the manufacturers of the generic alternatives. The Bush administration needed huge supplies of the expensive Cipro during the 2001 anthrax crisis and it threatened to override the Bayer’s patent for Cipro if the company did not cut its price. Namely, the U.S. government threatened Bayer with compulsory licensing to obtain huge price cuts (USpressBay). The U.S. government could import large quantities of the inexpensive, generic versions of the patented Cipro from generic manufacturers. Second, right before the deal was made, the Canadian Health Ministry had overridden the Bayer’s patent for

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<sup>689</sup> Bradsher, K. & Andrews, E. (2001, October, 24). A nation challenged: Cipro; U.S. says Bayer will cut cost of its Anthrax drug. The New York Times [Electronic Version]. Retrieved November 17, 2008, from <http://query.nytimes.com/gst/fullpage.html?res=9D03E1D71431F937A15753C1A9679C8B63>

<sup>690</sup> 2001 Anthrax attacks (2001). History Commons [Electronic Version]. Retrieved November 17, 2008, from [http://www.historycommons.org/timeline.jsp?anthraxattacks\\_other=anthraxattacks\\_cipro\\_\\_\\_bayer&timeline=anthraxattacks](http://www.historycommons.org/timeline.jsp?anthraxattacks_other=anthraxattacks_cipro___bayer&timeline=anthraxattacks)



Cipro (CApressBay) and ordered a million tablets of a generic version from a Canadian company (“2001 Anthrax attacks”, 2001)<sup>691</sup>. Third, when the anthrax crisis happened, three drug manufacturers (i.e. Bristol Meyers Squibb, GSK, and Johnson and Johnson) announced that they could supply large quantities of their antibiotics free for the U.S. government to treat the anthrax crisis. In addition, Eli Lilly and Pfizer offered to provide their antibiotics at cost (ComptPressBay) (Charatan, November, 2001)<sup>692</sup>. Lastly, although Bayer had announced its intention to cut the price of Cipro in the U.S., a class action suit by over one million Americans was filed against Bayer (and two other companies) alleging that Bayer had paid \$200 million to two competitors to make them not to produce the generic versions of Cipro (LegPressBay) (“2001 Anthrax attacks”, 2001)<sup>693</sup>.

### **(30) The tension between AIDS Healthcare Foundation (AHF) and GSK**

In 2002, GSK faced a “Glaxo: Do the Right Thing” corporate campaign, a “Black Christmas” hunger strike to call attention to its pricing policies in South Africa (CampPressGsk) (Dawkins, 2005)<sup>694</sup>. Furthermore, GSK faced a legal action by the AIDS Healthcare Foundation (AHF), the largest AIDS organization in the U.S. (LegPressGsk1). The AIDS Hospice Foundation was founded in 1987 based on Los

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<sup>691</sup> 2001 Anthrax attacks (2001). History Commons [Electronic Version]. Retrieved November 17, 2008, from [http://www.historycommons.org/timeline.jsp?anthraxattacks\\_other=anthraxattacks\\_cipro\\_\\_\\_bayer&timelin e=anthraxattacks](http://www.historycommons.org/timeline.jsp?anthraxattacks_other=anthraxattacks_cipro___bayer&timelin e=anthraxattacks)

<sup>692</sup> Charatan, F. (2001, November 3). Bayer cuts price of ciprofloxacin after Bush threatens to buy generics. BMJ [Electronic Version]. Retrieved November 17, 2008, from <http://www.bmj.com/cgi/content/full/323/7320/1023>

<sup>693</sup> 2001 Anthrax attacks (2001). History Commons [Electronic Version]. Retrieved November 17, 2008, from [http://www.historycommons.org/timeline.jsp?anthraxattacks\\_other=anthraxattacks\\_cipro\\_\\_\\_bayer&timelin e=anthraxattacks](http://www.historycommons.org/timeline.jsp?anthraxattacks_other=anthraxattacks_cipro___bayer&timelin e=anthraxattacks)

<sup>694</sup> Dawkins, C. E. (2005). First to Market: Issue Management Pacesetters and the Pharmaceutical Industry Response to AIDS in Africa. *Business & Society*, 44, 244-282.

Angeles by a small group of grassroots activists who committed themselves to “fight for the living and care for the dying” (The AIDS Healthcare Foundation)<sup>695</sup>, and, later, in 1990, the AIDS Hospice Foundation officially changed its name to the AIDS Healthcare Foundation (AHF). According to Dawkins (2005)<sup>696</sup>, the AHF alleged that Azidothymidine, the HIV/AIDS medicine marketed under the name of Zidovudine or Retrovir, was originally developed by the National Institutes of Health with public funding as a possible cancer drug, and, then, shown to be effective against HIV/AIDS by the scientists at the National Institutes of Health in the mid-1990s. As a result, although it did not happen, in December 2002, at the WTO meeting, the pharmaceutical industry was prepared to permit the production of generic version of this HIV/AIDS medicine (WTOpress). However, Dawkins (2005)<sup>697</sup> argues that “the American pharmaceutical companies effectively lobbied the George W. Bush administration to block the agreements” (p. 265). That is, in January 2003, the Bush administration announced the Emergency Plan for AIDS Relief (PEPFAR), a 5 year, \$15 billion initiative, to treat and prevent HIV/AIDS in developing countries (Pepf). Consequently, as Dawkins (2005)<sup>698</sup> points out, the lawsuit filed by the AHF against GSK was dismissed in March, 2003<sup>699</sup> (AHFmiss).

### **(31) Voluntary licensing: Pharmacia**

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<sup>695</sup> The AIDS Healthcare Foundation Web-site,

[http://www.aidshealth.org/index.php?option=com\\_content&task=view&id=713&Itemid=264](http://www.aidshealth.org/index.php?option=com_content&task=view&id=713&Itemid=264)

<sup>696</sup> Dawkins, C. E. (2005). First to Market: Issue Management Pacesetters and the Pharmaceutical Industry Response to AIDS in Africa. *Business & Society*, 44, 244-282.

<sup>697</sup> Ibid.

<sup>698</sup> Ibid.

<sup>699</sup> The case was initially dismissed “without prejudice”, which allowed the AHF to amend and re-file its motion. The AHF re-filed the case in late spring of 2003.

In January 2003, Pharmacia<sup>700</sup> licensed its HIV/AIDS drug, Delavirdine, to the nonprofit organization, i.e., the International Dispensary Association of the Netherlands (PhaVL). In turn, the International Dispensary Association of the Netherlands would line up generic manufacturers to produce the medicines for the use in developing countries. Dawkins (2005)<sup>701</sup> contends that the then CEO of Pharmacia, Fred Hassan, who perceived the merits of the continuing debate about patents on pharmaceutical products in a different manner in comparison with his contemporaries, contributed to the voluntary licensing decision of Pharmacia. It can be argued that, to the extent that urgency of action is indicative of moral sensitivity, Hassan's emphasis on making things happen demonstrated a sense of urgency about humanitarian crisis that seemed to be lacking in the pharmaceutical industry at large. However, it is also noted that, although Pharmacia was one of the industry leaders at the time (the company was ranked as 9th in the global therapeutic sales in 2001), it was not heavily invested in HIV/AIDS research (Dawkins, 2005)<sup>702</sup>. In this respect, Love (2003)<sup>703</sup> argues the following:

Today's announcement from Pharmacia is not so much about providing treatment as it is a proposal for managing patents on essential medicines. This is mostly about the future of the intellectual property regime in developing countries. Pharmacia is saying, with an example of an AIDS drug that almost no one uses, that AIDS drug should be licensed on a non-exclusive basis to generic firms, for the poorest countries, or those with high infection rate...The cost of this announcement to Pharmacia will be next to nothing, since the drug is not likely to be used in any case. But Glaxo will have to respond, as will every company with an AIDS product. (p. 1)

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<sup>700</sup> Pharmacia was purchased by Pfizer in April 2003.

<sup>701</sup> Dawkins, C. E. (2005). First to Market: Issue Management Pacesetters and the Pharmaceutical Industry Response to AIDS in Africa. *Business & Society*, 44, 244-282.

<sup>702</sup> Ibid.

<sup>703</sup> Love, J. (2003, January). CPTech statement on Pharmacia voluntary license for Delavirdine [Electronic Version]. Retrieved March, 2008, from <http://www.cptech.org/ip/health/aids/cptech01242003.html>

Therefore, it may be argued that, in the short-term, the voluntary licensing decision of Pharmacia could improve the stakeholder perception on the company's social responsibility without having a negative impact on its competitiveness within the pharmaceutical industry. However, as Love (2003)<sup>704</sup> criticizes above, in the long-term, Pharmacia could be hurt in the stakeholder management terms because of its symbolic, not substantial, tactic.

### **(32) The heightened attention and pressure: Roche**

As Dawkins (2005)<sup>705</sup> points out, the voluntary licensing decision of Pharmacia placed a great deal of pressure on its competitors within the pharmaceutical industry because of the company's leading role in the industry at the time. Dawkins (2005)<sup>706</sup> argues that "the Pharmacia initiative could now become the basis of similar requests to other companies" (p. 267). In February 2003, Roche cut the price of its HIV/AIDS medicine (i.e. Viracept) for sub-Saharan Africa and the least developed countries elsewhere (RochCut1), following the pressure by humanitarian groups (ActPressRoche). The company announced that it was going to offer no profit price for the medicine from its Swiss factory, starting March 1, 2003. Roche also announced that it cut the price of Invirase (RochCut2), another protease inhibitor, a medicine that cripples an enzyme the HIV virus needs to reproduce. Although MSF welcomed the announcement of Roche, it commented as follows:

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<sup>704</sup> Love, J. (2003, January). CPTech statement on Pharmacia voluntary license for Delavirdine [Electronic Version]. Retrieved March, 2008, from <http://www.cptech.org/ip/health/aids/cptech01242003.html>

<sup>705</sup> Dawkins, C. E. (2005). First to Market: Issue Management Pacesetters and the Pharmaceutical Industry Response to AIDS in Africa. *Business & Society*, 44, 244-282.

<sup>706</sup> Ibid.

...it had been putting pressure on Roche for some time...the long struggle to reduce the price of this Roche drug is proof of the limitations of a fully voluntary system. For new drugs there needs to be an internationally supported enforceable system that reduces prices to affordable levels in developing countries. (“Roche cuts prices of its AIDS drug to poor countries”, 2003)<sup>707</sup>

In essence, from April 2002, Médecins Sans Frontières (MSF) had been urging Roche to reduce the price for Viracept, a crucial second-line HIV/AIDS drug that was priced out of reach of most patients in the developing world. The price cut for Viracept by Roche could be seen a result of the long campaign that had been implement by MSF (MSFpressRoch). In the “Bowling to Pressure” (2003)<sup>708</sup>, MSF argues that the generic competition remains the most effective means to push prices down. However, for newer drugs, for which no generic equivalents are available, a system of affordable price from the originator companies is critical (“Bowling to Pressure”, 2003)<sup>709</sup>. It is noted that Roche had been under a lot of pressure from NGOs and activist groups because the company had pursued more defensive price reduction policy than that of the others. For instance, although Roche signed the AAI in 2000, it had been less active than the rest of the companies in carrying out what it signed. Specifically, MSF reported in the “Bowling to Pressure” (2003)<sup>710</sup> that “while other AIDS drug producers taking part in the UN Accelerating Access Initiative had long ago set up a differential pricing system for poor countries and were offering drugs at 87-92% off Swiss prices, Roche was only offering a 40-50%

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<sup>707</sup> Roche cuts prices of its AIDS drug to poor countries (2003, February, 13). The Associate Press [Electronic Version]. Retrieved March, 2008, from <http://www.aegis.com/news/ap/2003/AP030200.html>

<sup>708</sup> Bowing to pressure, Roche cuts its price for AIDS drug nelfinavir. (2003, February 13). Medecins Sans Frontieres, Retrieved November 10, 2008, from [http://www.msf.ca/press/2003/pr\\_030213\\_roche.htm](http://www.msf.ca/press/2003/pr_030213_roche.htm)

<sup>709</sup> Ibid.

<sup>710</sup> Ibid.

discount". As Trullen et al (2006)<sup>711</sup> argue, since the actions of NGOs (and activist groups) are aimed at not only the companies which are central players within the pharmaceutical industry (e.g. GlaxoSmithKline) but also the companies which are more defensive in terms of the price reductions (e.g. Roche and Pfizer), Roche had been under a lot of pressure from NGOs and activist groups.

### **(33) The heightened attention and pressure: GSK**

Particularly after the South African lawsuit, the reputational damage to the pharmaceutical industry in general and GSK in specific was severe (Kennedy et al., 2004)<sup>712</sup>. In the case of GSK, the public relations disaster, in 2003, was involved with the key stakeholders of the company. That is, in April 2003, the California Public Employees' Retirement System (CalPERS), a major shareholder of GSK, expressed strong concern, stating that the company's corporate behavior in response to the HIV/AIDS pandemic was inadequate and damaging to GSK's reputation (Kennedy et al., 2004)<sup>713</sup>. Worried that the GSK policies would undermine the value of its stock, the CalPERS suggested GSK to reconsider the company's approach to the AIDS pandemic, including its humanitarian programs, drug prices, and voluntary licensing to generic producers (SharePressGsk). Shortly after the expression of concern by the CalPERS, in May 2003, GSK announced a price cut of 40%-50% (GskShareCut) on its top-selling AIDS drugs to the poorest countries. The adverse reaction from the shareholder of GSK

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<sup>711</sup> Trullen, J., & Stevenson, W. B. (2006). Strategy and Legitimacy: Pharmaceutical Companies' Reaction to HIV Crisis. *Business & Society*, 45, 178-210.

<sup>712</sup> Kennedy, C. R., Harris, F. H., & Lord, M. (2004). Integrating public policy and public affairs in a pharmaceutical marketing program: The AIDS pandemic. *Journal of Public Policy and Marketing*, 23, 128-139.

<sup>713</sup> Ibid.

was also expressed at the company's annual meeting in May 2003. Namely, the institutional investors for GSK, such as the CalPERS, the Association of British Insurers, the National Association of Pension Funds, and the Trade Unions Congress, rejected the \$36 million retirement package for Garnier, the then CEO of GSK (InstPressGsk) (Kennedy et al., 2004)<sup>714</sup>. The institutional investors worried about possible more reputational damage against GSK in addition to the high financial cost (Kennedy et al., 2004)<sup>715</sup>.

#### **(34) The AHF's pressure on GSK and GSK's price reduction**

As described in the case 30 above, the initial lawsuit filed by the AHF against GSK was dismissed in March, 2003. However, in May 2003, the AHF reopened its patent challenge and antitrust complaint against GSK (LegPressGsk2). In specific, the lawsuit charged GSK with false advertising, centering on the company's claim that it made no profit on drug sales to the poorest countries (The AIDS Healthcare Foundation)<sup>716</sup>. It is argued that the price reduction made by GSK in May 2003 was also connected with this lawsuit by the AHF. After GSK announced its price reduction, the AHF dropped the lawsuit (AHFdrop). It is highly noted that, according to Kennedy et al. (2004)<sup>717</sup>, behind the scenes, the AHF strongly encouraged the CalPERS to take an aggressive stance against GSK (AHFpressShare), as described in the previous case (AHFpressShare).

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<sup>714</sup> Kennedy, C. R., Harris, F. H., & Lord, M. (2004). Integrating public policy and public affairs in a pharmaceutical marketing program: The AIDS pandemic. *Journal of Public Policy and Marketing*, 23, 128-139.

<sup>715</sup> Ibid.

<sup>716</sup> The AIDS Healthcare Foundation Web-site, [http://www.aidshealth.org/index.php?option=com\\_content&task=view&id=713&Itemid=264](http://www.aidshealth.org/index.php?option=com_content&task=view&id=713&Itemid=264)

<sup>717</sup> Kennedy, C. R., Harris, F. H., & Lord, M. (2004). Integrating public policy and public affairs in a pharmaceutical marketing program: The AIDS pandemic. *Journal of Public Policy and Marketing*, 23, 128-139.

### **(35) The U.S. Present's Emergency Plan for AIDS Relief (PEPFAR)**

In 2003, the U.S. President George W. Bush launched the U.S. Present's Emergency Plan for AIDS Relief (PEPFAR) to fight the global HIV/AIDS epidemic. In May 2003, after the approval of the U.S. Congress, President Bush signed into law - 'the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003' (PepfLegist). This legislation approved the expenditure of up to \$15 billion over five years (from 2003 to 2008)<sup>718</sup>. The first new money of \$35 million was made available by the U.S. Congress in January 2004 and the full implementation of PEPFAR began in June 2004<sup>719</sup>. PEPFAR initially aimed at providing the antiretroviral treatment (ART) to two million HIV-infected people in the developing world, to prevent seven million new infections, and to support care for ten million people by 2010, i.e., the 2-7-10 goals ("About PEPFAR")<sup>720</sup>. PEPFAR has increased the number of Africans receiving ART from 50,000 at the start of the initiative in 2004 to at least 1.2 million in early 2008 ("About PEPFAR")<sup>721</sup>. PEPFAR has been called the largest health initiative ever initiated (i.e. a commitment of \$15 billion) by one country to address a single disease in history ("About PEPFAR")<sup>722</sup>. Although, prior to the implementation of PEPFAR in 2004, the U.S. government was already spending significant sum on combating HIV/AIDS outside of the U.S., the

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<sup>718</sup> On July 30, 2008, President Bush signed into law (i.e. H.R. 5501, THE Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis and Malaria Reauthorization Act of 2008), and, thus, PEPFAR was authorized to continue for a further five years (from 2009 to 2013).

<sup>719</sup> AVERT (n.d.). President's Emergency Plan for AIDS Relief (PEPFAR). Retrieved November 12, 2008, from <http://www.avert.org/pepfar.htm>

<sup>720</sup> The United States President's Emergency Plan for AIDS Relief (n.d.). About PEPFAR. Retrieved November 11, 2008, from <http://www.pepfar.gov/about/index.htm>

<sup>721</sup> Ibid.

<sup>722</sup> Ibid.



spending has greatly increased under PEPFAR (“President’s emergency”)<sup>723</sup>. It is noted that PEPFAR was, initially, criticized on the ground that the medicines purchased by it were only branded, patented antiretroviral drugs instead of cheap, generic ones. However, PEPFAR began to distribute generic medicines through its programs in 2004-2005 (specifically, PEPFAR began to distribute generic drugs in late 2005) (PepfGene). Although PEPFAR started to distribute generic drugs through its programs, critics argue that unnecessary bureaucracy has slowed the transition to using generic medicines<sup>724 725</sup>.

### **(36) The changes in the Pharmaceutical Research and Manufacturers of America (PhRMA)**

In June 2003, the Pharmaceutical Research and Manufacturers of America (PhRMA) created a public affairs division, revamped its web-site, and launched several advertising campaigns that announced an increased focus on patients (PhRMACHan) (“Pharma puts”, 2003)<sup>726</sup>. An article titled “Pharma Puts on a Human Face: Pharmaceutical Companies are doing more than ever to communicate their Value” (2003)<sup>727</sup> describes the changes in the PhRMA and indicates the pharmaceutical industry’s sensitivity to the questions about its legitimacy.

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<sup>723</sup> The spending of the U.S. government on combating HIV/AIDS outside the U.S. has increased under PEPFAR from \$1.5 billion in 2003 to \$6 billion in 2008 (AVERT (n.d.). President’s Emergency Plan for AIDS Relief (PEPFAR). Retrieved November 12, 2008, from <http://www.avert.org/pepfar.htm>).

<sup>724</sup> AVERT (n.d.). President’s Emergency Plan for AIDS Relief (PEPFAR). Retrieved November 12, 2008, from <http://www.avert.org/pepfar.htm>

<sup>725</sup> Today, generic antiretrovirals are widely used to treat HIV/AIDS in the developing world. They have been integrated into many treatment programs including PEPFAR (Avert (n.d.). AIDS, drug prices and generic drugs. Retrieved November 12, 2008, from <http://www.avert.org/generic.htm>)

<sup>726</sup> Pharma puts on a human face: Pharmaceutical companies are doing more than ever to communicate their value (2003, June). Med Ad News, 22, 4.

<sup>727</sup> Ibid.

**(37) The WTO Decision on Implementation of the Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health**

Whether the exceptions to the patent protection represented in the TRIPS Agreement (1994) can be applied to a public health crisis was one of the critical issues at the WTO's Fourth Ministerial Conference in Doha, Qatar, in November 2001. During the conference, the WTO released its declaration on the TRIPS Agreement and public health, i.e., the Doha Declaration – Access to Medicines for All. The Doha Declaration (2001) granted countries the power to manufacture generic drugs made before the introduction of the TRIPS Agreement and the power to produce new drugs through compulsory licensing to increase access to medicines in the developing world. However, unfortunately, the Doha Declaration failed to resolve whether further exceptions could be made to supply drugs to the countries which lack sufficient manufacturing capacity to make effective use of the compulsory licensing provisions in the TRIPS Agreement. In August 2003, the WTO General Council adopted a decision entitled: 'The WTO Decision on Implementation of the Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health'. This Decision allows any member country that produces the generic copies of patented medicines under a compulsory license to export these products to eligible importing countries. In other words, the WTO members agreed on the rule changes that would make it easier for developing countries to import the cheap generic versions of the patented medicines made under compulsory licensing if they are unable to manufacture the drugs themselves (2003Decision). The PhRMA issued a statement stating that "with the patent issue resolved, governments and the public health community could now concentrate on the challenge of delivering the medicines to the

world's developing countries" (Dawkins, 2005)<sup>728</sup>. However, as Anderson (2006)<sup>729</sup> argues, although the Decision (2003) was intended to provide clarification, it created, instead, a complex mechanism that has not improved the status of access to essential, life-saving medicines in the developing world, and, also, has not aided the generic drug production in such countries as India and Brazil. Nevertheless, it should be noted that, although it is insufficient, the Decision (2003) can be considered as a concession on the part of the pharmaceutical industry. Not only social and moral pressure from the stakeholders of the pharmaceutical industry but also coercive lawsuits filed by the member states of the WTO could induce this concession from the pharmaceutical industry (Anderson, 2006)<sup>730</sup>.

### **(38)The issuance of a compulsory license by Malaysia**

After the 2001 Doha Declaration on the TRIPS Agreement and Public health, in October 2003, Malaysia was the first Asian country to issue a compulsory license, a two-year 'government use order', to import the generic versions of the patented ARVs (i.e. Didanosine, Zidovudine, and Combivir) from an Indian pharmaceutical manufacturer, Cipla, for the supply of government hospitals (MalaCL) (Shashikant, 2005)<sup>731</sup>. The Malaysian government also offered GSK and Bristol Meyers Squibb, the patent holders of the medicines, a compensation - 4% of the value of the stocks in connection with the

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<sup>728</sup> Dawkins, C. E. (2005). First to Market: Issue Management Pacesetters and the Pharmaceutical Industry Response to AIDS in Africa. *Business & Society*, 44, 244-282.

<sup>729</sup> Anderson, A. J. (2006, March). Global pharmaceutical patent law in developing countries – Amending TRIPS to promote access for all [Electronic version]. *ExpressO Reprint Series, Working Paper 1052*. Retrieved December 24, 2006, from

<http://law.bepress.com/cgi/viewcontent.cgi?article=5237&context=expresso>

<sup>730</sup> Ibid.

<sup>731</sup> Shashikant, S. (May, 2005). More countries use compulsory license, but new problems emerge. *Third World Network Info Service on Health*. Retrieved November 11, 2008, from <http://www.twinside.org.sg/title2/health.info/twninfohealth004.htm>

generic drugs actually delivered (Shashikant, 2005)<sup>732</sup>. Initially, the pharmaceutical industry pressed the Malaysian government to negotiate lower prices with the companies which had the patents, instead of issuing a compulsory license. Nevertheless, the Malaysian government “demonstrated a political will and enforced the country’s rights under the TRIPS Agreement to use compulsory licensing, reducing the price of 1st line ARVs by 81 percent (from \$315 to only \$58)” (Oxfam International, November, 2006, p. 22)<sup>733</sup>. However, although the ‘government use order’ ended in November 2005, the Malaysian government decided not to extend it and to negotiate the prices of the medicines with the patent holders. It is noted that, following the issuance of the compulsory license by the Malaysian government, the patent holders (i.e. GSK and Bristol Meyers Squibb) reduced the prices of the patented medicines by more than 50% (MalaGskBmsCut) (“Brazil moves on compulsory licenses”, May, 2007)<sup>734</sup>. However, it is also noted that, although the patent holding companies reduced the prices of the medicines at the moment, the status of the access to these patented medicines in Malaysia in the future is uncertain. That is, currently, Malaysia is negotiating a Free Trade Agreement (FTA) with the U.S. and this FTA may severely limit the country’s future ability to enforce a compulsory license through the ‘TRIPS-plus’ provisions which may be represented in this bilateral trade agreement.

### **(39) The patent waivers: GSK and Boehringer Ingelheim**

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<sup>732</sup> Shashikant, S. (May, 2005). More countries use compulsory license, but new problems emerge. Third World Network Info Service on Health. Retrieved November 11, 2008, from <http://www.twinside.org.sg/title2/health.info/twninfohealth004.htm>

<sup>733</sup> Oxfam International (2006, November). Patents versus patients: Five years after the Doha Declaration [Electronic version]. Retrieved April 13, 2007, from

[http://www.oxfamamerica.org/newsandpublications/publications/briefing\\_papers/patent\\_patients/Doha5\\_Fi](http://www.oxfamamerica.org/newsandpublications/publications/briefing_papers/patent_patients/Doha5_Fi)  
<sup>734</sup> Brazil moves on compulsory licenses after failed talks with drug company. (2007, May 3). Third World Network, Retrieved November 11, 2008, from <http://www.twinside.org.sg/title2/wto.info/twninfo05703.htm>

In December 2003, the AIDS activist group of South Africa, i.e., the Treatment Action Campaign (TAC), signed a deal with GSK and Boehringer Ingelheim that would see the pharmaceutical companies grant up to four different generic manufacturers licenses to produce their patented HIV/AIDS medicines, with 5% of profits going to the patent holders (GskBIwaiv) (Nolen, 2003)<sup>735</sup>. Based on the agreement, the generic producers would be allowed to sell the medicines to both the public and the private sector and to export them to sub-Saharan Africa. It is noted that, as Nolen (2003)<sup>736</sup> points out, such an agreement was the first time on the continent. The AIDS activists welcomed the breakthrough agreement with the two largest pharmaceutical companies in South Africa and they expected the agreement would help more poor patients get vital HIV/AIDS medicines. Before this agreement was made, a group led by TAC filed a complaint against the pharmaceutical companies with the South African Competition Commission (TACpress). That is, the activist group which filed the complaint argued that, in the case of GSK, although the company had an agreement with a generic manufacturer, Aspen Pharmacare, to produce its generic version of AIDS medicines, with only one company licensed, there had been no competitive lowering of the price (Nolen, 2003)<sup>737</sup>. The Competition Commission ruled that “their complaint against the pharmaceutical makers had merit and should go before a tribunal with the authority to impose fines and penalties” (SApressPharma) (Nolen, 2003, p. 1)<sup>738</sup>. However, it is noted that not the complaint itself but the Canadian government’s decision to override the patent law

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<sup>735</sup> Nolen, S. (2003, December). Drug companies make patent concessions [Electronic Version]. Globe and Mail. Retrieved November 11, 2008, from <http://www.theglobeandmail.com/servlet/story/RTGAM.20031211.waidsdrug1211/BNSStory/International/>

<sup>736</sup> Ibid.

<sup>737</sup> Ibid.

<sup>738</sup> Ibid.

influenced the pharmaceutical companies to sign the deal (CApressPharma). That is, the AIDS activists cited that “the Canadian government’s decision to override patent law for essential drugs for Africa as one key factor in persuading the pharmaceutical makers to loosen their hold on patents” (Nolen, 2003, p. 1)<sup>739</sup>. In the same manner, the national secretary of TAC commented that he “credits the Canadian legislative change, which overrides patent law so that generic makers can make drugs on the World Health Organization’s list of essential medicines and export them to the developing world, with having influenced the decision of GlaxoSmithKline not to fight the complaint with the competition commission” (Nolen, 2003, p. 2)<sup>740</sup>.

#### **(40) The issuance of a compulsory license by Indonesia**

In October 5, 2004, Indonesia issued a government use of a compulsory license (IndoCL1) to manufacture the generic versions of the two HIV/AIDS medicines, i.e., Lamivudine and Nevirapine, until the end of the patent term in 2011 and 2012 respectively (Love, 2007)<sup>741</sup>. The Indonesian government, through a Presidential decree, explained that the exploitation of the patents by the government on ARVs was issued in the light of the urgent need of community in the effort to control HIV/AIDS epidemic (Shashikant, May 2007)<sup>742</sup>. Under the compulsory license, the Indonesian government could appoint a pharmaceutical company, PT Kimia Farma, a state-owned

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<sup>739</sup> Nolen, S. (2003, December). Drug companies make patent concessions [Electronic Version]. Globe and Mail. Retrieved November 11, 2008, from

<http://www.theglobeandmail.com/servlet/story/RTGAM.20031211.waidsdrug1211/BNStory/International/>

<sup>740</sup> Ibid.

<sup>741</sup> Love, J. P. (2007). Recent examples of compulsory licensing of patents [Electronic Version].

Knowledge Ecology International. Retrieved November 15, 2008, from

[http://www.keionline.org/index.php?option=com\\_content&task=view&id=41](http://www.keionline.org/index.php?option=com_content&task=view&id=41)

<sup>742</sup> Shashikant, S. (May, 2005). More countries use compulsory license, but new problems emerge. Third World Network Info Service on Health. Retrieved November 11, 2008, from

<http://www.twinside.org.sg/title2/health.info/twninfohealth004.htm>

pharmaceutical company, as the patent exploiter on behalf of the government to produce the two ARVs: Lamivudine for 8 years and Nevirapine for 7 years (Shashikant, May 2007)<sup>743</sup>. The compulsory license included a royalty rate of 0.5% of the net selling value of the generic medicines (Love, 2007).<sup>744</sup> Indonesia was the second Asian country in the post –Doha Declaration period to issue a government use of a compulsory license. After the compulsory license had issued by the Indonesian government, the generic medicines were distributed freely through the governmental hospitals, and the cost of the HIV/AIDS treatment went down significantly in Indonesia. It is noted that the prices of the patented HIV/AIDS medicines in Indonesia have come down since the local pharmaceutical company started to produce the generic versions of the patented drugs (IndoPriceCut) (New, 2007)<sup>745</sup>. However, it is uncertain that the patent holding pharmaceutical companies will keep the prices of the patented medicines low without the pressure of potential compulsory licenses and competition from generic medicines. In this respect, in March 2007, the Indonesian government renewed the Presidential decree to issue a compulsory license in order to cover another ARV medicine, Efavirenz, which replaced Nevirapine as the first-line HIV/AIDS drug (IndoCL2) (New, 2007)<sup>746</sup>.

#### **(41) The amendment of the Indian patent law**

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<sup>743</sup> Shashikant, S. (May, 2005). More countries use compulsory license, but new problems emerge. Third World Network Info Service on Health. Retrieved November 11, 2008, from <http://www.twinside.org.sg/title2/health.info/twninfohealth004.htm>

<sup>744</sup> Love, J. P. (2007). Recent examples of compulsory licensing of patents [Electronic Version]. Knowledge Ecology International. Retrieved November 15, 2008, from [http://www.keionline.org/index.php?option=com\\_content&task=view&id=41](http://www.keionline.org/index.php?option=com_content&task=view&id=41)

<sup>745</sup> New, W. (2007, November 26). Indonesia mulls compulsory licenses on three more HIV/AIDS medicines [Electronic Version]. Intellectual Property Watch. Retrieved November 15, 2008, from <http://www.ip-watch.org/weblog/index.php?p=841>

<sup>746</sup> Ibid.

India, a major source of the inexpensive HIV/AIDS medicines, became the TRIPS Agreement compliant in 2005. That is, India was obliged to introduce the TRIPS Agreement compliant IPRs regime on the first day of 2005. In December 2004, India was ushered in the Product Patents Regime by introducing the 'Patents (Amendment) Ordinance, 2004'. In March 2005, after having debated the provisions of the ordinance, the Indian Parliament passed the 'Patents (Amendment) Bill, 2005' (IndiLaw) (Biradar et al, 2006)<sup>747</sup>. The new patent law, amending India's 1970 Patent Act, started to affect everything from electronic to pharmaceutical industry. The new patent law had been expected for years as a condition for India to join the WTO (Biradar et al, 2006)<sup>748</sup>. But, as McNeil Jr. (2005)<sup>749</sup> describes, since millions of poor people in India and elsewhere – including, by some estimates, half of the AIDS patients in the Third World – relied on the India's generic drug industry, not only the lobbyists for the multinational pharmaceutical companies but also the activists fighting for the cheap generic medicines descended in India to try to influence the outcome of the new patent law. The new India's patent law was not as restrictive as the AIDS activists had worried thanks to the pressure from the civil society. At least, in the case of a medicine is desperately needed, the new Indian patent law allows the Indian government to declare an emergency and cancel the patent for the medicine. It is noted that the civil society pressure ensured the inclusion of the crucial safeguards (ActpressIndi): the 'Patents (Amendment) Bill, 2005' excludes the patent protection for new forms or new uses (indications) of already patented medicines,

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<sup>747</sup> Biradar, S. S., Hunshyal, R. D., & Bhagavati, S. T. (2006). IPRS in pharmaceutical sector [Electronic version]. The Internet Journal of World Health and Societal Politics, 3. Retrieved March 11, 2007, from <http://www.ispub.com/ostia/index.php?xmlFilePath=journals/ijwh/vol3n1/iprs.xml>

<sup>748</sup> Ibid.

<sup>749</sup> McNeil Jr., D. G. (2005, March 24). India alters law on drug patents. The New York Times [Electronic Version]. Retrieved November 16, 2008, from <http://www.nytimes.com/2005/03/24/international/asia/24aids.html>



a permissible limitation under the TRIPS Agreement (Oxfam International, 2006)<sup>750</sup>. By narrowing the scope of patentability, the Indian government tried to prevent the pharmaceutical companies from abusing the patent system through ‘evergreening’ or through introducing only the second forms or indications of older medicines, neither novel nor inventive, as new medicines (Oxfam International, 2006)<sup>751</sup>. The new Indian patent law also permitted any individual or entity to contest the patent applications filed by the pharmaceutical companies<sup>752</sup>. Since India qualified for a transition period under the TRIPS Agreement, these patent applications were treated as ‘mailbox’ applications (Oxfam International, 2006)<sup>753</sup>. Although the generic competition was allowed during these intervening years, the patent holders could enforce their patent rights, thus, could jeopardize the generic production of medicines. In sum, under the new Indian patent law, although the sellers should pay the licensing fees, all the generic medicines already approved in India could still be sold. There were also the provisions allowing the companies that make generic versions of the patented medicines to copy the patented medicines in the future. However, there were relatively tough criteria for such copying, for instance, under the new Indian patent law, a generic producer could apply to copy a patented medicine but only after it had been marketed for three years (and, in addition, the patent owner could object against the application). Moreover, although the new Indian

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<sup>750</sup> Oxfam International (2006, November). Patents versus patients: Five years after the Doha Declaration [Electronic version]. Retrieved April 13, 2007, from [http://www.oxfamamerica.org/newsandpublications/publications/briefing\\_papers/patents\\_patients/Doha5\\_Final\\_paper\\_101106\\_2.pdf](http://www.oxfamamerica.org/newsandpublications/publications/briefing_papers/patents_patients/Doha5_Final_paper_101106_2.pdf)

<sup>751</sup> Ibid.

<sup>752</sup> There were nearly 10,000 applications registered between 1995 and 2005 in India. Oxfam International (2006, November).

<sup>753</sup> Oxfam International (2006, November). Patents versus patients: Five years after the Doha Declaration [Electronic version]. Retrieved April 13, 2007, from [http://www.oxfamamerica.org/newsandpublications/publications/briefing\\_papers/patents\\_patients/Doha5\\_Final\\_paper\\_101106\\_2.pdf](http://www.oxfamamerica.org/newsandpublications/publications/briefing_papers/patents_patients/Doha5_Final_paper_101106_2.pdf)

law did not define the term ‘reasonably’, as described above, the generic producers should pay a reasonable royalty to the patent holders (Oxfam International, 2006)<sup>754</sup>. The AIDS activists predicted that the prices for newly invented medicines would be much higher because drug makers would have the same 20-year patent monopolies as they had in the West (McNeil Jr., 2005)<sup>755</sup>. The AIDS activists also predicted that the new HIV/AIDS treatments with new medicines would become less affordable (McNeil Jr., 2005)<sup>756</sup>. In addition, it was unclear whether or not the generic medicine producers in other countries, such as Brazil, China, and Thailand, could fill any increasing demand for the cheaper medicines. For example, in Africa, the exports by the Indian generic manufacturers, particularly Cipla and Ranbaxy Laboratories, helped to drive the cost of ARV treatment down dramatically (McNeil Jr., 2005)<sup>757</sup>. Many critics worried that the new Indian patent law would make it far more difficult for the poor patients in the developing and the least-developed world to access essential, life-saving medicines, particularly the new ones, at affordable prices. Nevertheless, in May 2006, Novartis, a Swiss pharmaceutical company, manufacturing Gleevec, filed two cases in India, challenging the rejection of the Gleevec patent application and the Indian Patent Law (NovChallIndi). The challenges of Novartis against the Indian Patent Law are described in detail below in the cases 43 and 48.

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<sup>754</sup> Oxfam International (2006, November). Patents versus patients: Five years after the Doha Declaration [Electronic version]. Retrieved April 13, 2007, from [http://www.oxfamamerica.org/newsandpublications/publications/briefing\\_papers/patents\\_patients/Doha5\\_Final\\_paper\\_101106\\_2.pdf](http://www.oxfamamerica.org/newsandpublications/publications/briefing_papers/patents_patients/Doha5_Final_paper_101106_2.pdf)

<sup>755</sup> McNeil Jr., D. G. (2005, March 24). India alters law on drug patents. The New York Times [Electronic Version]. Retrieved November 16, 2008, from <http://www.nytimes.com/2005/03/24/international/asia/24aids.html>

<sup>756</sup> Ibid.

<sup>757</sup> Ibid.

**(42) Brazil's attempt to issue a compulsory license: Abbott's decision on the price reduction of Kaletra in Brazil**

As described in detail below (case 47), the Brazilian government actually broke, for the first time, the patent for Efavirenz, an antiretroviral (ARV) medicine manufactured by Merck & Co., in May 2007, by issuing a compulsory license. But, the Brazilian government has repeatedly managed to get steep price cuts on the patented medicines from the multinational pharmaceutical companies by threatening to break patents. The Ministry of Health of Brazil issued a decree in June 2005 declaring that the Lopinavir/Ritonavir combination (marketed by the brand name, Kaletra) was a public interest medicine. In addition, on numerous occasions, the Brazilian government indicated that it would issue a compulsory license for Kaletra (BrazAttCL) (Pharmaceutical business review, May, 2007)<sup>758</sup>. Based on the flexibilities represented in the TRIPS Agreement, the Brazil's decision on a compulsory license for Kaletra was legal and did not breach any international agreements on intellectual property rights. The decree declared by the Brazilian government in June 2005 was the first step towards issuing a compulsory license, but the Ministry of Health of Brazil also sent a letter to Abbott introducing a ten-day deadline. In the letter, the Brazilian government allowed Abbott to propose the price reduction for Kaletra and also requested technology transfer of its manufacturing process. Otherwise, the Brazilian government would issue a compulsory license for Kaletra (Balasubramaniam, 2007)<sup>759</sup>. In July 2005, Abbott agreed

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<sup>758</sup> Pharmaceutical business review (May, 2007). Breaking Merck patent may drive investment away from Brazil. Retrieved November 13, 2008, from [http://www.pharmaceutical-business-review.com/article\\_feature.asp?guid=8A869BFC-88...](http://www.pharmaceutical-business-review.com/article_feature.asp?guid=8A869BFC-88...)

<sup>759</sup> Balasubramaniam, T. (May, 2007). Brazil moves on compulsory license after failed talks with drug company. Retrieved November 11, 2008, from <http://www.twinside.org.sg/title2/wto.info/twninfo050703.htm>

to keep the price of Kaletra at the current level for the next six years in return for Brazil not to break the patent on Kaletra (Pharmaceutical business review, May, 2007)<sup>760</sup>. However, the Brazilian government dismissed the agreement and announced that it would continue to negotiate for a lower price or the local manufacturers would break the patent on Kaletra to sell the medicine for a highly reduced price (Pharmaceutical business review, May, 2007)<sup>761</sup>. The threat of issuing a compulsory license eventually led to an agreement, in October 2005, between the Brazilian government and Abbott, forcing the patent holder, Abbott, to lower the price of Kaletra in Brazil (AbtCutBraz). Activist groups and NGOs strongly have supported the Brazilian government's forward actions (NgoActivSupBraz). For instance, the Working Group on Intellectual Property (GTPI) of the Brazilian Network for the Integration of Peoples (REBRIP) commented that "the issuance of a compulsory license constitutes historical decision and contributes to the sustainability of the state policy guaranteeing universal access to medicines, demonstrating also the maturity of Brazilian institutions that used to vacillate when facing international pressure" (Balasubramaniam, 2007, P.3)<sup>762</sup>. It seems that the pharmaceutical companies prefer to decrease their prices in order to retain the control over the Brazilian market rather than to lose it completely. It was proved again when a compulsory license was issued by the Brazilian government in 2007 against Merck. This case is described in detail below (case 47).

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<sup>760</sup> Pharmaceutical business review (May, 2007). Breaking Merck patent may drive investment away from Brazil. Retrieved November 13, 2008, from [http://www.pharmaceutical-business-review.com/article\\_feature.asp?guid=8A869BFC-88...](http://www.pharmaceutical-business-review.com/article_feature.asp?guid=8A869BFC-88...)

<sup>761</sup> Ibid

<sup>762</sup> Balasubramaniam, T. (May, 2007). Brazil moves on compulsory license after failed talks with drug company. Retrieved November 11, 2008, from <http://www.twinside.org.sg/title2/wto.info/twninfo050703.htm>

### **(43) Novartis's challenges against the Indian Patent Law**

As explained above (case 41), on May 17, 2006, the Swiss pharmaceutical company, Novartis, filed two sets of cases challenging the rejection of the Gleevec (a cancer drug) patent application and the Indian Patent Law in the Chennai High Court in India. The first case challenged the patent order of the Chennai Patent Office rejecting the Gleevec patent application filed by Novartis. The legal representatives of the Cancer Patients Association appeared on their behalf before the court. They argued that Novartis's constant litigation had threatened the lives of cancer patients and had renewed the fears about the future availability of medicines if the patent case of Gleevec was reopened ("Novartis challenges", 2006)<sup>763</sup>. The second case filed by Novartis challenged the constitutionality of the section 3(d) of the Indian Patents Act, specifically introduced by the Indian Parliament as a safeguard against the misuse of the product patent regime. In its petition, Novartis claimed that the section was not in compliance with the TRIPS Agreement, and, thus, should be declared unconstitutional ("Novartis challenges", 2006)<sup>764</sup>. Before Novartis filed these cases, the Cancer Patients Association had filed an opposition on behalf of cancer patients in the Chennai Patent Office where the patent application of Novartis for Gleevec had been pending (CPAoppNov). Under the new Indian patent law, any person or group can oppose a patent application. In January 2006, the Chennai Patent Office rejected the Novartis's patent application on the ground that the application claimed only a new form of an old drug ("Novartis challenges", 2006)<sup>765</sup>. As a result, Novartis filed two sets of cases in India in May 2006. It is noted that the court case

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<sup>763</sup> Novartis challenges the Indian patent law (2006, September 10). Berne Declaration. Retrieved November 13, 2008, from <http://www.evb.ch/en/p25011414.html>

<sup>764</sup> Ibid.

<sup>765</sup> Ibid.

brought by Novartis in India shows how the pharmaceutical industry distributes the discount medicines in the developing world while maintaining profits. In the court, Novartis contested that the new Indian patent law could leave millions without access to affordable medicines. The company argued that patents save lives: that is, if the patent law is undermined the way it was in India, there would be no more investment into the discovery of the essential, life-saving medicines. However, NGOs and activist groups accused Novartis of squeezing competition. MSF commented that the generic competition had reduced dramatically the cost of the HIV/AIDS medicines. NGOs and activist groups launched a petition against Novartis while hundreds of activists protested on the streets of New Delhi, India (NgoActPressNov) (Allen, 2007)<sup>766</sup>. It is noted that, although it filed cases against the new Indian patent law, Novartis announced that it would continue to offer Gleevec free to the patients in India who cannot afford it (NovOffer). As described below (case 48), in August 2007, the cases filed by Novartis were dismissed in the Indian court (IndiPressNov).

#### **(44) Compulsory licensing: Thailand**

In November 2006, Thailand decided to break the patent on Efavirenz, an antiretroviral (ARV) medicine manufactured by Merck & Co., by applying compulsory licensing (ThaiCL1). Thailand's Ministry of Health announced that it would issue a compulsory license allowing the Thailand's Government Pharmaceutical Organization (GPO) to produce its own version of Efavirenz and/or to import the generic version of the medicine from India (GeneThai) until the domestic production would come on line. In specific, the

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<sup>766</sup> Allen, M. (2007, January 29). India: Novartis challenges India's patent law. CorpWatch [Electronic Version]. Retrieved November 17, 2008, from <http://www.evb.ch/en/p25011414.html>

Thai government announced that the GPO would produce the generic version of Efavirenz under a five-year compulsory license (until 2011), reducing the cost of the medicine to \$20 per month (Aidsmap, 2006)<sup>767</sup>. The patent holder for Efavirenz, Merck & Co., would be paid a royalty of 1% on sales in Thailand (Aidsmap, 2006)<sup>768</sup>. After the Thai government issued the compulsory license, Merck & Co. announced that it might seek to negotiate with the Thai government to agree on a voluntary license for the generic production of Efavirenz or to offer it a lower price for the medicine (MkCutThai) (“Thailand issues”, 2006)<sup>769</sup>. The PhRMA and the USTR government expressed their concerns over the Thailand’s compulsory license. In particular, they commented that the issuance of the compulsory license by the Thai government without any attempt to negotiate with the patent owner, Merck, was of grave concern (“Thailand issues”, 2006)<sup>770</sup>. In contrast NGOs, such as MSF, Oxfam, and Global AIDS Alliance, urged Thailand to go further (Baker, 2007)<sup>771</sup>. In January 2007, the Thai Ministry of Public Health also announced that it would issue a compulsory license for Kaletra (ThaiCL2). Kaletra is a fixed dose protease inhibitor combination containing Lopinavr and Ritonavir, and is recommended by World Health Organization as a second-line medicine for HIV/AIDS (Aidsmap, 2007)<sup>772</sup>. In response to the announcement of issuing a compulsory license, Abbott Laboratories, the manufacturer of Kaletra, in February 2007, has offered

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<sup>767</sup> Aidsmap (2006, November). Thailand issue compulsory license for efavirenz. Retrieved November 12, 2008, from <http://www.aidsmap.com/en/news/A774C0DF-0EB5-401B-A2DC-7E196831F8ED.asp>

<sup>768</sup> Ibid.

<sup>769</sup> Thailand issues compulsory license for patented AIDS drug (2006, December 13). International Center for Trade and Sustainable Development [Electronic Version]. Retrieved September 10, 2008, from <http://ictsd.net/i/news/bridgesweekly/7181/>

<sup>770</sup> Ibid.

<sup>771</sup> Baker, G. (2007, January 1). U.S. reaction to Thai compulsory license for AIDS medicine. Essential Medicines News [Electronic Version]. Retrieved November 30, 2008, from <http://www.emednews.org/2007/01/01/us-reaction-to-thai-compulsory-license-for-aids-medicine/>

<sup>772</sup> Aidsmap (November, 2006). Thailand issue compulsory license for efavirenz. Retrieved November 12, 2008, from <http://www.aidsmap.com/en/news/A774C0DF-0EB5-401B-A2DC-7E196831F8ED.asp>

to cut the price it charges the Thai public health system for the drug (AbtCutThai) in a bid to persuade the Thai government from pursuing a compulsory license that would allow a generic version to be imported from India (Aidsmap, 2007)<sup>773</sup>. This Abbott's offer was the development in an increasingly aggressive strategy of the cost containment pursued by the Thai government which began in November 2006 with the announcement of a compulsory license for Efavirenz manufactured by Merck. In Thailand, civil society organizations have campaigned for the introduction of compulsory licensing of HIV/AIDS medicines in order to reduce the cost of antiretroviral treatment (NgoActSupThai) (Aidsmap, 2006)<sup>774</sup>. Concerning the compulsory licenses of Thailand, Janssen (2008)<sup>775</sup> comments that "the bold move also brought the previously little-known term, "compulsory licensing", into the international media spotlight" (PubMedThai) (p.1). The Thai government's decisions on the compulsory licenses were the efforts to provide the cheap generic copies of the patented medicines to the people living with HIV/AIDS who could not afford to purchase the patented drugs at market prices. AIDS activists argue that "the use of compulsory licensing is an important bargaining chip in forcing giant pharmaceutical companies to lower their prices in developing countries" (Janssen, 2008, p.2). For instance, after the issuance of the compulsory license by Thailand, the price of Kaletra has been dropped by half in many developing countries. It is noted that the U.S. Trade Representative admitted that the Thai government was within its rights represented in the Doha Declaration to issue the compulsory licenses to address

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<sup>773</sup> Aidsmap (February, 2007). Abbott offers price cut to thwart Thai compulsory license on Kaletra. Retrieved November 12, 2008, from <http://www.aidsmap.com/en/news/08E18120-7D15-4E1C-98DC-145C515EFBAC.asp>

<sup>774</sup> Aidsmap (November, 2006). Thailand issue compulsory license for efavirenz. Retrieved November 12, 2008, from <http://www.aidsmap.com/en/news/A774C0DF-0EB5-401B-A2DC-7E196831F8ED.asp>

<sup>775</sup> Janssen, P. (July, 2008). Compulsory licensing sets precedent. Bangkok Post [Electronic Version]. Retrieved November 2, 2008, from <http://www.bangkokpost.com/topstories/topstories.php?i=129131>



effectively significant public health emergencies (“Abbott offers price cut”, 2007)<sup>776</sup>. However, for the pharmaceutical companies, the compulsory licenses issued by Thailand were emergencies of another kind. As Janssen (2008)<sup>777</sup> describes, the pharmaceutical companies feared that “Thailand’s initiative might be copied worldwide and would undermine the global patent protection system for new drugs” (p. 1). In this respect, the reactions of Abbott and the U.S. government to the compulsory licenses issued by Thailand are noted. In 2007, Abbott announced that it would not seek the licenses for the seven new products in Thailand in retaliation for the Thai government’s decision to issue a compulsory license for Kaletra (AbtRetThai). “Thailand was also placed on the U.S. Trade Representative Priority Watch List of countries seen to be committing intellectual property piracy” (AVERT, p.6)<sup>778</sup>, following its decisions to issue compulsory licenses on Efavirenz and Kaletra (USoppThai).

#### **(45) The second compulsory licensing by Indonesia**

As illustrated earlier (case 40), a Presidential decree was issued in Indonesia, in 2004, authorizing the Minister of Health to appoint a manufacturer to exploit the patents on Lamivudine and Nevirapine on behalf of the Indonesian government. The decree specified the royalty rate of 0.5% of the net generic sales price. The authorization would last for seven years in the case of Nevirapine and for eight years in the case of

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<sup>776</sup> Aidsmap (February, 2007). Abbott offers price cut to thwart Thai compulsory license on Kaletra. Retrieved November 12, 2008, from <http://www.aidsmap.com/en/news/08E18120-7D15-4E1C-98DC-145C515EFBAC.asp>

<sup>777</sup> Janssen, P. (July, 2008). Compulsory licensing sets precedent. Bangkok Post [Electronic Version]. Retrieved November 2, 2008, from <http://www.bangkokpost.com/topstories/topstories.php?=129131>

<sup>778</sup> AVERT (n.d.). AIDS, drug prices and generic drugs. Retrieved November 12, 2008, from <http://www.avert.org/generic.htm>

Lamivudine, respectively (“Countries experiences”, 2008)<sup>779</sup>. In March 2007, the 2004 Presidential decree of Indonesia was amended to include Efavirenz. In other words, the Indonesian government renewed the Presidential decree to issue a compulsory license in order to cover another ARV medicine, Efavirenz, which replaced Nevirapine as the first-line HIV/AIDS drug (IndoCL2) (New, 2007)<sup>780</sup>. The Indonesian Presidential decree had been issued in 2004 and, then, subsequently amended in 2007 in a low key manner, and does not appear to have attracted any criticism (“Countries experiences”, 2008)<sup>781</sup>.

#### **(46) The price reduction of Kaletra by Abbott Laboratories**

In April 2007, Abbott Laboratories, the maker of the HIV/AIDS medicine, Kaletra, announced that it would reduce the price of Kaletra by 55% for the patients in the low and lower-middle income countries (AbtCutKal). This price reduction happened after an agreement between Abbott and the World Health Organization (WHO) had been reached (UNpressAbt). Abbott and the WHO agreed on a balanced approach to provide Kaletra to more patients in the developing world, while supporting continued long-term biopharmaceutical research and development (“Abbott reduces”, 2007)<sup>782</sup>. In the interest of the global public health, the WHO approached Abbott to discuss how to improve the

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<sup>779</sup> Country experiences in using TRIPS safeguards (February, 2008). World Health Organization [Electronic Version]. Retrieved December 19, 2008, from <http://www.wpro.who.int/NR/rdonlyres/BF754A7E-5A35-464C-9409-13CB07BB1D99/0/Briefingnote4countryexperiences.doc>

<sup>780</sup> New, W. (2007, November 26). Indonesia mulls compulsory licenses on three more HIV/AIDS medicines [Electronic Version]. Intellectual Property Watch. Retrieved November 15, 2008, from <http://www.ip-watch.org/weblog/index.php?p=841>

<sup>781</sup> Country experiences in using TRIPS safeguards (February, 2008). World Health Organization [Electronic Version]. Retrieved December 19, 2008, from <http://www.wpro.who.int/NR/rdonlyres/BF754A7E-5A35-464C-9409-13CB07BB1D99/0/Briefingnote4countryexperiences.doc>

<sup>782</sup> Abbott (April, 2007). Abbott reduces price of Kaletra/Aluvia in low and low-middle income countries to \$1,000. Retrieved November 14, 2008, from [http://www.abbott.com/global/url/pressRelease/en\\_US/60.5:5/Press\\_Release\\_0442.htm](http://www.abbott.com/global/url/pressRelease/en_US/60.5:5/Press_Release_0442.htm)

affordability and access while maintaining the incentives to support developing new medicines (“Abbott reduces”, 2007)<sup>783</sup>. However, it is highly noted that this decision on the price cut of Kaletra by Abbott was resulted from the combined pressure which had been exerted by activist groups/NGOs in connection with the generic competition, by the intervention of the WHO, and by the issuance of a compulsory license by Thailand, in January 2007, for Kaletra, against Abbott. In this respect, AIDS activists and NGOs criticized Abbott Laboratories. The Student Global AIDS Campaign (SGAC) argued that “while this is an initial step in increasing access to Kaletra, Abbott’s shameful actions in Thailand last month to withdraw a heat-stable version of Kaletra continues to be a driving issue for activists to campaign against” (“Abbott’s Greed”, 2007)<sup>784 785</sup>. Activist groups and NGOs called on Abbott to provide Kaletra at one low price to all the countries classified as low income, lower-middle income, and the least developed (NgoActPressAbt). Although the Abbott’s decision on the price reduction of Kaletra would definitely improve the state of access to Kaletra in the developing world, most activist groups and NGOs still thought the decision of Abbott was not sufficient (“Abbott’s Greed”, 2007)<sup>786</sup>.

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<sup>783</sup> Abbott (April, 2007). Abbott reduces price of Kaletra/Aluvia in low and low-middle income countries to \$1,000. Retrieved November 14, 2008, from [http://www.abbott.com/global/url/pressRelease/en\\_US/60.5:5/Press\\_Release\\_0442.htm](http://www.abbott.com/global/url/pressRelease/en_US/60.5:5/Press_Release_0442.htm)

<sup>784</sup> Abbott’s Greed (April, 2007). SGAC recognizes Abbott’s decision to reduce price of Kaletra a step in right direction. Retrieved January 20, 2008, from [http://www.abbottsgreed.com/index.php?title=SGAC\\_Recognizes\\_Abbott's\\_Decision\\_to\\_Reduce\\_Price\\_of\\_Kaletra\\_a\\_Step\\_in\\_Right\\_Direction](http://www.abbottsgreed.com/index.php?title=SGAC_Recognizes_Abbott's_Decision_to_Reduce_Price_of_Kaletra_a_Step_in_Right_Direction)

<sup>785</sup> SGAC called on the WHO to defend and support Thailand’s decision to issue a compulsory license for Kaletra by providing technical support and assistance to the Thai government to enforce the compulsory license (“Abbott’s Greed”, 2007).

<sup>786</sup> Abbott’s Greed (April, 2007). SGAC recognizes Abbott’s decision to reduce price of Kaletra a step in right direction. Retrieved January 20, 2008, from [http://www.abbottsgreed.com/index.php?title=SGAC\\_Recognizes\\_Abbott's\\_Decision\\_to\\_Reduce\\_Price\\_of\\_Kaletra\\_a\\_Step\\_in\\_Right\\_Direction](http://www.abbottsgreed.com/index.php?title=SGAC_Recognizes_Abbott's_Decision_to_Reduce_Price_of_Kaletra_a_Step_in_Right_Direction)

#### **(47) Compulsory licensing: Brazil**

Brazil has followed Thailand's lead in terms of compulsory licensing. After the patent holder, Merck & Co., had failed to reduce, adequately<sup>787</sup>, the price of Efavirenz, the Brazilian government, in May 2007, issued a compulsory license to allow the import of the generic versions of Efavirenz (BrazClef) (Alcorn, 2007)<sup>788</sup>. That is, after Brazil had failed to secure a deal with Merck (the Brazilian government had conducted negotiations with Merck since 2006 over the price of Efavirenz), it decided to bypass the patent on Efavirenz and started to import the generic version of the medicine from India. This was the first time for the Brazilian government to issue a compulsory license. The Brazilian government has consistently sought the lower prices for the ARV medicines in order to limit the cost of its national HIV treatment program which provides the free access to anti-HIV treatment for the HIV-positive Brazilians (Alcorn, 2007)<sup>789</sup>. Brazil has been considered a model country in the fight against HIV/AIDS, and the success of Brazil in fighting against HIV/AIDS has depended on the cheap ARV medicines that have been secured from the pharmaceutical companies through fierce struggle. Today, Brazil is also producing its own generic versions of the anti-AIDS medicines. AIDS activists and NGOs have pushed the Brazilian government to cut drug costs by making the generic copies of the patented drugs and strongly supported the move of the Brazilian government which has tried to increase the access to HIV/AIDS medicines

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<sup>787</sup> In April, 2007, the Brazilian government warned Merck that unless Brazil could buy Efavirenz at the same price offered to the Thai government (i.e. the 60% price reduction) at the time, it would issue a compulsory license. In May, 2007, the Brazilian government rejected the Merck's offer of a 30% price reduction and proceeded to issue a compulsory license (Alcorn, 2007).

<sup>788</sup> Alcorn, K. (May, 2007). Brazil issues compulsory license on efavirenz. Retrieved November 11, 2008, from <http://www.aidsmap.com/en/news/0550CE62-3F90-4603-932C-EF69E1B4485D.asp>

<sup>789</sup> Ibid.

(NgoActSupGene) (Alcorn, 2007)<sup>790</sup>. Although they have been successful for Brazil in terms of the HIV/AIDS treatment, the strategies that have been taken by the Brazilian government to fight against HIV/AIDS have created conflict with the large, multinational pharmaceutical companies. The compulsory license for Efavirenz issued by the Brazilian government was legal under both the national and international trade law. However, once again, the government was heavily criticized by Merck and other pharmaceutical companies (Alcorn, 2007)<sup>791</sup>. The pharmaceutical companies argued that “the production of low-priced drugs may lead to increased parallel trading – the process where pharmaceutical products that are available in one country are exported and resold in another country for a higher price by an intermediary, fuelled by significant price differences between countries” (Pharmaceutical Business Review, 2007, p. 2)<sup>792</sup>. The U.S. Chamber and the U.S.-Brazil Business Council also stated that “the decision on breaking the patent of Merck’s Sustiva was a major step backward in intellectual property law and warned it could harm development” (Pharmaceutical Business Review, 2007, p. 2)<sup>793</sup>. It is noted that the Wall Street Journal also condemned the compulsory license issued by the Brazilian government saying that “further compulsory license would be bad for intellectual property rights worldwide, and a...disaster for the world’s poor” (Alcorn, 2007, p. 2)<sup>794</sup>.

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<sup>790</sup> Alcorn, K. (May, 2007). Brazil issues compulsory license on efavirenz. Retrieved November 11, 2008, from <http://www.aidsmap.com/en/news/0550CE62-3F90-4603-932C-EF69E1B4485D.asp>

<sup>791</sup> Ibid.

<sup>792</sup> Pharmaceutical business review (May, 2007). Breaking Merck patent may drive investment away from Brazil. Retrieved November 13, 2008, from [http://www.pharmaceutical-business-review.com/article\\_feature.asp?guid=8A869BFC-88...](http://www.pharmaceutical-business-review.com/article_feature.asp?guid=8A869BFC-88...)

<sup>793</sup> Ibid.

<sup>794</sup> Alcorn, K. (May, 2007). Brazil issues compulsory license on efavirenz. Retrieved November 11, 2008, from <http://www.aidsmap.com/en/news/0550CE62-3F90-4603-932C-EF69E1B4485D.asp>

#### **(48) The failure of the Novartis's challenges against the Indian patent law**

As described earlier (case 43), in May 2006, Novartis challenged the Indian Patent Office in an Indian court, the Chennai High Court, after its rejection of the Novartis's patent application for Gleevec on the basis that the medicine was a new formulation of an existing drug. Novartis also challenged the constitutionality of the section 3(d) of the Indian Patens Act, specifically introduced by the Indian Parliament as a safeguard against the misuse of the product patent regime. In August 2007, the court dismissed the Novartis's claims on the ground that it believed it did not have jurisdiction to rule on whether the Indian patent laws were in compliance with the WTO's intellectual property laws ("Novartis challenges", 2007)<sup>795</sup>. Activists argued that if Novartis had won the cases, it potentially could have set a precedent for other pharmaceutical companies seeking the patent protection for medicines including ARVs ("Indian court rejects", 2007)<sup>796</sup>. Although Novartis decided not to appeal the decision, the company did not agree with the ruling. That is, a Novartis's statement said that the ruling would have long-term negative consequences for the R&D into better medicines for patients in India and abroad ("Indian court rejects", 2007)<sup>797</sup>. However, the public health activist groups were pleased with the court decision as a preservation of India's ability to produce inexpensive, generic medicines for the developing world ("Novartis challenges",

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<sup>795</sup> Novartis challenges Indian's patent office decision (2007, September 6). My Intellectual Property Rights [Electronic Version]. Retrieved November 11, 2008, from <http://www.myintellectualpropertyrights.com/news-ticker/2007/09/06/novartis-challenges-indias-patent-office-decision.php>

<sup>796</sup> Indian court rejects Novartis' challenge to country's patent law (2007, August 8). Medical News Today [Electronic Version]. Retrieved November 17, 2008, from <http://www.medicalnewstoday.com/articles/78906.php>

<sup>797</sup> Ibid.

2007)<sup>798</sup>. MSF in India announced that “we absolutely welcome this court order...it basically means fewer patents will be granted by the Indian patent office, and that means more affordable drugs can be produced by Indian manufacturers” (“Indian court rejects”, August 8, 2007)<sup>799</sup>.

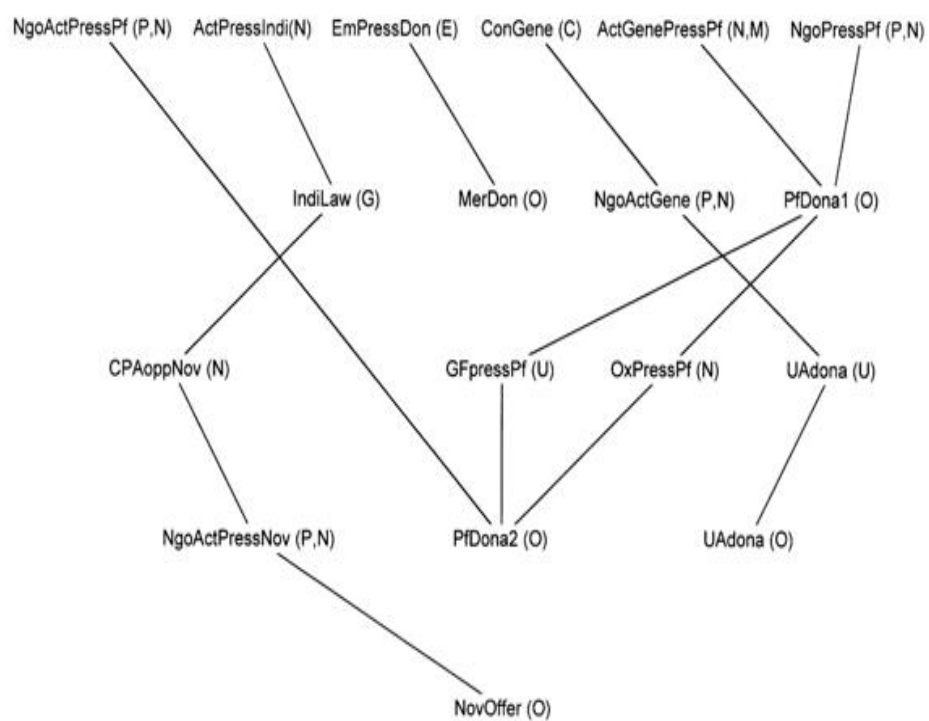
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<sup>798</sup> Novartis challenges Indian’s patent office decision (2007, September 6). My Intellectual Property Rights [Electronic Version]. Retrieved November 11, 2008, from <http://www.myintellectualpropertyrights.com/news-ticker/2007/09/06/novartis-challenges-indias-patent-office-decision.php>

<sup>799</sup> Indian court rejects Novartis’ challenge to country’s patent law (2007, August 8). Medical News Today [Electronic Version]. Retrieved November 17, 2008, from <http://www.medicalnewstoday.com/articles/78906.php>

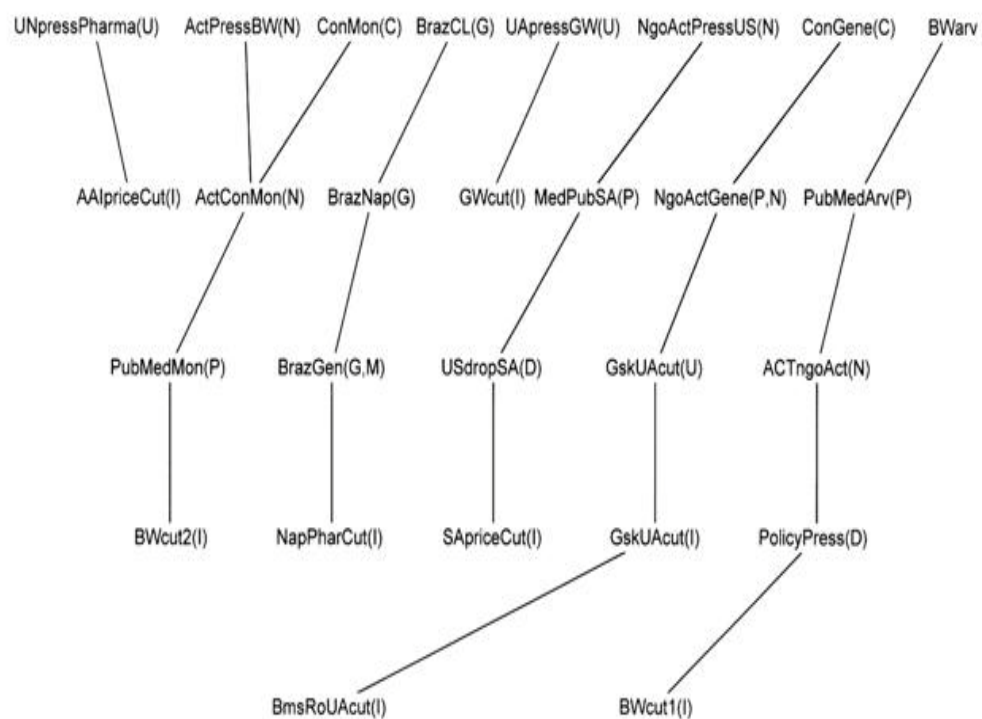
## Appendix 2: Ethno Diagrams

**Figure 1: ETHNO Diagram – The Antecedent Event Categories and the Consequent Event Category of Donation (D)**

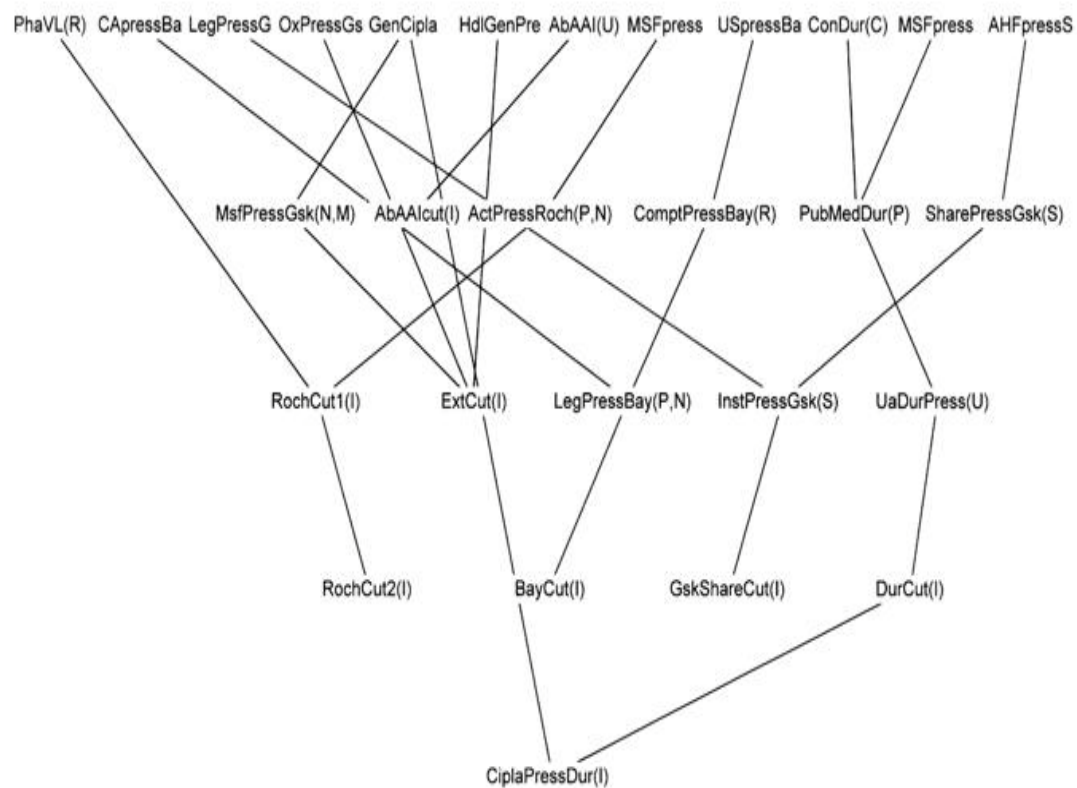




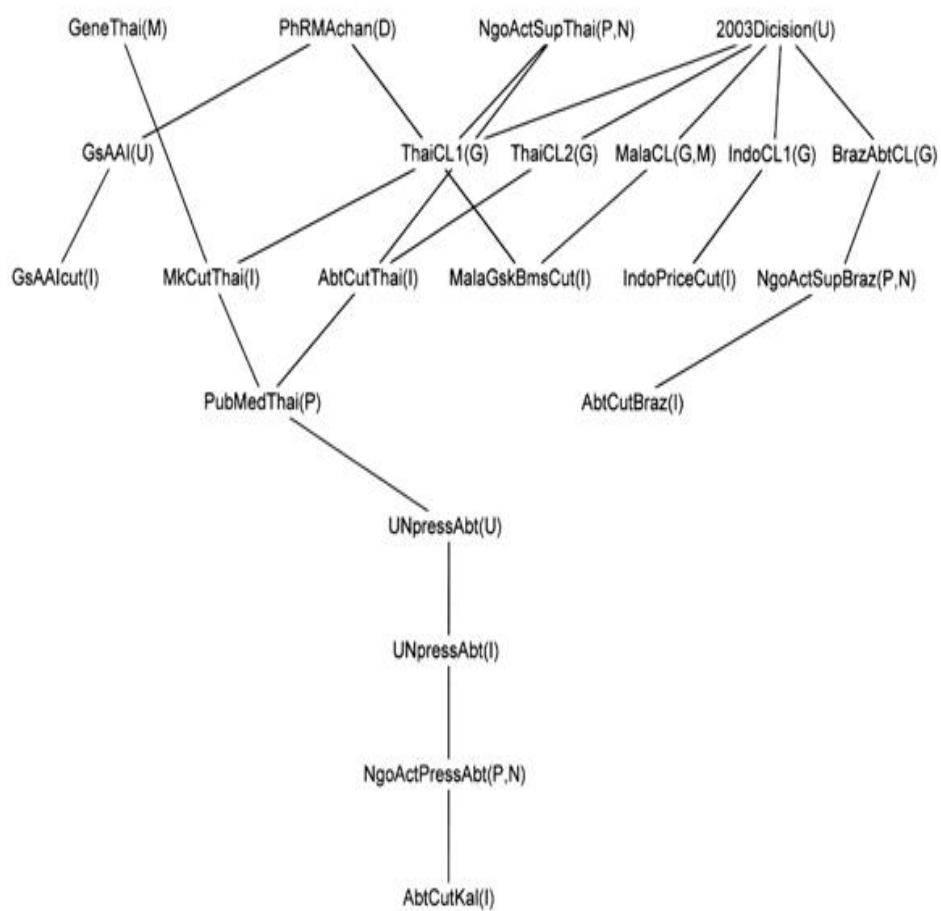
**Figure 2-1: ETHNO Diagram - The Antecedent Event Categories and the Consequent Event Category of Price Reduction (I)**



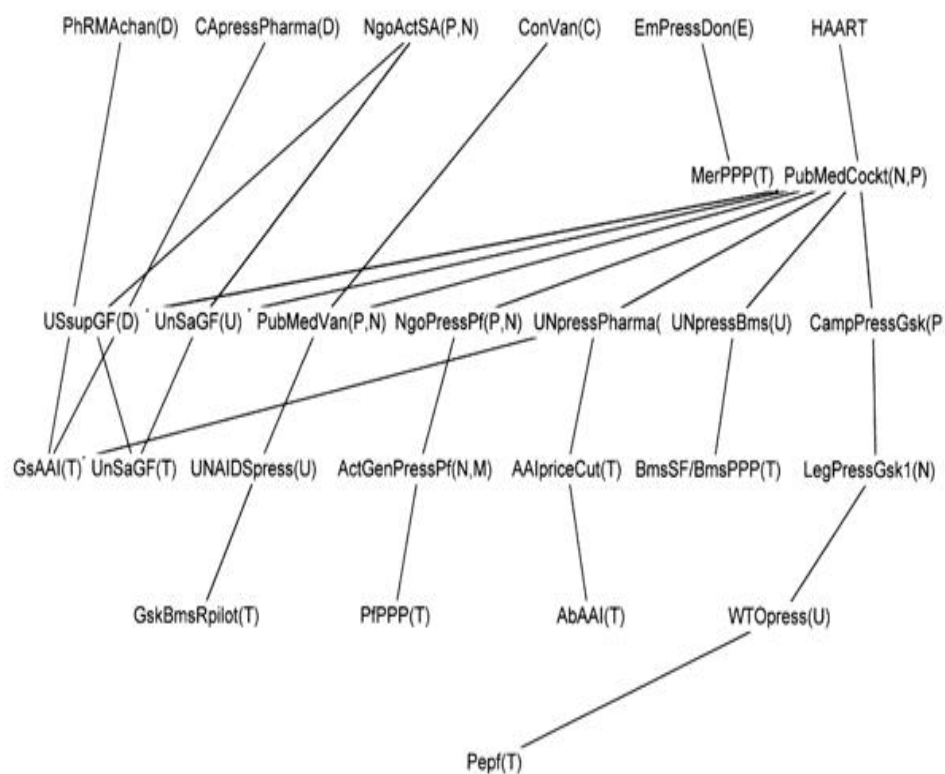
**Figure 2-2: ETHNO Diagram - The Antecedent Event Categories and the Consequent Event Category of Price Reduction (I)**



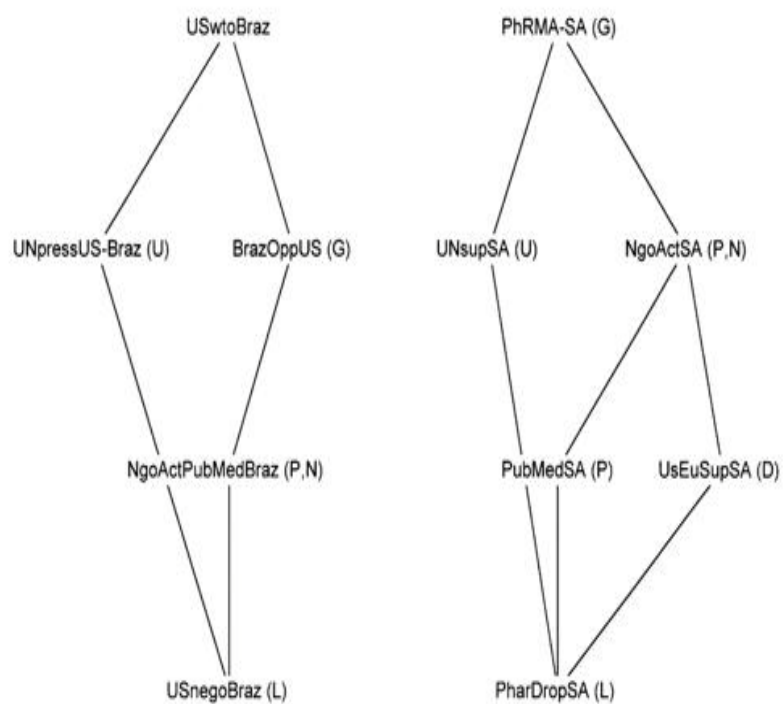
**Figure 2-3: ETHNO Diagram - The Antecedent Event Categories and the Consequent Event Category of Price Reduction (I)**



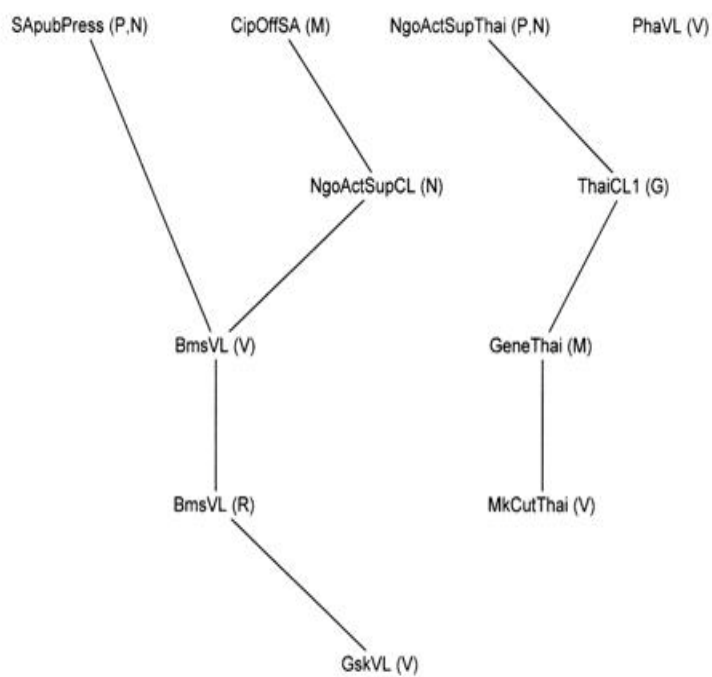
**Figure 3: ETHNO Diagram - The Antecedent Event Categories and the Consequent Event Category of Public-Private Partnership (T)**



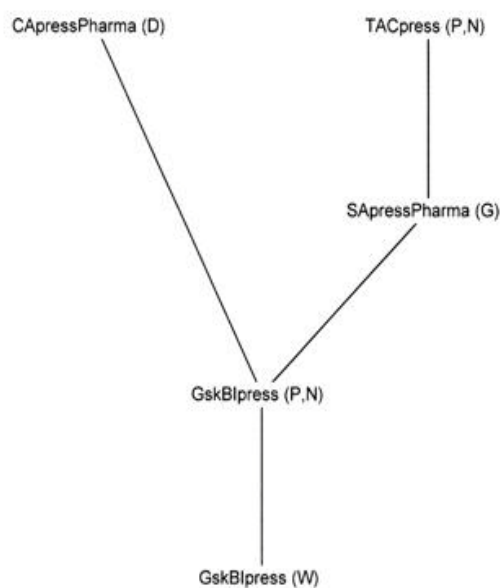
**Figure 4: ETHNO Diagram - The Antecedent Event Categories and the Consequent Event Category of Withdrawal of Lawsuit or Dispute (L)**



**Figure 5: ETHNO Diagram - The Antecedent Event Categories and the Consequent Event Category of Voluntary Licensing (V)**



**Figure 6: ETHNO Diagram - The Antecedent Event Categories and the Consequent Event Category of Patent Waiver (W)**



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### **Curriculum Vitae**

1968	Born February 15th in Seoul, Korea
1986	Graduated from Han Sung High School, Seoul, Korea
1993	Bachelor of Arts from Seoul National University, Seoul, Korea, Majored in Korean Language and Literature, Seoul National University Scholarship (1989 -1993)
1993 – 1998	Employed as Manager (Department of International Market Research and Analysis) at RAMS KOREA, Seoul, Korea
2003	Master of Science from Seton Hall University, Newark, New Jersey, Majored in International Business, Specialized in International Management, Master's Thesis: "The Issues related to Multinational Corporations"
2003	Elected to Membership in Beta Gamma Sigma, the National Scholastic Honor Society for Students in Business and Management
2003 – 2004	Doctor of Business Administration (DBA) from Golden Gate University, San Francisco, California, Specialized in Strategic Management (Completed Foundation and Core Curriculum Courses), Dissertation Proposal: "Business, Social Responsibility, and Public Policy – The Case Study of McDonald's"
2004	Student Excellent Award in International Business: Awarded by Deans and Faculty Members of Stillman School of Business at Seton Hall University in recognition of Excellent Academic Performance and Achievement
2005	Admitted to Graduate Program in Global Affairs, Rutgers University, Newark, New Jersey
2007	Passed Comprehensive Examination with Distinction
2010	Master of Science from Rutgers University, Newark, New Jersey, Majored in Global Affairs, Specialized in International Business/Global Management
2010	Ph.D. from Rutgers University, Newark, New Jersey, Majored in Global Affairs, Specialized in International Business/Global Management, Ph.D. Dissertation: "Organizational Strategy Development for the Pharmaceutical Industry – Event Structure Analysis, Comparative Boolean Analysis and Analogical Reasoning Model"