

The Challenges of Keeping “Private” International Dispute Resolution in the Private Healthcare Sector

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Abstract

Private healthcare companies operating globally often elect to resolve disputes outside local courts to expedite and control the resolution process, maintain privacy, avoid judicial bias against foreigners, and minimize disruption to business. But private dispute resolution involving health attracts the keen interest of government, which bears responsibility for the health and well-being of its citizens. This is a responsibility sometimes shared with neighboring governments that protect their borders from the threat of global disease and increasingly observe health as an international human right. Settling healthcare disputes when healthcare is the duty of government can never be completely “private.” Accordingly, healthcare companies may find it worthwhile to re-think the benefits of private dispute resolution—autonomy, discretion, privacy, and expediency—within the context of a mandate for the health of the global community, and draft settlements that serve the commercial interests at stake and advance the related government health policies as well.

I. Introduction

Private companies operating globally often elect to resolve disputes between themselves outside the courts of the diverse jurisdictions in which they operate. Instead they choose private through private dispute resolution, avoiding the courts because certain factors associated with running a business in a foreign jurisdiction often impede the operational efficiency enjoyed by the nationals of the country of investment.¹

One consideration is national controls on foreign exchange and limits on repatriation of capital, a factor which, with globalization, varies from market to market, and within a

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1. See Karl Sauvant, *The Rise of FDI Protectionism* 31 (The World Bank, Working Paper No. 5050, 2009); see also Karl P. Sauvant, *Driving and Countervailing Forces: A Rebalancing of National FDI Policies*, in *YEARBOOK ON INTERNATIONAL INVESTMENT LAW AND POLICY* 2008-2009 215-19, 233-34, 239 (Karl P. Sauvant ed., 2009).

given market swings between protectionism and openness.² A second consideration is mandatory employment of local talent.³ This requirement presents a challenge for the foreign employer inexperienced in local norms and practices.⁴ The challenge may be compounded because local talent relative to the professional and technical expertise of the industry of the foreign investor may be limited for historical or societal reasons, including underdevelopment and political oppression. For example, the ‘Bantu’ education system of South Africa under apartheid produced little opportunity for blacks, which therefore produced few black professionals for positions with foreign companies.⁵ Former World Bank President Robert McNamara stated: “I have seen very few countries in the world that have such inadequate educational conditions. I was shocked at what I saw in some of the rural areas and homelands. Education is of fundamental importance. There is no social, political, or economic problem you can solve without adequate education.”⁶ While such a protectionist requirement may compromise the foreign employer’s human resources practices and policies designed to guard international career developmental opportunities for select employees of “leadership potential,” absent such a local requirement, prospects for local talent to move into key positions in the local country would be diminished.⁷

Finally, there is a potential for a host government to be transitional, unstable, or in such need of investment so as to create an environment susceptible to corruption. “Whenever corruption and its consequence cannot be controlled and contained, the credibility of government suffers, the security of property rights erodes, and the level of uncertainty and risk in the economy increases,” all of which discourages foreign investment.⁸ Representing distinct challenges for the foreign investor, these factors are intensified by investor uncertainties about local *fora* expressly designated for resolving disputes—the courts—and a perception that local courts may be biased against foreigners seeking judicial redress. Accordingly, global companies competing in new environments may forego pursuing remedies in local courts and instead seek redress through private dispute resolution, the process of which they feel may better serve them.

2. See Diana Farrell, Jaana K. Remes & Heiner Schulz, *The Truth About Foreign Direct Investment in Emerging Markets*, MCKINSEY QUARTERLY, Feb. 2004, http://www.mckinseyquarterly.com/The_truth_about_foreign_direct_investment_in_emerging_markets_1386 (noting that “even as developing nations dole out lucrative incentives to attract foreign investment, they are often wary of multinational companies. Attempting to protect domestic industry and to ensure that foreign investment benefits the local economy, many of these nations restrict the way foreign companies can operate.”).

3. See Tsun-Yan Hsieh, Johanne Lavoie & Robert A. P. Samek, *Think Global, Hire Local*, MCKINSEY QUARTERLY, Nov. 1999, http://mkqpreview1.qdweb.net/Think_global_hire_local_368.

4. *Id.*

5. See SOUTH AFRICA: A COUNTRY STUDY (Rita M. Byrnes, ed., 1996), <http://countrystudies.us/south-africa/56.htm>.

6. Robert McNamara, Former President, World Bank, Speech in *During a Visit to South Africa* (1982); see also COUNCIL ON FOREIGN RELATIONS, *BEYOND HUMANITARIANISM: WHAT YOU NEED TO KNOW ABOUT AFRICA AND WHY IT MATTERS*, 82-83 (Princeton N. Lyman & Patricia Dorff, eds., 2007) (discussing the “lost generation” in underdeveloped, “battled-scarred and traumatized countries”).

7. *Id.*

8. INSTITUTE FOR INT’L ECON., *CORRUPTION AND THE GLOBAL ECONOMY* 193 (Kimberly Ann Elliot, ed., 1997); see also Karl Sauvant, *Africa: The FDI Opportunities are Local*, INTERNATIONAL TRADE FORUM, Aug. 28, 2007, <http://www.tradeforum.org/news/fullstory.php/aid/1129> (noting that “Africa has traditionally not been on the radar screen of foreign direct investors. The reasons include . . . its weak infrastructure and an image problem: in much of the world Africa’s image is dominated by pictures of civil war, sickness and famine”).

This paper will highlight a few of the features of private dispute resolution that are attractive for foreign investors generally and those that are especially beneficial for healthcare companies. Next, the paper will caution that the promise of autonomy, privacy, flexibility, and expediency associated with private dispute resolution may be compromised by the policies and politics of global health, increasingly dictated by government and international law and influenced by the promise and obligation associated with the corporate responsibility of the private sector. Last, the paper will stress the importance of anticipating potential disputes between private healthcare companies to obviate public policy arguments related to health at the time of an award's enforcement, as well as the importance of drafting settlements that serve the private commercial interests at stake, satisfy requirements of good corporate citizenship with respect to human rights, and advance the corresponding government health policies.

II. Benefits of Private Dispute Resolution

There are perceived benefits in resolving disputes outside foreign courts and to some degree outside the control of a foreign government. The benefits have been examined and widely accepted.⁹ One benefit is confidentiality, a sure measure for protecting proprietary data on which innovation (the cornerstone of a successful global economy) depends.¹⁰ Routine disclosure of proprietary data to the government is a necessary step throughout the various stages of the life of a business. But at the time of a dispute, when disclosure of detailed data may be desired for a full and proper examination of the issues, it may be more prudent for the actual examination of issues to occur in private, rather than in court. This would be of particular concern for a pharmaceutical company, for example, which seeks to protect the valuable scientific data associated with discovery and development of life-enhancing medicines produced and gathered over years of research and testing. It stands to reason that, unless required to do so, companies will prefer not to seek redress in the courts where such information is likely to be made public and discussed broadly.¹¹ Other reasons that a disputing company may value resolution in private is the

9. COMM'N ON LEGAL EMPOWERMENT OF THE POOR, *MAKING THE LAW WORK FOR EVERYONE*, 63-64 (2008), http://www.undp.org/legalempowerment/report/Making_the_Law_Work_for_Everyone.pdf (Although many modern businesses have looked to alternative dispute resolutions processes as a viable option in today's commercial world, dispute resolution has taken multiple forms through history. Informal dispute resolution, for example, was not uncommon in underdeveloped societies. The vast majority of the world's poor rely on non-state, informal justice systems. "Third Party Arbitration Courts (TPACs) . . . offer effective protection of rights and/or effective resolutions of disputes over contested property arrangements, especially for disenfranchised women."); see also JOHN MARKAKIS, *ETHIOPIA: ANATOMY OF A TRADITIONAL POLITY* 296 (1974).

10. Janice A. Roehl, *Private Dispute Resolution* 4, (National Symposium on Court-Connected Dispute Resolution Research Working Paper, 1993), available at http://www.ncsconline.org/WC/Publications/KIS_ADROthNadSympCtDispPvt.pdf.

11. See generally Andrew Witty, Chief Executive Officer, GlaxoSmithKline, *Open Labs, Open Minds: Breaking Down the Barriers to Innovation and Access to Medicines in the Developing World* (Jan. 20, 2010), http://www.cfr.org/publication/21273/open_labs_open_minds.html (commenting on confidentiality and the usefulness of sharing proprietary know-how and infrastructure).

likely ease in complying with evolving privacy laws and in managing and/or obviating a local perception that its business culture is one of contention and agitation.¹²

Private dispute resolution is also desired because the process is often speedier and less disruptive than the judicial process.¹³ The disputing parties can set a mutually convenient date for the proceedings and limit the length and scope of arguments to ensure that the process accommodates the exigencies of their businesses.¹⁴ Companies are not in business to litigate, and they seek to resolve disputes with as little disruption to business as possible.¹⁵ In the case of a company that relies on a sole distributor, licensee, or other third party representative, litigation may threaten the continuation of the local operations; private dispute resolution in such a case is considered a form more conducive to sustaining an ongoing business.¹⁶ Furthermore, for the healthcare company, cognizant of the tremendous responsibility associated with its role of supplier of health products and services, resolving disputes quickly with minimal disruption becomes a business imperative.¹⁷ In this regard, government may see that prompt resolution of disputes between healthcare companies is in its own interest as well, so that potentially vital health services and products are not kept from the market pending resolution of the dispute.

Unfamiliarity with the local courts is another reason that private dispute resolution may be sought.¹⁸ Although foreign investors rely on and value local lawyers,¹⁹ the investor's overall unfamiliarity with local laws and inexperience before the local courts tends to steer redress away from litigation. Consider China, where written laws are just now becoming broadly published and readily available.²⁰ Until recently, legal practitioners would often need to visit the relevant regulatory agency in person to read the laws, a situation that was especially impractical for a non-Chinese lawyer.²¹ This is why private dispute resolution, under which selection of substantive and procedural laws falls within the discretion of the private parties, is often chosen.

The ability of private parties to agree on a decision-maker who is knowledgeable in the subject field of the dispute is of particular benefit for healthcare companies. For the healthcare company, non-commercial disputes (those based primarily in science and chemistry) are especially challenging for courts because law, remedial in nature, lags be-

12. ALBERT FIADJOE, *ALTERNATIVE DISPUTE RESOLUTION: A DEVELOPING WORLD PERSPECTIVE I* (2004).

13. Roehl, *supra* note 10.

14. NANCY F. ATLAS, STEPHEN K. HUBER & E. WENDY TRACHTÉ-HUBER, *ALTERNATIVE DISPUTE RESOLUTION: THE LITIGATOR'S HANDBOOK 20-21* (American Bar Association Section of Litigation 2000).

15. *Id.* at 21.

16. See Curtis H. Barnette, *The Importance of Alternative Dispute Resolution: Reducing Litigation Costs as a Corporate Objective*, 53 *ANTITRUST L. J.* 277 (1984).

17. See Alan Bloom, Michael Dempsey, Ila S. Rothschild, Rocco Scanza & James L. Hall, *Alternative Dispute Resolution in Health Care*, 16 *WHITTIER L. REV.* 61, 66 (1995).

18. FIADJOE, *supra* note 12.

19. See generally Abenaa A. Ori-Prempeh, U.S. Foreign Direct Investment in Developing Countries: a Case Study of Malaysia, Mexico and South Africa (2003) (unpublished L.L.M. theses, University of Georgia School of Law), http://digitalcommons.law.uga.edu/cgi/viewcontent.cgi?article=1039&context=stu_llm.

20. See generally Joan Liu & Wen Luo, *A Complete Research Guide to the Laws of the People's Republic of China (PRC)*, LAW LIBRARY RESOURCE XCHANGE, Jan. 15, 2003, <http://www.llrx.com/features/prc.htm>.

21. *Id.* (noting that "For a long period of time, the difficulty in accessing legal information was the major obstruction to conduct legal research in [China]").

hind science.²² Accordingly, decision-makers with special knowledge in health and science are strongly desired to tackle the disputes based in their field of expertise.²³ Parties also seek to agree on a decision-maker that is neutral, as this neutrality presumably preempts a potential bias of local judges against the foreign interests involved in seeking redress.²⁴ All of these factors are seen objectively as benefits, especially for a healthcare company.

III. The Inevitable Role of Courts and Government in the Healthcare Sector

But while private companies have the opportunity to settle disputes with the referenced benefits—neutrality, technical expertise, privacy, expedition and for the healthcare company, the privilege of “standing” before special settlement *fora*—involvement of the government is inevitable.²⁵ Despite its advantages, private dispute resolution involving healthcare can never wholly be private, that is, outside the fundamental control of government. Just as the national court examines and resolves problems within a context of norms that observe and adhere to public policy, it also enforces decisions and awards that derive from private dispute resolution within the same context. To this point, an international treaty recognizes that deference must be given to national courts when enforcement of an award resulting from private dispute resolution would put public policy issues at risk.²⁶ An arbitral award will not be enforced if “recognition or enforcement of the award would be contrary to the public policy of that country.”²⁷ It is expected that the national court will not abdicate its role in confirming, validating, and enforcing non-judicial decisions, rulings, and awards of public policy concern, including healthcare related concerns.

For the healthcare company, the public policy component is especially challenging because health is a paramount public policy concern. Health is a sure path to the government priorities of development and productivity, and to advance these policies individual governments assume the responsibility for the healthcare of their citizens as a matter of

22. See, for example, Peter J. Rugg-Gunn, Ubaka Ogbogu, Janet Rossant & Timothy Caulfield, *The Challenge of Regulating Rapidly Changing Science: Stem Cell Legislation in Canada*, 4 CELL STEM CELL 285 (2009); Tamar Lewin, *In Genetic Testing for Paternity, Law Often Lags Behind Science*, N.Y. TIMES, Mar. 11, 2001, <http://www.nytimes.com/2001/03/11/us/in-genetic-testing-for-paternity-law-often-lags-behind-science.html>; Diane Levin, *Does Law Lag Behind Science? Psychologists Question Supreme Court campaign finance decision*, MEDIATION CHANNEL, Jan. 31, 2010, <http://mediationchannel.com/2010/01/31/does-law-lag-behind-science-psychologists-question-supreme-court-campaign-finance-decision/>.

23. WIPO Arbitration and Mediation Center, <http://www.wipo.int/amc/en/> (last visited July 21, 2010) (“The [arbitration, mediation and expert determination] procedures offered by [the World Intellectual Property Organization (“WIPO”) Arbitration and Mediation Center] are widely recognized as particularly appropriate for technology, entertainment and other disputes involving intellectual property” between private parties.).

24. FIADJOE, *supra* note 12.

25. See WIPO Caseload Summary, <http://www.wipo.int/amc/en/center/caseload.html> (last visited July 22, 2010) (consider the example of healthcare companies that dispute their issues before WIPO).

26. See, for example, Convention on the Recognition and Enforcement of Foreign Arbitral Awards, July 6, 1988, http://www.uncitral.org/pdf/english/texts/arbitration/NY-conv/1958_NYC_CTC-e.pdf.

27. U.N. Conference on Int'l Commercial Arb., N.Y., U.S., June 7, 1959, *Convention on the Recognition and Enforcement of Foreign Arbitral Awards*, art. 5.

law and policy.²⁸ At times and at the expense of private interests, explicit acts of government—drug approvals; licensing; recalls; supply and price controls; hospital formulary listing of drugs; drug manufacturing oversight; vaccination campaigns; clinical trial requirements; protection of proprietary drug information through patents; certification of healthcare professionals; and the control of public dissemination of information—will inevitably bear on how private disputes are resolved. In the United States, healthcare was a priority at the outset of the Obama presidency.²⁹ The government regulates because it is in the government's best interest "to improve access to health care, the quality of such care, and the sustainability of the health care system."³⁰ In India, access to nutrition and health is essential, according to Prime Minister Manmohan Singh.³¹ "Tackling the developing world's diseases has become a key feature of many nations' foreign policies . . . It takes states, healthcare systems, and at least passable local infrastructure to improve public health in the developing world."³²

Government responsibility for healthcare has long been recognized under international law as well as under the laws of individual nations. The *Universal Declaration of Human Rights* and the *Constitution of the World Health Organization* identify health as a right.³³ Such recognition has led to each government's interest in seeing that its neighboring governments take care of the health needs of their respective citizens, resulting in a collective government responsibility for health extending beyond national borders.³⁴ "Today, all health threats are universal, and everyone on the planet is affected."³⁵ International cooperation represents the most effective way to confront pandemics, which makes interdependence not a mere policy option but "quite literally a matter of life and death."³⁶ In this regard, multiple global initiatives are underway to draw attention to and address health and development and to the need for international interdependence and cooperation. For

28. See Robert Costanza et al., *An Integrative Approach to Quality of Life Measurement, Research, and Policy*, 1 S.A.P.I.E.N.S. 17 (2008).

29. See Organizing for America (BarackObama.com), *Barack Obama and Joe Biden's Plan to Lower Health Care Costs and Ensure Affordable, Accessible Health Coverage for All*, <http://www.barackobama.com/pdf/issues/HealthCareFullPlan.pdf>.

30. Establishment of White House Office of Health Reform, 74 Fed. Reg. 69, 17071, 17071 (Apr. 8, 2009).

31. See Richard Hass, President And Director of the Woodrow Wilson International Center For Scholars, *A Conversation with Prime Minister Dr. Manmohan Singh* (Nov. 23, 2009).

32. Laurie Garret, *The Challenge of Global Health*, FOREIGN AFFAIRS, Jan.—Feb. 2007, at 14, available at <http://www.foreignaffairs.com/articles/62268/laurie-garrett/the-challenge-of-global-health>.

33. Universal Declaration of Human Rights, G.A. Res. 217A, art. 25, U.N. Doc. A/RES/217(III) (Dec. 10, 1948) ("Everyone has the right to a standard of living adequate for the health and well-being of himself and his family, including food, clothing, housing and medical care and necessary social services, and the right to security . . ."); World Health Org. [WHO], *Constitution of the WHO*, Introduction (July 22, 1946), available at http://www.who.int/governance/eb/who_constitution_en.pdf ("The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being . . .").

34. See, for example, Benjamin Mason Meier & Ashley M. Fox, *International Obligations Through Collective Rights: Moving from Foreign Health Assistance to Global Health Governance*, 12 HEALTH & HUM. RTS. J. 61 (2010).

35. Dr. Nils Daulaire, President and CEO of Global Health Council, *A New Social Compact* (Nov. 28, 2007), available at http://www.globalhealth.org/view_top.php?id=544.

36. Pascal Lamy, World Trade Organization Director-General, *Strengthening Multilateral Cooperation on IP and Public Health* (July 14, 2009), available at http://www.wto.org/english/news_e/sppl131_e.htm ("The international IP system cannot operate in isolation from the broader public policy questions such as how to meet basic human needs for health, food and a clean environment.").

example, The World Justice Project advocates that increasing the rule of law leads to sustainable communities in which people have access to equity, safety, and health.³⁷

Furthermore, because incidences of disease have the potential to become pandemic and global health threats that have no boundaries, global health acquires even more prominence in the era of multiple and related global exigencies, including global security and climate change. “Climate change will likely have a severe impact on disease patterns and on agriculture: so health, food security and adaptation to climate change are fundamentally interlinked.”³⁸

Accordingly, the collective government responsibility for global health is understood in a world committed to development, concerned with security, and observant of human rights. Because of this, each government will have an interest in seeing a resolution of a health dispute between private parties within its borders inuring to the well-being of its citizens. With recognition that government will always have an interest in and a responsibility for health, government has been granted a role in resolving disputes not solely in the courtroom but implicitly at the private negotiating table as well.³⁹

Private healthcare companies may not only be forced to react to the demands of government and national courts. Private companies, increasingly expected to exhibit the principles of corporate responsibility, may have to affirmatively adopt or partner with the government agenda, sometimes against their own interest, to ensure that results of disputes are consistent with public policy, in the best interest of the affected community, and in line with human rights.⁴⁰ The emergence of private initiatives for corporate responsibility has been an important trend in international business over the last thirty years,⁴¹ and the success of such initiatives requires an appropriate alliance with government.⁴² Conse-

37. About the World Justice Project, <http://www.worldjusticeproject.org/about/> (last visited July 22, 2010) (“The World Justice Project is based on two, complementary premises: [f]irst, the rule of law is the foundation for communities of opportunity and equity; and [s]econd, multidisciplinary collaboration is the most effective way to advance the [r]ule of [l]aw.”); see also Laurie Garrett & Isobel Coleman, *Foreign Aid Reflects Lack of Concern for Mothers*, TORONTO STAR, Aug. 8, 2006, at A17; NATIONAL COUNCIL FOR RESEARCH ON WOMEN (NCRW), GAINS AND GAPS: A LOOK AT THE WORLD’S WOMEN 12-13 (NCRW 2006).

38. Lamy, *supra* note 36; see generally Stephen E. Flynn & Daniel B. Prieto, *Neglected Defense: Mobilizing the Private Sector to Support Homeland Security*, COUNCIL SPECIAL REPORTS, Mar. 2006, available at http://www.cfr.org/publication/10457/neglected_defense.html; William Onzivu, *Tackling the Public Health Impact of Climate Change: The Role of Domestic Environmental Health Governance in Developing Countries*, 43 INT’L LAW. 1311 (2009).

39. See World Trade Organization, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, 41 I.L.M. 755, 755 (2002) (There are telling examples related to patents where the rights of the private party-patent holder are subject to national emergencies. The Doha Declaration clarified TRIPS by permitting the least developed countries to delay implementation and enforcement of patent rules, stating that governments could afford priority to public health needs over intellectual property rights). World Trade Organization, Ministerial Declaration of 14 November 2001, ¶ 17-19, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002).

40. The Special Representative to the Secretary-General, *Protect, Respect and Remedy: a Framework for Business and Human Rights*, ¶ 9, delivered to the Human Rights Council, U.N. Doc. A/HRC/8/5 (Apr. 7, 2008) (The 2008 Report of John Ruggie, UN Secretary-General’s Special Representative, posited the “corporate responsibility to respect human rights” as one of three core principles).

41. Organization for Economic Co-Operation and Development, Corporate Responsibility, http://www.oecd.org/department/0,3355,en_2649_33765_1_1_1_1_1,00.html (last visited July 21, 2010).

42. Lamy, *supra* note 36 (“Effective partnership also means we [government and the private sector] have to recognize that we have complementary roles, different areas of expertise, and distinct mandates—we will make most progress if we each play to our strengths and recognise [sic] the strengths of our partners . . . To

quently, health and the disputes resulting from providing health involve a public-private dimension that is conflictive as well as collaborative, and one that is national as well as international. Accordingly, it may be worthwhile to re-think the supremacy of “liberty of contract”⁴³ and the benefits of private dispute resolution—autonomy, discretion, expedition, and independence—for healthcare companies within the context of certain current global realities.

This gives healthcare companies cause to question if a “health” component can be seen reasonably as lying at the core of each and any of their disputes. If this is the case, the success of settling health related disputes in the private sector without government interference is improbable.⁴⁴ So what does this entail for the healthcare company? It may be useful at the time of contract drafting to distinguish potential breaches as primarily commercial by emphasizing the financial, logistical, and operational components that may lie at the core of the potential breach. As an example, it may be argued that an award upholding a licensor’s right to terminate is consistent with the terms of the underlying license agreement because the licensee’s failure to pay royalties or maintain inventory levels would be deemed commercial and not threatening public policy. In such a case of award enforcement, the licensor would be free to select another licensee to carry on its activities for the good of the market, the community, and the licensor itself. It would be difficult to argue that public policy was threatened in enforcing such an award. But with respect to an award upholding a licensor’s right to delete a medicine from a product line under license to a licensee, based on a licensor’s contractual right to do so and proprietary interest, a potentially significant impact on access to health could be foreseen as a strong public policy concern if such a deletion would diminish or compromise a vital therapy for the community. A court’s challenges to such an award would be reasonable and strong.

IV. Conclusion

The objective of a collective community good associated with government responsibility, a universal desire for global health, and corporate responsibility may preclude the private good that may come from the flexibility and independence associated with private settlement. But this need not be always the case. It will be necessary to draft agreements for private dispute resolution that take into consideration the commercial consequences as well as health access consequences of potential disputes. This can best be done with the understanding that global health and development will not thrive without respect for the valuable and proper combination of, on the one hand, the government’s duty for the health of its citizenry, and, on the other hand, the private health sector’s continued commitment to research, sustained innovation, superior market performance, and good corporate citizenship.

retreat behind borders . . . is not an option.”); see generally Shelley Hayes, *Health Threats to the Global Economy: Corporate Responses to Emerging and Reemerging Infectious Diseases*, INT’L. L. NEWS, Winter 2010 at 22-24; see HENRY STEINER ET AL., *BUSINESS AND HUMAN RIGHTS* 9 (1999).

43. BLACK’S LAW DICTIONARY 937 (8th ed. 2004).

44. For example, in the pharmaceutical industry where patents, trademarks, product registrations, and marketing authorizations are granted by the regulatory agencies, any private arrangements between the parties may be trumped and rendered meaningless by regulatory imperative.