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THEORY: THE POST-WTO ERA**

Daniel Benoliel e Bruno Meyerhof Salama

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Towards an Intellectual Property Bargaining Theory: The Post-WTO Era

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This article proposes a positive bargaining theory for intellectual property-based technologies in the post-WTO era. It focuses on negotiations between patent-sensitive industries and developing countries over legal endowments and access conditions in an archetypical patent-sensitive industry, namely the pharmaceutical industry. The ability on the part of developing countries to issue, or threaten to issue, compulsory licenses over pharmaceutical products serves as a working example.

The article's analysis of the bargaining power possessed by developing countries combines a conventional assessment of market size with a qualitative analysis that highlights the effects of these countries' propensity to innovate. The ensuing bargaining situation yields numerous insights, the primary ones being as follows: Firstly, innovation in intellectual property-based technologies, such as within the fields of pharmaceuticals, software, information communication technologies (ICTs), and plant genetics, creates a paradoxical effect within the group of innovative Newly Industrialized Countries (NICs). The paradox is based on the notion that innovation weakens, rather than boosts, the countries' bargaining power vis-à-vis the prospect of bargaining retaliations. This conspicuously is the case of the prospects of issuance of compulsory licenses over pharmaceutical patents.

Secondly, the resulting bargaining dynamic deemphasizes the practical significance of the Least-Developed-Country (LDC) carve-out contained in the TRIPS and other WTO agreements. Specifically, it is argued, distributive justice policies contained in TRIPS should be geared toward a broader group of weak developing countries extending beyond the group of LDCs. This theory points out to a tentative threefold typology of developing countries, defined based on their bargaining power. Accordingly, developing countries are modeled as HBPs, MBPs, and LBPs depending on whether they are relatively high-, medium-, or low-bargaining power countries, respectively.

In its conclusion, this article contends, based on the model presented, that strong protection of intellectual property rights could have significant negative allocative consequences for developing countries. Such is the case without contributing to--and even impeding--their technological development. Arguably, the HBP-MBP-LBP underlying developmental inequality shifts the optimal balance between static and dynamic efficiencies. In that sense, TRIPS may prove ineffective in promoting dynamic long-term innovation policies for developing countries.

I. Introduction

This article proposes a positive bargaining theory for intellectual property-based technologies in the post-WTO era. It focuses on negotiations over legal endowments and access conditions in an archetypical patent-sensitive industry, namely the pharmaceuticals industry. The ability of developing countries to issue, or threaten to issue, compulsory licenses over pharmaceuticals serves as a working example. A compulsory license forces the patentee to license the patent to the issuing government, thus permitting local production or importation of generic copies of the drug for payment of below-market compensation to the patentee.

The WTO-sponsored Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) contains numerous loopholes that provide plasticity for national governments to respond to political exigencies.³ In reality, these loopholes consist of flexibilities and safeguards that allow WTO members to minimize the potential negative effects of intellectual property protection.⁴ From among such loopholes, the authorization for WTO members to compulsorily license patents is of particular relevance. While TRIPS mandates that all WTO members enact and enforce TRIPS-compliant patent laws in their territories, in limited circumstances it also allows national governments to force the patentee to grant use of the patent for payment of below-market royalties.⁵ Yet, the issuance of a compulsory license is largely dependent upon whether the country possesses sufficient bargaining power, the existence of legal loopholes notwithstanding.

In the post-WTO era, it is commonly thought that the GATT/WTO system has proven increasingly subject to legal, rather than political, control.⁶ Indeed, the Uruguay Round of negotiations that ended in 1994 “legalized” the international negotiations.⁷ One of the alleged achievements of the Uruguay Round was that it promoted a reduction in the power held by developed countries.⁸ That assertion is often grounded on a set of treaty provisions that were purportedly designed to limit the use of power, both in the context of dispute resolution and more broadly in trade negotiations.⁹ The establishment of legal rules, such as those set forth for instance under the TRIPS Agreement, begs the use of legal discourse.¹⁰ Consequently, even

³ Judith Goldstein et al., “Introduction: Legalization and World Politics” (2000) 54 *International Organization* 393.

⁴ Robert Weissman, A Long, Strange TRIPS: The Pharmaceutical Industry Drive To Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries, 17 *U. Pa. J. Int'l Econ. L.* 1069, 1096 (1996).

⁵ Antony Taubman, Rethinking TRIPS: “Adequate Remuneration” For Non-Voluntary Patent Licensing, 11 *J. Int'l Econ. L.* 927 *passim* (2008).

⁶ See generally, John H. Jackson, *The World Trading System* 109-111 (2d ed. 1997) (comparing the new rule-based system of the WTO after the Uruguay Round with the prior power-oriented system of GATT). See also Peter M. Gerhart & Archana Seema Kella, *Power and Preferences: Developing Countries and the Role of the WTO Appellate Body*, 30 *N.C.J. Int'l L. & Com. Reg.* 515 (2005).

⁷ Kenneth W. Abbott et al., *The Concept of Legalization*, *International Organization*, 54(3) *Int'l Org.* 409 (2000).

⁸ In this article, the term “developed countries” includes the United States, Canada, European Union countries, Cyprus, Malta, Slovenia, Israel, Japan, South Korea, Hong Kong, Singapore, Taiwan, Australia, and New Zealand. See IMF *Advanced Economies List*. *World Economic Outlook, Database—WEO Groups and Aggregates Information*, October 2008. Available at <http://www.imf.org/external/pubs/ft/weo/2008/02/weodata/groups.htm#ae>.

⁹ See generally WTO, *Understanding on Rules and Procedures Governing the Settlement of Disputes*, Apr. 15, 1994, WTO Agreement, Annex 2, 33 *I.L.M.* 112 (1994) [hereinafter WTO, *Understanding*], Article 23 (on channeling disputes between countries concerning the obligations in the WTO treaties into the dispute settlement procedure). See also WTO, *Agreement on Safeguards*, available at http://www.wto.org/english/docs_e/legal_e/25-safeg.doc, Article 11 (prohibiting the use of unilateral action to seek voluntary restraints on trade between member countries).

¹⁰ Abbott *supra* note 5.

where disagreement exists over the exact interpretation of a rule, negotiations can no longer be carried out exclusively in terms of interests and power.¹¹ However, as this article demonstrates, in the context of bargaining between patent-sensitive industries and developing countries, the demise of the power-based system is in many ways unlikely. As is to be argued, the basis on which the relevant law is made is best understood through a power-based system.¹² This reality explains the usefulness of applying bargaining theory as an analytical tool.¹³

Equally important is the notion that the bargaining situation of developing countries has typically been understood from a relatively narrow standpoint. Conventional analysis measures power by a ballpark estimate of market size that is based on the overall size and diversity of each country's economy.¹⁴ It adopts the perspective of governments which treat domestic market opening as a cost, and foreign market opening and associated increases in export opportunities as domestic political benefit.¹⁵ Both in theory and practice, however, this framework is flawed in two ways. Firstly, it tends to ignore the broader options before each developing country in the course of the bargaining process. Bargaining theory illuminates these options by describing two additional factors beyond the issue of market power. The first of these factors is the country's 'outside option', which entails its expected payoff in the absence of an agreement with the patentee. The identification of the outside option is significant, for instance because reaching an agreement with the patentee may become unappealing if the alternative, the unilateral issuance of a compulsory license, is sufficiently attractive.¹⁶ The second factor relates to the country's 'inside options', which are the actions that the country may take in order to derive positive payoffs while temporarily disagreeing in the course of the bargaining process.¹⁷ Developing countries make use of an inside option, for instance, when they avoid de facto protecting intellectual property rights while formally complying with the TRIPS Agreement.¹⁸

¹¹ *Id.* See also Richard H. Steinberg, Judicial Lawmaking at the WTO: Discursive, Constitutional, and Political Constraints, 98 A.J. I.L. 247, 257-262 (April 2004).

¹² Joseph Straus, The Impact of the New World Order on Economic Development: The Role of Intellectual Property Rights System, 6 J. Marshall Rev. Intell. Prop. L. 1, 10 (2006) (with reference to the power-based system within the FTAs and TRIPS-Plus agreements); Joseph Straus, Bargaining around the TRIPS Agreement: The Case for Ongoing Public-Private Initiatives to Facilitate Worldwide Intellectual Property Transactions. A Comment on the Paper Presented by David Lange and J.H. Reichman, 9 Duke J. Comp. & Int'l L. 91, 95 (1998); Peter M. Gerhart, The Two Constitutional Visions of the World Trade Organization, 24 U. Pa. J. Int'l Econ. L. 1 (2003).

¹³ Richard H. Steinberg, In the Shadow of Law or Power? Consensus-Based Bargaining and Outcomes in the GATT/WTO, 56 Int'l. Org. 339 (2002); Gregory Shaffer, Power, Governance and the WTO: A Comparative Institutional Approach, in Power and Global Governance (Michael Barnett & Raymond Duvall, eds. 2004).

¹⁴ Richard H. Steinberg, *supra* note 11.

¹⁵ *Id.*

¹⁶ Abhinav Muthoo, A Non-Technical Introduction to Bargaining Theory, 1 World Econ., 159 (2000) [hereinafter Muthoo, Non-Technical Bargaining]. See also Robert D. Cooter, The Strategic Constitution, 274 (2000) (referring to the outside option as a party's "threat value"); Leigh L. Thompson, The Mind and Heart of the Negotiator (2001) (referring to the outside option as the "reservation value" or "disagreement value").

¹⁷ Muthoo, Non-Technical Bargaining, *supra* note 14, at 149, 157-160.

¹⁸ Robert M. Sherwood, The TRIPS Agreement: Implications for Developing Countries, 37 IDEA 491, 544 (1997) [hereinafter Sherwood, The TRIPS Agreement] (noting that "the judicial systems in perhaps eighty percent of the countries of the world are simply not up to the task of supporting intellectual property rights, much less dealing effectively with other matters"); and Robert M. Sherwood, Some Things Cannot Be Legislated, 10 CARDOZO J. INT'L & COMP. L. 37, 42 (2002). See also TRIPS, Article 41 (defining the four key tenets of national enforcement provisions, which are largely modeled on American intellectual property law).

A second way in which the GATT/WTO system is flawed in its attempt to explain the bargaining situation of developing countries in the post-WTO era relates to two special characteristics of contemporary intellectual property-sensitive bargaining. The first feature is that innovation in intellectual property-sensitive technologies creates a paradoxical effect within the group of innovative Newly Industrialized Countries (NICs). The paradox lies in that innovation weakens, rather than boosts, their bargaining power vis-à-vis the prospect of bargaining retaliations. This conspicuously is the case of the prospects of issuance of compulsory licenses over pharmaceutical patents. The second insight deemphasizes the practical significance of the Least-Developed-Country (LDC) carve-out contained in TRIPS and other WTO agreements. Specifically, as this article shows, distributive justice policies contained in TRIPS should be geared toward a broader group of weak developing countries extending beyond the group of LDCs. This theory points out to a tentative threefold typology of developing countries based on their bargaining power. Accordingly, developing countries are modeled as HBPs, MBPs, and LBPs depending on whether they are relatively high-, medium-, or low-bargaining power countries, respectively.

Part II describes the transition between the pre- and post-WTO legal and institutional frameworks pertaining to intellectual property bargaining. It claims the new framework crystallized a two-tiered bargaining situation over the conditions of access by developing countries to intellectual property-based products and technologies generated in developed ones. In this two-tiered bargaining situation, developing countries bargain simultaneously with governments of developed countries (Tier-1 bargaining) and with the industry (Tier-2 bargaining).¹⁹ Against this backdrop, post-WTO international intellectual property regulation generally influenced the bargaining power of developing countries, but unequally so. This lays the conceptual foundations for the description of the bargaining situation of developing countries in terms of their outside option, inside options, and market power. The pharmaceutical industry, being a prototypical patent-sensitive industry, serves as a working example in which to apply this framework.

Part III employs concrete case studies to propose a conceptual shift. That shift would usher the analysis from the current dichotomic view of a developing-developed country typology, into a more complex one that divides developing countries in three categories, namely High-Bargaining Power Countries (HBPs), Medium-Bargaining Power Countries (MBPs), and Low Bargaining Power Countries (LBPs). While limited to assessing the country's ability to circumvent TRIPS provisions through compulsory licenses, this typology highlights: the distinctive position of NICs in comparison to the remainder of developing countries; the existence of unequal levels of innovation within parts of the developing world, particularly within certain NICs; and perhaps most importantly, the notion that distributive justice policies contained in TRIPS should be geared toward a broader group of countries.

Part IV concludes with a set of policy ramifications. It contests the institutional favoritism of LDCs over a broader group of developing countries, such as within the 2005 Hong Kong declaration. In addition, it argues that the HBP-MBP-LBP underlying developmental inequality shifts the optimal balance between static and dynamic

¹⁹ See Ravi Ramamurti, *The Obsolescing 'Bargaining Model'? MNC-Host Country Relations Revisited*, 32 *J. Int'l Bus. Stud.* 23-39 (2001); Robert D. Putnam, *Diplomacy and Domestic Politics: The Logic of Two-Level Games*, 42 *INT'L ORG.* 427 (1988).

efficiencies. In that sense, TRIPS may prove ineffective in promoting dynamic long-term innovation policies for developing countries.

II. The Post-WTO IPR Bargaining Situation

A. Overview

The post-WTO intellectual property regulation framework weakened the bargaining power of developing countries, but unequally so. This argument can be broken into two subsets. Firstly, the legalization of international intellectual property regulation under TRIPS reduced the transactions costs for beneficiaries of intellectual property protection in the developed world to promote favorable action by their governments. This is true regarding the issuance of trade sanctions, but also more broadly with respect to diplomatic pressure. As such, the TRIPS Agreement and the post-WTO framework in general crystallized a two-tiered bargaining dynamic over the conditions for access by developing countries to intellectual property-based products and technologies generated in developed countries.²⁰

In what is the first tier of negotiations, bargaining involves only national governments.²¹ Typically, such “Tier-1” bargaining tend to oppose net exporters and importers of intellectual property-based products and technologies.²² Simultaneously, developing countries undergo a second tier of negotiations. “Tier-2” bargaining involves governments of developing countries and the industry.²³ Because nowadays holders of intellectual property rights, and patentees in particular, are commonly multinational enterprises (MNEs), the bargaining between the technology ‘haves’ and the ‘have-nots’ typically cuts transnationally as well.²⁴ In practice, one of the most important aspects of this two-tiered bargaining dynamic is that it consolidates a two-tiered sanctions cost structure that may be levied against developing countries. To illustrate, developing countries that issue compulsory licenses run the risk of being sanctioned at both bargaining levels. In what are Tier-1 sanctions, such developing countries may be sanctioned by the governments of developed countries; and in what are Tier-2 sanctions, they may be sanctioned by the industry as well. This dual sanction cost structure is in reality the main way in which the post-WTO intellectual property framework may be said to have generally reduced the bargaining power of developing countries.

Secondly, the disempowerment of developing countries has not been uniform. Proponents of TRIPS usually claim that the agreement positively impacts Foreign Direct Investment (FDI), trade and innovation within developing countries. However, the way in which these variables play out in developing countries primarily depends on localized and country-specific considerations. In this respect, a development inequality principle²⁵ suggests, firstly, the existence of a divide between NICs and the remaining developing countries. NICs differ in that their large and fast-growing

²⁰ Putnam, *supra* note 17.

²¹ See Ramamurti, *supra* note 17.

²² See e.g. Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (2d ed. 2003); and Peggy B. Sherman & Ellwood F. Oakley, *Pandemics and Panaceas: The World Trade Organization's Efforts To Balance Pharmaceutical Patents and Access to AIDS Drugs*, 41 *Am. Bus. L.J.* 353, 363-382 (2004). *But see* G. Richard Shell, *supra* note 118 (highlighting historical antagonism between Europe and the United States over the need for a strong, binding system of dispute resolution for the GATT).

²³ See Ramamurti, *supra* note 17. See also Putnam, *supra* note 17.

²⁴ Peter Drahos & John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (2002). See also Eyal Benvenisti, *Exit and Voice in the Age of Globalization*, 98 *Mich. L. Rev.* 167 (1999).

²⁵ The “development inequality principle” is described in further details in Section II.B.2.

domestic markets position them as strategic destinations for FDI and trade. To a certain extent, NICs can make use of this advantage irrespective of their general institutional framework or their intellectual property framework.²⁶ In addition, this development inequality principle reveals that there is another divide within developing countries, namely the divide between innovative and non-innovative developing countries. Yet, and perhaps to the surprise of the TRIPS aficionados, the number of innovative developing countries remains extraordinarily small.

B. Bargaining Transition in the Post-WTO Era

1. Development Inequality Principle

Policy and academic analyses of TRIPS often dispense little attention to the various ways in which the agreement affects different developing countries.²⁷ Traditional approaches typically depart from the well-known North/South dichotomy, or some variation thereof.²⁸ This framework highlights the asymmetries between Northern countries, which are deemed to generate innovative products and technologies, and Southern countries, which are generally deemed to consume them.²⁹ A closer look at developing countries, however, reveals that the effects of the TRIPS Agreement are much more varied and can hardly be understood along this bipolar line of North/South. Developing countries differ not only in their propensity to attract FDI, trade, and technology, but also in their abilities to innovate and to make use of intellectual property protection as a tool that fosters domestic innovation. This set of circumstances, which unequally impacts the bargaining power of developing countries, is herein referred to as the development inequality principle.

To begin with, there had been a sharp divide in the economic development strategies employed within the developing world in the period preceding the adoption of TRIPS worldwide. A few countries, particularly Japan and the East Asian “tigers” of Hong Kong, South Korea, Singapore and Taiwan, had managed to successfully adopt an export promoting industrialization (EP) strategy, rather than an import substituting (IS) strategy.³⁰ Successful implementation of the EP strategy assisted these countries in receiving higher levels of sustained inflows of FDI and in deriving more benefits therefrom.³¹ By the turn of the last century, the East Asian Tigers were no longer

²⁶ Ha-Joon Chang, Institutional Development in Historical Perspective, in *Rethinking Development Economics* (Ha-Joon Chang, ed.) [2003] at 499-522.

²⁷ For official surveys, see: World Intellectual Property Organization (WIPO, 1985), and the United Nations Department of Economic and Social Affairs (UNCTAD, 1974). For theoretical and empirical studies, see Grundmann, Foreign Patent Monopolies in Developing Countries: An Empirical Analysis, 12 *J. Dev'tl Stud.* 186 (1976); J. Katz, Patents, the Paris Convention and Less Developed countries, Discussion Paper no. 190, at 24-27 (Yale Univ. Economic Growth Center, Nov. 1973); Greer, The Case against Patent Systems in Less-Developed Countries, 8 *J. Int'l L. & Econ.* 223 (1973); Vaitos, Patent revisited: Their function in developing countries, 9 *J. Dev'tl Stud.* 71, 89-90 (1972). *But see* Daniel C.K. Chow, The Role of Intellectual Property in Promoting International Trade and Foreign Direct Investment, in 4 *Intellectual Property and Information Wealth* 73 (Peter K. Yu ed., 2007), at 187, 187 (stressing China's ability to attract foreign direct investment despite weak intellectual property rights); and also F. M. Scherer, *Industrial Market Structure and Economic Performance* (1980).

²⁸ See Paul Krugman, A Model of Technology Transfer, and the World Distribution of Income 87 *J. Pol. Economy* 253, 254-255 (1979).

²⁹ See Carlos M. Correa, Intellectual Property Rights, the WTO and Developing Countries 11 (2000).

³⁰ Howard Handelman, *The Challenge of Third World Development*, 297-300 (5th ed. 2009).

³¹ Jagdish Bhagwati, *The Wind of the Hundred Days: How Washington Mismanaged Globalization* 28 (2001).

deemed to be developing countries, but rather developed.³² In the course of their transition toward becoming exporters of technology-based products, they rapidly foresaw the benefits of adhering to the TRIPS-package.

Most of the remaining latecomers to post-World War II industrialization embraced IS strategies.³³ Academics debate about whether IS was merely a poor policy choice or a natural consequence of local economic, political and social conditions that prevented countries from pursuing EP strategies.³⁴ Nonetheless, the fact remains that IS proved to be a less successful path than EP.³⁵ Grounded on dependency theories of development, IS theorists concluded that freer trade would immiserate countries of the ‘periphery.’³⁶ Local policies responded accordingly, and these countries grew increasingly suspicious of foreign investment and trade liberalization. In the past two decades, however, fears of economic integration within the developing world have yielded far greater optimism.³⁷ In what has been referred to as an ironic reversal, anti-globalization sentiments now seem to be more prevalent in wealthier than in poorer countries.³⁸ In fact, as of the 1980s and 1990s, most developing countries opened their markets to foreign investment and trade, leaving behind decades of inward-oriented industrialization policies. Again, foreseeably, the results of adherence to free market policies were generally uneven.³⁹

Although most developing countries had reservations about strengthening intellectual property rights, signing the TRIPS Agreement was a condition for participating in the WTO. Being a WTO-member was, and still is, generally viewed as an essential component of their participation in the international wave of trade and prosperity of a globalized world.⁴⁰ The TRIPS Agreement consists of a broad, but controversial, reform agenda for an intellectual property regime that applies almost flatly to all WTO-members.⁴¹ The mandatory adoption of TRIPS standards creates two imperative costs for developing countries, namely reduced access to new technologies and knowledge and higher royalty payments.⁴² Against that backdrop, defenders of TRIPS have tried to cast intellectual property protection as a central pillar of modern economic policy and a catalyst for development, an argument that is twofold.⁴³ Firstly, intellectual property protection is said to explicitly encourage

³² See IMF Advanced Economies List. World Economic Outlook, Database—WEO Groups and Aggregates Information (October 2008).

³³ For a detailed description of import substitution strategies, see Cláudio D. Shikida, Brazil: From Import Substitution to the 21st Century. What is Left to Do? Ibmecc MG Working Paper – WP30.

³⁴ See for instance Rethinking Development Economics, supra note 24.

³⁵ Bhagwati, supra note 29, at 143.

³⁶ Raul Prebisch, Commercial Policy in the Underdeveloped Countries, 49 Am. Econ. Rev. 251, 251 (1959). See also Fernando Henrique Cardoso & Enzo Faletto, Dependency and Development in Latin America (1979).

³⁷ Bhagwati, supra note 29, at 144.

³⁸ Jagdish Bhagwati, In Defense of Globalization 8 (2004).

³⁹ This is true even if one assumes, as many do, that this “new” form of capitalism benefits everyone – a proposition which we neither accept nor dispute. See e.g. Bhagwati, supra note 36; Diane Coyle, Paradoxes of Prosperity: Why the New Capitalism Benefits All (2001).

⁴⁰ John A. Harrelson, TRIPS, Pharmaceutical Patents, and the HIV/AIDS Crisis: Finding the Proper Balance Between Intellectual Property Rights and Compassion, 7 Wid. L. Symp. J. 175, 178 (2001).

⁴¹ See e.g. Michael Blakeney, The International Protection of Industrial Property: From the Paris Convention to the TRIPS Agreement, WIPO National Seminar on Intellectual Property, 2003, WIPO/IP/CAI/1/03/2, at 16.

⁴² Christopher S. Gibson, Globalization and the Technology Standards Game: Balancing Concerns of Protectionism and Intellectual Property in International Standards, 22 Berkeley Tech. L.J. 1403, 1404-1406 (2007).

⁴³ See Shahid Alikhan, Socio-Economic Benefits of Intellectual Property Protection in Developing Countries 1-10 (WIPO 2000); Kamil Idris, Intellectual Property: A Power Tool for Economic Growth 1 (2d ed. 2003); Ali Imam, How Patent Protection Helps Developing Countries, 33 AIPLA Q.J. 377 (2005).

domestic innovation in developing countries, similarly to the set of events that took place in the early history of the United States.⁴⁴ Secondly, intellectual property protection is equally considered to induce more inward technology transfer, particularly by means of enhanced FDI and trade that is carried out by MNEs.⁴⁵ According to this theory, the availability of intellectual property protection would be akin to a “passive” industrial policy – it would stimulate innovation without requiring large investments of public funds often lacking in the developing world.⁴⁶

This uniform analysis when broadly applied to all developing countries, however, overlooks the fact that the pro-TRIPS and anti-TRIPS considerations play out dissimilarly in different parts of the developing world. Firstly, the existence of an intellectual property protection-innovation link is in many cases highly questionable. Historically, a strong intellectual property system appears to have been neither necessary nor sufficient for progress at national and company level.⁴⁷ In fact, it is a well recognized fact that broad intellectual property protection in cumulative innovation processes can stifle subsequent innovation.⁴⁸ Moreover, more modern research on the contributions of strong intellectual property systems internationally, and particularly the TRIPS Agreement, also failed to demonstrate how a more stringent intellectual property regime can foster innovation in the developing world at large.⁴⁹ Innovation springs from the creative application of knowledge, but its underlying conditions are necessarily complex; many are not easily altered by policy;

⁴⁴ See e.g. Robert M. Sherwood, *Human Creativity for Economic Development: Patents Propel Technology*, 33 *Akron L. Rev.* 351 [2000]. See also F. M. Scherer, *The Political Economy of Patent Policy Reform in the United States*, at <http://www.researchoninnovation.org/scherer/patpolic.pdf>, (draft of September 2007), at 37-38. Scherer reminds us that the argument also overlooks the fact that during the first forty-seven years of its existence, the United States provided strong patent protection to domestic residents, but denied patents to foreigners, whereas less developed countries were being asked under TRIPS to increase the scope of their patent protection to both domestic and foreign residents.

⁴⁵ Keith E. Maskus, *Intellectual Property Rights in the Global Economy* (2000); Keith E. Maskus, *The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer*, 9 *Duke J. Comp. & Int'l L.* 109 [1998] [hereinafter Maskus, *The Role of Intellectual Property Rights*]; Daniel J. Gervais, *Information Technology and International Trade: Intellectual Property, Trade & Development: The State Of Play*, 74 *Fordham L. Rev.* 505 [2005]; Carlos A. Primo Braga & Carsten Fink, *The Relationship Between Intellectual Property Rights and Foreign Direct Investment*, 9 *Duke J. of Comp. & Int'l L.* 163 [1998]; Keith E. Maskus & Mohan Penubarti, *How Trade-Related are Intellectual Property Rights?*, 39 *J. Int'l Econ.* 227, 229-30, 237-43 [1995]; and Edmund W. Kitch, *The Patent Policy of Developing Countries*, 13 *UCLA Pac. Basin L.J.* 166 [1994].

⁴⁶ Kenneth Dam, *The Economic Underpinnings of Patent Law*, 23 *J. Legal Stud.*, 247, 271 [1994]. See also Robert D. Cooter & Hans Bernd Schaefer, *Solomon's Knot: How Law Can End the Poverty of Nations* (2009), available at http://works.bepress.com/robert_cooter/151, chapter 3 [last visited August 26, 2009].

⁴⁷ Ove Granstrand, *Innovation and Intellectual Property Rights*, in *The Oxford Handbook of Innovation*, 284 [2005]. See also Josh Lerner, *The Economics of Technology and Innovation: 150 Years of Patent Protection*, 92 *Am. Econ. Rev. Papers & Proceedings* 221 [2002]; Erich Kaufer, *The Economics of the Patent System* 25 [1989]; Petra Moser, *How Do Patent Laws Influence Innovation? Evidence from Nineteenth-Century World's Fairs*, 95 *Am. Econ. Rev.* 1214 [2005]; and Fritz Machlup & Edith Penrose, *The Patent Controversy in the Nineteenth Century*, 10 *J. Econ. Hist.* 1, 24 [1950].

⁴⁸ Roberto Mazzoleni & Richard R. Nelson, *The Benefits and Costs of Strong Patent Protection: A Contribution to the Current Debate*, 27 *Res. Pol'y* 273, 281 [1998]; Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 *Colum. L. Rev.* 839, 890-93 [1990]; Nancy Gallini & Suzanne Scotchmer, *Intellectual Property: When Is It the Best Incentive System?*, in 2 *Innovation Policy and the Economy* 67 (Adam B. Jaffe et al. eds., 2001); and Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law*, 5 *J. Econ. Persp.* 29, 37 [1991]. But see Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 *J.L. & Econ.* 265 [1977] (sustaining that broad patents stimulate further developments); and Jerry R. Green & Suzanne Scotchmer, 26 *Rand J. Econ.* 20, 31 [1995]; and Oren Bar-Gill and Gideon Parchomovsky, *The Value of Giving away Secrets*, 89 *Va. L. Rev.* 1857, 1884 [2003] (showing that in some circumstances the inventor will prefer a narrow patent).

⁴⁹ Granstrand, *supra* note 45.

and some are the result of cultural evolutionary processes which extend beyond the reach of short-term policymaking.⁵⁰

In addition, there is now evidence that the weight of domestic research and development on productivity is largely dependent on the market size of an economy.⁵¹ Since Romer's endogenous growth models were proposed,⁵² development economics has increasingly focused its attention on endogenous technological change to explain the growth patterns of world economies. In endogenous growth models, technological innovation begins with research and development sectors that make use of available human capital and knowledge stock. Technological innovation is then applied in the production chain, leading to permanent increases in the growth rate of output. These models are essentially premised on the assumption that innovation that is endogenously determined makes sustained economic growth possible. Recent studies suggest, however, that a key determinant of innovation is the potential market size of users.⁵³ That is, the availability of a large domestic market significantly determines the ability of a country to increase its innovation by investing in research and development.⁵⁴ It follows that larger developing countries can potentially derive higher benefits from intellectual property protection.

Secondly, whether intellectual property protection is an important determinant in the locational competition for FDI in R&D remains unsettled.⁵⁵ Both theoretical and empirical considerations suggest an ambiguous relationship between intellectual property protection and the distribution of FDI within developing countries.⁵⁶ Host-country characteristics are significant because intellectual property protection has weaker effects in countries with strong market-related pull factors for FDI, such as large markets of abundant natural resources.⁵⁷ There is also some evidence that FDI responds to intellectual property protection only in host-countries that have reached a minimum threshold of development and have a capacity to imitate inventions.⁵⁸ Naturally, the impact of intellectual property protection is stronger in human-capital and technology intensive industries such as pharmaceuticals, cosmetics and health care products, chemicals, machinery and equipment, and electrical equipment.⁵⁹ Nevertheless, even in these industries, investment decisions remain contingent on

⁵⁰ See e.g. David Landes, *The Wealth and Poverty of Nations: Why Some Are So Rich and Some So Poor* (1998).

⁵¹ See Daron Acemoglu & Joshua Linn, *Market Size and Innovation: Theory and Evidence from the Pharmaceutical Industry*, NBER Working Paper 10038 (2003); and Hulya Ulku, *Innovation, and Economic Growth: An Empirical Analysis*, IMF Working Paper No. 04/185 (2004).

⁵² See Paul M. Romer, *Increasing Returns and Long-Run Growth*, 94 *J. Pol. Econ.* 1002 (1986); *Endogenous Technical Change*, 98 *J Polit Econ* 71 (1990); and *The Origins of Endogenous Growth*, 8 *J. Econ. Persp.* 3 (1994).

⁵³ Acemoglu & Linn, *supra* note 49.

⁵⁴ Ulku, *supra* note 49.

⁵⁵ Peter Nunnenkamp & Julius Spatz, *Intellectual Property Rights and Foreign Direct Investment: The Role of Industry and Host-Country Characteristics*, Kiel Institute for World Economics, Kiel Working Paper No. 1167, at 2.

⁵⁶ Comm'n on Intellectual Prop. Rights, *Integrating Intellectual Property Rights and Development Policy* 22-23 (2002) [hereinafter *Comm'n on IPR*], available at http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf.

⁵⁷ Nunnenkamp & Spatz, *supra* note 53.

⁵⁸ *Id.*

⁵⁹ See Carlos A. Primo Braga & Carsten Fink, *International Transactions in Intellectual Property and Developing Countries*, 19 *Int'l J. Tech. Mgmt.* 35, 38-42 (2000); Beata K. Smarzynska, *The Composition of Foreign Direct Investment and Protection of Intellectual Property Rights: Evidence from Transition Economies*, in *Intellectual Property and Development* 19, 20 (Carsten Fink & Keith E. Maskus eds., 2005); and Edwin Mansfield, *Intellectual Property Protection, Foreign Direct Investment, and Technology Transfer* 27 (*Int'l Fin. Corp. Discussion Paper No.* 19, 1994).

many other factors.⁶⁰ It must also be noted that intellectual property law is not the only mechanism for protection of knowledge and information, and at times not even the most important.⁶¹ This statement remains true even for patent-sensitive industries, and remarkably so.⁶² In the chemicals industry, for instance, there is evidence that MNEs tend to prefer stand-alone operations abroad and to employ a relatively small number of workers as a means of knowledge protection.⁶³ Another important patent-sensitive industry that tells a similar story is the bioagriculture and plant genetics. As such industry, the scientific industrial nature of agricultural biotechnology noticeably shifts agriculture from land-based farming to the interdisciplinary patent-based industries of therapeutics, pharmaceuticals and chemicals and thus is of central importance to the Post-WTO bargaining model and the developing countries inequality principle herein.⁶⁴

With agricultural biotechnology, therefore, the inequality principle is thus also ever-present. The International Union for the Protection of New Varieties of Plants (UPOV) establishes the plant variety protection (PVP) framework known as the Plant Breeders' Rights (PBRs) regime for UPOV member states.⁶⁵ PBRs provide a site for understanding intellectual property's role in the intersection between the international agriculture regime, traditional agricultural practices (TAPs) deployed by indigenous and local farming communities, and food security. In this regard, since the 1980s, the FAO has been involved in the juridical evolution of the concept of "farmers' rights" as a counterbalance to PBRs.⁶⁶ Farmers' rights, to be sure, are integral to a regime of open access to genetic resources in *ex situ* public seed banks. The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) regulates them.⁶⁷ With time, regrettably, the usage of these resources, noticeably in regard to access to the genetic resources from the putative common pool, created a crisis of confidence between the developed and the underdeveloped world, but unevenly so.⁶⁸ In addition, farmers' rights are subject to pre-existing national laws and bilateral treaty obligations of differing financial effect. These for the

⁶⁰ Comm'n on IPR, *supra* note 54, at 23-24.

⁶¹ See, e.g., Lawrence Lessig, *Free Culture* (2004); Yochai Benkler, *Coase's Penguin, or, Linux and The Nature of the Firm*, 112 *Yale L.J.* 369 (2002); Yochai Benkler, *Through the Looking Glass: Alice and the Constitutional Foundations of the Public Domain*, 66 *Law & Contemp. Probs.* 173 (2003).

⁶² Henrique M. Barros, *The Impact of the Distribution of R&D Expenses on Firms' Motivations to Patent*, *Ibmec Working Papers*. Available at: http://ideas.repec.org/p/ibm/ibmecp/wpe_138.html.

⁶³ Nunnenkamp & Spatz, *supra* note 53.

⁶⁴ See, Sheldon Krinsky & Roger P. Wrubel, *Agricultural Biotechnology and the Environment: Science, Policy, and Social Issues* 227 (1996); Organization for Econ. Co-Operation & Dev., *Biotechnology and the Changing Role of Government* 12 (1988). To be sure, the TRIPS agreement brings animals, plants, and plant varieties within the scope of patentable protection, subject however, to the individual members' regulatory choice. See, TRIPS Agreement, art. 27.3(b). In relation to plant varieties, in particular, it offers members the option to choose modes of protection between "patents or ... effective sui generis system or ... any combination thereof." *Id.*

⁶⁵ See UPOV website, at: <http://www.upov.int/index.html> (last visited Aug. 26, 2009).

⁶⁶ See, e.g., Laurence R. Helfer, *Intellectual Property Rights in Plant Varieties: An Overview with Options for National Governments*, (FAO Legal Papers Online, No. 31, 2002), <http://www.fao.org/Legal/Prs-OL/lpo31.pdf>.

⁶⁷ International Treaty on Plant Genetic Resources for Food and Agriculture, Nov. 3, 2001, available at www.fao.org/Legal/treaties/033s-e.htm [hereinafter ITPGRFA]. A chief example for the latter is the well known International Agricultural Research Centers (IARCs) designed to preserve the world's scarce genetic resources for food and agriculture. For other seed banks, see e.g., International Undertaking on Plant Genetic Resources for Food and Agriculture, Report of the Conference of FAO, FAO Conference, 22d Sess., art. 1, U.N. Doc. C/83/REP (1983); FAO Res. 5/89, U.N. Doc. C/89/24 (1989).

⁶⁸ See, Chidi Oguamanam, *Agro-Biodiversity and Food Security: Biotechnology and Traditional Agriculture Practices at the Periphery of International Intellectual Property Regime Complex*, 2007 *Mich. St. L. Rev.* 215, 246 (2007).

most part include PBRs and patents both under the UPOV and the TRIPS standards.⁶⁹ The ability of farmers' rights to serve as an effective balancing regime to PBRs in particular, and intellectual property rights in general hence remains further unsatisfactory for the underdeveloped world.⁷⁰

Consequently, a major study conducted in NIC countries primarily, found little correlation between the range of plant material available to farmers or increased innovation and PVP protection.⁷¹ More broadly, in the United States there was no evidence that total R&D activity had increased as a result of the introduction of PVP.⁷² The great majority of private research is conducted in NICs in Asia and Latin America. Of worldwide private research expenditure over bio-agriculture and plant genetics totalling \$11.5 billion however, only \$0.7 billion is attributable to developing countries at large.⁷³ Moreover, research expenditures by these countries grew at 5-7% annually between 1976 and 1996, while they stagnated in Sub-Saharan African.⁷⁴ Although the joint public (FAO-UNDP) and private agricultural research at large, commonly referred as the Consultative Group on International Agricultural Research (CGIAR)⁷⁵ spends approximately \$340 million per year,⁷⁶ funding by the donor community, has deduced substantively since 1990.⁷⁷ Moreover, while funding from the aid donor community has stagnated, little private sector R&D in bioagriculture is directed to poor farming in developing countries.

Similarly in the software industry, there is no flat trend suggesting an increase in overseas R&D spending in any correlation with IPRs policies in the underdeveloped world. With respect to the United States, the most recent data from the National Science Board actually shows a "re-concentration" of investments in high technologies: "strong growth in U.S. companies' domestic R&D financing (up to 10%), coupled with a 7% decline in industry's overseas R&D spending, reduced the overseas share to 8.9% of U.S. companies' funding total."⁷⁸ Out of this given small amount, developing countries capture only a marginal 6%.⁷⁹ With emphasis on software, the OECD Information Technology Outlook describes the situation as such that with very

⁶⁹ See ITPGRFA, supra note 65, art. 9.3.

⁷⁰ See, Chidi Oguamanam, Intellectual Property Rights in Plant Genetic Resources: Farmers' Rights and Food Security of Indigenous and Local Communities, 11 Drake J. Agric. L. 273 (2006).

⁷¹ Van Wijk, J. & Jaffe, W. Impact of Plant Breeders Rights in Developing Countries, Inter-American Institute for Cooperation on Agriculture, San Jose, and University of Amsterdam (1995).

⁷² Butler L. & Marion, B., The Impacts of Patent Protection on the US Seed Industry and Public Plant Breeding, Food Systems Research Group Monograph 16 (1985). It appeared, however, to have had some impact on soya beans and possibly wheat.

⁷³ Philip G. Pardey & Nienke M. Beintema, Slow Magic: Agricultural R&D a Century After Mendel, in Agriculture Science and Technology Indicators Initiative 10 (2001), available at http://www.card.iastate.edu/research/stp/papers/pardey-Slow_magic_Text_Oct_01_Final.pdf

⁷⁴ Pardey & Beintema, supra note 71, at 4. As for public sector investment in R&D is more present. As compared to medical research, there is a great deal more agricultural R&D undertaken by, and of relevance to, developing countries. In 1995, total expenditure by the public sector on agricultural research in developing countries, although unevenly distributed, amounted to \$11.5 billion dollars compared to the \$10.2 billion spent in developed countries. *Id.*

⁷⁵ Established in 1971, CGIAR is a strategic partnership, whose 64 members support 15 international Centers worldwide. See <http://www.cgiar.org>.

⁷⁶ Originally CGIAR led the Green Revolution, and they presently act as the guardian of the world's largest collection of genetic resources. See, <http://www.cgiar.org>.

⁷⁷ Pardey & Beintema, supra note 71, at 8.

⁷⁸ See Nat'l Sci. Bd., 1 Science and Engineering Indicators 59-60 (2000), available at <http://www.nsf.gov/sbe/srs/seind00/start.htm>.

⁷⁹ *Id.*

few exceptions, work outsourced does not involve “the development of mission-critical applications, nor do projects involve very sophisticated technology”.⁸⁰ Instead,, the OECD Report adds, “From a life-cycle perspective, systems requirements, high-level design, and installation and testing are typically not outsourced.”⁸¹ To summarize, the various means by which intellectual property rights influence FDI are subtle, and intellectual property protection alone does not clearly generate sufficient incentives for MNEs to invest in a developing country.⁸²

This set of considerations explains why the effects of the TRIPS Agreement are too often highly inconsistent. Focusing on the effects of TRIPS on FDI and trade on one hand, and on innovation on the other, the development inequality principle sets out two dividing lines within the developing world. The first line is drawn between larger economies, particularly NICs, and the remaining developing countries. The category of NIC is a socioeconomic classification applied to several countries by geographers, economists, and political scientists. Manufacturing must account for a significant fraction of the NIC’s gross domestic product, but aside from that there is no undisputed or official set of criteria that allow a country to be labeled an NIC.⁸³ According to Bradford, the emergence of NICs is a “generalized historical movement in which industrialized countries vacate intermediate sectors in industrial production in which advanced developing countries are currently more competitive and advanced developing countries, in turn, vacate more basic industrial sectors in which the next tier of developing countries have a relative advantage.”⁸⁴ NICs are therefore those countries that fulfill the intermediary stages in the international division of labor; and since this division is ever changing, the categorization of a country as an NIC changes as well.⁸⁵ A popular method of categorization would treat as NICs only Brazil, Mexico, South Africa, China, India, Malaysia, Philippines, Thailand and Turkey,⁸⁶ and would refer instead to the archetypical East Asian tigers of Hong Kong, South Korea, Singapore and Taiwan as “developed.”⁸⁷

Essentially, NICs differ from the remaining developing countries because they possess large and relatively diversified domestic economies. This fact awards them the status of being strategic and fast-growing markets in and with which MNEs typically cannot refrain from investing or trading.⁸⁸ Consequently, NICs capture a

⁸⁰ Org. For Econ. Cooperation & Dev., OECD Information Technology Outlook 2000: ICTS, E-Commerce and the Information Economy 137-138 (2000), available at www.oecd.org/dataoecd/30/56/1939833.pdf (last visited Aug. 26, 2009).

⁸¹ *Id.*

⁸² See Maskus, *The Role of Intellectual Property Rights*, *supra* note 43, at 128.

⁸³ Anis Chowdhury & Iyanatul Islam, *The Newly Industrialising Economies of East Asia 4* (1997). See also Nigel Grimwade, *International Trade: New Patterns of Trade, Production and Investment* 312 (1989).

⁸⁴ Colin I. Bradford Jr., *The Rise of the NICs as Exporters on a Global Scale*, in L. Turner N. McMullen (eds.), *The Newly Industrializing Countries: Trade and Adjustment*, London (1982). Accordingly, NICs tend to be more advanced than other developing countries, and less so than developed countries. There is no official or undisputed set of criteria to define an NIC, so each author sets a list of countries according to her own criteria and methods. See, Mauro F. Guillén, *Multinationals, Ideology, and Organized Labor, The Limits of Convergence* (2003); David Waugh, *Geography, An Integrated Approach*. Nelson Thornes Ltd. (3rd ed., 2000); and N. Gregory Mankiw, *Principles of Economics*, (4th ed, 2006).

⁸⁵ Guillén, *supra* note 82.

⁸⁶ *Id.* See also Waugh, *supra* note 82 and Mankiw, *supra* note 82.

⁸⁷ See, Pawel Bozyk, *Newly Industrialized Countries, Globalization and the Transformation of Foreign Economic Policy* 164 (2006). But note that many authors still treat countries such as Singapore and South Korea as NICs.

⁸⁸ Just consider, for instance, the fact that China already has the same number of mobile-phone users as the whole of Europe, namely five hundred million ones. See *Technology in Emerging Economies*, *The Economist* (U.S. Edition) February 9, 2008.

disproportionally large portion of the FDI that flows to developing countries.⁸⁹ In turn, the remaining developing countries receive proportionally much smaller shares of FDI. Such is the case not only for LDCs, but also for a much broader group of developing countries. Accordingly, bargaining power within NICs is generally greater than among the remaining developing countries.

This market size approximation, however, fails to recognize a second divide that exists within developing countries – that is, the divide between innovative and non-innovative developing countries. While all developing countries are innovative on some level, only a small fraction of them are innovative in the area of intellectual property-based technologies. China and India are effectively the only developing countries that, aside from being scientifically proficient, are also able to produce technology-based products in patent-sensitive industries in large scale.⁹⁰ Yet, and regrettably for TRIPS enthusiasts, these countries do not display the highest standards of TRIPS compliance within the developing world.

One could still abide by dependency theories upholding that developing countries at large – that is, Southern countries – are almost exclusively consumers of technology. Consistent with that claim, vertical industrial policies were widely applied in China and India in their steady, and yet uncertain, process of ‘catch up’.⁹¹ Again, academics sharply disagree on the value of such vertical policies, and positions range from claims that these policies were crucial to the claim that they created more harm than good.⁹² Either way, the causes of the “miracle” in India and China are of no concern here; what matters is the conclusion that TRIPS plays out dissimilarly in the developing world, including with respect to its interaction with innovative activities.

At any rate, in comparison with the remaining developing countries, NICs bear an advantage not only in terms of their ability to attract FDI and trade, but also in their ability to promote endogenous innovation. This reality does not mean however that all NICs make use of their theoretical or potential ability to innovate in the same fashion. Although helpful, the availability of large domestic markets is far from a sufficient condition for a developing country to become innovative. In fact, there is a sharp divide between the “innovative” and the “non-innovative” NICs. As will be argued later in this article, the divide between innovative and non-innovative NICs results in sharp, if somewhat counterintuitive, effects on each NIC’s bargaining power over legal endowments and access conditions to intellectual property-based technologies.

2. The Case of Bargaining Power in Pharmaceutical Patents

The pharmaceutical industry is the prototypical patent-sensitive industry, and for that reason, it serves well as a working example in which to apply the development inequality principle. In negotiations over patented products and technologies, the bargaining power of a developing country essentially hinges on three variables,

⁸⁹ See e.g. Ilene Grabel, *International Private Capital Flows and Developing Countries*, in *Rethinking Development Economics*, supra note 24, at 327-328.

⁹⁰ Rand Corporation, *News Release: Rand Study Says Advanced Countries Will Benefit Most from Progress in Technology, with Lesser Benefits to Other Nations* (June 1, 2006).

⁹¹ See World Bank, *The East Asian Miracle, Economic Growth and Public Policy* (1993).

⁹² For a defense of the exceptionalism of industrial policy in East Asia see Alice Amsden, *Asia’s Next Giant: South Korea and Late Industrialization* (1989), and Robert Wade, *Governing the Market? Economic Theory and the Role of the Government in East Asian Industrialization* (1990). For a critique see Cooter & Schaefer, supra note 44, and Bhagwati, supra note 29.

namely, the country's outside option, inside options, and market power. Firstly, the outside option represents the country's expected payoff in the absence of an agreement. The identification of the outside option is significant, for instance because reaching an agreement with a patentee may become unappealing if the alternative, the unilateral issuance of a compulsory license, is sufficiently attractive.⁹³ Secondly, the developing country's bargaining power also depends on the availability of inside options. Under bargaining theory, inside options are the actions that a party may take in order to derive positive payoffs while temporarily disagreeing in the course of the bargaining process.⁹⁴ An inside option differs from an outside option in that as a result of the latter negotiations break up and the parties stop bargaining, whereas the former assumes continued bargaining.⁹⁵ Developing countries make use of an inside option, for instance, when they avoid de facto protecting IPRs while formally complying with TRIPS.⁹⁶ Thirdly, a developing country's bargaining power depends also on the extent of its market power, if any exists. A developing country purchasing a patented product or technology will be deemed to have market power insofar as it is able to profitably pay less than the competitive price.⁹⁷

a. Outside Option: Instrumentality of Patent Compulsory Licenses

In voluntary exchanges, a bargaining problem arises because the parties have to negotiate ex ante the allocation of the cooperative surplus that is expected to be generated ex post by their decision to cooperate.⁹⁸ When this problem is not solved, mutual cooperation and agreement fails to take place. Bargaining theory commonly refers to this alternative as the "outside option", because it is the best alternative available for a country should it decide or be pushed to withdraw from negotiations.⁹⁹ Naturally, to reach an agreement, each party must expect to receive a payoff higher than that of its outside option.¹⁰⁰

In bargaining over the purchase price of pharmaceuticals, the issuance of a compulsory license can be viewed as an outside option available for developing countries. In this case, the payoff represented by the issuance of a compulsory license is mainly a function of three variables. Firstly are the expected net savings that arise upon the issuance of the compulsory license; secondly are the expected sanctions costs, which are the retaliatory costs that patentees and their home governments can impose on the country that issued compulsory licenses; and thirdly are the expected administrative costs associated with the more lax IP institutional framework suggested or created by the issuance of the compulsory license.

The net savings, being the first variable determining the payoff represented by an outside option, are in reality the expected balance of direct costs and benefits that the country expects to obtain with the issuance of the compulsory license. A country

⁹³ Muthoo, Non-Technical Bargaining, *supra* note 14, at 159.

⁹⁴ Muthoo, Non-Technical Bargaining, *supra* note 14, at 149, 157-160.

⁹⁵ Abhinay Muthoo, *Bargaining Theory with Applications*, 137 (1999) [hereinafter Muthoo, *Bargaining Theory*].

⁹⁶ Sherwood, *The TRIPS Agreement*, *supra* note 16.

⁹⁷ See US Submissions to OECD and other International Competition Fora, Roundtable on Monopsony and Buyer Power – Note by the United States (October 2008), available at <http://www.ftc.gov/bc/international/ussubs.shtml> (last visited Aug. 26, 2009) [hereinafter US Submissions].

⁹⁸ See, e.g., Robert Cooter, *The Cost of Coase*, 11 *J. Legal Stud.* 1 (1982); Robert D. Cooter & Thomas Ulen, *Law & Economics* 78-80 (4th ed. 2004); and Thompson, *supra* note 14.

⁹⁹ Muthoo, *Non-Technical Bargaining*, *supra* note 14, at 149, 154-160.

¹⁰⁰ Cooter, *supra* note 14, at 274.

issuing a compulsory license avoids the payment of royalties to the patent holder; but issuing a compulsory license will only be cost-effective if that country is able to either buy or produce the drugs at a lower cost.¹⁰¹

This first variable determining the outside option value tends to play out more favorably in larger and more industrialized developing countries, such as NICs. These countries potentially obtain larger net savings upon the issuance of a compulsory license primarily because they possess unique features that render them suitable places for the development of an indigenous generics production capacity. (The term “generics” refers to drugs that can be obtained from multiple sources, as opposed to drugs that are sold only by the originator company or its exclusive licensees.¹⁰²) The establishment of a viable and competitive generics pharmaceutical industry requires large consumer markets, local technical capacity, and proper manufacturing conditions.¹⁰³ In addition, even for generic drugs, some research and development is necessary for the manufacture of high-quality products, and the expenses and time incurred are often underestimated.¹⁰⁴ Together, these considerations explain why a generics production capacity cannot be reproduced easily in most places in the world.

The availability of a generics manufacturing capacity can greatly increase the net savings of the country issuing a compulsory license. The reason for the increase is essentially that such a capacity lends credibility to the threat of issuing a compulsory license. Unlike the calls for distributive justice often put forth by countries with no such manufacturing capacity,¹⁰⁵ the ability to produce generics empowers a country to make use of compulsory licenses if and when necessary.¹⁰⁶ In fact, for many years it appeared that the only practical use of compulsory licenses was as a negotiating tool.¹⁰⁷ With a credible threat of compulsory drug licensing and the local manufacture of them, governments are able to press patent holders to grant large discounts on drugs.¹⁰⁸

Generic medicines are typically priced at considerably lower rates than the brand drugs.¹⁰⁹ As such, their availability generally reduces a country’s dependence on drugs supplied by big pharmaceutical companies. To illustrate, in Brazil, 56% of AIDS drugs distributed in 2001, commonly known as ‘antiretrovirals’ (ARVs), were

¹⁰¹ Warren A. Kaplan & Richard Laing, *Local Production: Industrial Policy And Access To Medicines: An Overview of Key Concepts, Issues, and Opportunities for Future Research*, (World Bank, HNP Discussion Papers, 2005).

¹⁰² Andreas Seiter, *Pharmaceuticals: Local Manufacturing*, The World Bank HNP Brief #3, at 2 (Mar. 2005), available at http://siteresources.worldbank.org/healthnutritionandpopulation/resources/281627-1109774792596/hnpbrief_3.pdf (last visited Aug. 26, 2009).

¹⁰³ See World Health Organization, *Manufacture of Antiretrovirals in Developing Countries and Challenges for the Future*, at 1, EB114/15 (Apr. 29, 2004), available at www.who.int/gb/ebwha/pdf_files/EB114/B114_15-en.pdf. See also Kaplan & Laing, *supra* note 99.

¹⁰⁴ World Health Organization, *supra* note 101 at 1.

¹⁰⁵ Amrita Narlikar, *International Trade and Developing Countries: Bargaining Coalitions in the GATT and WTO 77* (2003).

¹⁰⁶ Peter K. Yu, *Access to Medicines, BRICS Alliances, and Collective Action*, 34 *Am. J. L. and Med.* 345, 358 (2008).

¹⁰⁷ Brent Savoie, *Thailand's Test: Compulsory Licensing in an Era of Epidemiologic Transition*, 48 *Va. J. Int'l L.* 211, 238 (2007).

¹⁰⁸ Keith E. Maskus, *Ensuring Access to Essential Medicines: Some Economic Considerations*, 20 *WIS. INT'L L.J.* 563, 571 (2002).

¹⁰⁹ Seiter, *supra* note 100, at 2 (also noting that “generic drugs are not always lower priced – some local ‘branded generics’ are sold at prices equal to or higher than the originator product, depending on market conditions, access barriers and price transparency.”)

locally produced.¹¹⁰ While these drugs were not protected by patents,¹¹¹ their production as generics made possible a price reduction of 82% in the period between 1996 and 2001.¹¹² Other countries have followed a similar path. For instance, Thailand's Government Pharmaceutical Organization has been producing generic AZT for a quarter of the price of the brand name version for several years.¹¹³

The case of Brazil illustrates how a local generics manufacturing capacity can serve as a powerful strategic tool to increase net savings through price negotiations.¹¹⁴ Brazil's state-owned laboratory, Far-Manguinhos, produces seven of the sixteen medicines used in the antiretroviral 'cocktail' freely offered in the country.¹¹⁵ The Brazilian government has largely premised its price negotiations with the international pharmaceutical industry on the credible threat of locally producing generics.¹¹⁶ Brazil repeatedly threatened to issue compulsory licenses for AIDS medicines only to retract at the last minute after achieving what was widely perceived as a negotiation victory.¹¹⁷ A recent study concluded that in the period from 2001 to 2005 Brazil saved approximately USD \$1.2 billion solely in ARVs used for treatment of infection by retroviruses, primarily HIV.¹¹⁸ In spite of its numerous threats, Brazil thus far has only issued one compulsory license, in 2007.

The second variable influencing a country's outside option relates to its expected sanctions costs. Generally speaking, these are the costs that may be imposed on a country that unilaterally breaks pharmaceutical patents. Big pharmaceutical companies often develop concerted efforts with their home governments in order to build a dual structure of sanctions costs. In the post-WTO two-tiered patent bargaining framework, sanctions costs may come from governments of the developed world, in what is defined in this article as Tier-1 sanctions, or from the pharmaceutical industry itself, in what is defined herein as Tier-2 sanctions.

An alleged breach of TRIPS potentially may give rise to the submission of a complaint to the WTO. TRIPS rules on compulsory licenses are somewhat ambiguous as to what constitutes sufficient grounds authorizing the issuance of a compulsory license over pharmaceuticals, leaving an open flank that may be explored through litigation in most cases.¹¹⁹ The outcome of such litigation may be the authorization to

¹¹⁰ Alexandre Grangeiro et al., *Sustentabilidade da Política de Acesso a Medicamentos Anti-Retrovirais no Brasil*, *Revista de Saúde Pública*, 40 (Supl): 60-69, at 64 (2006) (noting that expenditures in 1998 were R\$ 346 million jumping to R\$ 557 million in 2001).

¹¹¹ Comm'n on IPR, *supra* note 54.

¹¹² Grangeiro et al., *supra* note 108.

¹¹³ Judy Rein: *International Governance through Trade Agreements: Patent Protection for Essential Medicines*, 21 *NW. J. INT'L L. & BUS.* 379 (2001).

¹¹⁴ See Jorge A. Z. Bermudez, et al., *What is at Stake?*, at 36, in *Intellectual Property in the Context of the WTO TRIPS Agreement: Challenges for Public Health* [Bermudez & Auxiliadora Oliveira eds., 2004] [hereinafter *Challenges for Public Health*]. See also Comm'n on IPR, *supra* note 54.

¹¹⁵ Far-Manguinhos is part of the Oswaldo Cruz Foundation – FIOCRUZ, a non-profit research foundation linked to the Brazilian Ministry of Health. See www.fiocruz.br. See also Comm'n on IPR, *supra* note 54.

¹¹⁶ Benjamin Coriat & Fabienne Orsi, *Pharmaceutical Patents, Generic Drugs and Public Health under the TRIPS Agreement*, Background paper to the Concluding Roundtable Discussion on IPR at the DRUID Summer Conference 2003 on Creating, Sharing and Transferring Knowledge (2003).

¹¹⁷ Robert C. Bird & Daniel R. Cahoy, *The Emerging BRIC Economies: Lessons from Intellectual Property Negotiation and Enforcement*, 5 *NW. J. TECH. & INTELL. PROP.* 400, 421 (2007).

¹¹⁸ Amy S. Nunn et al., *Evolution of Antiretroviral Drug Costs in Brazil in the Context of Free and Universal Access to AIDS Treatment* 4 *PLoS MED.* 1804 (2007). See also Jane Galvão, *Access to Antiretroviral Drugs in Brazil*, 360 *Lancet* 1862, 1864 (2002).

¹¹⁹ Thomas F. Cotter, *Market Fundamentalism and the TRIPS Agreement*, 22 *Cardozo Arts & Ent LJ* 307 (2004).

impose trade sanctions on the country deemed to have acted illegally.¹²⁰ Although the Doha Round broadened the legally acceptable scope of compulsory licensing, the possibility of authorization by the WTO to apply trade sanctions remains a tangible risk. The dearth of case law by the DSB on the topic adds an additional element of uncertainty as to the outcome of such litigation.

Government-imposed Tier-1 sanctions may also originate from unilateral state action. In recent decades, the United States took a leading role in attempting to shape and increase international patent protection.¹²¹ Even in the post-WTO era, the United States Trade Representative (USTR) retains powers to act unilaterally,¹²² and uses them to persuade other countries, particularly developing countries, to enhance their intellectual property protection system. Such unilateral sanctions can be traced back to the mid-1970s, a period when intellectual property-sensitive industries pressed the United States government to set up an aggressive unilateral intellectual property agenda designed to curtail piracy and recover part of what were perceived to be unfair economic losses.¹²³ Unilateral initiatives of this kind, however, remain a mostly non-legalized aspect of patent bargaining that takes place in the shadows of the WTO rule-based international system.

Similarly to net savings, trade sanctions also do not affect all developing countries in the same manner.¹²⁴ First and foremost, countries with more diversified economies tend to be less vulnerable to trade sanctions on specific products.¹²⁵ In addition, some emerging economies are large enough to pose a genuine threat of counter-retaliating trade sanctions imposed by developed countries. Such was noticeably the case in the dispute between the United States and China over the latter's intellectual property laws, a situation that in the mid-1990s almost led to a trade war.¹²⁶ Another important aspect of trade sanctions is that as world powers compete for geopolitical influence, distinctive strategic advantages may reduce the prospects of employing sanctions among certain developing countries.¹²⁷ To use the example of China again, during the aforementioned dispute, the United States bore a

¹²⁰ *Id.* See also Laurence R. Helfer, Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking, 29 Yale J. Int'l L. 1 (2004) and G. Richard Shell, Trade Legalism and International Relations Theory: An Analysis of the World Trade Organization, 44 Duke L.J. 829, 843-44 (1995).

¹²¹ See Marney L. Cheek, The Limits of Informal Regulatory Cooperation in International Affairs: A Review of the Global Intellectual Property Regime, 33 Geo. Wash. Int'l L. Rev. 277, 284 (2001).

¹²² See Omnibus Trade and Competitiveness Act of 1988, 19 U.S.C. 2242 (1999).

¹²³ For a general discussion of the Act, see Paul C.B. Liu, U.S. Industry's Influence on Intellectual Property Negotiations and Special 301 Actions, 13 UCLA Pac. Basin L.J. 87 (1994); Judith Bello & Alan Holmer, "Special 301": Its Requirements, Implementation and Significance, 13 Fordham Int'l L.J. 259 (1989 - 90). See also Cheek, *supra* note 119, at 292, and Robert Krupka, et al., Section 337 and the GATT: The Problem or the Solution? 42 Am. U. L. Rev. 779 (1993).

¹²⁴ Robert C. Bird, Defending Intellectual Property Rights in the BRIC Economies, 43 Am. Bus. L.J. 317 (2006).

¹²⁵ Eyal Benvenisti & George W. Downs, Distributive Politics and International Institutions: The Case of Drugs, 36 Case W. Res. J. Int'l L. 21, 27 (2004).

¹²⁶ See Assafa Endeshaw, A Critical Assessment of the U.S.-China Conflict on Intellectual Property, 6 Alb. L. J. Sci. & Tech. 295, 318-319 (1996); Peter K. Yu, From Pirates to Partners: Protecting Intellectual Property in China in the Twenty First Century, 50 Am. U. L. Rev. 131, 140 (2000); Richard J. Ansson, Jr., International Intellectual Property Rights, the United States, and the People's Republic of China, 13 Temp. Int'l & Comp. L.J. 1 (1999).

¹²⁷ See William P. Alford, How Theory Does - And Does Not - Matter: American Approaches to Intellectual Property Law in East Asia, 13 UCLA Pac. Basin L.J. 8, 21-23 (1994) (sanctioning can undermine long term international relations). See also Barry E. Carter, International Economic Sanctions: Improving the Haphazard U.S. Legal Regime, 75 Cal. L. Rev. 1162 (1987); and Martine de Koning, Why the Coercion-Based GATT Approach is not the Only Answer to International Piracy in the Asia-Pacific Region, 19 Eur. Intell. Prop. Rev. 59 (1997).

specific interest in preventing China from selling nuclear technology and equipment to Iran, Pakistan and Algeria, which enhanced China's bargaining position.¹²⁸

Aside from governments, the pharmaceutical industry itself may also be in a position to impose sanctions costs on countries that issue compulsory licenses. Compulsory licenses undermine the overall intellectual property protection system of a country, impacting IP-sensitive industries such as chemicals, computer software, and pharmaceuticals.¹²⁹ Pharmaceutical patentees that are either harmed by the licensing, or receive a credible threat of compulsory licensing of their patents, can retaliate through a number of ways. Depending on the circumstances, they can impose sanctions costs through reduced FDI, reduced technology transference and local R&D, and reduced trade.¹³⁰ In addition, and because innovation in pharmaceuticals is largely deemed to be patent-sensitive, a local pharmaceutical industry, while it exists, can also impose sanctions costs, most notably in the form of reduced innovation. In India, for example, the issuance of a compulsory license could send a disturbing signal to the innovation-prone sectors of its home pharmaceutical industry, which would probably be prompted to reduce innovation efforts.¹³¹ The example of India actually illustrates why the existence of an indigenous innovative pharmaceutical industry can ironically impair the bargaining power of some developed countries, as will be discussed further later in this article.

The extent of industry-sponsored sanctions costs, also referred herein as Tier-2 sanctions costs, are particularly difficult to predict. This is mainly because of the conceptual divide between static and dynamic efficiency, a theme that arises almost unavoidably in a discussion of patent policies.¹³² Effective patent protection entails a trade off between static losses arising from monopoly rents of patentees, and potential dynamic gains to society at large due to enhanced innovation.¹³³ The problem of industry-specific sanctions mirrors this discussion in that sanctions costs can be evaluated both in terms of welfare effects in equilibrium and welfare effects during the transition process toward equilibrium.¹³⁴

Regardless of how Tier-2 sanctions costs are measured, middle income developing countries are generally less likely to receive such sanctions than lower income countries. International pharmaceutical companies typically cannot afford to lose or alienate large markets that contain, or potentially contain, lucrative middle

¹²⁸ *Id.*

¹²⁹ Gervais, *supra* note 43; Ha-Joon Chang, *Globalisation, Economic Development and the Role of the State* 286-288 (2003).

¹³⁰ See Elhanan Helpman, *Innovation, Imitation, and Intellectual Property Rights*. 61 *Econometrica* 1247, 1249 (1993) [arguing that the analysis of intellectual property protection should be carried out through at least for dimensions, namely the terms of trade, the interregional location of manufacturing, product availability, and R&D investment patterns].

¹³¹ Padmashree Gehl Sampath, *Economic Aspects of Access to Medicines after 2005: Product Patent Protection and Emerging Firm Strategies in the Indian Pharmaceutical Industry* (WHO-CIPIH Studies 2005) [available at <http://www.who.int/intellectualproperty/studies/PadmashreeSampathFinal.pdf>].

¹³² For early works on the distinction between static and dynamic efficiency see e.g. Simon Kuznets, *Static and Dynamic Economics*, 20 *Am. Econ. Rev.* 426 (1930) [also noting that the distinction was first introduced into economic theory by J. S. Mill, who in his turn took it from Comte]; and J. M. Clark, *Static Models and Dynamic Aspects*, 45 *Am. Econ. Rev.* 450 (1955) [arguing that dynamic theory accepts indeterminateness of various kinds]. For a more modern discussions see e.g. Anne O. Krueger, *The Political Economy of the Rent-Seeking Society*, 64 *Am. Econ. Rev.* 291 (1974); and Chang, *supra* note 127, at 184-190.

¹³³ William D. Nordhaus, *Invention, Growth, and Welfare* (1969). See also Cooter & Schaefer, *supra* note 44, at 16.

¹³⁴ Alan O. Sykes, *TRIPS, Pharmaceuticals, Developing Countries, and the Doha "Solution,"* 3 *Chi. J. Int'l L.* 47 (2002).

classes.¹³⁵ A recent report by PriceWaterhouseCoopers predicts that by 2020, Brazil, China, India, Indonesia, Mexico, Russia and Turkey will represent one-fifth of global pharmaceutical sales, an increase of 60% since 2004.¹³⁶ As the economy in these countries improves, local populations are expected to face the kinds of chronic health issues that are typical in wealthier countries. In addition, changes in environmental conditions may also cause the spread of diseases that are more prevalent in the developing world such as cholera and malaria, among others. At the same time, longer life expectancy in these countries tends to positively impact drug sales as well.

The case of Brazil's intellectual property law illustrates the lower levels of vulnerability of NICs to Tier-2 sanctions.¹³⁷ Brazil enacted a TRIPS-compliant intellectual property law in 1997.¹³⁸ The law then enacted, however, incorporated a number of TRIPS flexibilities and contained several mechanisms that left room for future compulsory licenses. For instance, the law included a "local working" provision which allows for subjecting a patent holder to compulsory licensing if, among other factors, she fails to manufacture the product within Brazilian territory.¹³⁹ Upon the enactment of this law, the pharmaceutical industry issued a communiqué stating that any actions furthering the issuance of compulsory licenses would ensure that companies whose patents are violated will not sell their next generation AIDS drugs, or any other medication, in Brazil.¹⁴⁰ Unimpressed by such threats of the pharmaceutical industry, Brazil continued to negotiate drug discounts from international pharmaceutical companies premised on a threat of its own, namely the prospects of issuance compulsory licenses. The Brazilian government finally issued a compulsory license in 2007; to date, however, the realization of the pharmaceutical industry's retaliatory threats remains improbable.

Lastly, a developing country's outside option depends on a third consideration. Aside from the net savings and the sanctions costs involved, the outside option is also a function of the effects of the issuance of a compulsory license on administrative costs, which operates in two ways.¹⁴¹ On the one hand, a country issuing a compulsory license has, by definition, a less stringent intellectual property system. Thus, the compulsory license can be said to contribute to a reduction in the overall costs related to the administration of the intellectual property system. On the other hand, a country issuing a compulsory license faces the risk of incurring costly litigation, a meaningful consideration for poorer developing countries.¹⁴² This risk of litigation is enhanced by the fact that, under TRIPS, applications for compulsory licenses must be

¹³⁵ Benvenisti & Downs, *supra* note 123, at 44.

¹³⁶ PriceWaterhouseCoopers, *Pharma 2020: The vision - Which path will you take?* (2007), available at <http://www.pwc.com/gx/eng/about/ind/pharma/pharma2020final.pdf> (last visited Aug. 26, 2009).

¹³⁷ Brazilian Federal Law No. 9,279 of May 14, 1996.

¹³⁸ Maria Auxiliadora Oliveira et al, *Brazilian Intellectual Property Legislation*, at 155, in *Challenges for Public Health*, *supra* note 112 (noting however that under TRIPS, Brazil could have made use of a transition period but waived this prerogative).

¹³⁹ Bird & Cahoy, *supra* note 115.

¹⁴⁰ Cited in Ubirajara Regis Quintanilha Marques et al., *Brazil's AIDS Controversy: Antiretroviral Drugs, Breaking Patents, and Compulsory Licensing*, 60 *Food & Drug L.J.* 471, 474 (2005).

¹⁴¹ James Love, *Access to Medicine and Compliance with the WTO TRIPS Accord: Models for State Practice in Developing Countries*, in *Global Intellectual Property Rights: Knowledge, Access and Development* (Peter Drahos & Ruth Mayne eds., 2002).

¹⁴² Cotter, *supra* note 117. See also Gregory Shaffer, *Recognizing Public Goods in WTO Dispute Settlement: Who Participates? Who Decides? The Case of TRIPS and Pharmaceutical Patent Protection*, 7 *J. Int'l Econ. L.* 459 (2004).

considered on their individual merits.¹⁴³ Taking both sides into account, the net impact of the issuance of a compulsory license on administrative costs is not only difficult to measure but also difficult to predict.¹⁴⁴ What is clear however is that litigation costs at WTO's DSB can be a deterrent only for smaller and poorer developing countries.¹⁴⁵

b. Inside Options: National Opportunism within TRIPS

The outcome of a bargaining process, although constrained by the outside option, is also determined by the inside options available to the parties. Inside options are actions that provide positive payoffs while bargaining is still underway. Inside options are therefore resources available to the parties during the course of negotiations.¹⁴⁶ A desirable outside option demonstrates why a developing country can genuinely threaten to terminate cooperation with patentees if it is solely able to obtain a larger payoff through the issuance of a compulsory license. Conversely, the availability of desirable inside options shows why a developing country can credibly threaten to temporarily suspend or prolong negotiations simply in order to hold out for a better offer.¹⁴⁷

To begin with, a compulsory license can function both as an outside option and as an inside option. As described in the previous subsection, at a Tier-2 level, namely the level in which developing countries negotiate with the pharmaceutical industry over drug prices, *inter alia*, the compulsory license is the outside option par excellence. As was shown earlier, the issuance of a compulsory license typically reflects the preferred option of a developing country when negotiations with patentees break down. Yet, the issuance of a compulsory license can work as an inside option as well. In order to understand why, consider the Tier-1 level negotiations in which countries bargain over the legal endowments that will be set forth under domestic and international intellectual property laws. In the course of such negotiations, the issuance of a compulsory license potentially permits a country to obtain a positive payoff without leaving the negotiations table, where a legal endowment may be at stake. For instance, in the course of the negotiations within the Doha Round, some developing countries indeed threatened to issue compulsory licenses while not leaving the negotiations table at the WTO.

There are several additional inside options available for developing countries. The ability of a developing country to make use of inside options, however, is to a large extent dependent upon the specific tenets of its national patent laws and regulations. While the dominant legal rules affecting intellectual property systems are essentially extraterritorial in nature, the incorporation of TRIPS flexibilities by each country is not mandatory and has to be established under domestic laws.¹⁴⁸ Each state adjusts international standards to its own intellectual property policies and establishes their

¹⁴³ See TRIPS Agreement, art. 31(a).

¹⁴⁴ Carlos M. Correa, *New International Standards for Intellectual Property: Impact on Technology Flows and Innovation in Developing Countries*, 24 *Sci. & Pub. Pol'y* 79, 85 (1997) (discussing administrative costs of implementing the TRIPS Agreement).

¹⁴⁵ Paul Rothstein, *Moving All-In with the World Trade Organization: Ignoring Adverse Rulings and Gambling With The Future of the WTO*, 37 *Ga. J. Int'l & Comp. L.* 151, 166-167 (2008) & Fn. 95 and accompanying text.

¹⁴⁶ Jon Elster, *Arguing and Bargaining in Two Constituent Assemblies*, 2 *U. Pa. J. Const. L.* 345, 399-400 (2000).

¹⁴⁷ *Id.* See also Muthoo, *Non-Technical Bargaining*, *supra* note 14, at 149, 157-160.

¹⁴⁸ See J.H. Reichman & David Lange, *Bargaining around the Trips Agreement: The Case for Ongoing Public-Private Initiatives to Facilitate Worldwide Intellectual Property Transactions*, 9 *Duke J. Comp. & Int'l L.* 11, 62 (1998).

enforcement level, thereby setting the ground for a bargaining process in which political actors at the national and supra-national level lobby in order to influence lawmaking at the national level.¹⁴⁹ Nevertheless, recent studies have shown that many developing countries failed to fully incorporate TRIPS' flexibilities into their national patent legislation, reducing the available inside options.¹⁵⁰

TRIPS indeed contains authorizations for a number of outside options that may be utilized by developing countries. Firstly, in some cases developing countries can hinder patenting by foreigners through discrete changes in legislation that are expressly permitted under TRIPS. Secondly, it is possible to narrow the legal definition of patentability, or simply deny patentability altogether, for certain categories of products such as plants and animals.¹⁵¹ Thirdly, a country can intensify the use of the doctrine of prior user's rights in order to lower licensing costs.¹⁵² This doctrine offers a personal defense for someone who non-publicly uses an invention undergoing the patenting process by another, and permits the non-patent holder user to continue using the invention. Its practical effect is to authorize a party other than the patentee to continue to put into practice an invention that was created at the time the patentee's application was filed.¹⁵³ A fourth inside option available to a developing country is the imposition of supplementary disclosure obligations on patentees.¹⁵⁴ TRIPS authorizes a country to establish duties to disclose the origin of plant genetic resources used in an invention,¹⁵⁵ to compel the patent offices to publish the application for a patent shortly after its submission,¹⁵⁶ or to require that a patentee reveal the "best mode" for practicing the invention.¹⁵⁷ A best mode provision requires the patent applicant to disclose the specific embodiment of the invention, thereby prohibiting inventors from disclosing only what they consider to be their second-best

¹⁴⁹ Benvenisti & Downs, *supra* note 123.

¹⁵⁰ See for instance Phil Thorpe, Study on the Implementation of the TRIPS Agreement by Developing Countries 17 (Commission on Intellectual Property Rights, Study Paper No. 7, 2002), available at http://www.iprcommission.org/papers/pdfs/study_papers/sp7_thorpe_study.pdf; B. K. Keyla, Review of National Patent Legislations of India, Indonesia, Sri Lanka & Thailand. New Delhi: National Working Group on Patent Laws, 2003; Maria Auxiliadora Oliveira et al., Has the Implementation of the TRIPS Agreement in Latin America and the Caribbean Produced Intellectual Property Legislation that Favors Public Health? 82 *Bull World Health Organ*, 815, 818-9 (2004); Médecins sans Frontières, Implementation of the Doha Declaration on the TRIPS Agreement and Public Health: Technical Assistance - How to Get it Right, http://www.accessmed-msf.org/prod/publications.asp?scntid=22220021548172&content_type=PARA&; and World Health Organization, Antiretrovirals and Developing Countries: Report by the Secretariat, EB 115/32 (Dec. 16, 2004), available at http://www.who.int/gb/ebwha/pdf_files/EB115/B115_32-en.pdf.

¹⁵¹ Except for micro-organisms. See TRIPS Agreement, Article 27(3)(b). See Jayashree Watal, Intellectual Property Rights in the WTO and Developing Countries 93 (2001).

¹⁵² See Ruth Okediji, Toward an International Fair Use Doctrine, 39 *Colum. J. Transnat'l L.* 75 (2000).

¹⁵³ Heald, *supra* note 154.

¹⁵⁴ TRIPS Agreement, Article 62(1) [authorizing members to "require, as a condition of the acquisition or maintenance of the intellectual property rights ... compliance with reasonable procedures and formalities"].

¹⁵⁵ Nuno Pires de Carvalho, Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications Without Infringing the TRIPS Agreement: The Problem and the Solution, 2 *Wash. U. J.L. & Pol'y* 371, 372 (2000) ("what is at stake is the possibility of detecting commercial gains from the use of genetic resources, so that countries supplying those resources can demand their share in the benefits.")

¹⁵⁶ Paul J. Heald, *The TRIPS Game*, 88 *Minn. L. Rev.* 249 (2003).

¹⁵⁷ TRIPS Agreement, Article 29(1) ["Members ... may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application."]; see also J.H. Reichman, From Free Riders to Fair Followers: Global Competition Under the TRIPS Agreement, 29 *N.Y.U. J. Int'l L. & Pol.* 11, 33 (1997), at 33 [defending the implementation of the best mode requirement].

embodiment, while retaining the best for themselves.¹⁵⁸ Other inside options available for developing countries under TRIPS include the use of counterbalancing regulatory measures in competition law,¹⁵⁹ or the use of safeguards permitted within the TRIPS Agreement.¹⁶⁰

A number of more commonly controversial inside option policies exist as well. The TRIPS Agreement does not stipulate exceptions to the patent rights it protects.¹⁶¹ As a result, developing countries are able to deviously discourage patent applications by foreign firms by pursuing myriad alternatives, such as making the process of patenting overly costly, lengthy, and bureaucratic,¹⁶² or simply taking advantage of (and failing to improve) its judicial system. The latter alternative is closely related to the much broader context of failures in the rule of law,¹⁶³ a familiar trait amongst developing countries.¹⁶⁴ All of these alternatives avoid de facto protecting intellectual property rights, while formally complying with TRIPS.¹⁶⁵

In conclusion, the availability of inside options increases the bargaining power of developing countries by increasing their willingness to enter into an agreement with patentees and their home governments.¹⁶⁶ In addition, the availability of inside options may reduce the short-term costs of compliance with the patent sections of the TRIPS Agreement, both by rendering patenting less attractive and by creating the conditions for a reduction in costs to consumers of patented products.¹⁶⁷ From the developing country's perspective, the goal of discouraging foreign patenting is twofold. It aims at seizing the positive welfare effects offered by intellectual property laws, while at the same time reducing the cost to consumers and local industry of complying with the TRIPS Agreement. All of this may be accomplished without deliberately breaching TRIPS. What is more, this scheme/system often allows a developing country to

¹⁵⁸ *In re Nelson*, 280 F.2d 172, 126 USPQ 242 (CCPA 1960). See also *Eli Lilly & Co. v. Barr Laboratories Inc.*, 251 F.3d 955, 963, 58 USPQ2d 1865, 1874 (Fed. Cir. 2001) ["The best mode requirement creates a statutory bargained-for-exchange by which a patentee obtains the right to exclude others from practicing the claimed invention for a certain time period, and the public receives knowledge of the preferred embodiments for practicing the claimed invention"].

¹⁵⁹ TRIPS Agreement, art. 40(2) ["Nothing in this agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market."].

¹⁶⁰ TRIPS Agreement, art. 7.

¹⁶¹ Reichman & Lange, *supra* note 146, at 21; Frederick M. Abbott, *The New Global Technology Regime: The WTO TRIPS Agreement and Global Economic Development*, 72 *Chi.-Kent L. Rev.* 385, 399 (1996); Rochelle Cooper Dreyfuss & Andreas F. Lowenfeld, *Two Achievements of the Uruguay Round: Putting TRIPS and Dispute Settlement Together*, 37 *Va. J. Int'l L.* 275 (1997); and Reichman, *supra* note 155.

¹⁶² Heald, *supra* note 154.

¹⁶³ Sherwood, *The TRIPS Agreement*, *supra* note 16, at 493. See also Arie Reich, *From Diplomacy to Law: The Juridicization of International Trade Relations*, 17 *J. Intl. L. Bus.* 775, 805 (1997); and Luciana Gross S. Cunha, *Rule of Law and Development: The Discourses on Institutional Reforms in the Justice System*, *Direito GV Working Paper No.* 21 (2009), available at <http://www.direitogv.com.br/interna.aspx?PagId=HTKCNKWI&IDCategory=26&IDSubCategory=146>.

¹⁶⁴ See for instance Cooter & Schaefer, *supra* note 44, at 16-19; Richard Posner, *Richard A. Posner, Creating a Legal Framework for Economic Development*, 13 *The World Bank Research Observer* 1 (1998); Maria Dakolias, *The Judicial Sector in Latin America and the Caribbean: Elements of Reform* (World Bank, Technical Paper No. 319, 1996); Robert J. Barro, *Economic Growth in a Cross Section of Countries*, 106 *THE Q.J. OF ECON.* 407 (1991).

¹⁶⁵ Sherwood, *The TRIPS Agreement*, *supra* note 16, at 544.

¹⁶⁶ Muthoo, *Non-Technical Bargaining*, *supra* note 14, at 148-152.

¹⁶⁷ Heald, *supra* note 154.

recapitulate some of the rewards of foreign innovation while bearing as little of the cost as possible.¹⁶⁸

c. Market Power: Competition and Substitutes

Finally, a developing country's bargaining power is dependent on the extent of its market power, should it bear any. In both economics and law, market power generally refers to the ability of a seller to profitably charge more than the competitive price for what it sells, or the ability of a buyer to profitably pay less than the competitive price for what it purchases.¹⁶⁹ In the case of pharmaceutical patents, market power would express itself in the ability on the part of a developing country buying a patented drug to gainfully pay less than the competitive price.¹⁷⁰ Conversely, existing data suggests that situations such as this are quite rare. The average wholesale drug prices are almost as high in developing as in developed countries, notwithstanding the fact that incomes are much higher in the latter.¹⁷¹ This data intimates that the extent of the market power of the overall group of developing countries is low.¹⁷² Similarly, a software industry requires an innovative-based infrastructure, such as electricity, computers and networks. This in turn requires an educated labor force. In addition to all these things, the developing country must already value intellectual property as a sellable commodity in order for a software industry to materialize. Because software is such an advanced form of trade, LBPs, especially African ones, are far from developing any profitable industry, let alone a profitable software industry.¹⁷³ When viewed as a monolithic group, developing countries can be said to be 'price-takers.'¹⁷⁴

Yet, market power fundamentally varies among developing countries. Firstly, the availability of an indigenous pharmaceutical industry can serve as a powerful instrument for engendering competition among drug suppliers at the national level.¹⁷⁵ Secondly, the developing country's market power depends equally on its purchase volume, so developing countries with larger consumer markets tend to levy more market power.¹⁷⁶ Thirdly, in wealthier developing countries a sizeable share of the population will be covered by either public or private health insurance, such that governments or insurance companies based in these countries will respond to a

¹⁶⁸ The Preamble to the TRIPS Agreement suggests this option and the merits of flexibility are trumpeted by the WTO itself. See TRIPS Agreement, Article 8(1) ["Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement."].

¹⁶⁹ See US Submissions, supra note 95.

¹⁷⁰ *Id.*

¹⁷¹ See Maskus, supra note 106; and Frederick M. Scherer & Jayashree Watal, Post-TRIPS Options for Access to Patented Medicines for Developing Countries, WHO Commission on Macroeconomics and Health (2001).

¹⁷² See Maskus, supra note 106; and Scherer & Watal, supra note 169.

¹⁷³ See, Mary Kopczynski, Robin Hood Versus the Bullies: Software Piracy and Developing Countries, 33 Rutgers Computer & Tech L.J. 299, 328-329 (2007) & Fn. 213-215 and accompanying text.

¹⁷⁴ Fórum de Competitividade da Cadeia Produtiva Farmacêutica 2003-2006: O Desafio de Prosseguir, joint publication of the Minister of Health and the Minister of Development, Industry and Foreign Trade, Brasília, DF, 2007 [hereinafter, "Fórum de Competitividade"] at 13.

¹⁷⁵ See C.P. Chandrasekhar & Jayati Ghosh, WTO Drugs Deal: Does it Really Benefit Developing Countries?, Hindu Bus. Line, Internet Edition, Sept.9, 2003, available at <http://www.thehindubusinessline.com/2003/09/09/stories/2003090900140900.htm>.

¹⁷⁶ Benvenisti & Downs, supra note 123, at 44.

larger demand, potentially allowing them to negotiate larger price discounts.¹⁷⁷ In addition, a buyer's market power also depends on factors such as the availability of information and of substitute products, the buyer's price sensitivity, and the differential advantage of the products, all of which highlights the importance of factoring in local considerations.¹⁷⁸

In sum, measuring bargaining power is tricky. Relative market size typically offers the best preliminary assessment tool, but a more comprehensive understanding requires taking into account other considerations that shape a country's outside option, inside options, and market power.¹⁷⁹ In the post-WTO era, trade and intellectual property have merged into a single bargaining legal and institutional framework. For that reason, international patent regulation became necessarily entangled within a broader agenda of trade liberalization, foreign investment, and innovation policies.¹⁸⁰ This dynamic emphasizes the higher levels of bargaining power of those countries that fulfill the intermediary stages in the international division of labor and industrial production, such as NICs.¹⁸¹ At the same time, the propensity to innovate can sharply change the ability on the part of developing countries to issue compulsory licenses, as will be argued in the next section.

¹⁷⁷ Maskus, *supra* note 106, at 566-570. See also World Health Organization, Commission on Macroeconomics and Health, Working Group 4 Report, Health and the International Economy 49 (2002).

¹⁷⁸ See Michael E. Porter, *Competitive Strategy* (1980).

¹⁷⁹ Steinberg, *supra* note 12.

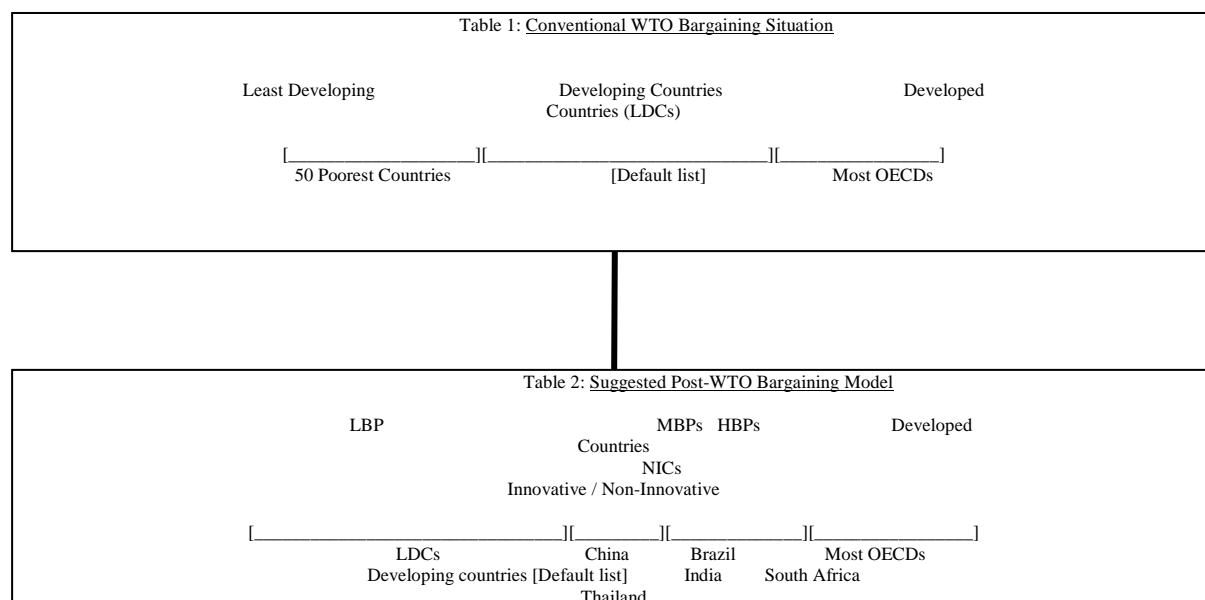
¹⁸⁰ Abbott, *supra* note 159, at 387-88; and Frederick M. Abbot, Protecting First World Assets in the Third World: Intellectual Property Negotiations in the GATT Multilateral Framework, 22 *Vand. J. Transnat'l L.* 689 (1989).

¹⁸¹ Chowdhury & Islam, *supra* note 81, Bradford Jr., *supra* note 82; Guillén, *supra* note 82; Waugh, *supra* note 82, Mankiw *supra* note 82.

II. The Innovation Bent over the Bargaining Cost Structure

A. Overview

Insofar as the ability to issue compulsory licenses is concerned, the post-WTO intellectual property-based bargaining environment requires a conceptual adaptation of existing bargaining models. Tables 1 and 2 depict graphically the suggested shift. Table 1 represents the standard view that WTO members negotiate market access and other commitments essentially premised on the size and diversity of their economies.¹⁸² The assumption is that members with the highest economic wealth and more diversified economies have more bargaining chips to offer, and less to lose, in case negotiations break down. Bargaining power is therefore viewed as a continuum that largely reflects market size and economic diversification.¹⁸³ In contrast, as depicted in Table 2, this article argues instead for a more nuanced view of bargaining power within the group of developing countries when intellectual property-based products and technologies are at stake. This nuanced view takes into account the overall higher levels of bargaining power of NICs in comparison with the rest of the group of developing countries, but it also considers the effects of varied levels of innovativeness in pharmaceuticals within the group of NICs. A typology emerges to divide developing countries into three groups. As will be explained, innovative NICs are categorized as Medium Bargaining Power countries (or “MBPs”), and non-innovative NICs are categorized, somewhat paradoxically, as High Bargaining Power Countries (or “HBPs”). The remaining developing countries are represented collectively as Low Bargaining Power Countries (or “LBPs”).



¹⁸² Richard H. Steinberg, Trade-Environment Negotiations in the EU, NAFTA, and the WTO: Regional Trajectories of Rule Development, 91 A.J.I.L. 231, 233 (1997); Gerhart & Seema Kella, *supra* note 4, at 522.

¹⁸³ *Id.*

The presence of innovation in pharmaceuticals, particularly, serves as a threshold between two groups of NICs. These groups are the innovation ‘haves’, sometimes referred to as ‘innovative developing countries,’¹⁸⁴ and the innovation ‘have-nots’.¹⁸⁵ Currently, only two NICs are undergoing the process of becoming innovators in pharmaceuticals. This small group of innovative NICs effectively includes only India and China. To be sure, this transition is clearer in India, which already displays robust signals of pharmaceutical innovativeness. In China, still, there are indications that the country’s innovative industry is as promising. In this group of countries, pharmaceutical innovation plays a twofold role. On the one hand, it boosts the countries’ technology-based economy, rendering them more competitive and efficient.¹⁸⁶ On the other hand, pharmaceutical innovation harms the ability of their governments to issue compulsory licenses that would make drugs more affordable to their needy and sizeable populations.¹⁸⁷

In ‘innovative NICs,’ or MBPs as explained, the issuance of compulsory licenses causes the coming about of Tier-2 sanctions costs. That is to say, sanctions costs imposed by the pharmaceutical industry. The issuance of a compulsory license signals the existence of a less protective intellectual property system. In MBPs, the booming local pharmaceutical industry would be prompted to reduce innovation efforts out of fear that a less protective legal and institutional environment would be available to future pharmaceutical inventions. Such a reaction would certainly be the case both for the national pharmaceutical industry, as may be seen prominently in India, and for international MNEs performing R&D activities abroad, as is increasingly common in both India and China.

Conversely, ‘non-innovative NICs’, or HBPs as explained, neither innovate, nor appear to foresee becoming relevant innovators in pharmaceuticals in the immediate future. HBPs particularly include Brazil¹⁸⁸ and Thailand,¹⁸⁹ as well as South Africa as a threshold, or dubious, case.¹⁹⁰ Countries such as Brazil and Thailand share with China and India the feature of possessing bargaining power based on their large and diversified economies, although certainly on a smaller scale. Therefore, it may be proffered that HBPs are at best mildly fearful of Tier-1 sanctions costs. However, specifically because HBPs are non-innovative countries, the risk of industry-specific sanctions costs, or Tier-2 sanctions costs, is minimized. In these countries, a much less innovation-prone pharmaceutical industry will not be in a position to impose sanctions costs through reduced innovation.

¹⁸⁴ See Ramesh A. Mashelkar, *Nation Building through Science & Technology: A Developing World Perspective*, 1 *Innovation Strategy Today* (2005); and Carlos Morel et al., *Health Innovation in Developing Countries to Address Diseases of the Poor*, 1 *Innovation Strategy Today* (2005).

¹⁸⁵ See Ulku, *supra* note 49, at 20 (noting that market size is an important factor in determining the effectiveness of R&D sectors).

¹⁸⁶ Shahid Yusuf, *From Creativity to Innovation*, Development Research Group, World Bank (2007).

¹⁸⁷ See e.g. AVERT.org on India (<http://www.avert.org/aidsindia.htm>) and on China (<http://www.avert.org/aidschina.htm>).

¹⁸⁸ Fórum de Competitividade, *supra* note 172.

¹⁸⁹ See, general discussion at Savoie, *supra* note 105; Daniel R. Cahoy, *Confronting Myths And Myopia on the Road from Doha*, 42 *Ga. L. Rev.* 131 (2007).

¹⁹⁰ See, discussion at: Sykes, *supra* note 132. South Africa was the target of litigation initiated by a number of pharmaceutical manufacturers over South Africa’s Medicines and Related Substances Control Act of 1997.

B. The HBP Model: A Single-Sanction Cost Structure

1. Introduction

The group of HBPs entails a first sight paradoxical, or at least unusual, case in which overall weaker players are in a favorable position to bargain. HBPs such as Brazil and Thailand generally possess less market power than larger developing countries such as India or China; yet in the context of intellectual property bargaining they emerge stronger than the latter countries given their ability to issue compulsory licenses. Similarly, the most innovative applications of government's use of open source technology are coming from HBPs.¹⁹¹ Some examples are Citizen Service Centres in Brazil, ICT-based Electoral Reform in South Africa or Philippine Customs Reform. Innovative solutions based on open-source technologies primarily enable faster diffusion of locally-innovated ICT.¹⁹² The group of HBPs is basically composed of those countries that stand to benefit the most from bargaining around TRIPS through patent compulsory licensing. Their high bargaining power is essentially connected to three features. Firstly, they belong to the category of NICs, which signals a relatively higher market power than developing countries at large. Secondly, they do not innovate in pharmaceuticals and thus have lower innovation-related sanction costs. And thirdly, their current domestic laws contain limited TRIPS-plus provisions.

This third point deserves highlighting and further explanation. Not every non-innovative NIC can be considered an HBP. Mexico, for instance, a large non-innovative NIC, has a fairly limited ability to bargain either with developed countries or the pharmaceutical industry. Mexico is bound by the North American Free Trade Agreement (NAFTA)¹⁹³ and by an FTA which it signed with the European Union in the year 2000.¹⁹⁴ These agreements can render illegal issuances of compulsory licenses that under TRIPS alone would otherwise be deemed legal. As such, these agreements magnify the prospects of Tier-1 sanctions in the event of issuances of compulsory licenses.

2. The HBP-MBP Regional Thresholds

a) Brazil/South America

The case of Brazil shows that the absence of local innovation in pharmaceuticals can ironically boost the bargaining power of a large developing country. For decades, Brazil has been a leading voice for the developing world in South America and beyond, in international trade and intellectual property disputes. As such, it has

¹⁹¹ Compare: United Nations University, Free Software in Developing Countries Vital to Future Prosperity and Good Governance: UNU Technology Experts, available at <http://www.unu.edu/media/archives/2006/files/mre-iist-3-06.pdf> (last visited Aug. 26, 2009) [hereinafter Free Software in Developing Countries].

¹⁹² *Id.*

¹⁹³ See, North American Free Trade Agreement, Dec. 17, 1992, 32 I.L.M. 289, 670 (1993). Under such agreement, Mexico specifically undertook to protect IPRs under the stringent standards defined in chapter 17 of the agreement.

¹⁹⁴ The Free Trade Agreement between Mexico and the European Union (MEUFTA). See also Bryan Mercurio, TRIPS-Plus Provisions in FTAs: Recent Trends; in *Regional Trade Agreements and the WTO Legal System* (Lorand Bartels, Federico Ortino, eds.), 221 (2006) [noting that Mexico has FTAs with over 42 countries, many of which were negotiated subsequently to NAFTA].

opportunistically funneled its commercial interests into an aggressive form of bargaining with developed countries.

Brazil is herein categorized as an HBP primarily because it has a high value outside option in negotiations over the conditions for access to patented pharmaceuticals. This outside option is available to Brazil firstly because the country possesses a generics industry that is in a position to produce patented drugs that may be compelled to obtain compulsory licenses. Since the issuance of compulsory licenses in Brazil can generate net savings, threats of compulsory licensing become a powerful negotiation weapon. Secondly, a non-innovative NIC like Brazil faces a combination of mild to low Tier-1 and Tier-2 sanctions costs. On a Tier-1 level, Brazil's large and diversified economy grants the country some leeway to endure threats of retaliation from the developed world. On a Tier-2 level, Brazil's large and growing consumer markets guarantee reasonable to high private investment levels in production.¹⁹⁵ At the same time, a less stringent patent regime does not harm sufficiently its largely non-innovative pharmaceutical industry.¹⁹⁶ Thirdly, an NIC such as Brazil can withstand the prospects of costly litigation upon the issuance of compulsory licenses.

All of these factors have contributed to shaping Brazil's aggressive bargaining behavior.¹⁹⁷ In the backdrop of that, Brazil has now become world renowned for being the most successful developing country in tackling the AIDS epidemic.¹⁹⁸ Key to the effectiveness of Brazil's AIDS program was the country's aggressive negotiation stance designed to obtain large discounts on HIV/AIDS medication produced by big pharmaceutical companies. Its strategy was largely premised on the issuance of compulsory licenses, or the threat thereof, on patent rights over these drugs.¹⁹⁹

As part of this process, in 2007 Brazil issued a compulsory license over Merck's Efavirenz, an ARV.²⁰⁰ The country seemingly suffered only modest sanctions costs upon its issuance of the compulsory license. To begin with, no sanctions were raised

¹⁹⁵ Tech's Future; With Affluent Markets Maturing, Tech's Next 1 Billion Customers will be Chinese, Indian, Brazilian, Thai... In Reaching them, the Industry will be Deeply Transformed, Business Week, September 27, 2004 (through: lexisnexis).

¹⁹⁶ Carlos H. de B. Cruz & Luiz de Mello, Boosting innovation performance in Brazil, OECD Economics Department Working paper No. 532, at 5 (showing that scientific and applied R&D are highly disconnected in Brazil, thus the country is by and large incapable of converting knowledge into productivity gains for its business sector). See also Alan Wright, Innovation in Brazil: Public Policies and Business Strategies, Woodrow Wilson International Center for Scholars, March/2008 (Brazilian scientists and research institutions developed and established the country's capacity to produce state-of-the-art knowledge in various fields; innovation, or the ability to apply knowledge in the development and production of goods and services, however, remains largely absent in most sectors of the economy.)

¹⁹⁷ Bird & Cahoy, supra note 115, at 406. See also Yu, supra note 104, at 349 (defining Brazil as the "poster child of the use of--or, more precisely, the threat to use--compulsory licenses to promote access to essential medicines").

¹⁹⁸ The Economist, Brazil's AIDS programme: A conflict of goals, May 10, 2007. See also Ellen 't Hoen, TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha, 3 Chi. J. Int'l L. 27, 32 (2002).

¹⁹⁹ See Request for Consultations by Brazil, United States--US Patents Code, WT/DS224/1 (Feb. 7, 2001). See also Shaffer, supra note 140, at 471.

²⁰⁰ Announcement of the Ministry of Health, Brazil, Brasil decreta licenciamento compulsório do Efavirenz (May 4, 2007), available at http://portal.saude.gov.br/portal/aplicacoes/noticias/noticias_detalhe.cfm?co_seq_noticia=29717 (last visited Aug. 26, 2009); see also Celia W. Dugger, Brazil Overrides Merck Patent on AIDS Drug, N.Y. Times, May 5, 2007, at A6. Brazil also included Abbott's Kaletra in its compulsory license threat (Thai Flu Moves South, Wall St. J., May 7, 2007, at A14) but later came to an agreement with the pharmaceutical company on a significantly discounted price (Brazil Gets Abbott Discount, Wall St. J., July 5, 2007, at B7).

at the WTO or other international fora, as the compulsory license was largely viewed as legal under international law.²⁰¹ The Special 301 Report issued by the USTR criticized Brazil's discussions with patent holders,²⁰² but the United States did not impose formal sanctions. Merck indeed issued a press release stating that Brazil's action was an "expropriation of intellectual property" that "will have a negative impact on Brazil's reputation as an industrialized country seeking to attract inward investment, and thus its ability to build world-class research and development."²⁰³ The extent to which these threats may come to fruition remains to be seen. True to Merck's claim, there are no clear signs of revamping of the pharmaceutical sector in Brazil, particularly insofar as innovation is concerned. On the other hand, there are no obvious signs of reduced FDI in Brazil. The opposite, remarkably so, was true as of the year 2007: Brazil's share of FDI in 2007 totaled USD \$34.6 billion, almost twice as much as the previous year and representing one of the highest shares in the world amongst developing countries;²⁰⁴ in the pharmaceuticals industry, specifically, FDI in 2007 reached USD \$164.4 million,²⁰⁵ which is consistent with the historic investment levels observed in previous years.²⁰⁶

In fact, Brazil's aggressive bargaining behavior has exceeded specific TRIPS policies over pharmaceuticals, an assertion that may be demonstrated by at least five separate examples. Firstly, Brazil remains the only developing country that has ever requested consultations pursuant to the WTO dispute settlement process with any developed country concerning the noncompliance of intellectual property laws with the TRIPS Agreement.²⁰⁷ Secondly, Brazil exercised aggressive leadership in GATT; alongside India and eight other developing countries,²⁰⁸ Brazil strongly opposed attempts to expand the mandate of the GATT to cover substantive intellectual property issues.²⁰⁹ Thirdly, Brazil vigorously led the campaign to support the free and open source software movement, noticeably alongside developed countries such as Spain and Finland.²¹⁰ In fact, the open source movement's largest concentration of

²⁰¹ See, e.g., Tove Iren S. Gerhardsen, Brazil Takes Steps to Import Cheaper AIDS Drug Under Trade Law, IP-Watch, May 7, 2007, available at <http://www.ip-watch.org/weblog/index.php?p=614&res=1280&print=0> (last visited Aug. 26, 2009).

²⁰² 2007 Special 301 Report, at 30.

²⁰³ Press Release, Merck & Co., Statement on Brazilian Government's Decision to Issue Compulsory License for Stocrin (May 4, 2007), available at http://www.merck.com/newsroom/press_releases/corporate/2007_0504.html (last visited Aug. 26, 2009).

²⁰⁴ Source: Central Bank of Brazil (www.bcb.gov.br). See also Foreign Direct Investment in Brazil Doubles in 2007 to US\$ 35 Billion, Brazil Magazine, available at <http://www.brazzilmag.com/content/view/9086/> (last visited Aug. 26, 2009).

²⁰⁵ Source: Central Bank of Brazil (www.bcb.gov.br).

²⁰⁶ See, Table 1: FDI in pharma in Brazil (production of pharmaceutical inputs + production of medicines, in USD), at Avaliação da Política Industrial, Tecnológica e de Comércio Exterior – PITCE para o Setor Farmacêutico, Brazilian Federation of Pharmaceuticals Industry - FEBRAFARMA, July 2007.

²⁰⁷ See Request for Consultations by Brazil, *supra* note 197.

²⁰⁸ The other LBPs were Argentina, Cuba, Egypt, Nicaragua, Nigeria, Peru, Tanzania, and Yugoslavia. See, Press Release, World Intellectual Property Organization [WIPO], Member States Agree to Further Examine Proposal on Development (Oct. 4, 2004), available at www.wipo.int/edocs/prdocs/en/2004/wipo_pr_2004_396.html; Press Release, WIPO, Member States Adopt a Development Agenda for WIPO (Oct. 1, 2007), available at www.wipo.int/pressroom/en/articles/2007/article_0071.html (last visited Aug. 26, 2009).

²⁰⁹ See, Watal, *supra* note 149, at 19.

²¹⁰ See Brian Fitzgerald & Nic Suzor, Legal Issues for the Use of Free and Open Source Software in Government, 29 Melb. U. L. Rev. 412, 422 (2005).

supporting countries presently lies in South America, clearly under the leadership of Brazil.²¹¹

Brazil has also become the first country to require any company or research institute that receives government financing to develop software to license it as open-source, meaning the underlying software code must be free to all.²¹² Open-source represents a small share of the global software market, but Linux and open source solutions will find their biggest markets in developing countries, particularly in MBPs, as China and India, but also HBPs, as in East Asia and South America.²¹³ These countries have begun turning to open source for various reasons, not least of them a sense of not wanting to be beholden to MNEs such as Microsoft.²¹⁴ In turn, Microsoft has become a progressively harsher opponent of the open-source software model, in which the underlying code for software is freely shared for users to modify and distribute. Similarly to the fields of pharmaceutical patents and information and communications technology (ICT), it upholds that the open source approach undermines innovation at large.²¹⁵

Fourthly, Brazil serves as one of the leaders in the G-20 organization, which essentially congregates the twenty largest economies in the world, both from within the developed and the developing worlds. Brazil's HBP-type leadership was also demonstrated in 2003 at the Cancun Ministerial during the Fifth WTO Ministerial Conference,²¹⁶ where Brazil led a coalition of twenty one developing countries together with China and India.²¹⁷ Lastly, one year after the Ministerial in Cancun, Brazil was seated at the forefront of the process that led to the establishment of a development agenda within WIPO.²¹⁸

This article thus suggests that Brazil's strategy derives from a distinct set of incentives hidden within the TRIPs Agreement. These hidden incentives render it convenient for non-innovative NICs, such as Brazil, to use compulsory licenses as part of a hard-line negotiation strategy with big pharmaceutical corporations. Brazil is able to obtain net benefits from such aggressive behavior mostly because it is able to produce generics locally, something that smaller and weaker developing countries are unable to do. In turn, in a country with weak institutions and high taxation such as Brazil, the expected long-term effects of maintaining an overall weaker patent protection system in the pharmaceutical industry are less dramatic than in more innovative countries, such as India. Brazil, unlike India, is by and large a non-innovative country, particularly in pharmaceuticals. As such, in Brazil, the issuance of

²¹¹ Daniel F. Olejko, Comment, Charming a Snake: Open Source Strategies for Developing Countries Disillusioned with TRIPs, 25 PA. ST. INT'L L. REV. 855, 858 (2007) (Argentina, Chile, Peru, and Venezuela have also display a wide acceptance of open source even in comparison to developed countries' standards.)

²¹² Todd Benson, Brazil: Free Software's Biggest and Best Friend [29 March 2005], at: <http://www.nytimes.com/2005/03/29/technology/29computer.html> (last visited Aug. 26, 2009).

²¹³ Free Software in Developing Countries, *supra* note 189.

²¹⁴ Brazil Gives Nod to Open Source, *Wired*, 16/11/2003, <http://www.wired.com/techbiz/it/news/2003/11/61257>

²¹⁵ See, Sanjiva Weerawarana & Jivaka Weeratunga, Open Source in Developing Countries 32 (2004), available at <http://www.eldis.org/fulltext/opensource.pdf>.

²¹⁶ See, G-20, G-20 Members, www.g-20.mre.gov.br/members.asp.

²¹⁷ Pablo A. Ormachea, Agriculture Subsidies and the Free Trade Area of the Americas, 13 *Law & Bus. Rev. Am.* 139, 149 (2007).

²¹⁸ See, Press Release, World Intellectual Property Organization [WIPO], Member States Agree to Further Examine Proposal on Development (Oct. 4, 2004), available at www.wipoint.edocs/prdocs/en/2004/wipo_pr_2004_396.html; Press Release, WIPO, Member States Adopt a Development Agenda for WIPO (Oct. 1, 2007), available at www.wipo.int/pressroom/en/articles/2007/article_0071.html (last visited Aug. 26, 2009).

compulsory licenses, at best, modestly hinders innovation in the pharmaceutical industry over time, because such innovation tends not to occur for reasons more influential than the compulsory licenses.

All in all, the case of Brazil does not demonstrate that patents are uncorrelated with innovation in pharmaceuticals. Although it remains a highly controversial topic, there is some evidence of the existence of a link between patent protection and pharmaceutical innovation.²¹⁹ Indeed, the lack of a more stringent enforcement of intellectual property laws may well be one of the many causes for lack of innovation in the Brazilian pharmaceutical sector. However, even supporters of stronger patent protection systems will concede that an effective intellectual property regime is in-and-of itself neither sufficient to attract pharmaceutical FDI nor to spring innovation.²²⁰ Early adherence to TRIPS has failed to cause, at least as a sole factor, the emergence of technological innovation in the Brazilian pharmaceutical industry. To generalize, in non-innovative NICs, TRIPS does not operate as a “carrot” for more innovation; rather, it functions as a “stick” for less piracy.

b) Thailand/Asia

Thailand is arguably another HBP country. The case of Thailand has a number of similarities to that of Brazil. Like Brazil, Thailand has adopted an aggressive stance on both patent bargaining and software protection. In Asia, to illustrate, some of the highest overall Free/Libre/Open Source Software (FLOSS) related activity seems to be taking place in innovative developing countries, namely NIC countries like India, China and Taiwan, followed by South Korea, Malaysia, Singapore and Thailand.²²¹ Moreover, Thailand has been one of the few developing countries to actually carry out compulsory licenses of drugs. It did so for the first time in 2006, with the compulsory license of Merck’s Efavirenz, the same drug on which Brazil imposed a compulsory license.²²² Only a few months later, Thailand issued two more compulsory licenses, one for Abbott’s Kaletra, an AIDS drug, and another for Sanofi-Aventis’ Plavix, a heart medicine.²²³ The compulsory license over Plavix represents a particularly clear expression of high bargaining power on the part of Thailand, given that whether a heart disease drug meets the TRIPS criterion of “national emergence” is questionable

²¹⁹ See Andréanne Léger, *The Role(s) of Intellectual Property Rights for Innovation: A Review of the Empirical Evidence and Implications for Developing Countries*. Paper provided by DIW Berlin, German Institute for Economic Research in its series Discussion Papers of DIW Berlin with number 707, available at <http://www.diw.de/documents/publikationen/73/61916/dp707.pdf>. See also Colleen Chien, *Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?*, 18 *Berkeley Tech. L.J.* 853, 856 (2003).

²²⁰ Douglas Lippoldt, *Intellectual Property Rights, Pharmaceuticals and Foreign Direct Investment*, Policy Brief, Groupe d’Economie Mondiale de Sciences Po (November 2006), available at: http://www.gem.sciences-po.fr/content/publications/pdf/lippoldt_IPRs_Pharma_FDI1106.pdf (last visited Aug. 26, 2009).

²²¹ <http://www.linuxjournal.com/article/6884>

²²² Letter from the Department of Disease Control to Merck Sharp and Dohme (Nov. 29, 2006), in Ministry of Pub. Health & Nat’l Health Sec. Office Thail., *Facts and Evidence on the 10 Burning Issues Related to Government Use of Patents on Three Patented Essential Drugs in Thailand 47-48* (Vichai Chokevivat ed., 2007), <http://www.moph.go.th/hot/White%20Paper%20CL-EN.pdf> (last visited Aug. 26, 2009).

²²³ Thail. Dep’t of Disease Control, Ministry of Pub. Health, *Decree Regarding Exploitation of Patent on Drugs & Medical Supplies by the Government on Combination Drug Between Lopinavir & Ritonavir* (Jan. 29, 2007), available at http://www.cptech.org/ip/health/c/thailand/thai-cl-kaletra_en.pdf; Thail. Dep’t of Disease Control, Ministry of Pub. Health, *Announcement Regarding Exploitation of Drugs and Medical Supplies for Clopidogrel* (Jan. 25, 2007), available at http://www.cptech.org/ip/health/c/thailand/thai-cl-clopidogrel_en.pdf (last visited Aug. 26, 2009).

as a matter of law.²²⁴ Such a compulsory license potentially could have given rise to Tier-1 sanctions authorized by the WTO – which in fact never happened – but the Thai government acted irrespective of that risk.

The dynamics of Tier-2 sanctions in Thailand are similar to those seemingly prevailing in Brazil. Firstly, Thailand is actually in a position to obtain net benefits with the issuance of compulsory licenses, the main reason being that it possesses an established manufacturing capability in pharmaceuticals.²²⁵ In fact, a state-run capacity to produce generics, particularly AIDS drugs, further enhances the ability of the country to pose a veritable threat of issuing compulsory licenses.²²⁶ Secondly, Tier-2 sanctions costs play out in Thailand in a similar fashion to that of Brazil. Like Brazil, the pharmaceutical industry in Thailand is relatively small in comparison to other sectors of the local economy. Moreover, the Thai pharmaceutical industry is mostly geared toward supplying the local market, rather than for export. In addition, the industry practically involves no research and development of new drugs and components.²²⁷ Over the coming years, Thailand will likely remain an overall importer of medicines, with the trade balance further shifting in favor of imports.²²⁸ Moreover, and although Abbot Laboratories recently withdrew seven registration applications for newly-developed pharmaceutical products in Thailand, the Thai government seemingly relies on the expectation that its markets are large enough to sustain sufficiently interested MNEs.²²⁹

Tier-1 sanctions costs appear to play out favorably for Thailand as well. In recent negotiations with the United States, Thailand notably rejected a proposed FTA.²³⁰ This FTA would have, among other things, required a greater commitment by the Thai government to enhance patent protection. This rejection again represents a typical HBP bargaining stance, paralleling that of Brazil. After all, Brazil thus far has not agreed to the framework laid out by the United States for the intended Free Trade Area of the Americas (FTAA), which contains similar TRIPS-plus provisions.²³¹

²²⁴ See, e.g., Tove Iren S. Gerhardsen, Drug Company Reacts to Thai License; Government Ready to Talk, IP-Watch, Feb. 16, 2007, available at <http://www.ip-watch.org/weblog/index.php?p=538&res=1280&print=0> (last visited Aug. 26, 2009); Bangkok's Drug War Goes Global, Wall St. J. (Asia), Mar. 7, 2007; and Ronald A. Cass, Thai Patent Turmoil, Wall St J., Mar. 13, 2007.

²²⁵ Rein, *supra* note 111.

²²⁶ Sanchai Chasombat et al., The National Access to Antiretroviral Program for Pha (Napha) in Thailand, 37 Southeast Asian J. Trop. Med. Public Health, 706 (2006).

²²⁷ See New Regulatory Trends In Thailand's Pharmaceutical Market published by Pacific Bridge Medical (March 1999), available at: <http://www.pacificbridgemedical.com/publications/html/ThailandMar1999.htm> (last visited Aug. 26, 2009).

²²⁸ In Thailand's Pharmaceutical Market Generics Are Likely to Be the Fastest-Growing Segment, Reaching US\$1.63bn in 2010 from US\$1.1bn in 2005, Business Wire, May 1, 2007, at http://findarticles.com/p/articles/mi_m0EIN/is_2007_May_1/ai_n27219824 (last visited Aug. 26, 2009).

²²⁹ Press Release, Médecins sans Frontières, MSF Denounces Abbott's Move to Withhold Medicines from People in Thailand (Mar. 15, 2007), available at <http://www.accessmed-msf.org/prod/publications.asp?scntid=15320071424114&content type=PARA&>; see also Nicholas Zamiska, Abbott's Thai Pact May Augur Pricing Shift, Wall St. J., Apr. 23, 2007, at A3. Kaiser Daily HIV/AIDS Report, Abbott To Stop Launching New Drugs in Thailand in Response to Country's Compulsory License for Antiretroviral Kaletra (Mar. 14, 2007), <http://www.kaisernetwork.org/daily-reports/rep-index.cfm?hint=1&DR ID=43558> (last visited Aug. 26, 2009).

²³⁰ See, e.g., Thai Human Rights Commission Criticizes FTA with US, Bilaterals.org, Jan. 26, 2007, http://www.bilaterals.org/article.php3?id_article=7012 (last visited Aug. 26, 2009).

²³¹ The FTAA, being a proposed agreement to eliminate or reduce the trade barriers among all countries in the Americas but Cuba, would increase intellectual property protection beyond TRIPS minimum standards. See FTAA Negotiating Group on Intellectual Property Rights, available at http://www.ftaa-alca.org/ngroups/ngprop_e.asp (last visited Aug. 26, 2009). See also Ormachea, *supra* note 215, at 145-146.

To conclude, the similarities between the cases of Thailand and Brazil are abundant. In spite of sharp differences in their political systems,²³² to date the only developing countries that have achieved universal access to ARV therapy to AIDS patients have been Brazil and Thailand.²³³ In both cases, more ambitious health programs were made possible by, among other things, aggressive price negotiations with big pharmaceutical companies. This strategy, in turn, was largely premised on the issuance – or more commonly, the real threat of issuance – of compulsory licenses over patented drugs.²³⁴ The ensuing paradox, to insist on this term, lies also in that overall less powerful countries such as Brazil and Thailand are proving more successful in dealing with the AIDS epidemic than other countries that are overall more powerful, such as India and China.²³⁵ This situation arises in countries such as Brazil and Thailand not in spite of their lack of pharmaceutical innovation, but in part because of it.

c) South Africa/Africa

A third HBP to practice aggressive bargaining is South Africa. The country boasts the largest economy in the African continent, and enjoys noticeable political influence over other African countries. In relative terms, it is expected to remain quite powerful vis-à-vis other developing countries.²³⁶ Similarly to Brazil and Thailand, South Africa is engaged in little to no innovation on the ground, particularly in pharmaceuticals. In that sense, it may be more narrowly classified as a non-innovative NIC.

There are three persuading indications of South Africa's HBP-like bargaining situation. Firstly, alongside with Brazil, South Africa was prominently involved in the negotiations²³⁷ that led to the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.²³⁸ In retrospect, there is wide consensus that South Africa made an important contribution to what is sometimes regarded as a turning point in the TRIPS debate.²³⁹ Secondly, the country has been noticeably influential in placing the issue of access to medicines on the human rights and public health agendas.²⁴⁰

²³² Thai's compulsory licenses were issued by a military government; Brazil's compulsory licenses by a democratic one.

²³³ Nathan Ford et al., *Sustaining Access to Antiretroviral Therapy in Developing Countries: Lessons from Brazil and Thailand*. AIDS 2007. 21 (suppl 4):S21–S29. World Health Organization. 3 by 5 progress report. Geneva: WHO; March 2006.

²³⁴ Grace C. *The Effect of Changing Intellectual Property on Pharmaceutical Industry Prospects in India and China: Considerations for Access to Medicine*, Issues Paper, Health Systems Resource Centre, Department of International Development, United Kingdom (2004).

²³⁵ See AVERT.org on Brazil (<http://www.avert.org/aids-brazil.htm>); Thailand (<http://www.avert.org/aidsthai.htm>); India (<http://www.avert.org/aidsindia.htm>); and China (<http://www.avert.org/aidschina.htm>).

²³⁶ Jim O'Neill, *Global Economics Paper 134, How Solid Are the BRICs?*, Goldman Sachs (2005).

²³⁷ See Sonia E. Rolland, *Developing Country Coalitions at the WTO: In Search of Legal Support*, 48 *Harv. Int'l L.J.* 483, 496 (2007) (mentioning also India in the same context).

²³⁸ General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 (Sept. 1, 2003), 43 *I.L.M.* 509 (2004).

²³⁹ See, e.g., Susan K. Sell, *Private Power, Public Law: The Globalization of Intellectual Property Rights* 146, 181 (2003) (observing that "[t]he HIV/AIDS pandemic was a contingency that sped up the revelation of the negative consequences of TRIPS"); Ruth Mayne, *The Global Campaign on Patents and Access to Medicines: An Oxfam Perspective*, in *GLOBAL INTELLECTUAL PROPERTY RIGHTS: KNOWLEDGE, ACCESS AND DEVELOPMENT* 244, 249 (Peter Drahos & Ruth Mayne eds., 2002) (noting that "[t]he South African government's decision to fight the case was a critical factor in generating global media interest").

²⁴⁰ See Peter K. Yu, *The International Enclosure Movement*, 82 *Ind. L.J.* 827, 865-66 (2007).

Thirdly, South Africa withstood great pressure from the United States in the process of amending its intellectual property law. In 1997 South Africa passed the Medicines Amendment Act,²⁴¹ allowing for parallel imports of pharmaceuticals.²⁴² Controversy erupted over this legislation, and the United States government threatened sanctions if the South African government put the Medicines Amendment Act into full force.²⁴³ The United States Congress included in its appropriations bill in 1998 a provision withholding aid monies for South Africa until the Medicines Amendment Act was repealed. The Clinton administration eventually backed away from its original stance, even though it was heavily lobbied by the pharmaceutical industry – the latter having reduced Tier-2-like sanction power vis-à-vis its HBP bargaining counterpart.²⁴⁴ Not too surprisingly, South Africa did not back down – much to the contrary.²⁴⁵ The United States government later withdrew its legislation after the South African government asserted that it was legally able to utilize parallel imports and compulsory licenses under TRIPS. On the South African side, the only compromise made was to repeat earlier promises that South Africa would abide by the WTO's TRIPS Agreement.²⁴⁶

To conclude, the explanation for HBPs' unique bargaining situation is threefold. Firstly, and most notably, HBPs stimulate a collapse of the Tier-2 sanction costs. This statement is true with respect to MNEs, and at times local investors, both of which refrain from conducting R&D locally, even in the face of strong patent laws. Furthermore, HBPs possess large consumer markets that tend to be highly desirable to large MNEs. As can be expected, early adherence to TRIPS strict patent policies has failed to cause, in-and-of itself, the emergence of research and development in innovation in the pharmaceutical industry in HBPs. Lack of innovation in what are thus 'non-innovative NICs' has transformed economically weaker NICs into stronger bargaining powers in patent-sensitive products, such as pharmaceuticals. Such is the case when such countries threaten to issue, or actually issue, patent compulsory licenses. Secondly, the shortage of local innovation frees HBP governments, such as Brazil, Thailand, or South Africa, from pressures from a local industry that requires more stringent patent protection. This economic-political reality facilitates, rather than harms, HBPs' power to issue compulsory licenses over pharmaceuticals. Thirdly, and more generally, in HBP countries, TRIPS does not effectively function as a

²⁴¹ Section 10 of Medicines and Related Substances Control Amendment Act 90 of 1997 (S. Afr.).

²⁴² Mary Beth Walker, *Assessing the Barriers to Universal Antiretroviral Treatment Access for HIV/AIDS in South Africa*, 15 *Duke J. Comp. & Int'l L.* 193, 210 (2004).

²⁴³ *Id.* at 211.

²⁴⁴ Pub. L. No. 105-277, 112 Stat. 2681 (1998). The specific language of the bill said "none of the funds appropriated under this heading may be made available for assistance for the central Government of the Republic of South Africa, until the Secretary of State reports in writing to the appropriate committees of the Congress on the steps being taken by the United States Government to work with the Government of the Republic of South Africa to negotiate the repeal, suspension, or termination of section 15(c) of South Africa's Medicines and Related Substances Control Amendment Act No. 90 of 1997"

²⁴⁵ Ellen 't Hoen, *supra* note 196, at 31.

²⁴⁶ See, James Love, *Five Common Mistakes by Reporters covering US/South Africa Disputes over Compulsory Licensing and Parallel Imports*, Consumer Project On Tech., Sept. 23, 1999, at <http://www.cptech.org/ip/health/sa/mistakes.html> (last visited Aug. 26, 2009). See European Commission, *Different Needs, Different Responsibilities: What is the EU Asking from Developing Countries?* (Dec. 14, 2005), available at <http://ec.europa.eu/comm/trade/issues/global/development/pr141205en.htm> (last visited Aug. 26, 2009) (stating that "advanced developing countries" include "the large emerging economies of the G20, who combine developing country status with high competitiveness in one or more export sector, such as Brazil (Agriculture), China (Manufacturing) and India (Services)").

“carrot” for more FDI or innovation; rather, it serves a “stick” to exert pressure in favor of Pax-American tailor-made intellectual property rights.

C. The MBP Model: A Dual-Sanction Cost Structure

1. Introduction

Among NICs, innovative countries are those that benefit the least from bargaining around TRIPS through compulsory licenses or threats thereof. Simply put, the main reason for this phenomenon is that in these countries compulsory licenses discourage local innovation. These countries paradoxically possess a weaker bargaining position in terms of their ability to issue compulsory licenses, mainly because MBPs are subject to a dual sanctions cost structure. First, on a Tier-1 bargaining level, a compulsory license can cause the United States government to impose sanctions. While strong in comparison to the rest of the developing world, MBPs remain dependent on strengthening their commercial ties with the developed world. Second, on a Tier-2 bargaining level, MBPs markets may be sanctioned by MNEs or national investors, particularly insofar as the issuance of compulsory licenses over pharmaceuticals may harm MBPs’ innovation incentives. The Tier-2 sanction costs are also ever-present with the bio agriculture and plant genetics patent-sensitive industries. Developed countries’ support for extreme biotechnology measures that threaten to supplant the conventional intellectual property regime and to undermine food security in the underdeveloped world is expressed in manipulative genetic use restriction technologies (GURTs). They are also jointly known as Terminator Technology.²⁴⁷ It stands for a genetic engineering method that limits genetic copy propagation by producing sterile seeds unfit for subsequent planting.²⁴⁸ Similar to Digital Rights Management (DRM) software technologies, it is a form of self-enforcing patents devoid of experimental use doctrines within patent law.²⁴⁹ The United States, Canada, Australia, New-Zealand and noticeably Argentinian MNEs, are all active supporters of terminator technologies, and have continued to press for commercial exploitation of GURTs.²⁵⁰

With software, in the United States, major MNEs align to lobby the government to enforce their interests under the umbrella of the IIPA.²⁵¹ The IIPA collects information about intellectual property piracy overseas and regularly reports it to the

²⁴⁷ See, e.g., World Braced for Terminator 2, *The Guardian*, 6 October 1999, available at <http://www.guardian.co.uk/science/1999/oct/06/gm.food2> (last visited Aug. 25. 2009) [hereinafter *The Guardian*]; Srinivasan & Colin Thirtle, *Impact of Terminator Technologies in Developing Countries: A Framework for Economic Analysis*, in *Economic and Social Issues in Agricultural Biotechnology* 159, 161 (R.E. Evenson et al. eds., 2002).

²⁴⁸ *The Guardian*, *Id.*

²⁴⁹ See, CBD, Montreal, Can., Nov. 10-14, 2003, Report of the Ad Hoc Technical Expert Group Meeting on the Potential Impacts of Genetic Use Restriction Technologies on Smallholder Farmers, Indigenous and Local Communities and Farmers’ Rights, Annex 1, PP 7 & 21, UNEP/CBD/SBSTTA/9/INF/6-UNEP/CBD/WG8J/3/INF/2 (Sept. 29, 2003) [hereinafter CBD, Report of the Ad Hoc Technical Expert Group].

²⁵⁰ See AG Biotech Infonet, Biodiversity Convention’s Terminator Decision Fails Biodiversity and Fails Farmers (June 28, 1999), available at <http://www.cbd.int/doc/meetings/sbstta/sbstta-09/information/sbstta-09-inf-06-en.pdf> (last visited Aug. 25. 2009). Notwithstanding this raised serious concerns by the CBD and a majority of the international community. See, CBD, Report of the Ad Hoc Technical Expert Group, *Id.* Within the realm of bio-agriculture alone, LBP Argentina should therefore exceptionally be considered as an MBP.

²⁵¹ See, e.g., Description of the International Intellectual Property Alliance (IIPA), <http://www.iipa.com/aboutiipa.html> (last visited Aug. 25. 2009).

USTR.²⁵² Overall, if the development economics history of developed countries should repeat itself, these MBPs eventually will want stronger intellectual property protection as an important means of transforming into fully developed countries. Having among other things demonstrated significant promise in carrying out health innovation in particular,²⁵³ China and India are most likely to be the first to reach a point at which creating stronger patent protection will be in their pure self-interest.²⁵⁴

2. India

A number of fundamental advantages position India as the more promising incubator for pharmaceutical innovation within the developing world.²⁵⁵ Having a burgeoning science and technology sector, skilled workforce, and a democratic government, India presents a uniquely situated laboratory for advanced developing country patent systems.²⁵⁶ Current academic work on the role of intellectual property law in advanced developing economies stills focuses more on China than on India.²⁵⁷ India however falls similarly within the category of innovative NICs, and is therefore an MBP as well.

The Indian pharmaceutical industry developed in a context of weak patent protection with the Indian Patent Act of 1970 denying product patent coverage altogether for pharmaceutical products and severely limiting process patents.²⁵⁸ The

²⁵² *Id.* Members include other alliances of industry specific groups such as: the Association of American Publishers (AAP), the Business Software Alliance (BSA), the Entertainment Software Association (ESA), the Independent Film & Television Alliance (IFTA), the Motion Picture Association of America (MPAA), the National Music Publishers' Association (NMPA), and the Recording Industry Association of America (RIAA). See, IIPA Members, <http://www.iipa.com/memberassociations.html> (last visited Aug. 25, 2009).

²⁵³ Morel et al, 2005, p. 2; Mashelkar, 2005.

²⁵⁴ Yu, *supra* note 104, at 391, referring to Chindia: How China And India Are Revolutionizing Global Business (Pete Engardio ed., 2006) [hereinafter Chindia]; Jairam Ramesh, Making Sense of Chindia: Reflections On China And India (2006); see Shubham Chaudhuri & Martin Ravallion, Partially Awakened Giants: Uneven Growth in China and India, in *Dancing With Giants: China, India, And The Global Economy* 175 (L. Alan Winters & Shahid Yusuf Eds., 2007); Robyn Meredith, The Elephant and the Dragon: The Rise of India and China and What It Means for all of Us 126 (2007). As the Goldman Sachs study forecasted, “[i]n US dollar terms, China could overtake Germany in the next four years, Japan by 2015 and the US by 2039.” Dominic Wilson & Roopa Purushothaman, Dreaming with BRICs: The Path to 2050, Goldman Sachs, 99 Global Economics Paper 4 (2003), available at <http://www2.goldmansachs.com/ideas/brics/book/99-dreaming.pdf> (last visited Aug. 26, 2009). See, also Daniel C.K. Chow, Why China Does Not Take Commercial Piracy Seriously, 32 Ohio N.U. L. Rev. 203, 208 (2006) (“China's ambitions to eventually dominate trade in high-technology sectors.”); Chindia, *supra* note 252, at 4.

²⁵⁵ Nicholas D. Kristof, They're Rounding the First Turn! And the Favorite Is . . ., N.Y. Times, Jan. 17, 2006, at A19, at A27.

²⁵⁶ Janice M. Mueller, The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation 68 U. Pitt. L. Rev. 491, 503 (2007).

²⁵⁷ Yu, *supra* note 104, at 391; Angus Maddison, Historical Statistics for the World Economy: 1-2003 AD (2007), www.ggdc.net/maddison/Historical_Statistics/horizontal-file_03-2007.xls; Straus, *supra* note 10; Robert Slate, Judicial Copyright Enforcement in China: Shaping World Opinion on TRIPS Compliance, 31 N.C. J. Int'l L. & Com. Reg. 665 (2006); Jeffrey A. Andrews, Pfizer's Viagra Patent and the Promise of Patent Protection in China, 28 Loy. L.A. Int'l & Comp. L. Rev. 1 (2006); Ke Shao, Look at My Sign!-Trademarks in China from Antiquity to the Early Modern Times, 87 J. Pat. & Trademark Off. Soc'y 654 (2005); Yu, *supra* note 124.

²⁵⁸ Sampath, *supra* note 129, at 24 (noting that process patents were limited to a period of seven years, or five years from the date of sealing of the patent, whichever was shorter. Moreover, the provisions on “local working” and licensing of rights contained in the Indian Patent Act of 1970 limited the scope of process patents further by providing that any pharmaceutical process on which a local patent was obtained had to be “worked” in India within three years from the date of sealing of the patent. After three years of sealing, the patent owner was subject to the provision on “licensing of rights,” i.e., the patent owner was obliged to license his process to a local manufacturer in cases where the patent was not locally worked for a royalty not exceeding 4%. The government also had the authority to grant a compulsory license on a process after three years from the date of sealing of the patent if the product was not available locally at “reasonable” rates. The Drug Price Control Order was primarily responsible

Indian industry focused mainly on reverse engineering and the production of generics,²⁵⁹ while it spent little on R&D in comparison with firms in Western countries.²⁶⁰ The generics industry that flourished in India allowed the country to gain its current rank as fourth globally in terms of medicine production (8% of global output volume) and thirteenth in terms of value.²⁶¹ India also boasts the largest number of manufacturing facilities approved by the US Food and Drug Administration (FDA) anywhere outside of the United States.²⁶² With this increase in production, part of the Indian pharmaceutical industry started a slow but steady shift toward developing a capacity to innovate.²⁶³

Major strengths of the Indian pharmaceutical market power include the cost-competitive manufacturing base that extends to clinical studies, and extensive production skills in chemistry and process development. The market further entails the ability to manufacture over 50% of the bulk drugs needed for its pharmaceutical production activities locally, as well as the emergence of a promising biotechnology industry. India also is known for its plethora of local scientists and R&D personnel of high scientific quality and a wide network of R&D.²⁶⁴ While the R&D expenditures of large-scale Indian pharmaceutical firms (1.9% of total revenues) is still relatively low in comparison with those of global pharmaceutical industries, they have been steadily growing at the rate of 18% per year.²⁶⁵

India is also at the crossroads concerning its intellectual property policies for the biotechnology sector. For a start, it has ambitious plans for a biotechnology industry and for its agricultural industry, it presently having the third-highest number of biotech companies in the Asia-Pacific after Japan and Korea.²⁶⁶ Conversely, India witnesses an internal persistent disagreement to a strengthening of the patent system related to biotechnological inventions.²⁶⁷ At the same time as India is only slowly and unwillingly opening the door to allow for a greater role of patents related to biotechnological inventions, it has been positive in the development of fairly unique plant variety legislation in the form of its the Protection of Plant Varieties and Farmers' Rights Act of 2001 (PPVFRA).²⁶⁸ Lastly, within the software patent-sensitive industry, India further stands for an archetypical Tier-2 sanction costs fearful MBP. Recent data shows that India is losing from software piracy, due to what in fact are

for determining these rates, and when a compulsory license was granted, the royalty rate for such a license was to be set by the government in all cases where the process patent owner and the licensee could not agree upon a rate between themselves. The Act also provided that the burden of proof in cases of patent infringement rested on the patent owner).

²⁵⁹ V. C. Vivekanandan, Post-TRIPS: Emerging issues for Pharma Industry – Pharmexcil Technical Session, July 11, 2008, available at pharmexcil.com/data/uploads/Prof.Vivekanandan.ppt (noting that Indian pharmaceutical companies currently produce between 20-22% of the world's generic drugs in value terms).

²⁶⁰ Sampath, *supra* note 129, at 31.

²⁶¹ Mashelkar, *supra* note 182; Morel et al., *supra* note 182; Vivekanandan, *supra* note 257.

²⁶² Pradhan, Jaya Prakash, Overcoming Innovation Limits through Outward FDI: The Overseas Acquisition Strategy of Indian Pharmaceutical Firms, MPRA Paper 12362, University Library of Munich, Germany (2008), available at http://mpra.ub.uni-muenchen.de/12362/1/MPRA_paper_12362.pdf.

²⁶³ Mashelkar, *supra* note 182.

²⁶⁴ IBEF, India Brand Equity Foundation and Ernst and Young 2 (2004); and Cheri Grace, The Effect of Changing Intellectual Property on Pharmaceutical Industry Prospects in India and China: Considerations for Access to Medicines 18 [DFID-HSRC, 2004].

²⁶⁵ Sampath, *supra* note 129, at 31. See also Vivekanandan, *supra* note 257.

²⁶⁶ Christoph Antons, Sui Generis Protection for Plant Varieties and Traditional Agricultural Knowledge: The Example of India, 29 *European Intellectual Property Review* 480 (2007).

²⁶⁷ *Id.*

²⁶⁸ *Id.* at 482.

high Tier-2 sanction costs.²⁶⁹ In its 2005 Piracy Study, the Business Software Alliance (BSA) notes: “India, whose IT exports are more than triple the size of its domestic IT market, still has a piracy rate of 74 percent--despite the strength of its world-class software development skills and government efforts to quell piracy.”²⁷⁰ This reality, in fact, stands as a central inhibitor to the growth of a local Indian packaged software industry.

3. China

China is already the second largest producer of pharmaceutical and agricultural ingredients in the world.²⁷¹ It is the world's largest producer of active pharmaceutical ingredients,²⁷² although the vast majority of this production is unpatented. In fact, China is one of the world's leaders in the production of counterfeit pharmaceuticals.²⁷³ Given that MBP countries herein have also been referred to as 'innovative NICs,' the case of China requires further exploration. The characterization of China as an MBP is essentially based on the fact that it faces large Tier-2 sanctions costs for the issuance of compulsory licenses, and for two reasons. The first reason is that China is undergoing a somewhat uncertain, yet steady, process toward becoming an evermore innovative country.²⁷⁴ The days in which China only produced cheap products of low quality are rapidly being left in the past. To begin with, for the past three years China has also been the world's largest exporter of ICT.²⁷⁵ Consecutively, tensions have developed between China and the United States regarding trade and technological standards.²⁷⁶ One point of contention concerns, on the one hand, China's approach to standard setting, particularly for ICT goods, and on the other, the role of IP rights in international standard setting.²⁷⁷ While the ICT industry increasingly demands harmonized standards to serve the imperatives of competition, interoperability, and efficiency, particularly in networked environments, China has signaled its intention to follow a different direction.²⁷⁸ By seeking to set its own domestic standards instead of relying on international standards, China not only creates tensions but also raises trade law issues under WTO rules.²⁷⁹ Thirdly, there is China's innovative-based agriculture industry. This is due to the noticeable fact that the U.S. Department of Agriculture (USDA) and China's Ministry of Science and Technology (MOST) renewed a 2002 protocol that supports the United States policy to establish and expand science and technology exchanges with China to improve

²⁶⁹ See, e.g., Press Release, Bus. Software Alliance, New BSA Study Shows That India's Dynamic IT Sector Could Nearly Triple by 2009 (Dec. 8, 2005); BMC Software to Invest \$12 M in India, Cyber India Online Limited (May 20, 2005); Intel Plans \$1bn India Investment, BBC News (Dec. 5, 2005).

²⁷⁰ Bus. Software Alliance & Int'l Data Corp., Second Annual BSA and IDC Global Software Piracy Study 3 (2005).

²⁷¹ Cheri Grace, The Effect of Changing Intellectual Property on Pharmaceutical Industry Prospects in India and China: Considerations for Access to Medicine, Issues Paper, Health Systems Resource Centre, Department of International Development (June 2004) [for penicillin, vitamin C, terramycin, doxycycline and cephalosporin, China is the largest producer in the world].

²⁷² Yu, *supra* note 104, at 363.

²⁷³ See Maria Nelson et al., Counterfeit Pharmaceuticals: A Worldwide Problem, 96 Trademark Rep. 1068, 1089 (2006).

²⁷⁴ Xin Fang, From Imitation to Innovation: A Strategic Adjustment in China's S&T Development, NPC, China, Chinese Academy of Science.

²⁷⁵ Technology in Emerging Economies, The Economist (U.S. Edition) February 9, 2008.

²⁷⁶ Gibson, *supra* note 40.

²⁷⁷ *Id.*

²⁷⁸ *Id.*

²⁷⁹ *Id.*

market access for agricultural products.²⁸⁰ In sum, there is now clear evidence that research and development activities in the Chinese economy have been growing steadily over the past decade within these fields.²⁸¹

Lastly, in reference to this article's focal case in point, in pharmaceuticals, an increased number of patents being filed locally are evidence that the country is increasingly gearing its economy toward becoming increasingly innovative. To be sure, the overall annual research and development expenditures of Chinese pharmaceutical firms in 2002 were still relatively low, corresponding to only 1.18% of turnover. This number, however, should not obscure the broader trend showing that research and development investments in pharmaceuticals have increased five times in the period between 1995 and 2004.²⁸² In a patent-sensitive industry such as pharmaceuticals, the issuance of compulsory licenses would be expected to negatively impact such a trend.

Secondly, the perception about the levels of patent protection in pharmaceuticals crosses over to other industries. The decision to invest in research and development in any sector is partly based on the perception by the investor of the overall legal and institutional environment.²⁸³ The perceived level of protection in pharmaceuticals accordingly interplays with that of other industries, because the issuance of a compulsory license over a pharmaceutical product may negatively impact a decision to conduct research and development activities in other industries, particularly in other patent-sensitive industries. The Chinese pharmaceutical industry remains less innovative, and grows less speedily, than other patent-sensitive sectors of the Chinese industry such as semiconductors and biotechnology.²⁸⁴ Nevertheless, the issuance of a compulsory license in pharmaceuticals could not only further delay the development of the pharmaceutical sector, but also that of other sectors.

Clear evidence of this phenomenon can be observed in the example of the North China Pharmaceutical Group Corporation (NCPC), China's leading pharmaceutical exporter.²⁸⁵ Indeed NCPC has been increasing the number of its patent filings with China's State Intellectual Property Office (SIPO). However, even in the peak year 2005, its filing numbered less than 20.²⁸⁶ In view of that fact, China has adopted what Professor Peter Yu refers as a "schizophrenic" nationwide intellectual property policy. Accordingly, China seeks stronger intellectual property in areas such as entertainment, software, semiconductors, and selected areas of biotechnology, while striving for weaker protection in less dynamic fields such as pharmaceuticals,

²⁸⁰ The United States-China Government Signing Ceremony Fact Sheet 2 [December 11, 2007], at <http://beijing.usembassy-china.org.cn/121107jct3.html> (last visited Aug. 25, 2009). Specific areas of cooperation include agricultural biotechnology, natural resource management, dairy production and processing, food safety, agricultural product processing, biofuels research and development, and water-saving agricultural technology. *Id.*

²⁸¹ Gary H. Jefferson, R&D and Innovation in China: Has China Begun Its S&T Takeoff? Prepared for the Harvard China Review [2004]. Available at: <http://people.brandeis.edu/~jefferso/HCR,%20August%2011,%2004a.pdf> (last visited Aug. 25, 2009).

²⁸² Huaiwen He & Ping Zhang, Impact of the Intellectual Property System on Economic Growth, Country Report-China 7 [2007], available at http://www.wipo.int/about-ip/en/studies/pdf/wipo_unu_07_china.pdf.

²⁸³ See e.g. The 2007 A.T. Kearney Foreign Direct Investment Confidence Index, available at http://www.atkearney.com/images/global/pdf/FDICI_2007.pdf (last visited Aug. 25, 2009).

²⁸⁴ See Peter K. Yu, International Enclosure, the Regime Complex, and Intellectual Property Schizophrenia, 2007 Mich. St. L. Rev. 1, 25-26 (2007).

²⁸⁵ He & Zhang, *supra* note 280 at 9.

²⁸⁶ *Id.*

chemicals, fertilizers, seeds, and foodstuffs.²⁸⁷ This policy means that in the case of China, Tier-2 sanctions costs for issuance of compulsory licenses over pharmaceuticals cross over to other sectors of its economy.

D. The LBP Model: A Positional Bargaining Situation

1. Introduction

A third category of developing countries is defined herein as the Low Bargaining Power countries (LBPs). As a generalization, the LBP model maintains that every developing country other than NICs is an LBP (per Table 2 above, the ‘Default List Countries’). That category logically includes the group of Least Developed Countries (LDCs), which are the fifty poorest countries in the world, but includes many others as well, bringing the number of countries in the group of LBPs to over one hundred. Similarly to the above HBP and the MBP, the LBP categorization reflects a shift from the market size approximation into a conceptualization of a more complex bargaining situation. The LBP model indicates that the market size approximation fails to describe the true bargaining situation in the post-WTO era. Instead of defining developing countries along the lines of ‘market power’, the real narrative of TRIPS, instead, sets the stage for a novel developing country categorization.

The LBP model makes a dual claim. Firstly, it contends that the over a hundred countries in this group possess low bargaining power in terms of their ability to issue compulsory licenses. That is to say, that they have a low outside option in price negotiations with pharmaceutical patentees. Secondly, the LBP model suggests that the group of LBP countries also has low bargaining power in trade disputes more broadly. This second claim represents, in fact, a partial conceptual shift in comparison to the MPB and the HBP models above. The LBP model contains not only a specific analysis of the relative abilities of the countries within this category to issue compulsory licenses, but also a discussion of bargaining power in trade disputes more broadly. In fact, this second claim – namely that LBPs have low bargaining power more generally, not only in terms of their power to issue compulsory licenses – serves the purpose of illuminating the practical significance of the Least-Developed-Country (LDC) carve-out contained in the TRIPS and other WTO agreements. This analysis shows that the LDC carve-out is too narrow and does not cover a large enough group of countries. More generally, the LBP model will reveal that the distributive justice policies contained in TRIPS should be geared towards a broader group of countries.

In international trade, the usual assumption is that low levels of bargaining power are markedly the feature of LDCs. The United Nations officially designates the poorest fifty countries in the world as LDCs.²⁸⁸ There exist three basic macroeconomic parameters in the way in which LDCs are defined.²⁸⁹ These

²⁸⁷ See Yu, *supra* note 282.

²⁸⁸ World Trade Organization, Least-Developed Countries, http://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm (listing the thirty-two LDCs which are WTO members) (last visited Aug. 25, 2009) [hereinafter LDCs members of WTO]; UN Office of the High Representative for the Least Developed Countries, Landlocked Developing Countries and Small Island Developing States, <http://www.unohrls.org> [hereinafter UN Office of the High Representative for the LDCs].

²⁸⁹ In continuation, there are two market power-based ways to become eligible for graduation. First, a country’s GNI per capita must exceed at least twice the threshold level, and the likelihood that the level of GNI per capita is

parameters include: a low-income criterion;²⁹⁰ a human capital status criterion, involving a composite Human Assets Index (HAI);²⁹¹ and an economic vulnerability criterion entailing a composite Economic Vulnerability Index (EVI).²⁹² To be added to the list, a country must satisfy all three criteria. Since the definition of the LDC category recognizes the existence of structural handicaps, it excludes large economies. Thus, to be designated an LDC the country's population must not exceed 75 million.²⁹³ For being the poorest countries, WTO agreements and TRIPS in particular contain some corrective and distributive justice policies, despite being largely procedural in nature.

In fact, the post-WTO era, with its two-tiered bargaining situation, demands the creation of a novel category of countries to include both LDCs and the remaining non-NIC developing countries alike. All of these countries arguably have little or no bargaining power in negotiations over patented goods, such as drugs, and thus should be jointly modeled as Low-Bargaining-Power countries, or LBPs. As this part of the article explains, a lack of bargaining power is also what facilitates a distinct form of bargaining policy on the part of developed countries toward the group of LBPs, namely 'positional bargaining'. This form of bargaining is premised on a unilateral offer of stringent intellectual property laws as a package deal. In addition, as a policy concern, existing TRIPS laws favoring LDCs as the poorest countries conceivably represent a discrepancy vis-à-vis the remaining LBPs. This differential approach is clearly demonstrated within the 2005 Hong Kong declaration, which arguably discriminated against most LBPs such as countries in Central and South America, Lower Asia and poorer Eastern European countries.

2. Least Developed Countries and Beyond

Neither the Agreement Establishing the WTO nor the TRIPS Agreement formally categorize Least-Developed-Countries (LDCs),²⁹⁴ or for that matter any other particular group of developing countries. Instead, these agreements merely use declaratory language in indistinctive reference to LDCs' individual development,²⁹⁵ their financial and trade "needs,"²⁹⁶ or their administrative and institutional "capabilities."²⁹⁷ The WTO is further noteworthy for voluntary listing LDCs.²⁹⁸

sustainable must be deemed high. *Id.* Second, a country must reach threshold levels for graduation for at least two of the aforementioned three criteria *Id.*

²⁹⁰ This is based on a three-year average estimate of the GNI per capita (under \$745 for inclusion, above \$900 for graduation). See, LDCs members of WTO, *supra* note 286; UN Office of the High Representative for the LDCs, *supra* note 286.

²⁹¹ This is based on indicators of: (a) nutrition; (b) health; (c) education; and (d) adult literacy rate. *Id.*

²⁹² This is based on indicators of: (a) population size; (b) remoteness; (c) merchandise export concentration; (d) share of agriculture, forestry and fisheries in gross domestic product; (e) homelessness owing to natural disasters; (f) instability of agricultural production; and (g) instability of exports of goods and services. *Id.*

²⁹³ *Id.*

²⁹⁴ The world's forty nine poorest countries are currently designated as least developed countries (LDCs). See <http://www.unohrrls.org/en/ldc/related/62/> (last viewed Aug. 26, 2009).

²⁹⁵ See The World Trade Organization (WTO) agreement, Article XI(2).

²⁹⁶ *Id.*

²⁹⁷ See WTO, Understanding, *supra* note 7, Article XI(2).

²⁹⁸ See LDCs members of WTO (last visited Aug. 26, 2009). The countries falling under this definition are: Angola, Bangladesh, Benin, Burkina Faso, Burundi, Cambodia, Central African Republic, Chad, Democratic Republic of the Congo, Djibouti, Gambia, Guinea, Guinea Bissau, Haiti, Lesotho, Madagascar, Malawi, Maldives, Mali, Mauritania, Mozambique, Myanmar, Nepal, Niger, Rwanda, Senegal, Sierra Leone, Solomon Islands, Tanzania, Togo, Uganda, and Zambia.

From a customary public international legal viewpoint, the WTO's definitions of LDCs most likely did not establish customary law within international intellectual property law. As a political phenomenon, however, it should be noted that beginning in the early 1960s, LDCs did set up a forum in the United Nations from which to proclaim their views and, in doing so, further challenged the package deals offered by the developed countries. From 1962 through the mid-1970s, in particular, the United Nations General Assembly – dominated by LDCs – passed a series of resolutions intended to emphasize the sovereignty of nations with respect to foreign investment. Even though General Assembly resolutions do not represent authoritative statements of international law, they are probative of the state of international law.²⁹⁹ That is such, particularly given their ever-changing legal nature with reference to foreign investment.³⁰⁰

Present-day WTO agreements merely recognize that this loosely theorized group of poor countries – LDCs, must benefit from the greatest possible flexibility and leniency. Consequently, WTO agreements commonly uphold the position that better-off members must make extra efforts to lower import barriers on LDCs' exports. Since the end of the Uruguay Round agreements in 1994, several decisions in favor of LDCs have been taken. To begin with, in a meeting in Singapore in 1996, WTO ministers agreed on a "Plan of Action for Least-Developed Countries."³⁰¹ This included technical assistance to enable them to participate better in the multilateral system and a pledge from developed countries to improve market access for least-developed countries' products. Secondly, a year later, in October 1997, six international organizations – the International Monetary Fund, the International Trade Centre, the United Nations Conference for Trade and Development, the United Nations Development Program, the World Bank, and the WTO – launched the "Integrated Framework," a joint technical assistance program designed exclusively for least-developed countries.³⁰² Thirdly, in 2002, the WTO further adopted a work program for least-developed countries. Again under the post-WTO market size approximation, the work program contained several broad policies that erroneously chose to focus solely on LDCs. Logically, these policies ranged from improved market access to increased technical assistance, such as providing support for agencies working on the diversification of least-developed countries' economies or a speedier membership process for LDCs negotiating to join the WTO.³⁰³

More particularly, using similarly broad declaratory language, the TRIPS Agreement employs a general rule for all developing countries. All Member States are held to the same international minimum standards of protection and enforcement.³⁰⁴ TRIPS does offer some form of equitable action toward LDCs alone,

²⁹⁹ See, e.g., *Texaco Overseas Petroleum Co. v. Libyan Arab Republic*, 17 I.L.M. 1, 30 [1978] ["Resolution 1803 (XVII) seems to this Tribunal to reflect the state of customary law existing in this field."]; see also Committee on Int'l trade and Investment of the ABA Section of International and Comparative Law, *The Protection of Private Property Invested Abroad* 18 n.57 (1963).

³⁰⁰ See, e.g., Andrew T. Guzman, *Why LDCs Sign Treaties that Hurt Them: Explaining the Popularity of Bilateral Investment Treaties*, 38 Va. J. Int'l L. 639, 648 (1998).

³⁰¹ Understanding the WTO: Developing Countries, available at http://www.wto.org/english/thewto_e/whatis_e/tif_e/dev4_e.htm (last visited Aug. 25, 2009).

³⁰² *Id.*

³⁰³ Meanwhile, however, a growing number of governments have unilaterally abandoned import duties and import quotas on all exports from LDCs. *Id.*

³⁰⁴ WTO, Understanding, *supra* note 7, Art. 1.

but it does so arguably unequally toward other LDPs, such as in Central and South America, Lower Asia and poorer Eastern European countries.

Thus, TRIPS favors LDCs, albeit procedurally, on three accounts. First, it allows both developing countries and what it defines as 'countries-in-transition'³⁰⁵ (referring mainly to former Soviet Bloc countries which were closed to FDI until approximately 1990) a five-year grace period within which to fulfill their obligations.³⁰⁶ The TRIPS Agreement recognizes technical adjustments that may further delay full compliance with the patent provisions for another five years.³⁰⁷ As for LDCs alone, however, TRIPS stipulates a ten-year period of immunity from the duty to implement its substantive or procedural standards.

Second, TRIPS endows its Council with the power to “accord extensions” of the initial ten-year grace period, upon a “duly motivated” request by an LDC member. In doing so, the agreement recognizes their “special needs and requirements” but only in a broad sense.³⁰⁸ LDCs continue to compete over intellectual property-based foreign trade in even terms with countries with much higher gross national products (GNP), especially the NICs.³⁰⁹ Third, developing countries were flatly labeled in reference to the topic of technological transfer, with a suggestive mode of differentiation vis-à-vis LDCs. The drafters of Article 66 of TRIPS described the “special needs and requirements” of these countries identically.³¹⁰ Preceding drafts of Article 66 and 67 do not point toward any major changes during the drafting stages, suggesting that LDCs were for all time granted a number of exemptions in adhering to TRIPS.³¹¹

This kind of affirmative action toward LDCs seems to have given rise to a misguided perception of the kind of bargaining that involves developing countries and the pharmaceutical industry. On the one hand, bargaining with the group of non-LDC developing countries is thought to generate ‘integrative bargains.’ The notion of integrative bargains refers to the potential for the parties' interests to be combined in ways that create joint value or 'enlarge the pie.'³¹² Potential for integration only exists when there are multiple issues involved in the negotiation.³¹³ Integrative bargains also assume the presence of some bargaining power.³¹⁴ Thus, international patent negotiations are viewed as exchanges between traditional manufactured goods and

³⁰⁵ Transition economies within TRIPS Article 65(3) are countries in Central and Eastern Europe that formed part of the former Soviet bloc. Article 65(3) of the TRIPS Agreement refers to them as “member[s] which [are] in the process of transformation from a centrally-planned [economy] into a market, free-enterprise economy and which [are] undertaking structural reform of [their] intellectual property systems” TRIPS, *Id.*

³⁰⁶ WTO, Understanding, *supra* note 7, Art 65.

³⁰⁷ WTO, Understanding, *supra* note 7, Art. 70(8), (9).

³⁰⁸ WTO, Understanding, *supra* note 7, Art 66(1). Professor Reichman argues that even TRIPS' general language suffices to de facto recognize the category of LDCs within TRIPS. See J.H. Reichman, Compliance with the TRIPS Agreement: Introduction to a Scholarly Debate, 29 Vand. J. Transnat'l L. 363, 373 (1996).

³⁰⁹ See Simon Lester, The Asian Newly Industrialized Countries to Graduate From Europe's GSP Tariffs, 36 Harv. Int'l L.J. 220 (1995).

³¹⁰ TRIPS Art. 66 (1).

³¹¹ Gervais, *supra* note 20, sec. 2.247.

³¹² David A. Lax and James K. Sebenius, "Interests: The Measure of Negotiation." In Negotiation Theory and Practice, eds. J. William Breslin and Jeffrey Z. Rubin, (Cambridge: The Program on Negotiation at Harvard Law School, 1991), 165.

³¹³ *Id.*

³¹⁴ See, Jonathan Sacks, The Politics of Hope, London, Vintage, 2000 (Revised edition), Chapter 17, “The Common Good”, pp. 198-209 (1997); Axelrod, Robert, The Evolution of Cooperation. NY: Basic Books (1984) pp. 3-24; 73-105.

agricultural products for codified obligations to respect intellectual property rights.³¹⁵ This paradigm has in fact represented the common political science narrative of WTO bargaining at large. On the other hand, for LDCs a more benevolent form of ‘Positional Bargains’ – a “take it or leave it” kind of agreement – is said to be in place.³¹⁶

3. Positional Bargaining over TRIPS

In reality, the developed world adopted what is known as positional bargaining in negotiating the international intellectual property framework with the group of LBP countries. In bargaining theory, positional bargaining is a negotiation strategy that involves holding on to a fixed idea, or position, of what one wants and advocating for it and it alone, regardless of the underlying interests.³¹⁷ Each negotiator begins with an extreme position and proceeds from there to negotiate and make concessions. Eventually, a compromise may be reached on dividing the bargain surplus. The WTO’s Uruguay Round of multilateral trade negotiations succeeded where prior WIPO’s negotiations independent of the international economic framework failed, particularly regarding developing countries.³¹⁸ That success can be explained in that TRIPS was presented as an economic package deal, or what Professor Donald Harris analogizes with a treaty,³¹⁹ or contract,³²⁰ of adhesion. Such a dynamic has in fact described the bargaining situation with most non-LDCs developing countries, such as in Central and South America, lower Asia and poorer Eastern European countries. And LBPs, at large, could not and did not resist this positional bargaining game.³²¹

The Uruguay Round and the TRIPS’ bargaining game in particular remarkably and similarly ‘offered’ LDCs, as well as non-LDC LBPs, greater access to markets for traditionally manufactured goods and agricultural products. This offer has come in exchange for stiff codified obligations to respect the intellectual property rights of the technology-exporting countries.³²² That being said, the United States has been pushing since the 1994 Summit of the Americas in Miami for a hemisphere-wide free trade zone and asking that developing countries, largely LBPs, in Central and South America eliminate their own barriers, while being able to maintain its own protectionist measures.³²³ Frederick Abbott lists the Uruguay Round bargaining chips employed as including: the reduction of subsidies for agriculture in industrialized nations,³²⁴ concessions with respect to imports of tropical products,³²⁵ the phasing out

³¹⁵ See e.g. Abbott, *supra* note 159, at 389; See Reichman & Lange, *supra* note 146, at 17.

³¹⁶ Roger Fisher & William Ury, *Getting to Yes: Negotiating Agreement Without Giving In* 5 (1981).

³¹⁷ *Id.*

³¹⁸ See, e.g., Ruth L. Gana, *The Myth of Development, the Progress of Rights: Human Rights to Intellectual Property and Development*, 18 *Law & Pol’y* 315, 334 (1996); Donald P. Harris, *Carrying a Good Joke Too Far: TRIPS and Treaties of Adhesion*, 27 *U. Pa. J. Int’l Econ. L.* 681, 724-38 (2006).

³¹⁹ Harris, *supra* note 316.

³²⁰ *Id.*

³²¹ See generally, Helfer, *supra* note 118, at 2-3 (2004); Abbott, *supra* note 159, at 387-88; Abbot, *supra* note 178.

³²² Reichman & Lange, *supra* note 146, at 17.

³²³ Ormachea, *supra* note 215, at 139.

³²⁴ See generally Abbott, *supra* note 159, at 387-88; and Abbot, *supra* note 178.

³²⁵ *Id.*

of quotas of textile products,³²⁶ substantial transition periods,³²⁷ incentives to transfer technology and compulsory licensing.³²⁸

Positional bargaining is not only practiced vis-à-vis LDCs. It is also the systematic practice used by the developed world in negotiations with non-LDC LBPs. As already alluded to, the products derived from plant genetic biodiversity, to mention a chief intellectual property case for LBPs, are major sources of wealth generation for developed countries.³²⁹ The International Union for the Protection of New Varieties of Plants (UPOV) establishes the plant variety protection (PVP) framework known as the Plant Breeders' Rights (PBRs) regime for UPOV member states.³³⁰ Originally established by leading developed countries with a head start in plant breeding and agricultural biotechnology, PVP is pivotal to food security in indigenous and local communities.³³¹ UPOV's legalization of private ownership of and proprietary interest in plant varieties stands for a major transition into the commercialization based on MNEs investment in R&D in developed countries within bio-agriculture and plant genetics.³³²

Thus, LBPs in which most of the plant genetics are housed only collect the rents from the consumption plant genetic resources.³³³ While developed countries are critical about LBPs for their destruction of biodiversity, they are also the principal cause for the international regime in which this destruction is the most attractive economic option available to LBPs.³³⁴

Bilateral agreements over agriculture in LBPs, more widely, run into problems with the United States' indisposition to lower agriculture protection. Concerns have been raised about impoverished corn farmers in non-LDC LBPs such as in Mexico and rice farmers in Honduras and Haiti being driven to other employment because of America's subsidized products.³³⁵ Rationally, an increase in imports unconstructively impacts domestic production. Although reducing or eliminating agriculture protections is particularly imperative for rural Latin American LBPs, the United States has shown little flexibility on the matter.³³⁶

³²⁶ *Id.*

³²⁷ *Id.*

³²⁸ *Id.*

³²⁹ Chetan Gulati, The "Tragedy of The Commons" In Plant Genetic Resources: The Need for a New International Regime Centered around an International Biotechnology Patent Office, 4 Yale Hum. Rts. & Dev. L.J. 63, 63-65 (2001).

³³¹ See Bongo Adi, Intellectual Property Rights in Biotechnology and the Fate of Poor Farmers' Agriculture, 9 J. World Intell. Prop. 91, 104-107 (2006); for research projects within the field, see, also, Ryerson University - Centre for Studies in Food Security, Indigenous Peoples & Food Security, at <http://www.ryerson.ca/foodsecurity/projects/indigenous/index.html>.

³³¹ See Bongo Adi, Intellectual Property Rights in Biotechnology and the Fate of Poor Farmers' Agriculture, 9 J. World Intell. Prop. 91, 104-107 (2006); for research projects within the field, see, also, Ryerson University - Centre for Studies in Food Security, Indigenous Peoples & Food Security, at <http://www.ryerson.ca/foodsecurity/projects/indigenous/index.html>.

³³² See, Chidi Oguamanam, Genetic Use Restriction (or Terminator) Technologies (GURTS) in Agricultural Biotechnology: The Limits of Technological Alternatives to Intellectual Property, 4 Can. J.L. & Tech. 59, 60 (2005), at 61-62; Tracking results in agriculture and rural development in less-than-ideal conditions. A sourcebook of indicators for monitoring and evaluation, in: <http://www.fao.org/docrep/011/i0380e/i0380e00.htm> (last visited Aug. 25, 2009).

³³³ *Id.*

³³⁴ *Id.*

³³⁵ Ormachea, *supra* note 215, at 150.

³³⁶ *Id.*

Argentina, Kazakhstan, and Pakistan, three secondary regional powers, them being non-LDCs LBPs, illustrate this proposition well. First, Argentina's lack of adequate and effective intellectual property protection has caused some friction in its bilateral trade relationship with the United States. In fact, Argentina has been on the Special 301 Priority Watch List since 1996.³³⁷ In April 2002, negotiations between the governments of the United States and Argentina clarified aspects of Argentina's intellectual property system, such as provisions related to the patentability of microorganisms and its import restriction regime.³³⁸ Yet Argentina's amendment of its patent law in December 2003, as required by the May 2002 agreement between the two governments, still did not lead to its removal from the Special 301 Priority Watch List.³³⁹ What may explain Argentina's LBP-like bargaining situation is its close alignment with the United States in the area of agricultural biotechnology, including as co-complainants in a WTO dispute challenging the EU moratorium on transgenic crops and its implementation of the Cartagena Protocol of Biosafety.³⁴⁰

A second case of a non-LDC LBP with which positional bargaining is practiced is Kazakhstan. The government's effort to diversify the economy away from the energy sector and spur the growth of a domestic technology-based industry, along with the WTO accession process, has led to a strong emphasis on intellectual property rights protection. Kazakhstan, however, has been unsuccessful in achieving bilateral trade agreements with a number of developed countries, including the United States, the European Union and Australia.³⁴¹ Not surprisingly, it being also a non-LDC LBP, and also a TRIPS transitory country, for the last thirteen years, since January 29, 1996, Kazakhstan has been unsuccessful in negotiating membership in the WTO.³⁴²

A third case exemplifying positional bargaining negotiations with a non-LDC LBP is Pakistan. The U.S. Government placed Pakistan on the Special 301 Watch List from 1989 to 2003 due to widespread piracy, and continuing IPR violations prompted the U.S. to place Pakistan on the Special 301 Priority Watch List in both 2004 and 2005.³⁴³ These Tier-1 sanction costs were left in place even after a twofold Pax-American intellectual property reform. Firstly, Pakistan enacted a patent law in the year 2000 that protects both process patents and product patents in accordance with its WTO obligations.³⁴⁴ Secondly, after August 2005, the U.S. noticeably led threats of sanction against Pakistan. These threats were posed in response to Pakistan's lack of a central intellectual property rights regulatory and enforcement authority, as well as Pakistan's failure to implement its obligations under TRIPS. In fear of these threats, Pakistan's president created the Intellectual Property Organization of Pakistan, an independent body under the administrative power of the Government's Cabinet

³³⁷ See, National Trade Estimate Report on Foreign Trade Barriers (Herein, NTE) – Argentina, which is the twenty-first in an annual series that surveys significant foreign barriers to U.S. exports. See, http://www.ustr.gov/Document_Library/Reports_Publications/2007/2007_NTE_Report/Section_Index.html (last visited Aug. 25. 2009).

³³⁸ *Id.*

³³⁹ *Id.*

³⁴⁰ *Id.*

³⁴¹ *Id.*

³⁴² *Id.*, NTE – Kazakhstan.

³⁴³ *Id.*, NTE – Pakistan. In April 2006, in recognition of Pakistan's efforts, USTR lowered Pakistan from the Special 301 Priority Watch List to the Watch List. *Id.*

³⁴⁴ *Id.*

Division, which consolidates into one body the authority over trademarks, patents, and copyrights – areas that were until that time handled by three separate ministries.³⁴⁵

To conclude, the effectiveness of the TRIPS positional bargaining situation vis-à-vis LBP may be understood twofold. Firstly, this positional bargaining situation allowed LBPs to have greater access global markets.³⁴⁶ Secondly, through the package/collective signing of TRIPS, LBPs presumably avoided unilateral actions by developed countries.³⁴⁷ Oftentimes, in theory as in practice, compromises do not satisfy the true interests of the disputants;³⁴⁸ instead, they simply split the difference between two positions, giving each side a part of what was sought. Creative, integrative solutions, on the other hand, hold the potential to provide everyone with all of what they desire.³⁴⁹ Positional bargaining is thought to be practiced only vis-à-vis LDCs in the post-WTO era. In reality, however, this strict bargaining approach is widely practiced with a much larger group of developing countries, namely the non-LDCs LBPs.

In international patent bargaining, arguably, a much larger group of developing countries – namely non-LDC LBPs – should be regarded as possessing low bargaining power over intellectual property-based technologies such as drugs or plant genetics. In light of that perspective, the distinction between LDCs/non-LDCs developing countries must be qualified as obsolete insofar as bargaining over patents is concerned. In bargaining terms, there is little room to argue that LDCs hold weaker bargaining power than other poor non-LDC LBPs, such as South American, lower Asian or even some of the poorest Eastern European countries. This proposition can be illustrated by the three elements of bargaining power, namely market power, outside option, and inside options, as follows.

a) Outside Option

The first explanation for LBPs' low bargaining power relates to their low outside option value.³⁵⁰ In theory, the issuance of a compulsory license could serve as an outside option at the Tier-2 bargain level, when bargaining with the industry and MNEs in particular. It is the case, however, that within the post-TRIPS regime, LBPs' Tier-2 outside option value is particularly limited. This reality is the result of two main factors, deriving from LBPs' short-run and long-run low payoffs for the issuance of compulsory licenses.

To begin with, as a short-run, or static efficiency concern, LBPs may see low payoffs in pursuing their outside option of purchasing generic drugs from HBP, such as India or China. As India and China move to adopt a TRIPS-compliant patent regime, LBPs increasingly face difficulties in conducting parallel imports of drugs from

³⁴⁵ *Id.*

³⁴⁶ Arie Reich, *The WTO As a Law-Harmonizing Institution*, 25 U. Pa. J. Int'l Econ. L. 321, 362 (2004), referring also to Gregory Shaffer, *Power and Global Governance: The Need for A Comparative Institutional Approach*, in *Power And Global Governance* 8 (Michael Barnett & Bud Duvall eds., 2004).

³⁴⁷ See, e.g., Correa, *supra* note 27.

³⁴⁸ Reichman & Lange, *supra* note 146, at 17 (The main premise underlying TRIPS' positional bargaining reflects the interests of high-tech producers on the short-term expense of technology-importers). Such is the case with most if not all LBPs.

³⁴⁹ Fisher & Ury, *supra* note 314.

³⁵⁰ Muthoo, *Bargaining Theory*, *supra* note 93, at 99-100; Abhinay Muthoo, *On the Strategic Role of Outside Options in Bilateral Bargaining Operations Research*, Vol. 43, No. 2 (Mar. - Apr., 1995), pp. 292-297.

generics producers. The TRIPS Agreement sets forth detailed rules that are to be followed by a WTO member nation willing to issue a compulsory license.³⁵¹ It outlines the prerequisites of patentability and the circumstances under which a nation can issue such a license. The TRIPS Agreement, as explained above, does not speak specifically to the issue of compulsory licensing between member nations.³⁵² This point is crucial for LBPs with no generics manufacturing capacity of their own, which primarily rely on the infrastructure of MBPs – India and China – or of developed countries to get hold of essential medicines.

In response to this set of concerns, at a WTO meeting in 2001, held in Doha, Qatar, the WTO adopted a Declaration on TRIPS and Public Health.³⁵³ Government officials have interpreted Paragraph 6 of the declaration to constitute an exception to the TRIPS Agreement, whereby a country that does not have the capacity to produce its own generic drugs in the face of a public health crisis may obtain the necessary drugs from a country that does have such capacity.³⁵⁴ By early 2005, the leading supplier of low-cost generic AIDS medicine was India.³⁵⁵ As India attempted to attain TRIPS-compliance, many health agencies stressed that the days of low-cost treatments for millions of poor patients around the world were ending.³⁵⁶ At the close of 2004, it appeared that the Indian government was drafting legislation that would extend beyond the basic TRIPS requirements and consequently endanger access to medicines for many poor patients – including by eliminating opportunities for compulsory licensing for LBPs.³⁵⁷ Numerous NGOs and health officials around the world urged the Indian government, in this leading case, not to disregard the Doha meeting interpretation of TRIPS.³⁵⁸ India ultimately adopted TRIPS-compliant legislation that to a large extent preserves its ability to furnish generics to developing countries.

A second explanation for LBPs' low outside option payoffs derives from their absent long-run innovation-based industries. There is increasing evidence that the weight of R&D on productivity depends heavily on size of the economy.³⁵⁹ This dynamic

³⁵¹ See TRIPS Agreement, Annex 1C, Art. 8(1).

³⁵² *Id.*

³⁵³ For text of the Doha Declaration on the TRIPS Agreement and Public Health see World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN (01)/DEC/2, 41 I.L.M. 746 [2002], available at www.wto.org/english/thewto_e/minist_e/minol_e/mindecl_trips_e.htm [hereinafter the Doha Declaration].

³⁵⁴ *Id.* In Doha, the WTO Ministerial Declaration on the TRIPS Agreement and Public Health stated that "the TRIPS 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." *Id.*

³⁵⁵ Editorial, AIDS Drugs Threatened, N.Y. TIMES, Mar. 5, 2005, at A1.

³⁵⁶ Press Release, Médecins sans Frontières, The Beginning of the End of Affordable Generics (Mar. 22, 2005), available at www.cptech.org/ip/health/c/indiaingos03222005.html.

³⁵⁷ Letter from Jim Yong Kim, HIV/AIDS Director of the World Health Organization, to Dr. A. Ramadoss, Minister of Health and Family Welfare of India (Dec. 17, 2004), available at www.cptech.org/ip/health/c/india/who12172004.html (last visited Aug. 25, 2009).

³⁵⁸ Letter from U.N. Special Envoys for HIV/AIDS to the Prime Minister and President of India on the Amendments to the Patents Act Under Debate (Mar. 11, 2005), www.cptech.org/ip/health/c/india/unaid03112005.html; Letter from Achmat Dangor, Director of Advocacy, Communication and Leadership for UNAIDS, to Kamal Nath, Minister of Commerce and Industry of India (Feb. 23, 2005), www.cptech.org/ip/health/c/india/unaid02232005.html (last visited Aug. 25, 2009).

³⁵⁹ IMF report on innovation and growth in developing countries (2004) - <http://imf.org/external/pubs/ft/wp/2004/wp04185.pdf> (last visited Aug. 25, 2009) (while innovation has a positive effect on per capita output everywhere, market size is an important factor in determining the effectiveness of R&D sectors; accordingly, only larger market OECD countries are able to increase their innovation by investing in R&D, and smaller OECD countries promote innovation by using the know-how of other OECD countries).

tends to hinder small-economy countries from overcoming their structural underdevelopment through a strategy of investing in R&D.³⁶⁰ Currently, LBPs and notably Sub-Saharan Africa have access to crucial ARV drugs because most of the ARVs produced in India and other developing countries are off-patent.³⁶¹ Since HIV/AIDS constantly mutates, scientists must continuously develop new treatments, based on future innovation.³⁶² While barriers exist in the creation of effective ARVs for specific Sub-Saharan African where there is rampant HIV/AIDS, the concern about the Indian Patents Act and other TRIPS-related laws is also related to a long-run payoff. These concerns derive from the need for new innovative technology and the possibility that HBPs like India will innovate and produce new technology to be used by patients in LBPs.³⁶³ Furthermore, this long-run concern is relevant primarily to ‘neglected diseases,’ or diseases of the developing world, and particularly LBPs outside LDCs, such as malaria or tuberculosis. Besides HIV/AIDS, these neglected diseases have been virtually eliminated from the innovation agenda in HBPs and developed countries alike.³⁶⁴ Yet they are still rampant in LBPs in Lower Asia, Central and South America and even poorer parts of Eastern Europe.³⁶⁵ As of today, it seems that the new Indian law would greatly hinder the ability of Indian firms to sustain an on-going innovative policy regarding low-cost medicines for LBPs’ neglected diseases.

b) Inside Option

The second explanation for LBPs' low bargaining power in trade negotiations relates to the latter's low value inside options.³⁶⁶ TRIPS ignores the small differences in bargaining power over compulsory licenses between LDCs and non-LDC LBPs, and it does so while undermining the latter's inside option cost structure. The present reasoning does not eliminate the production costs or the problems associated with distribution and the timely administration of medicines within this group of non-LDC LBPs.³⁶⁷ However, this argument implies low inside option cost considerations for most or all LBPs, on three grounds.

³⁶⁰ *Id.*

³⁶¹ See Kernel Nath's Statement on the Ordinance Relating to Patents (Third) Amendment, Press Info. Bureau, India [Dec. 29, 2004], pib.nic.in/release/release.asp?relid=6074 & lists.essential.org/pipermail/ip-health/2004-December/007318.html (last visited Aug. 25, 2009) (currently, 97% of all drugs manufactured in India are off-patent.).

³⁶² WHO Report on Global Surveillance of Epidemic-prone Infectious Diseases - Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (HIV/AIDS), World Health Organization, 2000, available at http://www.who.int/csr/resources/CSR_ISR_2000_1hiv/en (last visited Aug. 25, 2009).

³⁶³ See, Randeep Ramesh, Cheap AIDS Drugs Under Threat, *Guardian*, United Kingdom (Mar. 23, 2005), www.guardian.co.uk/world/2005/mar/23/india.aids1 (last visited Aug. 25, 2009) (quoting Ellen't Hoen: "But without the Indian drugs industry, where will they get cheap drugs from?").

³⁶⁴ See, e.g., Letter from U.N. Special Envoys for HIV/AIDS to the Prime Minister and President of India on the Amendments to the Patents Act Under Debate (Mar. 11, 2005), www.cptech.org/ip/health/c/india/unaid03112005.html; see Trade Organization, Intellectual Property: Protection And Enforcement, www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm (last visited Aug. 25, 2009); Randeep Ramesh, Cheap AIDS Drugs Under Threat, *GUARDIAN* (U.K.), Mar. 23, 2005, www.guardian.co.uk/world/2005/mar/23/india.aids1 (last visited Aug. 25, 2009).

³⁶⁵ *Id.*

³⁶⁶ See, e.g., Muthoo, Bargaining Theory, *supra* note 93, at 137-138.

³⁶⁷ See, e.g., Amir Attaran & Lee Gillespie-White, Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?, 286 *J. Am. Med. Ass'n.* 1886, 1886-1906 (2001); Srividhya Ragavan, The Jekyll and Hyde Story of International Trade: The Supreme Court in *PhRMA v. Walsh* and the TRIPS Agreement, 38 *U. Rich. L. Rev.* 777 (2004).

Firstly, the Tier-1 inter-governmental bargain level entails a disturbing institutional constraint within TRIPS, again discriminating against non-LDC LBPs by law. For a start, on December 6, 2005, shortly before the WTO Ministerial Conference in Hong Kong, WTO member states agreed to accept a protocol amendment to TRIPS.³⁶⁸ This amendment sought to provide a permanent solution to implement paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.³⁶⁹ If ratified, the new article 31bis of the TRIPS Agreement will allow countries with insufficient or no manufacturing capacity to import generic versions of on-patent pharmaceuticals.³⁷⁰

The Enabling Clause at the Hong Kong Declaration is based on what is officially called the “Decision on Differential and More Favorable Treatment, Reciprocity and Fuller Participation of Developing Countries,” which was adopted under GATT in 1979. It enables developed members to grant special and more favorable treatment to some developing countries. The Enabling Clause represents the WTO's legal basis for the Generalized System of Preferences (GSP). Under the GSP, developed countries offer non-reciprocal preferential treatment (such as zero or low duties on imports) to products originating in developing countries. Preference-giving countries unilaterally determine which countries and which products are included in their schemes. Within the Hong Kong Declaration vis-à-vis patent-sensitive industries in developing countries, this Enabling Clause should be thought to be a classic post-WTO legal basis for regional arrangements among developing countries and for the Global System of Trade Preferences (GSTP). Under such a scheme, a number of developing countries would exchange trade concessions among themselves.

This post-WTO policy of favoritism toward developing countries, however, has not been equally applied towards non-LDCs regional LBPs organizations, as within Asia, the Caribbean, or South America. In particular, these include the Southern Common Market in Latin America (MERCOSUR),³⁷¹ the Common Market for Eastern and Southern Africa (COMESA),³⁷² and the ASEAN Free Trade Area (AFTA).³⁷³

Thus, to facilitate the supply of essential medicines to countries with insufficient or no manufacturing capacity, as is the case of most LBPs, article 31bis(3) creates a

³⁶⁸ See General Council, Amendment of the TRIPS Agreement, WT/L/641 [Dec. 8, 2005], available at www.wto.org/english/tratop_e/trips_e/wt1641_e.htm [hereinafter TRIPs Amendment]; and TRIPs Agreement.

³⁶⁹ See World Trade Organization [WTO], Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002).

³⁷⁰ Although the initial deadline for ratification was December 1, 2007, the deadline was recently extended for another two years. William New, TRIPS Council Extends Health Amendment; Targets Poor Nations' Needs, INTELL. PROP. WATCH, Oct. 23, 2007, www.ip-watch.org/weblog/index.php?p=798 (last visited Aug. 25, 2009). As of this writing, slightly over a quarter of the 151 WTO member states, including the United States, India, Japan, China, and most recently members of the European Communities, have ratified the proposed amendment. Press Release, WTO, Countries Accepting Amendment of the TRIPS Agreement [Aug. 2, 2007], www.wto.org/english/tratop_e/trips_e/amendment_e.htm (last visited Aug. 25, 2009).

³⁷¹ MERCOSUR is a Regional Trade Agreement (RTA) between Argentina, Brazil, Paraguay and Uruguay founded in 1991 by the Treaty of Asunción. This treaty was later amended and updated by the 1994 Treaty of Ouro Preto. Its aim is to promote free trade and the fluid movement of goods, people, and currency. See MERCOSUR's home page at: www.mercosur.org.uy (last visited Aug. 25, 2009).

³⁷² The Common Market for Eastern and Southern Africa is a preferential trading area with nineteen member states stretching from Libya to Zimbabwe. See, COMESA's home page at: <http://www.comesa.int> (last visited Aug. 25, 2009).

³⁷³ ASEAN Free Trade Area (AFTA) is a trade bloc agreement by the Association of Southeast Asian Nations supporting local manufacturing in all ASEAN countries. AFTA is composed of the ten countries of ASEAN. See, e.g., John S. Wilson & Benjamin Taylor, Deeper Integration in ASEAN: Why Transport and Technology Matter for Trade," Trade Facilitation Reform Issue Brief, The World Bank. 2008.

special arrangement for both the affected countries, and also those countries belonging to a regional trade agreement. It did so, however, with implied reference only to the African agreement.³⁷⁴ Such an arrangement could have allowed the large group of LBPs³⁷⁵ to aggregate their markets to generate the purchasing power needed to render the development of an indigenous generics pharmaceutical industry attractive.³⁷⁶ It also could have paved the way for the development of regional supply centers,³⁷⁷ procurement systems,³⁷⁸ and patent pools and institutions, while facilitating technical cooperation within the region.³⁷⁹

Unfortunately, because article 31bis specifically requires that Least Developed Countries make up at least half of the membership of any beneficiary regional trade agreement, the provision would benefit only a limited number of developing countries, predominantly those in Sub-Saharan Africa.³⁸⁰ By referring solely to the LDCs classification, the other LBPs countries, such as within Asia, the Caribbean, or South America are once again ignored.

An important example of non-LDC LBPs is presented through the Andean Pact countries, referring to five South American developing countries, namely Venezuela, Ecuador, Peru, Colombia and Bolivia, as well as three other Latin American countries, namely Chile, Mexico,³⁸¹ and Cuba.³⁸² Like LDCs, these developing countries often have made a call for solidarity against the efforts by the developed world and the United States to press Andean Pact governments into enacting further amendments to protect intellectual property rights in Latin America.³⁸³ These non-LDCs countries, labeled herein as LBPs, have similarly implemented changes to their patent laws as a result of pressure from the United States.³⁸⁴

To be sure, foreign trade laws in contexts other than TRIPS' often waive and grant various regional national organizations affirmative action-tailored policies, as

³⁷⁴ TRIPs Amendment, art. 31bis(3).

³⁷⁵ The TRIPs Agreement distinguishes between developing and least developed countries. This Article uses "less developed countries" to denote both developing and least developed countries. When referring to the TRIPs Agreement, however, this Article returns to the terms "developing countries" and "least developed countries."

³⁷⁶ Yu, *supra* note 238, at 848.

³⁷⁷ See Frederick M. Abbott & Jerome H. Reichman, *The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPs Provisions*, 10 *J. Int'l Econ. L.* 921, 973-77 (2007) (discussing the potential benefits of pooled procurement strategies and the establishment of regional pharmaceutical supply centers).

³⁷⁸ See Sisule F. Musungu et al., *Utilizing TRIPs Flexibilities for Public Health Protection Through South-South Regional Framework*, xv-xvi (2004), www.southcentre.org/index2.php?option=com_docman&task=doc_view&gid=9&Itemid=68 (last visited Aug. 25, 2009) (advocating the establishment of "regional procurement systems where they would jointly conduct tendering through an entity acting on their behalf and a central purchasing agency managing the purchases on behalf of all the member countries"); see also *id.* at 70-73 (discussing regional procurement systems).

³⁷⁹ See TRIPs Amendment, art. 31bis annex P 5.

³⁸⁰ See *id.* art. 31bis(3) (requiring that "at least half of the current membership of [the regional trade agreement] is made up of countries presently on the United Nations list of least developed countries").

³⁸¹ Mexico, however, is certainly bound by the North American Free Trade Agreement (NAFTA). See, *North American Free Trade Agreement*, Dec. 17, 1992, 32 *I.L.M.* 289, 670 (1993). Under such agreement, Mexico specifically undertook to protect IPRs under the stringent standards defined in chapter 17 of the agreement.

³⁸² See, e.g., *Cuba backs Brazil in AIDS drug patent row*, [March 12, 2001] *Marketletter Publications Ltd.*

³⁸³ See, e.g., *Andean Pact Call To Fight Us IPR Pressure* (July 5, 1993), *Marketletter Publications Ltd. (UK)*

³⁸⁴ For the Pan-South American stand, see CILFA, at the 15th Assembly of the umbrella organization for Latin American pharmaceutical industries, ALIFAR in Bariloche, Argentina. See, e.g., *North and South Americans Against Patents*, May 30 1994, 1994 *Marketletter Publications Ltd. (UK)*.

granted by the General Council of the World Trade Organization.³⁸⁵ Recent examples of waivers include the EC/France Trading Arrangements with Morocco,³⁸⁶ the United States' Caribbean Basin Economic Recovery Act (CBERA),³⁸⁷ the Canadian Tariff Treatment for Commonwealth Caribbean Countries (CARIBCAN),³⁸⁸ the United States' Andean Trade Preference Act, and the ACP-EC Partnership Agreement.³⁸⁹

This narrow interpretation of the 31(bis)(3) Hong Kong Declaration provision, interpreted to include solely LDCs, in fact remains challenged within the WTO's pharmaceutical bargaining game. While the European Communities "insisted that the [provision] should be limited to what is effectively sub-Saharan Africa," other LBPs hold a much broader interpretation.³⁹⁰ Although these countries may be less poor than the group of LDCs, these remaining LBPs arguably need to be included in the 31bis arrangement, as under the TRIPS regime they are provided remarkably little bargaining power vis-à-vis technology-manufacturing MNEs and foreign governments alike.

The holdout effect by the United States toward all bargaining LBPs as one was evidently observed in numerous international trade rounds. The Doha rules of 2001 notably allowed LBPs to break patents to import, but did not authorize them to override patents for the purposes of export to countries in need. In December of 2002 in Geneva, although 143 of the WTO's 144 members agreed on a solution, the lone holdout, the United States, obstructed the agreement.³⁹¹ American negotiators lobbied to limit covered medicines to those for HIV/AIDS, malaria, tuberculosis, and a few additional diseases that primarily affect Africa. Other LBPs, as it were, jointly sought a more flexible approach on access to medicines that would allow nations to protect public health as they see fit.³⁹² As a result, no agreement was reached by close of the talks.³⁹³ As a result, there perhaps could be a need to relax this rigid LDCs-oriented trade rule by allowing other LBPs to obtain essential medicines at a more affordable cost.³⁹⁴

Secondly, low inside option cost considerations remain for LBPs, as there have been only a few reported initiatives on South-South technology transfer with reference to most LBPs alike.³⁹⁵ This fact again contributes to the low bargaining power of countries other than LDCs that belong to the LBP category. Certainly MBPs such as

³⁸⁵ Article IX:3 to the WTO Agreement states that such entities may use a notice of planned procurement or a notice regarding a qualification system as an invitation to participate in the deliberations herein.

³⁸⁶ On which decisions were taken at the 4th Ministerial Meeting; see WT/MIN(01)/15 and WT/MIN(01)/16.

³⁸⁷ *Id.*

³⁸⁸ *Id.*

³⁸⁹ *Id.*

³⁹⁰ Abbott & Reichman, *supra* note 375, at 945.

³⁹¹ See, Jeffrey Sparshott, U.S. Refusal Thwarts WTO Drug-Patent Talks; Bush Seeks Supporters of Interim Plan to Ease Enforcement for Poor Nations, *Wash. Times*, Dec. 25, 2002, at C10.

³⁹² See, Editorial, A Global Medicine Deal, *N.Y. Times*, Jan. 5, 2003.

³⁹³ After the fiasco in Geneva, the Bush administration, in balance, pledged not to bring trade pressure against countries that export cheap drugs for HIV/AIDS and other resource-poor country epidemic diseases. *Id.*

³⁹⁴ This article describes only the positive theory of bargaining, and does not focus on possible normative ramifications.

³⁹⁵ Joan Rovira, Creating and Promoting Domestic Drug Manufacturing Capacities: A Solution for Developing Countries, in *Negotiating Health in Negotiating Health, Negotiating Health: Intellectual Property and Access to Medicines* 235 (Pedro Roffe et al. eds., 2006). There are, however, a few examples for south-south trade worth mentioning. To illustrate, Thailand offered to help Ghana and Zimbabwe to set up factories to produce HIV/AIDS antiretrovirals. *Id.* Brazil, in comparison, offered a cooperation agreement, including technology transfer, to developing countries for the production of generic ARV drugs. Ellen 't Hoen, *supra* note 196, at 32.

China and India already possessed a manufacturing capacity and therefore are perceived to remain outside the scope of this limited LBP bargaining power narrative.³⁹⁶ Article 66 of the TRIPs Agreement, in particular, requires developed countries to provide incentives for their businesses and institutions to help create “a sound and viable technological base” in Least Developed Countries, realistically referring to other LBPs, by promoting and encouraging transfer of technology.³⁹⁷ However, it is unclear how these LBPs could enforce article 66, even with the assistance of the mandatory WTO dispute settlement process. Likewise, even though the Doha Declaration is full of verbal commitments and plans for capacity building, it is silent about how to fund the ambitious technical assistance programs.³⁹⁸ Furthermore, its legal nature as a ‘work program’ is particularly vague,³⁹⁹ further undermining LBPs’ inside option. With little LBP bargaining power, it was only natural that developed countries, MBPs and HBPs with ARV manufacturing capabilities eventually signed technology transfer agreements with the few LBPs that wished to manufacture generics locally.⁴⁰⁰ LBPs’ inside option value further diminishes as a result.

The disparity between MBPs and HBPs on the one hand, and LBPs, on the other, was also apparently perceived during the discussion of solutions to implementing paragraph 6 of the Doha Declaration. There, some LBPs underscored the importance of building local manufacturing capacity.⁴⁰¹ Their demands eventually created tension towards HBPs and MBPs alike. The African Group strived for an explicit agreement proposing the solution of building domestic manufacturing competence.⁴⁰² HBPs and MBPs, like Brazil and India, for their part, already had manufacturing know-how and consequently believed otherwise.⁴⁰³

LBPs bear low inside option value in the Tier-1 bargain for a third and additional reason deriving from the fact that changes in patent laws in MBPs with manufacturing capacity, such as India, further undermined LBPs’ inside option. LBPs heavily depend on drug imports from MBPs.⁴⁰⁴ Although LDCs are not obliged under the WTO rules enshrined in the 2001 Doha Declaration to grant or enforce pharmaceutical product patents until at least 2016, other developing countries saw this transition period end in January 2005. This list includes countries with significant manufacturing capacity, such as India, a major source of WHO prequalified generic ARVs. They were required to introduce new pharmaceutical patent legislation in order to comply with WTO rules. This requirement may be viewed to create fundamental bargaining implications for LBPs. Nonetheless, as long as the present LBPs’ price crisis is unresolved it is

³⁹⁶ Council for Trade-Related Aspects of Intellectual Prop. Rights, Communication from Kenya, the Coordinator of the African Group, Elements of a Paragraph 6 Solution, IP/C/W/389, P 15(a) (Nov. 14, 2002).

³⁹⁷ TRIPs Agreement, art. 66(2).

³⁹⁸ Sungjoon Cho, A Bridge Too Far: The Fall of the Fifth WTO Ministerial Conference in Cancun and the Future of Trade Constitution, 7 J. Int'l Econ. L. 219, 226 (2004).

³⁹⁹ *Id.*

⁴⁰⁰ See, e.g., UNAIDS, Report on the Global AIDS Epidemic, 10, 104 (2004).

⁴⁰¹ See Frederick M. Abbott, The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health, 99 AM. J. INT'L L. 317, 334 (2005).

⁴⁰² Council for Trade-Related Aspects of Intellectual Prop. Rights, Communication from Kenya, the Coordinator of the African Group, Elements of a Paragraph 6 Solution, IP/C/W/389, P 15(a) (Nov. 14, 2002).

⁴⁰³ *Id.*

⁴⁰⁴ Médecins Sans Frontières, Untangling the Web of Price Reductions: A Pricing Guide for the Purchase of ARVs for Developing Countries 7 (10th ed, 2007).

unclear how these recent or newer drugs may be made available at sustainable and affordable prices for LBP, further undermining their inside option value.⁴⁰⁵

On the Tier-2 bargain level, further evidence for the overall demise of LBP's inside option may be found. Under the current bargaining situation, access to life-saving medicines, in particular, for the LBP truly depends on the goodwill of MNEs towards LBP in tandem. MNEs voluntarily offer their most discounted prices to LBP including non-LDC LBP. However, MNEs have little or no economical incentive to do so.⁴⁰⁶ In reality, many LBP's endemic diseases could be prevented or treated with vaccines or pharmaceuticals that are not accessible to the populations in most LBP. To illustrate, almost 18 million people, mostly in LBP stretching from Africa to Central or South America, are infected with river blindness (onchocerciasis) which is curable by administering a single oral dose of Ivermectin (trade name B Mectizan) per year.⁴⁰⁷ Moreover, isoniazid and co-trimoxazole prophylaxis against tuberculosis⁴⁰⁸ and pneumonia, respectively, are highly effective but are rarely available to poor people in many LBP outside sub-African LDCs.⁴⁰⁹ Interventions for these and many other LBP-based diseases may be more cost effective and entail less risk than for the most expensive HIV therapies emphatically undermining their bargaining power within TRIPS.

c) Market Power

Most LBP alike have little or no market power in when bargaining with MNEs directly. To start, with regard to Tier-1 bargaining with the developed world, and particularly the United States, most if not all LBP are regulation-takers. The preferential edge for LBP, and originally NICs as well – that was built into the GATT (1947), GATT-Part IV (1965), and various GATT (1979) Codes, such as the Subsidies Code – has not been put into practice effectively by United States presidential administrations and trade authorities.⁴¹⁰ A double standard that at least favors LDCs is implicit in these arrangements.⁴¹¹ Political developments diminished the authority of existing international bodies in this area – such as the World Intellectual Property Organization (WIPO) and the United Nations Economic, Social and Cultural Organization (UNESCO) – while at the same time inconsistently dismissing GATT's basic purposes and premises.⁴¹² In the post-World War II era, the United States and United Kingdom as key players in early GATT rounds, due to their collective sense of responsibility for newly liberated colonies and Latin American nations, traded non-reciprocal leeway for more subsidies, protectionism, and multiple exchange rates to less developed countries.⁴¹³ The basic theme of providing unconditional most-favored-

⁴⁰⁵ *Id.*

⁴⁰⁶ *Id.*

⁴⁰⁷ The Carter Center, River Blindness Program (2002), available at

<http://www.cartercenter.org/healthprograms/showdoc.asp?programID=2&submenu=healthprograms>.

⁴⁰⁸ Rajesh Gupta et al, Responding to Market Failures in Tuberculosis Control, 293 Science 1049 (2001).

⁴⁰⁹ See, Karen Zwi et al., Cheaper Antiretrovirals to Treat AIDS in South Africa: They Are At Their Most Cost Effective in Preventing Mother to Child Transmission, 320 Brit. Med. J. 1551 (2000).

⁴¹⁰ William A. Lovett, Colloquium: Current World Trade Agenda: GATT, Regionalism, and Unresolved Asymmetry Problems, 62 Fordham L. Rev. 2001, 2006 (1994).

⁴¹¹ *Id.* at 2002.

⁴¹² See, e.g., Jerome H. Reichman, The TRIPS Component of the GATT's Uruguay Round: Comparative Prospects for Intellectual Property Owners in an Integrated World Market, 4 Fordham Intell. Prop. Media & Ent. L.J. 171 (1993).

⁴¹³ Lovett, *supra* note 408, at 2005 & Fn. 12.

nation treatment under Article II strongly favored the interests of weaker and smaller trading nations, such as LBPs and most NICs.⁴¹⁴ Today, however, LDCs continue to face substantial asymmetries rooted in the GATT,⁴¹⁵ uneven economic development through the IMF,⁴¹⁶ regional discrimination, and divergent industrial policies in the WTO. Whenever LBPs fail to comply with the United States-led policy concerning the issuing of compulsory licensing, American MNEs evenly pressure their government to issue economic sanctions towards all LBPs alike.⁴¹⁷

LBPs also have virtually no market power in Tier-2 bargaining with MNEs. In that sense, LBPs are also price-takers.⁴¹⁸ The primary explanation for this phenomenon is that LBP pharmaceutical consumer markets tend to be small.⁴¹⁹ Over the past two decades, a substantial amount of literature confirmed empirically the importance of host country market size – which LBPs typically lack – to attract FDI.⁴²⁰ In fact, most pharmaceutical FDI flows to the developed world or to NICs.⁴²¹ Pharmaceutical MNEs derive their above-average profitability from the continuous release of new drugs. The global market is estimated at approximately USD \$500 billion, and the leading 12 companies – all of which are headquartered in developed countries – account for approximately 45% of total sales.⁴²²

In conclusion, there are three central explanations for LBPs' low bargaining power. The first of the three relates to the fact that LBPs face low outside option payoffs, both due to static and dynamic inefficiencies. Concretely, LBPs increasingly face difficulties in accessing generics produced in India and China. Additionally, LBP markets provide implied incentives for drug innovation over neglected diseases,

⁴¹⁴ See William A. Lovett, Rethinking U.S. Industrial-Trade Policy in the Post-Cold War Era, 1 Tul. J. of Int'l & Comp. L. 135, 135-83 (1993); The asymmetry problem also has been analyzed extensively in William A. Lovett, World Trade Rivalry: Trade Equity and Competing Industrial Policies 8-11, 52-53, 75-96, 105-28 (1987). GATT, however, (at least until 1994) and United States domestic trade law still allowed considerable leeway for sensible adjustments and offsets to foreign subsidies, restrictions, and discounting for LDCs. Lovett, *supra* note 408, at 2006. Had the United States used its own GATT and national-law-trade remedies willingly, thereby overcoming local interest groups and other exogenous concerns, Lovett explains, most of the LDCs asymmetry problem would have been resolved. *Id.*

⁴¹⁵ As Wesche observes, structural realism would indicate that LDCs' involvement generates significant losses, leading them to refrain from participating unless forced to do so. However, in GATT's Uruguay Round, developing countries did choose to participate. See, Lisa Wesche, "The Impact of Uncertainty on Developing Countries' Decision to Negotiate in Multilateral Institutions" Paper presented at the annual meeting of the American Political Science Association, Boston Marriott Copley Place, Sheraton Boston & Hynes Convention Center, Boston, Massachusetts, Aug 28, 2002, at http://www.allacademic.com/meta/p65528_index.html (last visited Aug. 25. 2009).

⁴¹⁶ For a bibliography on the International Monetary Fund ("IMF"), the International Bank for Reconstruction and Development (later the World Bank), and the General Agreement on Tariffs and Trade ("GATT"), see Lovett, *supra* note 412, at 38-40.

⁴¹⁷ See, generally Shell, *supra* note 118 (describing the three statutory mechanisms of the Trade Act of 1974, as amended, used by the US industry to pressure the US government to issue trade sanctions on LDCs and developing countries at large, referring to section 301, 'Super 301,' and 'Special 301'); see also Jagdish Bhagwati, Aggressive Unilateralism: An Overview, in *Aggressive Unilateralism: America's 301 Trade Policy and the World Trading System 1* (Jagdish Bhagwati & Hugh T. Patrick eds., 1990).

⁴¹⁸ 'Price-takers' is a financial term that relates to individuals who respond to rates and prices by acting as though prices have no influence on them. See, Financial Dictionary (For: Price takers), at http://www.anz.com/edna/dictionary.asp?action=content&content=price_takersmakers (last visited Aug. 25. 2009).

⁴¹⁹ Source: Intercontinental Marketing Services (IMS), Top Pharmaceutical Markets Worldwide, 2007, available at http://www.imshealthcanada.com/vgn/images/portals/cit_40000873/8/42/79016672Trends16_En_07CORR.pdf (last visited Aug. 25. 2009) (the pharmaceutical markets of North America and Europe account for over 80% of drug sales worldwide).

⁴²⁰ Lippoldt, *supra* note 218.

⁴²¹ *Id.*

⁴²² Fórum de Competitividade, *supra* note 172, at 13.

particularly in India, which is currently their main supplier. The second explanation for LBPs' low bargaining power involves their limited inside options based on three factors: the existence of a disturbing institutional constraint in the TRIPS Hong Kong Declaration that discriminate against non-LDC LBPs; the limited availability of South-South technology transfers; and the fact that changes in patent laws in countries such as India further undermine LBPs' inside option. Finally, the low bargaining power over compulsory licenses by LBPs is mainly a function of the fact that these countries have very little, if any, market power in price and regulation negotiations with MNEs and their home governments. That is, when it comes to bargaining over international patent regulation and international prices of patented goods, LBPs are by and large both regulation-takers and price-takers.

III. Conclusion

This article puts forth a positive theory of bargaining power based on an empirical narrative of what is depicted herein as the post-WTO bargaining situation. The typology presented is rendered possible by the demise of the pre-WTO bargaining models of MNEs-host developing country relations developed in the 1970s and 1980s.⁴²³ During the post-WTO era these models have lost their explanatory power, a phenomenon that is particularly evident in negotiations between developing and developed countries over access by the former to medicines produced or developed in the latter. Numerous policy considerations ensue from this article's analysis.

For a start, lack of innovation carries paradoxical implications for certain developing countries in bargaining over TRIPS policies. A paradigm based on two-tiered and multi-party negotiations arguably stresses the special situation of NICs in this regard. NICs differ from other developing countries in that they possess sizeable and desirable markets, often coupled with an industrial capacity to produce generics. In particular, one can observe a paradoxical effect of innovation within innovative NICs, which weakens, rather than boosts, bargaining power over the prospects of issuing compulsory licenses. This notion explains why non-innovative NICs are modeled as HPBs to denote their higher levels of bargaining power, whereas innovative NICs are modeled as MBPs indicating medium levels of bargaining power. This dynamic is particularly relevant to the case of compulsory licenses, which serves as the working example here.

Furthermore, in highlighting certain specificities within NICs, the positive bargaining theory developed herein deemphasizes the practical relevance of the LDC carve-out contained in the TRIPS Agreement. It does so by considering all non-NICs as low-bargaining power countries, or LBPs. Under the existing state of affairs, access to medicines by the majority of developing countries depends on the goodwill – or perhaps, reputational concerns – of the pharmaceutical industry. The industry, however, bears little economic incentives to promote access in these countries.⁴²⁴

A third ramification, as shown above, flows from the argument that the Tier-1 inter-governmental bargaining level entails a reversible institutional favoritism towards LDCs. It thus may be argued that this bargaining situation discriminates against the remaining LBPs, particularly within the 2005 Hong Kong declaration. In attempting to facilitate the supply of essential medicines to countries with insufficient or no manufacturing capacity, as is the case for most LBPs, the proposed article 31bis(3) to the TRIPS Agreement creates a special arrangement not only for affected countries, but also for those belonging to a regional trade agreement – however the implied reference is only to the African ones.⁴²⁵ These LBPs now include numerous Central and South America, Lower Asia or even poor Eastern European countries. Specifically, these regional agreements presently consist of the Southern Common Market in Latin America (MERCOSUR), the Common Market for Eastern and Southern Africa (COMESA), and the ASEAN Free Trade Area (AFTA).

⁴²³ Ramamurti, *supra* note 17 (also noting that empirical tests using data from the 1970s and before confirmed the explanatory power of these models).

⁴²⁴ Médecins Sans Frontières, *supra* note 40, at 9.

⁴²⁵ TRIPs Amendment, art. 31bis(3).

Instead, the Hong Kong declaration should have allowed the large group of LBPs⁴²⁶ to aggregate their markets to generate the purchasing power needed to make the development of an indigenous pharmaceutical industry attractive.⁴²⁷ It also should have paved the way for the development of regional supply centers,⁴²⁸ procurement systems,⁴²⁹ and patent pools and institutions, while simultaneously facilitating technical cooperation within the region.⁴³⁰ If ratified, the new article 31bis of the TRIPs Agreement will allow countries with little or no manufacturing capacity to import generic versions of on-patent pharmaceuticals.⁴³¹

Beyond these three policy ramifications, it must be noted that there exist several constraints on this article's model. Firstly, and regrettably, by virtue of being a situational model, it does not – and cannot – reflect the long-run dynamic efficiency implications of the post-WTO regime. While the developed countries' emphasis on the protection of intellectual property rights has been heavily criticized as a “‘beggar thy neighbor’ approach,”⁴³² the TRIPS Agreement could be read to reflect a static economic efficiency of the structure of intellectual property, and particularly patent law. This article, therefore, does not address whether – or how – the TRIPS Agreement could be read for long-run efficiency, thereby allowing adjustments in national intellectual property regimes designed to reflect their specific innovative growth dynamics.⁴³³ An explanation for the present model's short-run focus lies within innovation theory. All things being equal, patents affect efficiency by spurring innovation while generating a deadweight loss. What is more, it is well understood that the first effect is positive and dynamic, while the second is negative and static.⁴³⁴ TRIPS, on the other hand, hinders the ability of policymakers to choose a protection level that strikes the right balance between the dynamic efficiency gain and the static efficiency loss. This is particularly so given the developmental inequality among HBPs, MBPs and LBPs, which is demonstrably relevant.

It may be contended, based on the present positive model, that strong protection for intellectual property rights may have significant negative allocative consequences in developing countries without contributing to – and in fact even impeding – their

⁴²⁶ The TRIPs Agreement distinguishes between developing and least developed countries. This Article uses “less developed countries” to denote both developing and least developed countries. When referring to the TRIPs Agreement, however, this Article returns to the terms “developing countries” and “least developed countries.”

⁴²⁷ Yu, *supra* note 238, at 848.

⁴²⁸ Abbott & Reichman, *supra* note 375, at 973-77 [discussing the potential benefits of pooled procurement strategies and the establishment of regional pharmaceutical supply centres].

⁴²⁹ Musungu et al., *supra* note 375.

⁴³⁰ See TRIPs Amendment, art. 31bis annex P 5.

⁴³¹ Although the initial deadline for ratification was December 1, 2007, the deadline has been extended by two years. William New, TRIPs Council Extends Health Amendment; Targets Poor Nations' Needs, *Intell. Prop. Watch*, Oct. 23, 2007, www.ip-watch.org/weblog/index.php?p=798 (last visited Aug. 25, 2009).

⁴³² Frederick M. Abbott, The Enduring Enigma of TRIPs: A Challenge for the World Economic System, 1 *J. Int'l Econ. L.* 497 (1998).

⁴³³ There is noticeably important evidence suggesting that—at least in the United States—patent rights over research opportunities have begun to hinder long-run efficiency by chilling innovation. See, e.g., Rebecca S. Eisenberg, Bargaining over the Transfer of Proprietary Research Tools: Is This Market Failing or Emerging?, in *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society* (Rochelle Dreyfuss et al. eds., forthcoming 2001); Carlos M. Correa, Internationalization of the Patent System and New Technologies, 20 *Wis. Int'l L.J.* 523, 528 (2002).

⁴³⁴ Joseph E. Stiglitz, Knowledge as a Global Public Good, in *Global Public Goods: International Cooperation in The 21st Century* 308 (Inge Kaul et al. eds., 1999); Gideon Parchomovsky & Peter Siegelman, Towards an Integrated Theory of Intellectual Property, 88 *Va. L. Rev.* 1455 (2002).

technological development.⁴³⁵ Thus, the HBP-MBP-LBP underlying developmental inequality shifts the balance between static and dynamic efficiencies, such that short-term access and affordability to innovative-based goods takes priority over long-term innovation policy goals where necessary.⁴³⁶ In that sense, the gain in dynamic efficiency from the greater innovative activity derived from intellectual property protection only unevenly balances out the losses from static inefficiency. This is true both for the undersupply of health care, for example, and for the underproduction of the goods, as pharmaceuticals, protected by the patent.⁴³⁷ The article's model thus leaves TRIPS' lawmakers to achieve merely a contextual policy of balancing minimum standards with flexibilities in the short-run, among HBPs and LBPs as non-innovative developing countries, and among MBPs as well.⁴³⁸

This article's modest static innovative hypothesis is also acutely relevant to the on-going debate in the United States about the merits of the Bayh-Dole Act.⁴³⁹ This seminal act allows recipients of government funding to take title to inventions developed with that funding and its purported consequences since the act's inception.⁴⁴⁰ The adoption of the Act in non-innovative developing countries, namely HBPs and LBPs, however, could lead to an increased focus on commercializing technology directed toward the local needs of developing countries. Regrettably, the result of equal enactment of such legislation in these developing countries may prove unlikely to have the same purported dynamic innovative impact on a similar scale to that which the Bayh-Dole Act supposedly had in the United States.⁴⁴¹

⁴³⁵ Carlos M. Correa, *Managing the Provision of Knowledge: The Design of Intellectual Property Laws*, in *Providing Global Public Goods: Managing Globalization* 414 (Inge Kaul et al. eds., 2003).

⁴³⁶ Stiglitz, *supra* note 423.

⁴³⁷ *Id.* at 311 (emphasis in original).

⁴³⁸ Compare: Claudia Chamas et al., *Current Issues of Intellectual Property Management in Health and Agriculture in Brazil*, in *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* 12 (Anatole Krattiger, et al. eds., 2007).

⁴³⁹ Bayh-Dole University and Small Business Patent Procedures Act, Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified as amended at 35 U.S.C. §§ 200-212 (2000)). See also, 35 U.S.C. § 200 (identifying the statute's policy and objective).

⁴⁴⁰ Sara Boettiger & Alan Bennett, *The Bayh-Dole Act: Implications for Developing Countries*, 46 *IDEA* 261 (2006); Michael S. Mireles, *The Bayh-Dole Act and Incentives for the Commercialization of Government-Funded Invention in Developing Countries*, 76 *UMKC L. Rev.* 525 (2007).

⁴⁴¹ South Africa, Malaysia, and the Philippines are considering or have adopted legislation similar to the Bayh-Dole Act. See Chris Bull, *Managing Intellectual Assets at Universities: The South African Government is Considering the Introduction of Legislation Similar to the US Bayh-Dole Act Governing intellectual property Arising from University R&D*, *Managing Intell. Prop.*, Apr. 1, 2005, available at http://www.accessmylibrary.com/coms2/summary_0286-6541410_ITM; South Africa: Should SA Follow US Lead on Patent Laws?, *Africa News*, Jan. 13, 2004; Local Scientists Hope to Reap Benefits via New Research Law, *Malaysia Econ. News*, Oct. 29 2004.