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Patent bargains in NICs: the case of Brazil

Bruno Salama †

Daniel Benoliel ††

Send your comments to: bruno.salama@fgv.br, dbenolie@law.haifa.ac.il.

1. Introduction

In development economics there is increasing consensus that strict patent laws enhance foreign direct investment (FDI) into poor nations.¹ More broadly, strict patent laws and their enforcement is noticeably a chief avenue through which both rich and poor countries have a common interest in improving law-in-practice in the latter.² Conspicuously, Cooter & Schaefer contest the notion that industrial policies can sprout growth in poor countries.

† Professor, Escola de Direito de São Paulo at the Fundação Getúlio Vargas, Brazil and Director of the Latin-American and the Caribbean Institute for Law and Economics (FGV-ILACDE). For further information, please email: bruno.salama@fgv.br.

†† Assistant Professor, Patent Law Director at the Haifa Center of Law & Technology (HCLT), University of Haifa, Faculty of Law. For further information, please contact: dbenolie@law.haifa.ac.il.

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¹ See, e.g., Robert D. Cooter and Hans-Bernd Schaefer, *Law and the Poverty of Nations* (2008), available at: http://works.bepress.com/robert_cooter/144, p. 56 (last reviewed on May 22, 2008). For the context of patent law, see Kunz-Hallstein and Hans Peter, *The Revision of the International System of Patent Protection in the Interest of Developing Countries*, 10 *Int'l Rev. of Indus. Prop. & Copyright L.* 649 (1979); Lall *supra* note 1; Jonathan Eaton & Samuel J. Kortum, *Trade in Ideas: Patenting and Productivity in the OECD*, 40 *J. Int'l Econ.* 251, 252 (1996). See, also, Keith E. Maskus, *Intellectual Property Rights in the Global Economy* 109-42 (2000) (hereinafter "IPRs in Global Economy"); Shahid Ali Khan, *Socio-Economic Benefits of Intellectual Property Protection in Developing Countries* 1 (2000), p. 2, 9; 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), at 130 ("hereinafter 'The Role of IP'"); Keith E. Maskus & Mohan Penubarti, *How Trade-Related are Intellectual Property Rights?*, *J. Int'l Econ.*, Nov. (1995), at 227, 229-30, 237-43; Ali Imam, *How Patent Protection Helps Developing Countries*, 33 *AIPLA Q.J.* 377 (2005), p. 379. *But see*, Alan Deardorff, *Should Patent Protection Be Extended to all Developing Countries?* 13 *The World's Econ.* 497 (1990); and *Welfare Effects of Global Patent Protection*, 59 *Economica* 35 (1992); F. M. Scherer, *A Note on Global Welfare in Pharmaceutical Patenting*, 27 *The World Econ.* 1127 (2004); Carlos A. Primo Braga and Carsten Fink, *The Relationship Between Intellectual Property Rights and Foreign Direct Investment*, 9 *Duke J. of Comp. & Int'l L.* 163 (1998).

² Traditionally policy and theory alike solely referred to the dichotomy between developed and developing countries, ignoring NICs' special characteristics concerning intellectual property policies altogether. For official surveys, see: World Intellectual Property Organization (WIPO, 1985) and the United Nations Department of Economic and Social Affairs (UNCTAD, 1974).

Instead, they posit growth spurts as a result of an adequate and predictable legal framework, particularly in the fields of contract and property law.

As for poor countries, conventional analysis suggests thus far that strict, rule-based patent law enforcement is the optimal means of inducing to economic growth. Three advantages are deemed to follow from this proposition,³ assumed to be uniformly important for every underdeveloped country. First, the parties have less to dispute about patents, a fact that makes dispute resolution quicker and cheaper. Second, when few facts control the patent law's application, disguising bribes to officials is harder, so corruption is riskier. Third, precise patent laws demand less sophistication and legal education from officials applying those laws.

This proposition is in fact promoted by ring of developed countries, predominated by the United States, and through the provisions of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, in which Articles 31(b) and 8 discouraging compulsory licensing. It is also promoted through the World Trade Organization's (WTO) Declarations on the TRIPS Agreement and on Public Health adopted at Doha in 2001. Both set rules that largely repel the issuance of compulsory licenses, which authorize a third party to make, use, or sell a patented invention without the patent owner's consent. Moreover, neither TRIPS nor the Doha Declaration provide a clear exception on public health grounds, or change the existing rules in TRIPS concerning compulsory licensing.

In the backdrop of this strict regulatory regime flatly adopted by the WTO for all nations, certain countries do occasionally threaten to issue compulsory licenses which may sway overseas companies into selling drugs with large discounts or granting voluntary licenses domestically.⁴ Indeed, countries of varying degrees of development have resorted to aggressive negotiation strategies – including TRIPS' most outspoken paladin, the United States.⁵ However, in this paper we focus only on the specific dynamics and the implications of negotiations involving big pharma and Newly Industrialized Countries (NICs).

The Brazilian pharmaceutical industry is a case in point. While the classic innovation-diffusion trade-off in patent protection a theoretical blunder, there is now an increasing consensus that patents are crucial for the development of certain IPRs-sensitive industries such as the pharmaceuticals industry.⁶ Brazil illustrates well a bargaining theory of international negotiations over pharmaceuticals because it has routinely resorted to a negotiation strategy for price reductions premised on the credible threat of issuing compulsory licenses.⁷ Brazil's experience illustrates why, unlike in the case of developing

³ Richard A. Posner, *Creating a Legal Framework for Economic Development*, World Bank Research Observer, vol. 13, 1, 1998; Hans-Bernd Schaefer, *Rules versus Standards in Rich and Poor Countries: Precise Legal Norms as Substitutes for Human Capital in Low-Income Countries*, in: *Supreme Court Economic Review*, University of Chicago Press, Vol. 14, (2006), 113 - 135; Cooter & Schaefer, *supra* note 1, at 4.

⁴ NICs are typically viewed as those countries that fulfill the intermediary stages in the international division of labor. See, C. 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: George Allen & Unwin (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 a 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*, Princeton University Press, (2003); David Waugh, *Geography, An Integrated Approach*. Nelson Thornes Ltd., 3rd ed., (2000); and N. Gregory Mankiw, *Principles of Economics*, 4th ed. (2007). See, also, discussion in Part II.A, herein.

⁵ Other examples of health-related compulsory licenses can be found in www.cptech.org/ip/health/cl/recent-examples.html (last reviewed on May 22, 2008).

⁶ Primo Braga & Carsten Fink, *supra* note 1.

⁷ The specific application of the Brazilian model to other NICs will depend on comparative empirical work on the strength of their health systems, treatment guidelines, intellectual property regimes, differing capacities for local drug production, and on global drug prices, all of which continue to evolve.

countries, NICs may potentially benefit from such bargains without significantly curtailing FDI and enhanced R&D. That is, in the backdrop of an altogether weaker patent enforcement regime.⁸

Over the past decade, in numerous occasions, such as when negotiating price reductions for drugs such as Nelfinavir and Efavirenz or Gleevic, Brazil used aggressive tactics with big pharma that were made possible largely because of the country's credible threat of issuing compulsory licenses for generic manufacture. Lower-income developing countries typically enjoy the lowest global prices for patented pharmaceuticals but often do not integrate the most costly testing into treatment guidelines, but Brazil is different. On the demand side, as a middle-income country, it opts to issue (or threaten to issue) compulsory licenses because importing generics may be cheaper and more feasible than producing drugs locally. Furthermore, the existence of a relatively strong domestic generic industry feeds back the process by making the threat of issuance of a compulsory license credible. On the supply side, Brazil suffers from a vast set of governmental constraints, which are closely intertwined with the country's political governance that curtails its competitive edge for inwards FDI in pharmaceuticals.

As this paper argues, compulsory licensing with respect to pharmaceutical products may not only be efficient but presumably is also politically appealing, as it promises governments and consumers a lower price on pharmaceuticals products. In essence, this paper argues that for NICs – unlike developing countries – the notion that the lack of a strict patent regime particularly curtails FDI in R&D is potentially a false, or at least largely a vague, proposition. Considering the little correlation between the two, discretionary usage of compulsory licensing within TRIPS' public health exception in pharmaceutical patents may, in fact, uphold a social bargaining surplus for NICs like Brazil.

In such settings, opportunistic bargains on compulsory licensing may, in times of public health crises within its TRIPS' rather moderate interpretation, not only be morally but also economically appealing.

The alternative explanation is to be found in the distinct neoclassic political economics of NICs, as Brazil. In NICs, different than in poor developing countries, deficient political institutions, not the lack of strict IPRs is what essentially curtails foreign direct investment (FDI). Neoclassic political economics narrations, such as of Brazil's political economy, in fact, sets a novel understanding of the failure of its mid-1990s IPRs reforms in spurring inwards FDI.

The study proceeds with the following. Part II sets the normative framework for the preset FDI-IPRs correlation while critically taking on its flawed analysis of NICs, such as Brazil. Part III explains how NICs like Brazil may at times prefer to adhere to negotiations strategies of bargaining around TRIPS while threatening the issuance of compulsory licensing, in the backdrop of an altogether weaker patent law regime. Part IV then generates an understanding of why in the face of weak governance and institutional constraints NICs as Brazil may be better off as a second-best solution using these negotiation strategies. Part V concludes by laying down an interpretative rule of policy, arguing that in times the threat to issue compulsory licenses by NICs is not only morally but also economically appealing.

⁸ Law-and-economics generally regards compulsory licensing of patents to bestow negative social costs due to the free riding problem it entails (see, e.g., Thomas Cotter & Roger Blair, *An Economic Analysis of Damages Rules in Intellectual Property Law*, 39 *William & Mary Law Review* 1585-1694 (1998)). In that sense, NICs arguably benefit themselves opportunistically.

2. FDI in NICs: the normative framework

2.1 Overview

While the value of patent rights varies across different countries and fields of technology, it is generally considered to be significant in developing countries, suggesting that stronger patents would induce further R&D as well as patent applications.⁹ The protection for intellectual property and patents in particular, are commonly presented as a central pillar of modern economic policy and "a catalyst for development."¹⁰

In the past, it has been argued that it is economically unsound for developing countries to have a patent system if an overwhelming majority of patents are granted to foreigners.¹¹ Many scholars, on the other hand, concluded quite the opposite, stating that patent systems are advantageous to developing countries.¹²

Edmund Kitch noticeably contends that developing countries should be motivated to join the world intellectual property system based largely on the American model simply because it is in their self-interest to do so.¹³ This paper negates this proposition for NICs as will be explained herein. In the last few decades this view seems to have prevailed, with patent systems expanding to a vast number of developing countries in a seemingly irreversible fashion.¹⁴ Higher standards of patent protection under the TRIPS Agreement are said to optimize the provision of needed incentives to invest in the innovative sectors of some developing economies, in order to make high-technology products available to local industries, promote new licensing agreements and FDI.¹⁵

Strict rules, within the framework patent law, are therefore premised on the notion that developed countries rely basically on the private sector as their engine of growth,¹⁶ with the state supporting growth policies indirectly through the supply of legal and physical infrastructure. In such rich countries, business develops under protection of the rule of law, which especially means a law of rules, an efficient and honest judiciary, and effective enforcement of court decisions.

⁹ See, Eaton & Kortum, *supra* note 1.

¹⁰ Alikhan, *supra* note 1.

¹¹ See, e.g., U. Anderfelt, *Internaitonal Patent-Legislation and Developing Countries* 137-139 (1971); E. Penrose, *The economics of the international patent system* 110-17 (1951); Greer, *The Case against Patent Systems in Less-Developed Countries*, 8 J. Int'l L. & Econ. 223 (1973); Grundmann, *Foreign patent monopolies in developing countries: An empirical analysis*, 12 J. Dev'tl Stud. 186 (1976); Kronstein & Till, *A reevaluation of th einternational patent convention*, 12 Law & Contemp. Probs. 765, 766 (1947); Vaitos, *Patent revisited: Their function in developing countries*, 9 J. Dev'tl Stud. 71, 89-90 (1972); J. Katz, *Patents, the Paris Convention and Less Developed coountries*, Discussion Paper no. 190, at 24-27 (Yale Univ. Economic Growth Center, Nov. 1973).

¹² Stephen P. Ladas, *Patents, Trademarks, and Related Rights. National and International Protection*, Harvard University Press (1975); Dale & Huntington, *A cost-benefit study of the domestic and international patent system*, 11 IDEA: The pat. Trademark & Copyright J. Res. & Educ. 351 (1967); Kunz-Hallstein & Hans Peter, *supra* note 1; Lall, *supra* note 1.

¹³ Edmund W. Kitch, *The Patent Policy of Developing Countries*, 13 UCLA Pac. Basin L.J. 1, 166-167 (1994), 178.

¹⁴ See, e.g., *The WIPO Index of Patent Systems*, at http://www.wipo.int/ipstats/en/resources/patent_systems.html (last visited May 22, 2008). See, also, Samuel Oddi, *The International Patent System and Third World Development: Reality or Myth?*, Duke L. J. vol. (1987) 831, p. 833 Fn. 6, referring to Patent law od the People's Republic of China of MAAR. 12, 1984, reprinted and translated in 27 Pat. Trademark & Copyright J. (BNA) No. 673, at 530 (Mar. 29, 1984).

¹⁵ See, e.g., Maskus, *IPRs in Global Economy*, *supra* note 1; Keith E. Maskus, Kamal Saggi & Thitima Puttitanun, *Patent Rights and International Technology Transfer Through Direct Investment and Licensing*, in *International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime* (Hardcover) by Keith E. Maskus (Editor), Jerome H. Reichman (Editor) 265, 265. *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).

¹⁶ Cooter & Schaefer, *supra* note 1, at 4.

More broadly, development economics has increasingly been upholding that strict patent laws are a chief avenue through which rich and poor countries have a common interest in improving law-in-practice in the latter.¹⁷ The argument then goes to suggest that, by and large, precise rules which allow for simple or even mechanical decisions have a higher capacity to reduce costs in low-income countries than vague norms.¹⁸ Accordingly, precise norms (rules), which allow for simple or even mechanical decisions, have a higher capacity to reduce costs in low-income countries than vague norms, and that vague norms (standards), which require complex and policy-oriented decisions by the judiciary and the civil service, are better suited to reduce costs in high-income countries.¹⁹

As so, a legal norm might be precise in the sense that it is a blueprint for action by a judge, civil servant or citizen; or it may be imprecise, stating the desired end result, and indicating the direction in which the law requires decisions to be made.²⁰

The operation of substantive legal commands in the physical world typically involves three consecutive stages. First, regulators and lawmakers decide whether conduct will be governed by a rule or a standard. These determinations are not always clear, as standards and rules differ in degree of generality, with standards being more general than rules. Rules and standards, in fact, are at opposite ends on the continuum of legal generality: rules are specific, applying detailed legal consequences to a definite set of detailed facts, and creating a sharp line between forbidden and permissible conduct; standards are general and open-ended, specifying only a general limit of permissible conduct and requiring application of the standard to the particular facts of the case.²¹ Thus, the choice between rules and standards is also one of degree.²² Moreover, in cases where rules and standards play the same role, they may differ not even in matter of degree but merely in the formal means of their classification.²³ Nevertheless, following the prevailing theory, this paper treats the distinction in its polarized sense.

In the second stage, individuals make behavioral choices either to comply with the legal commands or not. Since most individuals are imperfectly informed, they first decide

¹⁷ Cooter & Schaefer, *supra* note 1, at 57 ("intellectual property is one more reason why rich and poor countries have a common interest in improving law-in-practice in poor countries").

¹⁸ Equally argued, vague norms (standards), which require complex and policy-oriented decisions by the judiciary and the civil service, are better suited to reduce costs in high-income countries. See, e.g., Schaefer, *supra* note 3; Cooter & Schaefer, *supra* note 1, at 20-121; Posner, *supra* note 3.

¹⁹ See, e.g., Isaac Ehrlich & Richard A. Posner, *An Economic Analysis of Legal Rulemaking*, 3 J. Legal Stud. 257, 267 (1974); See, also discussion hereafter.

²⁰ *Id.*

²¹ See Kaplow, *supra* note 21, at 560, 561-62 n.6 (referring to Ruth Gavison, *Comment: Legal Theory and the Role of Rules*, 14 Harv. J.L. & Pub. Pol'y 727, 750-52 (1991)) (modelling degree of precision and time of application); see also Ehrlich & Posner, *supra* note 19, at 258 (modelling degree of precision); Kennedy, *supra* note 21, at 1687 (studying the influence of the degree of generality); Roscoe Pound, *Hierarchy of Sources and Forms in Different Systems of Law*, 7 Tul. L. Rev. 475, 482-83, 485-86 (1933); Frederick Schauer, *Rules and the Rule of Law*, 14 Harv. J.L. & Pub. Pol'y 645, 650-51 (1991).

This distinction is not accepted by all. Dworkin, for instance, calls both rules and standards "principles"; other times, the term "standard" is described as a broad type of rules, standards, principles, and policies. Ronald Dworkin, *Taking Rights Seriously*, Cambridge: Harvard University Press, (1977) at 22-28, 72-80. Then, both are used as synonyms. See Frederick Schauer, *Playing by the Rules: A Philosophical Examination of Rule-Based Decisionmaking in Law and in Life* 12-15 (1991); Thomas C. Arthur, *Workable Antitrust Law: The Statutory Approach to Antitrust*, 62 Tul. L. Rev. 1163, 1225-28 (1988) (advocating a middle position in which the legislature identifies goals and offers examples as guides for courts); Margaret Jane Radin, *Reconsidering the Rule of Law*, 69 B.U. L. Rev. 781, 783-90, 795-96 & n.44 (1989); Pierre Schlag, *Rules and Standards*, 33 UCLA L. Rev. 379, 406 (1985) (suggesting that any comparison might be a tautology or result in demonstrably untenable views).

²² See, e.g., Kaplow, *supra* note 21, at 600; Kathleen M. Sullivan, *The Justices of Rules and Standards*, 106 Harv. L. Rev. 22, 57-58 n.231, 61 (1992).

²³ See, e.g., Dworkin, *supra* note 21, at 28.

whether to acquire legal advice about the application of the legal commands to their situation. In the final stage, the legal command is enforced (or fails to be enforced) by the political institutions such as the courts and the police. Roughly speaking, such a pattern takes place in developing countries, developed countries, and NICs alike.²⁴

Back in the 1970's Economists at Cambridge and Oxford Universities undertook research on how the absence of patent proportion would affect the research and development behavior of British companies. They found that across all industries, covered, the weighted average reduction in R&D expenditures if all patents, anywhere in the world, were subjected to compulsory licensing with reasonable modest royalties would be eight percent.²⁵ However, in pharmaceuticals, a negative impact of 64 percent was predicted.²⁶ As a regulatory concern, the 70's also marked the concentrated American effort to bring the full array of less developed countries up to American strict patent law standards,²⁷ a process that was largely influenced by the American pharmaceutical industry.²⁸

U.S. advocates of TRIPS argued inter alia that less-developed countries should welcome strengthened patent laws because they would encourage domestic innovation which among other things flourished in the early history of the United States.²⁹ A second reason was that it would induce more inward technology transfer through foreign direct investment by multinational enterprises.³⁰ As a third reason, the belief that stronger patent laws would presumably enhance foreign trade as the exporting countries would be less concerned about piracy in the importing countries. Unsurprisingly, advanced industrialized countries tend to demand higher protectionist standards than those favored by policymakers in developing countries. The United States -- indeed developed countries generally -- has resisted the inclusion of exceptions to patentability, such as the issuance of compulsory licenses in the presence of severe health or environmental crises, or the protection of genetic resources and traditional knowledge.³¹ In fact, the United States appears to be taking the position that any agreement reached must reflect the standards of protection found in U.S. law. Such intransigence does not bode well for the kind of compromising required to produce an instrument that truly accommodates diverse needs.³²

The deduced form of this argument suggests that pharmaceutical companies thus fear expanding R&D in countries where patent protection is weak. To attract and sustain flows of

²⁴ This discrepancy arises from three sources: (1) the equilibrium between the sunk, fixed costs of command promulgation and variable costs (per case) of command enforcement of standards, (2) the degree of legal precision, and (3) the optimal timing of the lawmaking cost evaluation. See, e.g., Daniel Benoliel, *Technological Standards, Inc.: Rethinking Cyberspace Regulatory Epistemology*, 92 Cal. L. Rev. 1069.

²⁵ See, C. T. Taylor & Z. A. Silberston, *The Economic Impact of the Patent System* (1973), at 199.

²⁶ *Id.*

²⁷ See, F. M. Scherer, *The political economy of Patent Policy reform in the United States*, see at: <http://www.researchoninnovation.org/scherer/patpolic.pdf>, (draft of September 2007), at 37-38, referring also to Michael Santoro: *Global Protection of Intellectual Property*, Harvard Business School case study 9-392-073 (1992); Michael P. Ryan, *Knowledge Diplomacy: Global Competition and the Politics of Intellectual Property* (1998).

²⁸ *Id.*

²⁹ See, Scherer, *supra* note 27, at 40. 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 foreigners. Economic theory provided at best ambiguous guidance on all alleged benefits to poor countries of strong and open patent systems.

³⁰ *Id.*

³¹ Daniel Gervais, *The Trips Agreement: Drafting History and Analysis*, 2d ed. (2003), at 228-34; *cf.* Dawson Chem. Co. v. Rohm and Haas Co., 448 U.S. 176, 215 & n.21 (1980) (noting resistance to the adoption of compulsory licensing provisions in U.S. patent law).

³² See, Karen M. Hauda, *The Role of the United States in World-Wide Protection of Industrial Property*, in *The Future of Intellectual Property in The Global Market of the Information Society* 89, 97 (Frank Gotzen ed., 2003).

R&D, developing countries are generally inclined to reform their patent-protection systems to include stricter patent regimes.³³ Advocates of this argument often refer to a classic econometric study by Edwin Mansfield suggesting that, in the United States between 1981 and 1983, 65% of pharmaceutical inventions would not have been introduced, and 60% would not have been developed, had patent protection not been obtainable.³⁴ In the chemical sector, according to that same study, the respective percentages would be 30% and 38%.³⁵

Traditionally, the IPRs-FDI equilibrium has been firmly presented. On the one hand, a weak IPR regime increases the probability of imitation, which makes a host country a less attractive location for foreign investors.³⁶ On the other hand, strong protection may shift the preference of multinational corporations from FDI towards licensing.³⁷

On that note, there are two misbalancing phenomena. The first is that despite the introduction of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), many developing economies, in fact, are not eager to strengthen their IPR legislation and its enforcement fearing that the losses resulting from this action would outweigh its benefits.³⁸ The second, and the focal point of this paper relates to the unique case of NICs, upon their practice to bargain around TRIPS, such as when threatening to issue patent compulsory licenses, while officially maintaining TRIPS' strict IPRs rhetoric and importing it within local legislation altogether.

Conceptually, there are four main ways through which Multi National Enterprises (MNEs) promote foreign markets, as in the case of NICs.³⁹ The first is to export at arm's-length to a particular country or region.⁴⁰ The second is through a joint venture with some defined share of input costs, technology provision, and profits or losses, especially in unknown or regulated markets, for example, China.⁴¹ The third is where MNEs license, typically cross-borderline, a technology, product, or service, leading to complicated issues of bargaining over license fees and royalty payments.⁴² Yang and Maskus support the proposition that licensing should also be sensitive to IPRs as stronger protection reduces the contracting costs in arm's length licensing and allows for better monitoring and disciplining of licensees.⁴³ Apart from FDI, international trade and cross-border licensing represent the most important internationalization strategies.⁴⁴ The fourth and the focal point of this paper,

³³ See, e.g., Imam, *supra* note 1, at 384.

³⁴ Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 *MGMT. SCI.* 173, 180 (1986).

³⁵ *Id.*, at 175.

³⁶ Smarzynska, Beata (2002), *Composition of Foreign Direct Investment and Protection of Intellectual Property Rights: Evidence from Transition Economies*, The World Bank, Working Paper Series No. 2786, http://econ.worldbank.org/files/12031_wps2786.pdf (last reviewed on May 22, 2008), at 1.

³⁷ *Id.*, at 1, 3.

³⁸ *Id.*, at 1.

³⁹ Imam, at 377.

⁴⁰ See, Maskus & Penubarti, *supra* note 1, at 227, 229-30. See, also, generally, Guifang Yang and Keith E. Maskus, *Intellectual Property Rights and Licensing: An Econometric Investigation*. *Weltwirtschaftliches Archiv* 137 (1): 58-79 (2001).

⁴¹ See, James R. Markusen, *The Boundaries of Multinational Enterprises and the Theory of International Trade*, 9 *J. Econ. Persp.*, Spring (1995), at 169, at 170; Richard E. Caves, *Multinational Enterprise and Economic Analysis* 25 (2d ed. 1996), at 77-78.

⁴² See, Maskus, *supra* note 1, The Role of IP, at 114, & Fn. 28, referring to Ashish Arora, *Contracting for Tacit Knowledge: the Provision of Technical Services in Technology Licensing Contracts*, 50 *J. Dev. Econ.* 233, 234-38 (1996).

⁴³ This proposition is argued by Maskus and Yang empirically by showing that royalties and license fees received by US companies rise with stronger IPR protection in 23 partner countries. See, generally, Yang & Maskus, *supra* note 40.

⁴⁴ The relationship between IPR protection and FDI is, thus, affected by substitution effects between FDI and other internationalization strategies which will not be discussed herein. For further discussion, see, Peter Nunnenkamp & Julius Spatz, *Intellectual Property Rights and Foreign Direct Investment: The Role of Industry and Host-Country Characteristics* (2003), Kiel Working Paper No. 1167, at:

indeed is deciding to undertake FDI, which requires selecting where to invest and in what kind of facilities, whether to purchase existing operations or construct new plants ("Greenfield investments"), which production techniques to pursue, and how large an equity position to take with potential local partners.⁴⁵

Both theoretical and empirical researches on the motivation for FDI emphasize differing causal variables. Noticeably, as surveys of multinationals have shown FDI varies also across industries.⁴⁶ This paper wishes to take upon the pharmaceutical industry as a case in point. In the seminal work of Maskus, it is further upheld that a correlation exists between the category of the technology and the strength of a country's IPR.⁴⁷ That is, in suggesting that the higher the technology is, the more IPRs affect the amount and kinds of investments that foreign corporations will make.⁴⁸ Maskus further calls for an industry-specific approach to FDI-IPR analysis. As he suggests, IPRs should take on different levels of importance in different sectors with respect to encouraging FDI. Investment in lower-technology goods and services, such as textiles and apparel, electronic assembly, distribution, and hotels, depends less on the strength of IPRs and relatively more on input costs and market opportunities. Investors with a product or technology that is costly to imitate may also pay little attention to local IPRs in their decision-making.⁴⁹

The problem however is that this analysis still goes on to assume that developing countries are overall better off with strong IPRs, and merely differ on its degree of strictness. This paper wishes to take here on an alternative path, in suggesting that the former understanding of the FDI-IPRs correlation is potentially flawed in a second-best socio-economical environment, at least in the case of NICs such as Brazil. In the latter, strict IPRs do not promote FDI as much as they impair the production of national public goods, such as health care in the case of pharmaceuticals.

The various means by which IPRs influence FDI are subtle and complex, and strong IPRs alone naturally do not sufficiently generate strong incentives for firms to invest in a country.⁵⁰ If that were the case, China, Brazil, and other high-growth, large-market developing economies with weak patent protection would have attracted much less FDI.⁵¹

http://papers.ssrn.com/sol3/papers.cfm?abstract_id=425240, p. 11 (last reviewed on May 22, 2008), referring also to Peter Nunnenkamp and Agarwal P. Jamuna, Erich Gundlach, Globalisation of Production and Markets. Kiel Studies 262, (1994) Tübingen: J.C.B Mohr., 1994: Sections III and V.

⁴⁵ See, Keith E. Maskus & Guifang Yang, Intellectual Property Rights, Foreign Direct Investment, and Competition Issues in Developing Countries, 17 Int'l J. Tech. Mgmt. (1999), at 173; Caves, *supra* note 41, at 77-78.

⁴⁶ Smarzynska, *supra* note 36, at 1.

⁴⁷ Maskus, *supra* note 1, The Role of IP (referring to Edwin Mansfield, Intellectual Property Protection, Foreign Direct Investment, and Technology Transfer 19-21 (International Fin. Corp. Discussion Paper 19, 1994), at 3-4).

⁴⁸ *Id.*

⁴⁹ See, Maskus, The Role of IP, *supra* note 1, at 131-132 & references there.

⁵⁰ See Maskus, The Role of IP, *supra* note 1, at 128. As Maskus explains, strong IPRs attract FDI, but are not sufficient for this purpose. Several studies show that a country hoping to attract FDI requires, among other factors, political and economic stability, adequate infrastructure, a strong educational system, a skilled labor force, and a large market or proximity to markets. See generally David Wheeler & Ashoka Mody, International Investment Location Decisions: the Case of U.S. Firms, 33 J. Int'l Econ. 57, 71-72 (1992) (studying inter-government competition for foreign investment with tax and other short run incentives); Harry Grubert & John Mutti, Taxes, Tariffs, and Transfer Pricing in Multinational Corporate Decision Making, 73 Rev. Econ. & Stat. 285, 288-290 (1991); (studying the impact of host country taxes and tariffs on international trade patterns); S. Lael Brainard, An Empirical Assessment of the Proximity-Concentration Tradeoff Between Multinational Sales and Trade, 87 Am. Econ. Rev. 520 (1993) (finding that FDI increases relative to exports the higher the transport costs and trade barriers and the lower the investment barriers and scale economics at the plant level relative to the corporate level); Markusen, *supra* note 41, at 169, 174 (focusing on the circumstances that lead a firm to serve a foreign market by exports versus foreign production and why firms choose FDI versus some alternative mode of entry, such as a joint venture or a licensing arrangement).

⁵¹ See, Maskus, The Role of IP, at 129.

We will focus on the role that governance plays in the IPRs-FDI correlation. Several development economics studies show that a country hoping to attract FDI requires, among other factors, political and economic stability, adequate infrastructure, a strong educational system, a skilled labor force, and a large market or proximity to markets.⁵² Most economists, it should be noted however, do seem to limit this argument in reference particularly to small, poor countries mentioning sub-Saharan Africa and Eastern Europe, in comparison to large growing countries flatly including NICs such as Brazil or China. In essence, only for the former do they tend to contend that strong IPRs attract FDI, but are not sufficient.⁵³

The category of NIC, conceptually, is a socioeconomic classification applied to several countries by geographers, economists, and political scientists. Manufacturing must account for a significant fraction of the country's GDP,⁵⁴ but aside from that there is no undisputed or official set of criteria that allow a country to be labeled a NIC.⁵⁵ One can identify two broad aspects in the way the term NIC is typically employed.⁵⁶ The first is historical and isolates the phenomenon of industrialization on the post-WWII period, most notably in East Asia after the 1960s. As so, a NIC is basically a latecomer to the game of modern capitalist economy, in opposition to the old players that underwent industrialization earlier, and also in opposition to the least developed nations that are yet to reach the point of industrialization. As so, the NICs par excellence are South Korea, Taiwan, Hong Kong, and Singapore. Japan is an interesting case, because having started its industrialization process in the 1950s it is sometimes treated as a NIC, and sometimes not. From this historical perspective, a country can be considered a NIC regardless of its economic status as a developed or developing country. For instance, countries like the Philippines, Mexico and Japan could all be viewed as NICs, even though Mexico's GDP per capita is three times that of the Philippines, and Japan's is three times that of Mexico.⁵⁷

The second view is comparative-dynamic and sees the emergence of NICs as the outcome of a change in the world production structure.⁵⁸ According to Bradford,⁵⁹ the emerge 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." From this standpoint, NICs are 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 a NIC can change too.⁶⁰ Since industrialization and economic development are continua, the question then is how to find an operational definition for a country to be deemed a NIC. To deal with this problem, analysts have used additional yardsticks such as the country's share in world trade,⁶¹ per capita income,⁶² and proportion

⁵² See, also, generally Wheeler & Ashoka, *supra* note 50; Grubert & Mutti, *supra* note 50; Brainard, *supra* note 50.

⁵³ See, p. Fn 124 & Tbl. 3, *infra*.

⁵⁴ Anis Chowdhury and Iyanatul Islam, *The newly industrialising economies of East Asia*, London, Routledge, 1997, at 4.

⁵⁵ N. Grimwade, *International trade: New patterns of trade, production and investment*, London: Routledge, 1989, at 312.

⁵⁶ Chowdhury & Islam, *supra* note 54, at 2.

⁵⁷ Source: CIA Country Factbook.

⁵⁸ *Id.*, at 3.

⁵⁹ Bradford Jr., *supra* note 4.

⁶⁰ Guillén, *supra* note 4.

⁶¹ See for example L. Turner & N. McMullen (eds.), *The newly industrialized countries: Trade and adjustment*, London: George Allen & Unwin, 1982.

⁶² See for example B. Balassa, *The newly industrializing countries after the oil crisis*, World Bank Staff Working Papers, No. 437.

of manufacturing over GDP.⁶³ Economic development can also be assessed from a qualitative standpoint, so the definition of a NIC has increasingly hinged on measurements of income equality and human development.⁶⁴ Accordingly, a seemingly popular categorization would treat as NICs only Brazil, Mexico, South Africa, China, India, Malaysia, Philippines, Thailand and Turkey,⁶⁵ and refer to the archetypical East Asian tigers of Hong Kong, South Korea, Singapore and Taiwan as “developed” instead.⁶⁶

2.2 *The flawed developing-developed countries dichotomy*

FDI refers to cross-border investments made with the objective of establishing a lasting interest in an entity that is resident in a market other than the investor’s home market.⁶⁷ The investment may consist of equity capital,⁶⁸ reinvested earnings,⁶⁹ and other capital contributions.⁷⁰ As a source of both technology and capital, Maskus explains that FDI is not strictly related to finance alone.⁷¹ While the capital for financing FDI may come from the host country or from global financial markets, it may also be raised on the local capital markets of the recipient nation. For that matter, there are two means of raising capital. The first is on the local market as commonly is the case for financing horizontal investments among industrialized nations.⁷² OECD countries, in fact, attract the bulk of the inflows.⁷³ China noticeably has grown in importance and has been a top destination in recent years, it accounting for about 10% of global net inflows in 2002.⁷⁴ The second and the focal point of this paper along with more common development economics framework, is by rising of external financing more commonly characterizes FDI in emerging countries.⁷⁵ On the latter account, it is assumed that MNEs must enjoy some efficiency advantages, meaning that they bring potential gains to host countries. A convenient framework to illustrate those advantages is Dunning’s ownership-location-internalization (OLI) paradigm.⁷⁶ Under the OLI

⁶³ *Id.*

⁶⁴ Chowdhury & Islam, *supra* note 54, at 3.

⁶⁵ See Guillén, *supra* note 4; Waugh, *supra* note 4; and Mankiw, *supra* note 4.

⁶⁶ See, Pawel Bozyk, *Newly Industrialized Countries, Globalization and the Transformation of Foreign Economic Policy*, Ashgate Publishing, Ltd, 164, 2006. In this paper we are concerned with the implications of post-WWII industrialization for assessing a policy interpretative rule for TRIPS, so coming up with a cohesive list of countries that can be treated as NICs is not fundamental and we will not attempt to do that. For present purposes, it suffices to say that the list of NICs encompasses the nine core countries of Brazil, Mexico, South Africa, China, India, Malaysia, Philippines, Thailand and Turkey. The four East Asian “tigers” will generally be dealt with as being NICs, although some of the claims presented here that are said to generally apply to NICs might not fit well these latter countries that are more advanced in their transition towards becoming fully “developed”. Because we care more for economic substance than for historical taxonomies, Japan will not be treated as a NIC. Some of the claims of this paper might incidentally apply to other developing countries such as Egypt, Indonesia, Jordan, Pakistan, and Russia that are in some literature treated as NICs, but we make empirical of theoretical assessment thereof.

⁶⁷ See, for a detailed definition of direct investment and related terms, OECD (2006b), *International Investment Perspectives: 2006*, Paris, Box 1.1, at 20 (“hereinafter, OECD 2006”).

⁶⁸ See, OECD 2006, *Id.*; *Industrial Evolution in Developing Countries: Micro Patterns of Turnover, Productivity, and Market Structure* 9, 84-89, 202, 263, 287, 315 (Mark Roberts & James Tybout eds. 1996), at 185.

⁶⁹ *Id.*

⁷⁰ *Id.*

⁷¹ See Maskus, *The Role of IP*, *supra* note 1, at 120 & Fn. 61, referring to Markusen, *supra* note 41, 169, at 174-75.

⁷² See Caves, *supra* note 41, at 65-71.

⁷³ See, World Bank, *World Development Indicators*, on-line edition (last reviewed on May 22, 2008).

⁷⁴ *Id.* See also on China, *High standards of IP protection in MUFTA attracts FDI* (2003), at: http://www.bilaterals.org/article.php3?id_article=7317 (last reviewed on May 22, 2008).

⁷⁵ See James R. Markusen et al., *International Trade: Theory and Evidence*, McGraw-Hill, Boston (1995), at 105, 181-86, 394-95. See, Maskus, *The Role of IP*, *supra* note 1, at 110, 120 & Fn. 64 referring to *Industrial Evolution in Developing Countries: Micro Patterns of Turnover, Productivity, and Market Structure* (Mark Roberts & James Tybout eds., 1996), at 185.

⁷⁶ See John H. Dunning, *International Production and the Multinational Enterprise* 110, 113 (1981).

paradigm, MNEs are characterized by some ownership advantage. Their main advantages derive from intangible assets upon their financial incentives, i.e., patents, trade secrets or trademarks.⁷⁷

Emphasizing the promotion of FDI and enhanced R&D, and according to that rationale, policy and theory alike referred basically to the dichotomy between developed and developing countries, ignoring NICs special characteristics concerning intellectual property policies.⁷⁸ In this sense, FDI is also the act of establishing or acquiring a foreign subsidiary over which the investing firm has substantial management control.⁷⁹

The flawed comparison ignores, therefore the incoherency between FDI flows between developing countries and NICs. Comparing developing countries to NICs at large, however, shows a substantive discrepancy. In the 1990s, China's share of U.S. FDI tripled and investment stock in Hong Kong doubled. Mexico's share also rose sharply, which likely is partly a result of NAFTA. In contrast, Africa experienced an absolute decline in investment stock over the period, indicating a sizable disinvestment, with its share falling from 2.6% to 0.9%. This uneven development was particularly acute in the 1980s.⁸⁰ In that decade, a total of fifteen countries received 80% of all FDI inflows to the developing areas.⁸¹ These flows were highly concentrated within regions as well. For example other NICs, i.e., Singapore, China, Hong Kong, Malaysia, Indonesia, Korea, Taiwan, and Thailand absorbed more than 90% of investments in Asian developing countries over the decade.⁸²

Cooter & Schaefer question the notion that industrial policies can spring growth based on FDI in poor countries. They posit that growth springs from having an adequate and predictable legal framework, particularly stable contract and property law. Thus, in high-income countries, development economics argue that cost minimization requires less precise legal norms, as within patent law, whose interpretation requires policy considerations and complex decision-making by judges, civil servants and citizens.⁸³

Rich and poor countries strike a different balance between use and creation. Rich countries have more educated people, well-equipped laboratories, and superior universities, so rich countries favor creators over users. Thus rich countries tend to favor strong and effective intellectual property rights.⁸⁴ As Cooter & Schaefer argue, conversely, poor countries have fewer creators and more users, so poor countries favor users over creators. Poor countries may do better by copying from rich countries instead of creating for themselves.⁶¹ Thus many Latin American countries historically refused to recognize pharmaceutical patents, and so did India until pressured to change while joining the World

⁷⁷ Id.

⁷⁸ For official surveys, see: WIPO, 1985, *supra* note 2, and UNCTAD, 1974, *supra* note 2. For theoretical and empirical studies, see, also, Grundmann, *supra* note 11; Katz, *supra* note 11; Greer, *supra* note 11; Vaitos, *supra* note 11. But see, F. M. Scherer, *Industrial Market Structure and Economic Performance*, Houghton Mifflin: Boston (1980). But see Chow, *supra* note 15, at 187 (stressing China's ability to attract foreign direct investment despite weak intellectual property rights).

⁷⁹ See, Caves, *supra* note 41, at 1. Firms that engage in FDI operate in more than one country and are MNEs. The location of the firm headquarters is called the home or source country, while the location of the subsidiary is called the host or recipient country. See Markusen et al., *supra* note 75, at 4.

⁸⁰ See, Hooshang Amirahmadi & Weiping Wu, *Foreign Direct Investment in Developing Countries*, 28 J. Developing Areas 167, 168 (1994).

⁸¹ See, Hooshang & Wu, *supra* note 80, at 173.

⁸² Id.

⁸³ See, e.g., Schaefer, *supra* note 3, at 113, 115 & Fn. 2, referring to Bernard S. Black, Reiner Kraakman, *Corporate Law from the Scratch*, in Roman Frydman, Cheryl Gray and Andrzej Rapczynski, 1 *Corporate Governance in Central Europe and Russia: Insiders and the State*, 247, 257 (Central European University, 1996)).

⁸⁴ Cooter & Schaefer, *supra* note 1, at 55.

Trade Organization. The citizens of many Latin American countries and India have enjoyed cheap medical drugs that are invented abroad and manufactured locally.

This flawed dichotomy for NICs is based on the following criteria. First, the parties have less to dispute about patents which make dispute resolution and the regulatory process quicker and cheaper. Second, when few facts control the patent law's application, disguising bribes to officials is harder, so corruption is riskier. Third, precise patent laws demand less sophistication and education from the legal officials who apply the law, as follows.⁸⁵

2.2.1 *The lack of regulatory information*

First is the lack of information for the application of strict rules. The development economics argument then goes on suggesting that applying precise patent rules requires little information.⁸⁶ In low-income countries we are told, there are reasons for having a more rule-based legal system, which allows for relatively simple decisions by the judiciary and the civil service.⁸⁷ Low-income countries may be able to minimize the sum total of these costs through rulemaking, even if this results in higher costs of drafting and a loss of flexibility in adjudication.⁸⁸ Schäfer gives one good example of the new Russian corporation law, where a group of American experts explicitly took into consideration the low qualification of judges in the former Soviet Union. To curb opportunistic behavior of managers and owners, Schäfer describes, the American experts drafted a corporate law with precise and self-enforcing mandatory rules for the protection of outside investors, which do not require much expertise for judges or regulators to apply.⁸⁹

It thus appears that the notion that the state should play the role of an engine of growth in the process of development came under relentless attack from the supporters of the EOI strategy. Indeed, Little regards this phenomenon as the resurgence of neoclassical economists in development economics.⁹⁰ As applied to the role of the state in economic development neoclassical economists manifests itself in the specific form of neoclassical political economy.⁹¹

The essence of neoclassical political economy can perhaps be best exemplified by focusing on a particular example. Suppose that the central policy makers of a hypothetical low-income country are able to establish that there is underinvestment by the private sector in a socially desirable industry, such as within the pharmaceutical industry. It then decides to target this industry as a priority investment area and tries to achieve this aim through a complex array of policy instruments. Thus, it offers subsidies credit, restrains competing imports through a combination of tariffs and quotas, regulates entry to the industry by issuing licenses to a limited of firms and provides a captive market for the products of the industry through its procurement policies.⁹² The net effect of these policy interventions is to create monopoly rents or scarcity premiums. The presence of such rents can induce responses among private sector participants that go beyond the public interest objectives of

⁸⁵ *Id.*, at 11.

⁸⁶ *Id.*, at 121; Oddi, *supra* note 14, at 846.

⁸⁷ Cooter & Schaefer, *supra* note 1, at 121.

⁸⁸ *Id.*

⁸⁹ *Id.* See, also, A. Goudie and D. Stavage, *Corruption: The Issues: Research Programme on Political Economy and Development in Africa*, Technical Paper No. 122, OECD, Paris (1997).

⁹⁰ See, I. M. D. Little, *Economic Development: Theory, Policy and International Relations*, New York: Basic Books (1982).

⁹¹ See, T. Srinivasan, Neoclassical Political Economy, the State and Economic Development, *Asian Development Review*, 3(2): 38-58 (1985).

⁹² Chowdhury & Islam, *supra* note 54, at 45.

the policy makers. Thus the private sector could form Olsonian distributional coalitions and engage in lobbying activities designed to capture the rents.⁹³

Development economics further upholds that precise standards demand less sophistication and education from the legal officials who apply the law. Officials in poor countries usually have less education and narrower experience than officials in rich countries.⁹⁴ In addition, there may be an inefficient allocation of trained technical personnel, probably already in short supply in a developing country, for the administration of a patent-granting agency.⁹⁵ However, in order to use emerging technologies as a tool for economic development, developing countries have to increase the skills of their workforces.⁹⁶ Developing countries can learn from developed countries about teaching and training programs to inspire creativity in their scientists and researchers.⁹⁷ Strong patent protection prepares scientists and researchers for developmental activities. They can gain economic benefits by licensing their patented invention or by developing and marketing their patented products on their own.

Thus, the least-developed countries might not benefit from patent protection, simply because the cost of reforming or creating a new patent-protection system outweighs the potential benefits.⁹⁸ For example, in Bangladesh, a more pressing concern is to reduce unemployment and provide education to about 124.8 million people, only 40.1% of whom are literate.⁹⁹ In contrast, NIC economies tend to be more dynamic, and their levels of human development tend to be better. To illustrate, the lowest level of illiteracy amongst NICs is South Africa's 17.6%; although somewhat high in absolute terms, this is the second lowest in Sub-Saharan Africa.¹⁰⁰ In Brazil, the illiteracy rate is 11.8%.¹⁰¹

2.2.2 *The cost of bribery and corruption*

Second is the flawed comparison between developing-developed countries vis-a-vis the presence of corruptive institutions which curtail the advantage of decentralized regulation through discretionary standards. The net effect of policies revolving around the problem of underinvestment may lead in developing countries to the creation of monopoly rents or scarcity premiums. These rent-seeking activities – which can range from lobbying within legal limits to outright bribery and corruption – are unproductive in developing countries in the sense that they yield income or profits to private interests but do not produce goods or services that add to societal output.¹⁰²

New political economy pays insufficient attention to the fact that there is a range of institutional arrangements for achieving relative state autonomy.¹⁰³ Failure to emphasize the functional equivalence of institutional arrangements for achieving state autonomy leads new

⁹³ Id. (referring to Mancur Olson, *The Rise and Decline of Nations: Economic Growth, Stagflation and Social Rigidities*, New Haven: Yale University Press, 1982).

⁹⁴ Cooter & Schaefer, *supra* note 1, at 121.

⁹⁵ Oddi, *supra* note 14, at 846.

⁹⁶ Imam, at 380.

⁹⁷ Imam, at 380.

⁹⁸ Carlos M. Correa & Sisule F. Musungu, *The WIPO Patent Agenda: The Risks for Developing Countries* 26 (S. Ctr., Trade-Related Agenda, Development and Equity (T.R.A.D.E.) Working Papers, Paper No. 12, Nov. 2002).

⁹⁹ World Intellectual Prop. Org., *Intellectual Property Profile of the Least Developed Countries* 11 (2001).

¹⁰⁰ Source: United Nations Development Programme Report 2007/2008.

¹⁰¹ Id.

¹⁰² Chowdhury & Islam, *supra* note 54, at 45.

¹⁰³ See, Ragowski, 1987; Haggard and Moon, 1990.

political economy into the trap of implying that authoritarianism within developing countries is necessary for economic growth.¹⁰⁴

When few facts control the patent law's application, disguising bribes to officials is harder, so corruption is riskier.¹⁰⁵ In countries with weak legal institutions, economic cooperation usually involves people with personal ties, especially relatives and friends. In the example from Jakarta, the businessman gathers everyone needed to produce a particular product into a single factory, where his relatives can monitor the other employees.¹⁰⁶

MNEs, this overgeneralization for NICs upholds, are less likely to invest in countries with risks of expropriation, limited and variable profit repatriation rules, terrorism and violence, corruption, bureaucracy and red tape, ineffective legal systems, and considerable income inequality.¹⁰⁷ Thus, both macroeconomic certainty and political stability are important to MNEs. How significant this factor is in relation to others depends on the type and duration of investment. One related finding worth mentioning is that countries that repress labor organization rights, in the hope that a stable, quiescent, and low-wage labor force will attract FDI, do not receive more investment as a result.¹⁰⁸ Apparently, it is far less important to provide firms with artificial advantages and far more important to develop a stable and transparent set of rules for business operation.¹⁰⁹

2.2.3 Ineffective institutions for enforcing property and contract laws

The third and the most fundamental defect in law that retards economic growth in poor countries, development economists flatly uphold, is ineffective property law, followed by ineffective contract law, and ending with ineffective business law.¹¹⁰ Inadequate institutions to enforce property and contract law, it is argued, is the most pervasive and fundamental defect in the legal framework of poor countries that impede growth.¹¹¹

At the lowest level, ineffective protection of property rights devastates an economy, as for example, happened in the 1990s with the case of central African Diamonds, where producing and transporting diamonds in recent years occurred in conditions that approached anarchy.¹¹² The example of Indonesian textiles is a further illustration of how weak contract law keeps trade too local and organizations too small.¹¹³ This form of ineffective protection also has been noticed with lack of contracts, as in the case of family run businesses in poor countries.¹¹⁴ Development economics further upholds that parties have less to dispute about, which makes dispute resolution quicker and cheaper. Previous chapters explained that many poor countries need quicker and cheaper dispute resolution in order to make property and contract laws effective.¹¹⁵

¹⁰⁴ Chowdhury & Islam, *supra* note 54, at 46.

¹⁰⁵ Cooter & Schaefer, *supra* note 1, at 121.

¹⁰⁶ Cooter & Schaefer, *supra* note 1, at 12.

¹⁰⁷ See The World Bank, *Integration with the Global Economy*, in *World Development Report* (1991), at 94-95, 128-32; Maskus, *The Role of IP*, *supra* note 1, at 143.

¹⁰⁸ See, See Organization for Economic Cooperation and Development, *Trade, Employment, and Labour Standards* 112-21 (1996); Maskus, *The Role of IP*, *supra* note 1, at 143.

¹⁰⁹ Maskus, *The Role of IP*, *supra* note 1, at 143.

¹¹⁰ Cooter & Schaefer, *supra* note 1, at 11.

¹¹¹ *Id.*, at 12, 20.

¹¹² *Id.*, at 11.

¹¹³ *Id.* at 11-12.

¹¹⁴ *Id.*

¹¹⁵ *Id.* at 121.

3. NICs patent bargain theory

3.1 Overview

In voluntary exchanges a bargaining problem arises because the parties have to negotiate ex ante the allocation of the cooperative surplus that can be generated by their agreement.¹¹⁶ Such negotiations tend to be particularly difficult where there are no clear price standards that the parties can use as benchmarks for their exchanges. To reach an agreement, each party has to receive at least its threat value¹¹⁷ (also named “reservation value”, “disagreement value”, or “outside option”, which equals the payoff that the party can obtain on its own without cooperation from others).¹¹⁸ Typically, threat values are not disclosed during the negotiation, as in most cases such disclosure leads to less appealing outcomes. This means that in negotiations the players typically behave strategically, that is, they move sequentially making alternating offers that depend, amongst other things, on their expectations of the other players’ reactions.

Unlike smaller developing countries, NICs can develop a capacity for producing generics, thus raising their threat values. A robust capacity for the local production of generics can thus be strategically used as a negotiation weapon designed to signal a credible threat of compulsory license.

The standard prescription of enhanced IPRs suggests that by undermining the whole intellectual property system in Brazil, to use this case study, the issuance of compulsory licenses by the Brazilian government also undermines domestic R&D investments. While the counterfactual exercise of estimating the additional R&D that would have been made were it not for the issuance of compulsory license is a notoriously difficult one, the standard prescription is not completely unwarranted. Indeed, as illustrated by Table 1, countries with lower levels of IPRs protection on pharmaceuticals such as Brazil and Italy may end up having a lower proportion of their overall private R&D invested in pharmaceuticals.

Table 1: Private Investments in R&D in Selected Countries as a Proportion of Overall Private R&D Investments.

Country	Year	Instruments (1)	Electronics (2)	Pharmaceuticals (3)	Office and industry machinery computer (4)
Germany	2005	6,8	8,5	8,8	1,4
Australia	2003	4,6	3,1	3,7	0,7
Brazil	2005	2,5	8,4	4,4	2,6
Canada	2006	1,5	16,6	8,7	2,4
Korea	2005	1,0	47,6	1,9	1,6
Spain	2004	2,1	2,8	12,1	1,1
USA	2003	8,7	11,0	7,2	3,8
France	2003	6,6	12,8	13,8	1,0
Italy	2006	4,9	11,0	5,7	0,5
Japan (2003)	2005	4,6	13,1	8,2	12,7
Mexico	2005	0,1	0,7	6,7	2,3
Portugal	2005	0,5	16,7	...	0,4

¹¹⁶ See, e.g., Robert D. Cooter & Thomas Ulen, *Law & Economics*, The Addison-Wesley series in economics, 4th ed., at 78-80.

¹¹⁷ Robert D. Cooter, *The Strategic Constitution*, Princeton, Princeton University Press (2000), at 274.

¹¹⁸ Leigh L. Thompson, *The mind and heart of the negotiator*, 2nd ed, New Jersey (NY): Prentice Hall; 2001.

UK	2005	3,2	5,9	24,7	0,5
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Source: Brazilian Minister of Science and Technology

This assessment can easily lead to the suggestion that the absence of a strong patent regime curtails the development of a Brazilian innovative pharma industry. But claims of this kind must be approached with care. In fact, the low levels of technological innovation within Brazilian pharma replicate the low levels of technological innovation that can be found in the whole Brazilian economy, and over time such levels of technological innovation have given limited responses to changes in the strictness of the country's IP legislation in pharmaceuticals.

The scope of the Brazilian IPRs regulatory narration is circular, dating before World-War II. At that time, Brazilian IPRs legislation granted patent protection for pharmaceutical products and processes in Brazil. Such protection reflected a longstanding legal tradition in Brazil of offering patent protection for inventions,¹¹⁹ a tradition that however had little practical implications in a pre-industrialized country.¹²⁰ In 1945, the law was amended to rule out the protection of inventions related to medicines, foodstuffs, materials and substances obtained by chemical means or processes.¹²¹ A restriction of IPRs in technology-intensive industries suited well the inward-oriented, state-led economic model of import substitution industrialization (ISI) that prevailed in Brazil – indeed, in basically every Latin American country – in the post-WW II era. As so, patenting in the pharmaceutical sector was eliminated altogether in 1969, when the government amended the Brazilian Industrial Property Code.

It was not until the mid-1990s that the Brazilian IP law reinstated patent protection to inventions related to medicines and other substances obtained by chemical means and processes. As a signatory of the TRIPS agreement in 1994, Brazil viewed itself under the need to reform its IPRs laws. Pursuant to article 65 of TRIPS, Brazil could wait until January of 2005 to extent protection to pharmaceutical products and processes, but due to intense commercial pressure from the United States¹²² patent protection was set forth to start much sooner, as of January of 1997.¹²³

The new Brazilian IP law was embedded in a broad context of structural changes that encompassed, but were not limited to, the pharmaceutical sector. Starting with Chile in the early 1970's, and continuing with Argentina and Mexico in the 1980's and Brazil in the 1990's, most countries in Latin America and the Caribbean have opened up their economies to foreign competition, de-regulated markets and privatized economic activities in search for faster productivity growth, better international competitiveness and more equity in the

¹¹⁹ Oliveira et al., Brazilian Intellectual Property Legislation, in Intellectual Property in the Context of the WTO TRIPS Agreement: Challenges for Public Health, Jorge A. Z. Bermudez and Maria Auxiliadora Oliveira (eds.), WHO/PAHO Collaborating Center for Pharmaceutical Policies National School of Public Health Sergio Arouca Oswaldo Cruz Foundation, Rio de Janeiro (2004) (hereinafter, "Brazilian IP Legislation"), pp. 153-162, at 153 (noting that Brazil was the fourth country in the world and the first in Latin America to extend patent protection to an invention's novelty and use; previously to that Brazil was a Portuguese colony and it was Portugal's policy to exploit Brazil's natural resources and block most innovations in the colony). Brazil was also one of the 16 countries that signed the Paris Convention, which established the three pillars of the current patent system, namely independence of patents and trademarks, equal treatment of nationals and foreigners and priority rights.

¹²⁰ P. Ben-Ami, Manual de Propriedade Industrial. São Paulo: Promocet, 1983.

¹²¹ Oliveira et al., supra note 119, at 154.

¹²² For example, the US instated trade sanctions on 100% of all Brazilian exports in other sectors, such as paper, chemical and electrical products until Brazil drafted industrial property legislation with the required changes. See M. H. Tachinardi, A Guerra das Patentes. Rio de Janeiro: Editora Paz e Terra, 1993.

¹²³ Federal Law No. 9,279 of May 14, 1996 (hereinafter, "Brazilian IP Law").

distribution of the benefits of technical progress. With greater or lesser emphasis, all of them proceeded into the liberalization of trade and the de-regulation and privatization of economic activities in the 1980's and 1990's,¹²⁴ phasing out the era of 'inward-oriented', 'state-led' growth policies.

The liberalizing reforms that swept Brazil in the 1990s have been less positive than a priori expected.¹²⁵ On one side, they were successful in providing foundations for a solid macroeconomic management and the eradication of chronic inflation, and a highly positive development of these facts happened in April of 2008, when Standard & Poor's, a credit rating agency, upgraded Brazil's long-term foreign currency sovereign debt to investment-grade.¹²⁶ Yet Brazil's R&D intensity remains comparatively low by OECD standards (Table 2) and also overly reliant on government spending.¹²⁷ That is, as is common in countries with relatively low R&D intensity. As so, opening up to foreign competition, de-regulating markets, and privatizing economic activities has not been a sufficient condition for the country to attain a more vibrant development of domestic technological capabilities, with negative impacts on the country's ability to attain faster productivity growth and more international competitiveness.¹²⁸ In pharmaceuticals, this state of affairs lead to a concentration of production in stages of lower added value and to a strong increase in imports which largely replaced local production.¹²⁹

Table 2:¹³⁰ R&D Intensity (in % of GDP)

Note: The dots identify the R&D intensity levels in 1995)

¹²⁴ Jorge Katz, The limits of the prevailing orthodoxy: technology and education as restriction to productivity growth and international competitiveness in Latin America. In: DRUID SUMMER CONFERENCE 2004, Copenhagen ("It can be said without hesitation that contemporary Latin American capitalism is indeed a very different animal from the one it was not so long ago, during the years of 'inward-oriented' industrialization - 1940-1980").

¹²⁵ See A. O. Krueger, The political economy of the rent-seeking, *American Economic Review*, n.64, p.291-303, 1974; and J. Williamson, Comments on macroeconomic policy and growth, *The World Bank Conference of Development Economics*. Washington, D.C.: The World Bank, 1990.

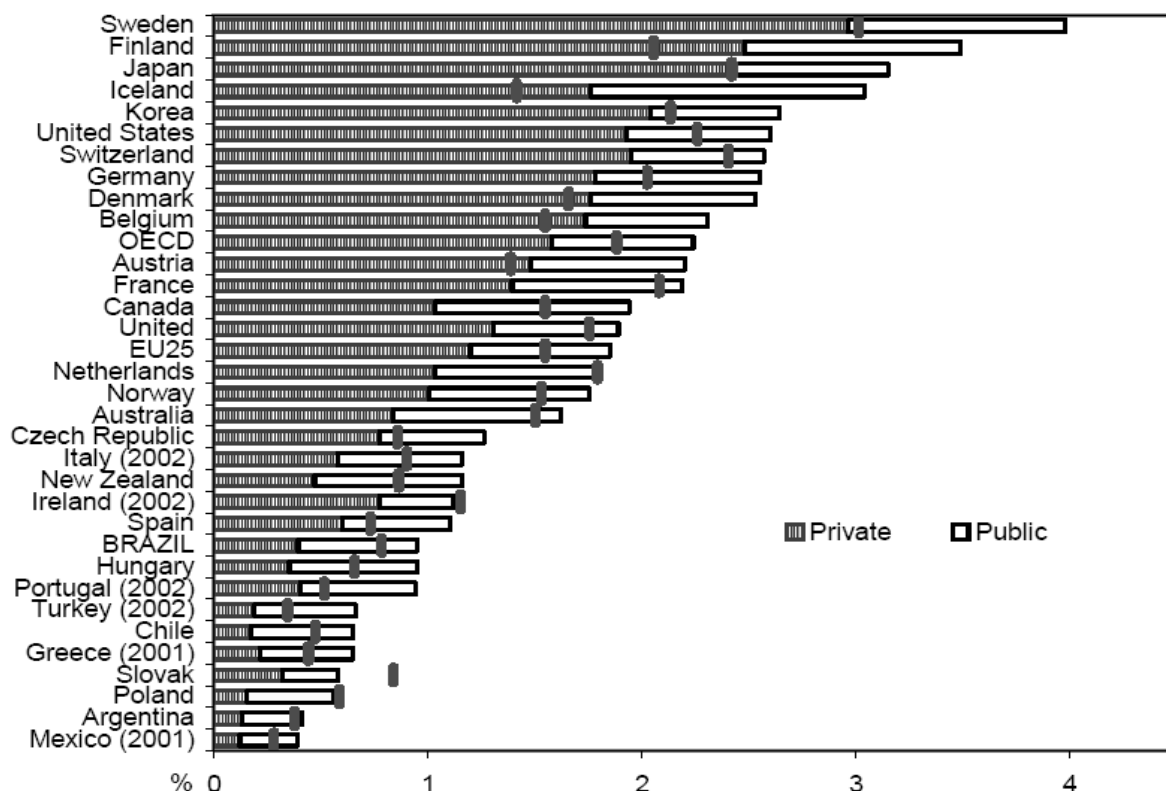
¹²⁶ Bloomberg.com, Brazilian Debt Raised to Investment Grade by S&P (Update4), April 30, 2008.

¹²⁷ Carlos H. de B. Cruz and Luiz de Mello, Boosting innovation performance in Brazil, *OECD Economics Department Working paper No. 532*, at 7 (noting that About 60% of R&D activity is carried out and financed by the government). See, also, comparative data showing Brazil lagging approximately two to four times behind all OECD countries, see Table 1, at WIPO 2006, cited in Alan Wright, *Innovation in Brazil: Public Policies and Business Strategies*, Woodrow Wilson International Center for Scholars, March/2008.

¹²⁸ Id., at 7 (noting that About 60% of R&D activity is carried out and financed by the government).

¹²⁹ Graziela F. Zucoloto & Rudinei Toneto Júnior, Esforço tecnológico da indústria de transformação brasileira: Uma comparação com países selecionados, *R. Econ. contemp.*, Rio de Janeiro, 9(2): 337-365 (May/Aug 2005); Luciana Xavier de Lemos Capanema and Pedro Lins Palmeira Filho, Indústria Farmacêutica Brasileira: Reflexões sobre sua Estrutura e Potencial de Investimentos, in *Perspectivas do Investimento 2007/2010*, Ernani T. Torres Filho and Fernando P. Puga (eds.), Rio de Janeiro: BNDES, 2007, at 163-206.

¹³⁰ See, Ministry of Science and Technology, Conicyt (for Chile), Ricyt (for Argentina and Mexico), and OECD (cited in Cruz & Mello, supra note 127).



Naturally, the liberalizing reforms of the mid-1990s had different impacts in each sector of the Brazilian economy. To illustrate, in the sectors of wooden products, pulp and paper, oil, and airplanes, Brazilian companies' current investments in R&D as a proportion of total production are respectively 116.2%, 106.7%, 205.5%, and 100.5% of the averages of OECD countries (Brazil is not a member of OECD). However, most sectors of the Brazilian economy have been found to severely underperform in comparison with OECD countries. For instance, in chemicals (excluding pharma) the ratio of R&D as a proportion of total production was only 33.3% of the same ratio prevailing in OECD countries. In electronics, it was 22.8%, and informatics 31.2%.

Most importantly, pharmaceuticals was identified as the exact industry where Brazilian investments in R&D as a proportion of total production are lowest in comparison to the average of the same ratio in OECD countries, a mere 9.3% (Table 3). Naturally, in comparison with the top-tier of the OECD countries this ratio went as low as 6.7%.¹³¹

¹³¹ Zucoloto & Toneto Júnior, *supra* note 129

Table 3:¹³² Brazilian Expenditures in R&D as a Proportion of Total Production Value (per Industry) (as of 2000)

Industry	Brazil (%)	OECD countries				Brazil/OECD Average (%)
		Average (%)	1. High R&D effort (%)	2. Medium R&D Effort (%)	3. Low R&D effort (%)	
Process Industry (globally)	0.67	1.82	3.14	1.75	0.74	37.1
Process Industry – Oil excluded	0.59	1.82	3.14	1.75	0.74	32.7
Food, Beverages and Tobacco (1)	0.24	0.31	0.46	0.41	0.14	78.1
Textile, leather and footwear	0.26	0.42	0.63	0.34	0.32	61.0
Wooden products (2)	0.20	0.17	0.32	0.11	0.08	116.2
Pulp and paper (3)	0.36	0.33	0.61	0.25	0.19	106.7
Pulp, paper and publishing (4)	0.23	0.27	0.50	0.18	0.12	84.7
Oil refining and others (5)	0.93	0.45	0.65	0.35	0.32	205.5
Chemicals	0.70	3.96	6.08	4.92	1.32	17.7
- Chemicals excluding pharmaceuticals (6)	0.66	1.97	2.92	2.32	0.73	33.3
- Pharmaceuticals (6)	0.93	10.03	14.02	12.05	4.37	9.3
Rubber and plastic	0.38	1.00	1.63	0.91	0.54	38.0
Non-metallic mineral products (4)	0.29	0.61	1.05	0.49	0.28	47.3
Basic metallurgy (7)	0.40	0.70	0.99	0.74	0.41	57.9
- Steel products (8)	0.44	0.65	0.96	0.72	0.28	67.8
- Non-ferrous metals and smelting (8)	0.33	0.70	1.07	0.40	0.52	47.4
Metal products	0.35	0.46	0.70	0.40	0.29	76.3
Machinery and equipment (4)	1.20	1.98	2.59	2.19	1.16	60.3
Informatics	1.33	4.28	5.57	5.55	2.08	31.2
Electrical materials	1.82	2.23	3.75	2.10	1.04	81.6
Electronic/telecommunication materials (9)	1.73	7.57	8.03	7.04	7.54	22.8
Instrumentation	1.85	4.94	8.70	4.64	1.44	37.4
Automobile	0.99	2.23	3.64	1.67	1.51	44.4
Other equipment for transportation	2.80	4.17	6.72	2.78	3.18	67.0
- Aircrafts (11)	8.00	7.96	9.73	5.68	8.56	100.5
Furniture and miscellaneous industries (12)	0.33	0.51	0.80	0.51	0.21	65.9

Does not include (1) France and Sweden, (2) Norway and UK, (3) Australia, Denmark, USA, Japan, Norway, and UK, (4) Canada, (5) Canada, Denmark, Ireland and Czech Republic, (6) Australia and Poland, (7) Australia, (8) Australia, Netherlands, and Poland, (9) Netherlands, (10) Canada and Netherlands, (11) Ireland and Poland, (12) Australia and Norway.

The most recent data available¹³³ suggests that the extension of patent protection to pharmaceuticals did not to cause relevant impacts in the amounts of private investments in R&D in the pharmaceuticals industry in Brazil. In 1998, according to the Brazilian Institute of Geography and Statistics (IBGE), expenditures in R&D by private pharmaceuticals companies (controlled by Brazilian or foreign capital) corresponded to only 0.53% of total sales.¹³⁴ In the year 2000, the percentage of expenditures in R&D increased reaching to 0.83% of total sales. But what was first perceived as a positive trend soon came to be a wreck: in the year 2003, expenditures fell again reaching a figure as low as 0.5%, which is the same level prevailing before the enactment of the new IP law.¹³⁵ In contrast, current

¹³² Id.

¹³³ As informed by the Ministry of Health, the Ministry of Science and Technology, and a number of other governmental bodies, the most recent data available on R&D as a proportion of total sales dates back to the year 2003. The pharmaceuticals industry has only released information on the amounts invested in clinical research.

¹³⁴ Valéria Delgado Bastos, *Inovação Farmacêutica: Padrão setorial e perspectivas para o caso brasileiro*, BNDES Setorial, Rio de Janeiro, n. 22, p. 271-296, set. 2005, at. 290.

¹³⁵ The Ministry of Health informs that it does not monitor R&D investments in pharma and as so it was not possible to find more recent data on this topic.

OECD standards of R&D investments in pharmaceuticals correspond to over 14% of total sales¹³⁶ (being 21% of total sales in the United States).¹³⁷

This part follows hereafter in two stages. First, the more descriptive part of describing the bargaining game around TRIPS based on its unique two-step procession. It begins with what may comfortably be referred to as the '*First Order Bargain*,' in which NICs practically circumvent a number of regulatory "loopholes" in order to minimize potential negative effects of patent protection on access to medicines. Consecutively is the second step in the bargain process, based in a '*Second Order Bargain*' or second round of negotiations between NICs and developed countries that aim at influencing lawmaking in these countries.

In the second stage of this Part, a normative set of considerations is then introduced, arguing how in fact, NICs may potentially become better off by threatening to issue compulsory licensing, or otherwise actually do so.

3.2 Patent compulsory licensing bargaining narration

One hundred and seventeen nations, including all NICs and thus Brazil, signed the TRIPS Agreement allowing intellectual property rights to be enforced by trade sanctions.¹³⁸ Although many of them had reservations about strengthening intellectual property rights, signing the TRIPS Agreement was a condition for participating in the WTO, which was then viewed as an essential component for them to take part in the international wave of trade and prosperity of a globalized world.¹³⁹ By situating the TRIPS Agreement within the framework of multilateral trade relations, the Agreement benefits from the increased incentive for nations to enforce intellectual property rights through the threat of trade sanctions.¹⁴⁰ The TRIPS Agreement envisages that the threat of trade sanctions will propel the forward motion of respect and protection of IPRs worldwide.

The negotiations and eventual execution of the TRIPS Agreement gave rise to a new set of negotiations over the delineation of the flexibilities and safeguards set forth under TRIPS articles 8 and 31. These negotiations encompassed not only decisions over the correct interpretation of the TRIPS agreement, but most importantly lobbying concerning the reception and incorporation of these flexibilities and safeguards into the intellectual property laws of each country. The issue rapidly became salient because developing countries were growing increasingly needy of a number of patent-protected drugs, particularly anti-retroviral

¹³⁶ Source: The pharmaceutical innovation platform: sustaining better health for patients worldwide. International Federation of Pharmaceutical Manufacturers Association (IFPMA), Oct. 2004 (also noting that in the period of 2000 – 2003, the IBGE found that the overall investments in innovative activities (which comprise internal R&D activities and also the purchase of foreign R&D, investments in machinery and equipment, investments in the marketing of new products, industrial projects and training) fell from 5.7% of sales income to 3.4%).

¹³⁷ A indústria farmacêutica no Brasil: Uma contribuição para as políticas públicas. Report prepared by the Brazilian Federation of Pharmaceutical Industry (FEBRAFARMA). Set/2006, at 18. See also Brazil: Investment Climate Assessment, Document of the World Bank, 2005 (suggesting that the mid-1990s reform did not deliver to Brazil what was expected in terms of international competitiveness, technological absorption and development of the Brazilian industry in general).

¹³⁸ George K. Foster, Opposing Forces in a Revolution in International Patent Protection: The U.S. and India in the Uruguay Round and its Aftermath, 3 UCLA J. Int'l. L. & For. Aff. 283, 283-84 (1998).

¹³⁹ John A. Harrelson, IV. Note, 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).

¹⁴⁰ As part of the GATT, violation of the TRIPs Agreement gives rise to the legitimate use of trade sanctions against the Contracting Party. While the TRIPs Agreement provides for dispute prevention and settlement, under the general framework of GATT a Contracting Party, after failure to resolve a dispute, may invoke trade sanctions against another Contracting Party who has acted inconsistently with its GATT obligations. See generally Final Act Embodying the Results of the Uruguay Round of the Multilateral Trade Negotiations, Apr. 15, 1994, Legal Instruments - Results of the Uruguay Round vol. 1, art. XXIII (1994), 33 I.L.M. 1125 (1994).

drugs (ARVs) designed to fight the HIV/AIDS epidemic, as famously has been the case in Brazil. Accordingly, the delineation – in fact, the negotiation – of the legal framework of the TRIPS flexibilities and safeguards (particularly vis-à-vis the possibility of issuing compulsory licenses and importing/reselling patented drugs without the consent of the patent holder) became a critical factor in determining the ability of developing countries to bargain for price reductions in their purchases of ARVs from developing countries. This legal framework dramatically affected threat costs – thus, payoffs as well – of developing countries willing to obtain cheaper ARVs from the patent holders.

3.2.1 First Order Bargain: Filling The “Loopholes” Within TRIPS

Although the TRIPS agreement appears to impose a U.S.-style patent regime on member states, there are a number of “loopholes”¹⁴¹ that give developing countries room to maneuver in order to minimize potential negative effects of patent protection on access to medicines.¹⁴² The TRIPS Agreement flexibilities and safeguards related to drug policy include setting standards for patentability which reflect public health concerns, legislative provision for compulsory licensing, exceptions to exclusive rights and other measures which promote competition, and the full use of the transitional period and legislative provision for parallel importation. Table 4 summarizes the most relevant provisions.

Table 4: Flexibilities and safeguards related to drug policy under TRIPS Agreement¹⁴³

Provisions	TRIPS Agreement Article	Definition
Transition period to adapt national legislation to the TRIPS Agreement	Art. 65 – Transitional arrangements / Art. 66 – Least developed countries	As of January 1995, WTO Member countries were granted the following deadlines to adapt their national intellectual property laws so as to become TRIPS-compliant: 1. Developed countries: 1 year until Jan/1996 2. Developing countries: 5 years until Jan/2000* 3. Least developed countries: 11 years until Jan/2006. * An additional 5-year period is granted for countries that upon signature of TRIPS have granted patents on fields of technology not protected before TRIPS.
Transition period to recognize patents in technological sectors not protected before the TRIPS Agreement	Art. 65.4	Developing countries have an additional 5 year period (until 2005) to recognize patents in the abovementioned sectors Note: The Ministerial Doha Declaration on TRIPS Agreement and Public Health (WTO, 2001) established in

¹⁴¹ Robert Weissman, A Long, Strange TRIPS: The Pharmaceutical Industry's 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, 1071-1072 (1996), at 1096.

¹⁴² See D. Penchansky & J. Thomas, The Concept of Access: Definition and Relationship to Consumer Satisfaction. Medical Care; 20 (2): 127-40, (1981) (explaining that the concept of access in health encompasses some distinct, although correlated, dimensions, which address the compatibility between the patient and the health care system: availability, accessibility, accommodation, affordability and acceptability).

¹⁴³ See, Jorge A. Z. Bermudez, et al., Intellectual Property in the Context of the WTO TRIPS Agreement: What is at Stake?, at 33. In Brazilian IP Legislation, supra note 119, pp. 23-62; Gabriela Costa Chaves & Maria Auxiliadora Oliveira, WTO TRIPS Agreement Implementation in Latin America and the Caribbean. In Brazilian IP Legislation, supra note 119, pp. 117-128, at 120. See also Carlos Correa, Intellectual Property Rights, the WTO and Developing Countries. The TRIPS Agreement and Policy Options. London and New York: ZED Books and Penang: Third World Network, 2000.

		paragraph 7 that Least Developed Countries could extend the transition period for pharmaceutical products and processes until Jan/2016
Parallel imports on exhaustion of rights at regional and/or international levels	Art. 6 – Exhaustion of rights	Parallel imports involve the import and resale in a country without the consent of the patent holder, of a patented product which was put on the market of the exporting country by the title holder or in another legitimate manner
Bolar Exception (<i>early working</i>)	Art. 30 – Exceptions to Rights Conferred	This exception allows a company to complete all the procedures and tests necessary to obtain market approval for a generic product, before the original patent expires
Compulsory Licensing	Art. 31 - Other Use Without Authorization of the Right Holder	Allows exploitation of a patented object without patent holder consent through government authorization
Experimental Use	Art. 30 – Exceptions to Rights Conferred	The patent should not prevent experimental use of the invention by third parties for scientific purposes or for commercial purposes that do not unreasonably conflict with a normal exploitation of the patent and that do not unreasonably prejudice the legitimate interests of the patent owner

Although TRIPS does not use the term "compulsory license," the language of Article 31 implies compulsory licensing.¹⁴⁴ Grounds explicitly mentioned in article 31 of TRIPS are national emergency, anti-competitive practices, public non-commercial use and dependent patents. Further grounds can be found in article 8(1), which allows members to 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. Furthermore article 8(2) permits members to take necessary measures to prevent the abuse of IPR by right holders and practices that unreasonably restrain trade or adversely affect the international transfer of technology.¹⁴⁵ Signatories of the TRIPS can also use these provisions to deny patentability to a drug and produce and distribute it non-commercially through a state-owned marketing board, quasi-state entity, single non-profit manufacturer, or system of non-profit manufacturers.¹⁴⁶

The transition period for patent protection in the pharmaceutical sector could be used so as to permit developing countries to build local industry.¹⁴⁷ India is a good example of a country that opted to utilize the full transition period to strengthen local technological capacity. This has enabled the development and consolidation of infrastructure for research and development as well as manufacturing capabilities, which has allowed India to conquer a greater international market share. One important result of this policy has been the ability to market medicines, such as those needed to treat HIV/AIDS. These generic versions are available at significantly lower prices than those offered by patent holding transnational

¹⁴⁴ The United States pharmaceutical industry lobbied against the TRIPs agreement, relying on the "slippery slope" argument, a legal fiction, believing that once one country was awarded a compulsory license, then all developing or least-developed countries would request licensing. See Frederick M. Abbott, Discontinuities in the Intellectual Property Regime: The TRIPS - Legality of Measures Taken to Address Public Health Crises: A Synopsis, 7 *Wid. L. Symp. J.* 71, 72, (2001) (discussing the "slippery slope" argument).

¹⁴⁵ Anselm Kamperman Sanders, The Development Agenda for Intellectual Property: Rational Human Policy or "Modern-Day Communism"?, lecture presented at Universiteit Maastricht (May 20, 2005), available at <http://www.unimaas.nl/bestand.asp?id=3827> (last reviewed on May 22, 2008), at 14

¹⁴⁶ Weissman, *supra* note 143, at 1100.

¹⁴⁷ J.A.Z. Bermudez, *Indústria farmacêutica, Estado e Sociedade. Crítica da Política Nacional de Medicamentos*. São Paulo: HUCITEC, 1995.

companies in other countries.¹⁴⁸ The parallel imports flexibility represents an important pro-competition tool to promote access to lower-cost medicines. This tool aims to take advantage of current differential pricing practices used in several countries. There is no violation of the TRIPS Agreement because the patent holder's right was already exhausted in the country where the product was originally commercialized at a lower price.¹⁴⁹

3.2.2 Second order bargain: delineation of local IPRs

The incorporation of TRIPS flexibilities and safeguards is not mandatory and has to be incorporated within each WTO member country internal legal framework. This sets the ground for a second round of negotiations between developing and developed countries and NICs that aim at influencing lawmaking in these countries. There should be mentioned seminal studies of Thorpe,¹⁵⁰ Keyla¹⁵¹ and Oliveira et al.,¹⁵² analyzing industrial property legislation of WTO Member States in Africa, Asia and Latin America and the Caribbean. These three studies examined the incorporation of the TRIPS Agreement provisions into national intellectual property legislation. The countries studied were: Argentina, Brazil, Mexico, the Andean Community (Bolivia, Colombia, Ecuador, Peru and Venezuela), Honduras, Panama, the Dominican Republic, India, Indonesia, Thailand, Sri Lanka, Member States of the African Intellectual Property Organization (Benin, Congo, Guinea, Nigeria, Burkina Faso, Ivory Coast, Equatorial Guinea, Mali, Chad, Central African Republic, Gabon, Mauritania, Togo) and Members of the African Regional Industrial Property Organization (Botswana, Lesotho, Somalia, Uganda, Gambia, Malawi, Sudan, Zambia, Ghana, Mozambique, Swaziland, Zimbabwe, Kenya, Sierra Leone, Tanzania). The results demonstrated that these countries did not fully incorporate all the TRIPS flexibilities and safeguards, which could enhance the bargain power of the governments of these countries in situations involving public interest.¹⁵³

a) Bargains over national law

Brazil is a good example of a country that - in spite of intense pressure from the United States¹⁵⁴ - has partly implemented a number of flexibilities and safeguards allowed under the TRIPS Agreement.¹⁵⁵ First and foremost, the Brazilian Intellectual Property Law of 1996 set

¹⁴⁸ C. Morrison, Intellectual Property Rights, the Free Trade Area of the Americas & Access to Medicines. Satellite Meeting on Financing Care in Latin America and the Caribbean: Options for Large Scale Programs. In: 2nd Forum on HIV/AIDS and STI of Latin America and the Caribbean, Havana, April of 2003.

¹⁴⁹ Bermudez et al., supra note 143, at 34.

¹⁵⁰ P. Thorpe, Study on the Implementation of the TRIPS Agreement by Developing Countries, Study Paper No 7. London: CIPR, 2001.

¹⁵¹ B. K. Keyla, Review of National Patent Legislations of India, Indonesia, Sri Lanka & Thailand. New Delhi: National Working Group on Patent Laws, 2003.

¹⁵² M. Oliveira, J. A. Z. Bermudez and G. Velasquez, Has the implementation of the TRIPS agreement in Latin America and the Caribbean produced intellectual property legislation that favors public health? Bull World Health Organ 2004; 82:815-21, 2004.

¹⁵³ Bermudez et al., supra note 143, at 46.

¹⁵⁴ Tachinardi, supra note 122.

¹⁵⁵ See also Thiru Balasubramaniam and Andrew Goldman, Selected Compulsory Licensing, Government Use, and Patent Exceptions Provisions in Various Countries, WIPO-Industrial Property Laws and Treaties, WIPO-Industrial Property Laws and Treaties, 2000, available at <http://www.cptech.org/ip/health/cl/examples2.html> (showing that currently not only developing but also a number of developed nations have compulsory licensing laws, including Germany and the United States) (last reviewed on May 22, 2008). See B. Zorina Khan, Intellectual Property and Economic Development: Lessons from American and European History, Study Paper 1a, Commission on Intellectual Property Rights, 2002, available at http://www.iprcommission.org/papers/pdfs/study_papers/sp1a_khan_study.pdf (showing that compulsory licensing is has been largely used by developing countries as a tool for economic development) (last reviewed on May 22, 2008).

forth a broad array of circumstances allowing the Brazilian government to compulsorily license a patent. The first is when the patent owner exercises his rights in an abusive manner or if he uses it to abuse economic power under the terms of an administrative or judicial decision.¹⁵⁶ The second is in case of failure to locally manufacture the subject matter of the patent (or failure to completely use the patented process) on the territory of Brazil within a few years after the patent is granted.¹⁵⁷ The third is in case the local sales do not satisfy the needs of the local market.¹⁵⁸ The fourth is where there is a dependency of one patent on another.¹⁵⁹ The last one arises in cases of national emergency or public interest.¹⁶⁰ Brazilian IP Law also recognized the principle of international exhaustion of rights,¹⁶¹ thus permitting parallel imports,¹⁶² pursuant to which Brazil can import protected inventions from any country after issuing a compulsory license, even if such invention is not under patent protection. On the other hand, it must also be recognized that pressure from developed countries has led Brazil to fail to implement certain TRIPS flexibilities. Chiefly among them, and in sharp contrast to India, Brazil did not make use of the ten-year transition period to become TRIPS compliant, and rushed to extend patents over pharma in its IP Law as soon as May of 1996.¹⁶³

b) The national-supra national legal deficit

In the past, there has been some controversy as to whether Brazilian IP Law would breach WTO agreements. Although the Brazilian intellectual property law was politically motivated by the design to permit the supplying of generic anti-retroviral AIDS drugs produced under threat of compulsory licenses, the law was worded in very broad terms – so broad that it would technically permit the compulsory license of any good regardless of its social importance. The United States were quick to pinpoint the general nature of the compulsory licensing provisions contained in the Brazilian IP Law and the USTR filed a complaint over the Brazil's Intellectual Property Law in the WTO Dispute Settlement Body in January of 2001.¹⁶⁴ The United States sustained¹⁶⁵ that the permission for compulsory licenses to be

¹⁵⁶ Brazilian IP Law, art. 68, main provision.

¹⁵⁷ Except for failure to work due to lack of economic viability, in which case importing shall be admitted. Brazilian IP Law, art. 68, item I.1.

¹⁵⁸ Brazilian IP Law, art. 68, item I.2.

¹⁵⁹ Brazilian IP Law, art. 70 (dependency of one patent on another justifies compulsory licensing only if the subject matter of the dependent patent constitutes a substantial technical advance in relation to the earlier patent and the owner fails to reach agreement with the owner of the independent patent on the exploitation of the earlier patent).

¹⁶⁰ Brazilian IP Law, art. 71.

¹⁶¹ The principle of international exhaustion of rights grants a country the possibility of legally importing a product protected by intellectual property rights after the product has legitimately been put on the market elsewhere. These imports - made by a party without the authorization of the title-holder but recognised as legal by TRIPS Article 6 - are generally known as "parallel imports". As originally enacted, Brazilian IP Law did not recognize the principle of international exhaustion of rights, so it only permitted parallel imports of patent protected drugs from any country where the invention has already been put on the market by the patent holder or with the patent holder's consent.

¹⁶² Brazilian IP Law, art. 68, item IV, and Presidential Decree No. 3201 of October 6, 1999, art. 10, as modified by Presidential Decree No. 4830 of September 4, 2003 to permit importation of the invention from a country where it is not under patent protection (Decree 4830/03 was issued with a view to permitting importation of products from countries that were still using the transition period to grant patents for pharmaceutical products and process, such as India and China).

¹⁶³ Oliveira et al., *supra* note 119, at 154 (noting that before 1945, Brazilian industrial property legislation granted patent protection for pharmaceutical products and processes. In that year, the legislation was modified to exclude protection of inventions related to: foodstuffs, medicines, materials and substances obtained by chemical means or processes. In 1969, a change in the Brazilian Industrial Property Code completely eliminated patenting in the pharmaceutical sector, until the current Industrial Property Law was enacted on May 14th, 1996).

¹⁶⁴ WTO Dispute Settlement Body, Brazil--Measure Affecting Patent Protection--Request for Consultations by the United States, WTO Doc. WT/DS199/1.

issued in situations where the patent holder does not locally manufacture the patented product (the "local working" provision referred to in item (ii) of the above paragraph) contravened TRIPS article 27(1)¹⁶⁶ which prohibits national patent protection laws from discriminating with regard to the locale of invention.¹⁶⁷

Although the Brazilian IP Law does indeed grant the possibility of compulsory license to any goods, as is therefore controversial as a matter of law, Brazil managed to tie the American questioning over its IP Law to the extremely controversial AIDS debate raging between developing countries and pharmaceutical enterprises.¹⁶⁸ In the end, Brazil successfully lobbied for a United Nations Commission on Human Rights resolution affirming the right of access to medication.¹⁶⁹ Brazil then took an offensive stance and filed a complaint with the WTO challenging the U.S. patent code. Brazil argued that 30 U.S.C § 202, which stated that products arising from small business or non-profit patent rights in inventions made with federal assistance shall be made substantially in the United States, was non-compliant with TRIPS.¹⁷⁰ Brazil's position gained political momentum as India joined the dispute, claiming that it had a "systemic interest" in the proceeding.¹⁷¹ As a result of the ensuing negative publicity,¹⁷² in June of 2001 the United States withdrew the complaint against Brazil, and in turn Brazil agreed to provide a prior notice to the United

¹⁶⁵ The USTR claimed that "Brazil has asserted that the U.S. case will threaten Brazil's widely-praised anti-AIDS program, and will prevent Brazil from addressing its national health crisis. Nothing could be further from the truth. For example, should Brazil choose to compulsory license anti-retroviral AIDS drugs, it could do so under Section 71 of its patent law, which authorizes compulsory licensing to address a national health emergency, consistent with TRIPS, and which the United States is not challenging. In contrast, Section 68 - the provision under dispute - may require the compulsory licensing of any patented product, from bicycles to automobile components to golf clubs. Section 68 is unrelated to health or access to drugs, but instead is discriminating against all imported products in favor of locally produced products. In short, Section 68 is a protectionist measure intended to create jobs for Brazilian nationals." U.S. Special 301 report, 2001, www.ustr.gov/enforcement/special.pdf on the dispute before the WTO with Brazil. See Bird & Cahoy, *supra* note 168.

¹⁶⁶ TRIPS art. 27(1) establishes that "... patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."

¹⁶⁷ In its defense, the Brazilian government argued that its industrial property legislation had been drafted based on Article 5(2) of the 1967 Paris Convention, which states that "each country of the Union can adopt legislative measures, such as compulsory licensing, to prevent abuses resulting from exercising exclusive rights conferred by the patent, which include the lack of exploitation". The Brazilian government also suggested that any attempts to impair its compulsory licensing legislation would harm its anti-AIDS program. See Bermudez et al, *supra* note 143, at 46. See also Carlos Correa, *Acuerdo TRIPS*. Buenos Aires: Ed. Ciudad Argentina, 1996 (noting the existence of a contradiction within the TRIPS Agreement, namely that article 27.1 prohibits any type of discrimination as to the place of invention, the field of technology and whether products are imported or locally produced, at the same time that article 2.1 allows member states to abide by the clauses described in article 1 through 12 and 19 of the 1967 Paris Declaration).

¹⁶⁸ Robert C. Bird and Daniel R. Cahoy, *The Emerging BRIC Economies: Lessons from Intellectual Property Negotiation and Enforcement*, *Northwestern Journal of Technology and Intellectual Property*, Volume 5, Number 3, 2007 (noting that Brazil used South Africa as a comparison point to show off its successful anti-AIDS program, suggesting that this program would be at risk if the United States succeeded before the WTO. During that period, 39 pharmaceutical firms were suing the South African because of its Medicines and Related Substances Control Amendment Act of 1997 which adopted a regime of international exhaustion thus permitting the parallel importation of patented ARVs. At that point, approximately 4.2 million individuals, or 20% of South Africa's adult population, were infected with the HIV virus).

¹⁶⁹ Sanders, *supra* note 145, at 16 (noting that the United States was the only abstention within the 53 member body, in which every member voted to pass the resolution).

¹⁷⁰ Sue Ann Mota, *TRIPS: Ten Years of Disputes at the WTO*, 9 *Computer L. Rev. & Tech.* 455, 477 (2005).

¹⁷¹ WTO Request to Join Consultations, U.S. – U.S. Patents Code, WT/DS2124/2 (Feb. 16, 2001), available at, <http://docsonline.wto.org/DDFDocuments/t/WT/DS/224-2.doc>.

¹⁷² Chakravarthi Raghavan, *US beats a (tactical) retreat over Brazil's patent law*, *THIRD WORLD NETWORK*, <http://www.twinside.org.sg/title/tactical.htm> (referring to the situation as a "public relations disaster" for the United States) (last reviewed on May 22, 2008).

States if it were to issue a compulsory license.¹⁷³ The two countries also undertook to resolve any disputes through a bilateral "consultative mechanism."¹⁷⁴

At the WTO Doha Ministerial Conference of November 2001 that followed, developing countries managed¹⁷⁵ to push for a joint declaration that aimed at putting an end to challenges at the WTO to legislation setting broad grounds for the issuance of compulsory licenses concerning essential patented drugs.¹⁷⁶ The ensuing Declaration on TRIPS Agreement and Public Health¹⁷⁷ was designed to respond to concerns about the possible implications of the TRIPS Agreement for access to medicines and stressed that the implementation and interpretation of the TRIPS Agreement should be made "in a manner supportive of public health, by promoting both access to existing medicines and research and development into new medicines and, in this connection, are adopting a separate declaration."¹⁷⁸ In August of 2003, after a long period of discussions, the General Council of the WTO issued a decision regulating¹⁷⁹ the right of members to issue compulsory licenses.¹⁸⁰

c) Threat costs and national law

There is, however, a large difference between being legally able to issue compulsory licenses and being practically empowered to do so. Issuing a compulsory license only makes practical sense insofar as the country is able to obtain the same drugs at lower costs, either through local production or importation of generics. As so, during the course of the last decade, Brazil aligned the quest for a relatively liberal set of IP laws within the TRIPS framework with the development of a local industry of generics. Indeed, the development of a local industry of generics serves not only to directly provide cheaper drugs to the country's population, but also (and perhaps most importantly) to permit the country to join the

¹⁷³ In the aftermath of the wave of a large global movement for access to medicines set in motion by the disputes between the US and developing countries such as Brazil and South Africa, in June 2001 New York hosted the United Nations Special Session on HIV/AIDS, which produced the Declaration of Commitment on HIV/AIDS whereby governments of 189 countries committed to implement integral programs composed of national and international actions to combat the HIV/AIDS epidemic, demonstrating that care, including access to medicines, support and prevention are indivisible components for an effective response. See Bermudez et al., *supra* note 143, at 47.

¹⁷⁴ See Bird & Cahoy, *supra* note 168 (also noting that this agreement was not made public).

¹⁷⁵ Sanders, *supra* note 145, at 17 (noting that a "breakthrough" was possible because of the continuing media exposure of the lack of availability of antiretroviral AIDS drugs for the poor, of the fact that profit margins for big pharma were the highest of any industry, and of the Anthrax crisis in the USA in which the United States and Canada had threatened to issue a compulsory license against the German company Bayer, the producer of ciprofloxacin, during the anthrax scare and its use in biological terrorism). See also E. F. M. T'Hoen, TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way From Seattle to Doha, *Chicago Journal of International Law*, 3(1):27-48 (2002); Thomas F. Mullin, AIDS, Anthrax, and Compulsory Licensing: Has the United States Learned Anything? A Comment on Recent Decisions on the International Intellectual Property Rights of Pharmaceutical Patents, 9 *ILSA J Int'l & Comp L* 185 (2002); and Mike Godwin, Prescription Panic: How the Anthrax Scare Challenged Drug Patents, *Reason Found.*, Feb. 1, 2002.

¹⁷⁶ See Sanders, *supra* note 145, at 18 (noting that the United States and big pharma unsuccessfully tried to limit the scope of the Declaration to drugs for the treatment of HIV/AIDS, tuberculosis and malaria).

¹⁷⁷ Adopted on November 14, 2001, WT/MIN(01)/DEC/2, 20 November 2001.

¹⁷⁸ *Id.*, item 17.

¹⁷⁹ This data was generated based on the following source: Brazilian IP Legislation, *supra* note 119, at 55.

¹⁸⁰ See F. Fleck, Drugs could still be costly under World Trade Organization deal, *British Medical Journal*, 327: 639, 2003 (noting that international NGO representatives responded to the decision with criticism. They have pointed out that (i) the implementation procedures for compulsory licenses are slow, bureaucratic and increase administrative costs, which consequently increase drug prices; (ii) poor countries of Africa, Asia and Latin America have to go through unnecessary red tape to prove that they do not have manufacturing capacity; (iii) the bureaucratic procedures dissuade generic drug producers, because they generate investment risks; and (iv) the requirement for different packaging can increase medicine production costs).

negotiation table of big pharma and make the threat of imposing compulsory licenses credible.

The possibility of compulsorily licensing drug patents without breaching WTO rules combined with the possibility of manufacturing or importing generics has significantly enhanced Brazil's bargaining power for negotiating voluntary licenses and price reductions with big pharma.¹⁸¹ In the period of 2000-2004, the price of the three most important ARVs present in the drugs cocktail offered by the Brazilian government at no cost to local patients were severely reduced. The price of Merck's Efavirenz had an overall reduction of 73%, Abbot's Lopinavir/Ritonavir was reduced by 56.2%, and Roche's Nelfinavir was reduced by 73.8%. Moreover, Gilead's Tenofovir (which was incorporated into the program in 2003) was sold in Brazil for 43.6% less than the US price and Bristol-Myers' Atazanvir (incorporated in 2004) with a discount of 76.4%.¹⁸² Table 5 summarizes relevant information on the price reduction negotiations concerning three central components of Brazil's ARVs cocktail, namely Efavirenz, Lopinavir/Ritonavir and Nelfinavir.

Table 5: History of Bargaining Between the Brazilian Government and Big Pharma

Drug	Relevance	Result of negotiations	Additional comment
Efavirenz (negotiations in 2003) Brand name: Stocrin Manufacturer: Merck	Efavirenz then accounted for nearly 20% of Brazil's expenditures on its cocktail of 15 ARVs ¹⁸³	An additional 25% off, saving the country \$10m a year. Price reduction of almost 70% of the price in the US	Up to that point, negotiations managed to avoid compulsory licensing. Big pharma feared that a Brazilian compulsory license could prompt a cascade effect prompting other countries to pursue a similar path.
Efavirenz (negotiations in 2007)	Efavirenz is the imported ARV most widely used in Brazil (in May of 2007 38% of Brazilian soropositives used it). ¹⁸⁴	On May 4, 2007, President Silva determined the compulsory license of Efavirenz. Brazil then expected to save US\$ 30	Brazilian President Luiz Inácio da Silva signed the decree for the compulsory license in a televised ceremony shortly after Thailand decided on similar action with the same drug—efavirenz—and two others. ¹⁸⁶ In response, Merck declared that R&D-based pharmaceutical companies

¹⁸¹ See Brazilian IP Legislation, *supra* note 119, at 94 (discussing the case of South Africa and noting that "a combination of generic competition, advocacy and legislative provision of TRIPS safeguards had a significant pro-competitive effect on the price of medicines, as evidenced in the dramatic more than 95% price reduction in the indicative annual cost for a triple therapy antiretroviral regime from \$10000 in 1996 to \$140 in South Africa in 2003).

¹⁸² Alexandre Grangeiro et al., *Sustentabilidade da Política de Acesso a Medicamentos Anti-Retrovirais no Brasil*, *Revista de Saúde Pública* (2006); 40 (Supl): 60-69, at 64 (also suggesting that from 2005 on Brazil has been much less successful in achieving price reductions and also that its local capacity for cost-efficient production of generics has recently weakened).

¹⁸³ November 18, 2003. BBC. New Anti-HIV Drug Deal for Brazil, available at <http://news.bbc.co.uk/1/hi/world/americas/3281683.stm> (last reviewed on May 22, 2008).

¹⁸⁴ On April 24, 2007 the Health Minister of Brazil signed a decree declaring the patent of Efavirenz in the public interest and appropriate for compulsory licensing. In response, Merck offered an additional discount of 30%, or 1.10 per pill (down from \$1.57). Brazilian government wanted Merck to lower its price to \$0.65 per pill, which is the same price Thailand pays for Sustiva. The Brazilian government claimed it would be able to locally produce a generic version of such pills for only US\$ 0.45. Sources: Ministry of Health. *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 and *Pharmaceutical Business Review*, *Breaking Merck patent may drive investment away from Brazil*, May 9, 2007, available at http://www.pharmaceutical-business-review.com/article_feature.asp?guid=8A869BFC-88A5-4131-8CA3-231EE6F6E46C (last reviewed on May 22, 2008).

		million in 2007 and US\$ 236.8 until 2012. ¹⁸⁵	cannot sustain a situation in which the developed countries alone are expected to bear the cost for essential drugs in both least-developed countries and emerging markets, and reinforced the idea that it is essential to price medicines according to a country's level of development and HIV burden, thereby ensuring equitable access and the ability to of pharma to invest in future innovative medicines. Merck also stated that "as the world's 12th largest economy, Brazil has a greater capacity to pay for HIV medicines than countries that are poorer or harder hit by the disease." ¹⁸⁷
Lopinavir / Ritonavir (negotiations In 2005) Brand name: Kaletra Manufacturer: Abbott	Similar to that of Efavirenz	Through negotiations, Brazil obtained an additional price reduction of 46%	An agreement between the government and Abbott was issued after the Health Minister signed a decree declaring the patent of Kaletra in the public interest and appropriate for compulsory licensing, which was the final bureaucratic step before the issuance of the compulsory license.
Nelfinavir Brand name: Viracept Manufacturer: Roche (negotiations in 2001)	Nelfinavir was then used by 25% of the 100,000 patients who used anti-AIDS drugs in Brazil. In the previous year, Nelfinavir alone accounted for 28% of the country's expenditure in ARV therapy which then corresponded to US\$ 303 million ¹⁸⁸	Negotiations led to an additional price reduction of 40%. As so, Viracept started to be sold in Brazil for about 30% of what Roche charges in the US. ¹⁸⁹	In August 22, 2001, Brazil's Health Minister stated that "following six months of negotiations [...] the Brazilian Minister of Health [...] decided to break the patent of the drug Nelfinavir [...] The generic version of Nelfinavir will be manufactured by the Brazilian government laboratory Far-Manguinhos [which] has succeeded in producing the drug at a saving of 40% over that charged by Roche." However, within only ten days the parties resumed talks and reached an agreement whereby Roche agreed to sell the drug in Brazil at an additional 40% discount, and Brazil agreed not issue the compulsory license.

3.2.3 The threat costs-benefit bent

NICs, while being the primary target of TRIPS, are in reality the countries that benefit the most from bargaining around TRIPS through patent compulsory licensing or issuing threats to do so. This is so for three main reasons. The first, derives from two sanction costs

¹⁸⁵ Source: Ministry of Health. 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.

¹⁸⁶ Source: Jon Cohen for Science Magazine, Brazil, Thailand Override Big Pharma Patents, May 11, 2007, available at <http://www.cptech.org/ip/health/aids/2g/science05112007.pdf> (last reviewed on May 22, 2008).

¹⁸⁷ Merck & Co., Inc. 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 reviewed on May 22, 2008).

¹⁸⁸ Source: Statement by Jose Serra, Minister of Health, of August 22, 2001.

¹⁸⁹ Source: Roche Reaches Accord on Drug With Brazil, The New York Times, September 1, 2001.

considerations: on one hand, NICs markets are too desirable to be sanctioned by industry; on the other hand, NICs the relative weight of sanctions in larger economies is lower, meaning that NICs can endure more sanctions even if imposed. The second is that compulsory licensing with respect to pharmaceutical products may not only be efficient but presumably is also politically appealing, as it includes the promise of lower prices to governments and consumers for pharmaceutical products. The third explanation for the efficacy of threatening to issue compulsory licensing by NICs derives from the existence of a strong domestic generic industry that supports the process by making the threat even more credible.

a. Sanction costs considerations

1. NICs' 'outside option' costs

The first sanction cost consideration is that NICs can bare “disagreement costs” in the face of sanctions if imposed. To reach an agreement, each party has to receive at least its threat value, also named “reservation value” or “disagreement value” or “outside option” which equals the payoff that it can obtain on her own without cooperation of others.¹⁹⁰

NICs like Brazil arguably find it difficult to compete in new drugs, so the development of a local generic industry nurtures the country's hope of developing a national pharmaceutical industry. Brazil as argued in this section is a case study of a country that has adopted a policy of local production of generics; not only to obtain medicines at a lower price but also in order to strengthen its pharmaceutical industry.

By and large, the international pharmaceutical industry can be characterized as a highly competitive oligopoly which derives its above-average profitability from the continuous release of new drugs. The global market is estimated in approximately US\$ 500 billion, and the leading 12 companies - all of which are headquartered in developed countries - respond for approximately 45% of total sales.¹⁹¹ Historically, developing countries have used patent law instrumentally to foster the development of local industries, but because of the classic trade-off between innovation and dissemination there is a large disagreement about the role to be played by patent laws. Brazil illustrates the case of a country that, having resorted a decade ago to a more strict system of patent protection, has thereafter used compulsory license also as a tool for the development of a local expertise in pharmaceuticals.

Until 1945, Brazilian IP legislation granted patent protection for pharmaceutical products and processes but in that year the law was amended to rule out the protection of inventions related to medicines, foodstuffs, materials and substances obtained by chemical means or processes.¹⁹² In 1969, a change in the Brazilian Industrial Property Code eliminated patenting in the pharmaceutical sector altogether. That framework was instrumental for the government's policy of import substitution which was in force during the 1970s and 1980s. To secure a market and encourage national production, the Brazilian government implemented a policy of centralized purchasing that favored locally produced medicines. Import taxes on medicines were levied at prohibitive levels, at the same time that

¹⁹⁰ Cooter, *supra* note 117, at 274.

¹⁹¹ 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.

¹⁹² Oliveira et al., *supra* note 119, at 154.

the intermediary inputs for local production were taxed mildly and local production was subsidized.¹⁹³

With the opening of the economy to foreign competition in the 1990s, the Brazilian pharmaceutical industry started to decline rapidly, a process which was arguably accelerated by the passage of a new IP law that reinstated patenting of pharmaceutical products and processes in 1996. The government abandoned its system of preferred purchases, and local production was progressively substituted by importation. From 1990 to 2003, the importation of medicines increased almost seventeen times, from US\$ 60 million per year to US\$ 1 billion, and the importation of pharmaceuticals grew from US\$ 500 to US\$ 900 per year.¹⁹⁴ In turn, exportations grew at a much slower pace¹⁹⁵ and the imports of intermediary products for the local production decreased from US\$ 150 million per year to only US\$ 10 million.¹⁹⁶

This trend toward a decrease in the size of the Brazilian pharmaceutical industry has been counterbalanced (although limitedly so) by the surge of a Brazilian generics industry in the last decade. The permission of the sale of generics had long been requested by health activist groups in Brazil, but it was not until 1999 that the Brazilian government finally succeeded in passing a law (known as the “Generics Act”) that would permit the marketing of generics in Brazil.¹⁹⁷ A generic medicine was defined as a product similar to the reference product which was expected to be interchangeable with the latter. Generics are typically produced after the expiration or waiver of patent protection or any other exclusive rights.

The introduction of generic drugs created a dynamic investment option in the pharmaceutical industry. According to data from the Brazilian Generic Medicines Industry,¹⁹⁸ generic medicines in Brazil currently account for approximately 14% of local sales, still less than half than the market share of generics in countries like Germany (29%), United Kingdom (34%) and United States (35%), yet speedily growing. The enhancement of the generics production also served to enhance the Brazilian generics industry. Currently, the four main companies operating in that segment are held by Brazilian capital, and approximately 80% of the units of generic medicines sold in Brazil are manufactured locally. Moreover, the development of a generics industry helped the government in revamping its network of 18 public laboratories, which were set to produce medicines and biologicals to supply the public health system.¹⁹⁹ Currently, the production of these public laboratories represents approximately 3% of the national production in monetary value and 10% in unit numbers.²⁰⁰

All of that suggests that the relative advantages of issuing compulsory licenses are different in developing countries depending on whether they are in a position to develop the

¹⁹³ Bermudez et al., *Expanding Access to Essential Medicines in Brazil: Recent Regulation and Public Policies*, (2004), in *Brazilian IP Legislation*, supra note 119, at. 129-130.

¹⁹⁴ Fórum de Competitividade, supra note 191, at. 11.

¹⁹⁵ *Drugs and Pharmaceuticals in Brazil*, International Business Strategies, October 2003, at 7.

¹⁹⁶ Fórum de Competitividade, supra note 191, at 11.

¹⁹⁷ Law No. 9.787/99. Supplementary measures, particularly Decree No. 3.181/99 and Resolution No. 391/99 of ANVISA (National Health Surveillance Agency) regulated various aspects in the implementation of generic drug policy in Brazil, such as establishing technical standards and norms and defining the concepts of bioavailability and bioequivalence for generic, innovative, reference, and similar medicines. ANVISA also set the criteria and conditions for licensing and controlling generic drugs in the Brazilian pharmaceutical market. See Bermudez et al., supra note 193, at 136.

¹⁹⁸ Associação Brasileira das Indústrias de Medicamentos Genéricos – Pró Genéricos (<http://www.progenericos.org.br>) (last reviewed on May 22, 2008).

¹⁹⁹ This network of 18 laboratories is spread in various public administration entities such as the Ministry of Health, the Armed Forces, state governments and universities. Existing production capacity is estimated at 11 billion pharmaceutical units per year.

²⁰⁰ Bermudez et al., supra note 193, at 141.

infrastructure and technology base to manufacture generics. In poorer developing countries that are not able to manufacture the drugs, the issuance of compulsory licenses would generate the downside of new frictions with the countries where the patent-holders are located without the upside of developing a local industrial base or producing lower-priced drugs.²⁰¹ Contrary to low-income developing countries - which typically enjoy the lowest global prices for patented pharmaceuticals but often do not integrate the most costly testing into treatment guidelines - Brazil is different. In the latter, as a middle-income country, it opts to issue compulsory licenses, even if importing generics could sometimes be cheaper and more feasible than producing drugs locally.

In the aftermath of these negotiations processes, Brazil became worldwide renowned for being the most successful 'developing country' that tackled AIDS.²⁰² The World Bank predicted that by the year 2000, 1.2m Brazilians would carry HIV, the virus that causes it, but prevention schemes have held the number to roughly half of that, or 0.61% of the country's population.²⁰³ Key to Brazil's success was its National STD/AIDS Program (NSAP) created in the 1990s by the Brazilian federal government. The program currently guarantees free access to highly active antiretroviral therapy (HAART) for all individuals living with HIV/AIDS in need of treatment. In 2006, NSAP had an annual budget of approximately US\$ 770 million, representing almost 3% of the Health Ministry's budget.²⁰⁴ In 2007, the NSAP supplied²⁰⁵ different ARV drugs to nearly 200,000²⁰⁶ of Brazil's estimated 600,000 HIV/AIDS patients.²⁰⁷ The expenditures for the purchase of ARVs (including generics locally manufactured and imported) amounted to approximately US\$ 570 million.²⁰⁸

In its quest to drive ARVs prices down, Brazil produces non-patented generic ARVs, negotiates price reductions with the laboratories, and recently even issued a compulsory license to import one patented ARV, Merck's Efavirenz. The rationale for the issuance of such compulsory has many aspects. For one, by reducing the price per day from US\$1.56 to \$0.45 by buying Indian generics, the Brazilian government expects to save \$30 million in 2007 and \$237 million between now and 2012 (when the Efavirenz patent expires).²⁰⁹ Moreover, the actual issuance of a compulsory license (which in the past had frequently been threatened but had never really been put in place) enhances Brazil's threat costs in the course of future bargains with laboratories.

Nunn. et al. investigated the drivers of recent ARV cost trends in Brazil through analysis of drug-specific prices and expenditures between 2001 and 2005.²¹⁰ They estimated the savings attributable to Brazil's reduced prices for patented drugs and concluded that "in the absence of price declines for patented drugs, Brazil would have spent

²⁰¹ Harrelson, *supra* note 139.

²⁰² The Economist, Brazil's AIDS programme: A conflict of goals, May 10th 2007.

²⁰³ UNGASS – Brazilian Response 2005-2007, Country Progress Report, at 11.

²⁰⁴ *Id.*, at 24.

²⁰⁵ Grangeiro et al, *supra* note 182, at 62.

²⁰⁶ The WHO estimates that fewer than 5% of those who require treatment for HIV/AIDS are receiving ARVs. Only about 230,000 of the 6 million estimated to be in need of such treatment in the developing world actually receive it, so nearly half of these people live in Brazil. Source: WHO Press Release (WHO/58), 9 July 2002. Source: www.who.int/inf/en/pr-2002-58.html.

²⁰⁷ Efavirenz: Questões sobre o Licenciamento Compulsório, Official Communication issued by the Brazilian Ministry of Health, May 4, 2007.

²⁰⁸ UNGASSs, *supra* note 203, at 25.

²⁰⁹ Brasil decreta licenciamento compulsório do Efavirenz, official communication issued by the Brazilian Ministry of Health, May 4, 2007.

²¹⁰ A. S. Nunn, et al., Evolution of Antiretroviral Drug Costs in Brazil in the Context of Free and Universal Access to AIDS Treatment. *PLoS Med.* 2007;4(11):e305.

a cumulative total of US\$2 billion on drugs for HAART between 2001 and 2005, implying a savings of US\$1.2 billion from price declines.” They also pointed out that the “negotiated drug prices in Brazil are lowest for patented ARVs for which generic competition is emerging” and that “in recent years, the prices for Efavirenz and Lopinavir–Ritonavir (Lopinavir/R) have been lower in Brazil than in other middle-income countries,” although “the price of Tenofovir is US\$200 higher per patient per year than that reported in other middle-income countries.”²¹¹

2. *WTO's ineffective preventive measurements*

The second sanction cost consideration is that NICs markets are too desirable to be sanctioned by industry. Attempts to issue compulsory licenses inevitably lead to pressure from the country that hosts the patent owners. Consider, for instance, the negotiations for reduction of drug prices that took place in 2005 between the Brazilian government and American laboratories. When Brazil threatened to issue a compulsory license over certain ARVs, the pharmaceutical industry replied that such action would “*ensure that companies whose patents are broken will not be selling their next generation AIDS drugs, or any other medication for that matter, in Brazil.*”²¹² Likewise, when Brazil issued a compulsory license on Merck's Stocrin (Efavirenz) in 2007, Merck released an official statement saying that “*this decision by the Government of Brazil 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.*”²¹³

But the extent to which such threats on sanctions made by big pharma are credible is unclear. Indeed, there were no official trade sanctions because the compulsory license was viewed as legal both from the standpoint of Brazilian and international law. This fact is also relevant because it gives international legitimacy to the compulsory license. Moreover, there are no obvious signs of reduced FDI in Brazil (Brazil's share of FDI in 2007 totaled US\$ 34.6 billion, almost twice as much as the previous year and one of the highest in the world amongst developing countries).²¹⁴ In pharma, FDI in 2007 reached USD 164.4 million,²¹⁵ which is consistent with the historic investment level observed in previous years.²¹⁶

b. *The national benefit of compulsory licensing*

The third is that compulsory licensing with respect to pharmaceutical products may not only be efficient but presumably is also politically appealing. To begin with, the investments in AIDS care in Brazil are said to have paid off. Although Brazil's National STD/AIDS Program (NSAP) is expensive, the costs avoided due to reduced illness, hospitalization and other impacts of HIV/AIDS can balance the budget. According to statistics released by the Brazilian Ministry of Health, hospital admissions decreased by 80% in the period 1996 to 2001, and in

²¹¹ Id.

²¹² Bird & Cahoy, *supra* note 168.

²¹³ Merck's statem, *supra* note 187.

²¹⁴ Source: Central Bank of Brazil (www.bcb.gov.br). See also Foreign Direct Investment in Brazil Doubles in 2007 to US\$ 35 Billion, *Brazzil Magazine*, available at <http://www.brazzilmag.com/content/view/9086/> (last reviewed on May 22, 2008).

²¹⁵ Source: Central Bank of Brazil.

²¹⁶ 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.

2001 the final cost of NSAP incorporating reduced morbidity expenditure was negative, resulting in net savings of US\$50 million.²¹⁷

In recent years, the fight against HIV/AIDS has consolidated its position as a priority within Brazil's health policy agenda.²¹⁸ The increased use - indeed, more often the threat of use - of compulsory licenses is part of this broader political context. Although the prioritization of AIDS has not been free of criticism, it is commonly defended on the grounds that AIDS is potentially more catastrophic than other diseases. The issuance of compulsory licensing is thus politically appealing, as it encapsulates the promise of lower prices of pharmaceutical products to governments and consumers. On top of all of that - and to some extent, irrespective of the net results of the balance of pros and cons associated with issuing compulsory licenses, politicians can capture votes on the promise of defense of national interests, as evidenced by the fact that Brazilian President Luiz Inácio da Silva signed the decree for the compulsory license of Efavirenz in a televised ceremony.²¹⁹

c. The circular increase in threat costs

The fourth explanation for the efficacy of threatening to issue compulsory licensing by NICs derives from the existence of a strong domestic generic industry that supports the process by making the threat even more credible.

Strengthening local production works as an effective instrument in supporting government health policies. Not only does it help the government in regulating prices, but (perhaps most importantly) it plays a strategic role in the course of price negotiations with patent holding transnational laboratories. The existence of a strong domestic generic industry leverages the position of the government in such negotiations by making the threat of issuance of a compulsory license more credible. In other words, the existence of a strong domestic generic industry enhances the bargaining power of developing countries by making the threat of issuance of compulsory licenses more credible.

To use the case of Brazil, there the laboratory Far-Manguinhos,²²⁰ which is the main government drug producer, has developed reverse-engineering technology for pharmaceutical ingredients which strategically support policies of the Ministry of Health. Far-Manguinhos has often played a strategic role in the course of the negotiations with big pharma by supplying reference prices for the ARVs, thus contributing to the financial sustainability of strategic Ministry of Health programs.²²¹ This laboratory already produces seven²²² of the sixteen medicines used in the antiretroviral cocktail (freely) offered in Brazil (none of these drugs are patented in Brazil).²²³ In 2001, 56% of ARVs distributed in Brazil

²¹⁷ Grangeiro et al., *supra* note 182, at 62. (suggesting that investments in ARVs have permitted the government to save US\$ 2 billion between 1997 and 2003). See also Vitória Levi, *Fighting against AIDS: the Brazilian Experience* (2002), and Teixeira, Vitória and Barcarolo, *Antiretroviral treatment in resource poor settings: the Brazilian experience* (2004).

²¹⁸ A recent study argued that a steep rise in the price of ARVs has led to "predatory competition" for resources within the Ministry of Health, leaving other crucial projects underbudgeted. See Grangeiro et al., *supra* note 182, at 65.

²¹⁹ Source: Jon Cohen for Science Magazine, Brazil, Thailand Override Big Pharma Patents, May 11, 2007, available at <http://www.cptech.org/ip/health/aids/2g/science05112007.pdf> (last reviewed on May 22, 2008).

²²⁰ Far-Manguinhos is part of the Oswaldo Cruz Foundation – FIOCRUZ, a non-profit research foundation linked to the Brazilian Ministry of Health.

²²¹ Bermudez et al., *supra* note 193, at 129-150.

²²² Integrating Intellectual Property Rights and Development Policy, Report of the Commission on Intellectual Property Rights, London, September of 2002, available at http://www.iprcommission.org/graphic/English_Intro.htm (last reviewed on May 22, 2008).

²²³ Integrating Intellectual Property Rights and Development Policy, Report of the Commission on Intellectual Property Rights, London, September of 2002, available at http://www.iprcommission.org/graphic/English_Intro.htm.

were locally produced, which made possible a reduction of 82% in the prices of these drugs from 1996 to 2001.²²⁴

3.3 Conclusions

In research-intensive industries such as pharmaceuticals, there is abundant evidence that company growth is intimately related to innovativeness.²²⁵ In pharma, high cash flows created by earlier innovations leads to further investments in R&D, manufacturing capacity and marketing sales, and the cost of subsequent R&D projects are cut by sharing accumulated knowledge, research facilities and marketing networks, leading to further specialization, innovation and profits.²²⁶ A small group of no more than 30 companies headquartered in only five countries (USA, Germany, Switzerland, UK and France) are responsible for 70% of all the innovations in pharmaceuticals in the period of 1800-1990.²²⁷ As so, a handful of highly competent pharmaceutical companies enjoyed substantial competitive advantages which consolidated their position in the world markets by research intensity, corporate technology tradition, corporate growth (including because of mergers and acquisitions of foreign companies), rendering it extremely difficult the entry of new competitors.

(To illustrate the problem of economies of scale in pharma, in 2005 the total sales of Aché, the largest Brazilian pharmaceutical laboratory, corresponded to USD 635.8 million, or 6.9% of the Brazilian market. In that same year, Pfizer's sales reached USD 51.3 billion, which is 80 times more and 6 times the overall size of the Brazilian market.²²⁸ Moreover, the total cost for developing a new medicine has recently been estimated in close to USD 900 million.²²⁹)

Outside Brazil, hundreds of small biotechnology firms started to appear over the past decades introducing cutting edge, innovative science and technology. As noted by Achilladelis and Antonakis, that was indeed the first time in a very long period that significant output of new technology in pharma was introduced by newcomers. Venture capital, which became available to academic research teams, led to the formation of such firms.²³⁰ In the background of this process, IP protection of inventions became increasingly important, and R&D became increasingly intertwined with the quality of the institutional framework of each country and the availability of human capital.

The existence of academic excellence in niche areas such as photonics, materials science, biotechnology and tropical agriculture, together with a TRIPS-compliant IP legislation, point out to certain fields where Brazil can potentially develop competitive advantages in pharmaceuticals.²³¹ The country also possesses a sizeable and growing

²²⁴ Grangeiro et al., *supra* note 182, at 64 (noting that expenditures in 1998 were R\$ 346 million jumping to R\$ 557 million in 2001).

²²⁵ See E. Mansfield, *Industrial Research and Technological Innovation*, Norton, New York, 1968; C. Freeman, *The Economics of Industrial Innovation*, Penguin Books, Harmondsworth, Middlesex, 1974.

²²⁶ R. Henderson and I. Cockburn, *Scale, Scope and Spillovers: The Determinants of Drug Productivity in Drug Discovery*, *RAND J. Econ.* 27 (1), 32-59 (1996).

²²⁷ Basil Achilladelis and Nicholas Antonakis, *The dynamics of technological innovation: The case of the pharmaceutical industry*, *Research Policy*, No. 30, pp. 535-558, 2001.

²²⁸ Capanema & Palmeira Filho, *supra* note 129.

²²⁹ Joseph A. DiMasi et al., *The Price of Innovation*, *Journal of Health Economics* 22, 151-185, 2003.

²³⁰ Achilladelis & Antonakis, *supra* note 227.

²³¹ Alexandre de Freitas Barbosa et. al., *Avaliação da Política Industrial, Tecnológica e de Comércio Exterior para o Setor Farmacêutico*, *Estudos Febrapharma* No. 13, 2007, at 35-37.

consumers market,²³² a fairly stable²³³ (although problematic²³⁴) political system, and the largest biodiversity in the world. However, what has been repeatedly overlooked is that IP law – like every other body of law – does not work in a vacuum; it is the broader institutional framework that counts.

The instability in the institutional framework applying to the pharmaceuticals industry dramatically affects its competitiveness and the propensity of these firms to innovate. The interaction of the Brazilian state in the pharmaceuticals sector takes place within a relatively fickle institutional framework, and accordingly the governmental policies in that sector have been marked by inconsistencies over time.²³⁵ In the end, the introduction of IP protection within pharmaceuticals in the mid-1990s proves that IP laws will not produce the desired outcomes unless they are embedded in an adequate institutional environment.

Countries with a greater degree of development tend to have a much greater ability to put up with the prospect of trade sanctions. The larger, wealthier and developed a “developing country” is, the larger will be its ability to benefit from bargains for compulsory licenses and price reduction without significantly curtailing investment and enhanced R&D. That is, in the backdrop of an altogether weaker patent regime.

All in all, it is unlikely that Brazil would be better off without issuing (or threatening to issue) compulsory licenses over ARVs, and this is particularly true once we take into account the potential devastating effects that an increase in the AIDS epidemic can cause. True, the amounts invested by big pharma in R&D in Brazil has been negligible, but it is a widely known fact that economies of scope largely favor conducting R&D activities in their home countries.²³⁶ All things considered, the assumption that stricter patent regimes preventing compulsory licensing would have a significant effect on the overall levels of R&D in Brazil is debatable at best.

4. The localized FDI institutional consideration

4.1 Overview

The effect strong IPRs have on FDI is subject to two categories of balancing considerations.²³⁷ On the one hand, there is a trend toward harmonization of IPRs within TRIPS.²³⁸ Accordingly, the attractiveness of countries that strengthen their IPRs marginally increases, whereas the relative attractiveness of those already affording strong IPRs marginally decreases.²³⁹

As Maskus explains, this global trend toward markedly stronger IPR protection is not surprising when viewed in the context of economic globalization, which is the transcendent

²³² In 2005, Brazil was the tenth world’s largest pharmaceuticals market with sales in the amount of R\$ 22.2 bi (approximately USD 12 bi).

²³³ Bruno Meyerhof Salama, *El modelo político y económico brasileño, Perspectivas económicas y políticas en América Latina* (2007), available at http://works.bepress.com/bruno_meyerhof_salama/12/.

²³⁴ Barry Ames, *The deadlock of democracy in Brazil*, University of Michigan Press, 2001.

²³⁵ Maria Fernanda Macedo and Eloan dos Santos Pinheiro, *Encontro internacional de atração de investimento direto externo: Documento setorial – Fármacos*, CEPAL (Comissão Econômica para a América Latina e o Caribe), LC/BRS/R.146, Dec./2003, at 2.

²³⁶ See OECD Science, Technology and Industry Scoreboard (2005), at 178 (noting that OECD countries still maintain a comparative advantage in certain sectors of manufacturing activity, in some of which demand has been quite strong, e.g. pharmaceuticals).

²³⁷ See, generally, Maskus, *The Role of IP*, supra note 1, at 136; Keith E. Maskus, *The International Regulation of Intellectual Property*, Band 134 *Weltwirtschaftliches Archive Rev. of World Econ.* 186, 186 (1998), at 201-202.

²³⁸ *Id.*

²³⁹ *Id.*

commercial and political force of this era.²⁴⁰ Globalization, in that sense, is the process by which national and regional markets become more tightly integrated through the reduction of governmental and natural barriers to trade, investment, and technology flows.²⁴¹ To be sure, the channels through which globalization affects economies include expanded trade in merchandise and services, product and technology licensing, greater international portfolio investment, and FDI.²⁴²

On the other hand, there is a competing category of consideration, generally known as the localized ones. The prevailing assumption herein is that even with seemingly objective ownership advantages, MNEs must still decide on investment destinations. These decisions then depend on 'location advantages,' particular characteristics of target countries that make it profitable for the firm to produce abroad rather than at home.²⁴³

A variety of such localized characteristics are well familiar within development economics writings. To begin with, a primary factor and the focal point of this study, as discussed in Part III, is the political stability of the country.²⁴⁴ Another important factor is the prospect of an increased market demand; for instance, a recent study has found a positive correlation between sales expansion and R&D investments in Brazil.²⁴⁵ Another study has argued that the level of enforcement of trade secrecy laws is more relevant for foreign investment decisions than the availability of strict patent protection laws.²⁴⁶ In the decision of where to invest, other potentially relevant factors include (but are not limited to) macroeconomic stability,²⁴⁷ availability of an appropriate physical infrastructure for setting up technological facilities,²⁴⁸ availability of human capital (for instance, abundance of qualified scientists and engineers, proximity to high level universities and research institutes, etc.),²⁴⁹ market size and level of local competition, input prices, proximity to consuming markets, existence of bilateral investment treaties and double taxation treaties, risk of expropriation by local governments, general regulatory environment and red tape, tariffs and general levels of taxation, transportation costs, development of capital markets, degree of currency convertibility, the existence of historical and cultural ties, levels of corruption, predictability and speed of law enforcement, and levels of criminality. In fact, a large degree of HIV contamination within the population of a certain country can itself be a serious constraint for foreign investment, as explained.

²⁴⁰ See, *Id.*, at 110; See Keith E. Maskus, Intellectual Property Rights in the Global Information Economy, in Policy Frameworks for a Knowledge Economy 231, 234-60, (Thomas J. Courchene ed., 1996).

²⁴¹ *Id.*

²⁴² See, Caves, *supra* note 41; Peter J. Buckley & Mark Casson, The Economic Theory of the Multinational Enterprise 113-44 (1985).

²⁴³ See Dunning. See John H. Dunning, International Production and the Multinational Enterprise 110, (1981), at 266-68; Markusen, *supra* note 41; Gene Grossman & Elhanan Helpman, Innovation and Growth in the Global Economy 238, 336-38 (1991); The World Bank, Integration with the Global Economy, in World Development Report (1991), at 88-96; Hooshang & Wu, *supra* note 80, at 185.

²⁴⁴ Oddi, *supra* note 14, at 849.

²⁴⁵ IBGE (Brazilian Institute of Geography and Statistics), Pesquisa e Inovação Tecnológica (hereinafter, "PINTEC 2005"), at 43.

²⁴⁶ Paul J. Heald, Misreading a Canonical Work: An Analysis of Mansfield's 1994 Study, 10 J.Intell. Prop. L. 309 (2003); reprinted in 16 Info. Econ. Pol'y 57 (2004).

²⁴⁷ PINTEC 2005, *supra* note 245, at 44 (highlighting the influence of positive macroeconomic expectations on private investments in technological innovation in Brazil in the period of 2003-2005).

²⁴⁸ Mariana Zanatta et. al., National Policies to attract FDI in R&D: An assessment of Brazil and some selected countries. In: 5th Globelics (Global Network for Economics of Learning, Innovation, and Competence Building Systems) International Conference, 2007, Saratov.

²⁴⁹ *Id.*

We illustrate the problem of localized factors with a brief analysis of the Brazilian political and economical institutional framework. Essentially, we suggest that it renders the Brazilian state weak on a fundamental level. By weak state one means a state that is captive to a wide array of distributional coalitions and thus is exposed to ravages of rent-seeking groups.²⁵⁰ In contrast, a strong state is able to develop a relative autonomy from such ravages.²⁵¹ It is critical to emphasize relative autonomy because the public good as a metaphysical entity does not exist and no state operates in the vacuum. The archetypical strong state associates with some modernizing interests but restricts the access of more narrowly based groups to the policy-making process, so it is generally able to design policies that are broadly in line with societal needs. Conversely, the archetypical weak state is infested by rent-seeking groups that undermine the quality of policy- and law-making.

A strong state (meaning one that is relatively autonomous and insulated from rent-seeking groups) is necessary for development both from the standpoint of a more orthodox, neoclassical political economy, and from the standpoint of a more heterodox, new political economy. That a strong state is necessary to implement a more heterodox agenda of growth is straightforward, because patronage-based and rent-seeking activities adapt easily to state-led or industrialization.²⁵² A common justification for state intervention is the pervasiveness of market failure, and a weak state is destined to fail. But a strong state is required from the neoclassical standpoint too. The neoclassical agenda puts forward a relatively simple institutional framework for minimizing government failure: de-regulate industries, open the economy for foreign trade, downsize the government and avoid overspending, and provide rule of law and property rights. Yet, these are things that only a relatively autonomous (and for that matter, strong) state can promote. To see why, notice that liberalization disentangles rent-seeking groups, and that enforcement of property rights requires a relatively a well equipped – thus well funded – bureaucracy.

How does the Brazilian Constitutional framework render weak the Brazilian state? Firstly, by fragmenting political power without creating the strong party system that would be necessary to ensure programmatic coherence for long-run government actions.²⁵³ Weak parties and strong politicians act in a strong Congress, increasing the number of “veto players” in the political process,²⁵⁴ so the transactions costs of law- and policy-making are high. Even though the Executive Power controls the policy-making agenda,²⁵⁵ implementing such agenda is intricate. Political bargaining over law and policy-making ends up strongly desinstitutionalized, in that the Executive often needs to negotiate with individuals, not with parties. In a system where Congressmen are hardly accountable to anyone, negotiations between the Executive Power and Congressmen are largely premised on pork and

²⁵⁰ Chowdhury & Islam, *supra* note 54, at 47.

²⁵¹ S. Haggard, *The politics of industrialization in the Republic of Korea and Taiwan*, in H. Hughes (ed.), *Achieving industrialization in Asia*, Cambridge: Cambridge University Press, 1988; and S. Haggard, *Pathways from the periphery: Politics of growth in the Newly Industrialized Countries*, Ithaca and New York: Cornell University Press.

²⁵² Judith Chubb *The Social Bases of an Urban Political Machine: The Case of Palermo*. *Political Science Quarterly* 96 (1):107-25 (1981).

²⁵³ Scott Mainwaring, *Rethinking Party Systems in the Third Wave of Democratization: The Case of Brazil*, Stanford: Stanford University Press (1999); Ames, *supra* note 234, at 53 (arguing that that the Brazilian political framework further weakens the Brazilian state by distorting representation of voters in Congress. In the Chamber of Deputies, seats are allocated by population, but since no state can have less than eight and more than 70 seats, the number of voters per deputy varies enormously. A number of political scientists have studied the effects of disproportional apportionment of voting and concluded that it reinforces patronage-dependent forces).

²⁵⁴ George Tsebelis, *Decision making in political systems: Veto players in presidentialism, parliamentarism, multicameralism, and multipartism*, *British Journal of Political Science* 25:289-325.

²⁵⁵ Ames, *supra* note 234, at 17.

patronage.²⁵⁶ This discourages programmatic commitments and encourages the “bureaucratic combats” internally in the government coalition. In the end, Brazilian Congress is extremely active in bartering political support for distributive policies, but relatively inactive on relevant issues at the national level. Government appointments premised exclusively on political connections are routinely used in law-making bartering in the Congress. The pervasiveness of this phenomenon is such that political parties expect to appoint party faithful (with no technical credentials) to rather technical and often important jobs in the government, even in the lower echelons of power.

Secondly, the Brazilian political framework renders weak the Brazilian state by favoring a structure that deeply entrenches rent-seeking interests of certain fractions of the society. As pointed out by Barry Ames, the tragedy of the Brazilian political system is not that it benefits elites. Instead, the problem is that it primarily benefits itself – that is, its politicians and civil servants.²⁵⁷ Politicians are unlikely to devote much effort to making the bureaucracy less oppressive and remote because they profit from mediating between the constituents and the bureaucrats.²⁵⁸ It is therefore not surprising that the fiscal and social security reforms that could consolidate macroeconomic stabilization in Brazil have never been approved, and that is why the Brazilian state has done so little to increase productivity – even in the backdrop of clean and democratic elections with very high turnouts. This also helps to explain why political leaders have made basically no progress at all in reducing the overall cost of government.

4.2 The Localized FDI Governance Deficiency

Early theorists in development economics²⁵⁹ regarded underdevelopment as a case of endemic “market failure”,²⁶⁰ which justified the pervasive array of direct interventions in the economy. Such interventions ranged from minimum wage laws, and interest rate controls, to tariff concessions on imported capital inputs and tax subsidies on investment and capital equipment, controlled exchange rates, and economic dirigisme based on large state-owned companies. There is now a robust body of theory and evidence that has demonstrated that the costs of ISI have outweighed its benefits,²⁶¹ and the liberalizing reforms of the 1990s emerged in the footsteps of such literature.

As of the 1980s, a number of theorists have tried to reinstate the credibility of state-led development processes.²⁶² Their starting point, as noted by Bardhan, is that the rent-seeking literature is better at explaining failures rather than success stories.²⁶³ That is, particularly of

²⁵⁶ *Id.*

²⁵⁷ Ames, *supra* note 234, at 3.

²⁵⁸ *Id.*

²⁵⁹ P. N. Rosenstein-Rodan, Problems of industrialisation of Eastern and South-Eastern Europe, *Economic Journal* 53, 202-211, 1943; R. Prebisch, Commercial policy in the underdeveloped countries, *American Economic Review Papers and Proceedings* 49, 251-273, 1959.

²⁶⁰ Milton Friedman, *Capitalism and Freedom*, Chicago, The University of Chicago Press, 4th ed., 2002.

²⁶¹ I. M. D. Little, T. Scitovsky and M. Scott, *Industry and trade in some developing countries: A comparative study*. London: Oxford University Press, 1970; J. B. Donges, A comparative survey of industrialization policies in fifteen semi-industrialized countries, *Wirtschaftliches Archiv*, 112 (4): 626-59; A. Krueger, *Foreign trade regimes and economic development: Liberalization attempts and consequences*, New York: National Bureau of Economic Research, 1978; Chowdhury & Islam, *supra* note 54.

²⁶² See for instance Robert Wade, *Governing the Market: Economic Theory and the Role of Government in East Asian Industrialization*, Princeton: Princeton University Press, 1990; Paul Krugman (ed.), *Strategic Trade Policy and the New Institutional Economics*, Cambridge: MIT, 1986; and Alice Amsden, *Asia's next Giant: South Korea and Late Industrialization*, New York: Oxford University Press, 1989.

²⁶³ P. Bardhan Symposium on the State and Economic Development, *Journal of Economic Perspectives*, 4(3):3-8, 1990, at 5.

state-led industrialization, but there have been some dramatic cases of the latter. This literature contends that at the core of the most dramatic cases of ‘catching up’ – namely, that of East Asian NICs – lays a significant amount of ‘enlightened’²⁶⁴ policy activism of national governments.²⁶⁵ Proponents also support their position with the argument that the East Asian NICs have been as interventionists as many of the much less successful Latin American developing countries (for instance, the share of the GDP in state enterprise was apparently higher in Taiwan and South Korea than in many Latin American countries).²⁶⁶ Sen and Sachs have accordingly argued that what matters to economic development was not the extent, but indeed the quality of the state intervention.²⁶⁷

Thus, the low quality of the Brazilian ISI strategy in comparison to that of East Asian countries has been sustained based on the fact that the Brazilian industrialization was largely aimed at supplying the local market, so it did not need to innovate in order to keep up with the international competition that an export-oriented industrialization would require.²⁶⁸ Moreover, the governmental protections given to East Asian firms were conditioned on such firms reaching certain performance targets over time, whereas such clauses of discontinuances were not *ex ante* established in Brazil.²⁶⁹ It has also been argued that, contrary to the case of Brazil, the government handouts given to East Asian companies were designed to be reduced over time, and eventually eliminated.²⁷⁰ Finally, Brazilian industrial policy has been heavily (and rightly) questioned for having established a number of barriers to the absorption of new technologies, whereas governments of East Asian countries strove to facilitate such processes.²⁷¹ In this vein, many economists have argued that if such problems had been timely corrected the results reached in other NICs (particularly East Asian countries) could be reproduced in Brazil.²⁷²

Still, the case in favor of the possibility of good quality state interventions that overmatch market mechanisms should not be overstated. Policymaking is not a process in which the private sector responds mechanically to bureaucratic initiative, but instead it is a matter of negotiation and compromise, carrying with it the risk that private parties capture political consensus to the detriment of broader societal interests.²⁷³ It has also been argued that the success of East Asian countries, usually explained by successful industrial policies, is chiefly the result of adequate horizontal policies.²⁷⁴ Moreover, there is a substantive body of literature suggesting that the horizontal policies have more potential to foster technological development in NICs.

²⁶⁴ Chowdhury & Islam, *supra* note 54, at 47.

²⁶⁵ Paul Krugman, *supra* note 262, at 15 (arguing that the “the idealized theoretical model on which the classical case for free trade is based will not serve us any more. The world is more complex than that, and there is no question that the complexities do open, in principle, the possibility of successful activist trade or industrial policy”).

²⁶⁶ Chowdhury & Islam, *supra* note 54, at 47.

²⁶⁷ Amartya Sen, *Development: Which Way Now?* Economic Journal, 93, December: 745-62. Jeffrey Sachs, *External Debt and Economic Performance in Latin America and East Asia*, Brookings Papers on Economic Activity, 2:523-64, 1985.

²⁶⁸ L. E. Westphal, *Industrial policy in an export-propelled economy: Lessons from South Korea’s experience*, Journal of Economic Perspectives, v. 4, p. 41-59, 1990; D. Rodrik, *Getting interventions right: How South Korea and Taiwan grew rich*, Economic Policy, v. 20, p. 55-107, 1995.

²⁶⁹ Amsden, *supra* note 262.

²⁷⁰ Mauricio Canêdo-Pinheiro et al., *Por que o Brasil não precisa de política industrial*, Fundação Getulio Vargas, EPGE, No. 644, March 2007.

²⁷¹ *Id.*

²⁷² H. J. Chang, *Chutando a escada – A estratégia do desenvolvimento em perspectiva histórica*. São Paulo: Unesp, 2003.

²⁷³ See R. Samuels, *The Business of the Japanese State: Energy Markets in Comparative and Historical Perspectives*, Ithaca: Cornell University Press.

1987 (describing a complex dynamics of policy-making in East Asia as the “politics of reciprocal consent”).

²⁷⁴ Canêdo-Pinheiro, *supra* note 270.

4.3 *One institutional letdown; three competing paradigms*

There are two competing paradigms to explain failures of the liberalizing reforms to produce more innovation and trade performance in the Brazilian economy.²⁷⁵ The first is associated with a more orthodox, neoclassical political economy;²⁷⁶ the second, with a more heterodox view.²⁷⁷ Roughly speaking, the key distinction between the two is the role to be played by the government: while the former emphasizes the market as the engine of growth, the latter places the burden of fostering development on activist policies to be carried out by the state.²⁷⁸ IPRs laws play a very different role within each of such frameworks: while the former embraces IPRs protection with few reservations, the latter assigns a much more discrete, or even non-existent, role for IPRs protection. The dividing line between the two paradigms is often blurry because there is a significant degree of overlap between the state and the market. This suggests the possibility of an eclectic theory that draws on both sides of the debate. A more balanced view of IPRs protection emerges in the backdrop of such assorted analysis, with important implications for the interpretation of TRIPS, as follows.

4.3.1 *Of neoclassical political economics*

From the more orthodox neoclassical political economics standpoint, the crucial factors that would explain the absence of a more vibrant and innovative framework in Brazilian pharmaceuticals are the mismanagement of the macroeconomic environment (particularly the failure to control public spending),²⁷⁹ the insufficient provision of 'pure public goods' (especially public infrastructure and enforcement of property rights, including IP rights and contractual rights),²⁸⁰ the microeconomic inefficiencies²⁸¹ that became entrenched on the economic system as a consequence of ill-designed industrial policies (particularly special interest groups interested in retaining monopoly privileges), and the failure to take bolder steps towards further trade liberalization and market de-regulation.²⁸²

Adherent of the more orthodox stream start out by arguing that the crucial tenets of the horizontal policies in place in East Asia were not present in Brazil. Canêdo-Pinheiro et al. have compared a number of macroeconomic data for three NICs, Brazil, South Korea, and Taiwan, and also Japan, Chile and USA, and concluded that Brazil has consistently underperformed the other countries in crucial tenets of its macroeconomic policy.²⁸³ Brazil has time and again failed to control its public spending²⁸⁴ having therefore incurred much

²⁷⁵ Jorge Katz, *supra* note 124.

²⁷⁶ T. Srinivasan, *supra* note 91 (coining the expressional "neoclassical political economy").

²⁷⁷ Chowdhury & Islam, *supra* note 54, at 46.

²⁷⁸ *Id.*

²⁷⁹ Jorge Katz, *supra* note 124.

²⁸⁰ Cooter & Schaefer, *supra* note 1, at 59 et seq.

²⁸¹ Mancur Olson, *The Rise and Decline of Nations: Economic Growth, Stagflation and Social Rigidities*, New Haven: Yale University Press, 1982 (noting that the private sector can engage in distributions coalitions and engage in lobbying activities designed to capture rents).

²⁸² Jorge Katz, *supra* note 124; Armando Castelar Pinheiro & Jairo Saddi, *Direito, Economia e Mercados*. Rio de Janeiro: Elsevier, 2005.

²⁸³ Canêdo-Pinheiro et al., *supra* note 270. However, there are also positive signals in the Brazilian economy: inflation has been under control since 1994, the public debt/GDP ratio has been decreasing and in April of 2008 Standard & Poors, a credit rating agency, awarded a much-coveted investment degree rating.

²⁸⁴ See E. Baldacci et al., *Growth, governance, and fiscal policy transmission channels in low-income countries*, *European Journal of Political Economy*, v. 20, p. 517-549, 2004 (suggesting that public spending in poorer countries is less efficient).

larger inflation rates (Table 6).²⁸⁵ Moreover, the reduction of public deficit that took place from the early 2000 decade was implemented by means of increased taxation and decreased investments in infrastructure.²⁸⁶ The upshot is that taxation in Brazil became one the highest in the developing world²⁸⁷ and the infrastructure for robust growth is lacking (Table 7).²⁸⁸ Brazil has also failed to tame its ever-growing, inept bureaucracy with negative effects to the overall efficiency of its economy.²⁸⁹

Table 6:²⁹⁰ Annual Average Inflation Rate (consumers' price index)

	1960-1969	1970-1979	1985-1989	1990-1999	2000-2005
Brazil	42.82%	32.59%	271.7%	280.4%	7.71%
South Korea	13.00%	15.05%	8.08%	5.71%	3.04%
Japan	5.35%	8.97%	2.51%	1.20%	-0.37%
Taiwan	4.77%	8.90%	4.44%	2.87%	0.78%
Chile	24.16%	130.36%	20.29%	10.28%	2.82%
United States	2.17%	6.46%	4.17%	2.46%	2.12%

Table 7:²⁹¹ Corruption and quality of state bureaucracy (2004)

	Corruption monitoring (1)		Government efficiency (2)	
	Index (3)	Ranking (4)	Index (3)	Ranking (5)
Brazil	-0.15	95th	0.02	87th
South Korea	0.17	78th	0.95	42th
Japan	1.19	29th	1.21	29th
Taiwan	0.64	54th	1.15	32th
Chile	1.44	24th	1.27	28th
United States	1.83	16th	1.80	14th

(1) Measures the extent of corruption, that is, the extent to which power is exercised to obtain private gains.

²⁸⁵ See M. Noland & H. Pack, *Industrial Policies and Growth: Lessons from International Experience*, in: Loyaza, N., Soto, R. (ed.). *Economic Growth: Sources, Trends, and Cycles*. Santiago: Central Bank of Chile, 2002, and M. Noland & H. Pack, *Industrial Policy in an Era of Globalization – Lessons from Asia*, Washington: Institute for International Economics (noting that Japan, South Korea and Taiwan have maintained fiscal austerity on the post WWII period). See A. Mansoorian & L. Michelis, *Money, habits and growth*, *Journal of Economic Dynamics & Control*, v. 29, p. 1267-1285, 2005 (suggesting that high inflation tends to diminish economic growth).

²⁸⁶ See S. Gupta et al., *Fiscal Policy, expenditure composition, and growth in low-income countries*, *Journal of International Money and Finance*, v. 24, p. 441-463, 2005 (suggesting that in low-income countries reduction of public spending tends to be more efficient than the reduction of investments in infrastructure or tax increases).

²⁸⁷ FEBRAFARMA report, *supra* note 137, (noting that in the period of 2000-2004 the overall tax burden in pharmaceutical products corresponded to 35.07% of the final price of the medicines, a fairly high rate especially if we consider that Brazil does not have a policy of reimbursement of such expenses).

²⁸⁸ Canêdo-Pinheiro et al., *supra* note 270.

²⁸⁹ See S. Herrera and G. Pang, *Efficiency of Public Spending in Developing Countries: An Efficiency Frontier Approach*, World Bank Policy Research Working Paper, n. 3645, 2005 (suggesting that the public sector tends to be less efficient in countries in which the public expenditures as a proportion of GDP are higher); see M. Habib & L. Zurawicki, *Corruption and foreign direct investment*, *Journal of International Business Studies*, 33(2), 291-318, 2002 (suggesting that corruption has a negative effect on foreign direct investment); A. S. Rajkumar & V. Swaroop, *Public Spending and Outcomes: Does Governance Matter?*, World Bank Policy Research Working Paper, n. 2840, 2002 (suggesting that the quality of state bureaucracy and the level of state corruption negatively impact public policy).

²⁹⁰ See, IMF, *International Financial Statistics*, Washington: IMF (2005) and Bureau of Statistics - Republic of China (2005), *apud* Canêdo-Pinheiro et al., *supra* note 270.

²⁹¹ See, D. Kauffmann et al., *Governance Matters IV: Governance Indicators for 1996-2004*, draft, 2005, *apud* Canêdo-Pinheiro et al., *supra* note 270.

(2) Jointly measures the quality of public service, the quality of the state bureaucracy, proficiency of public civil servants, the independence of public service from political pressure, and the credibility of government's commitment to public policies.

(3) Ranges from -2.5 to 2.5.

(4) From 204 countries.

(5) From 209 countries.

4.3.2 *Of heterodox political economics*

More heterodox newer political economics views challenge the orthodoxy on four accounts. First is by questioning the empirical foundations of the orthodoxy. For instance, it does so by pointing out that all of the East Asian countries that are catching up with the developing world have relied heavily on industrial policies,²⁹² or by suggesting that what matters to the process of economic development is not the extent, but instead the quality of state intervention.²⁹³ Second is by noting that the risk of government failure that is inherent to any activist industrial policy can be minimized through appropriate institutional arrangements. Third is by postulating that the objective of the country's industrial policy should be that of winning export markets through strategic intervention in key industries (instead of focusing on picking winners and protecting domestic markets as was common during the times of ISI).²⁹⁴ Fourth is by remembering that heterodox groups contest the notion that industrial innovation is simply a by-product of macroeconomic stability. Accordingly, the state should act proactively to address the microeconomic aspects of technological advancement, notably the dynamics of technology innovation at the level of the institutions that significantly affects the country's productive structures and its international competitiveness. Thus, while the heterodoxy does not have a coherent agenda of its own, a unifying topic is that it sees a broader role to be played by the state,²⁹⁵ particularly in enhancing domestic technological absorption capabilities, implementing vertical policies, adopting a more protective stance in international trade negotiations and in some cases providing missing consumers markets for local industry.

In research intensive industries, such as pharmaceuticals, there is abundant evidence that company growth is intimately related to innovativeness.²⁹⁶ In pharmaceuticals, high cash flows created by earlier innovations leads to further investments in R&D, manufacturing capacity and marketing sales, and the cost of subsequent R&D projects are cut by sharing accumulated knowledge, research facilities and marketing networks, leading to further specialization, innovation and profits.²⁹⁷ A small group of no more than 30 companies headquartered in only five countries (USA, Germany, Switzerland, UK and France) are responsible for 70% of all the innovations in pharmaceuticals in the period of 1800-1990.²⁹⁸ As so, a handful of highly competent pharmaceutical companies enjoyed substantial competitive advantages which consolidated their position in the world markets by research intensity, corporate technology tradition, corporate growth (including mergers and acquisitions of foreign companies), rendering it extremely difficult the entry of new competitors. R&D is a service activity with very demanding skill, knowledge and support

²⁹² R. Wade, *The role of government in overcoming market failure: Taiwan, Republic of Korea and Japan*, in H. Hughes (ed.), *Achieving industrialization in Asia*, Cambridge: Cambridge University Press, 1988; Wade, *supra* note 262.

²⁹³ P. Bardhan, *Symposium on the state and economic development*, *Journal of Economic Perspectives*, 4(3): 3-8; Sen, *supra* note 267; Jeffrey Sachs, *supra* note 267.

²⁹⁴ Celso Furtado, *Um projeto para o Brasil*. RJ, Saga, 1968; Prebish, *supra* note 259.

²⁹⁵ D. Kupfer, *Política Industrial*. *Econômica*, v. 5, p. 281-298 (2003).

²⁹⁶ See Mansfield, *supra* note 225.

²⁹⁷ Henderson & Cockburn, *supra* note 226.

²⁹⁸ Achilladelis & Antonakis, *supra* note 227.

needs, traditionally met only in developed countries with strong national innovation systems. Moreover, R&D is taken to be the least “fragmentable” of economic activities because it involves knowledge that is strategic to firms, and because it often requires intense knowledge exchange (much of it tacit) between users and producers within localized clusters.

To illustrate the problem of economies of scale in pharmaceuticals, in 2005 the total sales of Aché, the largest Brazilian pharmaceutical laboratory, corresponded to USD 635.8 million, or 6.9% of the Brazilian market. In that same year, Pfizer’s sales reached USD 51.3 billion, which is 80 times more than Aché and 6 times the overall size of the Brazilian market.²⁹⁹ Moreover, the total cost for developing a new medicine has recently been estimated as \$ 897 million.³⁰⁰ This cycle could only be interrupted if the government of newly-industrialized countries would implement compensatory industrial policies.³⁰¹

4.3.3 An ‘effects test’ synthesis

In light of competing explanations, the question remains about the drawing of a conclusion about the comprehensive cause of the dearth of innovation in pharmaceuticals in Brazil. First of all, it is easy to see such orthodox neoclassic political economy and its heterodox views from the perspective of a market solution standing in opposition to a solution through the state. But in reality the frontier is much more blurry because of dynamic feedback mechanism between the two in that the market needs the state, as much as the state needs the market.³⁰² In any case, it would be tempting to suggest that the issue should be resolved by making use of available evidence, but the problem is that the evidence available is equivocal, supporting elements of both paradigms. As Stiglitz notes,³⁰³ both government failure and market failure are common so the fundamental development challenge is to devise institutional arrangements which minimize government failure while at the same time preserving the benefits that flow from the rectification of market failure.³⁰⁴

Our explanation thus emphasizes the role of internal policy and political factors in Brazil, to suggest that the dearth of innovation in Brazil is ultimately related to its dysfunctional political system that imported into the democratic regime some of the worst features of the military regime which it succeeded. In the end, it is the lack of adequate political institutions, not lack of adequate IPRs laws, the most important– yet relinquished – topic in the Brazilian industrial policy agenda, and it is a key factor in explaining the failure of the mid-1990s IP reforms to spurt innovation and R&D investments in pharmaceuticals in Brazil.

Economic problems in Brazil are thus closely linked to its political and institutional structures. As in any Latin American country, the stability of the “rules of the game” plays a central role. At first glance, historic, economic, political and even cultural reasons suggest that democracy in Brazil ought to be seen as very fragile. The Brazilian Republic has existed for nearly 120 years, yet it has experienced three periods of ruling under military law. The transition of power from President Cardoso to current President, Luis Inacio da Silva (a.k.a “Lula”) was the first between two democratically elected presidents in more than 40 years. The most recent restoration of democracy in 1988 was premised on a 160-page Constitution

²⁹⁹ Capanema & Palmeira Filho, *supra* note 129.

³⁰⁰ DiMasi et al., *supra* note 229.

³⁰¹ *Id.*

³⁰² Chowdhury & Islam, *supra* note 54, at 53.

³⁰³ Joseph Stiglitz, *Economic Role of State*, London: Allen & Unwin, 1990.

³⁰⁴ *Id.*

that comprised of wacky items such as the grant of life tenure to bureaucrats and a 12% ceiling on real interest rates.³⁰⁵ This Constitution was drafted during a period of economic downturn and hyperinflation and its short history is quite turbulent.³⁰⁶ The first democratically elected president since the enactment of the Constitution, Fernando Collor, stayed less than 3 years in power and then was impeached by Congress on charges of corruption. In the following election, Fernando Henrique Cardoso was elected for a non renewable term of 4 years, but after a few years in power he championed a Constitution amendment to allow a one-term re-election for himself and also for governors and mayors. Congressional assent for such Constitutional reform came only after the executive doled out pork-barrel inducements and patronage to a significant proportion of Congressmen.³⁰⁷ During its 20 years of existence, the Brazilian Federal Constitution was amended no less than fifty-six times.

In a country with economic vulnerabilities such as Brazil, the recurring economic crises have usually been accompanied by recurring political and institutional crises. Although in recent times there have been a number of important advances,³⁰⁸ the country still faces an oppressive and costly state apparatus, economic inefficiency, and widespread poverty.³⁰⁹ The prevailing large socioeconomic inequality is a source of social and political tensions. Taken together, all of these factors tend to suggest that political instability in Brazil should be viewed as basically inevitable. However, the existing institutional design has vigorously limited this instability, meaning that that Brazilian democracy is less volatile than a hastier scrutiny would indicate. Strictly from a legal standpoint, the basic democratic framework is guaranteed by the existence of a certain set of non-amendable constitutional provisions (called “cláusulas pétreas”, the equivalent of “rocky clauses”). Of greater practical significance, and in spite of all its numerous shortcomings, the Federal Constitution fostered stability by dividing political power, creating a system of checks and balances that limit the ability of governments to carry out radical reforms in the political sphere. The Constitution established what has been referred to as a system of “presidential coalition”, in which the President has the force because it has broad to set the agenda of political and legal reform, yet he needs the legislature to govern.

The 1988 Constitution further reinforced democratic stability in a number of challenging ways. By increasing tax revenues of states and municipal governments it strengthened Brazil’s federalist system, so local politicians have an interest in maintaining

³⁰⁵ Upon the enactment of the Brazilian Constitution in 1988, the Supreme Court held that this ceiling was not self-applicable and the provision was revoked in 2002.

³⁰⁶ See Salama, *supra* note 233.

³⁰⁷ Ames, *supra* note 234, at 2. See also Dora Kramer, Uma senhora cruel chamada realidade, *Jornal do Brasil*, July 1 (with revelations that some incumbent governors had bribed certain Congressmen to support re-election in support for the reelection amendment than under debate in Congress).

³⁰⁸ Salama, *supra* note 233 (noting that inflation has been tamed since 1994, poverty is decreasing slowly, and even more surprising, inequality is declining. The number of people earning less than USD 1 per day continually falls (in 4.2% of the population in 2006) and the proportion of people without access to safe water decreased from 17.7% in 1992 to 10.2% in 2005. A society of mass consumption begins to consolidate itself: today, 97% of the households have electricity, 88% have refrigerators, and 19% computers (PCs). Inequality (Measure known by the “Gini index”) has fallen slightly, while poverty fell more among blacks and mulattos than among whites. Moreover, in recent years the country has managed to grow at higher rates, at the order of 4-5% of GDP. However, growth of the Brazilian economy in recent decades has been lower than in other developing countries. Less than the average growth of the world economy, and also lower than the average of the BRICs - group comprising Brazil, Russia, India and China, which are the countries that are expected to account for substantial parcels of world GDP in 40 years. Unemployment rates are relatively high (around 10%), and so are the rates of underemployment and informality).

³⁰⁹ High taxation stifles economic growth; the running costs of government as a percentage of GDP have more than doubled in the last two decades;³⁰⁹ and social security spending (around 11% of GDP) is the highest amongst NICs.

institutional order as a means of ensuring their status of power. The powers of Congress reinforced meaning that Executive Power needs the support of the legislature to govern, with which the Legislature becomes the arena for political debate par excellence. Finally, the Constitution sharply increased the degree of independence from the Judiciary. Indeed, an independent (although arcane) and relatively well funded Brazilian Judiciary can indeed stand as the “guardian” of the Federal Constitution, especially in that it has broad powers to overrule legislation passed by Congress and the President. The Constitution also created the conditions for a clean system of elections.³¹⁰

However, stability came at a high price. The same Constitution that set the grounds for political stability is however to blame for having engendered a political model premised by everlasting crises in government. Brazil is one of the world's most populous and important democracies but unlike Anglo-American, single-member plurality systems, Brazilian national parties are loosely disciplined. If, on the one hand, the weakness of political parties can reinforce stability by further fragmenting political power, on the other hand it requires large political coalitions as a condition for any president to govern. Congress is powerful, but the control of Congressmen by the population is largely inadequate. In a well-grounded book, political scientist Barry Ames has powerfully argued that the proportional system of open list voting laid out by the Brazilian Constitution influences the kinds of candidates who compete in elections (for the worst), their campaign strategies (for bargaining through cheap pork-barrel) and their behavior in office (for corruption and self-seeking rewards). Brazil's electoral system is extremely permissive in that it gives Congressmen wide room to maneuver and change parties. Brazil's electoral system for the Legislative Power is premised on proportional representation³¹¹ and open lists of candidates.³¹² Together with a number of other technical rules, this system undermines the authority of party leaders, personalizes politics and inhibits party building.³¹³ Most importantly, it makes it easy for deputies to evade their constituent monitoring.³¹⁴ Accordingly, the Brazil's institutional framework tends to produce pork-oriented legislators, who have little concern with national issues and conduct hard bargains with the president to bring the proverbial pork home.

In the history of Brazil's recent democracy no party has ever been strong enough to govern with less than at least half a dozen other parties joining a broad coalition that assembles a matrix of factions of no coherent tendency. Consider for instance the current political situation in the country. The PT,³¹⁵ which is the party to which Brazil's current President (namely Luis Inacio da Silva, or “Lula”) is affiliated, holds less than 20% of the existing 513 seats in Congress. The party governs the country together with a broad coalition of various parties that have no program of ideological consistency whatsoever. This main party in the coalition is the PMDB,³¹⁶ which is the largest party currently in Congress holding around 20% of the available seats. Yet, this same party that serves as the basis for political support to President Lula in Congress has run for the last presidential elections of 2006 in

³¹⁰ Counting of votes is done electronically, the votes are secret and popular participation is high.

³¹¹ Proportional representation means that seats in Congress are allocated to the parties in proportion to the total number of votes received by the party (unlike Anglo-American systems, which are based on the “first past the post” system). See Ames, *supra* note 234, at 41.

³¹² Under the open lists system, voters can choose to vote for the candidate (as is the case for 90% of voters) or for the party.

³¹³ Ames, *supra* note 234, at 65.

³¹⁴ Ames, *supra* note 234, at 41.

³¹⁵ PT: Partido dos Trabalhadores (Workers Party).

³¹⁶ PMDB: Partido do Movimento Democrático Brasileiro (Brazilian Democratic Movement Party).

the political alliance that opposed Lula. Even more interesting is the case of the PSDB³¹⁷ of former President Cardoso. The party is PT's major contender at the national level, yet it has recently decided to run for the municipal elections in the city of Belo Horizonte in an alliance with Lula's PT.

While in court cases the intentions of the 1988 legislators sometimes play a role, those discussions are essentially irrelevant for a theory of the effects of the institutional framework on governance. Institutions have a life of their own and may produce results that largely differ from those of their founders intentions.³¹⁸ As noted by Douglass North,³¹⁹ institutions exhibit path dependence, meaning that the consequences of small events and chance circumstances can determine solutions that, once they prevail, lead one to a particular path. Path dependence arises because any set of institutions creates entrenched interests that tend to be biased against change.

There are a number of important implications that follow from the institutional framework laid out by the 1988 Constitution. The first is that the definition of the Brazilian regime as a stable democracy has to be qualified in that the system is democratic and personalistic at the same time. Personalism means that a relatively large number of local politicians will have a relatively high personal weight in the course of Congressional debates and policy-making at the federal level. The term personalism also indicates that policy-making is largely influenced by the leadership of individuals with local pre-eminence and national influence, to the detriment of questions of ideology or programmatic coherence. To illustrate, 53% of the federal deputies elected in 2002 had a record of membership in more than one parties during their public careers, a feature that reflects no ideological change on their parts but simply their need to maximize opportunities for a successful political career.

4.4 Conclusions

The Brazilian frail innovation system is deeply rooted in the country's politically challenged history, and (thus far at least) the liberalizing reforms of the late 20th century have had a modest effect in changing this truism. Despite its status as South America's leading economic power, Brazil remains a largely unrealized potential, both within and outside its pharmaceuticals industry. Specifically within the Brazilian pharmaceutical industry, the amount of resources allocated for the purpose of producing and disseminating new technology is small, particularly when benchmarked with more developed industrial nations. Technical change 'embodied' in new vintages of imported machinery, as well as foreign licenses of new product designs have become the major 'carriers' of new technology, but the country remains irrelevant if we think of its innovation system as the source of fundamental innovation.

The political framework in Brazil undermines long-term policies and favors short-sighted ones also vis-a-vis R&D investments in the pharmaceutical industry, regardless of the strictness of Brazil's patent regime. Budgetary deficits not only constrain the ability of the

³¹⁷ PSDB: Partido da Social Democracia Brasileira (Brazilian Social Democratic Party).

³¹⁸ In political theory there are at least three theoretical frameworks for conducting an "institutional" analysis. For an Organizational Theory of Institutions see James G. March and Johan P. Olsen, *Rediscovering institutions: The organizational basis of politics*, New York: Free Press, 1989 (suggesting that the institutions themselves can be treated as political actors); for a Transactions Cost approach see Oliver Williamson, *Economic institutions of capitalism*, New York: Free Press, 1985 (relating transactions cost to economic efficiency and to the organizational form of the firm); for a theorization based on Rational Choice see Kenneth A. Shepsle, *The Giant Jigsaw Puzzle*, Chicago: University of Chicago Press, 1978 (examining institutions from the perspective of Game Theory).

³¹⁹ Douglass North *Institutions, Institutional Change and Economic Performance*, Cambridge: Cambridge University Press (1990).

government to implement meaningful vertical policies premised on subsidies, but also to implement horizontal policies premised on reduced taxation³²⁰ and base interest rates. Corruption and endemic rent-seeking hampers the ability of government to make technical choices in directing industrial policies to the right sectors, a process that has undoubtedly fuelled the extent of political appointments without credentials to key positions in the administration. Large bureaucracy undermines the efforts of government to create a more stable, business-friendly environment. The Executive Power has weak incentives to create autonomous or independent policy-making agencies because in so acting it would reduce the instruments that are available to it to buy political support. Political support is exchanged for government jobs and public works in every society, a proposition that requires no demonstration. Brazil is not unique in the presence of such practices, but in their breadth.³²¹ Pervasive pork and patronage particularizes policy-making in that politicians sustain themselves by supplying pork and services to individuals.³²² All of that has severely compromised the quality and motivation of public servants, their behaviour, and eventually the content of policy itself.

What is the lesson that the Brazilian political framework teaches? In the midst of political crises and fluctuations in the international economy, the Brazilian state will continue to seem a disfigured and moderately effective Frankenstein, which brings together parties relatively inconsistent, ranging from bureaucrats to competent agencies and ministries captured manipulated by political and economic groups.

5. Summary and conclusions

In Newly Industrialized Nations (NICs), different than in poor developing countries, deficient political institutions, not the lack of strict IPRs is what essentially curtails foreign direct investment (FDI). Neoclassic political economics narrations, such as of Brazil's political economy, in fact, sets a novel understanding of the failure of its mid-1990s IPRs reforms in spurring inwards FDI.

This conclusion is at odds with the classic development economics paradigm adopted also by the WTO at large, whereas strict patent laws enhance FDI into poor nations.

It is more broadly contested that lack of industrial policies is suffices to curtail innovative growth in NICs, such as Brazil. In the latter, technologically-based economics growth had not grow as a result of the adoption of TRIPS Pax American patent regime with emphasis on its compulsory licensing rule.

Instead, bargaining around TRIPS's patent compulsory licensing with respect to pharmaceutical products, as some NICs practice, may not only be efficient but presumably is also politically appealing, as it includes the promise of lower prices to governments and consumers for pharmaceutical products.

In numerous occasions, such as when considering compulsory licenses for pharmaceutical patents on nelfinavir and efavirenz or Gleeevic, Brazil used aggressive negotiations with big pharmaceutical companies, combined with the credible threat of issuing compulsory licenses for generic manufacture, to bring down the prices of patented drugs. Brazil, as other NICs, is different to other low-income developing countries, which

³²⁰ In 2005, taxation in Brazil reached 37% of GDP which is the highest in the world for countries with similar per-capita income.

³²¹ Barry Ames, *supra* note 234, at 24.

³²² To illustrate the pervasiveness of such practices, Brazil's military regime had Congressional elections, yet Congressmen were basically excluded from the most important political decisions. As so, their performance became measured by the ability to supply favor from the state bureaucracy for the groups to which were linked.

typically enjoy the lowest global prices for patented pharmaceuticals but often do not integrate the most costly testing into treatment guidelines. In the latter, as a middle-income country, it opts to issue compulsory licenses, whereas importing generics may be cheaper and more feasible than producing drugs locally. Furthermore, the existence of a strong domestic generic industry helps the process by making the threat even more credible.

The least-developed countries of the world attract virtually no FDI due to extremely low productivity, education, and skills.³²³ Other factors hurting those countries are underdeveloped infrastructures, relatively closed markets, and poorly designed, intrusive, and non-transparent government regulations that encourage corruption. NICs, on the other way act differently. In the latter, the dearth of innovation, *mutatis mutandis*, as in the Brazilian pharmaceutical industry, is ultimately related to its dysfunctional political system that imported into the democratic regime some of the ineffective features of the military regime which it succeeded.

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³²³ See, United Nations Conference on Trade and Development, The TRIPS Agreement and Developing Countries 18, U.N. Doc. UNCTAD/ITE/1, U.N. Sales No. 96.II.D.10 (1997); The World Bank, World Development Report 1994: Infrastructure for Development 14-20 (1994), at 36-38.