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PHARMACEUTICAL PATENT BARGAINS:
THE BRAZILIAN EXPERIENCE

Daniel Benoliel e Bruno Meyerhof Salama

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Pharmaceutical patent bargains: the brazilian experience

Bruno Salama[1] *& Daniel Benoliel*[2]

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Table of Contents

Introduction 4
1 Pharmaceutical Patent Bargaining Situation 6
1.1 Overview 6
1.2 Patent Compulsory Licensing Bargaining Narrative 11
1.2.1 Bargains over National Law 11
1.2.2 Inside Options within an Unstable Balance of Power 13
1.2.3 The National-Supra National Legal Deficit 15
1.3 The Outside Option-Benefit Bent 17
1.3.1 Sanction Costs Considerations 17
1.3.1.1 Big Pharma 18
1.3.1.2 Local Pharma 19
1.3.1.3 Other Trade Sanctions 20
1.3.2 The Circular Increase in Outside Option Values 21
1.3.3 The National Benefit of Compulsory Licensing 22
1.4 Conclusions 24
2 The Localized Governance Consideration 27
2.1 Overview 27
2.2 One Institutional Letdown; Two Competing Paradigms 29
2.2.1 Of Neoclassical Political Economy 30
2.2.2 Of Heterodox Political Economy 32
2.3 An 'Effects Test' Synthesis 33
2.4 Conclusions 37
Conclusion 39

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In the backdrop of the strict patent regime flatly adopted by the World Trade Organization (WTO) for all countries, a few countries constantly challenge this system through aggressive patent bargains. Within the pharmaceutical sector, noticeably, some countries now threaten to issue or otherwise actually issue compulsory licenses that may sway large pharmaceutical companies into selling drugs with large discounts or into granting voluntary licenses domestically. That is conspicuously the negotiation strategy adopted by Brazil in its negotiations with big international pharmaceutical companies.

This paper explains Brazil's aggressive bargaining approach based on an analysis of two aspects of its political economy. The first has to do with the international context of patent bargaining in the post-WTO era. Accordingly, the existence of large and fast growing domestic markets position countries such as Brazil as strategic destinations for Foreign Direct Investment (FDI) and trade. Together with an absence of a propensity to innovate in pharmaceutical products, these conditions boost Brazil's bargaining power for issuing compulsory licenses over pharmaceutical products. The second aspect is related to political economy dynamics inside Brazil. Accordingly, 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. This remains true regardless of the strictness of the patent regime in place. The lesson of Brazil is relevant arguably for other more powerful developing countries which presently examine Brazil's approach while further challenging the WTO's strict patent policy for the future.

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Introduction

Sérgio Buarque de Holanda, the father of modern Brazilian historiography, once defined the character of Brazilians as that of a "cordial man."[3] About half a century later this observation is allegorically challenged with the signaling of Brazil as the developing world's most aggressive bargainer over intellectual property rights (IPRs), and pharmaceutical patents in particular.

Since the creation of the WTO ever more stringent patent systems have been expanding to a vast number of developing countries in a seemingly irreversible fashion.[4] In the backdrop of the strict patent regime flatly adopted by the WTO for all countries,[5] a few countries constantly challenge this system through aggressive patent bargains.[6] Within the pharmaceutical sector, noticeably, some countries now threaten to issue or otherwise actually issue compulsory licenses that may sway large pharmaceutical companies into selling drugs with large discounts or into granting voluntary licenses domestically. A compulsory license forces the patentee to license the patent to the issuing government, thus making room for cost-effective local production or importation of generic copies of the drug for payment of below-market compensation to the patentee.

This article focuses on the political economy of negotiations involving big pharmaceutical companies and Brazil. 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 to obtain discounts from big pharmaceutical companies on medicines distributed in Brazil's public health system.[7] This aggressive behavior was made possible largely because of the country's credible threat of issuing compulsory licenses for generics manufacturing. The term "generics" designates drugs that can be obtained from various sources, as opposed to drugs that are sold only by the originator company or its exclusive licensees.[8]

To present the dynamics of the Brazilian experience with patent bargains, this article breaks down the analysis into two subsets. Part I places the case of Brazil in the international context. It highlights the fact that Brazilian policy choices take place against the legal backdrop of the TRIPS agreement, a WTO-sponsored legislation that aims at regulating patents internationally. Brazil's aggressive patent bargaining is

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[3] Sérgio Buarque de Holanda, Raízes do Brasil, 1936, 1994 (26ed.), chapter 5.

[4] See, e.g., The WIPO Index of Patent Systems, at: www.wipo.int/ipstats/en/resources/patent_systems.html. 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 of 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).

[5] Shamnad Basheer & Annalisa Primi, The WIPO Development Agenda: Factoring in the "Technologically Proficient" Developing Countries, in Implementing the World Intellectual Property Organization's Development Agenda 100, 110 (Jeremy de Beer ed., 2009); Jeremy de Beer, Defining WIPO's Development Agenda, in Implementing the World Intellectual Property Organization's Development Agenda, at 1, 3; James Boyle, A Manifesto on WIPO and the Future of Intellectual Property, 2004 Duke L. & Tech. Rev. 9, at 3-4, http://www.law.duke.edu/journals/dltr/articles/pdf/2004DLTR0009.pdf.

[6] Daniel R. Cahoy, Confronting Myths And Myopia on the Road from Doha, 42 Ga. L. Rev. 131 (2007); Peter K. Yu, Access to Medicines, BRICS Alliances, and Collective Action, 34 Am. J. L. and Med. 345, 358 (2008).

[7] 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.

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

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accordingly explained based on essentially two considerations. The first is the existence of large and fast growing domestic markets that position countries such as Brazil as strategic destinations for FDI and trade. In comparison with smaller developing countries, larger emerging economies generally have significantly more latitude to decide on their patent policies. This is conspicuously the case of potential issuances of compulsory licenses over patented medicines. Secondly, the dearth of innovation in the Brazilian pharmaceutical sector boosts the country's bargaining power for issuing compulsory licenses. As argued, the absence of domestic companies that could profit for more stringent patent protection system reduces the political pressure and the sanctions costs that Brazil faces when it issues compulsory licenses over pharmaceuticals.

Part II shifts the analysis to national or localized considerations within Brazil. It focuses specifically on governance constraints that have been hindering Brazil from making a shift towards becoming an innovation powerhouse. At its core, we suggest that Brazil's political structure renders the Brazilian state weak on a fundamental level. By weak state we mean a state that is captive to a wide array of distributional coalitions and thus is exposed to ravages of rent-seeking groups. This framework in Brazil favors short-sighted policies also in connection with research and development (R&D) investments in the pharmaceutical industry. This remains true regardless of the strictness of the patent regime in place. The final part concludes with the caveat. Accordingly, as long as the present localized governance consideration is present in emerging economies such as Thailand, South Africa or Brazil, the present WTO-bases patent regime will continue to incentivize, at times, aggressive non-cooperative bargaining situations.

1 Pharmaceutical Patent Bargaining Situation

1.1 Overview

In the pharmaceutical field a TRIPS-compliant legislation did poorly in fostering innovation in Brazil, while enhancing royalties' collection by multinational enterprises (MNEs). To understand why, one needs to start with the narration of the TRIPS agreement upon its early predicaments. TRIPS Agreement traditionally renders it mandatory the protection of pharmaceutical patents in mostly every WTO member country. At the same time, TRIPS contains a number of loopholes that provide plasticity for national governments to face political exigencies, such as health crises.[9] These loopholes are comprised of safeguards and flexibilities that allow WTO members to moderate the negative effects of intellectual property protection.[10] The authorization for WTO members to compulsorily license patents is a distinctively important flexibility enshrined the TRIPS Agreement. Accordingly, in some cases national governments are allowed to force patentees to grant use of the patent against payment of below market royalties.[11] In practice, however, the issuance of a compulsory license by a developing country is largely dependent upon whether it holds sufficient bargaining power to do so.

Bargaining power is a consideration to be explained by bargaining theory. 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.[12] 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 "outside option"[13] (also named "reservation value", "disagreement value", or "threat value"), which equals the payoff that the party can obtain on its own without cooperation from others.[14] Bargaining power is also a function of the country's "inside options", which are the actions that it can take in order to derive positive payoffs while strategically disagreeing in the course of the negotiation.[15] The prototypical example of an inside option occurs when a country *de facto* refrains from protecting patent rights while formally complying with the TRIPS Agreement.[16]

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[9] Judith Goldstein et al., "Introduction: Legalization and World Politics" (2000) 54 International Organization 393.
[10] Robert Weissman, A Long, Strange TRIPS: The Pharmaceutical Industry Drive To Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries, 17 U. Pa. J. Int'l Econ. L. 1069, 1096 (1996).
[11] Antony Taubman, Rethinking TRIPS: "Adequate Remuneration" For Non-Voluntary Patent Licensing, 11 J. Int'l Econ. L. 927 passim (2008).
[12] See, e.g., Robert D. Cooter & Thomas Ulen, Law & Economics, The Addison-Wesley series in economics, 4th ed., at 78-80.
[13] Robert D. Cooter, The Strategic Constitution, Princeton, Princeton University Press (2000), at 274.
[14] Leigh L. Thompson, The mind and heart of the negotiator, 2nd ed, New Jersey (NY): Prentice Hall; 2001.
[15] Abhinay Muthoo, A Non-Technical Introduction to Bargaining Theory, 1 World Econ., 159 (2000) [hereinafter Muthoo, Non-Technical Bargaining], at 149, 157-160.
[16] Robert M. Sherwood, The TRIPS Agreement: Implications for Developing Countries, 37 IDEA 491, 544 (1997) [hereinafter Sherwood, The TRIPS Agreement] (noting that "the judicial systems in perhaps eighty percent of the countries of the world are simply not up to the task of supporting intellectual property rights, much less dealing effectively with other matters"); and Robert M. Sherwood, Some Things Cannot Be Legislated, 10 CARDOZO J. INT'L & COMP. L. 37, 42 (2002). See also TRIPS, Article 41 (defining the four key tenets of national enforcement provisions, which are largely modeled on American intellectual property law).

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Brazil illustrates a bargaining theorization of international bargaining over pharmaceuticals because it has routinely resorted to a negotiation strategy for price reductions premised on the credible threat of issuing compulsory licenses.[17] Unlike smaller developing countries, larger economies such as Brazil can develop a capacity for producing generics, thus raising their outside option 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 issuance of a compulsory license.

There is now an increasing consensus that patents are crucial for the development of certain IPR-sensitive products such as the pharmaceuticals.[18] In line with such findings, the standard prescription of enhanced IPRs suggests that by undermining the whole intellectual property system in Brazil, the issuance of compulsory licenses by the Brazilian government also undermines domestic R&D investments in general. This assessment typically leads 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 most sectors of the Brazilian economy. More importantly, such levels of technological innovation have over time given limited responses to changes in the strictness of the country's intellectual property legislation in pharmaceuticals.

The scope of the Brazilian IPRs regulatory narrative is circular, dating from as early as before World-War II. At that time, Brazilian IPRs legislation granted patent protection for pharmaceutical products and processes in Brazil.[19] Such protection reflected a longstanding legal tradition in Brazil of offering patent protection for inventions, a tradition that however had little practical relevance in a pre-industrialized country.[20] In 1945 in the midst of a push for industrializing the country, the law was amended so as to rule out the protection of inventions related to medicines, foodstuffs, materials and substances obtained by chemical means or processes.[21]

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-

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[17] 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.

[18] Carlos A. Primo Braga & Carsten Fink, The Relationship Between Intellectual Property Rights and Foreign Direct Investment, 9 Duke J. of Comp. & Int'l L. 163 (1998).

[19] 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.

[20] P. Ben-Ami, Manual de Propriedade Industrial. São Paulo: Promocet, 1983.

[21] Oliveira et al., supra note __, at 154.

WW II era. As so, patenting in the pharmaceutical sector was eliminated altogether in 1969, when the government amended the Brazilian Industrial Property Code. 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 the intermediary inputs for local production were taxed mildly and local production was subsidized.[22]

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 intellectual property laws. Pursuant to article 65 of TRIPS, Brazil could have waited until January of 2005 to extent protection to pharmaceutical products and processes. But due to intense commercial pressure from the United States,[23] patent protection was eventually set forth to start much sooner, as of January of 1997.[24]

From that point on, the Brazilian pharmaceutical industry started to decline rapidly.[25] The government abandoned its system of preferred purchases, and local production was progressively substituted for 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.[26] In turn, exportations grew at a much slower pace and the imports of intermediary products for the local production decreased from US$ 150 million per year to only US$ 10 million.[27]

This trend toward a decrease in the size of the Brazilian pharmaceutical industry has been counterbalanced (but limitedly so) by the surge of a Brazilian generics industry in the last decade. The permission for 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 (know as the "Generics Act") that would permit the marketing of generics in Brazil.[28] 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.

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[22] Bermudez et al., Expanding Access to Essential Medicines in Brazil: Recent Regulation and Public Policies, (2004), in Brazilian IP Legislation, supra note 12, at. 129-130.

[23] 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.

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

[25] Drugs and Pharmaceuticals in Brazil, International Business Strategies, October 2003, at 7.

[26] 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. 11.

[27] *Id.*

[28] 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 16, at 136.

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The introduction of generic drugs created a dynamic investment option in the pharmaceutical industry.[29] According to data from the Brazilian Generic Medicines Industry, 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.[30] In a way, the enhancement of the generics production also served to partly revert to the decline of the Brazilian pharmaceutical 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.[31] Moreover, the development of a generics industry helped the government in revamping its network of public laboratories, which now have been set to produce medicines and biologicals to supply the public health system.[32] Currently, the production of these public laboratories represents approximately 3% of the national production in monetary value and 10% in unit numbers.[33]

The new Brazilian intellectual property legal framework was embedded in a broad context of structural changes that encompassed, but were not limited to, the pharmaceutical sector.[34] 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 investment and competition, partly de-regulated markets, and largely privatized economic activities. These reforms aimed to achieve faster productivity growth, better international competitiveness and more equity in the 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, phasing out the era of 'inward-oriented', 'state-led' growth policies.[35]

The liberalizing reforms that swept Brazil in the 1990s have been less positive than a priori expected.[36] On one hand, they were successful in providing foundations for a much more solid macroeconomic management and the eradication of chronic inflation. A highly positive development of these facts happened in April of 2008, when rating agencies started to upgrade Brazil's long-term foreign currency sovereign debt to "investment-grade".[37] A more stable economic environment paved the way for some economic growth and poverty reduction in the country.[38] At the same time,

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[29] Valor Econômico: Análise Setorial, Indústria Farmacêutica, 2006.
[30] Associação Brasileira das Indústrias de Medicamentos Genéricos – Pró Genéricos, at: www.progenericos.org.br.
[31] *Id.*
[32] 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.
[33] Bermudez et al., supra note 16, at 141.
[34] 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.
[35] *Id.* ("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").
[36] 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.
[37] Blomberg.com, Brazilian Debt Raised to Investment Grade by S&P (Update4), April 30, 2008.
[38] Special Report: Brazil, Financial Times (London), July 8, 2008.

Brazil's R&D intensity remains low by OECD standards, and also overly reliant on government spending.[39] That is, as is common in countries with relatively low R&D intensity. As so, partially opening up to foreign competition, de-regulating markets, and privatizing economic activities have not been a sufficient condition for the country to attain a more vibrant development of domestic technological capabilities.[40] 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.[41]

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).[42] 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.[43] In electronics, it was 22.8% and informatics 31.2%.[44] Most importantly, pharmaceuticals were 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%; and in comparison with the top-tier of the OECD countries this ratio went as low as 6.7%.[45]

To be true, the adoption of a TRIPS-compliant legislation did have a positive impact on the number of patent applications in Brazil.[46] Moreover, the increase in patent applications was particularly pronounced in the fields of chemicals and pharmaceuticals.[47] However, that does not evidence any increase in innovative activities in the Brazilian pharmaceutical industry: the reason is that the vast majority of such applications came from nonresidents as extensions of patents already granted abroad.[48] In fact, five big foreign industrial groups respond for the bulk of

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[39] 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.

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

[41] 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.

[42] *Id.*

[43] *Id.*

[44] *Id.*

[45] *Id.*

[46] Francesco Laforgia, Fabio Montobbio, and Luigi Orsenico, IPRs and Technological Development in Pharmaceuticals, in The Development Agenda: Global Intellectual Property and Developing Countries (Neil W. Netanel, ed.) (2009), at 307.

[47] *Id*, at 307.

[48] *Id*, at 309.

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pharmaceuticals and chemicals patent filings.[49] All of that suggests that in the pharmaceutical field a TRIPS-compliant legislation did very little to foster innovation in Brazil, and very much to boost royalties collection by big innovators located outside the country.

1.2 Patent Compulsory Licensing Bargaining Narrative

One hundred and seventeen nations, including Brazil, signed the TRIPS Agreement allowing intellectual property rights to be enforced by trade sanctions backed by the WTO.[50] Although many signatory countries 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.[51] By situating the TRIPS Agreement within the framework of multilateral trade relations, patentees benefit from the increased incentive for nations to enforce intellectual property rights through the threat of trade sanctions.[52] As argued herein, for numerous reasons the TRIPs Agreement wrongly envisaged that the threat of trade sanctions will propel the forward motion of respect and protection of IPRs worldwide.

1.2.1 Bargains over National Law

The negotiations and eventual execution of the TRIPS Agreement gave rise to a first and new set of intra-national bargaining constraint over pharmaceuticals. It does so over the delineation of the flexibilities and safeguards set forth under TRIPS articles 8 and 31.[53] 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 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 became a critical factor in determining the ability of developing countries to bargain for price reductions in their purchases of ARVs from developed countries. The most controversial aspects of such negotiations had to do with the conditions under which developing countries were allowed to issue

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[49] Id, at 313.

[50] 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).

[51] 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).

[52] 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).

[53] Carolyn Deere, The Implementation Game, 2009.

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compulsory licenses and importing or reselling patented drugs without the consent of the patent holder. Such conditions could dramatically affect payoffs of developing countries willing to obtain cheaper ARVs from the patent holders.

The incorporation of TRIPS flexibilities and safeguards is not mandatory and has to be incorporated within each WTO member country internal legal framework. This set the ground for a second round of negotiations between developed and developing countries over the delineation of national legislation in the latter. In the early 2000 decade, Thorpe,[54] Keyla,[55] and Oliveira et al.[56] analyzed 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 within developing countries. The results demonstrated that these countries had not incorporated all the TRIPS flexibilities and safeguards into their national legal systems. This means that, as a matter of fact, most developing countries posses TRIPS-plus legal systems, that is, legal systems that protect patents beyond the minimum standards set out under TRIPS. Such TRIPS-plus legislation further reduces these countries' bargaining power in situations involving public interest.[57]

Brazil exemplifies the case of a country that - in spite of intense pressure from the United States[58] - has partly implemented a number of flexibilities and safeguards allowed under the TRIPS Agreement.[59] First and foremost, the Brazilian Intellectual Property Law of 1996 set 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.[60] 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.[61]

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

[55] B. K. Keyla, Review of National Patent Legislations of India, Indonesia, Sria Lanka & Thailand. New Delhi: National Working Group on Patent Laws, 2003.

56 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.

[57] Bermudez et al., supra note 12, at 46.

[58] Tachinardi, supra note __.

[59] 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 February 10, 2010). 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 February 10, 2010).

[60] Brazilian IP Law, art. 68, main provision.

[61] 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.

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The third is in case the local sales do not satisfy the needs of the local market.[62] The fourth is where there is a dependency of one patent on another.[63] The last one arises in cases of national emergency or public interest.[64] Brazilian IP Law also recognized the principle of international exhaustion of rights,[65] thus permitting parallel imports,[66] 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.[67]

1.2.2 Inside Options within an Unstable Balance of Power

The negotiations over the incorporation of safeguards into national legal frameworks are not one-shot interactions. Rather, they reflect changes in the balance of power amongst the parties involved in the bargaining process. It follows that national intellectual property laws that are established in the wake of the execution of the TRIPS agreement can, and often do, generate political pressure from the groups affected by such legislation. This set of considerations stands as a second type of bargaining constraint over pharmaceuticals. These groups typically wish to steer governments into exploring the alternatives available within a national-TRIPS compliant law that can loosen the overall intellectual property regulatory framework. As argued, some of these actions can be treated as "inside options" because they allow Brazil to derive positive payoffs (through reduced royalties' payments) while the country discusses the broader international intellectual property framework.[68]

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[62] Brazilian IP Law, art. 68, item I.2.

[63] 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).

[64] Brazilian IP Law, art. 71.

[65] 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.

[66] 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).

[67] Oliveira et al., supra note __, 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).

[68] Abhinay Muthoo, A Non-Technical Introduction to Bargaining Theory, 1 World Econ., 159 (2000) [hereinafter Muthoo, Non-Technical Bargaining], at 149, 157-160.

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These dynamics are evidenced by Brazil's 1999 amendment to its national Industrial Property Law.[69] The 1999 amendment introduced a preventive model of patent office regulation into the country's basic TRIPS-compliant IP law, which had been in force since 1996.[70] The new mechanism consists of a prior request (or "anuência prévia") for the examination of pharmaceutical patents.[71] This mechanism was designed to split the analysis of patent filings for pharmaceutical products and processes within two federal bureaus: the Brazilian patent and trademark office (INPI) and the Brazilian sanitary supervision office (ANVISA).[72] In practice, it introduced an additional layer of bureaucratic approval before the granting of a patent. Accordingly, the patent office examines standard criteria of patentability and other procedural requirements (novelty, non-obviousness and utility).[73] The sanitary supervision office, in turn, holds a veto power for the granting of the patent. Specifically, it considers whether the granting of the patent is in line with the public interest.[74]

As expected, the 1999 amendment to the Brazilian IP Law rendered the granting of pharmaceutical patents and processes slower, costlier, and less predictable. Firstly, approval from the sanitary supervision office adds a period of six to twelve months for the final issuance of a patent.[75] The extension in the process of patent examination implies that the term of patent protection will be shortened.[76] Secondly, the patent office and the sanitary supervision office generally adopt an opposite stance regarding the TRIPS agreement: while the former is concerned with protecting innovation, the latter is concerned with exploiting legal flexibilities offered by TRIPS and the Doha Declaration.[77] Predictably, such opposite values have lead to opposite decisions between the two bodies. The best example is offered by recent attempts to patent second and subsequent medical uses in Brazil.[78] In these cases, the patent

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[69] The amendment was introduced by Provisional Measure No. 2,006 of Dec. 14, 1999, available at http://www.dannemann.com.br/CD Pharma/Legislation/PM 2006 1999.htm. This provisional measure was later converted into Law No. 10,196 of Feb. 14, 2001, art. 229, available at http://www.wipo.int/clea/docs new/pdf/en/br/br035en.pdf.

[70] Peter Drahos, "Trust Me": Patent Offices in Developing Countries, 34 Am. J. L. and Med. 151, 169 (2008).

[71] For a detailed examination of the "prior request mechanism" see Edson Beas Rodrigues Junior and Bryan Murphy, Brazil's Prior Consent Law: A Dialogue between Brazil and the United States over Where the TRIPS Agreement Currently Sets the Balance between the Protection of Pharmaceutical Patents and Access to Medicines, 16 Alb. L.J. Sci. & Tech. 423 (2006).

[72] The Brazilian patent office is the National Institute of Intellectual Property (INPI) subordinated to the Ministry of Development, Industry, and Trade (MDIC). The sanitary supervision office is the National Sanitary Supervision Agency (ANVISA).

[73] Brazilian IP Law, article 8.

[74] See Denis Borges Barbosa, A Inconstitucionalidade da Anuência da ANVISA no Procedimento de Concessão de Patentes como Manifestacao Discricionária da Administração Federal (questioning the constitutionality of ANVISA's Approval Process) (July 2004), http://denisbarbosa.addr.com/anuencia.doc.

[75] See Maristela Basso, The International Trade Law and Development Institute, Preliminary Background Paper on Prior Consent for Pharmaceutical Products by ANVISA in Brazil (2005), available at http://www.idcid.org.br/default.asp?sec=3&id=3947.

[76] See Eur. Fed'n of Pharm. Indus. & Ass'ns, Position Paper: Brazil 2 (2004), available at http://www.efpia.org/4 pos/Brazil2004.pdf.

[77] Rodrigues Junior and Murphy, supra note __, at 428.

[78] Second and subsequent use patents offer protection to discoveries of new uses for substances, molecules, active principles, and compounds that have been previously patented or are already in the public domain. See O. Mitnovetski & D. Nicol, Are Patents for Methods of Medical Treatment Contrary to the Ordre Public and Morality or "Generally Inconvenient"?, 30 J. Med. Ethics 470, 472 (2004), available at http://jme.bmjjournals.com/cgi/reprint/30/5/470.pdf.

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office admitted patentability, but the sanitary office denied it.[79] Additional areas of conflict between the two bodies include polymorphism and pipeline-type patents, among others.[80]

1.2.3 The National-Supra National Legal Deficit

There noticeably is a third set of constraint over the pharmaceutical bargaining situation in Brazil. It revolves around Brazil's complex political strategy to defend its IP laws. The Brazilian Intellectual Property Law initially was politically motivated by a desire to reach a compromise between two conflicting sets of interests: the need to allow big pharmaceutical companies to collect royalties on new medicines, and the need to create enough room for the supply of generic anti-retroviral AIDS drugs produced under threat of compulsory licenses. To do that, 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 argued that it breached WTO agreements. In January of 2001, the Office of the United States Trade Representative (USTR) filed a complaint over the Brazil's Intellectual Property Law in the WTO Dispute Settlement Body.[81] The United States sustained that the permission for compulsory licenses to be issued in situations where the patent holder does not locally manufacture the patented product (the "local working" provision referred to in the above paragraph) contravened TRIPS article 27(1)[82] which prohibits national patent protection laws from discriminating with regard to the locale of invention.[83]

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[79] ANVISA, Informes Técnicos, Esclarecimentos sobre Pedidos de Patentes dos Produtos e Processos Farmacêuticos (Aug. 25, 2004), available at http://www.anvisa.gov.br/divulga/informes/2004/250804.htm.

[80] See Basso, supra note __.

[81] WTO Dispute Settlement Body, Brazil--Measure Affecting Patent Protection--Request for Consultations by the United States, WTO Doc. WT/DS199/1. See also U.S. Special 301 report, 2001, www.ustr.gov/enforcement/special.pdf on the dispute before the WTO with Brazil (where the USTR claims 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". See also Bird & Cahoy, supra note __.

[82] 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."

[83] 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 12, 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).

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The Brazilian IP does indeed open the possibility of compulsory licenses for any goods, and is therefore controversial as a matter of law. The WTO however never actually had to pronounce itself over its lawfulness. The reason has to do with the political strategy adopted by Brazil to defend its IP laws. Brazil tied the American questioning over its IP law to the extremely controversial AIDS debate opposing developing countries and large pharmaceutical companies.[84] In the end, Brazil successfully lobbied for a United Nations Commission on Human Rights resolution affirming the right of access to medication.[85]

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.[86] Brazil's position gained political momentum as India joined the dispute, claiming that it had a "systemic interest" in the proceeding.[87] As a result of the ensuing negative publicity,[88] 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 States if it were to issue a compulsory license.[89] The two countries also undertook to resolve any disputes through a bilateral "consultative mechanism."[90]

At the WTO Doha Ministerial Conference of November 2001 that followed, developing countries managed to push for a joint declaration.[91] The goal was to put an

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[84] 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).

[85] Sanders, supra note __, 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).

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

[87] 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.

[88] Chakravarthi Raghavan, US beats a (tactical) retreat over Brazil's patent law, Third World Network, http://www.twnside.org.sg/title/tactical.htm (referring to the situation as a "public relations disaster" for the United States) (last reviewed on February 10, 2010).

[89] 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 __, at 47.

[90] See Bird & Cahoy, supra note __ (also noting that this agreement was not made public).

[91] Sanders, supra note __, 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

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end to challenges at the WTO to legislation setting broad grounds for the issuance of compulsory licenses concerning essential patented drugs.[92] The ensuing Declaration on TRIPS Agreement and Public Health was designed to respond to concerns about the possible implications of the TRIPS Agreement for access to medicines.[93] It 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."[94] In August of 2003, after a long period of discussions, the General Council of the WTO issued a decision,[95] regulating the right of members to issue compulsory licenses.[96]

1.3 The Outside Option-Benefit Bent

Brazil's distinctive ability to credibly threaten to issue compulsory licenses over patented drugs is further explained by three main reasons. All three extend the narration of its bargaining situation also to its being an emerging economy and a BRIC (Brazil-Russia-India-China) country. The first is connected to three sanction costs considerations: Brazilian fast-growing consumer markets are too desirable to be sanctioned by big international pharmaceutical companies; the absence of a domestic innovative pharmaceutical industry undermines the political significance of a more stringent patent protection in Brazil; and the existence of a larger and relatively diversified economy means that the country can more easily endure the prospects of trade sanctions that can potentially be issued by governments that back up patentees. The second reason derives from the existence of an increasingly strong domestic generics industry that supports Brazil's aggressive negotiation strategy and to some extent profits from it. The third reason is that compulsory licensing over pharmaceutical products is also politically appealing. It includes the promise of lower prices both to the Brazilian governments and consumers for pharmaceutical products, and at the same time breeds a local generics industry.

1.3.1 Sanction Costs Considerations

The first reason why a given country avoids issuing a compulsory license has to do with the prospects of sanctions costs that if faces. On the whole, these are the costs that can be imposed on a country that unilaterally sets to break pharmaceutical patents. Such sanctions costs can potentially come from three specific sources: big

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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.

[92] See Sanders, supra note __, 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).

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

[94] *Id.*, item 17.

[95] This data was generated based on the following source: Brazilian IP Legislation, supra note __, at 55.

[96] 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).

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international pharmaceutical companies, the local pharmaceutical industry, or the governments where big international pharma is located, as is typically carried out by the United States Trade Representative (USTR).[97] Emerging economies that carry out little innovation in pharmaceuticals, such as Brazil, face distinctively smaller chances of receiving sanctions on all of these levels. Lower prospects of sanctions render it credible the Brazilian threats of issuances of compulsory licenses over pharmaceuticals.

1.3.1.1 Big Pharma

Depending on the circumstances, big international pharmaceutical companies can impose sanctions costs through reduced FDI, reduced technology transference and local R&D, and reduced trade.[98] In a country such as Brazil, however, threats of sanctions of these kinds are more modest. The main reason is that international pharmaceutical companies typically cannot afford to lose or alienate large markets that contain, or potentially contain, lucrative middle classes.[99] To illustrate, a recent report by PriceWaterhouseCoopers predicts that by 2020, Brazil, China, India, Indonesia, Mexico, Russia and Turkey will represent one-fifth of global pharmaceutical sales, an increase of 60% since 2004.[100] As the economy in these countries improves, local populations are expected to face the kinds of chronic health issues that are typical in wealthier countries. Changes in environmental conditions may also cause the spread of diseases that are more prevalent in the developing world such as cholera and malaria, among others. At the same time, longer life expectancy in these countries tends to positively impact drug sales as well.

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."[101] 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."[102]

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

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

[99] Eyal Benvenisti & George W. Downs, Distributive Politics and International Institutions: The Case of Drugs, 36 Case W. Res. J. Int'l L. 21 (2004), at 44.

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

[101] Bird & Cahoy, supra note __.

[102] Merck's statemt, supra note __.

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The credibility of such retaliatory threats is however 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 signs of reduced FDI in Brazil. In fact, Brazil's share of FDI in 2007 totaled US$ 33.7 billion, almost twice as much as the previous year and one of the highest in the world amongst developing countries.[103] A new rise in 2008 brought this figure to the remarkable figure of USD 43.8.[104] In pharma, FDI in 2007 reached USD 164.4 million,[105] which (while relatively low) is consistent with the historic investment level observed in previous years.[106] Interestingly, in 2008 this figure rose sharply, reaching as much as USD 289.9 bi.[107]

1.3.1.2 Local Pharma

Secondly, and because innovation in pharmaceuticals is largely deemed to be patent-sensitive, a local pharmaceutical industry, while it exists, can also impose sanctions costs, most notably in the form of reduced innovation.[108] The Brazilian pharmaceutical industry, however, remains largely non-innovative, and this is seemingly so irrespective of the framework for the protection of patents. The most recent data available suggests that the extension of patent protection to pharmaceuticals did not to cause relevant impacts on innovative performance in the Brazilian pharmaceutical industry.[109] More stringent patent laws did not affect 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.[110] 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.[111] In contrast, current OECD standards of R&D

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[103] 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 February 10, 2010).
[104] Source: Central Bank of Brazil.
[105] Id.
[106] 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.
[107] Source: Central Bank of Brazil.
[108] Carlos A. Primo Braga & Carsten Fink, The Relationship Between Intellectual Property Rights and Foreign Direct Investment, 9 Duke J. of Comp. & Int'l L. 163 (1998).
[109] 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.
[110] 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.
[111] 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.

investments in pharmaceuticals correspond to over 14% of total sales[112] (being 21% of total sales in the United States).[113]

1.3.1.3 Other Trade Sanctions

Attempts to issue compulsory licenses typically lead to trade pressure from the country that hosts patentees. International pharmaceutical companies typically build up combined efforts with their home departments of commerce so as to back up their negotiations with developing countries with the threat of broader trade sanctions.[114] Firstly, compulsory licenses can lead to a submission of a formal complaint with the WTO. The dearth of case law by WTO's Dispute Settlement Body on this topic certainly adds some uncertainty as to the outcome of such kinds of litigation. In any case, the Doha Declaration to the effect that the TRIPS Agreement should be interpreted "in a manner supportive of public health" seemingly strengthened the position of countries making use of TRIPS flexibilities, including compulsory licenses.[115] Secondly, while backing up their home patentees, governments from developed countries may take unilateral action.[116] This is conspicuously the case of the USTR, which retains powers to act unilaterally even after the creation of the WTO.[117]

The prospect of issuance of state-sponsored trade sanctions, however, does not affect all developing countries in the same fashion.[118] Those developing countries with more diversified economies, such as Brazil, tend to be less vulnerable to trade sanctions on specific products.[119] In addition, some emerging economies are large enough to pose a genuine threat of counter-retaliating trade sanctions imposed by developed countries. As a matter of fact, this is exactly what is presently going on in a trade dispute involving Brazil and the United States, during the course of which Brazil announced that it will retaliate against products from the United States in the amount of US$ 900 million in exchange for past illegal US agricultural subsidies.[120]

In the wake a seven-year battle at the WTO, in August of 2009 the WTO authorized Brazil to issue trade retaliatory sanctions against US products. The reason

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[112] 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%).

[113] 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).

[114] See e.g. Daniel Gervais, The TRIPS Agreement: Drafting History and Analysis (2d ed. 2003); and Peggy B. Sherman & Ellwood F. Oakley, Pandemics and Panaceas: The World Trade Organization's Efforts To Balance Pharmaceutical Patents and Access to AIDS Drugs, 41 Am. Bus. L.J. 353, 363-382 (2004).

[115] *Id.*, item 17.

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

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

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

[119] Benvenisti & George W. Downs, supra note 96, at 27.

[120] Intellectual Property Watch, Brazil Issues Retaliation List Of US Products; IP-Protected Items In Next Round, November 17, 2010. Available at www.ip-watch.org/weblog/2009/11/17/brazil-issues-retaliation-list-of-us-products-ip-protected-items-in-next-round.

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is that American to farmers and the cotton industry was judged inconsistent with WTO rules and harmful to Brazilian cotton exports.[121] Whether Brazil will in fact make use of WTO's authorization for trade retaliation remains an open question. In the past, Brazil received six opportunities to retaliate, but never actually did it.[122] In any case, two points are worth taking notice. The first is that the simple fact that Brazil repeatedly challenged the US at the WTO is itself a demonstration of power: smaller and weaker developing countries seldom do that.[123] Secondly, and most relevant to the present discussion, is that half of Brazil's announced retaliatory measures is comprised of intellectual property–based payments, particularly pharmaceutical royalties. A recent statement by the Brazilian Board of Foreign Trade (CAMEX)[124] explained that compulsory licenses could be made easier through WTO sanctions.[125] This reinforces the argument that a stringent framework for patent protection is not perceived in Brazil to be a catalyst for development, as put forth by patent aficionados.[126]

1.3.2 The Circular Increase in Outside Option Values

The second explanation for the efficacy of threatening to issue compulsory licenses by Brazil derives from the existence of an increasingly strong domestic generics industry. This industry supports Brazil's price negotiations with big pharmaceutical companies by rendering threats of compulsory licenses credible.

There is 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. That explains why 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 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

[121] Intellectual Property Watch, WTO Ruling On Brazil-US Cotton Opens Door To Cross-Retaliation Against IP Rights, September 7, 2009. Available at http://www.ip-watch.org/weblog/2009/09/07/wto-ruling-on-brazil-cotton-opens-door-to-cross-retaliation-against-ip-rights.

[122] Intellectual Property Watch, Brazil Issues Retaliation List Of US Products; IP-Protected Items In Next Round, November 17, 2010. Available at www.ip-watch.org/weblog/2009/11/17/brazil-issues-retaliation-list-of-us-products-ip-protected-items-in-next-round.

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

[124] Câmara de Comércio Exterior – Camex.

[125] Intellectual Property Watch, Brazil Issues Retaliation List Of US Products; IP-Protected Items In Next Round, November 17, 2010. Available at www.ip-watch.org/weblog/2009/11/17/brazil-issues-retaliation-list-of-us-products-ip-protected-items-in-next-round.

[126] See e.g. Shahid Alikhan, Socio-Economic Benefits of Intellectual Property Protection in Developing Countries (WIPO 2000), pp. 1-10; and Edmund W. Kitch, The Patent Policy of Developing Countries, 13 UCLA Pac. Basin L.J. 166 (1994).

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and price reductions with big pharma.[127] To illustrate, 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 was sold in Brazil for 43.6% less than the US price and Bristol-Myers' Atazanvir with a discount of 76.4%.[128]

1.3.3 The National Benefit of Compulsory Licensing

In its quest to drive drug prices down, Brazil produces non-patented generics, negotiates price reductions with the laboratories, and recently even issued a compulsory license to import a patented drug, namely Merck's Efavirenz. The rational 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 saved $30 million in 2007 and $237 million between 2007 and 2012 (when the Efavirenz patent expires).[129] 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 credibility in the course of future price negotiations with laboratories. Finally, the issuance of compulsory licenses over pharmaceutical products is politically appealing. It encapsulates the promise of cheaper access to pharmaceuticals, and at the same time responds to claims of a growing domestic generics industry.

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.[130] 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 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."[131]

In the aftermath of these negotiations processes, Brazil became worldwide renowned for being the most successful developing country in tackling the AIDS

[127] See Brazilian IP Legislation, supra note __, 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).

[128] Grangeiro et al., supra note 4, 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).

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

[130] 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.

[131] Id.

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epidemic.[132] In the early 90s, the World Bank predicted that by the year 2000, 1.2 million Brazilians would carry HIV, the virus that causes AIDS. Prevention schemes however held the number to roughly half of that, or 0.61% of the country's population.[133] 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.[134] In 2007, the NSAP supplied[135] different ARV drugs to nearly 200,000[136] of Brazil's estimated 600,000 HIV/AIDS patients.[137] The expenditures for the purchase of ARVs (including generics locally manufactured and imported) amounted to approximately US$ 570 million.[138]

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. It is no coincidence that Brazilian President Luiz Inácio da Silva (a.k.a. "Lula") signed the decree for the compulsory license of Efavirenz in a televised ceremony.[139] In fact, and more broadly, both sides of the Brazilian political spectrum seem to be able to capitalize on aggressive drug policies. To illustrate, José Serra, President Lula's main political contender, still largely basis his political campaigning on having championed the creation of a generics industry and the issuance of compulsory licenses during his tenure at the Brazilian Ministry of Health in the early 2000 decade.[140]

Above and beyond circumstantial political disputes, investments in AIDS care in Brazil are said to have paid off in health care terms measured in Dollars. 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 2001 the final cost of NSAP incorporating reduced morbidity expenditure was negative, resulting in net savings of US$50 million.[141] That is an important component of the explanation for

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[132] The Economist, Brazil's AIDS programme: A conflict of goals, May 10th 2007.
[133] UNGASS – Brazilian Response 2005-2007, Country Progress Report, at 11.
[134] Id., at 24.
[135] Grangeiro at al, supra note 4, at 62.
[136] 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. See, at: www.who.int/inf/en/pr-2002-58.html.
[137] Efavirenz: Questões sobre o Licenciamento Compulsório, Official Communication issued by the Brazilian Ministry of Health, May 4, 2007.
[138] UNGASSs, supra note 125, at 25.
[139] 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 February 10, 2010).
[140] Amy Nunn, The Politics and History of AIDS Treatment in Brazil, p. 123-4 (2009).
[141] Grangeiro at al, supra note 4, 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).

why, in recent years, the fight against HIV/AIDS has consolidated its position as a priority within Brazil's health policy agenda.[142]

An additional element contributing to Brazil's aggressive negotiation strategies is that the development of a local generic industry nurtures the country's hope of developing a national pharmaceutical industry. This is by no means an easy task. 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.[143] 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 as an additional tool to safeguard some expertise in pharmaceuticals.

To illustrate, the laboratory Far-Manguinhos,[144] which is the main government drug producer in Brazil, has reverse-engineered 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.[145] This laboratory already produces seven[146] of the sixteen medicines used in the antiretroviral cocktail (freely) offered in Brazil (none of these drugs are patented in Brazil).[147] In 2001, 56% of ARVs distributed in Brazil were locally produced, which made possible a reduction of 82% in the prices of these drugs from 1996 to 2001.[148]

1.4 Conclusions

In research-intensive industries such as pharmaceuticals, there is abundant evidence that company growth is intimately related to innovativeness.[149] In pharma, high cash flows created by earlier innovations permits investments in R&D and enhances manufacturing capacity and marketing sales. With that, the cost of subsequent R&D projects are cut by sharing accumulated knowledge, research facilities and marketing

[142] 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 4, at 65.
[143] Fórum de Competitividade, supra note 23, at 13.
[144] Far-Manguinhos is part of the Oswaldo Cruz Foundation – FIOCRUZ, a non-profit research foundation linked to the Brazilian Ministry of Health.
[145] Bermudez et al., supra note __, at 129-150.
[146] Integrating Intellectual Property Rights and Development Policy, Report of the Commission on Intellectual Property Rights, London, September of 2002, available at: www.iprcommission.org/graphic/English_Intro.htm.
[147] Integrating Intellectual Property Rights and Development Policy, Report of the Commission on Intellectual Property Rights, London, September of 2002, available at: www.iprcommission.org/graphic/English_Intro.htm.
[148] Grangeiro at al, supra note 120, at 64 (noting that expenditures in 1998 were R$ 346 million jumping to R$ 557 million in 2001).
[149] See E. Mansfield, Industrial Research and Technological Innovation, Norton, New York, 1968; C. Freeman, The Economics of Industrial Innovation, Penguin Books, Harmondsworth, Middlesex, 1974.

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networks, leading to further specialization, innovation and profits.[150] 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.[151] 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.[152] Moreover, the total cost for developing a new medicine has recently been estimated in close to USD 900 million.[153]

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.[154] 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.[155] The country also possesses a sizeable and growing consumers market,[156] a fairly stable[157] (although problematic[158]) political system, and the largest biodiversity in the world. However, two important points tend to be repeatedly overlooked. Firstly, IP law – like every other body of law – does not work in a vacuum; it is the broader institutional framework that counts. Secondly, this institutional framework is not merely a matter of design, or "intelligent" policymaking. Rather, it is the product of historical evolution, but most

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[150] 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).
[151] Basil Achilladelis and Nicholas Antonakis, The dynamics of technological innovation: The case of the pharmaceutical industry, Research Policy, No. 30, pp. 535-558, 2001.
[152] Capanema & Palmeira Filho, supra note __.
[153] Joseph A. DiMasi et al., The Price of Innovaiton, Journal of Health Economics 22, 151-185, 2003.
[154] Achilladelis & Antonakis, supra note __.
[155] Alexandre de Freitas Barbosa et. al., Avaliação da Política Industrial, Tecnológica e de Comércio Exterior para o Setor Farmacêutico, Estudos Febrafarma No. 13, 2007, at 35-37.
[156] 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).
[157] Bruno Meyerhof Salama, Perspectivas económicas y políticas en América Latina (2007), available at http://works.bepress.com/bruno_meyerhof_salama/12/.
[158] Barry Ames, The deadlock of democracy in Brazil, University of Michigan Press, 2001.

importantly it is severely constrained by the interests of the groups involved with the expected outcomes of law making and law finding.

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.[159] 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.

Moreover, larger and relatively more dynamic developing countries 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.[160] 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, as explained predominantly by Brazil's localized governance.

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[159] 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.

[160] *Id*, 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).

2 The Localized Governance Consideration

2.1 Overview

The positive effects of stronger intellectual property rights on FDI, trade, technology transfer and R&D efforts are subject to two categories of balancing considerations.[161] On one hand, there is a trend toward harmonization of IPRs within TRIPS.[162] In theory, the attractiveness of countries that strengthen their IPRs marginally increases, whereas the relative attractiveness of those already affording strong IPRs marginally decreases.[163]

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 commercial and political force of this era.[164] 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.[165] 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.[166]

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, investors in general, and large innovative multinational enterprises (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.[167]

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 hereafter, is the political stability of the country.[168] 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.[169] Another study has argued that the level of enforcement of trade secrecy

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[161] See, generally, Maskus, The Role of IP, supra note __, 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.
[162] *Id.*
[163] *Id.*
[164] 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).
[165] *Id.*
[166] See, Caves, supra note 16, Peter J. Buckley & Mark Casson, The Economic Theory of the Multinational Enterprise 113-44 (1985).
[167] See Dunning. See John H. Dunning, International Production and the Multinational Enterprise 110, (1981), at 266-68; Markusen, supra note 143; 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 18, at 185.
[168] Oddi, supra note 23, at 849.
[169] IBGE (Brazilian Institute of Geography and Statistics), Pesquisa e Inovação Tecnológica (hereinafter, "PINTEC 2005"), at 43.

laws is more relevant for foreign investment decisions that the availability of strict patent protection laws.[170]

In the decision of where to invest, other potentially relevant factors include (but are not limited to) macroeconomic stability,[171] availability of an appropriate physical infrastructure for setting up technological facilities,[172] availability of human capital, particularly abundance of qualified scientists and engineers and proximity to high level universities and research institutes.[173] Relevant factors may also include 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.

We illustrate the problem of localized factors with a brief analysis of the Brazilian political structure. Essentially, we suggest that such structure renders the Brazilian state weak on a fundamental level. By weak state, we mean a state that is captive to a wide array of distributional coalitions and thus is exposed to ravages of rent-seeking groups.[174] In contrast, a strong state is able to develop a relative autonomy from such ravages.[175] 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 – again, 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 such a strong state is necessary to implement a more heterodox agenda of growth and developing is straightforward, because patronage-based and rent-seeking activities adapt easily to state-led

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[170] 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).
[171] PINTEC 2005, supra note __, at 44 (highlighting the influence of positive macroeconomic expectations on private investments in technological innovation in Brazil in the period of 2003-2005).
[172] 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.
[173] Id.
[174] Chowdhury & Islam, supra note __, at 47.
[175] 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.

industrialization.[176] 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 (or neoliberal) 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 and well funded bureaucracy.

2.2 One Institutional Letdown; Two 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.[177] The first is associated with a more orthodox view, as often summarized under the rubric of the "neoclassical political economy";[178] the second, with a more heterodox view, as encapsulated under the rubric of the "new political economy."[179] 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.[180]

A longstanding debate underlies these opposing views. Early theorists in development economics regarded underdevelopment as a case of endemic "market failure," which justified the pervasive array of direct interventions in the economy.[181] 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, import substitution and economic dirigisme based on large state-owned companies. There is now a robust body of theory and evidence suggesting that the costs of such strategies have outweighed their benefits;[182] the liberalizing reforms that swept both developing and developed countries as of the mid-70s emerged in the footsteps of such literature.

These reforms came premised on a diagnostic that the economic crises in the West and outside it were largely caused by wide spread rent-seeking practices.[183] Vast

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[176] Judith Chubb The Social Bases of an Urban Political Machine: The Case of Palermo. Political Science Quarterly 96 (1):107-25 (1981).
[177] Jorge Katz, supra note 22.
[178] T. Srinivasan, supra note 45 (coining the expressional "neoclassical political economy").
[179] Chowdhury & Islam, supra note 21, at 46.
[180] *Id.*
[181] 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.
[182] I. M. D. Little, T. Scitovsky and M. Scott, Industry and trade in some developing countries: A comparative study. London: Oxford Unviersity Press, 1970; J. B. Donges, A comparative survey of industrialization policies in fifteen semi-industrialized countries, Wltwirtschaftliches 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 __.
[183] John L. Campbell, Ove K. Pedersen, eds. The Rise of Neoliberalism and Institutional Analysis Princeton University Press, 2001.

amounts of state intervention had given rise to a dynamics whereby interest groups would encroach on state politics to guarantee monopolies and privileges, to the detriment of competitiveness and efficiency. The result was a pattern of stifled innovation, pervasive bureaucratic combat, widespread corruption, and repeated failures to capture opportunities to generate wealth for society.[184] In developing countries, this situation was aggravated by growing foreign indebtedness, political instability, and poor working of the existing institutional framework. Instead of promoting growth and reducing inequalities, in many countries interventionist policies had merely spread poverty.

As of the 1980s, a number of theorists have tried to reinstate the credibility of state-led development processes.[185] Their starting point, as noted by Bardhan, is that the rent-seeking literature is better at explaining failures rather than success stories.[186] This literature contends that at the most dramatic cases of 'catching up' – namely, that of East Asian newly industrialized countries (NICs) – contains a significant amount of 'enlightened'[187] policy activism of national governments.[188] 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. A common argument, for instance, is that the share of the GDP in state enterprise was apparently higher in Taiwan and South Korea than in many Latin American countries.[189] Sen and Sachs have accordingly argued that what matters to economic development was not the extent, but instead the quality of the state intervention.[190]

2.2.1 Of Neoclassical Political Economy

From the more orthodox, neoclassical political economy standpoint, the crucial factors that explain the absence of a more vibrant and innovative framework in Brazilian pharmaceuticals are the mismanagement of the macroeconomic environment. Accordingly, the lack of innovation in pharmaceuticals would not be related to shortcomings in the vertical policies in that area, but instead to horizontal problems that pervade the Brazilian economy as a whole.

As argued, such problems include the failure to control public spending;[191] the insufficient provision of pure public goods, especially public infrastructure and

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[184] Int'l Bank for Reconstruction & Dev., The State in a Changing World: World Dev. Rep. (1997).

[185] 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.

[186] P. Bardhan Symposium on the State and Economic Devleopment, Journal of Economic Perspectives, 4(3):3-8, 1990, at 5.

[187] Chowdhury & Islam, supra note 87, at 47.

[188] Paul Krugman , supra note 34, 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").

[189] Chowdhury & Islam, supra note 45, at 47.

[190] 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.

[191] Jorge Katz, supra note 22.

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enforcement of property rights, including intellectual property rights and contractual rights;[192] microeconomic inefficiencies that became entrenched on the economic system as a consequence of ill-designed industrial policies, particularly special interest groups interested in retaining monopoly privileges;[193] and the failure to take bolder steps towards further trade liberalization and market de-regulation.[194]

Adherent of the more orthodox stream notice that the crucial tenets of the horizontal policies in place in East Asia were not present in Brazil. For instance, Canêdo-Pinheiro et al. have compared a number of macroeconomic data for Brazil, South Korea, Taiwan, Japan, Chile and the United States. They concluded that Brazil has consistently underperformed the other countries in crucial tenets of its macroeconomic policy.[195] Brazil has time and again failed to control its public spending[196] having consistently incurred much larger inflation rates for over four decades.[197] 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.[198] The upshot is that taxation in Brazil became one the highest in the developing world[199] at the same time that the infrastructure for robust growth was still lacking.[200] Brazil has also failed to tame its ever-growing, inept bureaucracy with negative effects to the overall efficiency of its economy.[201]

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[192] Cooter &Schaefer, supra note 54, at 59 et seq.

[193] 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).

[194] Jorge Katz, supra note 22; Armando Castelar Pinheiro & Jairo Saddi. Direito, Economia e Mercados. Rio de Janeiro: Elsevier, 2005.

[195] Canêdo-Pinheiro et al., supra note 44. 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.

[196] 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).

[197] 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).

[198] 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).

[199] FEBRAFARMA report, supra note __, (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).

[200] Canêdo-Pinheiro et al., supra note __.

[201] 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).

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2.2.2 Of Heterodox Political Economy

More heterodox views challenge the orthodoxy on three accounts. Firstly, it questions 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,[202] or by suggesting that what matters to the process of economic development is not the extent, but instead the quality of state intervention.[203] The implication is that industrial innovation is not simply a by-product of macroeconomic stability, but rather the outcome of concerted efforts of private and state actors.[204]

Secondly, it notes that the risk of government failure that is inherent to any activist industrial policy can be minimized through appropriate institutional arrangements. For instance, as noted by Alice Amsden, 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.[205]

Thirdly, it postulates that the objective of the country's industrial policy should be that of wining export markets through strategic intervention in key industries, rather than on picking winners and protecting domestic markets as was common during the times of ISI in the 50s and 60s decades.[206] Contrary to East Asian's Export-Oriented Industrialization model, excessive protectionism under Brazil's Import Substitution Industrialization was largely aimed at supplying the local market, thus rendering innovation largely unnecessary for local companies.[207]

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.[208] This is particularly true in connection with 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.[209]

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 where the private sector simply responds mechanically to bureaucratic initiative; rather, it is a matter of negotiation and compromise, carrying with it the risk

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[202] 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 __.

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

[204] Mauro F. Guillén, Multinationals, Ideology, and Organized Labor, The Limits of Convergence, Princeton University Press (2003).

[205] Amsden, supra note __.

[206] Celso Furtado, Um projeto para o Brasil. RJ, Saga, 1968; Prebish, supra note __.

[207] 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.

[208] See generally Ha-Joon Chang, Globalisation, Economic Development and the Role of the State, Zed Books, London and New York, 2003

[209] D. Kupfer, Política Industrial". Econômica, v. 5, p. 281-298 (2003).

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that private parties capture political consensus to the detriment of broader societal interests.[210]

2.3 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 is that the market needs the state, as much as the state needs the market.[211] 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,[212] 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.[213]

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 intellectual property 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 intellectual property reforms to spurt innovation and R&D investments in pharmaceuticals in Brazil.

In essence, the argument is that 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. Rather, the problem is that it primarily benefits itself – that is, its politicians and civil servants.[214] 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.[215] 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.

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[210] 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").
[211] Chowdhury & Islam, supra note __, at 53.
[212] Joseph Stiglitz, Economic Role of State, London: Allen & Unwin, 1990.
[213] *Id.*
[214] Ames, supra note 97, at 3.
[215] *Id.*

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To a large extent, the institutional weakness of the Brazilian state can be traced to its constitutional framework. The country's latest constitution of 1988 fragmented political power without creating the strong party system that would be necessary to ensure programmatic coherence for long-run government actions.[216] Weak parties and strong politicians act in a strong Congress, increasing the number of "veto players" in the political process,[217] so the transactions costs of law- and policy-making are high.

Even though the Executive Power controls the policy-making agenda, implementing such agenda is intricate.[218] Political bargaining over law and policy-making ends up strongly deinstitutionalized, in that the Executive often needs to negotiate with individuals, not with parties. In a system where Congressmen are hardly being perceived as accountable, negotiations between the Executive Power and Congressmen are largely premised on pork and patronage.[219] 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 lowers echelons of power. In this sense, economic problems in Brazil, including low levels of innovativeness, can be linked to its political and institutional structures.

As in any Latin American country, the stability of the "rules of the game" is a salient point. 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 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 that comprised of wacky items such as the grant of life tenure to bureaucrats and a 12% ceiling on real interest rates.[220] This Constitution was drafted during a period of economic downturn and hyperinflation and its short history is quite turbulent.[221]

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[216] Scott Mainwaring, Rethinking Party Systems in the Third Wave of Democratization: The Case of Brazil, Stanford: Stanford University Press (1999); Ames, supra note __, 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).

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

[218] Ames, supra note 43, at 17.

[219] *Id.*

[220] 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.

[221] See Salama, supra note 89.

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In addition, the first democratically elected president since the enactment of the Constitution, Fernando Collor, stayed less than three 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 four 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.[222] During its 20 years of existence, the Brazilian Federal Constitution was amended no less than fifty-six times.

It must be noticed, however, the 1988 Constitution reinforced democratic stability in a number of ways. 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 diving 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 "presidentialism 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.[223]

The Federal Constitution also reinforced political stability by increasing tax revenues of states and municipal governments. In so doing, it strengthened Brazil's federalist system, so local politicians have an interest in maintaining institutional order as a means of ensuring their status and power. The powers of Congress were 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.[224]

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

[222] Ames, supra note 43, 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).
[223] Sérgio H. Abranches, "O Presidencialismo de Coalizão: O Dilema Institucional Brasileiro", In: Dados 31(1), 1988. But see Fernando Limongi "A democracia no Brasil: Presidencialismo, Coalizão Partidária e Processo Decisório", in: Novos Estudos CEBRAP, 76, (2006) (arguing instead that a Brazilian Congressmen face the dilemma of joining the government political block or waiting for the next election hoping that his block gets elected).
[224] Counting of votes is done electronically, the votes are secret and popular participation is high.

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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 representation[225] and open lists of candidates.[226] Together with a number of other technical rules, this system undermines the authority of party leaders, personalizes politics and inhibits party building.[227] Most importantly, it makes it easy for deputies to evade their constituent monitoring.[228] 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,[229] which is the party to which Brazil's current President 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 with little ideological consistency. The main party in the coalition is the PMDB,[230] which is the largest party currently in Congress holding around 20% of the available seats. Interestingly, 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 the political alliance that opposed Lula.

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

[225] 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 __, at 41.
[226] 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.
[227] Ames, supra note 43, at 65.
[228] *Id.*, at 41.
[229] PT: Partido dos Trabalhadores (Workers Party).
[230] PMDB: Partido do Movimento Democrático Brasileiro (Brazilian Democratic Movement Party).

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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.

2.4 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 one thinks 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. This remains true regardless of the strictness of Brazil's patent regime. Budgetary deficits not only constrain the ability of the government to implement meaningful vertical policies premised on subsidies, but also to implement horizontal policies premised on reduced taxation.[231] 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 also 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.[232] Pervasive pork and patronage particularizes policy-making in that politicians sustain themselves by supplying pork and services to individuals.[233] All of that has severely compromised the quality and motivation of public servants, their behavior, and eventually the content of policy itself.

Although in recent times there have been a number of important advances,[234] the country still faces an oppressive and costly state apparatus, economic inefficiency,

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

[232] Barry Ames, supra note __, at 24.

[233] 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.

[234] Salama, supra note __ (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

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and widespread poverty.[235] 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.

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).

[235] High taxation stifles economic growth; the running costs of government as a percentage of GDP have more than doubled in the last two decades;235 and social security spending (around 11% of GDP) is the highest amongst NICs.

Conclusion

The TRIPS agreement puts forth a roadmap for patent reform and harmonization worldwide but the direction of such reforms has been a highly contentious issue. This is so particularly in the developing world.[236] Defenders of TRIPS portray patent protection as a central pillar of modern economic policy and a catalyst for development.[237] They argue that patent protection is an effective tool to foster economic growth in all countries,[238] and offer a number of reasons why an enhanced patent regime may enhance domestic innovation,[239] inward technology transfer and FDI,[240] and foreign trade.[241] This vision of TRIPS as mutually beneficial for developed and developing countries is however far from consensual. Detractors of TRIPS not only question the empirical validity of the pro-TRIPS arguments,[242] but also point out to additional costs that TRIPS can impose to developing countries:[243] higher royalty payments,[244] higher prices for consumers,[245] higher administrative costs of running the country's legal and regulatory systems,[246] and theft of "traditional knowledge"

[236] See e.g. Michael Blakeney, The International Protection of Industrial Property: From the Paris Convention to the TRIPS Agreement, WIPO National Seminar on Intellectual Property, 2003, WIPO/IP/CAI/1/03/2, p. 16.
[237] Shahid Alikhan, Socio-Economic Benefits of Intellectual Property Protection in Developing Countries (WIPO 2000), pp. 1-10.
[238] Kamil Idris, World Intellectual Prop. Org., Intellectual Property: A Power Tool for Economic Growth 1 (2d ed. 2003); Ali Imam, How Patent Protection Helps Developing Countries, 33 AIPLA Q.J. 377 (2005).
[239] See e.g. Robert M. Sherwood, Human Creativity for Economic Development: Patents Propel Technology, 33 Akron L. Rev. 351 (2000). See also F. M. Scherer, The Political Economy of Patent Policy Reform in the United States, see at: http://www.researchoninnovation.org/scherer/patpolic.pdf, (draft of September 2007), at 37-38. Scherer reminds us that the argument also overlooks the fact that during the first forty-seven years of its existence, the United States provided strong patent protection to domestic residents, but denied patents to foreigners, whereas less developed countries were being asked under TRIPS to increase the scope of their patent protection to both domestic and foreigners.
[240] Keith E. Maskus, Intellectual Property Rights in the Global Economy (2000); Keith E. Maskus, The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer, 9 Duke J. Comp. & Int'l L. 109 (1998); Daniel J. Gervais, Panel III: Information Technology And International Trade: Intellectual Property, Trade & Development: The State Of Play, 74 Fordham L. Rev. 505 (2005); The Relationship Between Intellectual Property Rights and Foreign Direct Investment, 9 Duke J. of Comp. & Int'l L. 163 (1998).
[241] Keith E. Maskus & Mohan Penubarti, How Trade-Related are Intellectual Property Rights?, J. Int'l Econ., Nov. (1995), at 227, 229-30, 237-43; Daniel J. Gervais, Panel III: Information Technology And International Trade: Intellectual Property, Trade & Development: The State Of Play, 74 Fordham L. Rev. 505 (2005); and Edmund W. Kitch, The Patent Policy of Developing Countries, 13 UCLA Pac. Basin L.J. 166 (1994).
[242] See e.g. Andréanne Léger, The Role(s) of Intellectual Property Rights for Innovation: A Review of the Empirical Evidence and Implications for Developing Countries. Paper provided by DIW Berlin, German Institute for Economic Research in its series Discussion Papers of DIW Berlin with number 707. Available at http://www.diw.de/documents/publikationen/73/61916/dp707.pdf; and the Zedillo report on Financing for Development, in UN General Assembly paper A/55/1000, June 26 2001, at http://www.un.org/esa/ffd/a55-1000.pdf (IPRs are not mentioned in correlation to foreign direct investment or private capital flows). But See Wolfgang E. Siebeck, Strengthening Protection of Intellectual Property in Developing Countries: A Survey of the Literature 77 (Robert E. Everson et al. eds., 1990), at 56 (referring to other World Bank reporting to the contrary); and also Carlos Primo Braga et al., Intellectual Property Rights and Economic Development, 412 World Bank Discussion Paper 40 (March 2000).
[243] See Mark A. Lemley, Property, Intellectual Property, and Free Riding, 83 Tex. L. Rev. 1031, 1032-33 (2005).
[244] Ha-Joon Chang, Globalisation, Economic Development and the Role of the State, Zed Books, London and New York, 2003, p. 297.
[245] Ha-Joon Chang, Globalisation, Economic Development and the Role of the State, Zed Books, London and New York, 2003, p. 297.
[246] Ha-Joon Chang, Globalisation, Economic Development and the Role of the State, Zed Books, London and New York, 2003, p. 297.

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system.[247] For some, TRIPS harms developed and developing countries alike.[248] In light of these controversies, policy analysis of TRIPS remains largely inconclusive. As so, to understand the bargaining behavior of specific countries, one has to examine the political economy of patent regulation in each one of them. This analysis shifts the focus from the consequences of regulation to its explanation.[249]

The political economy of Brazil's experience with pharmaceutical products protected by patents reveals two lessons. Firstly, certain countries can potentially benefit from aggressive bargaining behavior without significantly curtailing FDI and trade. That is, in the backdrop of an altogether weaker patent enforcement regime.[250] Accordingly, discretionary usage of compulsory licensing within TRIPS' public health exception in pharmaceutical patents may, in fact, uphold a social bargaining surplus for countries such as 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. Secondly, legislation is put in place by means of legal provisions, but legal provisions (unlike other public goods such as roads or bridges) are often the product of historical evolution.[251] As so, the application and interpretation of international law, such as that reflected under the TRIPS agreement, is severely constrained by the prevailing political structures and the political interests of the groups involved with the expected outcomes.

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[247] Susan K. Sell, Post-TRIPS Developments: The Tension Between Commercial and Social Agendas in the Context of Intellectual Property, 14 FLA. J. Int'l L. 193, 202 (2002); Chidi Oguamanam, Intellectual Property Rights in Plant Genetic Resources: Farmers' Rights and Food Security of Indigenous and Local Communities, 11 Drake J. Agric. L. 273 (2006). See also Rural Advancement Foundation International – RAFI, Biopiracy-Sixth Annual Update, Communique 2, Issue #65 (2002), available at www.etcgroup.org/upload/publication/pdf_file/327; see also Marcia Ellen DeGeer, Note, Biopiracy: The Appropriation of Indigenous Peoples' Cultural Knowledge 9 New Eng. J. Int'l & Comp. L. 179, 180-2 (2002); and Jayati Ghosh (1999) Rules of international economic integration and human rights', a background paper for Human Development 2000, Jawahalal Nehru University.

[248] Jagdish Bhagwati, Afterword: The Question of Linkage, The American Journal of International Law, Vol. 96, No. 1 (Jan., 2002), pp. 126-134. See also Judith Goldstein and Lisa L. Martin, Legalization, Trade Liberalization, and Domestic Politics: A Cautionary Note, International Organization, Vol. 54, No. 3, Legalization and World Politics (Summer, 2000), p. 604 ("the weakly legalized General Agreement on Tariffs and Trade (GATT) regime was remarkably successful at liberalizing trade; it is not apparent that the benefits of further legalization will outweigh its costs").

[249] Lewis A. Kornhauser, The Design of Law: Legal Theory and the Challenge of Economic Analysis of Law. Work in progress, draft of 6 January 2010 (on file with authors).

[250] 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)).

[251] Curtis Milhaupt and Katharina Pistor, Law & Capitalism: What Corporate Crises Reveal About Legal Systems and Economic Development Around the World (2008).