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# Pharmaceutical Patent Bargains: The Brazilian Experience

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## ARTICLE

# PHARMACEUTICAL PATENT BARGAINS: THE BRAZILIAN EXPERIENCE

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### ABSTRACT

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 like Brazil as strategic destinations for Foreign Direct Investment (FDI) and trade. Combined with a near absence of pharmaceutical product innovation, these conditions boost Brazil's bargaining power for issuing compulsory licenses over pharmaceutical products. The second aspect, more exploratory, 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 research and development (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 particularly relevant 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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## I. INTRODUCTION

Sérgio Buarque de Holanda, the father of modern Brazilian historiography, once defined the character of Brazilians as that of a “cordial man.”<sup>1</sup> More than seventy years later this observation is

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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, increasingly stringent patent systems have expanded to a vast number of developing countries in a seemingly irreversible fashion.<sup>2</sup> In the backdrop of the strict patent regime flatly adopted by the WTO for all countries,<sup>3</sup> some nations constantly challenge this system through aggressive patent bargains.<sup>4</sup> 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 patent-holder (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.

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<sup>1</sup> SÉRGIO BUARQUE DE HOLANDA, *RAÍZES DO BRASIL* ch. 5 (26th ed. 1994).

<sup>2</sup> See, e.g., THE WIPO INDEX OF PATENT SYSTEMS, available at [http://www.wipo.int/ipstats/en/resources/patent\\_systems.html](http://www.wipo.int/ipstats/en/resources/patent_systems.html); see also Samuel Oddi, *The International Patent System and Third World Development: Reality or Myth?*, 1987 DUKE L. J. 831, 833 n.6 (referring to Patent law of the People's Republic of China of Mar. 12, 1984).

<sup>3</sup> Shammad 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 1, 3 (Jeremy de Beer ed., 2009); James Boyle, *A Manifesto on WIPO and the Future of Intellectual Property*, 2004 DUKE L. & TECH. REV. 9, 11-12, available at <http://www.law.duke.edu/journals/dltr/articles/pdf/2004DLTR0009.pdf>.

<sup>4</sup> Daniel R. Cahoy, *Confronting Myths And Myopia on the Road from Doha*, 42 GA. L. REV. 131, 133 (2007); Peter K. Yu, *Access to Medicines, BRICS Alliances, and Collective Action*, 34 AM. J. L. & MED. 345, 358 (2008).

This article focuses on the political economy of negotiations involving big pharmaceutical companies and Brazil. Over the past decade, on numerous occasions (as with negotiations for price reductions for drugs such as Nelfinavir and Efavirenz or Gleevec), Brazil has used aggressive tactics to obtain discounts from big pharmaceutical companies on medicines distributed in Brazil's public health system.<sup>5</sup> This aggressive behavior was made possible primarily 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.<sup>6</sup>

To present the dynamics of the Brazilian experience with patent bargains, this article breaks down the analysis into two subsets. Part II places the case of Brazil in the international context, highlighting Brazilian policy choices which have taken place against the legal backdrop of the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), a WTO-sponsored piece of legislation aimed at international patent regulation. Brazil's aggressive patent bargaining is also explained based on two considerations. The first is the existence of large and fast-growing domestic markets which 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 formulate their patent policies—as is the case with potential issuances of compulsory licenses for patented medicines. A second consideration is the dearth of innovation in the Brazilian pharmaceutical sector, which boosts the country's bargaining power for issuing compulsory licenses. As argued, the absence of domestic companies which could profit from a more stringent patent protection system reduces the political pressure and the sanctions costs which arise from the issuance of compulsory licenses for pharmaceuticals.

Part III shifts the analysis to national or localized considerations within Brazil, focusing specifically on governance constraints that have been hindering Brazil from becoming an

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<sup>5</sup> Alexandre Grangeiro et al., *Sustentabilidade da Política de Acesso a Medicamentos Anti-Retrovirais no Brasil* [Sustainability Policy for Access to Anti-Retroviral Drugs in Brazil], 40 *REVISTA DE SAÚDE PÚBLICA* [Journal of Public Health] 60, 64 (2006) (Braz.).

<sup>6</sup> ANDREAS SEITER, THE WORLD BANK, HNP BRIEF #3, PHARMACEUTICALS: LOCAL MANUFACTURING 2 (2005), available at <http://apps.who.int/medicinedocs/documents/s16758e.pdf>.

innovation powerhouse. At its core, we suggest that the country's political structure renders the Brazilian state weak on a fundamental level, meaning that it is captive to a wide array of distributional coalitions and thus is exposed to ravages of rent-seeking groups. This framework in Brazil also favors short-sighted policies in connection with 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 a caveat—as long as the current localized governance consideration is present in emerging economies such as Thailand, South Africa, or Brazil, the present WTO-based patent regime will continue to incentivize aggressive non-cooperative bargaining situations.

## II. PHARMACEUTICAL PATENT BARGAINING SITUATION

### *A. An Overview*

In the pharmaceutical field, TRIPS-compliant legislation did a poor job of fostering innovation in Brazil, while simultaneously enhancing the royalties collected by multinational enterprises (MNEs). The narration of the TRIPS Agreement and its early predicaments demonstrates this result. The TRIPS Agreement usually requires every member-nation to protect pharmaceutical patents. However, TRIPS contains several loopholes that provide flexibility for national governments facing political exigencies, such as health crises.<sup>7</sup> These loopholes allow WTO members to moderate the negative effects of intellectual property protection.<sup>8</sup> The provision allowing WTO members to forcibly license patents is a distinctively important safeguard enshrined the TRIPS Agreement. Accordingly, in some cases, national governments are allowed to force patentees to grant use of the patent at prices below market rate.<sup>9</sup> In practice, however, the issuance of a compulsory license by a developing country is largely dependent

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<sup>7</sup> Judith Goldstein et al., *Introduction: Legalization and World Politics*, 54 INT'L ORG. 393 (2000).

<sup>8</sup> 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).

<sup>9</sup> Antony Taubman, *Rethinking TRIPS: "Adequate Remuneration" For Non-Voluntary Patent Licensing*, 11 J. INT'L ECON. L. 927 passim (2008).

upon whether the nation holds sufficient bargaining power to do so.

Bargaining power can be explained by bargaining theory. In voluntary exchanges, a bargaining problem arises because parties must negotiate (*ex ante*) the allocation of the cooperative surplus that can be generated by their agreement.<sup>10</sup> Such negotiations tend to be particularly difficult when there are no clear price standards that the parties can use as benchmarks for their exchanges. To reach an agreement, each party must receive at least its “outside option”<sup>11</sup> (also known as reservation value, disagreement value, or threat value), which equals the payoff that that party can obtain on its own without cooperation from others.<sup>12</sup> Bargaining power is also a function of a country’s “inside options”—the actions it can take in order to derive positive payoffs while strategically disagreeing in the course of the negotiation.<sup>13</sup> 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.<sup>14</sup>

Brazil illustrates a bargaining theorization of international bargaining over pharmaceuticals because its negotiation strategy for price reductions has routinely been premised on the credible threat of issuing compulsory licenses.<sup>15</sup> Unlike smaller developing countries, larger economies such as Brazil can develop a capacity for producing generics, which raises their outside option values. A

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<sup>10</sup> The cooperative surplus is the enhancement to value generated through the parties’ cooperation. *See, e.g.*, ROBERT D. COOTER & THOMAS ULEN, *LAW & ECONOMICS* 78-80 (4th ed. 2003).

<sup>11</sup> ROBERT D. COOTER, *THE STRATEGIC CONSTITUTION* 274 (2000).

<sup>12</sup> *See generally* LEIGH L. THOMPSON, *THE MIND AND HEART OF THE NEGOTIATOR* (2d ed. 2001).

<sup>13</sup> Abhinay Muthoo, *A Non-Technical Introduction to Bargaining Theory*, 1 *WORLD ECON.* 145, 157-60 (2000) [hereinafter Muthoo, *Non-Technical Bargaining*].

<sup>14</sup> Robert M. Sherwood, *The TRIPS Agreement: Implications for Developing Countries*, 37 *IDEA* 491, 544 (1997) (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”); Robert M. Sherwood, *Some Things Cannot Be Legislated*, 10 *CARDOZO J. INT’L & COMP. L.* 37, 42 (2002). *See also* Agreement on Trade-Related Aspects of Intellectual Property Rights art. 41, Apr. 15, 1994 [hereinafter TRIPS] (defining the four key tenets of national enforcement provisions, which are largely modeled on American intellectual property law).

<sup>15</sup> 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.

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 pharmaceuticals.<sup>16</sup> According to 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 conclusion that the absence of a strong patent regime curtails the development of a Brazilian innovative pharma industry. However, claims of this kind must be assessed with care. In fact, the low levels of technological innovation within the Brazilian pharma industry replicate the low levels of technological innovation that can be found in many 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 before World-War II. At that time, Brazilian IPRs legislation granted patent protection for pharmaceutical products and processes in Brazil.<sup>17</sup> Such protection reflected a longstanding legal tradition in Brazil of offering patent protection for inventions; however, this tradition had little practical relevance in a pre-industrialized country.<sup>18</sup> In 1945, while Brazil was experiencing an industrialization boom, the law was amended to

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<sup>16</sup> See generally Carlos A. Primo Braga & Carsten Fink, *The Relationship Between Intellectual Property Rights and Foreign Direct Investment*, 9 DUKE J. COMP. & INT'L L. 163 (1998).

<sup>17</sup> Oliveira et al., *Brazilian Intellectual Property Legislation*, in INTELLECTUAL PROPERTY IN THE CONTEXT OF THE WTO TRIPS AGREEMENT: CHALLENGES FOR PUBLIC HEALTH 153, 153 (Jorge A. Z. Bermudez & Maria Auxiliadora Oliveira eds. 2004) [hereinafter *Brazilian IP Legislation*] (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; prior 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 sixteen 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. *Id.*

<sup>18</sup> See generally P. BEN-AMI, *MANUAL DE PROPRIEDADE INDUSTRIAL* [Industrial Property Manual] (1983) (Braz.).



rule out the protection of inventions related to medicines, foodstuffs, and materials and substances obtained by chemical means or processes.<sup>19</sup>

A restriction of IPRs in technology-intensive industries was well-suited to the inward-oriented, state-led economic model of Import Substitution Industrialization (ISI) which prevailed in Brazil—indeed, in nearly every Latin American country—in the post-WW II era. As a result, 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, while the intermediary inputs for local production were simultaneously subject to a more mild taxation scheme and local production was subsidized.<sup>20</sup>

It was not until the mid-1990s that the Brazilian IP law reinstated patent protection for inventions related to medicines and other substances obtained by chemical means and processes. After signing the TRIPS Agreement in 1994, Brazil found itself needing to reform its intellectual property laws. Pursuant to Article 65 of TRIPS, Brazil could have waited until January of 2005 to extend protection to pharmaceutical products and processes. As a result of intense commercial pressure from the United States,<sup>21</sup> however, patent protection was eventually scheduled to start much sooner (January 1997) than would have otherwise been required.<sup>22</sup>

Once the new patent protections were in place, the Brazilian pharmaceutical industry started to decline rapidly.<sup>23</sup> The government abandoned its system of preferred purchases, and

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<sup>19</sup> Oliveira et al., *supra* note 17, at 154.

<sup>20</sup> Bermudez et al., *Expanding Access to Essential Medicines in Brazil: Recent Regulation and Public Policies*, in *INTELLECTUAL PROPERTY IN THE CONTEXT OF THE WTO TRIPS AGREEMENT: CHALLENGES FOR PUBLIC HEALTH*, *supra* note 17, at 129-130.

<sup>21</sup> For example, the United States 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 generally* M. H. TACHINARDI, *A GUERRA DAS PATENTES* [The War of Patents] (1993) (Braz.).

<sup>22</sup> Lei No. 9.279, de 14 de Maio de 1996, DIÁRIO OFICIAL DA UNIÃO [D.O.U] de 15.5.1996 (Braz.) [hereinafter Brazilian IP Law].

<sup>23</sup> INTERNATIONAL BUSINESS STRATEGIES, *DRUGS AND PHARMACEUTICALS IN BRAZIL* 7 (2003).

local production was progressively substituted for importation. From 1990 to 2003, the importation of medicines increased almost seventeen-fold, from \$60 million<sup>24</sup> to \$1 billion annually, and the importation of pharmaceuticals grew from \$500 million to \$900 million per year.<sup>25</sup> In turn, exportations grew at a much slower pace, and the importation of intermediary products for domestic production decreased from \$150 million per year to only \$10 million.<sup>26</sup>

This trend toward a decrease in the size of the Brazilian pharmaceutical industry has been somewhat counterbalanced by a surge of the Brazilian generics industry over the past decade. Health advocacy groups in Brazil had long sought permission for the sale of generics in Brazil; it was not until 1999, however, that the Brazilian government successfully passed a law (known as the “Generics Act”) permitting the marketing of generics in Brazil.<sup>27</sup> A generic medicine was defined as a product which was similar to, and expected to be interchangeable with, the reference product. Generics are typically produced after the expiration or waiver of patent protection or any other exclusive rights.

The introduction of generic drugs created a dynamic investment option in the pharmaceutical industry.<sup>28</sup> According to data from the Brazilian Generic Medicines Industry, generic medicines in Brazil currently account for approximately 14% of domestic sales—still less than half of the market share of generics

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<sup>24</sup> All monetary amounts in this article are in United States Dollars, unless otherwise indicated.

<sup>25</sup> FÓRUM DE COMPETITIVIDADE DA CADEIA PRODUTIVA FARMACÊUTICA 2003-2006: O DESAFIO DE PROSEGUIR [Forum on Competition in the Pharmaceutical Production Chain 2003-2006: The Continuing Challenge] 11 (2007) (Braz.) [hereinafter FÓRUM DE COMPETITIVIDADE].

<sup>26</sup> *Id.*

<sup>27</sup> Lei No. 9.787, de 10 de Fevereiro de 1999, DIÁRIO OFICIAL DA UNIÃO [D.O.U] de 11.2.1999 (Braz.). 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., *Expanding Access to Essential Medicines in Brazil: Recent Regulation and Public Policies*, in *INTELLECTUAL PROPERTY IN THE CONTEXT OF THE WTO TRIPS AGREEMENT: CHALLENGES FOR PUBLIC HEALTH*, *supra* note 17, at 136 [hereinafter *Expanding Access*].

<sup>28</sup> VALOR ECONÔMICO [Economic Value], ANÁLISE SETORIAL: INDÚSTRIA FARMACÊUTICA [Sectoral Analysis: Pharmaceutical Industry] 19-23 (2006) (Braz.).

in countries like Germany (29%), the United Kingdom (34%), and the United States (35%)—and is still growing.<sup>29</sup> In a way, the enhancement of generics production also served to minimize the decline of the Brazilian pharmaceutical industry. Currently, the four main companies operating in that segment are held by Brazilian capital, while approximately 80% of the generic medicines sold in Brazil are manufactured domestically.<sup>30</sup> Moreover, the development of a generics industry assisted in government efforts to revamp its network of public laboratories, which now have been set to produce medicines and biological components to supply the public health system.<sup>31</sup> These public laboratories produce approximately 3% of the national generic production by monetary value and 10% by unit numbers.<sup>32</sup>

The new Brazilian IP legal framework was embedded in a broad context of structural changes that encompassed, but were not limited to, the pharmaceutical sector.<sup>33</sup> Beginning in Chile in the early 1970s, and continuing in Argentina and Mexico in the 1980s and Brazil in the 1990s, 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 sought to achieve faster productivity growth, improved international competitiveness, and increased equality in the distribution of the benefits of technical progress. With greater or lesser emphasis, these countries liberalized trade, while also de-regulating and privatizing economic activities in the 1980s and 1990s, thus phasing out the era of “inward-oriented”, “state-led” growth policies.<sup>34</sup>

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<sup>29</sup> PRÓ GENÉRICOS, ASSOCIAÇÃO BRASILEIRA DAS INDÚSTRIAS DE MEDICAMENTOS GENÉRICOS [, <http://www.progenericos.org.br> (last visited May 8, 2010).

<sup>30</sup> *Id.*

<sup>31</sup> 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.

<sup>32</sup> *Expanding Access*, *supra* note 27, at 141.

<sup>33</sup> *See generally* Jorge Katz, *The Limits of the Prevailing Orthodoxy: Technology and Education as Restrictions to Productivity Growth and International Competitiveness in Latin America*, (May 17, 2004) (unpublished manuscript), *available at* <http://www.druid.dk/conferences/summer2004/papers/ds2004-277.pdf>.

<sup>34</sup> *See id.* at 4 (“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”).

The liberalizing reforms that swept Brazil in the 1990s have been less positive than previously expected.<sup>35</sup> On one hand, they successfully provided foundations for a more solid macroeconomic management and the eradication of chronic inflation. Such positive developments were seen in April of 2008, when rating agencies started to upgrade Brazil's long-term foreign currency sovereign debt to "investment-grade".<sup>36</sup> A more stable economic environment paved the way for some economic growth and poverty reduction in the country.<sup>37</sup> At the same time, Brazil's R & D investment remains low by the standards of the Organization for Economic Cooperation and Development (OECD), and is also overly reliant on government spending.<sup>38</sup> This, however, is common in countries with relatively low R & D spending. Thus, Brazilian efforts—partially opening up to foreign competition, de-regulating markets, and privatizing economic activities—have been insufficient for the country to attain a more vibrant development of domestic technological capabilities.<sup>39</sup> In pharmaceuticals, this state of affairs led to a concentration of production in stages with lower added value and to a significant increase in imports, which largely replaced local production.<sup>40</sup>

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<sup>35</sup> See generally A. O. Krueger, *The Political Economy of the Rent-Seeking*, 64 AM. ECON. REV. 291 (1974); J. Williamson, *Comment on "Macroeconomic Policy and Growth," by Corden*, in PROCEEDINGS OF THE WORLD BANK ANNUAL CONFERENCE ON DEVELOPMENT ECONOMICS 1990 85 (Stanley Fischer et al., eds. 1991).

<sup>36</sup> Fabio Alves & Carlos Caminada, *Brazilian Debt Raised to Investment Grade by S&P*, BLOOMBERG.COM, (Apr. 30, 2008, 19:15 EDT), [http://www.bloomberg.com/apps/news?pid=newsarchive&sid=a86v4f6\\_W2Jg](http://www.bloomberg.com/apps/news?pid=newsarchive&sid=a86v4f6_W2Jg).

<sup>37</sup> See generally *Special Report: Brazil*, FINANCIAL TIMES (U.K.), July 8, 2008, available at <http://www.media.ft.com/cms/908347ae-4c43-11dd-96bb-000077b07658.pdf>.

<sup>38</sup> Carlos H. de B. Cruz & Luiz de Mello, *Boosting Innovation Performance in Brazil* (OECD Econ. Dep't, Working Paper No. 532, 2006), available at [http://www.oecd.org/officialdocuments/displaydocumentpdf?cote=eco/wkp\(2006\)60&doclanguage=eng](http://www.oecd.org/officialdocuments/displaydocumentpdf?cote=eco/wkp(2006)60&doclanguage=eng) (noting that approximately 60% of R & D activity is carried out and financed by the Brazilian government). See also ALAN WRIGHT, WOODROW WILSON INT'L CTR FOR SCHOLARS, *INNOVATION IN BRAZIL: PUBLIC POLICIES AND BUSINESS STRATEGIES* 7 fig.3 (2008) (showing Brazil lagging two to four times behind all OECD countries in number of patent filing per \$1 million in R & D expenditures) available at <http://www.wilsoncenter.org/topics/pubs/brazil.innovationreport.web.pdf>.

<sup>39</sup> *Id.* (noting that about 60% of R & D activity is carried out and financed by the government).

<sup>40</sup> See generally Graziela F. Zucoloto & Rudinei Toneto Júnior, *Esforço Tecnológico da Indústria de Transformação Brasileira: Uma Comparação com Países Selecionados* [Technological Efforts of Industry Transformation: A Comparison with Selected Countries], 9 REVISTA DE ECONOMIA CONTEMPORÂNEA [Journal of Contemporary Economics] 337 (2005) (Braz.); Luciana Xavier de Lemos Capanema & Pedro Lins Palmeira Filho, *Indústria Farmacêutica Brasileira: Reflexões sobre sua Estrutura e*

Naturally, the liberalizing reforms of the mid-1990s had different impacts in each sector of the Brazilian economy. To illustrate, in the wood-products, pulp and paper, oil, and aviation sectors, 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).<sup>41</sup> However, other sectors of the Brazilian economy have been found to severely underperform when compared with OECD countries. For example, in chemicals (excluding pharma) the ratio of R & D as a proportion of total production was only 33.3% of the same ratio as is typically found in OECD countries.<sup>42</sup> In electronics, it was 22.8% and informatics 31.2%.<sup>43</sup> Most importantly, pharmaceuticals were identified as the exact industry where Brazilian investments in R & D as a proportion of total production are lowest when compared with the OECD average, a mere 9.3%; when compared with the top-tier of OECD countries, this ratio dropped to 6.7%.<sup>44</sup>

The adoption of a TRIPS-compliant legislation, however, did have a positive impact on the number of patent applications in Brazil.<sup>45</sup> Moreover, the increase in patent applications was particularly pronounced in the fields of chemicals and pharmaceuticals.<sup>46</sup> Yet, that does not necessarily demonstrate an increase in innovative activities in the Brazilian pharmaceutical industry; indeed, the vast majority of such applications came from nonresidents as extensions of patents already granted abroad.<sup>47</sup> In fact, five large foreign industrial groups account for the bulk of pharmaceuticals and chemicals patent filings.<sup>48</sup> This suggests that, in the pharmaceutical field, TRIPS-compliant legislation did very little to foster domestic innovation in Brazil, and significantly

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*Potencial de Investimentos* [Brazilian Pharmaceutical Industry: Reflections on its structure and Potential Investment], in *PERSPECTIVAS DO INVESTIMENTO* [Perspectives in Investment] 163, (Ernani T. Torres Filho & Fernando P. Puga, eds. 2007) (Braz.).

<sup>41</sup> *Id.*

<sup>42</sup> *Id.*

<sup>43</sup> *Id.*

<sup>44</sup> *Id.*

<sup>45</sup> Francesco Laforgia et al., *IPRs and Technological Development in Pharmaceuticals*, in *THE DEVELOPMENT AGENDA: GLOBAL INTELLECTUAL PROPERTY AND DEVELOPING COUNTRIES* 307, 307 (Neil W. Netanel, ed. 2009).

<sup>46</sup> *Id.*

<sup>47</sup> *Id.* at 309.

<sup>48</sup> *Id.* at 313.

boosted royalties collection by innovative patent-holders located outside the country.

### *B. Patent Compulsory Licensing Bargaining Narrative*

The TRIPS Agreement, which allows intellectual property rights to be enforced by trade sanctions backed by the WTO, has been signed by 117 nations, including Brazil.<sup>49</sup> Although many signatory countries had reservations about strengthening intellectual property rights, signing the TRIPS Agreement was a condition for WTO participation, which has been viewed as an essential component for participation in the global economy, which has created an increase in international trade and prosperity.<sup>50</sup> By situating the TRIPS Agreement within the framework of multilateral trade relations, patentees benefit from an increased incentive for nations to enforce intellectual property rights through the threat of trade sanctions.<sup>51</sup> As argued herein, for numerous reasons the TRIPS Agreement misleadingly suggested that the threat of trade sanctions would equally propel the forward motion of respect and protection of IPRs worldwide.

#### *1. Bargains over National Law*

The negotiations and eventual execution of the TRIPS Agreement gave rise to a new set of intra-national bargaining constraints over pharmaceuticals. This is the result of the flexibilities and safeguards set forth under Articles 8 and 31 of the TRIPS Agreement.<sup>52</sup> Such negotiations encompassed not only decisions over the correct interpretation of the TRIPS Agreement,

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<sup>49</sup> 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).

<sup>50</sup> John A. Harrelson IV, Note, *TRIPS, Pharmaceutical Patents, and the HIV/AIDS Crisis: Finding the Proper Balance Between Intellectual Property Rights and Compassion*, 7 WIDENER. L. SYMP. J. 175, 178 (2001).

<sup>51</sup> 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. 23 (1994), 33 I.L.M. 1125 (1994).

<sup>52</sup> See *generally* CAROLYN DEERE, *THE IMPLEMENTATION GAME* (2009).

but most importantly lobbying concerning the reception and incorporation of these flexibilities and safeguards into the IP laws of each country. This issue rapidly became salient because of developing countries increasing demand for several patent-protected drugs, particularly anti-retroviral drugs (ARVs) designed to fight the HIV/AIDS epidemic, as has been the case in Brazil.

Accordingly, the negotiation of the legal framework of the TRIPS flexibilities and safeguards became a critical factor in determining developing countries' abilities to bargain for price reductions in their purchases of ARVs from developed countries. The most controversial aspects of such negotiations centered on the conditions under which developing countries were allowed to issue 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 must be incorporated within each WTO member country's internal legal framework. Thus the ground was set for a second round of negotiations between developed and developing countries over national legislation in the developing countries. In the early 2000s, Thorpe,<sup>53</sup> Keyla,<sup>54</sup> and Oliveira<sup>55</sup> analyzed the 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 such countries had not incorporated all the TRIPS flexibilities and safeguards into their national legal systems. Thus, most developing countries possess TRIPS-plus legal systems, that is, legal systems that protect patents

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<sup>53</sup> See generally Phil Thorpe, *Study on the Implementation of the TRIPS Agreement by Developing Countries* (Comm'n on Intellectual Prop. Rights, Study Paper No 7., 2001), available at [http://www.iprcommission.org/papers/pdfs/study\\_papers/sp7\\_thorpe\\_study.pdf](http://www.iprcommission.org/papers/pdfs/study_papers/sp7_thorpe_study.pdf).

<sup>54</sup> See generally B. K. KEYLA, WORLD HEALTH ORG. [WHO], NATIONAL WORKING GROUP ON PATENT LAWS, REVIEW OF NATIONAL PATENT LEGISLATIONS OF INDIA, INDONESIA, SRI LANKA & THAILAND (2003), available at [http://www.searo.who.int/LinkFiles/Reports\\_HSD-275-Patent.pdf](http://www.searo.who.int/LinkFiles/Reports_HSD-275-Patent.pdf).

<sup>55</sup> Maria Auxiliadora Oliveira, Jorge Antonio Zepeda Bermudez, Gabriela Costa Chaves & Germán Velasquez, *Has the Implementation of the TRIPS Agreement in Latin America and the Caribbean Produced Intellectual Property Legislation that Favors Public Health?*, 82 BULL. WORLD HEALTH ORG. 815, 815-21 (2004).

beyond the minimum standards set out under TRIPS. Such TRIPS-plus legislation further reduces these countries' bargaining power in situations involving the public interest.<sup>56</sup>

Brazil exemplifies the case of such a country—in spite of intense pressure from the United States,<sup>57</sup> Brazil has partly implemented several of the flexibilities and safeguards allowed under the TRIPS Agreement.<sup>58</sup> First and foremost, the Brazilian Intellectual Property Law of 1996 set forth a broad array of circumstances in which the Brazilian government may compulsorily license a patent: the first is when the patent owner exercises his rights in an abusive manner, or if he uses the patent to abuse economic power under the terms of an administrative or judicial decision;<sup>59</sup> the second is when the patentee has failed to domestically manufacture the patented product (or failure to completely use the patented process) in Brazilian territory in the years after a patent is granted;<sup>60</sup> the third is when domestic sales do not satisfy the needs of the Brazilian market;<sup>61</sup> the fourth is where there is a dependency of one patent on another,<sup>62</sup> and finally in cases of national emergency or public interest.<sup>63</sup>

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<sup>56</sup> See Bermudez et al., *Intellectual Property in the Context of the WTO TRIPS Agreement: What is at Stake?*, in *INTELLECTUAL PROPERTY IN THE CONTEXT OF THE WTO TRIPS AGREEMENT*, *supra* note 17, at 46.

<sup>57</sup> TACHINARDI, *supra* note 21.

<sup>58</sup> See THIRU BALASUBRAMANIAM & ANDREW GOLDMAN, *SELECTED COMPULSORY LICENSING, GOVERNMENT USE, AND PATENT EXCEPTIONS PROVISIONS IN VARIOUS COUNTRIES*, <http://www.cptech.org/ip/health/cl/examples2.html> (showing that both developing and developed nations have compulsory licensing laws, including Germany and the United States) (last visited February 10, 2010); see also B. Zorina Khan, *Intellectual Property and Economic Development: Lessons from American and European History* (Comm'n on Intellectual Prop. Rights, Study Paper 1a, 2002), available at [http://www.iprcommission.org/papers/pdfs/study\\_papers/sp1a\\_khan\\_study.pdf](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 visited February 10, 2010).

<sup>59</sup> Brazilian IP Law, *supra* note 22, art. 68, main provision.

<sup>60</sup> Except for failure to work due to lack of economic viability, in which case importing shall be admitted. *Id.* art. 68, item I.1.

<sup>61</sup> *Id.* art. 68, item I.2.

<sup>62</sup> *Id.* art. 70 (noting that the 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).

<sup>63</sup> *Id.* art. 71. See also MÓNICA STEFFEN GUISE, *COMÉRCIO INTERNACIONAL, PATENTES E SAÚDE PÚBLICA* 110 (2007).



Brazilian IP Law also recognizes the principle of international exhaustion of rights,<sup>64</sup> thus permitting parallel imports,<sup>65</sup> 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 should be noted that pressure from developed countries has led Brazil's decision not to implement other TRIPS flexibilities. For example, and in sharp contrast with 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 early as May of 1996.<sup>66</sup>

## 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 parties involved in the bargaining process. It follows that national intellectual property laws established in the wake of the TRIPS Agreement can, and often do, generate political pressure from the groups affected by such legislation. Such considerations stand as a second type of bargaining constraint over pharmaceuticals. These groups typically wish to steer governments into exploring the

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<sup>64</sup> 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 Article 6 of the TRIPS Agreement—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.

<sup>65</sup> *Id.* art. 68, item IV; Decreto No. 3.201, de 6 de Outubro de 1999, art. 10, DIÁRIO OFICIAL DA UNIÃO [D.O.U] de 7.10.1999, as modified by Decreto 4.830, de 4 de Setembro de 2003, DIÁRIO OFICIAL DA UNIÃO [D.O.U] de 5.9.2003 (Braz.) (permitting importation of an invention from a country where it is not under patent protection; primarily intended to permit importation of products from countries that were still using a transition period to grant patents for pharmaceutical products and process, such as India and China).

<sup>66</sup> Oliveira et al., *supra* note 17, at 154 (noting that prior to 1945, Brazilian industrial property legislation granted patent protection for pharmaceutical products and processes). In 1945, the legislation was modified to exclude protection of inventions related to: foodstuffs, medicines, materials and substances obtained by chemical means or processes. *Id.* 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. *Id.*

alternatives available within a national-TRIPS compliant law that can loosen the overall intellectual property regulatory framework. As argued below, 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.<sup>67</sup>

These dynamics are demonstrated by Brazil’s 1999 amendment to its national Industrial Property Law,<sup>68</sup> which introduced a preventive model of patent office regulation into the country’s basic TRIPS-compliant IP law (which had been in force since 1996).<sup>69</sup> The new mechanism consisted of a prior request (or “anuência prévia”) for the examination of pharmaceutical patents.<sup>70</sup> This was designed to split the analysis of patent filings for pharmaceutical products and processes between two federal bureaus: the Brazilian patent and trademark office (INPI) and the Brazilian sanitary supervision office (ANVISA).<sup>71</sup> In practice, it introduced an additional layer of bureaucratic approval before a patent could be granted. Accordingly, the patent office examines standard criteria of patentability and other procedural requirements (novelty, non-obviousness and utility),<sup>72</sup> while the sanitary supervision office holds a veto power for granting a patent. Specifically, this second bureaucratic layer considers whether the granting of the patent is in the public interest.<sup>73</sup>

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<sup>67</sup> Muthoo, *Non-Technical Bargaining*, *supra* note 13, at 157-60.

<sup>68</sup> The amendment was introduced by Provisional Measure No. 2.006 of Dec. 14, 1999. This provisional measure was later enacted into law. No. 10,196 of Feb. 14, 2001, art. 229.

<sup>69</sup> Peter Drahos, *Trust Me: Patent Offices in Developing Countries*, 34 AM. J. L. & MED. 151, 169 (2008).

<sup>70</sup> For a detailed examination of the “prior request mechanism,” see Edson Beas Rodrigues Junior & 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). See also Priscilla Maria D. G. César, *Flexibilidade do Direito Internacional da Propriedade Intelectual – Reflexões para Amenizar a Crise do Acesso a Medicamentos Essenciais*, in 2 PROPRIEDADE INTELECTUAL: ESTUDOS EM HOMENAGEM À PROFESSOR MARISTELA BASSO 43-76, 55 (2008).

<sup>71</sup> 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).

<sup>72</sup> Brazilian IP Law, *supra* note 22, art. 8.

<sup>73</sup> See generally Denis Borges Barbosa, *A Inconstitucionalidade da Anuência da ANVISA no Procedimento de Concessão de Patentes como Manifestação Discricionária da Administração Federal* [The Unconstitutionality of the Consent of ANVISA’s Procedure for Granting Patents as a Manifestation of the Federal Administration’s Discretion] (July 2004) (unpublished manuscript) (Braz.), available at

As expected, the 1999 amendment to the Brazilian IP Law made it slower and costlier to obtain a Brazilian patent, and rendered the outcomes less predictable. First, approval from the sanitary supervision office adds a period of six to twelve months for the final issuance of a patent.<sup>74</sup> The extension in the process of patent examination implies that the term of patent protection will be shortened.<sup>75</sup> Second, the patent office and the sanitary supervision office generally take opposing positions regarding the TRIPS Agreement: while the patent office is concerned with protecting innovation, the sanitary supervision office is concerned with exploiting legal flexibilities offered by TRIPS and the Doha Declaration.<sup>76</sup> Predictably, such opposing values have led to conflicting decisions between the two bodies. Recent attempts to patent second and subsequent medical uses in Brazil provide the best example of such conflicts.<sup>77</sup> In these cases, the patent office admitted patentability, but the sanitary office denied it.<sup>78</sup> Additional areas of conflict between the two bodies include polymorphism and pipeline-type patents, among others.<sup>79</sup>

### 3. *The National-Supra National Legal Deficit*

There is a third set of constraints on the pharmaceutical-bargaining situation in Brazil: a complex national political strategy to defend Brazilian IP laws. The Brazilian Intellectual Property Law was initially motivated by a political desire to reach a compromise between two conflicting sets of interests: the need to allow big pharmaceutical companies to collect royalties on new

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<http://denisbarbosa.addr.com/anuencia.doc>.

<sup>74</sup> See generally Maristela Basso, Preliminary Background Paper on Prior Consent for Pharmaceutical Products by ANVISA in Brazil (2005) (unpublished manuscript), available at <http://www.wissensgesellschaft.org/themen/publicdomain/priorconsent.pdf>.

<sup>75</sup> See Eur. Fed'n of Pharm. Indus. & Ass'ns, Position Paper: Brazil 2 (2004).

<sup>76</sup> Rodrigues Junior & Murphy, *supra* note 70, at 428.

<sup>77</sup> 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.bmjournals.com/cgi/reprint/30/5/470.pdf>.

<sup>78</sup> *Esclarecimentos sobre pedidos de patentes dos produtos e processos farmacêuticos* [Clarification of patent applications for pharmaceutical products and processes], ANVISA, available at <http://www.anvisa.gov.br/divulga/informes/2004/250804.htm> (last visited May 10, 2010).

<sup>79</sup> See Basso, *supra* note 74.

medicines, and the need to create enough room for the supply of generic anti-retroviral AIDS drugs produced under threat of compulsory licenses. In order to accomplish both objectives, 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 was 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 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.<sup>80</sup> The United States alleged that 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 Article 27(1) of the TRIPS Agreement,<sup>81</sup> which prohibits national patent protection laws from discriminating with regard to the locale of invention.<sup>82</sup>

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<sup>80</sup> Request for Consultations by the United States, *Brazil—Measure Affecting Patent Protection*, WT/DS199/1 (June 8, 2000), <http://www.wto.org/tw/SmartKMS/fileviewer?id=7408>; see also U.S. Special 301 report, 2001, <http://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 Robert C. Bird & Daniel R. Cahoy, *The Emerging BRIC Economies: Lessons from Intellectual Property Negotiation and Enforcement*, 5 NW. J. TECH. & INTELL. PROP. 1 (2007).

<sup>81</sup> TRIPS, *supra* note 14, art. 27(1) (establishing 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”).

<sup>82</sup> 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”. Paris Convention for the Protection of Industrial Property art. 5(A)(2), Mar. 20, 1883, as revised at Stockholm on July 14, 1967, 828 U.N.T.S. 11851. 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 56, at 46. See generally CARLOS CORREA, ACUERDO TRIPS (1996) (Arg.)

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The Brazilian IP Law indeed opens the possibility of compulsory licenses for any goods, and is therefore controversial. As a result of Brazil's political strategy to defend its IP laws, however, the WTO never actually reached a decision on the provision's lawfulness. Brazil tied the American allegations to the extremely controversial AIDS debate which divided developing countries and large pharmaceutical companies.<sup>83</sup> In the end, Brazil successfully lobbied for a United Nations Commission on Human Rights resolution affirming the right of access to medication.<sup>84</sup>

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 not compliant with TRIPS.<sup>85</sup> This position gained political momentum when India joined the dispute, claiming that it had a "systemic interest" in the proceeding.<sup>86</sup> As a result of the ensuing negative publicity,<sup>87</sup> the United States withdrew the complaint against Brazil in June 2001, and Brazil, in turn, agreed to provide a prior notice to the United States if it were to issue a compulsory

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(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).

<sup>83</sup> See generally Bird & Cahoy, *supra* note 80 (noting that Brazil used South Africa as a comparison point to show off its successful anti-AIDS program, and that this program would be at risk if the United States succeeded before the WTO). During that period, thirty-nine pharmaceutical firms were suing South Africa 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. *Id.* At that point, approximately 4.2 million individuals, or 20% of South Africa's adult population, were infected with the HIV virus. *Id.*

<sup>84</sup> Anselm Kamperman Sanders, *The Development Agenda for Intellectual Property: Rational Human Policy or "Modern-Day Communism"?* 16, Inaugural Lecture, Delivered on the occasion of the acceptance of the chair of European and International Intellectual Property Law (May 20, 2005) (noting that the United States was the only abstention within the 53 member body, in which every member voted to pass the resolution).

<sup>85</sup> Sue Ann Mota, *TRIPS: Ten Years of Disputes at the WTO*, 9 *COMPUTER L. REV. & TECH.* 455, 477 (2005).

<sup>86</sup> Request to Join Consultations by India, *U.S.—U.S. Patents Code*, WT/DS2124/2 (Feb. 19, 2001), available at <http://docsonline.wto.org/DDFDocuments/t/WT/DS/224-2.doc>.

<sup>87</sup> Chakravarthi Raghavan, *U.S. Beats a (Tactical) Retreat over Brazil's Patent Law*, THIRD WORLD NETWORK (June 25, 2001), <http://www.twinside.org.sg/title/tactical.htm> (referring to the situation as a "public relations disaster" for the United States).

license.<sup>88</sup> The two countries also undertook to resolve any disputes through a bilateral “consultative mechanism.”<sup>89</sup>

Subsequently, at the WTO Doha Ministerial Conference in November 2001, developing countries managed to push for a joint declaration.<sup>90</sup> The goal was to put an end to WTO challenges to legislation setting broad grounds for the issuance of compulsory licenses for essential patented drugs.<sup>91</sup> The ensuing Declaration on TRIPS Agreement and Public Health was designed to respond to concerns about the possible implications the TRIPS Agreement could have on access to medicines.<sup>92</sup> The declaration 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.”<sup>93</sup> In August of 2003, after a long period of discussions, the General Council of the WTO issued a

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<sup>88</sup> In the aftermath of the wave of a large global movement for access to medicines set in motion by the disputes between the United States 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 56, at 47.

<sup>89</sup> See Bird & Cahoy, *supra* note 80, at 47 (noting also that this agreement was not made public).

<sup>90</sup> Sanders, *supra* note 84, 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; the fact that profit margins for big pharma were the highest of any industry; and the Anthrax crisis in the United States 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*, 3 CHI. J. INT’L L., no. 1, 2002 at 27, 27-48; Thomas F. Mullin, *AIDS, Anthrax, and Compulsory Licensing: Has the United States Learned Anything? A Comment on Recent Decisions on the International Intellectual Property Rights of Pharmaceutical Patents*, 9 ILSA J INT’L & COMP L 185 (2002); Mike Godwin, *Prescription Panic: How the Anthrax Scare Challenged Drug Patents*, REASON FOUND., Feb. 1, 2002.

<sup>91</sup> See Sanders, *supra* note 84, 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).

<sup>92</sup> World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1 (2002).

<sup>93</sup> *Id.* at ¶17.

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decision<sup>94</sup> regulating the right of members to issue compulsory licenses.<sup>95</sup>

### *C. The Outside Option-Benefit*

There are three primary explanations for Brazil's distinctive ability to credibly threaten to issue compulsory licenses over patented drugs, all of which extend the narration of Brazil's bargaining situation and demonstrate the negotiating power of emerging economies in BRIC (Brazil-Russia-India-China) countries. The first is based on three sanction-cost considerations: Brazil's fast-growing consumer markets are too desirable to be sanctioned by large 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 which could potentially be imposed by governments supporting patent holders. The second derives from the existence of an increasingly strong domestic generics industry which supports Brazil's aggressive negotiation strategy—and to some extent profits from it. The third explanation is that compulsory licensing over pharmaceutical products is politically appealing; it includes the promise of lower prices both to the Brazilian governments and consumers for pharmaceutical products, while simultaneously improving the domestic generics industry.

#### *1. Sanction Costs Considerations*

The first reason a given country avoids issuing a compulsory license has to do with the prospects of sanctions costs that it faces. On the whole, these are the costs that can be imposed on a country

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<sup>94</sup> See Brazilian IP Legislation, *supra* note 17, at 55.

<sup>95</sup> See Fiona Fleck, *Drugs Could Still Be Costly Under World Trade Organization Deal*, 327 BRIT. MED. J. 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).

that unilaterally sets to break pharmaceutical patents. Such sanctions costs can come from three specific sources: large international pharmaceutical companies, the local pharmaceutical industry, or the governments of nations where big international pharma is located, which, in many instances is represented by the United States Trade Representative (USTR).<sup>96</sup> 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 credible the Brazilian threats of issuances of compulsory licenses over pharmaceuticals.

a. Big Pharma

Depending on the circumstances, large international pharmaceutical companies can impose sanctions costs through reduced FDI, reduced technology transference and local R & D, and reduced trade.<sup>97</sup> In a country such as Brazil, however, threats of such sanctions are more modest. The primary reason is that international pharmaceutical companies typically cannot afford to lose or alienate large markets that contain, or may contain, lucrative and fast-growing middle classes.<sup>98</sup> For example, 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.<sup>99</sup> As the economies in these countries improve, local populations are expected to face the kinds of chronic health issues 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. At

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<sup>96</sup> See Ravi Ramamurti, *The Obsolescing 'Bargaining Model'? MNC-Host Country Relations Revisited*, 32 J. INT'L BUS. STUD. 23 (2001); Robert D. Putnam, *Diplomacy and Domestic Politics: The Logic of Two-Level Games*, 42 INT'L ORG. 427 (1988).

<sup>97</sup> 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 four dimensions, namely the terms of trade, the interregional allocation of manufacturing, product availability, and R & D investment patterns).

<sup>98</sup> Eyal Benvenisti & George W. Downs, *Distributive Politics and International Institutions: The Case of Drugs*, 36 CASE W. RES. J. INT'L L. 21, 44 (2004).

<sup>99</sup> *Pharma 2020: The Vision*, PRICEWATERHOUSECOOPERS, <http://www.pwc.com/gx/eng/about/ind/pharma/pharma2020final.pdf> (last visited May 8, 2010).



the same time, longer life expectancy in these countries tends to positively impact drug sales.

Consider, for instance, the negotiations for reduction of drug prices 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.”<sup>100</sup> Likewise, when Brazil issued a compulsory license on Merck’s Stocrin (Efavirenz) in 2007, Merck released an official statement, saying “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.”<sup>101</sup>

The credibility of such retaliatory threats, however, is unclear. Indeed, there were no official trade sanctions because the compulsory license was viewed as legal both from the standpoint of Brazilian and international law. This fact is also relevant because it gives international legitimacy to the compulsory license. Moreover, there are no signs of reduced FDI in Brazil. In fact, Brazil’s share of overall FDI in 2007 totaled \$33.7 billion, almost twice as much as the previous year and one of the highest in the world among developing countries.<sup>102</sup> A new rise in 2008 brought this figure to a remarkable \$43.8 billion.<sup>103</sup> In pharma, FDI in 2007 reached \$164.4 million,<sup>104</sup> which (although relatively low) is consistent with the historic investment level observed in previous years.<sup>105</sup> Interestingly, in 2008, this figure rose sharply, reaching as high as \$289.9 billion.<sup>106</sup>

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<sup>100</sup> Bird & Cahoy, *supra* note 80, at 406.

<sup>101</sup> Press Release, Merck & Co., Statement on Brazilian Government’s Decision to Issue Compulsory License for Stocrin (May 4, 2007), available at [http://www.aidsportal.org/news\\_details.aspx?ID=4635](http://www.aidsportal.org/news_details.aspx?ID=4635) (last visited May 10, 2010).

<sup>102</sup> See BANCO CENTRAL DO BRASIL [Central Bank of Brazil], *Foreign Direct Investment Stock*, <http://www.bcb.gov.br/rex/Censo/ingl/CENSUS2000SectionIII-FDI%20Stock.xls> [hereinafter BANCO CENTRAL DO BRASIL]; 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 visited February 10, 2010).

<sup>103</sup> BANCO CENTRAL DO BRASIL, *supra* note 102.

<sup>104</sup> *Id.*

<sup>105</sup> See ALEXANDRE DE FREITAS BARBOSA ET AL., FEDERAÇÃO BRASILEIRA DE INDÚSTRIA FARMACÊUTICA (FEBRAFARMA) [Brazilian Federation of Pharmaceuticals Industry], AVALIAÇÃO DA POLÍTICA INDUSTRIAL, TECNOLÓGICA E DE

## b. Local Pharma

Secondly, and because innovation in pharmaceuticals is largely deemed to be patent-sensitive, a local pharmaceutical industry can also impose sanctions costs, most notably in the form of reduced innovation.<sup>107</sup> The Brazilian pharmaceutical industry, however, remains largely non-innovative, and this is seemingly so irrespective of the legal framework for the protection of patents. The most recent data available suggests that the extension of patent protection to pharmaceuticals has made no relevant impact on innovative performance in the Brazilian pharmaceutical industry.<sup>108</sup> More stringent patent laws did not affect the amounts of private R & D investments in Brazil's pharmaceuticals industry. 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.<sup>109</sup> In the year 2000, the percentage of expenditures in R & D increased, reaching 0.83% of total sales. But what was initially perceived as a positive trend soon became clearly negative: in the year 2003, expenditures fell again to as low as 0.5% of total sales, the level of investment previously seen before the enactment of the new IP law.<sup>110</sup> In contrast, current OECD standards of R & D investments in pharmaceuticals correspond to over 14% of total sales<sup>111</sup>

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COMÉRCIO EXTERIOR PARA O SETOR FARMACÊUTICO [Evaluation of Industrial, Technological, and Foreign Trade in the Pharmaceutical Sector] 43 tbl.1 (July 2007).

<sup>106</sup> BANCO CENTRAL DO BRASIL, *supra* note 102.

<sup>107</sup> See Carlos A. Primo Braga & Carsten Fink, *The Relationship Between Intellectual Property Rights and Foreign Direct Investment*, 9 DUKE J. COMP. & INT'L L. 163 (1998).

<sup>108</sup> 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 date back to the year 2003. The pharmaceuticals industry has only released information on the amounts invested in clinical research.

<sup>109</sup> Valéria Delgado Bastos, *Inovação Farmacêutica: Padrão Setorial e Perspectivas Para o Caso Brasileiro* [Pharmaceutical Innovation: Standard and Sectoral Perspectives for the Brazilian Case] 290 n.22 (BNDES Setorial, ed., 2005).

<sup>110</sup> 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.

<sup>111</sup> INT'L FED'N OF PHARM. MFRS. ASS'N (IFPMA), *THE PHARMACEUTICAL INNOVATION PLATFORM: SUSTAINING BETTER HEALTH FOR PATIENTS WORLDWIDE* 12 (2004) (noting also that from 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%).

(American pharmaceutical companies invest 21% of total sales in R & D).<sup>112</sup>

c. 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 domestic departments of commerce to bolster their negotiations with developing countries with the threat of broader trade sanctions.<sup>113</sup> First, 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 regarding the outcome of such 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.<sup>114</sup> Second, while backing up their home patentees, governments from developed countries may take unilateral action.<sup>115</sup> This is conspicuously the case of the USTR, which retains power to act unilaterally, even after the creation of the WTO.<sup>116</sup>

The prospect of state-sponsored trade sanctions, however, does not affect all developing countries in the same fashion.<sup>117</sup> Those developing countries with more diversified economies, such as Brazil, tend to be less vulnerable to trade sanctions on specific

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<sup>112</sup> FEBRAFARMA, A INDÚSTRIA FARMACÊUTICA NO BRASIL: UMA CONTRIBUIÇÃO PARA AS POLÍTICAS PÚBLICAS [The Pharmaceutical Industry in Brazil: A Contribution for Public Policy] 18 (Sept. 2006); *see also* 1 WORLD BANK, BRAZIL: INVESTMENT CLIMATE ASSESSMENT (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).

<sup>113</sup> *See generally* DANIEL GERVAIS, THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS (2d ed. 2003). *See also* Peggy B. Sherman & Ellwood F. Oakley, III, *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).

<sup>114</sup> Sherman & Oakley, *supra* note 113, at 367.

<sup>115</sup> *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).

<sup>116</sup> *See* Omnibus Trade and Competitiveness Act of 1988, 19 U.S.C. § 2242 (1999).

<sup>117</sup> *See generally* Robert C. Bird, *Defending Intellectual Property Rights in the BRIC Economies*, 43 AM. BUS. L.J. 317 (2006).

products.<sup>118</sup> In addition, some emerging economies are large enough to pose a genuine threat of counter-retaliation against trade sanctions imposed by developed countries. Such is the case in a trade dispute between Brazil and the United States, during which Brazil announced that it will retaliate against products from the United States in the amount of \$900 million in exchange for past illegal U.S. agricultural subsidies.<sup>119</sup>

In the wake of a seven-year battle, the WTO in August 2009 authorized Brazil to issue trade retaliatory sanctions against U.S. products. The rationale was that American farmers and the cotton industry were judged inconsistent with WTO rules and harmful to Brazilian cotton exports.<sup>120</sup> Whether Brazil will in fact make use of the WTO's authorization for trade retaliation remains an open question. In the past, Brazil has received six opportunities to retaliate but never utilized them.<sup>121</sup> In any case, two points are worth noting. First, Brazil repeatedly challenged the United States at the WTO, which is itself a demonstration of power since smaller and weaker developing countries seldom challenge the United States.<sup>122</sup> Secondly, and more relevant to the present discussion, is that one-half of Brazil's announced retaliatory measures is comprised of intellectual property-based payments, primarily pharmaceutical royalties. A recent statement by the Brazilian Board of Foreign Trade ("Câmara de Comércio Exterior" or "CAMEX") explained that the issuance of compulsory licenses could be made easier through WTO sanctions.<sup>123</sup> This reinforces the argument that a stringent framework for patent protection is not perceived in Brazil to be a catalyst for development, as often put forth by patent aficionados.<sup>124</sup>

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<sup>118</sup> Benvenisti & Downs, *supra* note 98, at 27.

<sup>119</sup> Claudia Jurberg, *Brazil Issues Retaliation List of US Products; IP-Protected Items in Next Round*, INTELL. PROP. WATCH (Nov. 17, 2010, 12:45 PM), available at <http://www.ip-watch.org/weblog/2009/11/17/brazil-issues-retaliation-list-of-us-products-ip-protected-items-in-next-round/> (last visited May 10, 2010).

<sup>120</sup> Catherine Saez, *WTO Ruling in Brazil-US Cotton Opens Door to Cross-Retaliation Against IP Rights*, INTELL. PROP. WATCH (Sept. 7, 2009, 5:40 PM), available at <http://www.ip-watch.org/weblog/2009/09/07/wto-ruling-on-brazil-cotton-opens-door-to-cross-retaliation-against-ip-rights> (last visited May 10, 2010).

<sup>121</sup> See Jurberg, *supra* note 119.

<sup>122</sup> John A. Harrelson, *TRIPS, Pharmaceutical Patents, and the HIV/AIDS Crisis: Finding the Proper Balance Between Intellectual Property Rights and Compassion*, 7 WIDENER L. SYMP. J. 175, 178 (2001).

<sup>123</sup> See Jurberg, *supra* note 119.

<sup>124</sup> See, e.g., SHAHID ALIKHAN, SOCIO-ECONOMIC BENEFITS OF INTELLECTUAL

## 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 exists a great distinction between being legally able to issue compulsory licenses and being practically empowered to do so. Issuing a compulsory license makes practical sense only insofar as the country is able to obtain the same drugs at lower costs, either through local production or importation of generics. This 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 generics industry serves not only to provide cheaper drugs to the country's population, but also (and perhaps more 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 and price reductions with big pharma.<sup>125</sup> For instance, between 2000 and 2004, the price of the three most important ARVs present in the drug cocktails offered by the Brazilian government at no cost to local patients was severely reduced. The price of Merck's Efavirenz was reduced by 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 U.S. price, and Bristol-Myers' Atazanvir was sold in Brazil for 76.4% less than the U.S. price.<sup>126</sup>

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PROPERTY PROTECTION IN DEVELOPING COUNTRIES 1-10 (2000); *see also* Edmund W. Kitch, *The Patent Policy of Developing Countries*, 13 UCLA PAC. BASIN L.J. 166 (1994).

<sup>125</sup> *See* Brazilian IP Legislation, *supra* note 17, at 94 (discussing the case of South Africa; 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").

<sup>126</sup> Grangeiro et al., *supra* note 5, at 64 (suggesting that from 2005 on Brazil has been much less successful in achieving price reductions and also that its local capacity for cost-

### 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, Merck's Efavirenz. There are several rationales for the issuance of such compulsory licenses. First, by reducing the price per day from \$1.56 to \$0.45 by buying Indian generics, the Brazilian government saved \$30 million in 2007 and may save up to \$237 million between 2007 and 2012 (when the Efavirenz patent expires).<sup>127</sup> Moreover, the actual issuance of a compulsory license, frequently threatened in the past but never instituted, enhanced 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 gives a developing nation the promise of cheaper access to pharmaceuticals, and at the same time responds to claims of a growing domestic generics industry.

Amy Nunn and her colleagues investigated the drivers of recent ARV cost trends in Brazil through analysis of drug-specific prices and expenditures between 2001 and 2005.<sup>128</sup> 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 \$2 billion on drugs for HAART [highly active antiretroviral therapy] between 2001 and 2005, implying a savings of \$1.2 billion from price declines."<sup>129</sup> Nunn also noted 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 \$200 higher per patient per year than that reported in other middle-income countries."<sup>130</sup>

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efficient production of generics has recently weakened).

<sup>127</sup> Ministério da Saúde [Ministry of Health], Brasil Decreta Licenciamento Compulsório do Efavirenz [Brazil Decrees Compulsory Licensing of Antivirals] (Braz.) (May 4, 2007).

<sup>128</sup> See generally A. S. Nunn et al., *Evolution of Antiretroviral Drug Costs in Brazil in the Context of Free and Universal Access to AIDS Treatment*, 4 PLOS MED. 1804 (2007).

<sup>129</sup> *Id.* at 1804

<sup>130</sup> *Id.*

In the aftermath of these negotiations processes, Brazil became renowned worldwide as the most successful developing country in tackling the AIDS epidemic.<sup>131</sup> In the early 1990s, the World Bank predicted that, by the year 2000, 1.2 million Brazilians would carry HIV, the virus that causes AIDS.<sup>132</sup> Prevention schemes, however, held that number to roughly half of that, or 0.61% of the country's population.<sup>133</sup> The key to Brazil's success was its National STD/AIDS Program (NSAP) created in the 1990s by the Brazilian federal government. The program guarantees free access to HAART for all individuals living with HIV/AIDS in need of treatment. In 2006, NSAP had an annual budget of approximately \$770 million, representing almost 3% of the Health Ministry's budget.<sup>134</sup> In 2007, the NSAP supplied<sup>135</sup> different ARV drugs to nearly 200,000<sup>136</sup> of Brazil's estimated 600,000 HIV/AIDS patients.<sup>137</sup> The expenditures for the purchase of ARVs (including generics locally manufactured and imported) amounted to approximately \$570 million.<sup>138</sup>

On top of all of that—and to some extent irrespective of the net results of the balance of costs and benefits associated with issuing compulsory licenses—politicians can capture votes by promising to defend national interests. It is no coincidence that Brazilian President Luiz Inácio da Silva (“Lula”) signed the decree for the compulsory license of Efavirenz in a televised ceremony.<sup>139</sup>

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<sup>131</sup> *Brazil's AIDS programme: A Conflict of Goals*, *ECONOMIST*, May 12, 2007.

<sup>132</sup> *Id.*

<sup>133</sup> United Nations General Assembly Special Session on AIDS/HIV [UNGASS]—Brazilian Response 2005-2007, Country Progress Report 11 (2008) [hereinafter UNGASS].

<sup>134</sup> *Id.* at 24.

<sup>135</sup> Grangeiro et al., *supra* note 5, at 62.

<sup>136</sup> The World Health Organization 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. See Press Release, WHO, 3 Million AIDS Sufferers Could Receive Antiretroviral Therapy by 2005: New Hope for Those in Developing World, WHO/58, (July 9, 2002), available at [http://whqlibdoc.who.int/press\\_release/2002/PR\\_WHO\\_58.pdf](http://whqlibdoc.who.int/press_release/2002/PR_WHO_58.pdf) (last visited May 10, 2010).

<sup>137</sup> *Efavirenz: Questões Sobre o Licenciamento Compulsório* [Efavirenz: Questions About Compulsory Licensing], MINISTÉRIO DA SAÚDE [Ministry of Health], [http://portal.saude.gov.br/portal/aplicacoes/noticias/noticias\\_detalhe.cfm?co\\_seq\\_noticia=29719](http://portal.saude.gov.br/portal/aplicacoes/noticias/noticias_detalhe.cfm?co_seq_noticia=29719) (Braz.) (last visited May 10, 2010).

<sup>138</sup> UNGASS, *supra* note 133, at 25.

<sup>139</sup> See Jon Cohen, *Brazil, Thailand Override Big Pharma Patents*, 316 *SCI.* 816, 816 (2007), available at <http://www.cptech.org/ip/health/aids/2g/science05112007.pdf> (last visited May 10, 2010).

In fact, both sides of the Brazilian political spectrum seem to be able to capitalize on aggressive drug policies. For instance, José Serra, President Lula's main political contender, still largely bases 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 2000s.<sup>140</sup>

Above and beyond circumstantial political disputes, investments in AIDS care in Brazil are said to have paid off in health care cost savings. Although Brazil's NSAP is expensive, the costs avoided—due to reduced illness, hospitalization, and other impacts of HIV/AIDS—have balanced the budget. According to statistics released by the Brazilian Ministry of Health, hospital admissions decreased by 80% in the period from 1996 to 2001, and in 2001 the final cost of NSAP incorporating reduced morbidity expenditure was negative, resulting in net savings of \$50 million.<sup>141</sup> These figures are an important part of the explanation of why, in recent years, the fight against HIV/AIDS has been made a priority in Brazil's health policy agenda.<sup>142</sup>

An additional element fueling 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. The international pharmaceutical industry can be characterized as a highly competitive oligopoly that derives its above-average profitability from the continuous release of new drugs. The global market is estimated at approximately \$500 billion, and the leading 12 companies—all of which are headquartered in developed countries—account for approximately 45% of total sales.<sup>143</sup> Historically, developing countries have used patent law to foster the development of local industries, however, due to the classic trade-off between innovation and dissemination, there is

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<sup>140</sup> AMY NUNN, *THE POLITICS AND HISTORY OF AIDS TREATMENT IN BRAZIL* 123-24 (2009).

<sup>141</sup> Grangeiro et al, *supra* note 5, at 62 (suggesting that investments in ARVs have permitted the government to save \$2 billion between 1997 and 2003). *See generally* Guido Carlos Levi & Marco Antonio A. Vitória, *Fighting Against AIDS: The Brazilian Experience*, 16 *AIDS* 2373 (2002); Paulo R. Teixeira et al., WHO, *Antiretroviral Treatment in Resource-Poor Settings: The Brazilian Experience*, 18 *AIDS* S5 (2004).

<sup>142</sup> 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 under budgeted. *See* Grangeiro et al., *supra* note 5, at 65.

<sup>143</sup> FÓRUM DE COMPETITIVIDADE, *supra* note 25, at 13.



widespread disagreement concerning the role to be played by patent laws. Brazil illustrates the case of a country that, having resorted to a stricter system of patent protection a decade ago, has since used compulsory licensing as an additional tool to safeguard some expertise in pharmaceuticals.

For example, the laboratory Far-Manguinhos,<sup>144</sup> the main government drug producer in Brazil, has reverse-engineered technology for pharmaceutical ingredients that strategically supports policies of the Ministry of Health. Far-Manguinhos has often played a key role in the course of Brazil's negotiations with big pharma by supplying reference prices for the ARVs, thus contributing to the financial sustainability of Ministry of Health programs.<sup>145</sup> This laboratory already produces seven of the fifteen medicines used in the antiretroviral cocktail freely offered in Brazil.<sup>146</sup> None of these drugs are patented in Brazil.<sup>147</sup> In 2001, 56% of ARVs distributed in Brazil were locally produced, which made possible a reduction of 82% in the drug prices from 1996 to 2001.<sup>148</sup>

#### *D. Conclusions*

In research-intensive industries such as pharmaceuticals, evidence demonstrates that company growth is intimately related to innovation.<sup>149</sup> In pharma, high cash flows created by earlier innovations permit investments in R & D and enhance manufacturing capacity and marketing sales. Accordingly, the costs of subsequent R & D projects are cut by sharing accumulated knowledge, research facilities, and marketing networks, leading to further specialization, innovation, and profits.<sup>150</sup> A small group of

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<sup>144</sup> Far-Manguinhos is part of the Oswaldo Cruz Foundation (FIOCRUZ), a non-profit research foundation linked to the Brazilian Ministry of Health. See Brazilian IP Legislation, *supra* note 17, at 129-50.

<sup>145</sup> *Id.* at 142.

<sup>146</sup> COMM'N ON INTELL. PROP. RIGHTS, INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY 43 (September 2002), available at [http://www.iprcommission.org/papers/pdfs/final\\_report/CIPRfullfinal.pdf](http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf) (last visited May 10, 2010).

<sup>147</sup> *Id.*

<sup>148</sup> Grangeiro et al., *supra* note 5, at 64 (noting that expenditures in 1998 were R\$346 million jumping to R\$557 million in 2000).

<sup>149</sup> See generally EDWIN MANSFIELD, INDUSTRIAL RESEARCH AND TECHNOLOGICAL INNOVATION (1968); CHRISTOPHER FREEMAN, THE ECONOMICS OF INDUSTRIAL INNOVATION (1974).

<sup>150</sup> Rebecca Henderson & Iain Cockburn, *Scale, Scope and Spillovers: The*

less than thirty companies headquartered in only five countries (the United States, Germany, Switzerland, the United Kingdom, and France) is responsible for 70% of all the innovations in pharmaceuticals from 1800 to 1990.<sup>151</sup> As such, a handful of highly competent pharmaceutical companies have enjoyed substantial competitive advantages that consolidated their position in the world markets in research intensity, corporate technology tradition, and corporate growth (mergers and acquisitions of foreign companies also helped), rendering the entry of new competitors extremely difficult.

To illustrate the impact of economies of scale in pharma, in 2005 the total sales of Aché, the largest Brazilian pharmaceutical laboratory, corresponded to \$635.8 million, or 6.9% of the Brazilian market. In that same year, Pfizer's sales reached \$51.3 billion, which is eighty times more than Aché's total sales and six times the overall size of the Brazilian market.<sup>152</sup> Moreover, the total cost for developing a new medicine has recently been estimated at close to \$900 million.<sup>153</sup>

Outside Brazil, hundreds of small biotechnology firms have begun to appear in recent decades, introducing cutting-edge, innovative science and technology. As noted by Achilladelis and Antonakis, this was the first time in many years that newcomers had introduced significant output of new technology in pharma. Venture capital, which became available to academic research teams, led to the formation of such firms.<sup>154</sup> 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 TRIPS-compliant IP legislation, point to certain fields where Brazil can potentially develop competitive

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*Determinants of Research Productivity in Drug Discovery*, 27 RAND J. ECON. 32, 55-56 (1996).

<sup>151</sup> Basil Achilladelis & Nicholas Antonakis, *The Dynamics of Technological Innovation: The Case of the Pharmaceutical Industry*, Research Policy No. 30, 535-538 (2001).

<sup>152</sup> Capanema & Filho, *supra* note 40.

<sup>153</sup> Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, J. HEALTH ECON., no. 2, 2003 at 151, 180.

<sup>154</sup> Achilladelis & Antonakis, *supra* note 151.

advantages in pharmaceuticals.<sup>155</sup> The country also possesses a sizeable and growing consumer market,<sup>156</sup> a fairly stable<sup>157</sup>—although problematic<sup>158</sup>—political system, and the largest biodiversity in the world. Two important points, however, are repeatedly overlooked. First, IP law—like every other body of law—does not work in a vacuum; it is the broader institutional framework that counts. Second, this institutional framework is not merely a matter of design, or “intelligent” policymaking. Rather, it is the product of historical evolution and, most importantly, it is severely constrained by the interests of the groups involved with the supply and demand of regulation.<sup>159</sup>

Indeed, Brazil’s activity 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.<sup>160</sup> Ultimately, the introduction of IP protection within the pharmaceuticals sector in the mid-1990s proved that IP laws will not produce desired outcomes unless other conditions are attained.

Moreover, larger and relatively more dynamic developing countries tend to have a much greater ability to withstand the prospect of trade sanctions. The larger, wealthier and more developed a “developing country” is, the greater its ability to benefit from bargains for compulsory licenses and price reductions—without significantly curtailing investment and enhanced R & D against 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. This is particularly true after taking into account the potential devastating effects that an increase in the AIDS epidemic could

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<sup>155</sup> BARBOSA ET AL., *supra* note 105, at 35.

<sup>156</sup> In 2005, Brazil was the world’s tenth-largest pharmaceuticals market with sales of R\$22.2 billion (approximately \$12 billion).

<sup>157</sup> Bruno Meyerhof Salama, *Perspectivas Económicas y Políticas en América Latina* (2007), available at [http://works.bepress.com/bruno\\_meyerhof\\_salama/12/](http://works.bepress.com/bruno_meyerhof_salama/12/).

<sup>158</sup> See generally BARRY AMES, *THE DEADLOCK OF DEMOCRACY IN BRAZIL* (2001).

<sup>159</sup> See generally NEIL K. KOMESAR, *LAW’S LIMITS: THE RULE OF LAW AND THE SUPPLY AND DEMAND OF RIGHTS* (2001).

<sup>160</sup> Maria Fernanda Macedo & Eloan dos Santos Pinheiro, Econ. Comm’n for Latin America and the Caribbean, (CEPAL), *Encontro Internacional de Atração de Investimento Direto Externo: Documento Setorial—Fármacos* [International Workshop on Attracting Foreign Direct Investment: Pharmaceutical Sector], at 2, U.N. Doc. No. LC/BRS/R.146 (June 8, 2005).

cause. While it is true that the amounts invested by big pharma in R & D in Brazil have been negligible, it is a widely known fact that economies of scope largely favor conducting R & D activities in their home countries.<sup>161</sup> All things considered, the proposition that stricter patent regimes, which would prohibit compulsory licensing, would have a significant effect on the overall levels of R & D in Brazil is debatable at best.

### III. THE LOCALIZED GOVERNANCE CONSIDERATION

#### *A. 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.<sup>162</sup> On one hand, TRIPS moves toward harmonization of IPRs.<sup>163</sup> In theory, countries that strengthen their IPRs become marginally more attractive, whereas those already affording strong IPRs become relatively less attractive to companies looking to invest in R & D.<sup>164</sup>

As Maskus explains, “[t]his 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.”<sup>165</sup> 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.”<sup>166</sup> The channels through which globalization affects economies include expanded trade in merchandise and

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<sup>161</sup> *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).

<sup>162</sup> See generally Keith E. Maskus, *The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer*, 9 DUKE J. COMP. & INT’L L. 109 (1998) (hereinafter Maskus, *Role of IP Rights*); Keith E. Maskus, *The International Regulation of Intellectual Property*, BAND 134 WELTWIRTSCHAFTLICHES ARCHIVE [REV. OF WORLD ECON.] 186, 201-02 (1998) (Ger.) (hereinafter Maskus, *International Regulation*).

<sup>163</sup> Maskus, *Role of IP Rights*, *supra* note 162, at 136.

<sup>164</sup> *Id.*

<sup>165</sup> *Id.* at 110; POLICY FRAMEWORKS FOR A KNOWLEDGE ECONOMY 231, 234-60 (Thomas J. Courchene ed., 1996).

<sup>166</sup> *Id.*

services, product and technology licensing, greater international portfolio investment, and FDI.<sup>167</sup>

On the other hand, there is a competing category of consideration, generally known as the “localized ones.” The prevailing assumption therein 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.<sup>168</sup>

A variety of such localized characteristics are familiar within development economics writings. To begin with, a primary factor and the focal point of this study as discussed hereafter is a country’s political stability.<sup>169</sup> 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.<sup>170</sup> Another study has argued that the level of enforcement of trade secrecy laws is more relevant for foreign investment decisions than the availability of strict patent protection laws.<sup>171</sup>

In deciding where to invest, other potentially relevant factors include (but are not limited to) presence of macroeconomic stability,<sup>172</sup> availability of an appropriate physical infrastructure for setting up technological facilities (particularly, proximity to high

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<sup>167</sup> See RICHARD E. CAVES, *MULTINATIONAL ENTERPRISE AND ECONOMIC ANALYSIS* 25 (2d ed. 1996); PETER J. BUCKLEY & MARK CASSON, *THE ECONOMIC THEORY OF THE MULTINATIONAL ENTERPRISE* 113-44 (1985).

<sup>168</sup> See JOHN DUNNING, *INTERNATIONAL PRODUCTION AND THE MULTINATIONAL ENTERPRISE* 110, 266-68 (1981); James R. Markusen, *The Boundaries of Multinational Enterprises and the Theory of International Trade*, 9 J. ECON. PERSP., no. 2, 1995 at 169; GENE GROSSMAN & ELHANAN HELPMAN, *INNOVATION AND GROWTH IN THE GLOBAL ECONOMY* 238, 336-38 (1991); *WORLD DEVELOPMENT REPORT* 88-96 (1991); Hoosang Amirahmadi & Weiping Wu, *Foreign Direct Investment in Developing Countries*, 28 J. DEV. AREAS 167 (1994).

<sup>169</sup> Oddi, *supra* note 2, at 849.

<sup>170</sup> Instituto Brasileiro de Geografia e Estatística (IBGE) [Brazilian Institute of Geography and Statistics], *PESQUISA DE INOVAÇÃO TECNOLÓGICA* [Research of Technological Innovation] (2005) [hereinafter PINTEC 2005].

<sup>171</sup> See Paul J. Heald, *Misreading a Canonical Work: An Analysis of Mansfield’s 1994 Study*, 10 J. INTELL. PROP. L. 309, 315-16 (2003).

<sup>172</sup> See generally PINTEC 2005, *supra* note 170 (highlighting the influence of positive macroeconomic expectations on private investments in technological innovation in Brazil in the period of 2003-2005).

level universities and research institutes),<sup>173</sup> and availability of human capital, particularly the availability of qualified scientists and engineers.<sup>174</sup> Relevant factors may also include market size, 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. Even a large degree of HIV contamination within the population of a country can bear some weight. On one hand, it can itself be a serious constraint for foreign investment, because it may signal the existence of deep socioeconomic problems. On the other hand, it possibly indicates the existence of a large consumer market for drugs.

This article makes no attempt to devise a broad theorization that combines or weights all these factors, but addresses one important aspect of a potential theorization of that kind, namely the Brazilian political structure. Essentially, we suggest that such structure renders the Brazilian state weak on a fundamental level. By “weak,” we mean a state that is captive to a wide array of distributional coalitions and thus is exposed to the ravages of rent-seeking groups.<sup>175</sup> In contrast, a “strong” state is able to develop a relative autonomy from such ravages.<sup>176</sup> It is critical to emphasize *relative* autonomy because the public good as a metaphysical entity does not exist and no state operates in a vacuum. Since the archetypical “strong” state associates with some modernizing interests but restricts the access to the policy-making process of more narrowly based groups, it is generally able to design policies

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<sup>173</sup> Mariana Zanatta et. al., *National Policies to Attract FDI in R & D: An Assessment of Brazil and Selected Countries 1* (World Inst. Dev. Econ. Research, Paper No. 2008/69, 2008), available at [http://www.wider.unu.edu/publications/working-papers/research-papers/2008/en\\_GB/rp2008-69/](http://www.wider.unu.edu/publications/working-papers/research-papers/2008/en_GB/rp2008-69/).

<sup>174</sup> *Id.*

<sup>175</sup> See generally ANIS CHOWDHURY & IYANATUL ISLAM, *THE NEWLY INDUSTRIALISING ECONOMIES OF EAST ASIA* (1997).

<sup>176</sup> Stephan Haggard, *The Politics of Industrialization in the Republic of Korea and Taiwan*, in *ACHIEVING INDUSTRIALIZATION IN EAST ASIA* 260, 262 (Helen Hughes ed., 1988); STEPHAN HAGGARD, *PATHWAYS FROM THE PERIPHERY: POLITICS OF GROWTH IN THE NEWLY INDUSTRIALIZED COUNTRIES* (Peter Katzenstein ed., 1990).

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that are broadly aligned 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 is necessary for development both from the standpoint of a more orthodox, neoclassical political economy, as it is 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 development is logical because patronage-based and rent-seeking activities adapt easily to state-led industrialization.<sup>177</sup> A common justification for state intervention is the pervasiveness of market failure, and a weak state is thus destined to fail.

At the same time, a strong state is also viewed as necessary from the neoclassical (or neoliberal) standpoint. The neoclassical agenda puts forward a straightforward 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 well-equipped and well-funded bureaucracy.

### *B. One Institutional Letdown, Two Competing Paradigms*

Two competing paradigms explain the failures of liberalizing reforms to produce more innovation in the Brazilian economy.<sup>178</sup> The first is associated with a more orthodox view and is often included under the rubric of the “neoclassical political economy”;<sup>179</sup> the second, with a more heterodox view, is encapsulated under the rubric of the “new political economy.”<sup>180</sup> Roughly speaking, the key distinction between the two is the economic role the government plays in each. While the former

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<sup>177</sup> See Judith Chubb, *The Social Bases of an Urban Political Machine: The Case of Palermo*, 96 POL. SCI. Q. 107 (1981) (explaining that critical local patronage mechanisms can endure independently of the flow of public resources).

<sup>178</sup> See Katz, *supra* note 33.

<sup>179</sup> Thirukodikaval Srinivasan, *Neoclassical Political Economy, the State and Economic Development*, in ECONOMIC POLICY AND STATE INTERVENTION (N.S.S. Narayana ed., 2001) (coining the expression “neoclassical political economy”).

<sup>180</sup> CHOWDHURY & ISLAM, *supra* note 175, at 46.

emphasizes the *market* as the engine of growth, the latter places the burden of fostering development on activist policies carried out by national governments.<sup>181</sup>

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 government interventions in the economy.<sup>182</sup> Such interventions include minimum wage laws, interest rate controls, tariff concessions on imported capital inputs, 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 large body of theory and evidence suggesting that the costs of such strategies have outweighed their benefits;<sup>183</sup> the liberalizing reforms that swept both developing and developed countries since the mid-1970s emerged in the footsteps of such literature.

These reforms came premised on a diagnostic that the economic crises in both developed Western nations and undeveloped countries were largely caused by widespread rent-seeking practices.<sup>184</sup> At the time, vast amounts of state intervention had given rise to 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.<sup>185</sup> In developing countries, growing foreign indebtedness, political instability, and poorly working institutional frameworks aggravated this situation.

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<sup>181</sup> *Id.*

<sup>182</sup> See P. N. Rosenstein-Rodan, *Problems of Industrialisation of Eastern and South-Eastern Europe*, 53 *ECON. J.* 202, 202 (1943); Raúl Prebisch, *Commercial Policy in the Underdeveloped Countries*, 49 *AM ECON. REV.* 251 (1959).

<sup>183</sup> See IAN LITTLE ET AL., *INDUSTRY AND TRADE IN SOME DEVELOPING COUNTRIES: A COMPARATIVE STUDY 1* (1970); Juergen B. Donges, *A Comparative Survey of Industrialization Policies in Fifteen Semi-Industrialized Countries*, 112 *WELTWIRTSCHAFTLICHES* 626 (1976); ANN O. KRUEGER, Nat'l Bureau of Econ. Research., *Foreign Trade Regimes and Economic Development: Liberalization Attempts and Consequences*, 6 *J. DEV. ECON* 447, 447-48 (1979); CHOWDHURY & ISLAM, *supra* note 175.

<sup>184</sup> See generally JOHN CAMPBELL & OVE PEDERSEN, *THE RISE OF NEOLIBERALISM AND INSTITUTIONAL ANALYSIS* (2001).

<sup>185</sup> See generally WORLD BANK, *WORLD DEVELOPMENT REPORT 1997: THE STATE IN A CHANGING WORLD* (1997).



Instead of promoting growth and reducing inequalities, interventionist policies in many countries had merely spread poverty.

More recently, a number of theorists have tried to reinstate the credibility of state-led development processes.<sup>186</sup> Their starting point, as noted by Pranab Bardhan, is that the rent-seeking literature is better at explaining failures than successes.<sup>187</sup> This literature contends that the most dramatic cases of “catching up”—namely, those of East Asia’s newly industrialized countries (NICs)—<sup>188</sup> contain a significant amount of “enlightened”<sup>189</sup> policy activism characteristic of national governments.<sup>190</sup> Proponents also argue that the East Asian NICs have been as interventionist as many less successful Latin American developing countries. A common claim, for instance, is that the share of the GDP in state enterprise was higher in Taiwan and South Korea than in many Latin American countries.<sup>191</sup> Amartya Sen and Jeffrey Sachs have thus argued that what matters to economic development is not the extent, but instead the quality, of the state intervention.<sup>192</sup>

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<sup>186</sup> See, e.g., ROBERT WADE, GOVERNING THE MARKET: ECONOMIC THEORY AND THE ROLE OF GOVERNMENT IN EAST ASIAN INDUSTRIALIZATION 111-12 (1990) (concluding that Taiwan’s successful markets were not guided to a greater extent than less successful countries by free markets and world prices); STRATEGIC TRADE POLICY AND THE NEW INTERNATIONAL ECONOMICS 19-20 (Paul Krugman ed., 1986); ALICE H. AMSDEN, ASIA’S NEXT GIANT: SOUTH KOREA AND LATE INDUSTRIALIZATION vi (1989).

<sup>187</sup> Pranab Bardhan, *Symposium on the State and Economic Development*, 4 J. ECON. PERSP. 3, 5 (1990).

<sup>188</sup> The category of NIC is a socioeconomic classification applied to several countries by geographers, economists, and political scientists. See CHOWDHURY & ISLAM, *supra* note 175, at 4 (listing four suggestive criterion for classification as a NIC, including a requirement that manufacturing account for at least twenty percent of the NIC’s gross domestic product). See also Colin I. Bradford Jr., *The Rise of the NICs as Exporters on a Global Scale*, in THE NEW INDUSTRIALIZING COUNTRIES: TRADE AND ADJUSTMENT 7 (Louis Turner Neil McMullen eds. 1982) (arguing that the emergence of NICs is a “generalized historical movement in which industrialized countries vacate intermediate sectors in industrial production in which advanced developing countries are currently more competitive and advanced developing countries, in turn, vacate more basic industrial sectors in which the next tier of developing countries have a relative advantage.”)

<sup>189</sup> CHOWDHURY & ISLAM, *supra* note 175, at 47.

<sup>190</sup> STRATEGIC TRADE POLICY AND THE NEW INTERNATIONAL ECONOMICS, *supra* note 186, at 15 (arguing that the “idealized theoretical model on which the classical case for free trade is based will not serve us anymore. 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”).

<sup>191</sup> CHOWDHURY & ISLAM, *supra* note 175, at 47

<sup>192</sup> See Amartya Sen, *Development: Which Way Now?*, 93 ECON J. 745 (1983). See

*C. Of Neoclassical Political Economy*

From the more orthodox, neoclassical political economy standpoint, the absence of a more vibrant and innovative framework in Brazilian pharmaceuticals is not related to shortcomings in the vertical policies in that area, but instead to horizontal problems that pervade the Brazilian economy as a whole.<sup>193</sup> Such problems include the failure to control public spending, the insufficient provision of public goods, especially public infrastructure, microeconomic inefficiencies that became entrenched in the economic system as a consequence of ill-designed industrial policies (particularly special interest groups interested in retaining monopoly privileges), lack of investment in human capital, low saving efforts, and failures to take bolder steps towards further trade liberalization and market de-regulation.

Adherents to the more orthodox stream note that the crucial tenets of the horizontal policies in place in East Asia were not present in Brazil. For instance, Canêdo-Pinheiro and colleagues have compared a significant amount of macroeconomic data from Brazil, South Korea, Taiwan, Japan, Chile, and the United States. They have concluded that Brazil, in comparison to the other countries, has consistently underperformed with respect to crucial tenets of its macroeconomic policy.<sup>194</sup> Brazil has repeatedly failed to control its public spending, having consistently incurred much larger inflation rates over four decades.<sup>195</sup> Moreover, the reduction of the public deficit that took place in the early 2000s was implemented by means of increased taxation and decreased investments in infrastructure.<sup>196</sup> The upshot was that tax rates in

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also Jeffrey D. Sachs & John Williamson, *External Debt and Macroeconomic Performance in Latin America and East Asia*, 1985 BROOKINGS PAPERS ON ECON. ACTIVITY 523, 547 (1985).

<sup>193</sup> Mauricio Canedo-Pinheiro et al., *Does Brazil Need an Industrial Policy* (Trade & Indus. Prop. Strategies, Working Paper 1090, 2007), available at <http://www.tips.org.za/node/1090>.

<sup>194</sup> *Id.*

<sup>195</sup> See Marcus Noland & Howard Pack, *Industrial Policies and Growth: Lessons from International Experience*, in *ECONOMIC GROWTH: SOURCES, TRENDS, AND CYCLES* (Loyaza & Soto eds., 2002). See also MARCUS NOLAND & HOWARD PACK, *INDUSTRIAL POLICY IN AN ERA OF GLOBALIZATION: LESSONS FROM ASIA* (1959) (noting that Japan, South Korea and Taiwan have maintained fiscal austerity during the post-WWII period). See also Arman Mansoorian & Leo Michelis, *Money, Habits and Growth*, J. ECON. DYNAMICS & CONTROL 1267-70 (2005) (suggesting that high inflation tends to diminish economic growth).

<sup>196</sup> See Sanjeev Gupta et al., Fiscal Policy, *Expenditure Composition, and Growth in*

Brazil became among the highest in the developing world,<sup>197</sup> while the infrastructure for robust growth was still lacking.<sup>198</sup> Brazil has also failed to tame its ever-growing, costly bureaucracy, arguably to the detriment of its overall economic efficiency.<sup>199</sup>

#### *D. Of Heterodox Political Economy*

The more heterodox view challenges the orthodoxy on three accounts. First, it questions the empirical foundations of the orthodoxy by pointing out that all of the East Asian countries that are catching up with the developing world have relied heavily on highly interventive industrial policies.<sup>200</sup> The suggestion, accordingly, is that what matters to the process of economic development is not the extent, but instead the quality, of state intervention.<sup>201</sup> The implication is that technological innovation is not simply a by-product of macroeconomic stability, but rather the outcome of concerted efforts of private and state actors.<sup>202</sup>

Second, the heterodox view notes that the risk of government failure inherent in any activist industrial policy can be minimized through appropriate institutional arrangements. For instance, as

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*Low-Income Countries*, 24 J. INT'L MONEY & FIN. 441, 443-44 (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).

<sup>197</sup> BARBOSA ET AL., *supra* note 105, (noting that in the period of 2000-04 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). See also Carga Tributária Comparada, Tribunal de Contas da União (2009), available at [http://portal2.tcu.gov.br/portal/page/portal/TCU/comunidades/contas/contas\\_governo/contas\\_09/Textos/Ficha%203%20-%20Carga%20Tributaria.pdf](http://portal2.tcu.gov.br/portal/page/portal/TCU/comunidades/contas/contas_governo/contas_09/Textos/Ficha%203%20-%20Carga%20Tributaria.pdf)

<sup>198</sup> Canêdo-Pinheiro et al., *supra* note 194.

<sup>199</sup> See Santiago Herrera & aobog. Pang, *Efficiency of Public Spending in Developing Countries: An Efficiency Frontier Approach* (World Bank Policy Research Working Paper No. 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 also Mohsin Habib & Leon Zurawicki, *Corruption and Foreign Direct Investment*, 33 J. INT'L. BUS. STUD. 291, 291- (2002) (suggesting that corruption has a negative effect on foreign direct investment); Andrew Sunil Rajkumar & Vinaya Swaroop, *Public Spending and Outcomes: Does Governance Matter?*, (World Bank Policy Research Working Paper No. 2840, 2002) (suggesting that the quality of state bureaucracy and the level of state corruption negatively impact public policy).

<sup>200</sup> Robert Wade, *The Role of Government in Overcoming Market Failure: Taiwan, Republic of Korea and Japan*, in *ACHIEVING INDUSTRIALIZATION IN ASIA* 129, 129-30 (Helen Hughes ed., 1988); Wade, *supra* note 186.

<sup>201</sup> Bardhan, *supra* note 187, at 4; Sen, *supra* note 192, at 4; Sachs, *supra* note 192.

<sup>202</sup> MAURO F. GUILLÉN, *THE LIMITS OF CONVERGENCE* 123 (2003).

noted by Alice Amsden, the governmental protections provided for East Asian firms were conditioned on such firms reaching certain performance targets over time, whereas such clauses of discontinuances were not established *ex ante* in Brazil.<sup>203</sup>

Third, the heterodox view postulates that the objective of the country's industrial policy should be aimed at winning export markets through strategic intervention in key industries, rather than at picking winners and protecting domestic markets, as was common during the times of Import Substitution Industrialization in the 1950s and 1960s.<sup>204</sup> Contrary to East Asia's Export-Oriented Industrialization model, excessive protectionism under Brazil's Import Substitution Industrialization was primarily aimed at supplying the local market, thus rendering innovation largely unnecessary for local companies.<sup>205</sup>

While the heterodoxy does not have a coherent agenda of its own, a unifying theme is a broader governmental role in economic affairs.<sup>206</sup> 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 consumer markets for local industry.<sup>207</sup>

Nonetheless, the argument favoring high 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 that private parties capture political consensus to the detriment of broader societal interests.<sup>208</sup>

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<sup>203</sup> AMSDEN, *supra* note 186, at vi. See also Katharina Pistor & Chenggang Xu, Governing Emerging Stock Markets: legal vs administrative governance, *Corporate Governance: An International Review*, Vol. 13, Issue 1, pp. 5-10.

<sup>204</sup> See e.g. Donald Hay, Industrial Policy in Brazil: A Framework". IPEA. Texto para Discussão 551, IPEA (1998)., Available at <http://www.ipea.gov.br/pub/td/td0551.pdf>.

<sup>205</sup> Larry E. Westphal, *Industrial Policy in an Export-propelled Economy: Lessons from South Korea's Experience*, 4 J. ECON. PERSP. 41 (1990); Dani.Rodrik et al., *Getting Interventions Right: How South Korea and Taiwan Grew Rich*, 10 ECON. POL. 55 (1995).

<sup>206</sup> See generally HA-JOON CHANG, GLOBALISATION, ECONOMIC DEVELOPMENT AND THE ROLE OF THE STATE (2003).

<sup>207</sup> D. KUPFER, POLÍTICA INDUSTRIAL, ECONÔMICA 281-98 (2003).

<sup>208</sup> See RICHARD J. SAMUELS, THE BUSINESS OF THE JAPANESE STATE: ENERGY MARKETS IN COMPARATIVE AND HISTORICAL PERSPECTIVES (1987) (describing a complex dynamics of policy-making in East Asia as the "politics of reciprocal consent").

*E. An 'Effects Test' Synthesis*

In light of competing explanations, the question remains about what conclusions can be drawn regarding the comprehensive cause of Brazil's lack of domestic pharmaceutical innovation. First, it is easy to see the orthodox neoclassic view of political economy and its competing heterodox views as a market-based solution standing in opposition to a state-imposed solution. In reality, the border between the two views is much blurrier, because the dynamic feedback mechanism between the two is that the market needs the state as much as the state needs the market.<sup>209</sup> It would be tempting to suggest that the issue should be resolved by making use of available evidence, however one problem is that the evidence which is available is equivocal, supporting elements of both paradigms. As Joseph Stiglitz notes,<sup>210</sup> both government failure and market failure are common, so the fundamental development challenge is to devise institutional arrangements that minimize government failure while simultaneously preserving the benefits that flow from the rectification of market failure.<sup>211</sup>

Our analysis of Brazil's localized consideration emphasizes instead the role of internal policy and political factors, suggesting that the Brazil's dearth of pharmaceutical innovation can be ultimately related to a dysfunctional political system that imported into the democratic regime some of the worst features of its preceding military regime. Accordingly, it is the lack of adequate political institutions - not the lack of adequate intellectual property laws - that is the most important (yet neglected) topic in the Brazilian industrial policy agenda. This is a key factor in explaining the mid-1990s intellectual property reforms' failure to spur innovation and R & D investments in pharmaceuticals in Brazil.

In essence, the argument is that the Brazilian political framework renders the Brazilian state weak by favoring a structure that deeply entrenches rent-seeking interests of certain fractions of the society. Politicians are unlikely to devote much effort to making a bureaucracy less oppressive and remote, since they profit from mediating between their constituents and government

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<sup>209</sup> CHOWDHURY & ISLAM, *supra* note 175, at 53.

<sup>210</sup> JOSEPH E. STIGLITZ ET AL., *ECONOMIC ROLE OF THE STATE* (1990).

<sup>211</sup> *Id.*

bureaucrats.<sup>212</sup> It is therefore unsurprising that tax and social security reforms which could consolidate macroeconomic stabilization in Brazil have never been approved; this explains why the Brazilian state has done little to increase productivity even against a backdrop of legitimate, democratic elections with very high turnouts. This could also explain why political leaders have made basically no significant progress in reducing the overall cost of government.

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 a strong party system that would be necessary to ensure programmatic coherence for long-run government actions.<sup>213</sup> Weak parties and strong politicians act in a strong Congress, increasing the number of "veto players" in the political process,<sup>214</sup> so the transactional costs of law and policy-making are high.

Even though the Executive Power in Brazil controls the policy-making agenda, implementing such agenda is intricate.<sup>215</sup> Political bargaining over law and policy-making ends up strongly de-institutionalized; the Executive must often 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.<sup>216</sup> This discourages programmatic commitments and encourages "bureaucratic combats" within the government coalition.

In the end, the Brazilian Congress is extremely active in bartering political support for distributive policies, but relatively inactive on relevant issues at the national level. Government

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<sup>212</sup> *Id.*

<sup>213</sup> SCOTT MAINWARING, *RETHINKING PARTY SYSTEMS IN THE THIRD WAVE OF DEMOCRATIZATION: THE CASE OF BRAZIL* (1999); AMES, *supra* note 158, at 53. Ames argues 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 seventy 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.

<sup>214</sup> George Tsebelis, *Decision Making in Political Systems: Veto Players in Presidentialism, Parliamentarism, Multicameralism, and Multipartyism*, 25 *BRITISH J. POL. SCI.* 289 (1995).

<sup>215</sup> AMES, *supra* note 158, at 17.

<sup>216</sup> *Id.*

appointments premised exclusively on political connections are routinely used in law-making bartering in the Congress. This phenomenon is so pervasive that often politicians expect to appoint party faithfuls (irrespective of technical credentials) to technical and sometimes important jobs in the government, including in the lower echelons of power. In this sense, economic problems in Brazil, including low levels of innovation, can be linked to its political and institutional structures.

At first glance, historic, economic, political, and even cultural considerations suggest that democracy in Brazil ought to be seen as very fragile. To begin with, as in many Latin American countries, the stability of the “rules of the game” is a salient point. The Brazilian Republic has existed for nearly 120 years, yet it has experienced three periods of military rule. The transition of power from President Cardoso to current President Lula was the first between two democratically-elected presidents in more than forty years. The most recent restoration of democracy in 1988 was premised on a 160-page constitution comprised of unusual provisions, such as those granting of life tenure to bureaucrats and creating a 12% ceiling on “real” interest rates.<sup>217</sup> This Constitution was drafted during a period of economic downturn and hyperinflation and its short history has been turbulent.<sup>218</sup>

Moreover, the first democratically-elected president since the enactment of the Constitution, Fernando Collor, held power for less than three years before being impeached by Congress on charges of corruption. In the subsequent election, Fernando Henrique Cardoso was elected for a non-renewable term of four years, however, after only a few years in power, he championed a constitutional amendment which allowed 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.<sup>219</sup> During its twenty two

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<sup>217</sup> 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.

<sup>218</sup> See Salama, *supra* note 89.

<sup>219</sup> AMES, *supra* note 158, at 2. See also Dora Kramer, *Uma senhora cruel chamada realidade* [A lady called cruel reality], JORNAL DO BRASIL (July 1, 1997) (describing revelations that some incumbent governors had bribed certain Congressmen to support re-election in support for the re-election amendment than under debate in Congress).

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years of existence, the Brazilian Federal Constitution has been amended at least sixty-six times.<sup>220</sup>

On the other hand, the 1988 Constitution reinforced democratic stability in several ways. From a strictly legal standpoint, the basic democratic framework is guaranteed by the existence of a certain set of non-amendable constitutional provisions (called “cláusulas pétreas,” translated as “rocky clauses”). Of greater practical significance, the Federal Constitution fostered stability by dividing political power, thus creating a system of checks and balances that limits the ability of government to carry out radical political reforms. The Constitution established what has been referred to as a system of “presidentialism coalition,” in which the President has broad power to set the agenda of political and legal reform but needs the legislature to govern.<sup>221</sup>

The Federal Constitution also reinforced political stability by increasing the tax revenues of state and municipal governments. In so doing, it strengthened Brazil’s federalist system, giving local politicians an interest in maintaining institutional order as a means of ensuring their status and power. Congressional power was also reinforced, in that the Executive Power needs the support of the Legislature to govern making the Legislature the arena for political debate par excellence. Finally, the Constitution sharply increased the degree of judicial independence. Indeed, an independent and relatively well-funded (though arcane) Brazilian Judiciary can stand as the “guardian” of the Federal Constitution,<sup>222</sup> especially since it has broad powers of judicial

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<sup>220</sup> See *Constituição do Brasil, Emendas Constitucionais*, available at [http://www.planalto.gov.br/ccivil\\_03/constituicao/EMENDAS/Emc/quadro\\_emc.htm](http://www.planalto.gov.br/ccivil_03/constituicao/EMENDAS/Emc/quadro_emc.htm) (official site from the Presidency of the Republic listing all constitutional amendments).

<sup>221</sup> Sérgio H. Abranches, *O Presidencialismo de Coalizão: O Dilema Institucional Brasileiro* [The Presidential Coalition: The Brazilian Dilemma], 31(1) *DADOS* 5-33 (1988). But see Fernando Limongi, *A Democracia no Brasil: Presidencialismo, Coalizão Partidária e Processo Decisório* [Democracy in Brazil: Presidentialism, Partisan Coalition and the Decision Process], 76 *NOVOS ESTUDOS* [New Studies] 17 (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).

<sup>222</sup> See “Judiciário e Economia”, a report produced by the Secretaria de Reforma do Judiciário, Ministério da Justiça (2004), at 10, available at [http://ojamazonia.com.br/wp-content/uploads/2009/10/judiciario\\_economia1.pdf](http://ojamazonia.com.br/wp-content/uploads/2009/10/judiciario_economia1.pdf) (showing that in 1997 Brazil spent 3.66% of its national budget with the Judiciary Power, the highest rate in a sample of 35 countries that averaged 0.97%).



review.<sup>223</sup> The Constitution also created the conditions for the later emergence of a fairly uncorrupted election system.<sup>224</sup>

Stability, however, came at a high price. The same Constitution that set the ground for political stability is likewise to blame for having engendered a political model premised on everlasting governmental crises. Brazil is one of the world's most populous and important democracies; yet, unlike Anglo-American, single-member plurality systems, Brazilian national parties are loosely disciplined. If, on one hand, the weakness of political parties can reinforce stability by further fragmenting political power, on the other hand, it requires large political coalitions as a condition for any president to govern. Congress is powerful, but the control of Congressmen by the population is largely inadequate.

In a well-grounded book, political scientist Barry Ames powerfully argues 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 worse), 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 broad leeway to maneuver and change parties. Brazil's electoral system for the Legislative Power is premised on proportional representation<sup>225</sup> and open lists of candidates.<sup>226</sup> When combined with a number of other technical rules, this system undermines the authority of party leaders, personalizes politics, and inhibits party building.<sup>227</sup> Most importantly, it makes it easy for deputies to evade constituent

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<sup>223</sup> See Keith S. Rosenn, *Judicial Review in Brazil: Developments under the 1988 Constitution*, 7 SW. J.L. & TRADE AM. 291 (2000); Keith S. Rosenn, *Federalism in Brazil*, 43 DUQ. L. REV. 577 (2005); Miyuki Sato, *Judicial Review in Brazil. Nominal and Real*, 3 GLOBAL JURIST ADVANCES, no.1, art. 4, 1 (2003); Joaquim Barbosa, *Reflections on Brazilian Constitutionalism*, 12 UCLA J. INT'L L. & FOR. AFF. 181 (2007); Maria Angela J. de S. C. Oliveira, *Reforming the Brazilian Supreme Federal Court: A Comparative Approach*, 5 WASH. U. GLOBAL STUD. L. REV. 99 (2006).

<sup>224</sup> Counting of votes is done electronically; the votes are secret and popular participation is high.

<sup>225</sup> 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 158, at 41.

<sup>226</sup> 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.

<sup>227</sup> AMES, *supra* note 158, at 65.

monitoring.<sup>228</sup> Accordingly, Brazil's institutional framework tends to produce pork-oriented legislators who have little concern about national issues and who 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 six other parties joining a broad coalition that assembles a matrix of factions with no coherent policy. Consider, for instance, the current political situation in the country: the PT (Partido dos Trabalhadores, translated as the Workers' Party), the party with which Brazil's current President Lula is affiliated, holds less than twenty percent of the 513 seats in Congress. The party governs the country through a broad coalition of various parties with little ideological consistency. The main party in the coalition is the PMDB (Partido do Movimento Democrático Brasileiro, translated as the Brazilian Democratic Movement Party), which is the largest party currently in Congress, holding around twenty percent of the available seats. Interestingly, this party that now serves as the basis for political support to President Lula in Congress was part of the political alliance that opposed Lula in 2006 during the last presidential election.

Several important implications follow from the institutional framework set forth by the 1988 Constitution. The first is that the view 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 carry relatively high influence in the course of Congressional debates and federal policy-making. Personalism is also present when 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. For example, fifty-three percent of the federal deputies elected in 2002 had been members of more than one party during their public careers; this does not necessarily reflect ideological change on their parts, but simply a need to maximize opportunities for a successful political career.

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<sup>228</sup> *Id.* at 41.

*F. Conclusions*

The frail Brazilian innovation system is deeply rooted in the country's politically challenged history, and (thus far at least) the liberalizing reforms of the late twentieth century have had only a modest effect in changing this truism. Despite its status as South America's leading economic power, Brazil's potential remains largely unrealized, 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 compared with resources allocated by 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; yet the country remains irrelevant if its innovation system is thought of as the source of applied technological innovation.

The political framework in Brazil undermines long-term policies and favors shortsighted ones vis-à-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 government's ability to implement meaningful vertical policies premised on subsidies, but also its ability to implement horizontal policies premised on reduced taxation.<sup>229</sup> Corruption and endemic rent-seeking hampers the government's ability to make technical choices in directing industrial policies to the proper sectors, a process that has undoubtedly increased the number unqualified political appointments to key positions in the administration.

Large bureaucracy also undermines government efforts to create a more stable, business-friendly environment. The Executive Power has little incentive to create autonomous or independent policy-making agencies because doing so would reduce the instruments available to him 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

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<sup>229</sup> In 2007, taxation in Brazil reached 34.9% of the GDP, which is the highest in the world for countries with similar per-capita income. *See also* Carga Tributária Comparada, *Tribunal de Contas da União* (2009), available at [http://portal2.tcu.gov.br/portal/page/portal/TCU/comunidades/contas/contas\\_governo/contas\\_09/Textos/Ficha%203%20-%20Carga%20Tributaria.pdf](http://portal2.tcu.gov.br/portal/page/portal/TCU/comunidades/contas/contas_governo/contas_09/Textos/Ficha%203%20-%20Carga%20Tributaria.pdf)

practices, but in their breadth.<sup>230</sup> Pervasive pork and patronage heavily influences policy-making in that politicians sustain themselves by supplying pork and services to individuals.<sup>231</sup> Such influences have compromised the quality and motivation of public servants, their behavior, and, eventually, the content of policy itself.

Although there have been a number of important advances in recent times, the country still faces an oppressive and costly state apparatus, economic inefficiency, and poverty.<sup>232</sup> Writing in 1997, political scientist Kurt Weyland observed that “[t]he [Brazilian] state will remain an agglomeration of incongruent parts, ranging from competent bureaucracies to agencies captured by business groups and politicians. For the time being, the Brazilian state will resemble a disfigured yet moderately effectual Frankenstein.”<sup>233</sup> For now, such analysis seems to have withstood the test of time.

#### IV. 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 particularly so in the developing world.<sup>234</sup> Defenders of TRIPS portray patent protection as a central pillar of modern economic policy and a catalyst for development.<sup>235</sup> They argue that patent protection is an effective tool to foster economic growth in all countries,<sup>236</sup> and

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<sup>230</sup> AMES, *supra* note 158, at 24.

<sup>231</sup> 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 they were linked. See Salama, *supra* note 157.

<sup>232</sup> *Brazil Takes Off*, ECONOMIST, Nov 12th 2009.

<sup>233</sup> Kurt Weyland, *The Brazilian State in the New Democracy*, 39 J. INTERAMERICAN STUDIES & WORLD AFFAIRS, no. 4, at 63, 86.

<sup>234</sup> See, e.g., Michael Blakeney, The International Protection of Industrial Property: From the Paris Convention to the TRIPS Agreement on Trade-Related Aspects on Intellectual Property Rights (the s), WIPO National Seminar on Intellectual Property for Faculty Members and Students of Ajman University 16 (May 5, 2004), available at [http://www.wipo.int/edocs/mdocs/arab/en/wipo\\_ip\\_uni\\_dub\\_04/wipo\\_ip\\_uni\\_dub\\_04\\_1.pdf](http://www.wipo.int/edocs/mdocs/arab/en/wipo_ip_uni_dub_04/wipo_ip_uni_dub_04_1.pdf) (last visited May 8, 2010).

<sup>235</sup> SHAHID ALIKHAN, SOCIO-ECONOMIC BENEFITS OF INTELLECTUAL PROPERTY PROTECTION IN DEVELOPING COUNTRIES 1-10 (2000).

<sup>236</sup> KAMIL IDRIS, INTELLECTUAL PROPERTY: A POWER TOOL FOR ECONOMIC GROWTH 1 (2d ed. 2003), available at [http://www.wipo.int/about-wipo/en/dgo/wipo\\_pub\\_888/index\\_wipo\\_pub\\_888.html](http://www.wipo.int/about-wipo/en/dgo/wipo_pub_888/index_wipo_pub_888.html) (last visited May 8, 2010); Ali

offer several reasons why an enhanced patent regime may enhance domestic innovation,<sup>237</sup> inward technology transfer and FDI,<sup>238</sup> and foreign trade.<sup>239</sup> This vision of TRIPS as mutually beneficial for developed and developing countries, however, is far from consensual. Detractors of TRIPS not only question the empirical validity of the pro-TRIPS arguments,<sup>240</sup> they also point to additional costs that TRIPS can impose on developing countries:<sup>241</sup> higher royalty payments,<sup>242</sup> higher prices for consumers,<sup>243</sup> higher administrative costs of running the country's legal and regulatory systems,<sup>244</sup> and theft of "traditional knowledge" systems.<sup>245</sup> For

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Imam, *How Patent Protection Helps Developing Countries*, 33 AIPLA Q.J. 377 (2005).

<sup>237</sup> 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*, 7 J. TELECOMM. & HIGH TECH. L. 167, 205. 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. *Id.*

<sup>238</sup> KEITH E. MASKUS, *INTELLECTUAL PROPERTY RIGHTS IN THE GLOBAL ECONOMY* 189 (2000); Maskus, *Role of IP Rights*, *supra* note 162; Daniel J. Gervais, *Intellectual Property, Trade & Development: The State of Play*, 74 FORDHAM L. REV. 505, 510 (2005); Carlos A. Primo Braga & Carsten Fink, *The Relationship Between Intellectual Property Rights and Foreign Direct Investment*, 9 DUKE J. COMP. & INT'L L. 163 (1998).

<sup>239</sup> Keith E. Maskus & Mohan Penubarti, *How Trade-Related are Intellectual Property Rights?*, 39 J. INT'L ECON. 227, 229-30, 237-43 (1995); Gervais, *supra* note 244; Kitch, *supra* note 124.

<sup>240</sup> 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*, DISCUSSION PAPER 702 OF THE GERMAN INST. FOR ECON. RESEARCH, available at <http://www.diw.de/documents/publikationen/73/61916/dp707.pdf>; *Report of the Secretary-General on the High-Level International Intergovernmental Consideration of Financing for Development*, U.N. Doc A/55/1000 (June 26, 2001), available at <http://www.un.org/esa/ffd/a55-1000.pdf> (failing to mention IPRs in correlation to foreign direct investment or private capital flows). *But see* STRENGTHENING PROTECTION OF INTELLECTUAL PROPERTY IN DEVELOPING COUNTRIES: A SURVEY OF THE LITERATURE 56 (Siebeck et al. eds., 1990) (referring to other World Bank reporting to the contrary). See also CARLOS A. PRIMO BRAGA ET AL., *WORLD BANK, INTELLECTUAL PROPERTY RIGHTS AND ECONOMIC DEVELOPMENT* 1240 (2000).

<sup>241</sup> See Mark A. Lemley, *Property, Intellectual Property, and Free Riding*, 83 TEX. L. REV. 1031, 1032 (2005).

<sup>242</sup> CHANG, *supra* note 206, at 297.

<sup>243</sup> *Id.*

<sup>244</sup> *Id.*

<sup>245</sup> 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'*

some, TRIPS harms both developed and developing countries alike.<sup>246</sup> In light of these controversies, policy analysis of TRIPS remains largely inconclusive. As such, in order to understand the bargaining behavior of specific countries, it becomes necessary to examine the political economy of patent regulation in each nation. This analysis shifts the focus from the consequences of regulation to its explanation.<sup>247</sup>

The political economy of Brazil's experience with pharmaceutical products protected by patents shows that certain countries can potentially benefit from aggressive bargaining behavior without significantly curtailing FDI and trade: that is, against the backdrop of an altogether weaker patent enforcement regime.<sup>248</sup> Accordingly, discretionary usage of compulsory licensing of pharmaceutical patents, as allowed by the TRIPS public health exception, may in fact uphold a social bargaining surplus for countries such as Brazil. In such settings, opportunistic bargains on compulsory licensing, in times of public health crises within TRIPS' rather moderate interpretation, may be not only morally but also economically appealing.

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*Rights and Food Security of Indigenous and Local Communities*, 11 *DRAKE J. AGRIC. L.* 273 (2006). See also *Biopiracy-Sixth Annual Update*, RURAL ADVANCEMENT FOUNDATION INTERNATIONAL [RAFI] (2002), available at [www.etcgroup.org/upload/publication/pdf\\_file/327](http://www.etcgroup.org/upload/publication/pdf_file/327); Marcia Ellen DeGeer, *Biopiracy: The Appropriation of Indigenous Peoples' Cultural Knowledge* 9 *NEW ENG. J. INT'L & COMP. L.* 179, 179-80 (2002); JAYATI GHOSH, *RULES OF INTERNATIONAL ECONOMIC INTEGRATION AND HUMAN RIGHTS* (1999).

<sup>246</sup> Jagdish Bhagwati, *Afterword: The Question of Linkage*, 96 *AM. J. INT'L L.* 126 (2002). See also Judith Goldstein & Lisa L. Martin, *Legalization, Trade Liberalization, and Domestic Politics: A Cautionary Note*, 54 *INT'L ORG.* 603, 604 (2000) (“[T]he 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.”).

<sup>247</sup> Lewis A. Kornhauser, *The Design of Law: Legal Theory and the Challenge of Economic Analysis of Law* (Jan. 6, 2010) (unpublished manuscript, on file with the author).

<sup>248</sup> Law and economics generally regard compulsory licensing of patents to bestow negative social costs due to the free riding problem it entails. See, e.g., Roger D. Blair & Thomas Cotter, *An Economic Analysis of Damages Rules in Intellectual Property Law*, 39 *WM. & MARY L. REV.* 1585 (1998).

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