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TRIPS AND BITs: AN ESSAY ON COMPULSORY LICENSES, EXPROPRIATION, AND INTERNATIONAL ARBITRATION

Peter B. Rutledge*

In the early 1980s, the World Bank forecast that more than 1.2 million people in Brazil would contract the HIV virus by 2000.¹ That catastrophe did not come to pass, due largely to an aggressive anti-AIDS campaign launched by the Brazilian government.² Brazil’s strategy contained a variety of elements, including public education, aggressive promotion of contraceptive, needle-exchange programs, and, most relevant for this article, the low-cost or free provision of antiretroviral drugs to affected populations.³ A key element to this strategy was aggressive negotiation over the price of medication used to treat patients suffering from HIV and AIDS.⁴

When the Brazilian government was unable to reach consensus with Merck over the price for Efavirenz, a patented-HIV treatment drug, it issued a compulsory license.⁵ The license allowed Brazil to manufacture or import a generic version of the drug.⁶ Brazil’s

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³ See Aids: The World Bank’s Partnership with Brazil, supra note 1.
⁴ Marques, supra note 2, at 472.
strategy put it at loggerheads with Merck and other private companies whose products were essential to treating the Brazilian populace. It also sparked controversy in its diplomatic relations with the United States. Merck responded by accusing Brazil of engaging in an “expropriation of intellectual property.”\footnote{See Ed Silverman, Brazil Breaks Merck Patent On AIDS Drug, Which Country Is Next?, PHARMALOT (May 4, 2007, 11:30 AM), http://www.pharmalot.com/2007/05/brazil_to_merck_you_cant_thai/.} The United States Trade Representative placed Brazil on its “priority watch list.”\footnote{Matthews, supra note 6, at 135.}

Through an agreement later negotiated between the parties, Merck was supposed to receive a 1.5% royalty fee as remuneration. When Brazil ordered Merck to transfer all technical documents necessary for the production process, the company provided only the corresponding patent.\footnote{Compulsory Licensing of Efavirenz in Brazil, ACCESS TO PHARMACEUTICALS (Feb. 23, 2010), http://www.accessto pharmaceuticals.org/case-studies-in-global-health/efavirenz-brazil/.} Farmanguinhos, a Brazilian entity that was to produce the generic brand, could not do so with the patent documentation provided and consequently had to import small quantities of Efavirenz from India.\footnote{Id.} Merck filed a preliminary injunction in a Brazilian court to stop the importation, but the court refused the request.\footnote{Id.} Brazil later had difficulty developing the local manufacturing processes of production for Efavirenz.\footnote{Id.} A program of government assistance accelerated production, and the drug came to market in 2009.\footnote{Id.} The price of Efavirenz declined by 93%.\footnote{Id.} Previously, Efavirenz was approximately 12% of the cost of the Brazilian Government’s expenditures for antiretroviral drugs, but after 2009 the cost dropped to 3.9%\footnote{See Brazil to Produce Generic Version of Merck’s Antiretroviral Efavirenz, EUR. AIDS TREATMENT GROUP (Sept. 18, 2008), http://www.eatg.org/eatg/Global-HIV-News/Access-to-treatment/Brazil-to-produce-generic-version-of-
The dispute between Brazil and Merck sparked an important debate lying at the intersection of intellectual property law and international investment law. Do such compulsory licenses actually violate developing countries’ treaty obligations? The relevant literature points to provisions in bilateral investment treaties and free trade agreements that protect “investments” (defined broadly enough to include patents) and prohibit the “expropriation” (whether direct or indirect) of that investment. Applied in the context of a situation such as the Brazil/Merck dispute, this literature argues that certain compulsory licenses could, under some circumstances, constitute an indirect “expropriation” of investments based on a company’s patent and, thereby, entitle the company to compensation. If accepted, the “indirect expropriation” theory has the potential to recalibrate significantly the parties’ bargaining positions in settings such as the Brazil/Merck conflict.

The stakes in such disputes are enormous and cut across countries and industries. Similar disputes have arisen in other countries such as Ecuador and Thailand. Moreover, putting the pharmaceutical industry to one side, at a higher level of abstraction

Merck's antiretroviral efavirenz; Compulsory Licensing of Efavirenz in Brazil, supra note 9.

16 See Henning Grosse Ruse-Khan, Protecting Intellectual Property Rights Under BITs, FTAs, and TRIPS: Conflicting Regimes or Mutual Coherence?, in EVOLUTION IN INVESTMENT TREATY LAW AND ARBITRATION 485, 495 (Chester Brown & Kate Miles eds., 2011).


18 See Donald Harris, TRIPS After Fifteen Years: Success or Failure, as Measured by Compulsory Licensing, 18 J. Intell. Prop. L. 367, 387–90 (2011); Matthews, supra note 6, at 134–37.
such cases involve a potential collision of interests between the profit-making motives of private companies and the development goals of foreign nations. Balancing the rights too heavily in favor of the private company may cripple a nation financially in an effort to avert a public health disaster. Balancing the rights too heavily in favor of the host nation may advance the public health goals of the developing country but at a potentially steep cost. Not only do they alienate the property rights of the investor, but they can also discourage future private investment due to concerns over the stability of property rights in the host country.

The substantive dispute—and the underlying stakes—raise separate, but no less important questions over precisely how, if at all, these claims will be adjudicated. Hometown justice concerns, sovereign immunity doctrines, judicial backlogs and jurisdictional limitations all may limit resort to national courts to resolve such disputes. Given these limitations, arbitration emerges as a viable alternative forum in which to examine these issues.

Such arbitrations can take one of two forms. In the first form, arbitration can take place under the auspices of the World Trade Organization. The World Trade Organization administers the TRIPS agreement, regulating the use of compulsory licenses of patented goods by WTO members. In state-state arbitration, a WTO arbitration panel can determine whether the compulsory license is TRIPS-compliant. In the second form, arbitration can take place under the auspices of an investment arbitral tribunal convened pursuant to a bilateral investment treaty. In an investor-state arbitration, the tribunal can determine whether the compulsory license constitutes an “indirect expropriation” and, if so, award the investor damages.

This essay examines the potential for arbitration to resolve these disputes between private companies and developing countries over the propriety of compulsory licenses. At bottom,

19 See GARY B. BORN & PETER B. RUTLEDGE, INTERNATIONAL CIVIL LITIGATION IN THE UNITED STATES ch. 3 (5th ed. 2011) (discussing the difficulties of suing foreign sovereigns).
20 Recent changes to the United States Model Bilateral Investment Treaty, discussed below, complicate this strategy.
my thesis is that arbitration supplies the medium through which to mediate the tension between the profit-seeking goals of private multinational companies and the development goals of foreign nations, especially in the developing world. The compulsory license debate raises a clash of fundamental interests between the patent holder, the patent holder’s state, and the host state. Arbitration can play an important role in balancing those interests, albeit a highly unusual one. Arbitration provides an essential forum through which to test the legality of a state’s compulsory license. This is particularly important where the patent holder cannot rely upon its own nation-state adequately to vindicate its interests. Despite the potential importance of arbitration in this context, patent holders curiously have not actually pursued this form of dispute resolution. Nonetheless, this does not render arbitration unimportant. Rather, it becomes an important background vehicle against which nation-states and patent holders can strike the bargains necessary to balance their respective interests in the development and exploitation of inventions such as pharmaceuticals in the context of a public health crisis.

The debates over compulsory licensing and indirect expropriation lie at the intersection of two areas of law—intellectual property law and international investment law. Both areas of law rest on a common premise. They attempt to create the legal conditions under which private companies are encouraged to invest in a manner that simultaneously benefits the company and the state.\(^{21}\) Both areas of law, though, raise important questions about how exactly the rights of the property holder will be protected and how the legality of the state’s conduct will be tested.

Begin with patent law. Scholars have long understood the importance of patents to industry, innovation, and economic growth.\(^{22}\) By granting inventors a temporary monopoly on the

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exploitation of their inventions, patents encourage investment in the research and development essential to promoting progress and advancing the public good, whether in the field of pharmaceuticals, computers, or something else. Thus, to the extent a patent facilitates the development of a prescription drug, society benefits when that drug comes to market and, thereby, addresses a public health concern. While that temporary monopoly is important, it is not limitless. Nor should it be. Limits on the duration and scope of patents ensure that the holder of the monopoly neither stifles innovation nor deprives the public of the benefits to be had from the invention.  

This simple account assumes a monopolar world—that is, a world with a single sovereign setting forth a set of unified property rights for a single society. Of course, as numerous scholars have noted, patents operate in a multi-polar setting. That is, while the patent may be issued by an individual nation-state, the invention potentially may be exploited in multiple nations.

This multi-polar setting raises distinct challenges. On the one hand, it raises distributional concerns. If property rights secured by a patent are immediately subject to recognition in other nations, such a regime locks in the first-mover advantage of the first nation and the first inventor. On the other hand, it risks undercutting the benefits of patents described in the simple model above. A patent may well lose some of its utility of the invention and simply be reverse-engineered in another country not obligated to respect the patent rights of the original inventor.

In this multi-polar setting, international treaties are used to attempt to balance these competing concerns. Currently, the dominant regime is the TRIPS Agreement.  

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TRIPS and BITs

effect on January 1, 1995, after the Uruguay Round of the GATT and created a minimum standard of intellectual property protection.\(^{26}\) Its provisions can be divided into three broad areas: standards of protection, domestic enforcement procedures and remedies, and dispute settlement at the WTO.\(^ {27}\) Obligations under the Agreement apply equally to all member states, although developing countries have a longer time to phase in the provisions.\(^ {28}\)

Among the important issues addressed by TRIPS is the relationship between the patent holders’ rights and the public health needs of a TRIPS member-state. Article 31 of TRIPS attempts to address this issue through a careful balance of the respective parties’ competing interests.\(^ {29}\) On the one hand, Article 31 of TRIPS contemplates the possibility that a state could issue a compulsory license for such patented material.\(^ {30}\) On the other hand, Article 31 also specifies various conditions for the license. Among other considerations:

- Each license “shall be considered on its individual merits”
- The license can be issued only after an effort had been made by the government to gain authorization from the

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\(^{27}\) Drahos, \textit{supra} note 26, at 791; \textit{Overview: The TRIPS Agreement, supra} note 26.

\(^{28}\) Drahos, \textit{supra} note 26, at 791; \textit{Overview: The TRIPS Agreement, supra} note 26.


\(^{30}\) \textit{Id.}
rights holder “on reasonable commercial terms and conditions”

- The license must be non-exclusive and non-assignable, with a “scope and duration . . . limited to the purpose for which it was authorized”
- The license must be used “predominantly for the supply of the domestic market”\(^{31}\)
- There must be “adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization”\(^{32}\)

This scheme raises an obvious question: how exactly is one to test whether a compulsory license comports with Article 31?\(^{33}\)

The answer to this question is critical. The Brazil/Merck debate might well be a close case subject to reasonable views on either side. But what if a country relied on Brazil’s logic to issue a compulsory license in a setting where the public health concerns were not as compelling? For example, Thailand issued a compulsory license for Plavix, a drug used to treat a chronic (rather than infectious) disease.\(^{34}\) The noninfectious nature of the health problem diminished the claim for the license’s necessity.

To resolve such disputes over whether a nation’s conduct comports with TRIPS, the treaty employs the espousal model

\(^{31}\) Changes to Article 31 waive this requirement. See note 33 infra (discussing Article 31bis).

\(^{32}\) TRIPS, supra note 29; Gibson, supra note 17, at 369.


\(^{34}\) Daniel R. Cahoy, Confronting Myths and Myopia on the Road from Doha, 42 GA. L. REV. 131, 133 (2007); Matthews, supra note 6, at 136.
familiar to scholars of international law.\textsuperscript{35} Under this model, the nation-state of the patent holder asserts a claim against the nation-state issuing the compulsory license. To return to the Brazil/Merck example, the United States would espouse a claim on behalf of Merck. Currently, such espousal would take place before a dispute settlement board of the World Trade Organization.

As several scholars have noted, espousal offers some advantages but also raises important agency problems.\textsuperscript{36} The primary advantage of espousal arises from the fact that the inventor’s nation-state serves as a filter through which any potential TRIPS claim must pass. This ensures that the nation-state can weigh the domestic political payoff of representing a patent holder’s interests against the diplomatic consequences of espousing a claim against a foreign nation. The downside of the espousal model (in the context of TRIPS) is that it assumes the nation-state will be an effective agent of the patent holder’s interests. But where the nation-state’s interests diverge from those of the patent holder, the limits set forth in Article 36 become hollow from the patent holder’s perspective.

Given the agency problems, the patent holder needs some alternative recourse. Litigation options are poor at best. A suit brought against the licensing nation in that nation’s own courts is hardly an appealing option. Under its own domestic law, the sovereign may be immune from suit.\textsuperscript{37} Even if it is not, concerns about hometown justice or judicial backlog may discourage the patent holder from believing that it can receive a fair hearing.\textsuperscript{38} Merck’s failed effort to block Brazil’s import of Efavirenz from India illustrates this problem.

Suit in the patent holder’s home courts might be slightly more appealing, but that option, too, raises problems. Hometown justice


\textsuperscript{37} See, e.g., United States v. Sherwood, 312 U.S. 584, 586 (1941).

concerns may drop out (and indeed, even work to the patent holder’s advantage). Yet the sovereign immunity rules of the home jurisdiction may preclude suit, particularly if they insist upon some “nexus” to or “effect” in the forum states, as American foreign sovereign immunity law generally does.\(^{39}\) Moreover, given the above-described agency problems, the patent holder can hardly have assurance that its own government will look favorably upon the suit or support it if asked by the local courts. Finally, enforcement and ultimate satisfaction of the judgment may prove difficult, either due to domestic restrictions on judgment execution against foreign sovereign property or due to the lack of a treaty between the judgment-rendering state and the state where the offending country has assets.\(^{40}\)

Given the limitations of the espousal regime and garden-variety civil litigation, the international investment regime has begun to emerge as a potentially viable alternative. Since the end of the Second World War, nations have sought to create the legal conditions necessary to facilitate cross-border direct investment.\(^{41}\) The primary model for doing so has been the development of bilateral investment treaties (“BITs”).\(^{42}\) To facilitate investments, BITs extend various rights to the investor such as the right to fair and equitable treatment or, relevant for our purposes, the right to compensation in case of an expropriation of the investment.\(^{43}\) More importantly for our purposes, while investment claims were at one time subject to the espousal regime, BITs now typically allow the investor to commence arbitration proceedings directly against the host state.\(^{44}\)

\(^{39}\) BORN & RUTLEDGE, supra note 19, at ch. 3.

\(^{40}\) Id. chs. 3,12.


\(^{42}\) Reliance estimates suggest that approximately 2900 such treaties are presently in force, and the United States is party to forty such treaties. Id. at 72–73.


\(^{44}\) Id.
TRIPS and BITs

Seen through this lens, arbitration pursuant to BITs potentially solves the agency problems created by the espousal model and addresses some of the shortcomings of litigation alternatives. Unlike the espousal model, the investor does not have to depend on a nation-state either to advance its interests or, indeed, approve the claim. Compared to litigation, BIT arbitration also avoids the sovereign immunity concerns. It also can surmount the enforceability problem. Awards in BIT arbitrations are subject to a very favorable pro-enforcement regime; by contrast, the lack of a multilateral, or even bilateral, treaty between the United States and a foreign country makes a comparable judgment made in domestic litigation far harder to enforce.45

While BITs became a potential solution to the limitations of the espousal regime under TRIPS, their effectiveness depends on the answer to an important substantive question: what is the relationship between compulsory licenses under TRIPS and the protection against expropriation under BITs?46 Is a TRIPS-compliant compulsory license automatically not an indirect expropriation under a BIT? Conversely, if a compulsory license is not TRIPS compliant, is it automatically an expropriation?47 Or, for those BITs lacking a provision like Annex B, is there some “space” between a TRIPS-non-compliant license and a full-blown expropriation?

The response to these questions has evolved. Early versions of BITs did not address the issue at all.48 More recent versions, exemplified by the United States-Uruguay BIT, follow a different course.49 They define an indirect expropriation by reference to

45 BORN & RUTLEDGE, supra note 19, at 1080.
47 Correa, supra note 17, at 373.
49 Agreement on the Encouragement and Reciprocal Protection of Investments, U.S.-Uru., Annex B, P 4(a), Nov. 4, 2005 [hereinafter U.S.-
several criteria including 1) the magnitude of the interference with property rights, 2) whether that interference rises to the level of expropriation as referenced in the treaty, and 3) character and motive behind the regulatory government action. Moreover, Annex B to the U.S. Model BIT now provides “[e]xcept in rare circumstances, non-discriminatory regulatory actions by a Party.”

These evolutions in the US Model BIT alter, but hardly eliminate, the ongoing debates over whether (and to what extent) compulsory that are designed and applied to protect legitimate public welfare objectives, such as public health, safety and the environment do not constitute indirect expropriations. This evolution simplifies but does not eliminate the debate. What are the “rare circumstances”? How is a regulation tested whether it is “non-discriminator” and is “designed and applied to protect legitimate public welfare objectives”?

These are difficult substantive questions, and the answer is unclear. My point, though, is not to resolve definitively the relationship between the substantive standards. Rather, it is to illustrate how the direct-action model of investment arbitration serves as an important vehicle by which to test the answers to these questions. Such a vehicle becomes particularly important where there is reason to doubt an alignment between the interests of the patent holder and the interests of his home jurisdiction. The evolution in the United States’ position on the model BIT exemplifies how such risks can arise. The United States may be especially reluctant to espouse a challenge to a compulsory license based on an indirect expropriation theory precisely because it

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50 Gibson, supra note 17, at 389.
53 Id.
54 Id.
wishes to preserve for itself just such a power (whether exercised against the patent holder or in another context).

Given the potential of investment arbitration to address the agency problems, one would expect to see a proliferation of such arbitrations in response to compulsory license cases. Over the last two decades, the number of BIT arbitrations has skyrocketed. Indirect expropriation claims have become an increasingly popular theory to advance in such arbitrations. And the litigious rhetoric of Merck and other companies reacting to compulsory licenses suggests that they are prepared to pick this fight.

Despite the ripeness of the conditions, however, something remarkable has occurred (or, to put the point more precisely, has not occurred). There does not appear to be any reported instance of a BIT arbitration filed (much less decided) on the basis of a claim that a compulsory license constituted an indirect expropriation. Despite an extensive secondary literature on the topic, none of that literature refers to an actual case, and my own research has not uncovered one. Why should this be so?

Several hypotheses are possible, the verification of which must be the subject for another paper. One possibility is that we may not know about them. While many investment arbitrations, such as those conducted under the auspices of ICSID or NAFTA, are generally subject to public disclosure, others are not. Some investment arbitrations are conducted on an ad hoc basis under the UNCITRAL Model Arbitration Rules, and others are conducted pursuant to the rules of a regional arbitral center such as the Stockholm Chamber of Commerce. Arbitration subject to these sorts of rules are not subject to disclosure obligations, and indeed some evidence suggests that, in a few cases, parties prefer the

anonymity of these systems for resolving their disputes. The problem with the confidentiality explanation is simply the difficulty of preserving it over the long-term. News of arbitration leaks, whether prompted by the parties, unearthed by watchdogs, or eventually reported in secondary literature.

Confidentiality is not the only possible explanation. Another might be a basic lack of confidence in the merits of the argument. Despite the fiery rhetoric of Merck’s officers and the articulate musings of scholars and seasoned practitioners, the investors may at the end of the day doubt whether they would win. The shift in the United States’ position on the relationship between TRIPS compliance and indirect expropriation may send a signal that the government does not buy the argument. Here too, that hypothesis seems incomplete. Even if certain compulsory licenses do not constitute indirect expropriations (as the US/Uruguay BIT suggests), that position still subjects the compulsory license to a set of standards. Thus, even in those cases where the Uruguay standard applies, there remains an open question whether a nation’s compulsory license satisfies that standard, and nothing should preclude an investor from testing that question.

A third possibility is a subtle variation of the preceding one. Perhaps the important fact is not the substance of the United States’ position but, rather, the fact that the United States is sending it. The international arbitration bar is a small one, and governments are logically the repeat players in such disputes. Potential arbitrators may be reluctant to embrace a theory on which the government has cast doubts. Doing so might harm the arbitrator’s reputation and, thereby, hamper his or her chances at future appointments. Here too, though, that argument seems a bit far-fetched. Under that logic, arbitrators should be reluctant ever to rule against governments in investment arbitrations, yet the annals of investment arbitration jurisprudence are filled with


\[59\) U.S.-Uruguay BIT, supra note 49, at 42.
examples of tribunals entering awards—both on jurisdictional and substantive matters—adverse to the government parties.

Whatever the cause, the lack of litigation may ultimately be beside the point. Rather, perhaps the mere threat of litigation is all that the company needs. That threat, if credibly issued, might simply enhance the investor’s bargaining position against the nation-state and enable the company ultimately to obtain a better price for the patented product. In other words, the possibility of a direct investor claim, unencumbered by the espousal process, shapes the bargaining in the shadow of international investment and intellectual property law.60

In sum, arbitration plays a critical role in the field of international intellectual property. Where disputes arise between an investor and a nation-state over the legality of a compulsory license, arbitration can overcome many of the shortcomings of other forms of dispute resolution. Compared to litigation, arbitration avoids both doctrinal problems of sovereign immunity and tactical problems of hometown justice. Compared to espousal under the TRIPS regime, arbitration serves as backstop in cases where the investor’s interests may diverge from those of the investor’s state. Despite its potential as a tool in these disputes, arbitration does not appear to have been actually employed. While several hypotheses might be tested to explain this phenomenon, the actual explanation may be secondary. Rather, the central value of arbitration comes through the credible threat—and possibility—of such a suit. The sheer possibility helps to protect the investor’s interests and to balance the competing values that underpin the distribution of intellectual property rights (and resulting benefits) in a multipolar world.

TRIPS and BITs