JONES DAY

OCTOBER 2012

TREATY PROTECTION FOR GLOBAL PATENTS: A RESPONSE TO A GROWING PROBLEM FOR MULTINATIONAL PHARMACEUTICAL COMPANIES

Patents held by multinational pharmaceutical companies are under assault in the developing world. Novartis is mired in a years-long case seeking to patent one of its drugs in India, and it is now challenging before the Supreme Court of India a provision of the Indian Patents Act that Novartis says violates international law.[1] Roche recently lost a major patent infringement case in India's courts, thereby allowing a massive generic manufacturer headquartered in India to continue marketing a generic version of Roche's cancer-treatment drug.[2] And Pfizer is reportedly being targeted for a compulsory license by another Indian generic drug manufacturer, which would allow the manufacturer to infringe Pfizer's patent with the imprimatur of the Indian State, and perhaps even export that infringing product abroad.[3]

But the most newsworthy case has been Bayer's. Last March, an Indian court granted an Indian generic drug manufacturer a compulsory license to manufacture and market one of Bayer's patented drugs, essentially expropriating Bayer's intellectual property in exchange for a mere 6 percent royalty.[4] The decision appears plainly discriminatory—the court specifically justified the outcome on the fact that Bayer's drug was produced in Germany, and not in India. Bayer appealed this decision, but only days after argument, the Indian appellate court denied Bayer's request to stay the lower court's order—thus allowing the infringement to continue while the appeal is pending.[5]

This is not an issue unique to India. China, too, has recently issued a new regulation setting out detailed procedures for applying for compulsory licensing.[6] This new trend toward compulsory licensing presents a material risk to multinational pharmaceutical companies because the essence of a patent is the right to exclude others from making and marketing infringing products. By forcing a compulsory license, the state is appropriating that valuable property right.

Worse still, local courts provide little respite for these discriminatory and expropriatory actions. India's court system is notoriously slow, and foreign patent holders have had little recent success in protecting their patent rights in Indian courts. While the rule of law is emerging in China and India, both countries still have a distance to travel in protection of intellectual property and other rights. The most recent "Worldwide Governance Indicators" published by the World Bank put both countries at or below the 50th percentile for "Rule of Law" and for "Regulatory Quality."[7]

INVESTMENT TREATY PROTECTION: A NEW WAY FORWARD

Bilateral Investment Treaties ("BITs") generally include a compulsory clause for the settlement of disputes that arise between a signatory state and a foreign investor of another signatory state. Thousands of BITs are now in force worldwide. China and India together have signed and placed into force 168 BITs with foreign countries, including the United Kingdom, Germany, France, and Switzerland—homes to many of the world's leading pharmaceutical companies.[8] These treaties enable protected foreign investors from one signatory state to bring claims against the other signatory state before an international arbitral tribunal. In the words of one U.S. court upholding the compulsory nature of BIT arbitration, "[a]ll that is necessary to form an agreement to arbitrate is for one party to be a BIT signatory and the other to consent to arbitration of an investment dispute in accordance with the Treaty's terms. In effect, [the Contracting State's] accession to the Treaty constitutes a standing offer to arbitrate disputes covered by the Treaty; a foreign investor's written demand for arbitration completes the 'agreement in writing' to submit the dispute to arbitration."[9] The arbitration typically takes place either before an *ad hoc* Tribunal pursuant to the UNCITRAL Rules, or under the auspices of the International Center for the Settlement of Investment Disputes ("ICSID").

Moreover, multinational pharmaceutical companies are typically considered protected "investors" in the parlance of modern BITs, in that they have made an injection of capital and maintain ongoing business operations in the foreign country.[10] Many modern BITs also specifically list "intellectual property rights, including patents" granted by the host state as "investments" deserving of treaty protection.[11]

The primary benefit of international investment arbitration is that it removes the dispute from the host state's domestic legal system, which may be biased against foreign investors, especially in cases challenging the conduct of the state itself. Furthermore, domestic courts often may not have the "legal expertise and experience to free themselves from the confines of their own domestic regimes so as to give proper attention and respect to international law."[12] This is precisely why investment treaty arbitration appeals to foreign investors who rightly may be concerned with the potential bias, inefficiency, or unfamiliarity of foreign courts.[13]

Perhaps the most potent feature of investor–state arbitration, however, is the enforceability of the ultimate award. Awards rendered by international investment tribunals are enforceable in the host state by virtue of the BIT itself, and virtually anywhere else in the world by virtue of the New York Convention (which India, China, and nearly 150 other states have signed), or, in the case of ICSID, the Washington Convention (which China, but not India, and nearly 150 other states have signed).[14]

GLOBAL PATENT PROTECTION CONTAINED WITHIN THE BITs

The bulk of investment treaty cases concern the expropriation of tangible assets or mistreatment of rights related to them—oilfields and heavy equipment, businesses, and concessions. But intellectual property is just as valuable (often more so), and just as protected by international law. It is thus no surprise that intellectual property cases in these fora are on the rise. One tobacco manufacturer has recently brought an investment claim against Australia challenging the country's plain-packaging laws.[15] The claim alleges that the forcible removal of the tobacco manufacturer's protected trademarks from product packaging is an expropriation under international law.[16] This case is but one example of claims that, while previously relegated to national courts or the state-to-state mechanisms provided

by the WTO, may now be brought directly against recalcitrant states by private companies. International investment arbitration provides a powerful mechanism to enforce patent rights around the globe.

Here are some of the grounds on which a patent holder may seek to enforce and protect its rights:

Fair and Equitable Treatment. Nearly every modern BIT guarantees "fair and equitable treatment" to foreign investors and their investments, which generally means that each state has assumed an obligation to treat investors in a manner that is not grossly unfair, discriminatory, or arbitrary and, in some cases, to protect the investor's legitimate expectations regarding its investment in the country.[17] To be sure, exclusivity is a central expectation flowing from ownership of a patent, and the revocation of that right of exclusivity may constitute a violation of the obligation to accord fair and equitable treatment. This conclusion is buttressed by articles contained in many modern BITs that incorporate "other international obligations" (like the Paris Convention and the WTO's Trade-Related Aspects of Intellectual Property Rights ("TRIPs") agreement) as binding obligations with respect to intellectual property.[18] These obligations arguably define a foreign pharmaceutical company's legitimate expectations and rights,[19] and to the extent that a host state acts in violation of these agreements, such a violation may also be independently actionable under the relevant BIT.[20] For example, the basic patentability standards of the TRIPs agreement have been guaranteed to Novartis' investments in India ever since India agreed to become TRIPs-compliant in 2005; denying a patent in violation of those standards therefore may constitute a violation of the fair and equitable treatment standard. In Bayer's case, the sheer length of time for which the compulsory license was granted to the Indian company—i.e., the "balance term of the patent"—and the fact that no national health "emergency" exists to justify such a license over a "non-life saving drug," are just two reasons to suggest that India has run afoul of Article 31 of TRIPs.

National Treatment. Foreign investors and their investments are also protected from discriminatory treatment at the hands of host governments and government officials,[21] which includes patent officials and courts. Elements of the recent decision against Bayer in India, however, seem patently discriminatory. For instance, when determining whether Bayer has sufficiently "worked" the patent in India, the Controller placed significant weight on the fact that Bayer did not manufacture the Nexavar drug in India, while the generic Applicant would. And because the grant of this compulsory license benefits a domestic Indian firm by granting it cheap access to patented technology (rather than, for instance, allowing the government to take a temporary license to address a public health emergency), its justification appears less tenable as a proper exercise of governmental authority.

Indirect Expropriation. Nearly all modern BITs forbid the expropriation of a foreign investment—which includes intellectual property—without due compensation.[22] Because exclusivity is a central feature to an intellectual property asset like a patent, the grant of a compulsory license significantly devalues that asset, and thus arguably "ha[s] an effect equivalent to … [an] expropriation" under international law.[23] In that situation, "compensation … shall be equivalent to the value of the expropriated … investment immediately before the date on which such expropriation … became publicly known"[24] A nominal 6 percent royalty—which Bayer received as compensation for the Nexavar compulsory license—may arguably fall below this threshold and give rise to an actionable claim for indirect expropriation.

"Effective Means." Many BITs also guarantee foreign investors and their investments an "effective means" to protect their rights within the domestic legal system.[25] As noted above, local courts in India have thus far given little respite to the aggrieved patent holder—even while appeals are pending. For instance, as Bayer appeals the compulsory license decision, two local Indian companies continue to manufacture and sell a generic equivalent of Bayer's patented drug.[26] The Indian courts have refused to stay the effect of the license as Bayer's appeal winds its way through the notoriously slow Indian court system at a glacial pace.[27] In BIT parlance, India may have presented Bayer with "[in]effective means" to defend its rights, thereby violating BIT guarantees independent of the expropriation of intellectual property. Indeed, in a recent international investment arbitration between an Australian investor and India, the tribunal held that the Indian judicial system had breached its obligation to provide an "effective means" for investors to defend their rights.[28]

ENSURING BIT PROTECTION FOR YOUR FOREIGN INVESTMENT

When it comes to access to rights under treaties, nationality is of the utmost importance. However, multinationals without treaty protection in their home jurisdiction can proactively seek it out before a dispute arises. A prudent investor will structure—or even restructure—the ownership of its investments in developing states to secure maximum protection under existing treaties. This sort of proactive planning for treaty protections is, according to one recent UNCITRAL Tribunal, "not unusual nor is there anything in the least reprehensible about it."[29] "[S]uch national routing of investments is entirely in keeping with the purpose of the instruments and motivations of the state parties."[30]

CONCLUSION

Global patent holders have a variety of means to protect their patents as they enter developing markets. With the rule of law still emerging in those markets, international mechanisms that exist below the state-to-state level ought to be considered alongside domestic court remedies. These mechanisms can provide efficient, depoliticized, and real relief for aggrieved companies that wish to protect their global patent portfolio.

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11 *See*, e.g., UK–China Bilateral Investment Treaty, art. 1(a)(iv); UK–India Bilateral Investment Treaty, art. 1(b)(iv); Germany–China Bilateral Investment Treaty, art. 1(1)(d); Germany–India Bilateral Investment Treaty, art. 1(b)(iv); France–China Bilateral Investment Treaty, art. 1(1)(d); Switzerland–China Bilateral Investment Treaty, art. 1(1)(d); Switzerland–India Bilateral Investment Treaty, art. 1(2)(d).

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19 *See supra* fn. 15, and accompanying text.

20 *See generally* Charles T. Kotuby Jr., "'Other International Obligations' as the Applicable Law in Investment Arbitration," 2011 Int'l Arb. L. Rev. 162 (2011).

21 *See*, e.g., UK–China Bilateral Investment Treaty, arts. 2(2) & 3; UK–India Bilateral Investment Treaty, art. 4; Germany–China Bilateral Investment Treaty, arts. 2(3) & 3(2); Germany–India Bilateral Investment Treaty, art. 4(1); France–China Bilateral Investment Treaty, art. 4(2); France–India Bilateral Investment Treaty, art. 5; Switzerland–China Bilateral Investment Treaty, art. 4(3); Switzerland–India Bilateral Investment Treaty, art. 4(1).

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26 *Supra* fn. 5.

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