Testimony

US-India Intellectual Property Rights Issues: Comment on USTR Special 301 Review

Arvind Subramanian
Dennis Weatherstone Senior Fellow, Peterson Institute for International Economics and Senior Fellow, Center for Global Development

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Summary and Conclusions

The main aim of the submission is to set the broader context and to map the contours of a possible solution to tensions between the two countries on intellectual property (IP) issues. The key policy message is that the United States Trade Representative (USTR) should desist from designating India as a priority foreign country and instead pursue, along with the new Indian government, the approach proposed below.

This hearing comes at a critical juncture. On May 16, a fortnight after the release of the USTR’s Special 301 report, a new government will take office in India, intent on reviving the investment climate for domestic and foreign business, and keen on restoring US-India trade and economic relations. At such a moment of transition, potentially transformational, designating India as a priority foreign country would be a serious mistake and have a number of unfortunate consequences.

- Placing India in the same category with Ukraine as the only post-WTO countries to be accorded priority-foreign-country designation would spark adverse reactions in India and around the world and raise serious questions about the institutions and processes of US economic diplomacy.

- As such, the designation would further set back, possibly dramatically, relations between two countries that have common strategic and economic interests—substantial and long term—and that need a constructive, new dynamic to help realize the relationship’s full potential.

- The unilateral nature of the designation, combined with the fact that intellectual property developments in India have comprised both the positive and restrictive (described below), carries this risk: that the United States will be seen as the deviant from international trade norms rather than India as the deviant from international intellectual property (IP) norms.
The designation risks holding the broader trade and indeed strategic relationship—characterized by vibrant and robust integration in goods, services, and foreign investment—hostage to narrowly sectoral (i.e. pharmaceutical intellectual property) interests.

This submission is in two sections. Section one briefly describes developments in intellectual property (IP) in India. Section two proposes a way forward for the two countries to settle issues in intellectual property rights, focusing on patent protection.

I. Context and Recent Developments

In implementing the World Trade Organization’s TRIPs (Trade-Related Aspects of Intellectual Property Rights) agreement, India’s domestic patent law was strengthened from virtually no protection for pharmaceutical product patents to some protection. But recent rulings and the underlying Indian law still tend to favor weaker rather than stronger protection of IP. This reflects the strength of the generic drug industry and of consumer groups advocating affordable health care. But, reflecting India’s TRIPs commitments and its international obligations, rulings have also taken into account the need for India to contribute its fair share toward financing the costs of global research and development.

The challenge for India will be to ensure that the law does not get out of step with the demands of a country that needs foreign investment and new technologies. Some of the strengthening of India’s patent regime will occur organically as India grows rapidly and as technology and skill become more important drivers of growth. India is transitioning from a development stage of being a net user of technology (which favored weak IP protection) to one of being both a user and producer of technology (which favors stronger IP protection). The drug industry too has evolved from exclusively comprising generic manufacturers to one with greater representation of research and development–based companies.

Recent complaints against India can be summarized as the alleged dilution of the intellectual property of foreign patent owners in the pharmaceutical sector. This dilution has taken the form of patent denial (Glivec), actual compulsory licensing (Nexavar), and offending provisions in India’s patent law, notably Section 3(d) and compulsory licensing for nonworking.

How should these actions be assessed? They can be grouped into three categories.

Positive Developments: Not all IP-related actions have been protectionist or inimical to foreigners. A very positive development, namely due process, has gone unnoticed. India has provided due process for foreign companies and patent holders comparable to those in advanced democracies. This was especially true in the Novartis patent denial case and also in the Nexavar compulsory licensing case. Patent offices have decided on patents and compulsory licensing granted to Indian companies; their verdicts have been challenged before an independent appellate body, whose verdicts have in turn been contested in the courts.

In every instance, the deciding authority has reviewed the arguments and facts, drawn on evidence, relied upon domestic and foreign precedents, and explained its decisions. Even if
outcomes have gone against foreign companies, there can be little doubt about procedure. And in a country notorious for interminable delays in administrative and judicial procedures, a number of patent-related cases have been decided in timely fashion.

Moreover, balance and fairness toward foreigners and to the demands of intellectual property rights have not been ignored. For example, the Indian Supreme Court decided to take on the Novartis case instead of waiting for the lower courts out of concern that delays could cut into the life of the patent. Also, when deciding on the compulsory licensing fee that generic drug makers should pay Bayer (the German maker of the cancer drug Nexavar), the Indian patent office opted for the highest end of the range recommended by the World Health Organization (WHO). In the subsequent review, the appellate body increased this fee further. And several recent cases have been decided in favor of higher protection of patents owned by foreign pharmaceutical companies (e.g. Bristol Myer’s Desatinib—for which a compulsory license application was rejected as recently as fall 2013; Roche’s Herceptin, and Schering’s compound for treating heart-disease).

Further, critics have suggested that India is a deviant for being the only country where Novartis’ claim has been rejected. But even in the United States, the Novartis application—which was really for a successor version of Glivec—was in fact first rejected by the patent office, only for a higher authority to overturn the initial ruling on appeal. Seen in this light, the Novartis decision seems less of an outlier than portrayed. The Indian verdict, like that of the US patent office, may well be more within the range of reasonable interpretations of what constitutes patentability than has been asserted by critics.

**Restrictive Developments:** In contrast, certain aspects of Indian patent law such as Section 3 (d) and compulsory licensing for nonworking are problematic. Apart from the fact that very few countries have the equivalent of the Section 3 (d) provision in their law and that defining efficacy can be arbitrary, there are other policy tools that can help India address frivolous patenting. And compulsory licensing for nonworking sits uneasily with Article 27.1 of the TRIPs agreement, which specifies that the enjoyment of the patent rights should not be based on whether patented products are imported or locally produced.

**Mixed/Open Developments:** In relation to other aspects of the Indian IP regime—especially patent denial and compulsory licensing for providing affordable drugs—however, the prima facie claims of unfairness to foreign holders of IP need to be more carefully assessed. The metrics can be crucial in assessing Indian actions.

If the Indian IP regime is to be compared with those in industrial countries or the richer trading partners of the United States, it will fall short. However, on a number of other metrics, the assessment would be different. If the metric is consistency with India’s WTO obligations or comparison with India’s TRIPs regime in a historical perspective, India’s IP regime does not fare badly. On the latter, table 1 below shows that most of today’s industrial countries adopted strong pharmaceutical protection when they were roughly ten to seventeen times as rich as India was when it undertook the TRIPs commitments.
Another metric might be an Indian calculus that balances three objectives: contributing to a “fair” share of the fixed costs of genuine global research and development (R&D) generation (which is consistent with the spirit of the TRIPs agreement), promoting technological development domestically, and providing affordable access to medicines for the domestic population. This is a more difficult calculus and is at the heart of disagreements about the strength of IP protection in India and other developing countries not least because, as the last column of the table shows, India’s level of development is still substantially below that of industrial countries.

### Table 1 Protection of pharmaceutical product inventions: A historical perspective

<table>
<thead>
<tr>
<th>OECD adopters</th>
<th>Year of adoption</th>
<th>GDP per capita at adoption</th>
<th>GDP per capita at adoption relative to India’s in 2011</th>
<th>GDP per capita relative to India’s in 2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Japan</td>
<td>1976</td>
<td>14,193</td>
<td>9.7</td>
<td>8.4</td>
</tr>
<tr>
<td>Switzerland</td>
<td>1977</td>
<td>24,309</td>
<td>16.7</td>
<td>12.4</td>
</tr>
<tr>
<td>Italy</td>
<td>1978</td>
<td>15,380</td>
<td>10.6</td>
<td>8.1</td>
</tr>
<tr>
<td>Netherlands</td>
<td>1978</td>
<td>19,127</td>
<td>13.1</td>
<td>10.6</td>
</tr>
<tr>
<td>Sweden</td>
<td>1978</td>
<td>17,584</td>
<td>12.1</td>
<td>10.0</td>
</tr>
<tr>
<td>Canada</td>
<td>1983</td>
<td>21,977</td>
<td>15.1</td>
<td>9.8</td>
</tr>
<tr>
<td>Denmark</td>
<td>1983</td>
<td>19,683</td>
<td>13.5</td>
<td>9.9</td>
</tr>
<tr>
<td>Austria</td>
<td>1987</td>
<td>18,824</td>
<td>12.9</td>
<td>10.4</td>
</tr>
<tr>
<td>Spain</td>
<td>1992</td>
<td>16,881</td>
<td>11.6</td>
<td>8.0</td>
</tr>
<tr>
<td>Greece</td>
<td>1992</td>
<td>15,176</td>
<td>10.4</td>
<td>6.6</td>
</tr>
<tr>
<td>Norway</td>
<td>1992</td>
<td>24,032</td>
<td>16.5</td>
<td>14.6</td>
</tr>
</tbody>
</table>

**Emerging Country adopters**

<table>
<thead>
<tr>
<th>Country</th>
<th>Year of adoption</th>
<th>GDP per capita at adoption</th>
<th>GDP per capita at adoption relative to India’s in 2011</th>
<th>GDP per capita relative to India’s in 2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brazil</td>
<td>1995</td>
<td>7,594</td>
<td>5.2</td>
<td>2.6</td>
</tr>
<tr>
<td>China</td>
<td>1992/93</td>
<td>2,297</td>
<td>1.6</td>
<td>2.2</td>
</tr>
<tr>
<td><strong>India</strong></td>
<td><strong>1995</strong></td>
<td><strong>1,456</strong></td>
<td><strong>1.0</strong></td>
<td><strong>1.0</strong></td>
</tr>
<tr>
<td>Argentina</td>
<td>1995</td>
<td>9,078</td>
<td>6.2</td>
<td>4.0</td>
</tr>
</tbody>
</table>

**Source:** Penn World Tables, 8.0 and Lanjouw (2002)

**Notes:** GDP per capita is in PPP, constant 2005 dollars; the year of adoption for emerging countries (excluding China) refers not to the enactment of their laws but to the TRIPs date for protecting pharmaceutical product inventions.

### II. Possible Way Forward

Resolving tensions on intellectual property is critical to the broader economic relationship. Is there a way forward? Yes, but each side must exhibit flexibility.

**What India Might Do**

In the short run, as a signal of good intentions and to clear the air, India could commit to a stay on government-initiated compulsory licenses (especially for drugs that are not on the WHO’s essential drugs list).

Beyond the short run, the following actions could be contemplated.
First, India could consider eliminating the additional efficacy requirement for patentability in Section 3 (d) of its patent law. This is an unnecessary red rag to the bull. Apart from the fact that very few countries have this provision in their law and that defining efficacy can be arbitrary, there are other policy tools that can help India address frivolous patenting. In the Indian Supreme Court ruling on Glivec, for example, the Court could have upheld the earlier ruling denying the patent even without recourse to the efficacy provision.

Second, India should give serious consideration to eliminating or severely narrowing the grant of compulsory licenses for nonworking. In the area of pharmaceuticals where compulsory licenses are most frequently employed, a nonworking provision for a country such as India is either misguided or probably a noncredible threat. It is misguided because it is premised on the view that a domestic monopoly is significantly better than an import monopoly. While this may be true generally because local production generates positive technological spillovers, in the case of pharmaceuticals, this is less true because technologies are easily copyable. On the other hand, where technologies are not copyable, the threat of compulsory licensing may not be credible: Even if the patent owner refuses to comply with the provision, alternative sources of production may not be easy to find. For India, the most important reason for using compulsory licensing is to ensure cheaper access to essential drugs, which a nonworking provision does not help accomplish.

But most importantly, India and the United States need to create a mechanism, possibly permanent, to discuss the broader issue of how and how much India should pay for the fixed costs that go into the process of R&D. The spirit of the TRIPs agreement was that all countries, especially the larger developing ones, would contribute their fair share of financing the R&D costs associated with technology development. A corollary being that as they grew rapidly and became larger markets, this share would also rise over time. The best way to do this would be through tiered pricing/price discrimination, whereby pharmaceutical companies charged lower prices in India compared to prices in the United States. It might perhaps be necessary to distinguish drugs that are essential and used predominantly by the poorer segments of the population from drugs (for example, cancer drugs) that are more widely used. Other ways to achieve such tiered pricing would include for example, higher remuneration for compulsory licenses and also for voluntary licenses.

In this regard, a model of cooperation between global pharmaceutical companies and developing countries is emerging that should be watched closely. A California-based pharmaceutical company—Gilead Sciences Inc.—and a number of Indian companies are evolving a partnership model based on effective protection of IP combined with tiered pricing and extensive licensing to domestic companies that ensures better diffusion of IP products at affordable prices in India (as well as in a large number of other developing countries). The long-term goal should be to ensure the success of such partnerships in tandem with a decent return for the innovating company.

Finally, India may also have to consider using global best practices in the granting of patents to improve patent quality without the need to use blunt and unique provisions related narrowly to therapeutic efficacy of new chemical forms.
What the United States Might Do
But there must also be a quid pro quo from the US side on patents. First, the United States could acknowledge the positive developments in India related to due process. One way to operationalize this would be to change the narrative about India in the United States that is currently uniformly negative. The United States might consider offering carrots and not just deploying sticks. Thus, complaints against India could be moderated and consideration should be given to taking India off the priority watch list under Section 301 as a possible carrot.

Second, if India does not address the problems created by Section 3(d) of the patent legislation or by compulsory licensing for nonworking, the United States should consider initiating WTO disputes against India. As I argued in recent congressional testimony: “… the United States should address frictions and conflict through dialogue and where Indian policy is egregiously protectionist address it through multilateral dispute settlement procedures…. This approach is desirable for a number of reasons. India takes its WTO obligations very seriously and has had a very good track record of implementing WTO dispute settlement rulings. …In fact, it is not widely recognized that arguably the most important and sweeping reform of Indian trade policy occurred because of a WTO dispute panel—initiated by the United States—that ruled against India’s quantitative restrictions on consumer goods. These restrictions were severe in intensity and very broad in scope.”

For the United States, the virtue of using WTO dispute settlement is that it would be diplomatically and politically less confrontational than unilateral and bilateral actions, would reassure the world of its faith in rule-based multilateral institutions, and above all, would bolster the legitimacy of its substantive claims about other countries’ IP laws. On the other side, it might be easier for India to change problematic aspects of its IP legislation pursuant to WTO rulings than unilaterally or in response to bilateral US pressures.

Third, the United States should temper some of its demands on IPR issues, such as lengthy regulatory data protection, covering of dosage forms or minor chemical variations, or patent linkage, as demanded in US free trade agreements with others, while respecting the WTO Doha Declaration on Public Health.

Fourth, there must be some agreement that sharing the costs of R&D should cover genuine cases of R&D incurred rather than frivolous ever-greening and patents based on minor changes.

Fifth, one possible avenue for the US government to explore is the introduction of positive measures to encourage licensing fees to be lowered and equitable contributions made to fixed costs of R&D through tax and other incentives. A specific suggestion made in Scherer and Watal (2002)—to amend a provision in Section 170 of the US Internal Revenue Code that permits deductions if the amount is used by the donee solely for the care of the ill, the needy, or infants anywhere in the world so as to exclude the 10 percent deduction limit on taxable income—should be pursued. This would make differential pricing or voluntary licensing at less than commercial rates an attractive and sustainable proposition for US-based R&D companies.

Finally, the United States could also consider giving appropriate incentives to its companies to enter into R&D collaborations with Indian companies.