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Washington stirs as India undermines patents

By David Weller and Himanshu Singh

India's approach to pharmaceutical patents is garnering increased attention in Washington, with recent high-level pressure on the Indian government to do more to protect intellectual property.

In particular, India's recent endorsement of compulsory licenses as a tool to address drug pricing has caused widespread concern in the biopharma sector, as well as in other sectors that rely on strong patent protection.

How India responds to these concerns, and what actions the U.S. government takes to press them further, will shape the climate for intellectual property protection in India and U.S.-India trade relations. It may also establish a precedent more generally on the circumstances under which governments can justifiably override patent rights in the name of other objectives.

In June, 40 senators wrote to Secretary of State John Kerry asserting that India's actions on pharmaceutical patents (as well as forced local sourcing of certain information technology products) are "inconsistent with international norms and appear to violate India's obligations in the World Trade Organization."

The senators urged Kerry to take "swift action and make clear to your Indian counterparts that the United States will consider all trade tools at its disposal if India does not end its discriminatory practices." In the House of Representatives, 171 members sent a similar letter. Seventeen leading U.S. trade associations wrote to President Barack Obama complaining about these issues and called for tough action. And in recent meetings with the Indian government, senior U.S. government officials have raised their concerns.

India has responded by defending its intellectual property policies as consistent with international rules and, to date, has not publicly suggested any willingness to change course.

The concerns expressed in Washington stem from several recent developments, each of which is concerning in its own right, and even more so when viewed in the aggregate.

First, the Indian government has looked to "compulsory licenses" — the forced overriding of patent rights — as a means to reduce drug prices, even in nonemergency contexts, and to support India's pharmaceutical industry by expanding the pool of drugs available for copying.

Second, in other sectors, India has also endorsed compulsory licenses as a tool. In its 2011 National Manufacturing Policy, aimed to support the local manufacturing industry, the Indian government invited a government-created technology fund to seek the issuance of a compulsory license for the "latest patented green technology" — where "technology is not being provided by the patent holder at reasonable rates or is not being worked in India to meet the domestic demand in a satisfactory manner."

Third, India has taken other actions of concern regarding patent protection. Novartis AG spent more than six years fighting the Indian Patent Office's decision to deny a patent for its anti-cancer drug Glivec, which is patented in at least 40 other countries. In April, the Indian Supreme Court affirmed the Indian Patent Office's decision, based in part on the controversial Section 3(d) of India's Patents Act.

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In October 2012, the Indian Patent Office revoked Pfizer's patent for kidney cancer drug Sutent on the basis that the patent does not involve any inventive steps, based on a hindsight analysis. (In June, the matter was sent back to the Indian Patent Office to reconsider its previous revocation.)

In November 2012, India's Intellectual Property Appellate Board revoked Roche's patent for anti-hepatitis drug Pegasys on the basis that, while providing improved performance, Pegasys did not produce surprising or unexpected improvements, again relying on Section 3(d) of the Patents Act.

It has been India's use of compulsory licenses that has caused perhaps the biggest concern among companies and policymakers. India's Patents Act gives the Indian government broad authority to issue compulsory licenses. Section 84 allows a company to apply for a compulsory license on various grounds, including where "the patented invention is not worked in the territory of India" or "that the patented invention is not available to the public at a reasonably affordable price." And under Section 92, a compulsory license can be granted on an expedited basis, without a request even having been made to the patent holder for a voluntary license.

In March 2012, India's patent controller issued a compulsory license under Section 84 that gave Natco (a Hyderabad-headquartered pharmaceutical company) the right to sell Nexavar, an oncology medication produced by Bayer, without its authorization. It was the first compulsory license granted by the Indian government to a local pharmaceutical company and it was not issued under a state of emergency. Rather, it was granted primarily for economic and access reasons that set a dangerous precedent for patent holders.

In the Nexavar case, the patent controller found that a compulsory license was justified because the Nexavar patent had not been "worked in the territory of India," which he determined to mean "manufactured to a reasonable extent in India."

This type of forced local manufacturing is abhorrent to international trade norms. And at the same time, the controller found Bayer's price was too expensive given India's average per capita income — a fact that would presumably be the case for many drugs absent adequate public financing of health care. In March, India's Intellectual Property Appellate Board denied Bayer's appeal and upheld the compulsory license grant.

In the months since, India's Ministry of Health has moved toward granting compulsory licenses on additional patented medications.

India's actions are causing high levels of concern because the government is using an extraordinary tool generally reserved for health emergencies — the forced overriding of patents — as part of a broader policy of trying to contain costs and a narrow industrial policy of assisting domestic companies.

With respect to the former — cost containment — this is an issue that faces most governments. India, without a doubt, faces serious public health challenges and is a developing country. But it also boasts a growing middle class of more than 300 million people.

Overriding patents to lower costs would represent a fundamental change to the patent system, taking away the value of a patent that incentivizes high-risk research. In any event, compulsory licenses for patented products do not necessarily lead to affordability.

In the case of Nexavar, the Indian pharmaceutical company is authorized to sell the drug at a monthly price that substantially exceeds India's monthly per capita income.

With respect to industrial policy, using patent policy to force local manufacturing or to support domestic industry runs directly at odds with international trade rules.

When India joined the World Trade Organization (WTO), it committed to implement WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), including provisions related to granting and enforcing patents. India negotiated a special phase-in for pharmaceutical products, in light of the fact that India had not traditionally provided patent protection.

Effective Jan. 1, 2005, pharmaceutical products were to be eligible for patent protection in India. TRIPS contains "national treatment" or nondiscrimination requirements, including that patents shall be fully available and enforceable regardless of whether the products are imported or the place of invention. TRIPS also contains detailed procedures that governments must follow if they seek to issue compulsory licenses.

In light of India's recent approach to compulsory licenses, as well as controversial decisions on patent issuance and revocation, there is likely to be increased scrutiny of whether India is complying with its WTO obligations. The level of concern and attention in Washington regarding India's patent policies is likely to only increase.

David Weller, *former deputy assistant U.S. trade representative for China, is a partner in the Washington, D.C. office of the WilmerHale law firm in its Regulatory and Government Affairs Department and a member of the International Trade, Investment and Market Access Practice Group. He represents clients regarding trade and regulatory impediments to accessing foreign markets in international dispute settlement proceedings and on trade policy issues. He may be reached at (202) 663-6544 or David.Weller@WilmerHale.com.*

Himanshu Singh *is a senior associate in the Palo Alto office of the WilmerHale law firm in its Litigation/Controversy Department. He has extensive experience in various stages of litigation, including complaint and answer, fact and expert discovery, trial preparation, motion practice and depositions, among others. He may be reached at (650) 858-6038 or Himanshu.Singh@WilmerHale.com.*


DAVID WELLER
WilmerHale


HIMANSHU SINGH
WilmerHale