Is Sobering Tone On India IP Laws An Early Signal Of Reconciliation By U.S.?

By Vikas Dandekar / Email the Author / PharmAsia News *May 2, 2012 4:42 PM GMT*
India / Word Count: 1209 / Article # 28120502001

Executive Summary

Some lawyers say views on India's patent laws may be softening despite India winding up again on the U.S. Priority Watch List.

MUMBAI – Unexpectedly sober language related to India's intellectual property protection policies in the latest Special 301 Annual Report of the U.S. Trade Representative has left some Indian patent lawyers pleased, while a few others continue to emphasize that adequate IP protection and enforcement is critical to engendering a robust, vibrant and innovative Indian pharma industry.

Lawyers representing Indian drug companies told *PharmAsia News* that the "relatively mellowed" approach by USTR probably reflects reconciliation with the changing situation on the ground, which is placing more emphasis on public health interests of developing nations.

Unlike recent years where scathing remarks were made about Indian patent laws and regulations, USTR chose this time to reference the Doha Declaration on TRIPS and Public Health and noted that the U.S. "respects a trading partner's right to protect public health and, in particular, to promote access to medicines for all, and supports the vital role of the patent system in promoting the development and creation of new and innovative lifesaving medicines."

Under Vigil But Softer Approach

However, USTR still kept India on its "Priority Watch List" alongside countries like China and Brazil, noting that "India made limited progress on IPR protection and enforcement in 2011, and its legal framework and enforcement system remain weak" (See: USTR 301 Report).

In one bright spot, USTR said it recognized India's recent efforts to address its patent application backlog, but urged "additional steps." The report also advises India to "streamline its patent opposition proceedings."

The United States called upon India to provide an effective system for protecting against unfair commercial use, as well as unauthorized disclosure of tests or other data generated to obtain marketing approval for pharmaceutical and agricultural chemical products. In 2009, the USTR had slammed India for weak policies on counterfeit drugs ("U.S. Urges India To Impose Strict Laws Against Counterfeit Drugs" — *PharmAsia News,* May 13, 2009 12:18 PM GMT).

The report commended India on progress in innovation and its promotion of domestic manufacturing, but it urged India to resist imposing discriminatory policies or other counterproductive measures in pursuit of those goals, and at the expense of protection of intellectual property rights.

But perhaps the most surprising part of the report is the language chosen by USTR related to a controversial decision this year by India's Controller of Patents to grant India's first compulsory license to **Natco Pharma Ltd.** against **Bayer AG**'s *Nexavar* (sorafenib) ("India Grants First Compulsory License To Natco For Bayer's Nexavar; Disappointed, Bayer May Challenge Decision" — *PharmAsia News,* Mar. 11, 2012 6:30 PM GMT).

USTR said it would "closely monitor developments concerning compulsory licensing of patents in India following the broad interpretation of Indian law" in the Natco decision, "while also bearing in mind the Doha Declaration on TRIPS and Public Health."

Shifting Stand?

Pointing at the toned-down language taken by the U.S., Gopakumar Nair, a lawyer who runs Patent Gurukul, said there may be a realization that the flexibilities in TRIPS need to be used to make drugs affordable and accessible to patients.

In a similar tone, Prashant Reddy a blogger for SpicyIP – a popular site that tracks India IP developments – said: "This is surprisingly sober language for an office which in the past has threatened to sue Brazil at the WTO because of the 'local working' provision in its law, apart from downgrading Thailand in its Annual 301 Report for the sole reason that its government had issue multiple CLs on pharma patents. The Indian CL decision is a combination of both the above scenario and yet we've only been threatened with a mild 'monitoring'" ("Sanofi Asks Thailand To Review Compulsory Licensing Policy" —*PharmAsia News,* Sep. 1, 2008 9:00 AM GMT).

"I was half expecting the USTR to come out all guns blazing in this particular report ..." –Prashant Reddy

Reddy added, "I was half expecting the USTR to come out all guns blazing in this particular report because this particular decision in the Bayer CL can be applied across the board for pretty much any pharmaceutical patent. Given that the U.S. now seems to be to quite understanding of India's need to issue compulsory licenses, the government need not worry about offending one of its biggest trading partners."

However, that view was not shared by other attorneys, who stressed the need for more robust IP regulations.

New Delhi-based Corporate Law Group, which represents several global companies in India on IP-related cases, told *PharmAsia News* in an e-mailed statement, "Adequate IP protection and enforcement are critical to engendering a robust and vibrant innovative pharma industry. The findings in the recent CL decision particularly that with regard to working of a patent is not compliant with India's TRIPS commitment (as well as its broader WTO obligations). The decision [to grant the CL to Natco] will have ramifications beyond pharmaceuticals and send a wrong signal to the international community. The research-based pharma companies will have less incentive to develop new medicines for Indian patients, knowing that getting a return on their investment will be difficult, if not impossible."

"Use of CL to expropriate patent rights is a limited exception under TRIPS, and should only be used in exigent circumstances when all other alternatives have been exhausted. It should not be used as a tool for business development for local industry," CLG noted.

Other Countries

Separately, USTR also singled out several additional Asian countries for its Priority Watch List due to pharmaceutical-related issues, including:

- **Indonesia**, which remains on the list for 2012. in part due to "widespread availability of counterfeit pharmaceutical products." USTR also urged Indonesia to develop an effective system for protecting against unfair commercial use and unauthorized disclosure of data generated to obtain marketing approval for biopharma and agricultural chemical products, and also singled out requirements that restricted the importation of medicines.
- **Pakistan**, which remains on the list for 2012. USTR advised Pakistan to develop an effective system for protecting against unfair commercial use and unauthorized disclosure of data generated to obtain marketing approval for

biopharma products, and to create a system “to address patent issues expeditiously in connection with applications to market pharmaceutical products.”

- **Thailand**, which remains on the list for 2012. USTR advised Thailand to develop an effective system for protecting against unfair commercial use and unauthorized disclosure of data generated to obtain marketing approval for biopharma and agricultural chemical products. The report also recommends that Thailand engage “in a meaningful and transparent manner” with stakeholders as it “considers ways to address Thailand’s public health challenges while maintaining a patent system that promotes investment, research, and innovation” – an oblique reference to Thailand’s own compulsory licensing issues.

  USTR also dedicates almost nine pages of its report to China, which remains on the Priority Watch List for 2012, noting that: “A wide spectrum of U.S. rights holders reports serious obstacles to effective protection and enforcement of all forms of IPR in China, including patents, trademarks, copyrights, trade secrets, and protection of pharmaceutical test data.”

  In particular, USTR highlights China’s data-exclusivity law, which is supposed to protect data submitted in support of a marketing application for a new drug for six years after approval. However, the report notes “there is evidence that generic manufactures have, in fact, been granted marketing approvals by the State Food and Drug Administration (SFDA) prior to the expiration of this period, and in some cases, even before the originator’s product has been approved.”