

A REALITY CHECK ON INTELLECTUAL PROPERTY CONCERNS

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The Working Group on Intellectual Property can serve as a platform where real time solutions to meet India's need for low-cost medicines can be addressed.

After what seemed like a historic trip for Prime Minister Narendra Modi, which held out the promise of reshaping India-U.S. relations positively, the initiation of the Out-of-Cycle Review (OCR) by the United States Trade Representative (USTR) has brought a sobering reality check as to what the future holds. The USTR has initiated a process whereby the OCR evaluates whether there has been any meaningful progress in engaging India's new government on intellectual property (IP) concerns. The impending OCR was indicated as part of its findings on the state of IP protection in India in the 2014 Special 301 Report, brought out by the USTR. India has been cited in every one of the Special 301 Reports but in 2013, it faced the prospect of a further downgrade of its status to Priority Foreign Country (from the Priority Watch List) and in 2014 India was categorised as a notorious market, a special status reserved for IP outcasts of the world.

The OCR will address the quality of engagement with the new government on a laundry list of issues from copyrights to trademarks and include concerns relating to Section

3(d), pre and post grant opposition, the grant of a compulsory licence and India's interpretation of what it means to work a patent in India for purposes of a compulsory licence. As many will recall, the U.S. pharma lobby had cried hoarse when a compulsory licence was issued for Nexavar, a drug to treat kidney and liver cancer, over which Bayer held a patent. That Nexavar was priced at \$4,700 per month, five times higher than the median annual income in a country facing significant public health challenges escaped critics who rebuked India for its abusive policies. Similar alarms were sounded when the Indian Supreme Court rightly refused to endorse ever-greening of patents and denied patent protection on Glivec, a drug owned by Novartis. Interestingly, in the past year the U.S. Supreme Court overturned the decisions of the Federal Circuit in five out of the six considered patent disputes.

An Ill-Conceived Move

The OCR, in simple terms, is a mistimed and ill-conceived move by the U.S. After all, the Prime Minister's visit concluded with a joint statement with the President of the U.S., where the two countries agreed to set up a high-level Working Group on IP within the Trade Policy Forum (TPF), which is evidence of India's commitment to have a substantive good faith dialogue on IP concerns.

That said, it is surprising that India did not specifically address its reservations with the impending OCR (as it was then in September) during Mr. Modi's visit. India therefore finds itself in a fix. Having committed itself to a dialogue in a specially designated bilateral forum, it nonetheless continues to be subject to unilateral scrutiny of its intellectual property regime by the USTR. In any event, with the establishment of the World Trade Organization (WTO), the role of the USTR in policing the world with the threat of unilateral sanctions appears highly questionable and there are indications that India may not shy from taking legal recourse at the WTO should the U.S. impose such sanctions.

That leaves us with the question of what would be an appropriate course of action for a country like India. Having established the Working Group on IP, now India should underline that this forum will discuss IP concerns of both countries. It is up to the Indian government to ensure that the agenda of the

Working Group is not hijacked by U.S. industry and pharma interests in particular. After all, it is no secret that PhRMA has been pushing for changes in India's patent laws and refuses to recognise India's legitimate public policy concerns and the flexibilities established as an outcome of international trade negotiations. The government should be careful not to dismantle a hard-bargained and well-established structure of the existing patent system. More importantly, India must use the access that the TPF will provide to address protectionist hurdles that Indian goods and services face in the U.S.

There have been indications that India will seek to address concerns on geographical indications (GIs), online piracy of Indian movies and traditional knowledge (TK) in the agenda of the Working Group. While these are certainly worthy goals to pursue, except for the alignment on efforts to curb online piracy, U.S. interests on GIs and TK are divergent to India's. While the divergence

in itself is no reason to abandon their pursuit, the debate on patents involves larger economic interests embodying more pressing issues that India can address through the Working Group. Further, the Working Group on IP can serve as a platform where real time solutions to meet India's need for low cost medicines can be addressed. India should emphasise that one way to avoid unpopular compulsory licensing is to instead focus on fostering a climate whereby innovator companies are encouraged to voluntarily license in collaboration with Indian generic companies much like Gilead has done recently to bring down the price of a hepatitis C drug by licensing to eight generic companies.

India can achieve meaningful results by engaging with industry experts to use the Working Group on IP as forum for setting tangible and realisable goals that will benefit constituents on both sides. The responsibility to make sure the forum delivers rests with both the U.S. and India.