

## **US rakes up Indian counterfeit drugs issue, wants data protection**

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Placing India yet again in the 'priority watch list in 2010', the United States has once again raked up the issue of counterfeit medicines as a grave concern, and has strongly sought protection for undisclosed test and other data generated for approval of pharma products.

In its 'special 301' report, the annual review of the global state of IPR protection and enforcement by the Office of the United States Trade Representative (USTR), the US wanted India to 'provide protection against unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical and agricultural chemical products'.

The report said the US has concerns on the proliferation of the manufacture, sale, and distribution of counterfeit pharmaceuticals in countries such as Brazil, China, India, Indonesia, and Russia. In many cases, bulk active pharmaceutical ingredients (API) that are used to manufacture pharmaceuticals that bear counterfeit trademarks are not made according to good manufacturing practices, it claimed.

"India continues to make gradual progress on efforts to improve its legislative, administrative, and enforcement infrastructure for IPR. India has made incremental improvements on enforcement, and its IP offices continued to pursue promising modernization efforts. Among other steps, the United States is encouraged by the Indian government's consideration of possible trademark law amendments that would facilitate India's accession to the Madrid Protocol. The United States encourages the continuation of efforts to reduce patent application backlogs and streamline patent opposition proceedings," it said.

"However, concerns remain over India's inadequate legal framework and ineffective enforcement. Piracy and counterfeiting, including the counterfeiting of medicines, remains widespread and India's enforcement regime remains ineffective at addressing this problem. The United States continues to urge India to improve its IPR regime by providing stronger protection for patents. One concern in this regard is a provision in India's Patent Law that prohibits patents on certain chemical forms absent in showing of increased efficacy. While the full import of this provision remains unclear, it appears to limit the patentability of potentially beneficial innovations, such as temperature-stable forms of a drug or new means of drug delivery. The United States also encourages India to provide

protection against unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical and agricultural chemical products,” according to the report.

Pharmaceutical Research and Manufacturers of America (PhRMA) has supported the report and backed up the call for IP protection. PhRMA and our members place a high priority on addressing the harm caused by inadequate IP protection and by the market access barriers put in place by some trading partners. The value of IP protection should not be undermined by discriminatory market access barriers. We welcome USTR’s recognition of market access barriers faced by US pharmaceutical companies,” its president Christopher Singer said in a statement.