

OPPI News Update**Tuesday, October 14, 2014****US to launch fresh review of India's patent regime****Publication:** [The Times of India](#)

Within days of Prime Minister Narendra Modi's return from the US, the US Trade Representative (USTR) has launched a fresh offensive against India's intellectual property rights (IPR) regime, a move that may lead to the government going slow on a bilateral dialogue with Washington. On Tuesday, USTR will launch what it calls an "out-of-cycle review" (OCR) of India's IPR regime, following a report released earlier this year, where India was put on the priority watch list due to "heightened level of concern about the deterioration in India's environment for IP protection and enforcement". Now, it is seeking public comments and information related to law, policies, or practices related to India's IPR.

Similar reports in-**Moneycontrol-** [USTR to initiate reviewing India's IPR laws from Tuesday](#)**Bloomberg –** [India Review, Vogue, Iggy Azalea: Intellectual Property](#)**Pharma patent regime may get stricter, say experts****Publication:** [Daily News & Analysis](#)

The joint statement issued on September 30 by the US and India to establish an annual high-level Intellectual Property (IP) working group has inevitably led to a debate. A section of the pharmaceutical industry feels that the government may give importance to increasing the dollar in-flows through foreign direct investments (FDI) rather than pushing the case of a "diluted" intellectual property rights (IPR) regime that the country followed so far. According to an industry expert, the government may choose to bow to the US pressure since it is keen on having more foreign companies investing in India. Srividhya Ragavan, professor of law, University of Oklahoma College of Law, said in an emailed response, "Whether India will be cowed down by Pharmaceutical Research and Manufacturers of America (PhRMA) pressure is yet to be seen. But the recent events do show that there is pressure from PhRMA directly as well as indirectly to effectuate patent amendments. As a sovereign nation that is compliant with its trade obligations, India is not required to succumb to this pressure. Any ill-conceived amendment to the patent statute will affect either the government's ability to facilitate access to medications, and/or result in low quality patents which in turn can affect the cost and access to those medications."

Drug pricing a big scam**Publication:** [Metro India](#)

As many as 24 pharmaceutical companies (28 over pricing cases) in India have collectively over-priced about Rs 253.85 crore worth of drugs between April and July this year, according to the drug price regulator, National Pharmaceutical Pricing Authority (NPPA). The figure has been a whopping Rs 3,636.38 crore, if one were to take into consideration the cut-off period of 1997 when the NPA became operational. The drug price regulator has been trying to keep a check on pharmaceutical companies which have been over-pricing their drugs. But, its role seems to have just stopped at that as the recovery rate has been negligible. Since August 1997 when NPPA became operational, about 1,043 overcharging cases have come to NPPA's notice amounting to Rs 3,636.38 crore of which the regulator could recover only Rs 67.14 crore. Between April and July this year, NPPA has found several Indian and multinational pharmaceutical companies violating pricing norms, but could recover only Rs 341.57 crore from the companies as of July 2014. Price escalations had been viewed strictly by nations globally.

Please note: The report quotes Bejon Misra.

NPPA Imposes Fine of Rs 300 cr on Novartis

Publication: [The Economic Times](#)

Drug major Novartis has been Rs 300-crore penalty by drug regulator NPPA for overcharging consumers on sale of Voveran, its best-selling painkiller medicine. The Swiss drugmaker, which did not confirm the quantum of the total penalty by the National Pharmaceutical Pricing Authority (NPPA), said the notice is “erroneous and entirely misconceived”. “Novartis has received a notice from NPPA and will duly respond to the same. Novartis believes the show cause notice to be erroneous and entirely misconceived and Novartis will challenge both the basis of the demand as well as the entire quantum of the demand,” Novartis India said in a filing to the BSE.

Similar reports in-

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Hindustan Times- [NPPA slaps Rs 300- cr fine on Novartis for overcharging](#) (*link unavailable, scan attached*)

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The Pioneer- [NPPA SLAPS RS 300-CR PENALTY ON NOVARTIS FOR OVERCHARGING](#)

Fierce Pharma- [India's NPPA fines Novartis \\$49M as price cap battles rage on](#)

FirstBiz- [Ouch: NPPA slaps Novartis with Rs 300 cr fine for over pricing](#)

NDTV- [Drug Pricing Regulator Slaps Rs. 300 Crore Penalty on Novartis: Report](#)

NPPA issues Internal Guidelines for making representation to NPPA against price notifications

Publication: [Pharmabiz](#)

The National Pharmaceutical Pricing Authority (NPPA) has issued Internal Guidelines for making representation to NPPA against price notifications. The proposed Guidelines will be applicable with prospective effect covering all pending cases at various levels in the office at present. According to the new Internal Guidelines, all the applicants have to first comply with the price notification. In case of non-compliance, representations will not be entertained at all. Any manufacturer making a claim about a particular PTR/MRP should have necessarily reported the same price in the return submitted by them in Form V of Schedule II to the DPCO 2013, to the NPPA, and the onus of providing documentary evidence in this regard shall lie with the applicants.

Pharmaceutical companies, WHO help India in HIV/AIDS drug crisis

Publication: [Reuters](#)

Indian companies and global health groups are stepping up efforts to provide a critical medicine for the country's free HIV/AIDS drugs programme after more than 150,000 patients risked going without their dosages this month. Delayed tender approvals and poor co-ordination with states left the National AIDS Control Organisation (NACO) scrambling for supplies. Reuters reported on October 1 that the supplies were due to run out next week.

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