

US Official Claims Commitments from India on IPR

IN PANIC MODE Drugmakers, public health activists alarmed, ask govt to make details public, warn agreeing to US demands may harm patients

INDIA- US Engage on IPR

American top trade official claims US has secured commitments from India on IPR

- US has been demanding changes in India's IP policy
- US demands include 1) data exclusivity 2) patent linkage

WHAT DOES IT MEAN?

- This will mean India's drug approval process will get linked to patent award process

CONCERNS IN INDIA

- Domestic drug makers and public health activists alarmed
- They warn giving in to US demands can delay launch of generic drugs
- Harm domestic drug makers' business, block access to low-cost medicine
- Say govt must reveal promises it is making to US on IPR

health of millions of patients by delaying access to low-cost generic drugs. It could also impact domestic drugmakers, whose business model relies on launching cheaper generic versions of new drugs discovered by the innovator multinationals. "What are these commitments government is making to the US? The secrecy around these ongoing IPR negotiations with the US is disturbing. The government must come clean on this matter and tell the public what commitments have been given," said Anand Grover, director at Lawyers Collective, a not-for-profit group that has represented patient groups in many landmark cases.

"There are indications that the Indian government is changing its stand and taking a favourable view to the US demand for data exclusivity and patent linkage. What is most troubling is that this move would only benefit foreign MNCs, leaving Indian generics makers in the lurch and risking the health of millions of patients in the bargain," he said.

A top government official dismissed

sed, alarm bells. "India has not made any behind the scene commitment to US on IPR. We are awaiting US inputs on the draft IP policy," said the official.

DC Shah, secretary general of Indian Pharma Alliance, a grouping of top drugmakers in the country, said Indian drug firms have already expressed their serious concerns on the matter to the government. "The government is miscalculating the serious impact these moves can have on public health and economy. These moves will significantly impact access to medicine and the future of generic industry," Shah said. "The government must disclose to the nation the nature of commitments it has made to the US on IPR issues."

The USTR, under its annual 'Special 301' report on the adequacy and effectiveness of trading partners' protection and enforcement of IPR, last year reviewed whether India's IP regime has deteriorated enough to warrant a downgrade in its status to 'priority foreign country'. Such a status would allow the US to impose trade sanctions on In-

dia. Early last year, the USTR deferred a decision on India till autumn, only to restart an out-of-cycle review after Modi returned from his maiden US trip. A USTR statement, however, made it clear that the US will not revisit India's designation in 2014.

Since then a joint working group with officials from both countries has been working to find a common ground on IPR issues. Among other things the US has demanded that India link its process of granting marketing approvals to drugs with that of award of patents, something it has till now consciously refrained from doing, dubbing it detrimental to public health and beyond its international commitments. Froman in his testimony before the senate committee, said the US has "laid out a work programme" with the Indian government to address IPR and other outstanding issues. ET reviewed the text of the written testimony available at the committee's website and the full transcript of the proceedings, where Froman fielded questions from US senators.

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