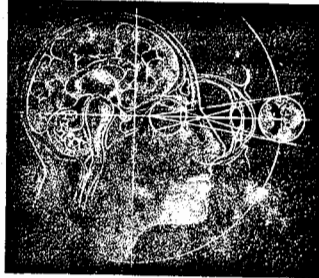


Big Pharma asks US to Keep IPR Heat on India

Groupings feel India's policies
on intellectual property rights
don't conform to global norms



Soma.Das1@timesgroup.com

New Delhi: Big Pharma groupings have urged the US government to keep nudging India to change its policies on intellectual property rights, which they claim don't conform to global norms. They don't want Washington to downgrade the country yet to a status that could attract trade sanctions - a climb down from their stand a year ago - but have told the US Trade Representative (USTR) office to conduct a special review of India's IPR environment soon to check whether India is acting out on its expressed intent to reform policies.

The Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Industry Organization (BIO) have raised the demands in their submissions to the US government, which is currently reviewing the IPR environment in different countries as part of its annual exercise.

IPR issues, especially over drugs, have long been a sticky point in India-US bilateral relations though both countries are now trying to resolve the differences through high-level talks. India is already on US' Priority Watch List, which means Washington is closely monitoring New Delhi's efforts to protect IPR.

Last year, US drug firms made out a case for downgrading India to Priority Foreign Country, a label that could at its worst trigger trade sanctions from the US.

But the American government deferred a decision, opting for an out-of-cycle review of India's IPR policies in October, where it chose not to downgrade the country, mainly in

the light of improved relations with the new government led by Narendra Modi. PhRMA and BIO are pushing for a similar review this year. In the filings, they have lauded improved dialogues between the two countries and establishment of a high-level working group, but said the concerns around IPR remained.

Since early 2012, at least 19 products have had their patent rights undermined in India, PhRMA has said. The groupings want India to do away with a clause - section 3(d) in the Indian Patents Act - which sets a higher and narrower standard of patentability than is prevalent in developed markets like the US and European Union. They fear India's example could be followed by others. "Not only is this a concern in the Indian market, but also in other emerging markets that may see India as a model to be emulated," said the submission.

They want India to link process of granting marketing approvals to drugs with that of award of patents, something India has consciously refrained from doing, dubbing it detrimental to public health and beyond its international commitments. At present, India's drug regulators don't consider the patent status of a drug while granting marketing approval.

The US pharma companies say they are also apprehensive of the way India may use compulsory licences.

The groups are also critical of the way India has implemented drug price control and clinical trial policies

Patent