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Indian drug firms are planning to boost tie-ups with foreign companies

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Indian drug makers are drawing support from independent medical relief organisation Medicins Sans Frontieres. Shailly Gupta, advocacy officer at the organisation's access campaign said, "There is constant pressure from the US government after the compulsory licence was issued in terms of lobbying at every level so that India backs off. One way or the other, they have been trying to put pressure. It is not really about generics, but about the policy environment in India, which is now generic friendly and multinationals do not like it. What India is doing is not wrong either. The Trips (Trade related aspects of intellectual property rights) agreement allows space to apply flexibilities and India has been following it."

Gupta says such pressures started after the compulsory licensing norms, with the global intellectual property center of the US chamber of commerce ranking India lowest among 11 countries in their new IP index. Later, the Novartis decision (where the Supreme Court rejected the company's secondary patent application on a leukemia drug) happened and the GIPC said India was moving in a wrong directionwith respect to advancing innovation and intellectual property.

Last September too, the US international trade commission, an independent trade committee, said it would investigate Indian industrial policies that discriminate against US imports and investment for the sake of supporting Indian domestic industries. It would cover agriculture, manufacturing and service sectors, as well as study the overall business environment and its impact on US industry and economy and sought opinions from US companies before April.

Even as Indian government has been facing international scrutiny over its patent laws, domestic companies are caught in mire as their manufacturing practices do not confirm to the USFDA's requirements. In all, exports have been affected ten Indian facilities. However, local drug makers do not believe it to be tit-for-tat action.

GV Prasad, chairman Dr Reddy's said, "I don't think MNCs have any role to do here. Although we feel there is an increased scrutiny by the USFDA, it is also happening in the US and other countries." PV Appaji, director general at the pharmaceuticals exports promotion council that comes under the commerce ministry, said, "The issue is mostly not about quality issues of drugs. The USFDA has found irregularities in terms of good manufacturing practices or date integrity and they are right to take such actions. But there has been adverse publicity about Indian generics in the developing world and most of them refer to such drugs as counterfeits, to malign the reputation. But we are closely involved with the DCGI (drug controller general of India) regarding the manufacturing issues and also trying to build confidence of regulators."

Even then, the Indian pharmaceuticals industry is pegged to grow its export numbers in US and pharmerging economies and also tap better profit margins backed by increased manufacturing facilities in the coming fiscal, according to India Ratings & Research. The growth recorded over FY08-FY13 at 22 per cent will continue in the medium term. It will be backed by $92 billion worth drugs going off patent in the next three years, increasing traction for generic drugs globally, Ind-Ra said in a report.

"This year there have been increased regulatory actions, with the USFDA issuing warning letters to ten manufacturing facilities. While the actions till now are not significant considering the size of the Indian market, further increase in regulatory actions will have negative implication for the industry," said Sreenivas Prasanna, senior director at ICRA.

Meanwhile, Indian companies are looking to enhance tie-ups with foreign companies for the sake of marketing, research and other business prospects, industry insiders say.

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