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Patent problems

US FDA issue needs deft handling

While the agreement between the US FDA and its Indian counterpart to share information and perhaps coordinate action is good news as both regulators will now be on the same page, the need of the day is for the Indian regulators to be more stringent and conduct more surprise tests in the manner the FDA does. Indeed, since Indian regulators are not contesting the US findings in the case of, for instance, a Ranbaxy, it is worrying that they have not detected such problems themselves. That said, the Indo-US problem goes deeper, to the US belief that India's IPR laws, particularly Section 3(d) of the Patents Act that deals with what is not patentable—and brings in the question of increased efficacy—are inadequate to protect US intellectual property. Whatever the US view, Indian authorities argue that the Patents Act is WTO-compliant. Also, the issue seems to have been further sealed with the Supreme Court ruling on the issue of 3(d) and on "efficacy" in the Novartis Glivec case—the Supreme Court has also upheld the Indian Pharmaceutical Alliance's view that Article 1(1) of TRIPS explicitly allows member countries to determine how to protect IP. Any further interpretation will have to await a ruling of a larger SC bench.

Even so, it has to be said the Indian action in the case of Bayer's liver and kidney cancer drug Nexavar looks quite arbitrary and probably added to the US ire with Indian IPR. The compulsory licensing, it is true, brings down the cost of treatment dramatically, from ₹2.8 lakh a month to ₹8,000, but surely it cannot be said that this was an epidemic situation that called for the use of compulsory licensing? Drug discovery is a very expensive process involving billions of dollars in R&D. Unless carefully thought through, irresponsible compulsory licensing of the Bayer kind will just give India a bad name. As for the moral outrage over the US FDA action against Indian pharma producers, the government would do well to keep in mind the well-publicised shortcomings of the Indian drug control process. The Central Drug Standard Control Organisation (CDSO) has under half its sanctioned strength—also, it has just 1,500 inspectors to oversee 10,500 manufacturing sites and several lakh chemist outlets. Indeed, a recent report of the Parliamentary Standing Committee points to several banned drugs being available in India as well as cases of new drugs being approved without the mandatory clinical trials being carried out and, in some cases, the approval was given by the CDSO's non-medical staff—in many cases, the doctors' testimonials cited for approving drugs were either identical or not backed with any test results, yet the doctors were not even reported to the Medical Council of India. No amount of railing at the perceived US high-handedness is going to fix this. As the FAA's downgrade of India's aviation safety shows, India's regulatory system has been caught napping once again.

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