Lack of clarity in drugs Act may hit generic cos

Ambiguity In Terms Such As 'Adulterated' & 'Spurious' May Complicate Patent Challenge & Regulation Of Firms

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MUMBAI

AMBIGUITY in the amended Drugs and Cosmetics Act over the definition of the terms 'adulterated' and 'spurious' drugs could affect Indian generic drug players. The amendment, which came into force on August 10 this year after receiving the Presidential assent in December 2008, could complicate both patent challenges as well as regulation of companies, industry observers said.

The amended law has provided for stricter punishment for companies charged with manufacturing 'adulterated' or 'spurious' drugs. Under the new law, evidence of both adulteration and manufacture of spurious drugs needs to be established for a person to be convicted.

However, the punishment for this has been increased to 10 years imprisonment from five years now, which could extend to life. The monetary fine has also been increased to Rs 1 lakh from Rs 10,000.

However, lawyers feel there is still some ambiguity in the Act, which needs to be addressed immediately. Shamnad Basheer, professor of intellectual property law at the National University of Juridical Sciences (NUJS), Kolkata, said, "Although the increase in penalties for dealing in spurious drugs may be welcome, the fact that the definition of 'spurious' remains substantially the same is a grave cause for concern. This definition could be interpreted to even catch within its fold legitimately-authorised generics of good quality and this is problematic."

Loopholes in the law have been noticed both by intellectual property lawyers and companies alike. This was evident in the recent Bayer-Cipla case. Bayer, in the recent drug patent linkage case, suggested that Cipla's generic version of Nexavar would qualify as 'spurious'.

"Given that the government is fighting international efforts such as IMPACT which attempt to define counterfeiting broadly to even catch legitimate generics, the government must, as a first step, clean up its own backyard by redefining 'spurious'. It must ensure that the term 'spurious' as used within the context of drug regulation be simply restricted to substandard drugs. IP issues should not form part of this definition. And in any case, barring straightforward violations of identical trademarks, the DCGI often does not have the institutional competence to decide complex trademark disputes," Mr Basheer said.

Another point in the law that is of concern is the non-binding power that it gives authorities. Milind Antani, co-head (pharma practice) at Nishith Desai Associates, said, "The purpose of the amendment is to curb the spread of adulterated drugs and that is a welcome move. But the powers given to authorities like the state Food and Drug Administration are non-binding on them and there are concerns that these may be misused." Not all adulterated drugs, he said, originate from the manufacturer. Some come in at various points in the supply chain and the concerns are that genuine companies may also be pulled up for such occurrences.

"With the lack of clarity on the definition of adulterated and spurious, large companies are more likely to use this as a way to block generic companies from challenging their patents and manufacturing generics. This could harm the generic industry as a whole and if it is not sorted out soon, we will see more lawsuits against Indian companies on such grounds," said the CEO of a generic company who did not want to be named.

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USFDA clears Cipla's facilities

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CIPLA has successfully addressed all the nine manufacturing deficiencies pointed out by the US Food and Drug Administration (FDA) at its Bangalore manufacturing plant. The company received an official communication about the approval from the USFDA about a month back, a senior company executive said.

In April this year, the FDA issued form FDA 483s — an inspection report pointing out deviations from US manufacturing standards — and listed nine deficiencies.

The Mumbai-based company had then said the deviations, which include one relating to data entry, 'were of routine minor nature, suggesting need for improvements in good manufacturing practices'. Cipla also submitted a response within the next 30 days. When contacted, Cipla's chairman and MD YK Hamied said all its plants are routinely inspected and are currently approved by the US drug regulator. But, he declined to comment on whether the company received any intimation from FDA, after it submitted its response to the drug regulator to correct the deviations at its Bangalore plant.

Ranjit Kapadia, Institutional Research (VP) and pharma analyst at HDFC Securities said in a note issued last week, "Cipla has been able to respond to the nine observations raised by the USFDA and has come out clean." Mr Kapadia said if the FDA does not raise further questions within the next few months, it is assumed the company's response is satisfactory. FDA periodically inspects all plants approved by it to ensure that drugs made at these facilities are safe to be sold in the US. For plants in India, the FDA usually makes a biannual inspection.

Cipla is among the list of the few Indian pharma companies besides Ranbaxy, Lupin and Sun Pharma's US arm Caraco Pharmaceuticals, who have been pulled up by the USFDA for not adhering to the US manufacturing standards in recent times.