IP Lab

October 26, 2009

DELHI HIGH COURT FREES INDIAN DRUG REGULATOR FROM THE SHACKLES OF "PATENT LINKAGE"

Bayer's bid to convince the court to usher patent linkage fails.

The Drug Controller General of India (DCGI), in April 2008, had announced that it was considering a 'linkage system' between the patent office and itself. A linkage would mean that until the time there exists a valid patent for a drug, its corresponding generic version shall not receive marketing approval from the DCGI. As a result, a generic version of a valid patented drug would never reach the marketplace.

In September 2008, however, the DCGI appeared to backtrack from its announcement. It clarified that it would not base its regulatory approvals on the patent status of a drug. On the point that patent rights are of no use if the DCGI granted marketing approval to generic manufacturers of patented drugs, the DCGI maintained the "*let the companies slug it out between themselves*" stand.

Consequently, battles between drug patent holders and home grown generic manufacturers reached the courts.

One such dispute that arose between Bayer Corporation's kidney and liver cancer drug Nexavar and Cipla Ltd.'s Soranib posed before the Delhi High Court the question whether there exists a drug regulator - patent office linkage in India.

We have analysed this decision of the Court in *Bayer Corporation and Ors. vs. Union of India and Ors.* wherein the Court held that such linkage does not exist under Indian law. We further analyse what leads to recurrent disputes between drug patent holders and generic manufacturers in India on issues like patent linkage and data exclusivity. The case study is available here.

Nishith Desai Associates is pleased to present a detailed analysis of the latest legal developments and trends. The iP Lab is our initiative to provide you in-depth, incisive and a detailed research based analysis of key happenings and landmark cases in the Intellectual Property domain with a view to sharing and inviting views and counter-views. We would be happy to have your views / comments on our initiative. Please read the disclaimer carefully.

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