

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.

This article is best viewed in Adobe Acrobat version 7.0

IP-Pharma Team

Aditi Nadkarni / Gowree Gokhale

DISCLAIMER

The contents of this hotline should not be construed as legal opinion. View detailed disclaimer.

This Hotline provides general information existing at the time of preparation. The Hotline is intended as a news update and Nishith Desai Associates neither assumes nor accepts any responsibility for any loss arising to any person acting or refraining from acting as a result of any material contained in this Hotline. It is recommended that professional advice be taken based on the specific facts and circumstances. This Hotline does not substitute the need to refer to the original pronouncements.

This is not a Spam mail. You have received this mail because you have either requested for it or someone must have suggested your name. Since India has no anti-spamming law, we refer to the US directive, which states that a mail cannot be considered Spam if it contains the sender's contact information, which this mail does. In case this mail doesn't concern you, please unsubscribe from mailing list.

Research Papers

Fintech

May 05, 2025

Medical Device Industry in India

April 28, 2025

Clinical Trials and Biomedical Research in India

April 22, 2025

Research Articles

2025 Watchlist: Life Sciences Sector India

April 04, 2025

Re-Evaluating Press Note 3 Of 2020: Should India's Land Borders Still Define Foreign Investment Boundaries?

February 04, 2025

INDIA 2025: The Emerging Powerhouse for Private Equity and M&A Deals

January 15, 2025

Audio

CCI's Deal Value Test

February 22, 2025

Securities Market Regulator's Continued Quest Against "Unfiltered" Financial Advice

December 18, 2024

Digital Lending - Part 1 - What's New with NBFC P2Ps

November 19, 2024

NDA Connect

Connect with us at events, conferences and seminars.

NDA Hotline

[Click here to view Hotline archives.](#)

Video

Vyapak Desai speaking on the danger of deepfakes | Legally Speaking with Tarun Nangia | NewsX

April 01, 2025

**SIAC 2025 Rules: Key changes &
Implications**

February 18, 2025