

IP Hotline

September 08, 2004

REMOVAL OF THE PATENT'S CONTROLLER OVER GRANT OF EMR

India's first Exclusive Marketing Right (**EMR**) in the pharma sector was granted to multinational Novartis for its anti-cancer drug Glivec in November. The allegations of irregular grant of this EMR and other allegations regarding the Controller General of Patent , Designs & Trade Marks' decisions, have been instrumental in the removal of the Controller General by the Government of India with effect from September 01, 2004. Wockhardt and Eli Lilly were the other two pharma companies that received EMRs during the tenure of the Controller General .

Upon receipt of the EMR, Novartis had obtained an ex parte injunction from Madras High Court restraining six companies from selling generic versions of the drug in India. On the other hand, the EMR grant to Novartis has been challenged in Courts by generic industry producers of the drug, mainly on the ground that the compound, being just a derivative of a molecule known prior to 1995, did not satisfy the novelty criteria set under the Indian Patents Act, 1970. This matter is currently sub-judice.

There has been continuous debate that the Patent Act, as amended in 2002, is ambiguous with respect to definitions of patentability, with terms like "novelty", "industrial application", "prior art", being interpreted by the patent authorities in inconsistent manners. The domestic pharma industry wants the law to be re-looked at in the Patent Amendment Bill, 2003 which has been referred to a Group of Ministers.

Earlier, some of the MNCs had also challenged the denial of EMR. GlaxoSmithKline had challenged the denial of EMR to Rosiglitazone (Avandia) in Delhi High Court and a writ petition of Hoffmann La Roche against denial of EMR to Saquinavir mesylate is pending disposal in the Kolkata High Court. The removal of the Controller General, the subjective evaluation of EMR applications and the plight of pharma companies who are forced to approach the courts against such irregular decisions have brought into light the shortcomings within the Patent office and the urgent need for improvements in the Indian Patent Act. The Indian Government needs to study the Patent Amendment Bill, 2003 seriously and while complying with TRIPS, endeavour to remove room for subjective interpretation of the law and set higher standards and accountability criteria for the officials of the Patent Office.

Vivek Kathpalia or Avadhut Sawant

Source: The Economic Times, dated September 8, 2004 page 5

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

