

## 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

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