Pharma & Healthcare Update

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FIRST EXCLUSIVE MARKETING RIGHTS GRANTED TO INDIAN PHARMACEUTICAL COMPANY

On September 5, 2003 India's Controller General of Patents, Designs and Trade Marks granted the first ever exclusive marketing right ('**EMR**') in India to United Phosphorous for sale of its fungicide, which is sold under the brand 'SAAF'. The few applications, which were filed earlier by various companies, were not approved by the Controller on various grounds.

EMR entitles the EMR holder to have the **exclusive** right by himself, his agents or licensees to **sell or distribute** in India the article or the substance on and from the date of approval granted by the Controller for a period of five years or till the date of grant or rejection of patent application, whichever is earlier.

The provisions for the grant of EMR were introduced in the Patents Act, 1970 by the Patents (**Amendment**) Act, 1999, to bring the Patents Act, 1970 in compliance with Agreement on Trade Related Aspects of Intellectual Property Rights (**TRIPS**). TRIPS required insertion of EMR provisions with effect from January 1,1995, pending introduction of the product patent regime in the developing countries. The product patent regime is scheduled to come into effect on January 1, 2005.

EMR's can be granted in respect of substances intended for use or capable for being used as medicine or drug. However, no EMR can be granted in respect of chemical substances which are ordinarily used as intermediates in the preparation or manufacture of any of the medicines or substances.

By the amendment of 1999, Patent Offices were required to accept the product patent applications and keep them in, what is known as the "Black Box" till January 1, 2005, when such applications will be examined for the grant of patent. In the meantime, the applicant can apply for obtaining an EMR, which is granted if the following requirements are satisfied:

For inventions made in India or outside India if	For inventions made in India
Before filing Indian application, applicant has filed an application for the same invention in a convention country on or after January 1st, 1995	Before filing Indian application, applicant has filed an application on or after January 1st, 1995 for method or process of manufacture for that invention relating to identical article or substance and has been granted the patent on such application.
The approval to sell or distribute the article or substance in the basis of appropriate test conducted on or after January 1st, 1995 is granted in such convention country	
And has received the approval to sell or distribute the article from the authority specified in this behalf by the Central Government.	

United Phosphorous had already received a process patent for SAAF in 2001 while the product was introduced in the market and had been gaining market share. This first approval of an EMR, paves the way for more favorable EMR decisions till the start of 2005 when the 'black box' will be opened and pharmaceutical patents will gain momentum.

DELHI MAKES TRADE MARK SEARCH MANDATORY BEFORE GRANTING MANUFACTURING LICENSE

In a move to curb the spread and sale of counterfeit drugs, the Drugs Control Department of the National Territory of Delhi has made search reports from the Registrar of Trade Marks mandatory before approving any drug manufacturing license under a particular brand name.

This initiative by the Delhi Drugs Authority is in pursuance of the observations in the decisions of the Supreme Court on Cadila Health Care Ltd. vs. Cadila Pharmaceuticals Ltd. (decided on March 26, 2001). In paragraph 41 of the said judgment the Supreme Court has observed as follows:

"Keeping in view the provisions of Section 17-B of the Drugs and Cosmetics Act, 1940 which inter alia indicates an imitation or resemblance of another drug in a manner likely to deceive being regarded as a spurious drug it is but proper that before granting permission to manufacture a drug under a brand name the authority under that Act is satisfied that there will be no confusion or deception in the market. The authorities should consider requiring such an applicant to submit an official search report from the Trade Mark office pertaining to the trade mark in question which will enable the drug authority to arrive at a correct conclusion."

This provision of requiring search reports of trade marks if adopted in the other States in India will eliminate the chances of approval of a deceptively similar and look-alike brand of drugs. The Government of India has appointed Mashelkar Committee to study the various aspects of the growing threat from spurious drugs and give its report thereon. The committee has submitted its interim report. The drug regulatory officials have echoed their feelings and hope to get a positive response from the report in this regard.

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