



PHARMACEUTICALS EXPORT PROMOTION COUNCIL

(Set up by Ministry of Commerce, Govt. of India)

COPY

Date : 06-07-2010

News / Story reproduced with thanks:- **Pharmabiz**

Industry urges govt to remove clause on 'Patent status' in Form-44 of D&C Rules

Tuesday, July 06, 2010 08:00 IST

Ramesh Shankar, Mumbai

Direct link to the News/Story:-

<http://www.pharmabiz.com/article/detnews.asp?articleid=56253§ionid=>

The pharmaceutical industry in the country has urged the union health ministry to remove the clause relating to the 'Patent status of the drug' from the Form-44 of Drugs and Cosmetics Rules on the plea that the clause on the patent status of the drug only favours the patent holder to delay the entry of a generic drug in the market.

According to industry source, Form-44 of the Drugs and Cosmetics Rules, which is submitted to the drug controller general of India (DCGI) for grant of permission to import or manufacture a new drug or to undertake clinical trial, has an entry at Point No 1 (8) as 'Patent status of the drug'. The industry wanted the government to remove the entry relating to 'patent status' from the Form-44 as it is associated the principle of 'patent linkage'.

The patent linkage is a practice which is followed in some countries like US and this practice favours the patent holder to delay the entry of a generic product in the market. But in India, the DCGI is not authorised to examine the patent status of a drug which is to be decided by the courts.

The industry pleads that since the DCGI is not the patent authority in India, the entry relating to patent status should be deleted from Form-44. Concerned over the issue, the industry is seeking Union health minister Ghulam Nabi Azad's intervention on the issue, industry sources said.

Though the multinational companies have been seeking the introduction of patent linkage system in India, it has failed in its efforts so far.

Earlier, In a landmark judgement, a division bench of the Delhi High Court comprising chief justice AP Shah and justice Muralidhar had some time back dismissed an appeal by Bayer Corporation, a multinational pharmaceutical company, seeking the introduction of patent linkage system in India.

Patent linkage is a system in which the Drug Controller refuses to grant or delays a marketing approval to a generic drug manufacturer to manufacture and sell a drug, if the drug is already patented. Patent linkage is known to be against public health interests as it will delay the entry of cheap, generic medicines into the market and keep medicines out of reach of those who need them.

On the issue of introducing patent linkage in India, the Delhi High Court held, "This court cannot possibly read into the statute a provision that plainly does not exist. The scheme of both the Patents Act and the Drugs and Cosmetics Act are distinct and separate and the attempt by Bayer to establish a linkage cannot be

countenanced. Whether patent linkage should be introduced is an issue that requires a policy decision to be taken by the government. It is not for the court to determine if the government should bring in a system of patent linkage."

In 2008, Bayer Corporation filed a Writ Petition before the Delhi High Court against Union of India, the DCGI and Cipla Ltd seeking an order that the DCGI should consider the patent status of its drug, Sorefenib tosylate, before granting a marketing approval to any generic versions of the drug and refuse marketing approval to any generic version. Sorefenib tosylate is used to treat renal cancer and is sold by Bayer at Rs 2, 85,000 for 120 tablets for a month dosage.