

Lee Pharma to appear for fresh hearing on compulsory licence

New Controller-General to look into firm's plea to make patented diabetes drug

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Hyderabad-based Lee Pharma will have to wait for some more time for a hearing of its plea for a compulsory licence (CL) to manufacture patented diabetes drug saxagliptin.

Although it appeared for a hearing before the office of the Controller-General (CG) of Patents, Designs and Trademarks last month, it will now have to appear for a fresh one as a new CG has been recently appointed, an official of the Department of Industrial Policy & Promotion (DIPP) told *BusinessLine*.

The London-headquartered AstraZeneca holds the patent for saxagliptin.

"Since the new CG OP Gupta was appointed so soon after the hearing, it was decided that there should be a fresh one carried out by him as it is an important case and would need to be followed in the future as well," the official said.

Lee Pharma's application for a

CL — permission given by the government to an interested party to manufacture a patented product without the permission of the patent holder — was prima facie rejected by the Patent Office, Mumbai, in August.

The company had then applied for a hearing. "The former CG gave a hearing to Lee Pharma last month, but will now not divulge his views. The fresh hearing by the new CG has to be done from scratch," the official said.

So far, India has granted only one CL — to domestic generic manufacturer Natco to produce the low-cost version of Bayer AG's kidney and liver cancer drug Nexavar, in 2012. This was met with severe criticism from drug MNCs as well as rich nations such as the US and the EU.

Not apologetic

"We are not at all apologetic about the CL issued to Natco, as it was well deserved. Most countries, including the US, issue CLs, but call it by some other name.

So far, India has granted only one CL — to Natco to produce the low-cost version of Bayer AG's kidney and liver cancer drug Nexavar, in 2012.

But, at the same time, we are very careful while scrutinising CL applications to ensure that it is issued only when it meets the established criteria of inaccessibility or public health crisis in spirit," the official said.

Public requirement

Lee Pharma applied for a CL on the grounds that the drug is not available at an affordable price in the country, public requirement is not being met, and that the patent owner has not taken adequate steps to manufacture the drug in the country.

The Patent Office rejected it prima facie as there are a number of alternative diabetes drugs available in the market, and Lee Pharma was not able to convincingly establish that patients were suffering due to AstraZeneca's actions, the official said.

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