

‘Govt Not Properly Briefed on Glivec Patent Suit’

Drugmakers' lobby writes to Dept of Industrial Policy regarding the patent

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The lobby group of leading Indian drugmakers has written to Department of Industrial Policy and Promotion (DIPP) saying that the government counsel is not being properly briefed on the Glivec patent suit, a case which has wide implications on public health and local drug industry.

After its patent claim for blood cancer drug Glivec was rejected by Intellectual Property Appellate Board (IPAB) under section 3(d) of the Indian patent laws, Novartis has moved the Supreme Court to seek legal interpretation of the section and clarity on definition of terms such as "efficacy" and "known substance". Section 3(d) rejects patent for incremental innovations, unless it provides significant therapeutic efficacy to known compounds.

A favourable interpretation of the controversial provision would enable global drugmakers to get more patents in India, says Médecins Sans Frontières a global health group. This will restrict generic competition and make drugs unaffordable in India and developing countries, it said.

The case is considered to have wide implications on public health and local drug industry

"We understand that the case file has not yet reached the office of the attorney general," D G Shah, secretary general Indian Pharmaceutical Alliance (IPA) said in a letter to Industry secretary RP Singh on September 5. This may be a strategy of vested interests group to weaken the government's defence, Shah told ET.

The case was scheduled to resume hearing on September 6 but has been postponed after one of the

judges recused himself from the case. Attorney general Goolam Vahanvati or additional solicitor general Haren Rawal is expected to represent the government in the case. Vahanvati declined comment. Officials of DIPP could not be reached for comments. Former solicitor general Gopal Subramanian is leading the argument for Novartis. Harish Salve and Pratibha Singh will represent Cipla in the case.

Besides concerns on impact on public health, the case will also have major consequences for the Indian drug industry. Using the provision, IPA members have successfully challenged patent claims of foreign drugmakers and are one of the most powerful tool to fight patent cases. About half a dozen drugmakers such as Ranbaxy Laboratories, Cipla, Sun Pharma, Natco and Hetero Drugs have launched their low-cost version of Novartis blood cancer drug Glivec in India, Shah said.