

**GOVERNMENT OF INDIA
CHEMICALS AND FERTILIZERS
LOK SABHA**

STARRED QUESTION NO:427
ANSWERED ON:25.04.2013
GENERIC VERSION OF CANCER DRUG
Shekhar Shri Neeraj;Singh Shri Yashvir

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

- (a) whether the Supreme Court has allowed the manufacturers to continue making generic version of Glivec cancer drug in a recent judgement;
- (b) if so, the extent to which this judgement is likely to help the large number of cancer patients in the country and also Indian pharmaceutical companies; and
- (c) the extent to which this judgement is likely to affect the new inventions and investment by foreign companies and availability of good quality of drugs to the patients?

Answer

MINISTER OF STATE (INDEPENDENT CHARGE) IN THE MINISTRY OF CHEMICALS AND FERTILIZERS AND MINISTER OF STATE (INDEPENDENT CHARGE) IN THE MINISTRY OF STATISTICS AND PROGRAMME IMPLEMENTATION (SHRI SRIKANT KUMAR JENA)

(a) to (c) A statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO PARTS (a) TO (c) OF THE LOK SABHA STARRED QUESTION NO. 427 FOR ANSWER ON 25.04.2013 REGARDING GENERIC VERSION OF CANCER DRUGS

(a) To (c): The judgment of the Supreme Court in the case of M/s Novartis AG vs Union of India deliberates upon the patentability of the invention claimed by M/s Novartis in its application filed in the patent office, Chennai on 17th July, 1998. The Supreme Court has decided that the said invention fails in the test of invention and patentability as provided under Sections 2(1)(j), 2(1)(ja) and 3(d) of the Patents Act, 1970. Accordingly, the SLP filed by M/s Novartis was dismissed. The said judgment does not contain any orders in respect of manufacturing of generic version of cancer drug Glivec. In light of the said judgment, the cancer drug Glivec as the beta crystalline form of ImatinibMesylate is not a patented product and hence there is no restriction on the generic drug manufacturing companies for manufacturing the said drug. The Indian's IPR regime is fully compliant with TRIPS Agreement. As such, there is no reason for any foreign company to be apprehensive about protection of IPRs and effect on the new inventions and investment by foreign companies and availability of good quality of drugs to the patients in India.