

Natco Pharma continues fight against cancer drug of Novartis

Our Corporate Bureau

Hyderabad, June 20 Natco Pharma Ltd said that they are still opposing the application of Novartis India for grant of a patent for anti-cancer drug, Imatinab Mesylate (a drug useful in the treatment of certain forms of Chronic Myeloid Leukemia). Natco has now filed a pre-grant opposition application with the Controller of Patents, Government of India, challenging the validity of patent application (No 1602/MAs/1998) concerning crystalline modification of the drug. The ground of opposition is that the application for patent would fall within the concept of 'evergreening', as the polymorph claimed is the same as that of the 1993 molecule, thus, resulting in no merit for the grant of a patent, a company release said.

Natco has also claimed 'lack of novelty and inventive step' in the said application for grant of a patent. According to Natco, the invention of the drug was made in 1993, and the Indian patent application merely claims a crystal form (Beta) version of the same substance, hence, would not deserve consideration, the release added.

Novartis had obtained exclusive marketing rights (EMRs) for the drug, in November, 2003. Subsequently, Natco had challenged the grant of EMRs to Novartis, and the case is presently before the Supreme Court. To curb a widely prevailing practice called the 'evergreening' strategies, which involves a manufacturer obtaining patent beyond the basic molecule, the Indian Patents Act was amended in April 2005, which excludes grant of patents to salts, esters, ethers, polymorphs and similar forms complexes, combinations of known substance unless they differ significantly in properties with regards to efficacy.