Novartis loses patent claim on cancer drug — Patents Controller upholds Natco contention

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IN a major setback, the Swiss pharmaceutical giant Novartis AG has lost a patent claim for an anti-cancer drug — Imatinib Mesylate — before the office of the Indian Controller of Patents and Designs on Wednesday.

Following serious objections raised by Natco Pharma Ltd, a Hyderabad-based pharma company, the office of the Controller of Patents & Designs at Chennai has ruled against the claim of Novartis AG.

The patents office has refused to proceed further with the application for a patent filed by Novartis AG for Gleevec (Imatinib Mesylate), a life-saving drug used in the treatment of chronic myeloid leukaemia, sources told *Business Line*.

Novartis was earlier granted exclusive marketing rights (EMRs) in India for Gleevac. Natco Pharma, which launched a generic version of Gleevac under the brand `Veenat', had challenged the grant of EMRs to Novartis. This case is currently pending before the Supreme Court.

Subsequently, Novartis had applied for an Indian patent and Natco had filed pre-grant opposition petition before the Controller of Patents & Designs, as provided in the amended Patents Act and Rules.

According to the judgment copy available with this newspaper, the patent application was rejected after due hearings on three grounds — anticipation by prior publication, obviousness, priority and also on the ground that the product was a derivative of a known substance.

Natco has submitted to the Controller that Novartis AG has filed claim for a polymorphic form of Imatinib Mesylate. As per Section 3(d) of the Patents Act, any salt, polymorph or derivative of known substance is not patentable unless such salt, polymorph or other substance shows enhanced efficacy of the substance.

The Controller was informed that the specification states that wherever beta-crystals are used, the Imatinib free base or other salts can be used.

Further, Natco has submitted that the technical expert has conducted studies to compare the relative bioavailability of the free base with that of beta-crystal form of Imatinib Mesylate and has said that the difference in bioavailability is only 30 per cent and also the difference in bioavailability may be due to the difference in their solubility in water.

"The present patent specification (of Novartis AG) does not bring out any improvement in the efficacy of the beta-crystal form over the known substances rather it states the base can be used equally in the treatment of diseases or in the preparation of pharmacological agents wherever the beta-crystal is used.

"Even the affidavit submitted on behalf of the Applicant (Novartis AG) does not prove any significant enhancement of known efficacy," Natco submitted to the Controller.

Following this, the Assistant Controller of Patents & Designs, Mr V. Rengasamy, in his ruling on Wednesday said he was not convinced with the contentions of Novartis AG that the patent application claims a new substance. "It is only a new form of a known substance. It is found that this patent application claims only a new form of a known substance without having any significant improvement in efficacy."

Further, stating that Novartis AG failed to prove enhanced efficacy of the beta-isomer over the known substance, the Assistant Controller has concluded that, "the subject matter of this (patent) application (filed by Novartis AG) is not patentable under Section 3(d) of the Patents Act 1970 as amended by the Patents (Amendment) Act, 2005."

Fonte:
http://www.thehindubusinessline.com/2006/01/26/stories/2006012601150500.htm
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