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India - Roche 'Pegasys' patent revoked by Appeal Board

In a recent decision, the Intellectual Property Appellate Board (IPAB) revoked the patent for Roche's Hepatitis C 'Pegasys' drug. The decision strikes yet another blow to the global pharmaceutical industry, but is likely to be appealed.

Background

Roche's patent, granted in 2006, was one of the very first product patents to be granted in India following amendments to the *Patents Act* in 2005 that made provision for such patents.

The patent was opposed, unsuccessfully, by two separate parties in post grant opposition proceedings. The main grounds of opposition were that the claimed invention was not novel and lacked any inventive step.

The Assistant Controller decided both opposition proceedings on the same day, holding that the patent was valid: the invention was novel, industrially applicable, and involved an inventive step.

One of the parties, the Sankalp Rehabilitation Trust, a non-profit organization, appealed the Assistant Controller's decision to the IPAB.

The IPAB hearing and decision

Roche argued that a post grant opposition can be filed only by a 'person interested' and that to be 'interested' a person must have a genuine commercial interest. As the appellant was a non-profitable organization working for the benefit of drug users, it could not be said to have an 'interest' for the purposes of the Act. The IPAB held that as the opponent was a society working for the community of HCV and HIV sufferers, and revocation of the patent would break the monopoly and reduce the price of the drug in question, the appellant was definitely a 'person interested'.

The main issues on appeal, however, related to issues of novelty, inventive step and section 3(d) of the Indian *Patents Act*.

The appellant cited certain prior art documents that demonstrated that PEGylation, the process used in manufacture of the patented product, was already known to improve the activity of proteins, and argued that, therefore, the invention lacked novelty and inventive step. The prior art discussed the PEGylation of proteins with the NH group of lysine amino acid, disclosed a similar interferon, and suggested use of an MW of 40,000 daltons for PEGylation, all similar to the claimed invention.

The appellant's main argument, however, was that the invention fell within section 3(d): the patentee had not shown that there was any enhancement of the known efficacy of the linear PEG conjugate which was the known prior art molecule (s.3 (d) of the *Patents Act*). It is to be noted that under section 3(d) a new form of a substance must enhance the known efficacy of the

substance in order to be patentable. The patentee, however, argued that the branched conjugate of the subject invention was derived from interferon alpha, and not from linear PEG interferon, and further that the data provided in the specification to prove efficacy of the claimed molecule over the known substance was sufficient for the purposes of s.3 (d).

In this connection, IPAB noted that the complete specification stated that the invention was "a new class of PEG derivatives", and that it was, therefore, the Respondent's own case that the invention related to a new form of PEG derivative interferon. Further, it noted that the complete specification repeatedly talks about "surprising activity" when compared to other conjugated interferon. It also referred to the citations filed by the Respondent which discussed comparative data for molecular weight of unmodified interferon linear PEG , linear PEG and branched PEG and clearly showed that the Respondent admits that it should have shown a significant difference between the PEG derivative of interferon and the new form of PEG derivative. Further, the "surprising activity" of the PEG derivative as claimed in the specification, i.e. higher anti-proliferative activity and virtually no antibody formation, was not adequately supported by examples. IPAB, therefore, held, pursuant to s.3 (d), that the patent was invalid for the lack of inventive step.

Roche plans to appeal in order to clarify what is considered a 'known substance' for the purposes of section 3(d).

Our comments

The above decision tests the applicability of the controversial Section 3(d) of the Indian *Patents Act*, and considers whether the invention concerned involved any inventive step or an enhancement of known efficacy. The decision, yet another blow to the pharma majors, has been greeted with enthusiasm by the Indian generic industry and agencies lobbying for cheaper medicines. It will, however, now be interesting to see how the Courts interpret section 3(d).

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