

## Patent Application for Pediatric Anti-aids Drug Nevirapine Rejected

The Indian Patent office at New Delhi rejected a patent application by German drug major Boehringer Ingelheim claiming syrup form of anti-AIDS drug nevirapine.

The brief facts of the case were as follows:

The base salt i.e. Nevirapine used as anti-AIDS drugs was invented way back in 1989 by Boehringer Ingelheim and the base salt was never patented in India. But later on Boehringer Ingelheim filed an application for Grant of Patent rights for syrup form of its anti-AIDS drug nevirapine. In due course the application was published in the Indian Patent Journal and under the provisions of Section 25(1) of the Indian Patent Act, the Indian Network of People Living with HIV/AIDS (INP+) and the Positive Women's Network (PWN) filed a pre-grant opposition against the said patent application of Boehringer Ingelheim in May 2006 at New Delhi Patent office.

The effect of filing of Pre Grant Opposition by any person is that the application may be examined but would not be granted unless the Pre Grant Opposition is set aside. The patent application was objected under the most controversial provision of the Indian Patent Act, i.e. Section 3(d) that prevents many "new forms" of known substances from being patented unless there is a significant improvement in their efficacy with regard to previously known form.

Besides that the application was also opposed under section 3(e) of the Indian Patent Act that renders "mere admixtures" of substances resulting in aggregation of properties of the components from being a patentable invention in India.

The relevant provisions of the Indian Patent Act read as under:

### CHAPTER II

#### INVENTIONS NOT PATENTABLE:

3. What are not inventions- the following are not inventions within the meaning of this Act,---

(d): the mere discovery of a new form of a known substance which does not result in the enhancement of known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one reactant.

Explanation: For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of

isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

Section 3 (e): a substance obtained by a mere admixture resulting only in the aggregation of the properties of components thereof or a process for producing such substance;

The Patent office agreed with the contention of the Indian Network of People Living with HIV/AIDS (INP+) and the Positive Women's Network (PWN) and rejected the patent application of Boehringer Ingelheim for syrup form of anti-AIDS drug nevirapine under Section 3(d) and (e) of the Indian Patents Act.