Issues concerning patentability of discoveries in India

Indian Patent Act provides a list of subject matters that are not patentable. The list is provided under Section 3 of the Act. One of the sub-clauses, Section 3(d), has been widely debated, and is the topic of this article.

Section 3(d) of the Act states:

> *What are not inventions:*
>
> *"the mere discovery of a new form of a known substance which does not result in the enhancement of the 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 process, machine or apparatus unless such known process results in a new product or employs at least one new 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(d) which earlier read: "the mere discovery of any new property or new use for a known substance …" in the Patents Act 2002, was substituted to be read as – 'the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance…' in the amendment in 2005.

On a general note, the Section states, a "mere discovery" of a new form or a new use of a known substance is not patentable. However, the interpretation the Section is far from simple. An attempt to decrypt the lines in Section 3(d) has been made below.

The Indian Courts:

A landmark decision to be considered under the section is the decision upheld by the Supreme Court of India in ***Novartis AG v Union of India***. The constitutional validity of Section 3(d) of was questioned on the ground that the section violated Article 14 of the Indian constitution and

did not comply with the regulations of TRIPS. The details of the case can be read in detail at http://supremecourtofindia.nic.in/outtoday/patent.pdf

The issue originated in the year 1997 when a patent application was filed by the petitioner before the Chennai patent office related to drug name 'GLIVEC', which was a different version of their already patented drug - 'ANTI LEUKAEMIA'. The Controller of Patents rejected the application under Section 3(d) of the Indian Patent Act 1970. The court upheld the Controller's decision. The Court further held that in India, in case of a conflict between the international laws and municipal laws, municipal laws prevail.

The key words that help in the interpretation of the section 3(d) are:

— "Mere Discovery"

The drug 'GLIVEC' was called only a "mere discovery" of a previously known drug.

With the use of the word "Mere discovery", the Section has drawn a line between the words "Invention" and "Discovery".

— "Efficacy"

The Section puts forward "enhancement of the known efficacy" as another requirement for a substance to be patentable. However, the term "efficacy" or its extent is not explained anywhere in the Act. Looking at the general meaning of the term, which is, "Power or capacity to produce a desired effect", it can be derived that a higher level of "invention"/ "effect" is important for a substance to be patented.

With reference to the case mentioned above, the Madras High Court applied a restrictive interpretation and held that the definition of "efficacy" could mean therapeutic efficacy only.

The EPO and the USPTO:

The European Patent office provides a list of exceptions that are not patentable; out of which, in the chapter II, Part 3.1 considers discoveries as un-patentable.

However, under the USPTO, the definition for Inventions reads -

> *Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.*

Conclusion:

TRIPS provides flexibility to member nations in framing their patent laws. Hence, patent laws of different countries may have varying stand on patentability of "discoveries". With respect to India, questions on patentability of discoveries, the differentiation between "Invention" and "Discovery", and scope of the word "efficacy" prevail, and the courts have a major responsibility to take over.

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Best regards – Team InvnTree