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# Get prudent with the patents law

To start with, India should rethink its 'ever-greening' argument given to justify Section 3(d) rules

Protection of intellectual property rights (IPR) is an important contributor to economic, social and technological progress in a country. Recently, IPR protection, particularly in the pharmaceutical industry but also related to other sectors, has generated much debate in India.

Patents are granted to encourage inventors to not only 'invent' but to disclose their invention rather than keeping them as trade secrets. Inventors, working independently or as part of the research and development department of a business enterprise, feel encouraged by a strong patent system and companies are able to recover their R&D investments from the exclusivity which the patents provide. According to international and Indian patent laws, for an invention to be patentable, it must satisfy three conditions, namely:

- it must be new (referred to as the novelty requirement),
- it must be non-obvious (often called the inventive step) and,
- it must be capable of industrial application (referred to as utility).

One of the issues that has been the subject of debate has been Section 3(d) of

the Indian Patent Law. Section 3(d) was inserted in Indian law in 1970, but in its present form, it was introduced only in the year 2005. Section 3(d) says that certain subject matters are not considered inventions and that the mere discovery of a new form of a known substance can only be regarded as an invention if the new form results in an enhancement in the known efficacy of that substance.

Many argue that Section 3(d) is necessary to prevent so-called 'ever-greening' or the attempts by companies to make trivial changes to the subject matter to keep prolonging the lifetime of their patented products beyond the 20-year life term. However, once a patent expires anyone can use that technology and apply for a patent on improvements that satisfy the three conditions to be patentable. Accordingly, if a company obtains a patent on a new form of a known compound, that need not prevent the public from manufacturing, using, or selling the compound in its original



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form once the earlier patent has expired. This means the idea of 'ever-greening' is simply unfair and not true.

In the Novartis Glivec case, the Indian Supreme Court held that provisions of Section 3(d) effectively added a fourth substantive criteria to patentability that of enhanced efficacy. Novartis' application for a patent

was objected to and denied by the Controller of Patents citing various reasons including that the application is barred under Section 3(d) of the Act. The Supreme Court held that pharmaceutical patents are subject to a higher threshold for patentability than non-pharmaceutical patents.

Some have also argued that Section 3(d) prevents frivolous patents and that the proof is in the tens of thousands of pharmaceutical patents that have been granted to companies. While it may be true that India has granted numerous pharmaceutical patents, looking at the total number of patents granted is not

the appropriate way to characterise the strength of the IPR environment. Pharmaceutical patents can be related to different inventions ranging from manufacturing steps to delivery devices to new molecule discoveries, and the number is not necessarily indicative of a single new drug.

The nuances of India's patent laws will continue to generate attention and it is important to understand the myriad complexities of Indian patent laws in the pharmaceutical and other arenas.

Just as each nation must take its own culture, values and norms into consideration when crafting laws and regulations, India's patent system must remain fundamentally Indian. The challenge for the Indian government will lie in creating a system that rewards innovation and risk and that also remains in sync with long-established international precedents and laws. The degree to which the government of India can accomplish this delicate balancing act will determine the future of innovation in India.

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