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Indian patent law on pharmaceuticals: challenges and opportunities

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Introduction

Indian patent law on pharmaceuticals differs from other countries in several ways, some of which are among the most debated IP topics domestically. The profound differences include:

- a stricter bar on the patenting of pharmaceutical inventions in general;
- some unique obligations during prosecution, such as section 8 requirements (relating to the corresponding application details);
- the requirement to provide an annual working statement and provisions on compulsory licensing;
- the possibility of multiple challenges at various stages of the life cycle of a patent (namely, pre- and post-grant oppositions, revocation and counterclaim in infringement suits);
- lack of patent term extensions; and
- lack of linkage between patent and drug regulatory provisions.

While some of these differences apply to non-pharmaceutical patents as well, the combination of these issues along with stricter patentability requirements poses significantly greater challenges to pharmaceutical patents.

Patentability requirements

Indian patent law provides for a stricter bar and an additional test of patentability for pharmaceuticals. Besides novelty and inventive step, pharmaceutical patents must undergo a test under section 3(d) of the Patents Act. Section 3(d) provides that "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" is not patentable under the Act. The explanation to the section states that substances such as salts, esters and polymorphs shall be considered as the same substance unless they differ significantly over the substance's known efficacy.

The explanation to section 3(d) lists many different types of substance, and the lack of proper interpretation has often led to a negative outcome for innovations. One of the key concerns is that the identification of what is "a known substance" and what is its "known efficacy" is often inconsistent and left up to the examiner's interpretation. Section 3(d) is often used and abused against primary patents as well. It is pertinent to note that the Act does not in any way bar the protection of incremental innovations, but only requires that they must pass the additional test of section 3(d). More often than not, opponents use this provision blatantly to challenge patents without its correct applicability to the claimed invention.

Oppositions

The lack of clarification in the Act has often led to opponents filing groundless serial pre-grant oppositions in pharmaceutical patents. Further, the trend of filing pre-grant oppositions is increasing exponentially. For example, the annual Intellectual Property Office Report confirms that while a total of 426 pre-grant oppositions were filed in 2018-19, in 2019-2020, this number had exponentially increased to 800 pre-grant oppositions, whereas the number of applications filed remained similar. Most oppositions were filed against pharmaceutical inventions.

In many cases, more than six pre-grant oppositions are filed in a single application. These pre-grant oppositions (which sometimes include even no name ("*benami*") oppositions) unnecessarily delay grants. The Mumbai High Court, in *Dhaval Diyora v Union of India and Ors*[(1)] strongly criticised such *benami* oppositions and noted that the legislature had not conferred the right under section 25(1) to any person to abuse the right. The Intellectual Property Appellate Board (IPAB) (during its existence) also came down heavily on such *benami* pre-grant oppositions and even directed that to curb the filing of pre-grant opposition by *benami* or fictitious applicants, "any person" filing a pre-grant opposition must submit their valid Aadhar card, voter ID, passport or driving licence to authenticate their identity.

Lack of patent term extensions or patent linkage

Additionally, Indian patent law has no provisions for term extensions or adjustments, unlike in the United States, so delays due to prosecution or pre-grant oppositions (or even due to regulatory delays) cannot be reclaimed.

There is also a lack of linkage in India between the patent and marketing approval process for drugs. This often brings complex challenges to innovators looking to enforce their patents in India. As such, it is advisable to watch for signs of infringement and take early action.

Comment

Despite the above issues, recent trends in local pharmaceutical patent enforcement and litigation have been encouraging. The decisions from the courts and the erstwhile IPAB have not only been well reasoned, but they have also been swift. Some of these decisions clarified

laws on various important aspects of Indian patent laws, such as oppositions by *benami* parties, criteria for filing divisional applications, scope of claim amendments and cross-examinations in oppositions.

For most of 2020, the Indian courts functioned virtually, before gradually moving to in-person hearings in 2021. They continued to enforce patents amidst the challenges from the pandemic.

A key development during the past year has also been the abolishment of the IPAB in April 2021, followed by the creation of a specialised Intellectual Property Division (IPD) by the Delhi High Court (within three months) to fill the gap. In early 2022, the Delhi High Court issued two rules – namely, the IPD Rules and the Rules governing Patent suits – which bring clarity on several points pertaining to IP rights matters before the Delhi High Court. The recent review of the IP rights regime in India by the Parliamentary Standing Committee on Commerce recommended that such dedicated benches be created in all High Courts.

Thus, despite the differences in the Indian pharmaceutical patent system, Indian patent law is evolving, and increasing litigation as well as efforts from the government at various levels is helping to shape the jurisprudence.

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Endnotes

(1) Writ Petition No. 3718 Of 2020.