

Freedom under TRIPS facilitates promotion of public health objectives in India

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Abstract

Within the mandate of TRIPS agreement India has set its own patentability standards which define grounds for rejecting a patent and patentee rights. India has in the year 2013 within the precincts of its amended patent laws, which are in alignment with TRIPS, passed two landmark rulings. Natco pharma was issued a compulsory license for manufacturing Bayers drug Nexavar and Novartis' drug Glivec was not issued patent protection. This article discusses the two cases in light of the TRIPS agreement that provides important flexibilities to a country's government to decide and set their own standards for patentability.

Keywords: TRIPS, Public health, India's compliance, compulsory license, IPAB, Natco, Evergreening, Glivec, Nexavar, Novartis

Introduction

India's compliance with TRIPS in 2005 saw its patent regime undergoing a vast and structured change in the area of pharmaceutical and agrochemical products. India started to recognize product patents and has started to grant them for 20 years.

The TRIPS agreement mandates that member countries adopt and enforce certain minimum standards of IPR protection (1). But most importantly the TRIPS agreement recognizes that it should provide certain flexibility to its member countries to find a balance where innovation is encouraged and nurtured by providing a well defined IP regime but also within the regime provisions can be made

whereby in certain situations public health can be protected by patent exclusion (2). This is especially relevant for developing nations who rely on affordable drugs and medicines for their population.

To become compliant with TRIPS India made three major amendments to the patent act of 1970 which were in 1999, 2002 and 2005 (3). The 2005 patent amendment contains many important features that derive from the flexibility that was permitted within the TRIPS agreement to promote and protect public health objectives.

In the past year (2012-13) India made two landmark court rulings using flexibility under TRIPS to exclude two multinationals from being granted patentee rights for the benefit of public health. Cited below are the two court rulings in detail.

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Provision to Grant Compulsory License

Compulsory licensing (CL) is when a government allows someone else to produce the patented product or process without the consent of the patent owner. It is one of the flexibilities on patent protection included in the WTO's agreement on intellectual property — the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement (4). Compulsory licensing is a mechanism that can limit the exclusive rights of the patent owner when certain objectives of public policy are needed to be fulfilled, particularly in order to ensure the availability of alternative sources for the supply of medicines at lower prices.

The Indian Patent office granted its first compulsory license in 2012 to Natco Pharma which was upheld by the IPAB in March 2013. The decision was taken on an appeal filed by Bayer Corporation against the Compulsory license issued to the generic drug manufacturer in March 2012 to manufacture and sell the generic version of Nexavar (5).

In the Indian Patents Act 1970 the Sections 84, 91 and 100 enlist the various ways that a CL can be issued. The Sections 91 and 100 are provisions for government to issue CL sans any application by a third party when it deems appropriate for example in disease outbreaks or other emergency situation. Section 84 can be cited for application of a CL by any third party. Natco cited section 84 in its application for CL for Nexavar (6).

Section 84:

“(1) At any time after the expiration of three years from the date of the 1[grant] of a patent, any person interested may make an application to the Controller for grant of compulsory license on patent on any of the following grounds, namely:— (a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or (b) that the patented invention is not available to the public at a reasonably affordable price, or (c) that the patented invention is not worked in the territory of India.”

The ruling in favor of NATCO was based on the findings that Bayer satisfied all of the above listed criterions:

1. Bayer supplied the drug to only 2% of the patient population; therefore the reasonable requirement of the public with respect to Nexavar was not met.
2. Bayer's drug was available at an unreasonably high price (Rs 2.8 lakhs for a months' supply of the drug) therefore it didn't doesn't fulfill the “reasonably affordable” price criterion.

3. Bayer did not sufficiently “work” the patent in India which was interpreted by the Controller to mean that the patentee didn't manufacture the drug to a reasonable extent in India.

India's decision of granting compulsory license for the drug Nexavar is compliant with the flexibility in patent regulations made available by TRIPs, which allows for such measures when a large number of patient lives are at stake. It shows that new drugs under patent can also be produced by generic makers at a fraction of the price, while royalties are paid to the patent holder, thus promoting access to medicines (7).

Provision to Prohibit Patent Evergreening

India in its patent law amendments for TRIPS compliance introduced laws that prohibited an industry strategy called “evergreening.” Evergreening is where a company extends its patent beyond 20 years on a drug by repatenting slightly modified follow-on drugs (8). India, Brazil, Thailand, and South Africa are one of the few countries with laws against evergreening. The Indian Patent Act, as amended by the Patents (Amendment) Act 2005, section 3(d) states that drugs cannot be patented if they result from

“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 cannot be considered as an invention” (9).

It further clarifies that “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” (9).

In a landmark case, in April 2013, India's Supreme Court rejected Swiss drug maker Novartis attempt to win patent protection for its cancer drug imatinib mesylate (marketed as Glivec). The court ruling stated that the product fails the tests of invention and patentability requirements of India's patent law as there had been no new innovation in the form of a new substance used in the drug (10).

Imatinib mesylate (Glivec) is used to treat several forms of cancer including chronic myelogenous leukaemia and is the salt form of its precursor imatinib. Novartis showed that imatinib mesylate had a 30% increase in bioavailability compared with imatinib. However, the Patent Office didn't

consider this sufficient to meet the “enhanced efficacy” requirement of the Indian Patent Act.

The Court decision was a balance between the need to promote R&D in science and technology and to keep private monopoly at the minimum. The arguments were in faithful compliance of the international treaties and protected India’s status as ‘the pharmacy of the world.

Conclusion

The year 2013 has seen two important state rulings that have set a benchmark for intellectual property cases in India where many patented drugs are unaffordable for most of its 1.2 billion people. The ruling also reinforces the role of Indian Pharmaceutical companies as major suppliers of inexpensive generics to the Indian market and also across the developing world.

At this point it is important to state that while India has rejected the Glivec and Nexavar for the reasons cited above, there are in all only 3% of patents filed by multinational pharmaceutical firms that are under dispute (11). Also between April 2010 and March 2013, India issued 1,001 drug patents of which 771 were given to foreign drug makers which are 77% of all patents won (12).

These statistics illustrate that while India is not overly guarded and reluctant to grant patents it is treading cautiously and has intervened where it deemed appropriate within the context of national health needs.

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