

India's patent laws under pressure

Pending cases against India's patent laws threaten public health and misinterpret international intellectual property agreements, say Peter Roderick and Allyson M Pollock.



The effect of the international harmonisation of patent laws is in the spotlight this month as global pharmaceutical giants Bayer and Novartis' legal challenges to key provisions of India's Patents Act come to a head.

India's Intellectual Property Appellate Board is reported to have reserved its decision last week after hearing Bayer's appeal, backed by the USA, against the first compulsory licence granted in India earlier this year to the generic producer Natco (panel 1). The Obama Administration has been consistent in its efforts to stop compulsory licences, with the Deputy Director of the US Patent and Trademark Office describing the granting of this licence as the "most egregious" example of anti-TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights) behaviour. Meanwhile, the Indian Supreme Court is due on Sept 11 to finally hear Novartis' sustained legal challenge to India's rejection in 2006 of the company's patent application for Glivec.

Also in September, chief negotiators from the European Union (EU) and India are due to meet to "take stock" of talks which have dragged on for 5 years to finalise a Free Trade Agreement, which would reportedly extend patent protection in the country beyond that agreed at the World Trade Organization (WTO).

This month therefore presents an opportune moment to consider the compatibility of key aspects of India's patent laws with its obligations under the TRIPS Agreement, made at the WTO in 1994 to harmonise international patent protection.

TRIPS obligations

The harmonising TRIPS Agreement sets out minimum standards of

protection for patents and other forms of intellectual property and general principles for domestic enforcement procedures, as well as making disputes

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between countries over intellectual property subject to the WTO's dispute settlement procedures. One of its most far-reaching requirements for many countries was mandatory patentability of pharmaceutical products. India, which had previously only allowed patents for pharmaceutical processes, amended its 1970 Patents Act three times—in 1999, 2002, and 2005—to comply with its TRIPS obligations.

In theory, several lawful opportunities exist for developing countries to minimise the impact of TRIPS on access to medicines. Taking advantage of them in practice, however, requires political will, legal expertise, and administrative effort. For example, countries are entitled to pay close attention to the preconditions for patent availability; to the permitted criteria and categories for excluding patentability; to the disclosure requirements of applicants; and to the discretions expressly granted in these connections. And they can set limited exceptions to the exclusive rights conferred by a patent. For example, the WTO dispute panel rejected the EU's challenge to Canada's pro-generics law which allowed third parties without the patent holder's

consent "to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required" for marketing approval.

If a patent has been lawfully granted, Article 31 of the TRIPS Agreement allows countries to authorise non-exclusive, non-assignable use of the subject matter of a patent, predominantly for the supply of the domestic market, subject to adequately remunerating the holder. Authorisation is subject to several further conditions, including scope and duration, and is also subject to prior negotiation attempts to get a voluntary licence. However, the grounds for such authorisations are not set out in Article 31.

Use by governments or by third parties authorised by governments,

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For the **UNDP report** see http://www.undp.org/content/india/en/home/library/poverty/five_years_into_theproductpatent_regimeindiasresponse.html

Panel 1: The battle over sorafenib

Sorafenib tosylate (Nexavar) was invented by Bayer in the 1990s and launched in 2005 for the treatment of advanced kidney and liver cancer. By 2008, Bayer had obtained an Indian patent, as well as import and marketing approval, and launched the drug. In early 2010, Cipla began selling a generic version of the drug in India. In December, 2010, Natco, another Indian generic producer, wrote to Bayer requesting a voluntary licence to sell the drug. It seems that Bayer did not reply to Natco's request. In April, 2011, Natco received a licence from the Drug Controller General of India to manufacture the drug in bulk and for marketing it in tablet form, and in July, 2011, applied for a compulsory licence. The licence was granted in March, 2012, with a 6% royalty awarded to Bayer. Bayer was charging about US\$5039 (INR 280 420) per month for the drug, Cipla about \$539 (INR 30 000—but is reported to have since dropped this amount to about \$123 (INR 6840), and the Natco licence authorises about \$158 (INR 8800) per month. Bayer's worldwide sales of the drug from 2006–10 were \$2.99 billion. In India in 2011, Bayer only sold 593 boxes—reaching on its own admission only 2% of eligible patients—compared with Cipla's 4686 boxes. In Natco's view, 70 000 boxes are needed annually.

Source: The information in this panel is mainly taken from the decision of the Indian Controller of Patents, in Natco versus Bayer, March 9, 2012. Current internet exchange rates have been used to convert amounts in Indian rupees to US dollars.

Panel 2: Section 3(d) of the Indian Patents Act 1970, as amended

3. 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 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.

are recognised examples of use without the patent holder's consent. These uses often take the legal form of a compulsory licence, a traditional and widely applied limitation on the monopoly power of patents that has been traced back to the Patent Congress held at Vienna's World Fair in 1873. The Paris Convention for the Protection of Industrial Property 1883 (as revised and amended), which is binding for TRIPS signatories, also states that countries have the right to make laws allowing for compulsory licences "to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work".

Under section 84 of the Indian Patents Act 1970 (amended twice post-TRIPS), 3 years after a patent has been granted, an application for a compulsory licence can be made on one of three grounds: that the reasonable requirements of the public with respect to the patented invention have not been satisfied; or that the patented invention is not available to the public at a reasonably affordable price; or that the patented invention is not worked in the territory of India. In the Bayer case, India's Controller of Patents was satisfied on each of the three grounds.

Section 84 of the Indian Patent Act seems to be entirely compliant with the TRIPS Agreement. The grounds on which a compulsory licence may be granted are not specified in the TRIPS Agreement, as emphasised by the 2001 Doha Declaration on the TRIPS Agreement and Public Health, paragraph 5(b) of which states that "Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted". And, as Nuno Pires de Carvalho, director of the IP and Competition Policy Division at the World Intellectual Property Organisation, states: "WTO Members that are Paris Union Members have been authorised for over one century to grant compulsory licences on grounds of a lack of working, regardless of the technological field of the patents in question. They have since been fully aware that compulsory licences might also be granted in the area of public health, and especially in situations of crisis."

The US seems though to be taking issue with the Indian Controller of Patent's view that "worked in the territory of India" means "manufactured to a reasonable extent in India". Even if this interpretation was either wrong in principle or not supported by the evidence, both of the other grounds in section 84 are met, and only one ground is needed for a compulsory licence application.

As well as being a well established basis for granting compulsory licences, "failure to work" was established by a famous US case nearly 70 years ago to be abusive when the patented article is important for public health purposes.

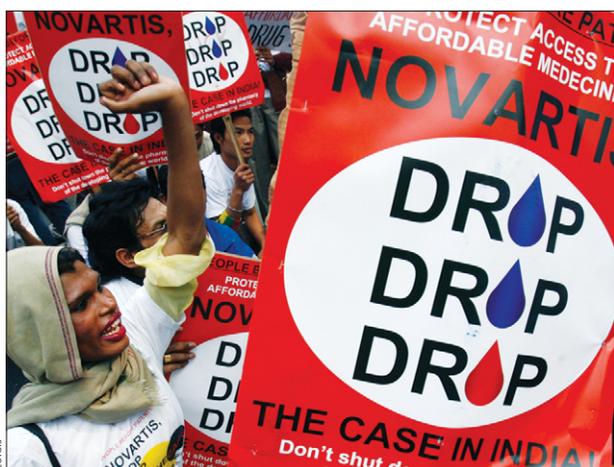
It might be that there are concerns that the licence has been granted without any suggestion of an urgent public health emergency being underway, but there is no support in Article 31 of the TRIPS Agreement for restricting licensing to such a situation. Of course, such a situation could merit such a licence, but the only relevance of such an emergency in Article 31 is to allow waiver of the precondition of first making reasonable efforts for a reasonable time to get a voluntary agreement.

The Novartis case

At stake in the Novartis challenge is section 3(d) of the Indian Patents Act, a provision aimed at preventing "low quality" or "secondary" patents for drugs that do not demonstrate enhanced efficacy (panel 2).

The company's antileukaemia drug Glivec—containing a β crystalline form of imatinib, a methanesulfonate salt—was refused a patent in January, 2006, based largely on this provision. Since then, the company has been engaged in several substantive and procedural challenges, before the Madras High Court, the Intellectual Property Appellate Board, and now the Supreme Court, all aimed at reversing the 2006 decision (panel 3). So far, it has failed in its arguments that section 3(d) violates Article 27(1) of the TRIPS Agreement and Article 14 of the Indian Constitution for being vague and arbitrary.

Section 3(d) is particularly important since many secondary patents have been granted in India following the inconsistent application of this provision, according to the UN Development Programme (UNDP). Its review also found that "in interpreting the meaning of 'efficacy'



Indian activists protesting against the Novartis patent case

in Section 3(d), an extremely high standard applies; an 'advantageous property' is not the same as efficacy and 'new forms' that result in advantageous properties with respect to bioavailability, stability, etc, are not patentable".

Article 27 of TRIPS generally mandates patentability where inventions are new, involve an inventive step (or are non-obvious), and are capable of industrial application (or are useful). Provisions such as section 3(d)—which has also, for example, been adopted in the Philippines—are examples of how countries can approach interpretation of each of these three preconditions of patentability. It is difficult to see the public interest in granting patents for minor modifications, which are not of improved public health benefit. In the context of the proliferation of drug patents—between 2005–11, 4064 Indian patents have been granted for pharmaceutical products, with a further 12 689 applications pending—ensuring patents are only granted for genuinely new and useful products, seems eminently sensible. Section 3(d)'s limited integration of efficacy considerations, more traditionally seen in drug-marketing laws, is a sound and long-overdue attempt to rectify the low level of proof of real utility that mars patent regimes. The provision goes some modest way to counteract the conclusion of UNDP's 5-year review of post-TRIPS experience in the country that "little has changed to dispute the conventional wisdom that developing countries should not grant product patent protection in pharmaceuticals. They are already paying the cost of high prices of patent protected products without having seen the supposed concomitant technological benefits".

Conclusion

In trying to limit compulsory licences and avoid efficacy tests on products, the Bayer and Novartis cases are

seeking to undermine public health considerations aimed at improving access and therapeutic advantage. The TRIPS Agreement does not limit the grounds on which compulsory licences can be granted, and does not prevent patent applicants from having to demonstrate enhanced efficacy for their allegedly new and useful inventions. There are many problems facing access to and

rational use of medicines in India but the provisions within the country's patent laws, if more extensively and properly applied, should help rather than hinder such access. India's laws and experiences could provide a useful example for low-income and middle-income countries worldwide.

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Panel 3: Timeline of Glivec's legal history in India

July 17, 1998: Novartis applies for a patent for "Crystal Modification of a N-Phenyl-2-Pyrimidineamine derivative, processes for its manufacture and its use", application No.1602/MAS/1998

May–July 2005: Cancer Patients Aid Association, Natco, Cipla, Ranbaxy, and Hetro file representations opposing the application

Jan 25, 2006: the Assistant Controller of Patents and Designs refuses the application, after hearings. Novartis subsequently challenges the refusal in the Madras High Court

April 2, 2007: the provisions of the Patents Act relating to appeals to the Intellectual Property Appellate Board (IPAB) are brought into effect, with the then Controller General of Patents, Designs and Trade Marks—Shri S Chandrasekaran—appointed as the Board's Technical Member (Patents)

July 20, 2007: the IPAB rejects a challenge by Novartis to Chandrasekaran sitting on its appeal, ruling that the appeal should be heard by the IPAB Chairman and Technical Member (Patents). Novartis had argued that this individual should not sit on its appeal as he had been the chief Controller of Patents when the Glivec patent application was refused in 2006

Aug 6, 2007: the Madras High Court rejects Novartis' arguments that section 3(d) of the Patents Act is not compliant with TRIPS and the Indian Constitution

Nov 13, 2007: the Madras High Court upholds Novartis' challenge to the IPAB's decision not to remove Chandrasekaran from the appeal, ordering the IPAB to constitute a special bench consisting of the Chairman and the Vice-Chairman—neither of whom are technical experts—to hear the appeal

Jan 28, 2008: the Indian Supreme Court rules that the appeal hearing should not proceed before an IPAB constituted as required by the Madras High Court, following a challenge brought by Natco, arguing that the particularly technical nature of the issues in the Glivec appeal require a technical expert

Oct 1, 2008: the Indian Supreme Court rules that the IPAB hearing the Glivec appeal must include a technical expert, namely Shri P C Chakraborti, Deputy Controller of Patents and Designs

Dec 24, 2008: the appeal hearing concludes before the IPAB, consisting of the Chairman (Shri Z Negi) with Shri P C Chakraborti as Technical Member

June 26, 2009: the IPAB rejects Novartis' appeal

Sept 11, 2012: Supreme Court hearing scheduled

Source: IPAB decision, June 26, 2009; judgment of the Madras High Court in *Novartis AG versus Union of India*, Aug 6, 2007; US Department of State cables released by Wikileaks, available here: <http://keionline.org/node/1253> (accessed Aug 23, 2012); Supreme Court Order, Aug 22, 2012, available here: <http://courtnic.nic.in/supremecourt/qydisp.asp> (accessed Aug 29, 2012).