

A critical view of the new Indian Patent (Amendment) Act 2005

On 23 March 2005 the Patent (Amendment) Bill 2005 was passed by the Rajya Sabha (Upper House). There has been very little public debate around the Bill to determine the effects of the amendments that have been made.

Several amendments have been made to the Ordinance (the new Patent Bill 2005). However, many of these fail to address the serious concerns of the issues relating to access to medicines.

From the text that has been made available, the following provides a critique of the key issues of the new law which were voted on and the potential impact:

Expansion of the Scope of Patentability:

TRIPS does not define the basic criteria of patents viz. novelty, inventive step and industrial application. Further, the only obligation under TRIPS Agreement is to protect pharmaceutical products. As a result implementing countries have the option to limit the patent protection only to a new chemical entity. However, according to latest reports data shows that there are 8926 applications pending for examination in the mailbox in India, the vast majority by U.S and E.U multinational pharmaceutical companies. However, only 274 new chemical entities received marketing approvals from the US FDA between 1995-2003. This is a clear indication that many of the applications in the mailbox are patenting of products with frivolous or marginal changes and, therefore, fall outside of the requirement of protection required for patents by TRIPS.

The clauses in the Bill to limit the scope of patentability are extremely ambiguous and full of technical loopholes which allow for "evergreening". Ideally the law should clearly limit patent protection to "new chemical entities".

Some of the key issues relating to the scope of patentability are given below.

Inventive Step :

The Bill provides the following definition of what is required of a patent application to meet the inventive step criteria:

"a feature of an invention that involves technical advance as compared to the existing knowledge **or** having economic significance or both that makes the invention not obvious to a person skilled in the art".

The above provision arguably broadens the existing provision to the benefit of patent holders and is ambiguous to the extent that it allows for two criteria for meeting an inventive step. As it stands, to meet an inventive step criteria the patentee will either have to show that the invention includes a "technical advance" or has economic significance, or both.

The provision should have required the applicant to comply with both requirements for an inventive step, namely "existing knowledge and having economic significance" and delete the term "or both". Otherwise, the requirement of technical advance is compromised and diluted by the fact that a patent could be simply granted on economic significance alone. Economic significance alone, cannot determine the inventive step of a patentable invention.

Pharmaceutical substance:

The amendment currently describes "Pharmaceutical substance" as "any new entity involving one or more inventive steps".

As it stands, the provision is too broad as it allows all types of pharmaceutical substances. The term "chemical" ought to have been inserted so as to read "any new chemical entity".

Inventions not patentable:

Section 3(d) has been amended to read:

"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 the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least employs one new reactant".

The use of the phrase "which does not result in the enhancement of the known efficacy" is ambiguous, too broad and potentially allows for new forms of existing substances to become patented. For example, "result in enhancement of efficacy" could be a minor amendment to an existing invention to in order to get around the provision as it stands.

In addition, the new Act retains the word "mere" which potentially causes ambiguities within the provision.

Also, the explanation supporting the above provision provides:

"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".

The phrase "unless they differ significantly in properties with regard to efficacy" is not necessary and offers an entry point in favour of the patentee, thus leading to excessive litigation. For example, certain properties are never known or are clear at the time of application in the claim so one would not know how they differ, thus leaving any recourse to opposition.

The definition of pharmaceutical substance is not linked to the provisions relation to the exclusion for patents and, therefore, stands alone. Furthermore, the inventive step requirement has been severely diluted. As a result, section 3(d) allows "evergreening".

Immunity to ongoing generic production:

The Bill permits generic manufacturers to continue producing generic version of new drugs which are in the mailbox. However, this only applies where the generic producer has made a significant investment provided they were producing and marketing the generic version prior to 1 January 2005. However, the generic companies are required to pay the patent holder a reasonable royalty.

The question of "significant investment" poses a threat of potential infringement suits as the generic producer would have to clearly show that it has made what would be considered a significant investment in producing

and marketing the generic drugs. With respect to the reasonable royalty¹ it creates the problem of excessive demands from the patent holder and litigation. The reasonable royalty rate should have been fixed at a particular percentage, the norm being 4%. For example in that in South Africa, Glaxo Smith Kline demanded a royalty of 25 % before the courts intervened.

Pre-grant Opposition:

The amendment has restored the ability for any member of the public to oppose patent applications before its grant. The grounds for bringing an opposition remain as before and provide recourse to challenging frivolous and legally invalid patents.

However, the effectiveness of the opposition process depends upon the access to information on the mailbox applications. The Patent Office in 2005 has issued a notification in its official journal that inventions either filed or claiming priority on 30 July 2003 have been deemed to have been published. However, there are no actual physical publications available. This lack of publication takes away the possibility of accessing information relating to the patent application and the ability to oppose the same.

Publication:

The Bill amends Section 11A of the Patents Act which prescribes the initial publication requirement. After the publication the applicant shall have the rights as if patent for the invention had been granted on the date of publication of the application. However, no infringement proceeding is permissible until the grant of patent. This means that one can get the privilege of patent from the date of publication i.e. even before filing the request for the examination of application. Lastly the Bill refers to the publication of an application, but fails to make the publication of the complete specification available to the public. This will greatly hamper opposition proceedings (see above).

Compulsory Licences:

The effective and efficient issuance of compulsory licences is imperative to curb the abuse of patent rights by the patentee. The amendment has only made cosmetic changes to quicken the process of dealing with an application for a compulsory licence in section 84(6) to the extent that where the applicant has made efforts to obtain a licence from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period, the Controller can now interpret "reasonable period" to mean a period not ordinarily exceeding 6 months.

However, the amendment does not remove the existing requirement that only after three years after the grant of a patent, (unless there is a national emergency, which has never been used) can a person make an application to the Controller for the grant of a compulsory licence. Therefore, in total the request for a compulsory licence does not have to be considered for at least 3 years and 6 months from the date of the grant of the patent. Furthermore, one also has to take into account that the Bill fails to provide a timeline within which the Controller must deal with compulsory licence application once made. Therefore, this could lead to a further delay before any licence can be issued as it is well known that MNC pharmaceuticals often refuse to deal with requests for compulsory licences or demand high royalties.

With respect to exporting drugs to a country which makes a request for a generic drug, the amendment no longer requires the importing country to

issue a compulsory licence. However, one question that arises is whether the procedure for the grant of the compulsory licence for the domestic market (under section 84(6) discussed above) will also be the same for compulsory licenses for export. It is quite possible to argue the procedure both ways, therefore, potentially delaying urgent new drugs that a developing or least developing country may require.

The Act further fails to provide the safeguard available within Article 44 of TRIPS, which effectively allows Member States to limit remedies to remuneration that would be available to the patent holder where third parties are authorised by the Government, without the authorization of the right holder, to use the patented good rather than issue an injunction.

Discretionary powers of the patent office:

The Ordinance took away the limitations imposed by the Act, and made it discretionary of the Patent Office by virtue of the Rules. As a result, the patent office can now tamper with the various time lines by amending the Rules as and when they choose. Under the amended ordinance, 7 types of time limits will be determined by the office through the Rules and not by the statute. The excessive and unbridled delegation to the Patent Office is further increased by the following provision: "The central government may, if it is satisfied that circumstances exist, which render it practically not possible to comply with such condition of previous publication, dispenses with such compliance". As a result, the public will not be given an opportunity to offer its comments to the Rules before it being amended.

Quick Examination:

As per the Ordinance the time frame for making the examination report is left to the Rules. The new Rules provide a period 1-month for the examination report to be issued following the application. This period was previously 18 months period.

This is likely to create immense pressure on the Indian Patent Office as there will not be enough examiners to deal thoroughly with the flood of applications which is likely to occur, thus resulting in improperly examined and legally invalid patents. Indeed, as the U.S Federal Trade Commission report mentioned in its 2003 report "the increasing rate of 10% of patent applications each year is causing examiners only having 8 to 25 hours to read, understand, search for prior art and evaluate the patentability of the applications". The Indian Patent Office does not have the infrastructure for research, access to information and capacity to face the challenge that the new Act will bring.

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