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Patent (Amendment) Ordinance, 2004

The President of India has promulgated The Patents (Amendment) Ordinance for the purpose of bringing the existing patents law into conformity with the obligations undertaken in the Agreement on Trade Related Aspects of Intellectual Property Rights. This is mainly related to the introduction of product patent protection in all fields of technology. The product patent prohibits others from making, using, offering for sale, selling or importing the patented product. As a result, the product patent gives a monopoly to the patent owner for the production of patented article during the term of the patent (20 years). Therefore, product patent protection for medicines and agro-chemicals creates a monopoly and eliminates competition in the market.

The Bill at a Glance

Highlights

- The Ordinance makes the Indian patent regime compliant with the obligations given in the TRIPs Agreement.
- The Ordinance expands the patentability criteria from drugs and agro-chemicals to other fields of technology, such as embedded software.
- The Ordinance has provided compulsory licensing for export of patented pharmaceutical products.
- Deletion of the provisions relating to Exclusive Marketing Rights (EMRs), and introduction of a transitional provision for safeguarding EMRs has been granted.

Lowlights

- The Ordinance does not make use of all the existing flexibilities given in the TRIPs Agreement.
- The Ordinance has relaxed the grounds on which granting of patents is opposed. Various checks provided in the Act to prevent frivolous patents do not exist anymore.
- The Ordinance has taken away the power of the Controller to take *suo moto* steps to refuse grant of patent on grounds of anticipated publication.
- The Ordinance provides for the patenting of microorganisms and non-biological and microbiological processes. It should have waited till the mandated review of Art 27.3(b) of the TRIPs Agreement was done.

Action Points

- India should fully take advantage of flexibilities available under TRIPs in order to safeguard accessibility and availability of drugs and medicines. The Government is going far beyond what is required under WTO rules.
- Should take away the provision regarding patenting of 'microorganisms', 'non-biological and microbiological processes' as they are under review by the WTO, ever since 1999.
- Should provide for a clear and wider definition of certain terms, like patentability of pharmaceutical products, microorganism and public non-commercial use, in order to avoid ambiguity.
- Should restore powers to the Controller to take *suo moto* steps to refuse grant of patent on grounds of anticipated publications.
- 'Opposition to Grant of Patent', as originally provided in the Patents Act 1970, is extremely important and relevant. It should not be diluted.
- Should simplify the compulsory licensing procedure, as the existing procedure is too lengthy and complicated.

Covering IPR abuses through Competition Act, 2002

The Competition Act, 2002, will also come up before the parliament for amendments pursuant to a writ petition in the Supreme Court. The coverage of the CA, 2002 on abuse of intellectual property rights, including patents, is very poor. Hence, parliamentarians may note this when the Competition Amendment Bill, 2005 comes up for debate.

INSIDE

Introduction

The Patent Amendment Ordinance of 2004 is the third and final step to make the patent regime of India fully compliant with the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) of the World Trade Organisation (WTO). India is a member of the WTO, and, therefore, is under an obligation to make all its laws compliant with WTO Agreements. Viewed from this perspective, the Patent Amendment Ordinance is a necessary evil.

The Patents (Amendment) Bill, 2003 had been introduced in Parliament a year ago by the previous government, but it lapsed. Now, the new Government desired to bring the Bill to Parliament first. But as it couldn't bring it in the previous session of Parliament, it necessitated the Ordinance. The Ordinance will be discussed in detail in Parliament in the Budget session. The Ordinance is an interim measure to fulfil our legal obligations within the stipulated time.

The Government of India issued the Patents (Amendment) Ordinance, 2004 on December 26, 2004. The Ordinance amends the Indian Patents Act, 1970 to introduce product patent protection for drugs, food and chemicals for the third time. The Ordinance, which came into effect from January 1, 2005, also makes a number of other changes in the Indian Patents Act.

Yet, the scope of this particular amendment should not be restricted just to make the Indian patent regime compliant with TRIPs. One also needs to examine this amendment from the perspective that it has made full use of the existing flexibilities given in the TRIPs Agreement or not, while complying with the obligations imposed by TRIPs.

An apprehension is being expressed that this Patent Amendment would lead to visible changes in the patenting of all new products, especially pharmaceutical and agricultural. Though the old medicines, which are already in the market, would remain untouched by the product patent regime, it would not be the same in the case of new medicines. Once these new medicines start entering the market, the prices would tend to escalate, as the generic versions would not be available. Although there would not be an immediate impact of product patents, gradually it would affect the availability of affordable medicines in the market.

It is feared that in cases of public health calamity, the new patent regime would have an adverse impact by reducing accessibility of medicines to the poor sections of the society. Apart from these, it is likely to affect the farm sector, as it extends the product patent regime to agro-chemicals, food and biotechnology products.

In this paper we look at some of the important provisions of the Ordinance.

Invention not Patentable

Section 3 of the principal Act provides for certain inventions that cannot be patented. However, there is a need to give more teeth to this particular section by defining certain terms, like patentability of pharmaceutical products, microorganisms and public non-commercial use.

It has also failed to define the emergency clause, whereby the government can step in and intervene in public interest. It mentions only national emergency and circumstances of extreme urgency, without stating specific emergencies, such as relating to health and environment. Also, while defining terms for "commercial use", it is necessary to check monopolies and encourage competition, which finds mention in Article 31 (b) of the TRIPs Agreement.

Apart from all these, patenting of 'microorganisms', 'non-biological and microbiological processes' ought to have been done away with, as they are under review by the WTO, ever since 1999. The same should be adopted in case of patentability of computer programmes, as it is not in the interest of our country to encourage monopolies by the likes of Microsoft. Patentability of these subject matters has enormous dimensions affecting public interest.

Change in Procedure

According to Patent Act 1970, as amended in 2002, a patent is granted after thorough scrutiny by the patent office and public. There are three stages of granting a patent, viz, initial publication after 18 months of filing under Section 11A, acceptance of complete specification after examination and scrutiny by the patent office, and inviting opposition from public on the accepted complete specification. The Ordinance has done away with the last two stages and directly proceeds to grant patent after the publication. As a result, the various checks provided in the Act to prevent frivolous patents do not exist anymore. Further, the amendment provisions took way the transparency nature of granting a patent.

The Ordinance has also done away with another important provision, Section 27 of the Patents Act. This Section had given powers to the Controller to take *suo moto* steps to refuse grant of patent on grounds of anticipated publications.

Exclusive Marketing Rights (EMRs)

India introduced EMRs as a transitory arrangement during its transition period, from 1 January 1995 to 31 December 2004 (the time period for switching over to product patent regime from a process patent regime), in pharmaceuticals and agricultural products. Chapter IV A in the Patents Act provides for an EMR. It is an exclusive right granted to a person to sell and distribute a particular substance or article concerned. So, once this right is granted, then no one else can sell or distribute the subject product without the EMR holder's authorisation.

This chapter is omitted under the Patents (Amendment) Ordinance 2004. However, there is a need to retain Section 24 B: Grant of exclusive marketing rights in a modified form. The modified form should provide for exclusive marketing rights, granted up to 31 December 2004, on any application filed for a claim for patent of an invention relating to pharmaceutical and agricultural products to remain valid.

The time period of such validity can be calculated in two ways. First, from the date of exclusive marketing rights granted by the Controller of Patents, till a period of five years. Second, till the date of grant of patent or the rejection of application for the grant of patent. Whichever time period is shorter can be used to determine the validity of such patenting claims.

Opposition to Grant of Patent

The title of this chapter 'Opposition to Grant of Patent', as originally provided in the Patents Act 1970, is extremely important and relevant. Its validity and usefulness has been proved through its existence for almost three decades. However, the third Patent Amendment Ordinance proposes to change the title of this chapter to 'Representation and Opposition Proceedings', which is not adequately justified.

The Ordinance has totally diluted the provisions of this chapter and has divided them into pre-grant representation and post-grant opposition. Earlier, there was a better patent examination system by weeding out non-patentable inventions. By doing away with this, the government is trying to

seriously affect the quality of patents. It can be said that it is just a move to bring this provision closer to the US patent system, where the quality of patents has seriously been affected. A similar situation in the post-grant opposition period would develop in India, leading to large-scale disputes.

Moreover, pre-grant opposition is necessary for a country of our size, so that our population, particularly the poorer section, does not suffer by issue of wrong patents. There are already huge numbers of Mailbox applications pending. Once the patent is granted, big drug companies, particularly MNCs, will see that opposition proceedings linger for as long as possible, so that they enjoy the benefits for years, till the patent is cancelled. An average NGO or Indian would be ill prepared to carry on a costly legal battle against a patent-holding multinational company.

Also, there is no requirement in TRIPs to change the pre-grant opposition, as attempted in the Ordinance. Therefore, full-fledged and appeal-able pre-grant opposition provisions must be retained. Incidentally, most EU countries have these.

For this reason, there is absolutely no justification to dilute the provision of Section 25, as it would directly hit the public interest and is not in the national interest also to have differential treatment, for reasons, which result in rejection of patents claim. Therefore, Section 25 should be modified suitably to lump together all the reasons for opposition to grant patents.

Term of Patent

Term of patent means the term or the period for which patent is being granted. Section 53 of the Principal Act provides for different terms of patent for different products.

However, the Patents Amendment Ordinance does not provide anything on terms of patent for those products for which patent applications were received during the period 1 January 1995 to 31 December 2004, i.e. for pharmaceuticals and agricultural products.

The amendment Ordinance should provide for a separate term of patent for these products. Granting EMR is like providing a product patent, and, therefore, the period during which the product enjoyed EMR should be counted in calculating the term of patent protection.

This would also be consistent with the TRIPs Agreement. Article 70(8)(c) of the TRIPS Agreement provides for such a provision. This important stipulation should be incorporated in Indian patent laws.

Surrender and Revocation of Patents

Section 66 of the Principal Act provides for revocation of patents in public interest. In the past, there have been contingencies when foreign suppliers were directed by their governments to block the supply of certain critical materials required in the country.

If such materials are under patent and there are similar contingencies, it should be possible through the suggested provision to revoke the patent without giving any reason or notice. The Indian enterprises would be then totally free to develop and produce the product for meeting the country's critical need. The proposed stipulations will also serve as a strong deterrent on the patentee not to block the supply of the concerned material.

Therefore, it is important that the third Patent Amendment Act provides for a separate provision to revoke the patent, especially when supply of the patented material is blocked, for political or other reasons.

Transparency in Screening of Patent Application Forms

Clause 31 of the Ordinance substitutes Section 39 of the Patents Act with a new provision, which provides more power to the Controller and the Central Government in screening the patent applications.

Under the proposed amendment, permission to make or cause to make any application "for the grant of a patent for an invention" outside India has to be brought in a prescribed manner.

The existing provision was for inventions relevant for defence and atomic energy only. Now, a prior permission is necessary from the government for any patent application to be filed in another country. Thus, it is now being expanded to cover any application outside India.

This is a welcome move. As it is necessary for the defence of the country, all applications for patents to be made outside India should be screened and decided by the relevant authorities, whether the country's defence is affected or not, rather than by the applicant himself. Though this will be prejudicial to the interest of domestic pharmaceutical companies filing patents for incremental inventions outside India, given the complexity of the filing, speed and the need for confidentiality.

Provisions Related to Compulsory Licensing

Provisions related to compulsory licensing are very important in a product patent regime of pharmaceutical products. As it has been discussed above, product patent regime for pharmaceutical products limits the scope of countries to produce or manufacture such products, especially life saving drugs. In case of such a limitation, the role of compulsory licensing increases manifold. Such licensing is a tool that would enable India to face the problems of calamities related to public health.

The Status of EMRs in India

Product (patent application no.)	Date of filing	Company
Granted		
Imatinib mesylate (1602/MAS/98)	17 July 1998	Novartis India
Carbendazim + Mancozeb (570/MUM/2000)	21 June 2000	United Phosphorus
Nadifloxacin, topical (306/MUM/2002)	28 March 2002	Wockhardt
Pending		
Tadalafil (Cialis) – Tetracyclic derivates, process for preparation and use (EMR/3/2003)	10 Oct 2003	Eli Lilly &Company
Moxifloxacin (315/DEL/2000)	27 March 2000	Bayer
A combination kit used for the treatment of malaria (501/MUM/2000)	31 May 2000	Nicholas Piramal India & CSIR
Peginterferon alfa-2b (IN/PCT/434/CHE)	25 Sept 2000	Schering Plough

The third Patent Amendment has to be examined in this context.

Unfortunately, the Ordinance is silent regarding the compulsory licensing procedure. The existing procedure is extremely lengthy and complicated. An applicant has to satisfy several intricate pre-conditions before such a license is approved: An applicant has to satisfy the Controller his competence and ability to manufacture the product, his ability to adequately provide risk capital and set up facilities for proper manufacturing of the product. At the same time, such an applicant has to prove that the patent holder has refused him a license and that there is demand for the product in India, and the patent holder is not satisfying the demand at a reasonable price.

A compulsory license is also not a free license. A license holder will have to pay royalties to the patent holder. At the same time, the patent holder will be entitled to examine the books of the licensee to ascertain whether proper royalties are being paid. It is also possible for the patent holder to delay the grant of a compulsory license for at least a period of three years and to oppose the grant of license. In short, the compulsory license procedures are not only complicated but also expensive.

The present procedure, being very time-consuming, defeats the very purpose of compulsory licensing, especially for urgently required drugs. There is a real need to simplify the procedures under Sections 87 and 88, so that compulsory licences for drugs and medicines are issued expeditiously in public interest, subject to payment of reasonable compensation to the patent-holder.

Also, the role of domestic enterprises is ensured through the compulsory licensing system, which is the core component of the patent law. There are several possibilities of granting compulsory licenses. The most important being provisions relating to licensing for commercial activity. Article 31(b) of the TRIPs Agreement provides that domestic enterprises, if they offer reasonable commercial terms and conditions to the patent holder and if their efforts remain unsuccessful and unanswered for a reasonable period, could approach the Patent Controller for the grant of compulsory licenses. This provision has been ignored in the amending process of our Patents Act. This would have provided a tremendous opportunity for the domestic enterprises to play a major role in the patented product and thus lead a competitive environment. This is one of the major possibilities to safeguard public interest. Many other countries have provided this provision in their patent laws, which we too should have.

Applications have been filed in the Mail Box for product patent of those products that are already available in the international markets and which are being produced by domestic enterprises in India. But, unfortunately, these enterprises would have to stop production once these applicants are granted product patent, leading to non-availability of these products. The patent holder would monopolise the market, selling his products at monopoly prices. This is a serious phenomenon and government should have provided some solution in the Ordinance so as to allow these domestic enterprises to continue their production, on payment of royalty.

Clause 49 of the Ordinance inserts a new provision, Section 92A, which incorporates India's obligations pursuant to the decision of 30 August 2003 by the Council for TRIPs on 'Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health'. With this, Indian manufacturers will now be able to manufacture and export patented medicines to countries, which have insufficient or no manufacturing capacity. It is a welcome provision and it would help our pharmaceutical industry in future, if their pricing were competitive.

But, for that, it has to fully implement the above decision of the WTO General Council on the implementation of paragraph 6 of the Doha Declaration for countries that lack sufficient domestic pharmaceutical manufacturing capacity,
as the draft amendment does not permit export of compulsorily licensed medicines from India without a compulsory license granted in the importing country. If the importing countries do not have a patent for the compulsorily licensed medicines in force, they would not be allowed to import compulsorily licensed medicines exported by India, even though the August 30th decision clearly permits this.

Conclusion

The third Patent Amendment Ordinance 2004 is a step to make Indian patent laws compliant with the TRIPs Agreement, before 1 January 2005, which it has. However, there are certain areas, as highlighted in the paper, where the Ordinance has not done complete justice in making the switch over from process patent to product patent regime. The Ordinance has not been able to utilise all flexibilities provided in the TRIPs Agreement and the Doha Declaration. We urge that, in the interest of peoples' health, the government should accept these proposals and consider revising the same before the Ordinance is transformed into 'The Third Patent Amendment Act'. If the Ordinance in its present form becomes law, it will seriously compromise the right to food and health.

Other Bill Blowups

1. **Competition Bill of India, 2001**
   A Right Step in the Right Direction
2. **Communications Convergence Bill, 2001**
3. **Biological Diversity Bill, 2000**
   A blueprint for the monopolisation of biodiversity or its beneficial use?
4. **The Infant Milk Substitutes... Amendment Bill, 2002**
   More a Formality than an Attempt to Address the Real Concerns?
5. **98th Constitutional Amendment Bill, 2003**
   Seeking to Create a National Judicial Commission
6. **Small Enterprises Development Bill**
   A Step in the Right Direction?

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