

Section V

Implementing Public Health Safeguards under Indian the Patents Act

The TRIPS agreement, once signed, placed a number of obligations on countries like India. The most important of these was the condition that required India to change to a product Patent regime in the area of pharmaceuticals and food, from the earlier system provided in the 1970 Act which did not provide for Product Patents in these areas. It may be noted here that it was this simple provision in the Indian Act which had catapulted India to a position where it is the 4th largest producer of pharmaceuticals and a large supplier of cheap generic drugs to poor developing countries. In order to conform to the TRIPS Agreement the Government of the day introduced Amendments to the 1970 Act in 1999 and 2002 and the Patents Ordinance of 2004.

Subsequently, the Ordinance was amended and the Patents Amendment Bill 2005 was adopted by Parliament in March 2005. The Patents Amendment Bill 2005 was designed to address a number of public health concerns. We have examined earlier, the flexibilities available under the TRIPS agreement that address public health concerns. However as we also discuss earlier, the TRIPS agreement is a broad framework. Finally, Patent laws are country specific and country laws determine the extent to which such flexibilities are used. We now turn to the specific provisions in the Indian Act which allow public health needs to be safeguarded.

5.1 Options in the Indian Patents Act to Ensure Access to Medicines

An essential public health goal with respect to Patent laws is to ensure that such laws do not hinder the access to medicines because of the monopoly rights enjoyed by Patent holders. Access can be compromised by Patents in two ways: due to inadequate availability and because of high prices. The principal instrument available in the

Indian Act is that of the option to issue a compulsory license (also called a "non voluntary license" - because it is issued without the consent of the patent holder). Compulsory Licensing is a procedure whereby a Government can allow any company, agency or designated person the right to make a patented product, or use a patented process under licence, without the consent of the original patent holder. The compulsory licensing system in any patent law lies at the heart of its ability to balance the rights of consumers with that of patent holders. It does so for the simple reason that the power of patents are exercised through the monopoly rights conferred to a patent holder. Compulsory licenses are specifically designed to curb monopoly and promote competition. There are three broad provisions in the Indian law, under which a compulsory license can be issued:

- 1) For Public Non-Commercial Use (also called "Government" use)
- 2) In situations of Emergency and Extreme Urgency
- 3) License for local manufacture of generics for various grounds

5.1.1 Government Use and Non-Commercial Use

The relevant section of the Indian Act which provides for issuing of a compulsory license for situations (1) and (2) above is as follows:

Special provision for compulsory licences on notifications by Central Government.

92 (1) If the Central Government is satisfied, in respect of any patent in force, in circumstances of national emergency or in circumstances of extreme urgency or in case of public non-commercial use, that it is necessary that compulsory licences should be granted at any time after the sealing thereof to work the invention, it may make a declaration to the effect, by notification in the Official Gazette, and thereupon the following provision shall have effect, that is to say.

- (i) the Controller shall on application made any time after the notification by any person interested grant to the applicant a licence under the patent on*

such terms and conditions as he thinks fit;

(ii) in settling the terms and conditions of a licence granted under this section; the Controller shall endeavour to secure that the articles manufactured under the patent shall be available to the public at the lowest prices consistent with patentees deriving a reasonable advantage from their patent rights.

(2) The provisions of sections 83, 87, 88, 89 and 90 shall apply in relation to the grant of licences under this section as they apply in relation to the grant of licences under section 84.

(3) Notwithstanding anything contained in sub-section (2), where the Controller is satisfied of the application referred to in clause (i) of sub-section (1) that it is necessary in -

- (i) a circumstance of national emergency; or*
- (ii) a circumstance of extreme urgency; or*
- (iii) a case of public non-commercial use,*

which may arise or is required as the case may be, due to public health crises, including those relating to Acquired Immuno Deficiency Syndrome, Human Immuno deficiency Virus, tuberculosis, malaria or other epidemics, he shall not apply any procedure specified in section 87 in relation to that application for grant of licence under this section.

Provided that the Controller shall, as soon as may be practicable, inform the patentee of the patent relating to the application for such non-application of section 87."

Here it needs to be understood that the provision envisages two different situations - 1) For public non-commercial use; 2) In emergency situations and in situations of extreme urgency. In the former case the license can be issued only for "non-commercial" use. While this is not defined further in the Act it can be assumed that the license can only be used to service the needs of the Government, viz. for its own national health programmes, for distribution through public health facilities, for use in the defence services, etc. However non-commercial use of a license does not mean that only public sector

manufacturers can be licensed - the Government can use the provision to mandate one or more private manufacturers to manufacture on behalf of the Government.

In the case of situations of extreme urgency or emergency, there is no bar on "commercial" use, i.e. the license can be freely used to service the private market as well. This is an important distinction, as in India over 70% of medicines are sold through private retail channels.

The advantages of using this provision are:

- 1) There is no requirement to wait for 3 years after the granting of a patent before a license is granted to another manufacturer - as is otherwise the case when a compulsory license is issued for local manufacture under Section 84 of the Indian Act (see later).
- 2) There is also no requirement to negotiate the royalty payable to the Patentee. The Patents Controller has the freedom to fix a royalty that he feels adequate. It is, in fact possible, for the royalty to be fixed at zero if this is considered necessary in public interest.
- 3) This is a broad provision and the Act itself clarifies that there is no bar on choosing the kind of diseases for which the provision is to be implemented. The same, as we have seen earlier, was also clarified in the Doha Declaration.

In order to operationalise this provision, however, it is necessary that the Government notifies the diseases and the medicines for which the provision is to be used. The Act does not lay down the manner in which such a notification is to be made. This means that any reasonably empowered public authority can issue such a notification. ***Ideally the Ministry of Health is ideally situated to be the agency to issue such a notification. It is suggested that the Ministry work out a procedure and create an instrument that is empowered to***

make such notifications.

5.1.2 License for local manufacture of generics

In addition to the special circumstances detailed above, the Indian Act has detailed provisions that allow licenses to be issued to generic manufacturers on various grounds. Sections 84 through to 89 detail the conditions, modalities and terms under which such licenses can be granted. These are provided in Annexure I. Here, let us examine some of the major grounds under which such licenses can be issued:

- ♦ An existing trade or industry or the development or the establishment of any new trade or industry in India is prejudiced.
- ♦ The demand for the patented article has not been met to an adequate extent or on reasonable terms.
- ♦ A market for export of the patented article manufactured in India is not being supplied or developed.
- ♦ Patented invention is not available to the public at a reasonably affordable price.
- ♦ The patented invention is not being worked in the territory of India on a commercial scale to an adequate extent or to the fullest extent that is reasonably practicable.
- ♦ The working of the patented invention in the territory of India on a commercial scale is being prevented or hindered by the importation from abroad of the patented article.

As would be obvious from the above, very broad and extensive grounds exist for compulsory licenses to be issued. Under these provisions, any legitimate manufacturer can approach the Patent Controller with a request for a license to manufacture a Patented medicine if any of the above conditions are satisfied and if the generic manufacturer has failed to obtain a voluntary license from the Patent holder on terms that are mutually acceptable.

There is an impression that has somehow been created that

compulsory licenses can be issued under very special and rare circumstances. A perusal of the Indian Act would, however, show that that is by no means the intent of the Act. ***Compulsory license provisions in the Indian Act are specifically designed to curb the monopoly rights of patent holders, especially when such rights run counter to public health goals. The Doha declaration has clearly clarified that when public health goals and patent rights are in conflict, the former should prevail.*** Moreover, the Act does not specify that compulsory license for a specific drug can be granted only to one generic manufacturer - so it is possible to issue multiple licenses to different generic manufacturers for the same drug in order to curb monopoly and promote competition.

The advantage of using this provision to license generic manufacture of patented drugs is that no separate declaration need be made, as is necessary in the case of non-commercial use or situations of extreme urgency or emergency. It can, thus, be used in the case of all class of drugs if availability and prices become an issue. The disadvantage is that, there is a three year "lock in" period from the date a patent is granted on a medicine before an application for a compulsory license is accepted. Another disadvantage of using this provision is that fixed time periods are not specified regarding how long it may take for a license to be granted, once the application for a compulsory license is accepted. The amended Act does, however, partially address the need to have time-bound procedures by specifying that the "reasonable" time period before the Patents Controller considers issuance of a compulsory license when such a license is denied by the patent holder "shall not ordinarily exceed six months." However no time periods are specified further regarding how long procedures would take beyond this stage. As royalty rates are also not specified in the Act, there could be delays on fixing rates based on objections raised by the Patent holder.

Some of these operational issues that may arise when issuing compulsory licenses are detailed later. If these are addressed, the

compulsory licensing system can in India can become more robust. However, even in its present form, the Indian Act provides the possibility to address public health goals by the judicious use of the compulsory licensing provisions.

5.2 Options in Indian Patents Act for Imports

India is the largest exporter on medicines among all developing countries. However, there may arise situations where we may need to import a specific medicine that is not manufactured in the country. If the medicine is not covered by Patents - either in India or in the country from which we wish to import - then the Indian Patents Act does not impinge on our ability to import the medicine. However if the medicine is patented in India or in the exporting country, the Patents Act comes into operation.

Drug companies are known to price their patented products differentially in different markets. An instrument available in the Indian Act (under Section 107A) allows us to take advantage of this and import patented drugs at the lowest available price in the global market. This process is called "Parallel importation" and works on the principle that the patent owner's rights have been "exhausted" through the first sale. Thus if a company sells a drug in another country at a lower price, its patent right over the drug is exhausted after this sale, and another entity can export the drug to another country without the consent of the patent holder and this would not be considered an infringement of the patent holder's rights.

5.3 Exports of Drugs from India

The Indian Patent Act and its amendment has attracted international attention because today Indian drugs are the principal source for cheap drugs for poor developing countries. For example, about 50% of all drugs used to treat HIV-AIDS patients globally come from India. This concern (that the source of cheap Indian drugs would dry up) had been expressed by a large number of international agencies such as the UNAIDS and WHO. India is the

largest exporter of medicines in the developing world, and Indian drugs - usually priced much lower than drugs produced by MNCs based in the North - constitute the lifeline for many countries in Asia and Africa. The ability of Indian companies to export new medicines that were patented elsewhere in the world was promoted by the Indian Patents Act of 1970 as it did not recognise patents on medicines. After 2005, with Product Patents being allowed on medicines under the Indian law, the situation has changed. Drugs that are not under Patents in India are, of course, not affected by the changes in the Indian Act. But it is expected that newly developed drugs would be granted Patents under the Indian law. There are two provisions in the Indian law which can be used to export such drugs.

1) If an Indian company is issued a compulsory license to produce a drug that is patented in India, the Indian law allows that the company may also export the drug. In fact, as we discussed earlier, one of the grounds for issuing a compulsory license in the Indian law is: "*if, by reason of the refusal of the patentee to grant a licence or licences on reasonable terms, a market for export of the patented article manufactured in India is not being supplied or developed*" (Section 84. 7 (a) (iii)). The Indian Act also specifies regarding a compulsory license which may be issued: "*that the licence is granted with a predominant purpose of supply in the Indian market and that the licensee may also export the patented product, if need be*" (section 90. (1) (vii)) Taken together, these provisions explicitly allow export of drugs patented in India that may be manufactured by generic companies under a compulsory license. However the permission to do so is circumvented by the phrase in the Act: "licence is granted with a predominant purpose of supply in the Indian market" This is a TRIPS requirement (Art.31(f) of TRIPS) and essentially means that more than half of the total quantum of drugs manufactured using a compulsory license should be sold in the domestic market in India - in other words just under half of the total manufacture (say 49%) can be exported. This is a very useful provision to export new drugs that may be under Patent protection in India.

especially given that the Indian market itself is fairly large and 49% of the total manufacture would constitute a large volume in most cases. The disadvantage of this provision is that the exports would need to wait till a compulsory license is issued - which would include the 3 year "lock in" period and the additional time that would be required before a license is granted after submission of an application for issuance of a compulsory license. The advantage of using this provision is that, once a compulsory license is granted, generic companies can start exporting without any other notifications or permissions being required, provided the volume of exports is less than half of the total manufacture for a particular product.

2) Drugs under Patent protection in India can also be exported using the new provision in TRIPS (Art. 31(bis)) that was specifically designed to address the concerns expressed in the Doha declaration (which we discuss earlier) regarding the need to have a mechanism by which countries without manufacturing capability can benefit from the use of cheaper generic versions of medicines under patent protection that may be produced under a non voluntary license. This mechanism is incorporated in the Indian Patent Act under Section 92A as under:

"92A. (1) Compulsory licence shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory licence has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India.

(2) The Controller shall, on receipt of an application in the prescribed manner, grant a compulsory licence solely for manufacture and export of the concerned pharmaceutical product to such country under such terms and conditions as may be specified and published by him".

The advantage of using this provision is that there is no requirement to wait for the issuance of a compulsory license and thus avoids the 3 year lock in period and the time taken to issue the license. So the mechanism can be set in operation at any time after a patent on a new drug is granted. However there are several disadvantages in using this provision for exports. The mechanism requires that in each case (i.e. each separate case of a medicine to be exported to a specific country) two sets of licenses (or notification) are necessary - one for the exporter in India and one for the importer in the importing country. This introduces a fair amount of uncertainty regarding the size of the market that exists for the exporter, especially as the license is issued only for exports and that too on a case by case basis for export to a particular country (thus if a company seeks to export to multiple countries it needs multiple licenses). As manufacture of medicines require substantial investment, companies might be reluctant to make such investments keeping in view the uncertain nature of the export market. Though this provision has been available for over two years now and several countries reflect this provision in their Patent laws, no manufacturer anywhere in the world has made use of this provision. However, this is an enabling provision that is available and it is possible that Indian manufacturers might make use of this if the licensing procedures are made easy to comply with.

5.4 Restrictions on Patentability

There were serious concerns that after Product Patents are allowed in all areas we would be deluged by Patents that could be granted on flimsy and frivolous grounds. There were concerns also that this would lead to "ever-greening" of patents, that is perpetuation of Patents monopoly beyond the stipulated 20 years by repeated Patent grants based on small changes made to the original molecule. The amended Indian Patent Act now restricts the scope for the granting of Patents on frivolous claims. It clarifies that an "inventive step" means a feature of an invention that "involves technical advances as

compared to the existing knowledge or having economic significance or both." The amendments also incorporate a new definition for "new invention" by stating that it means *"any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e. the subject matter has not fallen in public domain or that it does not form part of the state of art"* The amendments also provide a definition for **"pharmaceutical substance"** as being **"a new entity involving one or more inventive steps"**.

As part of the exercise to strengthen the possibility to deny Patents on frivolous claims the amendments clarify (under Section 3(d)) that "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy" is not patentable. It is further explained that: "Salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substances shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy".

Section 3(d) of the Indian Patents Act is a powerful instrument available to prevent frivolous patents. It is, however, a section that has attracted the ire of Multinational Pharma companies, as evident from the challenge filed on this section by the Swiss MNC, Novartis, in the Chennai High Court (see Boxin the next page).

Challenge to Indian Patents Act by Novartis

Novartis, a Swiss Multinational pharmaceutical company operating in India, through its subsidiary, was involved in challenging the India authorities through two petitions. In the first petition now referred to the Intellectual Property Appellate Board, Novartis has challenged the decision of the Indian Patent office in Chennai, rejecting its application for a patent on imatinib mesylate, which Novartis markets in India under the trade name: Gleevec. In the second application filed in the Chennai High Court, Novartis had challenged the constitutional validity of Section 3(d) of the Indian Patents Act by claiming that this section does not comply with the TRIPs agreement.

In the first case, Novartis challenged the order of the Indian Patent office in Chennai, rejecting its application for a patent on imatinib mesylate, which Novartis markets in India under the trade name: Gleevec. Imatinib mesylate is extremely useful in the treatment of chronic myeloid leukemia (CML). In addition to Novartis, several Indian companies - viz. NATCO, Cipla, Ranbaxy and Hetero -- also produce and market the drug. Treatment with Gleevec (manufactured and marketed by Novartis) costs rupees 1,20,000 per month, whereas Indian companies market the same drug at a price of about Rs. 8,000 per month. If a patent were to be granted to Novartis for imatinib mesylate, Indian companies would be forced to stop production of the drug. At a treatment cost of Rs.1,20,000 per month, this would mean that over 99% of patients requiring the drug would be denied access to it. The huge difference in the price of the same drug is an illustration of how a patent monopoly leads to enormous increase in prices of drugs.

The Indian Patent office had rejected the application for a patent on sound principles, entirely consistent with the country's laws and the agreement on Trade Related Intellectual Property Rights

(TRIPS). Novartis had obtained a patent for the same drug in 1993, i.e. two years before the TRIPS agreement was signed. At that time the Indian law did not recognise patents on pharmaceutical products. As per the TRIPS agreement, if a drug has been patented before 1995, countries like India, which did not recognise patents on medicines before the signing of the TRIPS agreement, do not have to recognise such patents. Novartis tried to circumvent this by filing a fresh patent application in India for the beta crystalline form of the same drug. Novartis claimed that this form of the drug was an advance on its earlier patent on the "amorphous" form, because it is less hygroscopic and hence more stable. The patent office rejected this application because it felt that the application was not for a "new" molecule and someone who understands the chemistry of the patented molecule (imatinib mesylate) would realise that the beta crystalline form of the molecule would have these useful properties. Thus it opined that the patent application failed on two counts for the required criteria of patentability - it did not demonstrate an "innovative step" and it was not a "non-obvious" invention. The Patent office further felt that the application by Novartis was not consistent with section 3(d) of the Indian Patent Act, which specifically states that a different structural form of a known substance cannot be patented. Hence in January 2006, the Patent office rejected the Gleevec patent application on the ground that the application claimed 'only a new form of an old drug'.

Novartis also filed a second case - one that challenged the constitutional validity of Section 3(d) of the Indian Patents Act by claiming that this section does not comply with the TRIPS agreement. Section 3(d) was specifically introduced by the Indian Parliament as a safeguard against the misuse of product patents on medicines. Novartis claimed that this section is not in compliance with the TRIPS agreement and is in violation of the Indian constitution. However, many experts have confirmed that

Section 3(d) conforms to the requirements of the TRIPS agreement, as the agreement clearly allows each country to set its criteria of patentability and does not prevent countries from including safeguards against the grant of fresh patents on old drugs. Section 3(d) is also in keeping with the "Doha Declaration on the TRIPS Agreement and Public Health" that was adopted by the Ministerial meeting of the WTO, held in Doha in 2001.

This challenge by Novartis is of particular concern for several reasons. It is a matter of grave concern that a foreign company chose to challenge the constitutionality of a law that has been passed by the Indian Parliament to safeguard public health. The company legally circumvented this issue by filing the case through its Indian subsidiary, but the fact remains that the challenge has been made on the directions of a foreign entity. Further, Indian courts cannot hear the company's contention that Section 3(d) of India's Patent Act violates the TRIPS agreement, as they do not hear appeals regarding conformity of Indian law to international treaties. Such a challenge needs to be made in the WTO's Dispute Settlement Mechanism, and that too can be made only by a member state of the WTO and not by a private corporation. No government has, till date, challenged the Indian law in the WTO. Interestingly, the company's arguments regarding the constitutional validity of the Indian law shifted continuously, even while the case was being heard. Initially it had not made out a case on the issue of constitutionality, but later changed its line of attack to argue that the language used in section 3 (d) was vague and not used anywhere in the world and that it did not give enough guidelines to the Patent Controller.

If Section 3(d) of the Indian Patents Act was to be removed it would open the door for a large number of trivial patents. This Section is the principal safeguard against the misuse of the Patent system by the patenting of known medicines, by making slight modifications in their structure. Such patents do not contribute

to any therapeutic benefits but do increase corporate profits by extending patent monopolies on frivolous grounds. Thus the removal of this important section would mean many new medicines would have to be granted patents on trivial grounds and multinational corporations like Novartis, who hold these patents, would charge exorbitant amounts for these medicines.

If the challenge by Novartis had been successful it would have opened the way for other as well. The consequences would not be limited just to India. Today India is known globally as the "Pharmacy of the Third World", because Indian companies export cheaper versions of patented drugs to over 150 countries. For example, over half the medicines currently used for AIDS treatment in developing countries come from India. If Indian companies are to be prevented from making generic versions of patented drugs, tens of thousands of poor patients in Africa, Asia and Latin America will be denied access to essential medicines. That is why hundreds of thousands of people all over the world signed an online 'drop the case' letter to Novartis, asking it to withdraw the case it has filed in the Chennai High Court. The 'Drop the Case' campaign was launched by the organisation 'Doctors Without Borders'. (<http://www.doctorswithoutborders.org/>) - winner of the Nobel Prize Award for best medical relief during the year 1999. Many reputed personalities publicly appealed to Novartis to withdraw the court case. They include Erik Solheim, Minister of International Development, Norway and Henry Waxman, Chairman, Congress of United States. Separately, the Indian Health Minister, Dr.Ambumani Ramados also appealed to Novartis to drop the legal challenges. In spite of such appeals, however, Novartis continued to pursue the court cases vigorously.

The Chennai High Court's decision on 6th August 07 to dismiss Novartis's plea has come as a huge relief. The Chennai Court agreed that Indian court does not have the jurisdiction to decide whether the Indian patent law is TRIPS compliant or not; the

appropriate forum, being the WTO Disputes Settlement Body. After this judgement, the Swiss govt. clarified that it would not take this issue to this body. Instead of giving up, Novartis has, however, decided to continue to pursue the second case to be heard by the Intellectual Property Appellate Board (regarding the rejection of its patent application for Gleevec).

5.5 Pre- and Post-grant Opposition to Patents

There have been widespread apprehensions that the amended Act would restrict the ability of any entity to oppose the grant of a Patent. The of 2004 Ordinance had reduced the number of grounds under which the grant of a Patent could be opposed from 9 to 2 and had also deleted the clause which provided for a hearing in person to the person making the opposition.

One of the most important changes of the 2005 amendments to the Indian Patent Act is the restoration of the two-stage opposition, i.e., pre-grant opposition and post-grant opposition. The procedure of the grant of patents has been completely refurbished by the substitution of Sections 25 and 26 in the amended Act. Now, there can be substantive opposition even before the grant of a patent.

Opposition before Grant of Patent - The Controller will publish the patent application and any person can file the application of opposition of the grant of patent under section 25 (1). The notice of Opposition must be filed before the grant of patent.

Opposition after Grant of Patent - Under Section 25(2), any person can file an opposition after the grant of patent but before the expiry of a period of one year from the date of publication of grant of patent.

Under the Indian patent law, one of the grounds for opposition of grant of a patent, as per Section 25 (1) (e) and Section 25 (2) (e), is no involvement of any inventive / innovative step. If an invention,

in so far as claimed in any claim of the complete specification in the application for a patent, is obvious and clearly does not involve any inventive step, it may be opposed and may be found to be non-patentable.

5..6 Continued Manufacture of Drugs with applications in the "mailbox"

The "mailbox" was an a mechanism that the TRIPS agreement mandated for use by countries like India who wished to use the transitional period of 10 years available to developing countries. Under this mechanism, while the TRIPS agreement came into force on 1st January, 1995, developing countries could choose to make the agreement fully operational in their country. But in this transitional period of 10 years, while product patents on medicines need not be granted, they would be accepted and filed in what was called a "mailbox". These patent applications would be examined only when the mailbox would be opened in 2005.

In India, such a mechanism was instituted through the Patents (amendment) Act of 1999. In the 10 years over 7,000 applications were filed in the mailbox. Concurrently many Indian companies started manufacturing medicines for which patent applications were filed in the mailbox as it was legally permissible to do so. One of the major concerns was that after the final amendment to the Indian Patent Act allowing for product patents from 2005, drugs which are being produced by Indian companies and for which patent applications are pending in the mailbox, would go off the market once the Patents are granted. It was apprehended that this would lead to a quantum jump in drug prices for these drugs as MNCs would use their Patent monopoly to hike up the prices for these drugs. This had been seen to happen in the case of the anti-cancer drug Glivec which was granted an Exclusive Marketing Right (EMR) in 2003 to the Swiss MNC Novartis, leading to a fifteen-fold hike in prices and misery to tens of thousands of patients. The new Act however clarifies that such Indian

companies who are already producing these drugs can continue to produce them after payment of a royalty even if the drug is granted a Patent. Specifically, it is now provided: "...the patent holder shall only be entitled to receive reasonable royalty from such enterprises which have made significant investment and were producing and marketing the concerned product prior to 1.1.2005 and which continue to manufacture the product covered by the patent on the date of grant of the patent, and no infringement proceedings shall be instituted against such enterprises."

5.7 Use of Patented Subject Matter for Research

While the subject matter of a Patent cannot be exploited for commercial purposes by any entity other than the Patent holder (unless the Patent is licensed to a third party), the TRIPS agreement allows exceptions in the case of use for non-commercial purposes - mainly for conducting research. This exception is also termed as the "Bolar exception" (provided for in Art. 30 of the TRIPS agreement). Patented products, thus, cannot be used commercially without prior approval from the patent holder but can be used for conducting research without such approval. This is an important provision as it allows generic companies to conduct research on a patented medicine to develop new processes for its manufacture and to generate data required to obtain approval of generic versions of the product. It allows them to be ready to market the generic versions as soon as the patent period on the original medicine expires. The Indian Act incorporates this under Section 107A(a): "any act of making, constructing, using, selling or importing a patented invention solely for use reasonably relating to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product";