The TRIPs agreement, together with the 1968 Stockholm Conference that adopted the revised Berne and Paris Conventions and created the World Intellectual Property Organization (WIPO), is undoubtedly the most significant milestone in the development of intellectual property in the twentieth century. Its scope is in fact much broader than that of any previous international agreement, covering not only all areas already protected under extant agreements, but also giving new life to treaties that failed and protecting for the first time rights that did not benefit from any multilateral protection. In addition, the TRIPs agreement enshrined detailed rules on one of the most difficult and, for rights holders, painful aspects of intellectual property rights' enforcement.\(^1\)

The Uruguay Round of multilateral trade negotiations resulted in the adoption of the Agreement Establishing the World Trade Organization (WTO Agreement) on April 15, 1994 in Marrakech. The TRIPs agreement was contained in the Annex to the WTO agreement, which entered into force on January 1, 1995. Built upon the foundations laid by the Paris Convention and the Berne Convention, the TRIPs agreement is an unprecedented international agreement in terms of its coverage, scope, specificities and enforceability.

As regards geographic coverage, the TRIPs agreement is binding on all WTO members. Compliance with its provisions is a precondition of joining the WTO, which deals with the rules of trade between members at a global level. Although intellectual property rights (IPRs) and their effects on trade have been advocated for a long time, the TRIPs agreement is the first international instrument to focus on trade-related aspects of IPRs. In view of the different levels of ‘preparedness’ among members to implement the TRIPs agreement under national laws, the TRIPs agreement sets out certain periods of time after the entry into force of the WTO Agreement before members are obliged to implement the TRIPs agreement.\(^2\) Different periods were prescribed for developed countries (January 1, 1996), developing countries (five years from the date on which the

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2 TRIPs Agreement, Articles 65 and 66.
TRIPs agreement becomes mandatory for developed countries) and least-developed countries (ten years from the date on which the TRIPs agreement becomes mandatory for developed countries). The targeted date for least-developed countries, which was January 1, 2006, has proved to be too ambitious, and was extended further to July 1, 2013.³

In the area of patents, the TRIPs agreement established the standards concerning the availability, scope and use of patent rights. They include: (i) basic standards for patentability and a limited list of exceptions to patentable subject matter;⁴ (ii) in terms of the availability of patents and the enjoyment of rights, no discrimination as to the field of technology, the place of invention and whether products are imported or locally produced;⁵ (iii) rights conferred by a patent and exceptions to the rights;⁶ (iv) conditions concerning the disclosure of the invention in a patent application;⁷ (v) compulsory licenses;⁸ (vi) availability of judicial review process for any decision to revoke or forfeit a patent;⁹ (vii) the term of protection¹⁰ and (viii) the burden of proof in deciding whether a product was obtained by a patented process.¹¹ Setting international standards on a number of issues is an extraordinary result achieved by the TRIPs agreement. However, the controversy as such has not disappeared with the adoption of the TRIPs agreement. Re-examination of provisions with respect to patents is under way.

Among all the provisions of the WTO agreement, the one relating to Trade Related Intellectual Property Rights (TRIPs) has possibly been the most widely debated in the country. There are very good reasons why this has been so. First, because provisions in TRIPs relate to the country’s Patent Laws and have a very serious bearing on major areas of the country’s well being – health, agriculture, research, etc. Second, because India has been particularly fortunate among all developing countries in having a very liberal Patents regime since 1970 that promoted the country’s interests. Third, because in the initial stages of the “Uruguay Round” of negotiations under the aegis of

⁴Article 27, TRIPs Agreement.
⁵Article 27.1, TRIPs Agreement.
⁶Articles 28 and 30, TRIPs Agreement.
⁷Article 29, TRIPs Agreement.
⁸Article 31, TRIPs Agreement.
⁹Article 32, TRIPs Agreement.
¹⁰Article 33, TRIPs Agreement.
¹¹Article 34, TRIPs Agreement.
the then General Agreement on Tariffs and Trade (GATT), which finally led to the formation of the World Trade Organisation (WTO), India had been extremely vocal in opposing the inclusion of Patent laws in the negotiations. While the Uruguay Round was initiated in 1986, it was only in 1989 that India did a sudden volte face and succumbed to pressure from the US and European countries by agreeing to include TRIPs in the negotiating agenda. Many, today, feel that if India had not succumbed in that crucial phase of the negotiations, the TRIPs agreement itself may never have seen the light of day.\footnote{Amit Sen Gupta, “Final Amendment to India’s Patent Act”, \textit{People’s Democracy}, Vol. XXVIII, No.40, October 03, 2004.}

6.1 TRIPs Agreement and Amendments to the Indian Patents Act 1970

India became signatory to the Agreement on Trade Related aspects of Intellectual Property Rights (TRIPs) of the World Trade Organization in 1995 along with other developing countries with a hope that TRIPs regime will result in free flow of trade, investment and technical know- how among the member countries by removing barriers that exists in the form of differences in the standards of intellectual property.

The unaltered earlier Indian patent regime under 1970 Indian Patents Act differed in many ways from that of the TRIPs agreement. The Patents Act drastically restricted the rights of patent holders in fields linked to basic needs. This is due to the fact that the adoption of the Patents Act 1970 was based on a lengthy legislative process and careful consideration of the socio-economic impacts of the patents in sensitive fields such as health and food. Therefore India had to considerably alter its patent law.

In order to fully comply with the TRIPs provisions India amended the Patents Act 1970, three times. The first two amendments to the patent legislation took place in 1999 and 2002 mainly to accommodate issues like ‘exclusive marketing rights’ (EMRs) and to extend the patent protection for the 20 years respectively. In 2005, the Patents Act 1970 has been amended for the third time. Immediately after this amendment the scientific, technical and business communities geared up for intense debate.
6.2 The Patents (Amendment) Act, 1999

In compliance to the provision of transitional arrangement and protection of existing subject matter as per Articles 65 and 70 of TRIPs, India notified an amendment to the Patents Act, 1970, by proposing and introducing Exclusive Marketing Rights (EMR) provisions on 1st January 1995. However, this notification failed to receive assent of the Parliament and lapsed thereafter. Consequently, India was dragged to Dispute Settlement Body (DSB) by United States and European Union. On receiving the adverse judgment from DSB, India successfully enacted in the 1st Amendment introducing the EMR provision for a period of 5 years or till the product patent is granted or patent application is rejected, whichever is earlier and the mailbox procedure for patent applications claiming pharmaceutical and agro-chemical products retrospectively from 1st January 1995.13

The main objective of the Patents (Amendment) Act 1999 is to remove exclusion of product patents in the area of food, medicine and drugs. According to the Government, this has been necessitated by India’s obligations as a signatory to the WTO. However, by merely introducing new clauses for exclusive marketing rights associated with product patent applications in the area of pharmaceuticals and agrochemicals as required by the TRIPs treaty without introducing new clauses for exclusion. The Patents Act 1970 had excluded large areas from patentability. The 1999 Act in contrast gives Exclusive Marketing Rights (EMRs) merely on the basis of foreign patents obtained after 1 January 1995 without any scrutiny on the basis of impact on public health, public morality or the public interest.14

The Patents (Amendment) Act, 1999 specified four pre-conditions to be met by an EMR applicant: (a) the applicant must hold a valid patent on pharmaceutical product granted after January 1, 1995 in any of the WTO member countries; (b) the applicant should have marketing rights in the member countries; (c) a product patent application should already have been made in India, and (d) marketing approval of the same product should have been granted in India. The first three conditions were as per the stipulation of

TRIPs agreement. The fourth clause was incorporated to meet the Indian drug regulatory approval. The other important change made was the removal of restriction on residents to apply for patents outside India. In the Patents Act (1970) it was obligatory for residents (section 39) to seek prior permission before applying for patent outside India.\textsuperscript{\ref{footnote:15}}

This Act sought to provide stronger patent protection for foreign pharmaceuticals and to create stronger domestic research capabilities. For example, an Indian company (Ranbaxy Lab, Inc.) signed a $90 million dollar joint venture with Eli Lilly & Co. to collaborate for pharmaceutical research and development. These Indian patent laws could allow the Indian pharmaceutical industry to modernize its pharmaceutical industry and compete with the developed world.\textsuperscript{\ref{footnote:16}}

\textbf{6.3 The Patents (Amendment) Act, 2002}

The second of the three amending Acts in the evolution of India’s patent law towards TRIPs compliance was the Patent (Amendment) Act, 2002, effective from 20 May 2003. The 2002 Act implemented a number of important changes, but most significant was the extension of patent term to twenty years. Uniform term of patent protection of 20 years for all categories of invention as per Article 33 of the TRIPs agreement has been prescribed. The 2002 Act amended the principal Act to provide that the term of all Indian patents would henceforth expire twenty years after their application filing date. Prior to this amendment, Indian process patents lasted only for the shorter of 5 years from sealing or 7 years from the date of the patent, while the term of all other types of patents (e.g., mechanical devices) was 14 years from the date of the patent.

Another notable aspect of the 2002 amendments was formal recognition in India’s Patents Act of the nations’ accession to two leading international intellectual property treaties, both administered by the United Nations-affiliated World Intellectual Property Organization (WIPO). As required by TRIPs, India brought its laws into compliance with the provisions of the Paris Convention for the Protection of Industrial Property, which entered into force in India on December 7, 1998. India henceforth had to abide by the Convention’s national treatment principle, which forbids discriminatory treatment of

\begin{footnotesize}
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\item \textsuperscript{\ref{footnote:15}} Supra note 13, p.437.
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foreign applicants, as well as its right of priority, which allows foreigners who have previously filed an application for patent in their home countries a twelve-month priority period in which to file an application directed to the same invention in India while retaining the benefit of their earlier home country filing date.\textsuperscript{17}

Also, as of December 7, 1998, India has been a party to the Patent Cooperation Treaty (PCT). As a PCT signatory, India had to begin accepting national phase filing of international applications originally filed abroad under the PCT and designating India; previously patent applications could only be filed directly with the Indian Patent Office. Accordingly, the Patents (Amendment) Act, 2002, included numerous provisions formally integrating Paris Convention and PCT terminology and provisions into the framework of India’s principal Act.

As of 2006, about 60\% of Patent applications received by the Indian Patent Office are PCT national phase filings; almost all of these are foreign-owned. However, India’s membership in the PCT is not benefit solely for foreigners - India’s own citizens are filing international applications under the PCT in growing numbers. In 2005, India was ranked third highest among the world’s developing countries in the number of PCT international applications filed by its nationals.\textsuperscript{18}

The Patents (Amendment) Act, 2002, implemented a myriad of other changes intended to bring India’s patent law into accord with the TRIPs agreement, including new definitions of ‘invention’ and ‘inventive step’,\textsuperscript{19} and new exclusion from patentable subject –matter like business methods,\textsuperscript{20} algorithms\textsuperscript{21} and traditional knowledge.\textsuperscript{22} The amendment also reversed the burden of proof provision involving cases of process patent

\textsuperscript{19} The Patents (Amendment) Act, 2002, (amending Section 2 (1), (j) and adding Sections 2 (1), (ja).
\textsuperscript{20} The Patents (Amendment) Act, Section 4 (adding Section 3 (k)).
\textsuperscript{21} Ibid.
\textsuperscript{22} The Patents (Amendment) Act, Section 4 (adding Section 3 (p)).
infringement\textsuperscript{23} and streamlined the compulsory licensing framework.\textsuperscript{24} The 2002 amendment also paved the way for patentability of microorganisms.\textsuperscript{25}

Some other important changes made were: (a) Redefining the scope of invention. Of particular significance were (i) allowing patents for treatment of plants (medicinal, surgical, curative and prophylactic process) to render them free of diseases or to increase their economic value or that of their products, and (ii) allowing patents covering microorganisms; (b) The source of geographical origin of biological material used in invention was made mandatory to be disclosed in the invention. A list of Authorized Depository Institutions were notified in the gazette of India, Part II, Section 3 for depositing the biological materials mentioned in the specification at the time of filing a patent application. This change was made as per compliance with Budapest Treaty; (c) Request for examination introduced implying all patent application in which First Examination Report have not been issued on or before 19th May 2003 were to be examined in serial order in which the request for examination is filed; (d) Reversal of burden of proof in case of process patent infringement from patent holder to the infringer (this was a requirement under TRIPs). The defendant has to prove that process used by him/her to obtain a product (identical to the product obtained by a patented process) is different from the patented process. The patentee is only required to prove that the product is identical to the product obtained by the patented process. (e) Provisions were made for filing as well as receiving patent application through PCT.

Additionally new grounds of opposition were introduced covering: (a) Non-disclosure or wrongly mentioning the source of geographical origin of biological material used in invention; (b) Anticipation having regard to the knowledge oral or otherwise available within the local indigenous community in India or elsewhere. As per TRIPs agreement, patent or some form of protection has to be provided for protecting plant varieties. Government introduced “protection of plant varieties and farmer’s rights act”

\textsuperscript{23} The Patents (Amendment) Act, Section 43 (adding Section 104 (A)).
\textsuperscript{24} The Patents (Amendment) Act, Section 39 (substituting the previous provisions with a whole new chapter dealing with Compulsory Licensing, Chapter XVI).
\textsuperscript{25} The Patents (Amendment) Act, Section 4 (adding new Section 3(j) dealing with plant varieties. India drafted a new law called Protection of Plant Varieties and Farmer’s Rights 2001 to give effective protection to plant varieties).
(PPVFR 2001) for providing protection to various plant related/derived products (plant extracts, various compositions derived from plant products).  

Secrecy direction (defense) is reconsidered by the central government at the interval of 12 months or on request made by the applicant. Prohibition to apply, under certain circumstances, for patents relevant for defence purposes, no person shall, apply for patent outside India relevant for defense purposes or related to atomic energy unless-

a. Written permit granted by the Controller,

b. an application for a patent for the same invention has been made in India, not less than six weeks before the application outside India; and

c. The Controller shall not grant written permission to any person to make any application outside India without the prior consent of the Central Government.

d. Foreign applicants, who has first filed an application in their country and further apply in India, is not likely to be affected with above conditions.

Patent shall be dated as of the date on which the application for patent was filed. Every International patent application under Patent Co-operation Treaty designating India shall be deemed to be application if corresponding application has also been filed in India. The international filing date of application is the date on which the complete specification is filed for the patent application. The definition of “convention country” has been broadened to include a group or union of countries or inter-governmental organizations such as European Union. A patentee has the exclusive right on his patented product/process, no person in public domain can make, use, sell, import his product in India without the consent of the patentee. After cessation of the grant of patent, restoring the patent by paying fees within 18 months. Secret trial or secret use of patent invention before the grant of the patent may be revoked. Administrative work in the Patent Office is now updated. Register of Patents is maintained in computer floppies, diskettes or any electronic form for safety. A written assignment of a patent, a mortgage, license has to be made within 6 months from the execution of the document. The person willing to protest their patented invention from any petitioner has opportunity by making a request for


27 Ibid.
hearing within 10 days before the expiry time limit. Use of invention by Central Government, Patentee shall not be paid more than adequate remuneration taking into account economic value of the use of patent. Central Govt. using the invention has to notify the patentee except in case of national emergency or other extreme emergency. Importation of the invention by the Central Government for the distribution in hospitals, dispensary, medical institution or any medical purposes is prohibited. Making, Constructing, selling, using and importation of a patented invention by the patentee in India or elsewhere for research and development of information under any law, is not an Infringement of the patent rights. Suit for an infringement of a patent for a process for obtaining a new product, the burden of proof, in certain circumstances, to show that the product is not made by the process used will lie on the defendant. The court may order to destroy the infringing goods. Any person disturb the secrecy direction enforced by the central government on the patent shall be either imprison for the term of two years or fine or both. Any person apply outside India for the grant of patent on his invention, unless written permission granted by the Controller, will be punished for either imprison for the term of two years or fine or both. Any person sold his product in the market without applying for patent application in India, is punished with fine. If any person, refuse or fail to supply any information required by the central government is punished with fine.28

Apart from these, another noteworthy addition is at section 3 of the Act, where it suggested that traditional knowledge be excluded from patentability. This clause has the practical significance in India. This provision, however, restates the uncontroversial position that knowledge in the public domain cannot be patented. The real issue is whether inventions based on traditional medicines can also be denied patentability. This refers to a broader problem concerning the definition of patentable inventions. TRIPs agreement does not impose on member states a specific definition of what constitutes non obviousness and Parliament could choose to provide an extensive definition which restricts not only the patentability of ayurvedic medicines but also derived medicines, which are essentially laboratory copies of the original.29

28 Supra note 13.
The 2002 amendments are substantially different from the 1999 draft with regard to compulsory licensing. Section 83, which provides a general framework to guide the issuance of compulsory licences, is particularly noteworthy. It constitutes a broader endeavour to incorporate some of TRIPs in-built flexibility in to the Patents Act. Interestingly, Section 83 specifically mentions that patents granted should not “impede protection of public health”, should not prohibit the central government from taking measures to protect public health and the patents should be granted to make the benefits of the patented invention available to the public at reasonably affordable prices.\(^{30}\)

Qualification of patent agents was amended restricting to only science, engineering and technology graduated to be patent agents. Additional exceptions,\(^{31}\) penalties and many other amendments were introduced to comply with TRIPs and to balance the rights and obligations. Appellate Board for patents was introduced under Chapter XIX, which came into effect much later in 2007.

6.4 The Patents (Amendment) Act, 2005

India became a party to the TRIPs agreement in April 1994. At that time, India’s current enactment, the Patent Act of 1970 directly contravened Article 27 of the TRIPs agreement. Upon coming into effect on January 1, 1995, TRIPs set out transitional periods for WTO members to introduce legislation complying with the obligations under TRIPs.\(^{32}\)

For developing countries like India, the deadline for complying with TRIPs was the year 2000. In addition, Article 65.4 of TRIPs provided a special transitional provision for those countries that did not grant product patents. The provision provided an additional five years (until 2005), from the initial TRIPs transitional period to introduce product patent protection. India took advantage of this extra transition period.

Technically speaking, only one amendment was required under TRIPs, i.e., the introduction of product patents for pharmaceutical inventions. However, the ordinance carried out a further 74 amendments to the Patents Act, thus taking it much beyond the

\(^{30}\) Ibid.
\(^{31}\) Section 107A, Patents Act, 1970.
TRIPs requirements. In effect these set of amendments took India into a ‘TRIPs plus’ regime.

On December 26, 2004, India issued a presidential decree to amend its law and meet this final dead line. The Patents (Amendment) Act of 2005 passed by the Indian Parliament, replaced that Ordinance.  

6.4.1 Product Patents for Pharmaceutical Inventions

Under TRIPs agreement, WTO members have to enforce product patents for agrochemicals and pharmaceutical compounds. About 50 developing countries, including India had not complied with this requirement during the Uruguay round of GATT negotiations. The much awaited and debated patents amendment was finally passed in parliament in March 2005. This third amendment to the Indian Patents Act 1970 brought India in the line with the TRIPs agreement.

Omission of product patents for agrochemicals and pharmaceuticals was our strength until now. This had contributed to widespread growth of generic pharmaceutical industries, also making available medicines to the public at very low cost. The Indian domestic pharmaceutical industry grew strong, highly competitive and a big supplier of medicines and drugs within the affordable prices to common man because of a regulatory system focusing only on process patents along with a rigid price control. India developed into a world class generics industry. In fact in 2002, India was the world’s largest producer of generic drugs in terms of volume. Introduction of product patent along with the new regulations will cause significant changes in the Indian IPR industry. Product patent regime will be particularly favorable to the players already developed and well-equipped in terms of scientific and technical resources. So, naturally, the main concern was about the fate of our pharmaceutical industry and consequent cost escalation of medicines when we allowed product patent form 1st January 2005. Hopefully Indian pharmaceutical industry will not be much impacted by the new Product Patent regime.

More specifically, it has been suggested that all countries should adopt product patents instead of process patents. Supporters of product patent argue that this regime

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actually provides more comprehensive protection to the inventor since the product itself is protected. Supporters of process patent argue that this regime promotes competition and may also inspire innovation of new technologies that are more efficient. Many countries, following process patent systems, have been forced to change their laws and start pursuing product patent regimes.\(^{35}\)

India moved from a process patent system to a product patent system in 2005. The patent law is one of the seven intellectual property laws protected under this agreement. Section 5 of the TRIPs agreement deals with Patents. Article 27 says that “patents shall be available for any inventions, whether products or processes in all fields of technology provided that they are new, involve an inventive step and are capable of industrial application”.

The most prominent and controversial change has been the deletion of section 5 of the Patents Act, 1970, thereby paving the way for product patents in the area of pharmaceutical and other chemical inventions. Section 5 of the Patents Act, 1970 (as it stood after the 2002 amendments) had provided that, in the case of inventions being claimed relating to food, medicine, drugs or chemical substances, only patents relating to the methods or processes of manufacture of such substances could be obtained.

This deliberate strategy of denying product patent protection to pharmaceutical inventions is traceable to the Ayyangar Committee Report,\(^ {36}\) a report that formed the very basis of the Patents Act, 1970. The Committee found that foreigners held between eighty and ninety percent of Indian patents and that more than ninety percent of these patents were not even worked in India. The Committee concluded that the system was being exploited by multinationals to achieve monopolistic control over the market, especially in relation to vital industries such as food, chemicals and pharmaceuticals. Medicines were arguably unaffordable to the general public and the drug price index was rising rapidly. The Committee therefore recommended that certain inventions such as pharmaceutical inventions, food and other chemical inventions be granted only process patent protection.


India’s well-developed generic industry today is testimony to the farsightedness of this report.\textsuperscript{37}

For the first time since 1972, India’s patents regime once again recognizes the potential patentability of pharmaceutical products. Section 4 of the Patents (Amendment) Act, 2005, is the cornerstone provision for bringing India’s patents law into compliance with TRIPs. Product Patent is the granting of patent to the ‘final’ product irrespective of the process used for obtaining the product. Once you obtain a patent on the product, then one is precluded from manufacturing that product, even though with a different process.\textsuperscript{38}

The immediate impact of this fundamental expansion of patentability in India was a huge influx of product patent applications. Approximately 9,000 mailbox applications were filed with the Indian Patent Office during the TRIPs transition period of January 1, 1995 to December 31, 2004 claiming substances capable of use as food, medicine or drug. During the first eighteen months of the new patents regime, i.e., during January 1, 2005 to June 30, 2006, summaries of approximately 6,700 of those mailbox applications have been published. The Indian Patent Office began taking up the mailbox applications for examination in January 2005. In addition, regular (non-mailbox) applications claiming pharmaceutical substances were also filed on or after January 1, 2005. The first pharmaceutical product patent to issue under India’s new patents regime was granted in March 2006 to Hoffman-La Roche for its Hepatitis C therapy sold under the brand name Pegasys.\textsuperscript{39}

The product patent regime replaced one of the important policy tools used for the development of the Indian pharmaceutical industry. In the absence of product patent protection prior to 2005, the Indian pharmaceutical industry was able to introduce new medicines in the Indian market and abroad within a short period of time at a fraction of the originator's price. Further, competition was generated among Indian pharmaceutical manufacturers because, with no product patents, many companies introduced the same products in the market. This competition, coupled with price control on essential


\textsuperscript{39} Supra note 18.
medicines up to the mid-1990s resulted in the availability of medicines at low prices. The reintroduction of product patentability takes away the freedom of Indian pharmaceutical companies to introduce generic versions of new chemical entities (NCEs) in the normal course because NCEs often come with product patent protection. Under the product patent regime, a generic version of a patented NCE can be introduced in the market only by having recourse to flexibilities in the patent law, viz., patent opposition, compulsory licensing or parallel importation.

Seven years after the introduction of product patent protection, there is ample evidence of growing control of MNCs in the Indian pharmaceutical market. Figures released by the Indian Patent Office reveal that out of 3,488 product patents issued from 2005 to March 2010, 3,079 were granted to MNCs.

A study (2011) examining the post-TRIPs behaviour of MNCs in India states, 'Strong IPRs [intellectual property rights] have not favoured India with the claimed benefits of increased access to good quality FDI, technology transfer, overseas product R&D and stimulation of domestic investment in R&D for product innovation for local needs.' On the technology transfer front, the study says, 'During the pre-TRIPs era foreign pharmaceutical firms often exhibited in India an almost near complete aversion to technology transfer in bulk drug production. Evidence collated on the recent patterns of technology transfer from foreign firms to domestic companies shows that the results are not very encouraging for pharmaceuticals.' Regarding investment in R&D for drug development, the study finds that Hoechst and Astra, which carry out limited drug discovery operations in India, still remain, 'while others have closed down the units that had the mandate to develop products for the benefit of local markets'.

The introduction of pharmaceutical product patent was supposed to have negative impacts on the Indian pharmaceutical industry. It would hamper the growth of the Indian pharmaceutical industry. The industry can no longer manufacture by reverse engineering and export drugs that product patents are effective. However, contrary to the expectations, the Indian pharmaceutical industry has been growing post-TRIPs period. The productivity of the Indian pharmaceutical industry has been improving even in post-

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TRIPs period. It can be said that the introduction of pharmaceutical product patent brings new business opportunity to the Indian pharmaceutical industry and promotes growth of the industry.\textsuperscript{41}

6.4.2 Software Patentability

Section 3(k) of the Patents (Amendment) Act, 2005 excluded “a computer program per se” from the scope of patentability. This exclusion met with conflicting interpretations at the patent office, with some examiners granting patents to software combined with hardware or software with a demonstrable technical application of some sort. The 2004 Ordinance therefore qualified this exclusion by stating that software with a “technical application” to industry or when “combined with hardware” would be patentable. Owing to vigorous opposition from the free software movement, this provision was removed from the 2005 Act. The earlier position under the Patents Act, 1970 that a computer program per se is not patentable now prevails. Interestingly enough, a draft of a recent manual of the Patent Office that attempts to lay down guidelines to interpret the Act arrives at a conclusion that is similar to what the Ordinance provision sought to achieve. It notes:

The statute excludes from patentability the software per se. The inventions relating to the application of the computer program or software is [sic] held patentable under the Indian Patent Act, 1970 when claimed in combination of hardware and software components of a computer which provide a “technical advancement” over the prior art. It is necessary for the applicant to describe the “technical contribution” to the prior art when the invention involves software. The technical problem, which needs to be solved by the invention, should be sufficiently described as to how the hardware is controlled by the software to overcome the previously described problem. The “technical character” of the invention should be brought out clearly in the claims.\textsuperscript{42}


\textsuperscript{42} Supra note 3.
6.4.3 Distinguishing Features of Patents (Amendment) Act 2005

‘New Invention’

The Patents Amendment Act, defines the term ‘new invention’ as “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 a 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 the art”.\(^{43}\)

It appears that the intent behind this provision is to define a ‘novelty’ standard - which, along with ‘non-obviousness’ (or ‘inventive step’) and ‘utility’ (‘industrial applicability’), are the three prerequisites for ‘patentability’.

However, a term such as ‘new invention’ raises the question of what an ‘invention’ is in the first place. Section 2(j) defines an invention as “a new product or process involving an inventive step and capable of industrial application”. Since ‘new’ is already a part of the term ‘invention’, introducing a term such as ‘new invention’ to define a novelty standard is circular and makes for shoddy drafting. A clearer way of doing this would have been to define the term ‘new’ as found in the term ‘invention’.

The ‘new invention’ definition suffers from yet another infirmity. While it appears to endorse an ‘absolute’ novelty ground, the Act still retains a ‘relative’ novelty ground in section 25. Section 25 stipulates that a patent application can be opposed on the ground that the invention was “publicly known or publicly used in India before the priority date of that claim”. To this extent, the ground for opposition is based on ‘relative novelty’, i.e. the invention should be known or used in India, whether or not it is so known or used in any other part of the world. The new definition under the 2005 Act however provides for ‘absolute’ novelty - in order to qualify as a ‘new invention’, the said invention should not have “been anticipated by publication in any document or used in the country or elsewhere in the world”.\(^{44}\)

Consider an application for invention X in India, where the said invention had already been used in China at some earlier point in time. It would appear that such application could be refused by the patent office on the ground that the invention had


\(^{44}\) Patents Act 1970, Section 25, as amended by Patents (Amendment) Act 2005.
been used in China and is not therefore a ‘new invention’. However, at the stage of opposition, a third party cannot take up this ground under section 25, since the invention had never been publicly used in India before the priority date of the claim. This difference in standard seems odd, given that an interested third party is more likely to be aware of a foreign use of the invention in question than an Indian patent examiner.\footnote{Supra note 37, p.20-21.}

The ‘Inventive Step’

The 2005 Act makes a critical change to the earlier ‘non-obviousness’ or ‘inventive step’ test. The definition now reads:

‘inventive step’ means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to the person skilled in the art.\footnote{Patents Act 1970, Section 2 (1) (j a), as amended by Patents (Amendment) Act, 2005.}

As can be seen from this definition, while the fundamental yardstick for measuring an ‘inventive step’ remains that which is “not obvious to a person skilled in the art”, a requirement that the invention involve a ‘technical advance’ or have an ‘economic significance’ of some sort has been added.

This change in the standard seems odd, given that the very purpose of the ‘inventive step’ criterion is to determine whether an invention sufficiently advances the technical arts so as to warrant an exclusive right. This is no doubt achieved in an optimal manner by the simple test of whether the invention, though novel, is non-obvious to a person skilled in the art. By itself, the non-obviousness test is a difficult one to apply - additional criteria such as ‘technical advance’ and ‘economic significance’ only further the complexity. Contrary to suggestions by some commentators, the addition of ‘technical advance’ or ‘economic significance’ to the ‘non obviousness’ test does not dilute the ‘inventive step’ requirement - on the contrary, it is susceptible to being interpreted in a manner that renders it more onerous to satisfy.\footnote{K. M. Gopakumar & Tahir Amin, “Patents (Amendment) Bill 2005: A Critique”, 40(15), Economic & Political Weekly, April 9, 2005, p.1503-1504.}

Further, ‘economic significance’ seems to be more of a ‘utility’ or ‘industrial applicability’ standard. By including such a criterion within a ‘non-obviousness’ or
‘inventive step’ standard, the Act creates considerable uncertainty. A commentator observes: “It interferes with the time-tested principles of patents law, and in that process has created a new definition that can lead to loose interpretations.”

Pharmaceutical Substances

The introduction of a new definition for “pharmaceutical substance” under Section 2(t a) of the Patents Act, as amended, defines a pharmaceutical substance as “any new entity involving one or more inventive steps”.

If the real objective of the definition was to narrow the scope of patenting of pharmaceutical products, it falls far short of meeting this objective. In fact, the existing definition opens the door for frivolous claims aplenty in this area. It has been argued for instance that the term ‘chemical’ should have been inserted so that the definition would be ‘any new chemical entity’. That this suggestion has considerable merit can be seen from the manner in which the Food and Drug Administration (FDA) deals with this issue. According to the FDA, new chemical entity (NCE) or a new molecular entity (NME) means a drug that contains no active moiety that has been approved by FDA in any other application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act. An active moiety means the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other non covalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance.

The ‘New Use’ Exclusion

Section 3(d) of the Patents Act, 1970 excluded a “new use for a known substance” from the ambit of ‘invention’. The 2005 Act has expanded on this exception by providing that “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” would not be patentable. It then

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states that salts, esters, ethers, polymorphs, metabolites, etc. shall be considered as the same substance unless they “differ significantly in properties with regard to efficacy”.

The introduction of a new definition for the term ‘substance’ through the explanation above would make for some nuanced interpretative battles. If, for example, X1 is a polymorphic\textsuperscript{50} form of X, then would a showing of increased efficacy for X1 change it to a new substance? In short, at what point would a showing of increased efficacy change a ‘new form’ of an existing substance to a new substance altogether?

In order to answer this question, one has to first address the issue of what exactly the term ‘efficacy’ means. Would this term be construed in a manner similar to how a drug approval agency would construe it?

It is interesting to note in this connection that this provision in the 2005 Act, which finds no parallel in any other patent legislation in the world, has been copied from a European Directive dealing with drug safety regulation.

As one can well appreciate, blindly transposing a provision that operates within the context of a drug regulatory regime to a patent regime can pose problems. For one, it makes it more likely that the term ‘efficacy’ would be construed in a drug-regulatory sense - consequently, the requirement would be a difficult one for most patent applicants to satisfy. Pharmaceutical companies generally file patent applications at the initial stage of discovery of a drug; it is only much later in the development process that clinical studies (phase III) are conducted to gather information pertaining to the therapeutic efficacy of the drug. The requirement of information on ‘efficacy’ at the stage of filing a patent application is therefore an onerous one.\textsuperscript{51}

If, on the other hand, the term ‘efficacy’ were to be construed in a liberal manner to include even a general hint of an added advantage in using the new form, it is possible that a good number of formulations would qualify as new substances upon the showing of an increased efficacy.

The amended section 3(d) appears to be limited to only new forms that demonstrate an increase in known efficacy. It does not, therefore, apply to a case where

\textsuperscript{50} A polymorph is “a solid crystalline phase of a given compound resulting from the possibility of at least two crystalline arrangements of the molecules of that compound in the solid state”.

the new form is found to have a completely different use (and not just an increased efficacy vis-à-vis the known use). If the intention behind this provision is to heighten the obviousness standard and weed out frivolous and fairly obvious patents, this seems a rather illogical result, as a new use for a new form is certainly more inventive than a mere showing of an increase in known efficacy.\textsuperscript{52}

\textit{Novartis Ag v. Union of India}

When pharmaceutical company Novartis challenged the rejection of its patent application for the leukemia drug Gleevec in \textit{Novartis AG v. Union of India},\textsuperscript{53} it became the first major legal challenge to India’s newly amended patent law. In 2005, India purportedly made the final changes required to bring its intellectual property laws in compliance with the Trade-Related Aspects of Intellectual Property Rights (TRIPs), the World Trade Organization’s (WTO) minimum standards for intellectual property protection, but its patent law is still fraught with a number of controversial provisions. The ability of pharmaceutical companies such as Novartis to secure patent protection in India not only is important in creating incentives for pharmaceutical research, but also greatly affects the Indian generic drug industry, and therefore the price of medicine available to patients. India is the world’s second most populous country and the second fastest growing major economy, but has 70\% of its population living on less than $2 per day, making Novartis AG of paramount importance.

Gleevec is used for the treatment of chronic myeloid leukemia (CML), a disease that afflicts nearly 5,000 new patients in the United States each year. Studies have shown that Gleevec, which targets specific cancer proteins, is almost ten times more effective than traditional interferon therapy. In 1993, Novartis filed patents worldwide for the active molecule imatinib. Novartis did not patent imatinib in India because the 1970 Act did not allow patenting of pharmaceutical products at that time. After India’s entry into the WTO in 1995, Novartis filed a “mailbox” patent application in the Madras Patent Office for imatinib mesylate, a beta crystalline form of the free base imatinib. In 2002, Novartis started its Gleevec donation program in India to provide Gleevec to patients

\textsuperscript{52} \textit{Supra} note 37, p.23-25.
who were unable to afford the medicine, but halted that program after Indian drug manufacturers began to produce a generic version of Gleevec. In 2003, the Patent Office granted Novartis Exclusive Marketing Rights (EMR) in India, which allowed Novartis to enjoin generic Gleevec manufacturers and raise the price of Gleevec almost ten-fold. When the Gleevec mailbox application came up for examination in 2006, some commentators suspected that the application was fast-tracked due to controversies over the donation program and the divisive rise in price. In January 2006, the Madras Patent Office refused to grant Novartis a patent for imatinib mesylate. The first major ground for rejection was that because imatinib mesylate was a salt form of the free base imatinib, and Novartis claimed all pharmaceutical salt forms of imatinib in its 1993 patents, the Indian application therefore lacked novelty and inventiveness. The second major ground for rejection was based on Section 3(d) of the 2005 Amendment, which required that new forms of a known substance could only be patented as a product if they demonstrated “enhanced efficacy.” Although Novartis disclosed information that imatinib mesylate had a 30% increase in bioavailability (the percentage of the drug absorbed into the bloodstream) as compared with imatinib, the Patent Office found this insufficient to meet the “enhanced efficacy” requirement of Section 3(d).  

In May 2006, Novartis petitioned the Madras High Court, opposed by the Indian Government, the Patent Office, several Indian generic drug manufacturers and an Indian public interest group. Novartis claimed that the Patent Controller erred in rejecting the Gleevec patent application, that Section 3(d) was not compliant with TRIPs, and that Section 3(d) was vague, ambiguous and in violation of Article 14 of the Constitution of India because it was discriminatory against Novartis. The case was bifurcated between the Madras High Court and the Intellectual Property Appellate Board (IPAB). The challenges on TRIPs compliance and constitutionality of Section 3(d) were heard by the Madras High Court, which issued a judgment against Novartis on August 8, 2007. IPAB rejected the claim, but gave certain findings favourable to the company.

The Madras High Court entertained three issues: First, whether courts in India have jurisdiction to review if Section 3(d) of the 2005 Amendment is compliant with

Article 27 of TRIPs, and alternatively, whether courts in India can grant declaratory relief that Section 3(d) is not compliant with TRIPs. Second, if courts do have jurisdiction, whether Section 3(d) complies with Article 27 of TRIPs. Third, whether Section 3(d) violates Article 14 of the Constitution of India because it is vague, arbitrary and confers uncontrolled discretion to the Patent Controller.\(^{55}\)

(i) Jurisdiction:

The Madras High Court held that it did not have jurisdiction to decide a case concerning the compliance of a domestic Indian law with an international treaty. In support of its arguments, Novartis relied on a case from the United Kingdom, *Equal Opportunities Commission & another v. Secretary of State for Employment*, in which the court held that British courts had jurisdiction to decide a case concerning the compatibility of a British law with the European Community Law. The Madras High Court distinguished the facts of the Novartis dispute with those under Equal Opportunities Commission, because the European Community Law had been “domesticated” as the domestic law of England through the European Communities Act, whereas the Indian government had not “domesticated” TRIPs. Furthermore, the Madras High Court asserted that the nature of an international treaty is contractual, and accordingly contains provisions for dispute settlement. Since Article 64 of TRIPs expressly provides that disputes should be taken to the Dispute Settlement Body of the WTO, the Madras High Court held that Novartis should seek to enforce TRIPs through that mechanism and not an Indian court. Concerning the alternative argument of granting of declaratory relief, the Madras High Court asserted that courts have broad discretionary power to grant declaratory relief under Article 32 of the Constitution of India. The court held, however, that declaratory relief should not be given where it would serve no useful purpose to the petitioner. Because Novartis could not compel the Indian parliament to enact or amend a law even if Novartis were to get a declaration that Section 3(d) was noncompliant with TRIPs, the court held that Novartis was not entitled to declaratory relief.

\(^{55}\) Id, p.300.
(ii) Compliance with TRIPs:

Because the Madras High Court held that it did not have jurisdiction to decide whether a domestic law violated an international treaty, it refused to decide whether Section 3(d) is compliant with TRIPs. Nevertheless, the court opined that TRIPs allows flexibility for the individual needs and situations of every member country. In complying with the TRIPs obligations, India has a constitutional duty to provide good health care to its citizens, and giving them access to affordable drugs. Thus, the court opined that the validity of Section 3(d) should be analyzed with consideration of its objectives of preventing ever-greening and making generic drugs available.

(iii) Constitutionality:

The court held that Section 3(d) did not violate Article 14 of the Constitution of India and was not vague or arbitrary, and did not confer uncontrolled discretion to the Patent Controller. The court rejected Novartis’s arguments that Section 3(d), which denies patents to new uses of known substances unless the patentee can show “enhancement of the known efficacy” or “differing significantly in properties with regard to efficacy,” was ambiguous and unclear. While these two phrases are not explicitly defined, the court held that it was a common practice for the legislature to use general language and leave the courts to interpret the language based on the context and facts of each case. Moreover, the court held that Novartis was a sophisticated party who had the technological expertise to comprehend the enhanced efficacy requirement.56

The court also rejected Novartis’s argument that Section 3(d) was arbitrarily enacted. Novartis argued that the actual amended Section 3(d) was not the same as the one originally proposed to the Parliament, which made no mention of an efficacy requirement, and was substituted in the current form of Section 3(d) without explanation. The court held that Section 3(d) was not arbitrarily enacted, referring to the parliamentary debates leading to the 2005 Amendment. The debates revealed that there was widespread fear that the earlier proposed amendments would deny Indian citizens of access to affordable medicines and open up the possibility of ever-greening. Thus, the court found that the legislature did not arbitrarily enact Section 3(d) in its final form.

56 Id, p.301-302.
Finally, the court held that Section 3(d) did not confer unlimited discretionary power to the Patent Controller and was not discriminatory. The court emphasized that discretionary power did not necessarily mean that it would be discriminatory. The Patent Controller’s discretionary power under Section 3(d) in deciding whether a known substance has enhanced efficacy did not automatically lead to an arbitrary exercise of discretionary power or discrimination against Novartis. Furthermore, the court opined that the judiciary should be more deferential to the legislature in the field of economic regulation. Because the Patent Act was designed to encourage the economic interests of India, the courts should be especially cautious before overruling the legislature.\(^\text{57}\)

The Hon’ble High Court of Madras, on the issue of compliance of section 3(d) of the Indian Patents Act 2005, with Article 27 of the TRIPs agreement, decided mainly on the jurisdictional issue and said that it lacked jurisdiction to entertain the issue. Court relied on using a ‘contractual’ approach and concluded on the basis of general principle, which states that ‘non-compliance with an international obligation does not provide private parties with the right to challenge a domestic statute unless the international instrument expressly grants such right’. The TRIPs agreement in this regard grants right only to member states.

The Court further mentioned that the WTO’s Dispute Settlement Understanding provides the exclusive remedy and a comprehensive dispute mechanism for violation of TRIPs agreement. The High Court looked into various previous decisions in case of conflict between the international law and municipal law and decided that municipal law prevails in such conflict. Moreover, in India, international treaties are not directly enforceable.

Thus, the decision leaves crucial question before the Court unanswered. It is a well-founded decision both on the understanding of settling the claims under the TRIPs agreement and also in the light of the precedents relating to the place of international law in the Indian legal regime.

It also rejected the second contention of Novartis regarding the unguided power granted to the Patent Controller by the impugned provision. While deciding on the issue,

the Court upheld that Section 3(d) is neither vague nor arbitrary and therefore is not violate Article 14 of the Indian Constitution. The Court also studied the requirements of the impugned provisions placed on the Patent Controller.

The whole argument of Novartis to hold Section 3 (d) vague and arbitrary rested on the fact that, since the term ‘efficacy’ was undefined, the term ‘enhanced efficacy’ was ambiguous. The Court is right in its decision because undefined terms cannot essentially be deciphered as lack of guidance to the patent controller. In fact, the explanation in Section 3(d) provides as to what constitutes ‘enhanced efficacy’. The Court also pointed out that intention of the provision is clear and simple- for a patent to be granted it must be shown that the substance discovered has a ‘better therapeutic effect’. Therefore, the Court concluded that the patent controller could competently determine the issue and the enhancement of a drug could also be most definitely determined.

Although the Court dismissed the petition, it acknowledged that the wording of section 3(d) is not perfect and it may still create interpretive problems and may lead to unintended results. However, it must be kept in mind that in this case the Court did not consider the broad question of dealing with the merits of section 3(d) but focused on the narrow issue whether it is was vague or arbitrary to the extent that it would satisfy an Article 14 challenge. Before dismissing the petition the Court made certain important observation and mentioned that the Amendment Act intended for: (i) preventing ever-greening; (ii) to provide easy access to the denizens of this country for life saving drugs; and (iii) to discharge their constitutional obligation of providing health care to its citizens.58

On August 2009, Novartis approached the Supreme Court of India. In a major blow to the Swiss pharma giant Novartis, the Supreme Court on Monday, April 1st, 2013, rejected its plea for a patent on cancer drug Glivec. The verdict is expected to pave the way for Indian firms to provide affordable drugs to lakhs of cancer patients.

Ending a seven –year legal battle by Novartis to have exclusive right for manufacturing Glivec, and to restrain Indian firms from making generic medicine, the

apex court held that there was no new invention and no new substance used in the drug prescribed for treating blood, skin and other cancers.59

The judgment allows suppliers to continue making generic copies of Swiss firm Novartis’ Glivec, which has been shown to fight chronic blood cancer effectively. While the Novartis drug costs Rs 1,20,000 or US $ 2,400 per month per patient, while generic versions are available at a cost of Rs 8,000 (US $ 160) to Rs 12,000 (US $ 240) per month, with doctors often advising patients to take it lifelong, the ruling would be a relief to some 300,000 patients in India currently taking the drug.

A bench of Supreme Court Justices Aftab Alam and Ranjana Desai said: “We firmly reject the appellant’s case that Imatinib Mesylate is a new product and the outcome of an invention beyond the Zimmermann (original) patent”. The Bench said that the patent application contains a “clear and unambiguous averment” that all the therapeutic qualities of the modified form, for which the patent was applied, “are possessed’ by the original version.

The court held that patents can be granted only for medicines that are truly new and innovative. For new forms and new uses of existing medicines, patent applicants should prove improved efficacy. The court said that the Patents (Amendment) Act, 2005 established that 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” is not an invention – for the purpose of patenting.60

Observers say that the Court’s judgment sets a precedent against the practice of “evergreening” – a strategy through which drug manufacturers introduce modifications of drugs to extend the five-year patents on them. They say that other “evergreening” patent applications could be rejected citing this judgment, helping to keep many life-saving drugs out of the patent regime and pushing down costs. Pfizer and Roche are fighting for similar patents on their Cancer and Hepatitis C drugs. Ruling is bad news for them.

It is a big boost to Indian generic drug suppliers and a big positive for generic manufacturers, patients and consumers and certainly a negative for multi-national pharma

59 The Times of India, Tuesday, April 2, 2013, p.1.
60 The Hindu, Tuesday, April 02, 2013, p.1.
companies as ruling sets a precedent against the practice of drug companies extending patents by introducing small modifications of old drugs. India exports $10 billion worth generic drugs. Indian drug giants such as Dr. Reddy’s share was up 2.64% at Rs. 1,813.00, Cipla rose 2.63 percent to Rs. 389.0, Natco jumped as much as 10.72 percent to Rs. 475.05 and Ranbaxy rose 2.77 percent to a high of Rs. 452.7 rupees. Novartis shares slumped 6.8 percent to Rs. 558.10 at the Bombay Stock Exchange – its lowest since January 2012 – after the ruling, before recovering marginally to Rs. 572.95.61

The objective of India’s Section 3(d) is not a radical departure from international practices to regulate the patenting of derivatives and new uses. Nevertheless, Novartis claimed that Section 3(d) was not compliant with TRIPs Article 27. Assuming that the patent laws of other countries are TRIPs-compliant and absent WTO ruling on the contrary, Novartis has likely overstated the noncompliance of Section 3(d).

TRIPs Article 27.1 states, “Patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.” This provision obliges member countries to grant product and process patents in all fields of technology and sets up three criteria, novelty, inventive step, and industrial applicability, for patentability. Inventive step and industrial applicability correlate to the concepts of non-obviousness and utility in the United States.

The 2005 Amendment extended product patent protection to pharmaceutical substances in order to fulfill Article 27.1’s requirements. However, “novelty,” “inventive step” and “industrial application” are not defined in TRIPs; member countries arguably have considerable flexibility in applying these three criteria. One perspective is that Section 3(d) is merely a codified non-obviousness standard in the context of pharmaceutical substances, and therefore permissible under TRIPs. India has limited discretion under TRIPs to decide the subject matter entitled to patent protection, but it has greater discretion to fine tune its patent regime by limiting the scope of protection available for derivatives and new uses by adjusting the inventive step criteria.

TRIPs also silent on the issue of whether new medical uses which itself is controversial and inconsistently treated by developed countries is patentable. Some

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61 Id, p.10.
commentators assert that new use patents lack novelty because they are mere discoveries of new properties of existing products. The EU approach sidesteps this obstacle by recognizing it as a “legal fiction” in which an invention can draw novelty from a new use. Furthermore, since new use patents frequently refer to new medical uses of known pharmaceutical substances, they may fall under the TRIPs exception on patenting of a therapeutic method.\(^\text{62}\)

### 6.4.4 Pre-Grant and Post-Grant Opposition

The Patents Act, 1970 is endowed with a fairly robust pre-grant opposition mechanism. It provides for several grounds on which a patent could be opposed including the lack of novelty, inventive step or utility (the traditional patentability criteria) or that the claimed invention does not fall within eligible subject matter or that the specification does not disclose the source or geographical origin of biological material used for the invention.\(^\text{63}\)

The 2005 Act has introduced a post-grant opposition mechanism for the first time. Within a year of the patent being granted, a ‘person interested’ can challenge the issued patent on grounds that are identical to the grounds available at the pre-grant opposition stage.\(^\text{64}\) The key difference between the pre-grant and the post-grant opposition mechanism appears to be that while ‘any person’ could challenge at the pre-grant stage, the challenger has to be a ‘person interested’ at the post-grant stage. “Any person” has been interpreted to cover potential generic competitors as well as social action groups representing interests of patients suffering from various diseases like cancer and AIDS.

India is one of the few systems to provide pre-grant as well as post-grant opposition proceedings. Interestingly, most advanced countries do not follow pre-grant opposition proceedings.\(^\text{65}\)

A competitor who fails to challenge a patent application at the pre-grant/post-grant stage has a further opportunity - he or she can seek revocation of the patent under

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\(^{62}\) Supra note 54, p.308-310.

\(^{63}\) The Patents Act, 1970, Chapter V (Section 25-28).

\(^{64}\) The Patents (Amendment) Act 2005, Section 25 (2).

section 64 of the Patents Act. Here again, the grounds that could be cited for revocation (whether by a direct petition to the Controller or as a counter-claim during infringement proceedings) are broadly similar to that available at the pre-grant and post-grant stage. This combination of a pre-grant opposition mechanism, a post-grant opposition mechanism and a revocation mechanism makes the regime a very effective one for filtering out frivolous claims.\textsuperscript{66}

\section*{6.4.5 Compulsory Licensing Regime}

India’s compulsory licensing provisions are the broadest and most comprehensive of all the world’s patent systems. Section 92 of the India Patents Act, 1970 (2005) allows the grant of compulsory licenses on notification of the Indian government “in circumstances of national emergency or [...] extreme urgency or in case of public non-commercial use.” Moreover, Section 92A of the Act creates a new avenue for compulsory licensing that permits the manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity to address public health problems. However, the grounds upon which compulsory licenses may be granted go far beyond national emergency, extreme urgent situations, and public health crises. For example, non-availability of the patented invention “at a reasonably affordable price” and the failure to work the invention in the territory of India can also be invoked to justify a compulsory license (Section 84).\textsuperscript{67}

This is one area where there have been major changes, both substantive and procedural.

\textbf{Automatic Compulsory Licenses for Mailbox Applications}

The biggest substantive change has been the addition of a new ground for compulsory licensing. As is well known, India amended the Patents Act in 1999 to provide that applications claiming pharmaceutical inventions would be accepted and put away in a mailbox, to be examined in 2005. These applications are commonly referred to as ‘mailbox applications’. This amendment was in pursuance of a TRIPs obligation

\textsuperscript{66} Patents Act 1970, Section 64.
aimed at preserving the novelty of pharmaceutical inventions in those developing and least developed country (LDC) members that did not grant product patents for pharmaceutical inventions in 1995. By virtue of this ‘mailbox facility’, applications would be judged for ‘novelty’ on the basis of the filing date and not with reference to 2005, the year in which product patents were first incorporated into the patent regime.

The Act provides that in the case of those mailbox applications that result in the grant of a patent, an automatic compulsory licence would issue to those generic companies that made a ‘significant investment’ and were ‘producing and marketing’ a drug covered by the mailbox application prior to 2005. Such licence is subject to a payment of a ‘reasonable royalty’. However, no specific yardstick is provided to determine ‘reasonableness’ and this term is likely to lead to disputes in coming years. Perhaps one will have to go by the broad criteria in section 90 of the Act - that while computing the royalty payable, one shall have regard to “the nature of the invention, the expenditure incurred by the patentee in making the invention or in developing it and obtaining a patent and keeping it in force and other relevant factors”.

It will be interesting to see how this new provision pans out in the years to come. It is reminiscent of the ‘licence of right’ provisions under the earlier patent regime. Inventions pertaining to food and medicine were subjected to an automatic endorsement (i.e. they were deemed to be so endorsed) with a ‘licence of right’ after a period of three years from the date of sealing of the patent. In other words, any person interested in working the patented invention, endorsed with a ‘licence of right’ could have a licence as of right, without needing to establish any specific grounds for it.

**Compulsory Licences for Exports**

In order to incorporate what is commonly referred to as the Paragraph 6 Decision, the Ordinance introduced section 92A, which provides for compulsory licences to enable exports of pharmaceutical products to those countries with no

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69 Patents Act 1970, Section 90.
70 Patents Act, 1970, Section 87, omitted by Patents (Amendment) Act, 2002. Since the 1970 regime provided only ‘process patents’ in the case of pharmaceutical inventions, it was not too surprising that this compulsory licensing provision was hardly ever invoked by generic manufacturers.
71 WTO General Council, The Implementation of Paragraph 6 of the Doha Declaration, the TRIPS Agreement and Public Health, WT/L/540 (Aug. 30, 2003), DDFD Documents/t/WTL/540.DOC.
manufacturing capacity of their own. Unfortunately, this suffered from a handicap - the provision required that the exporter obtain a compulsory licence from the importing country as well. In the process, the provision failed to cater to those situations where there was no patent in such importing country and no requirement for obtaining a compulsory licence there. The 2005 Act therefore seeks to rectify this by adding that an exporter can resort to section 92A where the importing country “has by notification or otherwise allowed importation of the patented pharmaceutical products from India”.

**Procedural Changes**

The general compulsory licensing procedure under Chapter XVI states that in most cases, a compulsory licensing application can be entertained only if negotiations towards a voluntary licence have not borne fruit within a reasonable time period. In order to prevent patentees from dragging on voluntary negotiations to the detriment of applicants, the Act caps a ‘reasonable’ period of negotiations at six months.

**6.4.6 Government Use**

Most patent regimes provide that, under certain circumstances, government is entitled to use an existing patent (commonly referred to as ‘government use’ provisions). Indian law also provides for a mechanism allowing the government to use the patented invention under certain circumstances. This is more or less in sync with TRIPs requirements, and the law provides adequate remuneration to the patentee in each case—considering the economic value of the use of the patent—and stipulates that the government notify patentees of the use as soon as practicable, except in cases of emergency. There is one more specific provision, dealing with medicines, that allows the government to import patented drugs or medicines “for the purpose merely of its own use or for distribution in any dispensary, hospital or other medical institution maintained by or on behalf of the Government” or designated under the Patents Act.

The 2005 Act expands the scope of ‘government use’ provisions in some respects and reduces it in others. Thus, sub-clause (iv) has been added to section 2(h) of the old

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72 Patents Act 1970, Section 92A.
73 Patents Act 1970, Section 100 (1).
74 Patents Act 1970, Section 47 (4).
act to include any ‘institution wholly or substantially financed by the Government’ within the ambit of a ‘government undertaking’ that can avail itself of a patent under the ‘government use’ provisions spelt out in Chapter XVII. However, the Council for Scientific and Industrial Research (CSIR), a premier science research institution, was excluded from the ambit of the term ‘government undertaking’. This, perhaps, was in recognition of the fact that CSIR has been patenting extensively and is a private player in several respects.  

Government use is another effective means to curb abuse of patents. It allows the government or its authorised agent to use the patents without the authorisation of the patent holder. Generally, the government can take over the patent invention without seeking a licence or to negotiate. This practice is available in most common law countries, especially in the US and the UK. In the UK, it is known as ‘in the service of Crown.’ In the US, it permits the government or its authorised person to use any patents on the ground of public use. The patent holder can sue the government only for compensation and no injunction remedy is available under the US law. The advantage of government use is that it can bypass most of the procedural hurdles of the compulsory licence. However, the purpose of government use is restricted to non-commercial use. A country like India, with a public sector pharmaceutical industry, should strengthen the government use provisions in its Patents Act. The TRIPs provision on the government use is mentioned in Article 31(b) as public non-commercial use. It permits skipping requirements of voluntary licence and negotiating requirements. An important issue often raised is that when government use is non-commercial use, whether it is possible to sell through private channels. The answer is in the affirmative and government can recover the cost of production and distribution from non-commercial use. The affordability of drugs can be ensured through a strong government use provision. (Indian context)

The Patents Act provides three types of government use. Firstly, a patent is granted in India with a condition that government can import the medicines for the distribution of drugs in public sector hospitals or any other hospitals to be notified in the

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75 Supra note 37, p.29.
gazette. Secondly, government or authorised persons can use a patent against a royalty payment. Thirdly, the central government can acquire a patent after paying compensation. Government can exercise these powers at any time. However, the main lacuna is that the patented article under the Act can be sold only for non-commercial use. This restriction may have far reaching effect, because the courts may restrict the sales of medicines to public sector hospitals only. Further, the Act provides room for challenging the government decision to use or acquire the invention in the High Courts. It means the patentee can delay such use and the government has to prove need before the court. Using the TRIPs flexibility, the government should have opted for administrative review. The government has also failed to use the TRIPs flexibility with regard to removing injunction as a remedy in the case of government use.

6.4.7 Exceptions in respect of Pharmaceutical Inventions

Section 107A of the Patents Act, 1970, as amended contains two notable exemptions. The first relates to what is better known as the “Bolar Exemptions” and the second exemption seeks to define the contours of parallel imports.

“Bolar Exemption”

One of the less focused areas of the Indian Patents Act, as amended, is the provision providing for the so-called “Bolar exemption”. The basic idea behind the “Bolar exemption” is to create conditions so that the generic drug manufacturers can introduce their products immediately after the patent on a drug lapses. With the leading firms in the Indian pharmaceutical showing considerable degree of dynamism in recent years, the “Bolar exemption” assumes considerable importance for the future of the generic producers in India.

The “Bolar exemption” became a feature of the US patent statute in 1984, following the ruling of the Court of Appeals for the Federal Circuit in Roche Products Patents Act 1970, Section 47.


Ibid.

Patents Act 1970, Section 100(6).

*Inc. v. Bolar Pharmaceuticals Co. Inc.*\(^{82}\) This case involved a generic manufacturer (Bolar Pharmaceuticals) who had used a patented invention to test and apply for marketing authorisation of its version of a patented medicine. The Court had determined that the common law “experimental use” defence only covered experimentation for scientific, not commercial, purposes, and that the generic manufacturer’s activities therefore amounted to an infringement of the relevant patents.

Section 271(e) (1) of the US patent law (35 USC), which provided the “Bolar” or “experimental use exception” allowed the generic firms to conduct research on patented drugs prior to the expiration of the patent, so long as the experiments were “reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products”. The effectiveness of the “experimental use exception” was however dependent on the interpretation of the term “reasonably related”, and not unexpectedly, this term was the subject matter of a litigation between Merck KGaA and Integra Lifesciences\(^{83}\), which was adjudicated upon by the US Supreme Court.

The “Bolar exemption” (“experimental use exception”) was included in the Second Amendment of the Indian Patents Act, 1970. Section 107A (a) of the amended law contains the relevant provisions:

- Any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to the development and submission of information required 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.

Section 107A of the Patents Act (as amended up to 2002) excluded from infringement “the act of making, using or selling a patented invention” for the purpose of obtaining information to be submitted to a regulatory authority. The 2005 Act expands this provision to bring even the act of ‘importing’ within its ambit. This will no doubt aid

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\(^{82}\) Inc 221 USPQ 937 (Fed Cir 1984).
\(^{83}\) 545 US 193 2005.
the efforts of generic manufacturers, who are exploring all possible means to help mitigate the adverse consequences of a pharmaceutical patent regime.\textsuperscript{84}

According to Indian law, any person may make or use the patented invention, whether it is a product or a process—or even an article or product made by a process—for the “purpose merely of experimentation or research including the imparting of instructions to pupils.”

Scholars note that this provision seems more liberal than corresponding provisions in most other countries, and that it is “wide enough to even support activities such as ‘inventing around’ the patented invention or the making of improvements thereto.” Along with this general experimental use exception, Indian law also exempts experimental trials conducted on patented drugs from the purview of patent infringement. This provision is much wider than the corresponding U.S. law, as it allows the “making, constructing, using or selling of a ‘patented invention’ for the purpose of generating regulatory data to comply with both domestic (Indian) drug regulatory law, and any corresponding foreign law,” while U.S. law exempts only activities connected with a regulatory submission within the United States.\textsuperscript{85}

**Parallel Imports**

One of the areas where there has been considerable debate has been the impact of TRIPs on public health. The concern has been that the product patent regime mandated by TRIPs will make, even life-saving drugs, particularly for diseases of the developing world unaffordable to its vast populations. Even though the Doha Declaration has once again reconfirmed that public health concerns will superecede commercial interests, the mechanism for remedying the problem of availability and accessibility of patented drugs have not been addressed. The conduit for achieving these is supposedly through the compulsory license route. However very few developing countries have the technical capability to produce modern drugs even if they have no patent hurdles. The way out would be to make compulsory licenses valid for imports of the patented goods in addition to manufacture. Alternatively, permitting imports from the cheapest source in the world

\textsuperscript{84} Supra note 37.
\textsuperscript{85} Supra note 62, p.341.
will ensure availability of the needed drugs at the lowest possible cost. That is where parallel imports come in.

Parallel imports are imports of goods produced under protection of a trademark, patent or copyright in one market, imported into a second market without the authorization of the local owner of the intellectual property.

Article 6 of the TRIPs recognizes the possibility of legally allowing parallel imports from the territory where it has been licenced, based on the principle of ‘exhaustion of rights’, which means, that, once the patent holder is has exercised his patent rights, they are considered to be exhausted. Once the goods are put in the market, he has no further rights to control the use or release of these products.\(^{86}\)

The earlier section 107A (b) provided that it was not an infringement to import a patented product provided such import was from an exporter who was “duly authorised by the patentee to sell or distribute the product”. The 2005 Act now makes such import easier by dispensing with the authorization required from the patentee - it only requires that the exporter of such patented product be “duly authorised under the law to produce and sell or distribute the product”.

Under this amended provision, it would appear that an Indian pharmaceutical company could set up base in Bangladesh to manufacture and export medicines to India. In the absence of a patent in Bangladesh and/or any other law barring manufacture/exports, such company would presumably be ‘duly authorised’ under the laws of Bangladesh to ‘sell or distribute the product’.

The provision therefore is extremely broad in scope and may contravene TRIPs. Article 6 of TRIPs agreement states in pertinent part that “…nothing in this agreement shall be used to address the issue of the exhaustion of intellectual property rights”.

The meaning of Article 6 is made clear by Article 5(d) of the Doha Declaration which states: “The effect of the provisions in the TRIPs agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge ...”

However, the above hypothetical example of an Indian company setting up base in Bangladesh does not involve an ‘exhaustion’. There is no first sale of the patented drug by the patentee - rather the drug is manufactured and then exported by a third party. In short, the very essence of an exclusive right to import mandated under Article 28 of TRIPs is affected.\(^\text{87}\)

### 6.5 Implications of the Patents (Amendment) Act, 2005

The stronger patent protection provided by the Patent (Amendment) Act 2005 would have impact across all the technological sectors. In complex technology areas that have multiple applications (such as information and communication technology, biotechnology), patented technologies would increasingly dominate the market. A substantial amount would have to be spent by Indian firms towards royalties and license fees. Foreign Direct Investment (FDI) in these sectors would include a major share in technology transfer comprising of patented technology. Thus increasingly Indian market would become technology driven market.

However, the main impact would be in the pharmaceuticals industry as product patent in pharmaceutical sector is possible by the Patent (Amendment) Act 2005. Post 1995 generic versions of patented drugs would have to withdrawn from the market. The criteria of patentability, compulsory license and other provisions would mainly effect patenting in this sector. Presently, Indian firms dominate the market accounting for 75\% of the drugs that are sold. The domestic firms meet 90\% of the country’s pharmaceutical demand including almost all of the 300 essential drugs.

Foreign firms were required to pay royalties for international drugs, while Indian companies could access the newest molecules from all over the world and reformulate them for sale in the domestic market. This thus resulted in the systematic weakening of patent rights for pharmaceutical products in India and helped domestic firms to overcome the patent barriers. This situation also put India in an enviable position among developing countries in generic drug formulation.\(^\text{88}\)

The direct implications of TRIPs would be that products that have been on the market before the signing of products patent will remain free of product patent;

\(^{87}\) Supra note 37.
\(^{88}\) Supra note 26.
companies that produce any of these products will be able to continue as before. On the other hand products patented post-1995 will be protected thereafter. Companies that produce products that fall under patent protection will have to stop manufacturing them or negotiate a licensing agreement with the (foreign) patent holder. The transition will cause move towards a monopoly market. Chemically identical products that were there in the market would cease to be available. Non identical products that perform the same function i.e. substitutes would remain. These substitutes can be patent protected or can be off patent generic drugs. Thus the future market would be of three kinds (a) patent drug (b) generic versions of drugs that are off patent, and (c) non-bio equivalent drugs.

Another major impact would be in filing patents. Accession to PCT in 1998 has opened another route for Indian institutions/individuals for filing patents in different countries. The PCT provisions helps in filing patent as an international patent through the Indian Patent Office. The countries that the applicant wishes to protect his/her invention is marked as designated country(ies) in the patent document. PCT route allows cost saving, not going through the trouble of filing the patent in each country as well as it maintains priority for at-least 12 months. Similarly, foreign applications can file patents in India through the PCT route by designate India in their PCT patent.\textsuperscript{89}

6.5.1 Access to Medicines

Although the 2005 Act has made wide-ranging changes to India’s patent regime, the most controversial provision is the one introducing product patents for pharmaceutical inventions. Civil society proponents are concerned that this would cause a steep rise in drug prices and adversely impact access to important drugs. They argue that the available TRIPs flexibilities have not been exploited appropriately and that adequate safeguards have not been built in to ensure an affordable supply of medicines.\textsuperscript{90}

The 2005 Act has a number of important safeguards built in to ensure that the production of existing generic versions of drugs is not jeopardised. It also has provisions to ensure affordable access to new drugs. Whether such provisions would in fact be interpreted in a manner conducive to public health needs remains to be seen. Some of the key provisions in the 2005 Act are:

\textsuperscript{89} Ibid.
\textsuperscript{90} http://www.healthgap.org/press_releases/05/020105_hgap_fs_india_ipr.pdg. Accessed on 8-8-2012.
Compulsory Licensing

As mentioned earlier, the provision of two new grounds for compulsory licensing (one in respect of exports to countries that lack manufacturing capabilities and the other in respect of the manufacture of drugs that are the subject matter of mailbox applications) would go a long way towards ensuring that local industry can continue to manufacture at a cost lower than the innovative drug company.

However, despite these new grounds, the new regime has done little to ease the administrative and procedural bottlenecks that constrained the invocation of compulsory licensing provisions under the old regime. Indeed, a rather stark example of the procedural delays inherent in compulsory applications is provided by a case under the old regime, where the compulsory licensing application was dragged on all the way to the Calcutta High Court, by which time the patent had almost expired.91

The 2005 Act has streamlined one such procedural hurdle by providing that ‘voluntary negotiations’ with a patentee should be concluded within six months.92 It could therefore well be the case that extensive provisions on paper may not translate easily into practice. Further, contentious terms such as ‘reasonable royalty rates’ (used in the context of the newly added compulsory licensing ground to permit generic companies to continue manufacturing drugs that are the subject matter of mailbox applications) could significantly slow down the compulsory licensing process.

It is nevertheless important to appreciate that possibly another reason for the non-optimal use of the compulsory licensing regime under the old regime was the absence of a well-developed local industry. Needless to say, in the context of pharmaceutical inventions, this is not an issue, as India has a well-developed local industry with extensive expertise and a readiness to exploit compulsory licensing provisions.93 In the years to come, India is likely to provide a fertile ground for the emergence of sophisticated compulsory licensing jurisprudence, at least with respect to pharmaceutical inventions.

92 A new explanation has been added to Section 84 (6) in this regard.
Retrospective Damages

The newly added proviso to section 11A of the Patents Act considerably dilutes the monopoly granted to pharmaceutical patents that flow from mailbox applications.

Section 11A(7) provides that patentees are entitled to claim damages retrospectively from the date of publication of their patent applications, which means that the moment a patent application is published (as opposed to a patent being granted), a third party runs the risk of damages in case of infringement. The Act, however, provides that such retrospective rights under section 11A do not apply to pharmaceutical mailbox applications. This result, coupled with the fact that the twenty-year patent monopoly term runs from the date of the mailbox application and not from the date of grant, will reduce the strength of drug patents that fructify from mailbox applications, a consequence likely to benefit the continued production of generics at low prices.

Therefore, the failure to grant retrospective remedies to mailbox applications, coupled with making them automatically susceptible to compulsory licensing provisions, will ensure that the supply of existing generic drugs at affordable prices is not unduly hampered. To a limited extent, generic manufacturers could also avail of the research exemption and the wide Bolar provision in section 107A.

The Patentability Threshold

The question of whether the new regime will have an impact on access to new drugs is more vexed. This will depend significantly upon the scope of patentability of pharmaceutical inventions. Notwithstanding calls by civil society to restrict the patentability of pharmaceutical inventions to only new chemical entities (NCEs), no such express limitations were introduced. However, this does not automatically mean that all such substances (including new chemical entities, formulations, new drug delivery systems etc) will merit patent protection. Rather, the more rigorous requirements for ‘inventive step’ introduced by the 2005 Act and the expansive ‘new use’ exclusion could help in curbing new grants. Indeed, as argued earlier, a very strict reading of the term

94 Section 47(3) encapsulates the ‘experimental use’ exception in the Indian context and provides that a patent may be used by any person ‘for the purpose merely of experimental or research including the importing of instructions to pupils’.
‘efficacy’ could result in very few patents for incremental pharmaceutical innovations that rely on new forms of existing substances.

Apart from the ‘new use’ exclusion, the Patents Act has several patent eligibility or subject matter exclusions such as the ‘method of medical treatment’ exception and the ‘product of nature’ exclusion. These could be effectively used to limit the scope of protection to pharmaceutical inventions.

In this regard, it bears noting that the Patent Office has a well-entrenched history of adopting a conservative approach towards patentability. Relying on the Ayyangar Report and the mantra that fewer patents are conducive to a more robust indigenous industry, the Patent Office has, in the past, demonstrated a ‘policy style’ approach to the issue of patentability and denied protection to several inventions that merited patents in other parts of the world. Indeed this trend was discernible in as late as 2001, when the patent office refused an application by Dimminaco AG (a Swiss biotechnology company) claiming a method of producing a live vaccine on the ground that the term ‘manufacture’ did not include a process that had a living substance as its end product.

Therefore, it is likely that patentability criteria and subject matter exclusions will be interpreted by the patent office in a rigorous manner so as to filter out inventions that do not represent a genuine therapeutic advance. The patent office could draw from the experience of developed countries that have strictly applied patentability criteria in some cases to prevent ‘evergreening’. For example, SmithKline’s secondary patent on a polymorph of cimetidine, granted approximately five years after the original patent, was invalidated in the UK and other countries on the grounds that such a polymorph could not

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95 The principle of ‘patent eligibility’ broadly refers to the requirement that a subject matter for which a patent is sought be inherently suitable for patent protection, in the sense of falling within the scope of subject matter that patent law prima facie exists to protect. The term ‘patentability’, on the other hand, refers to those set of principles that inform the requirements that must be satisfied for a patent eligible subject matter (i.e., an invention) to be granted a valid patent. Principally they are the requirements of novelty, inventiveness (non-obviousness), utility (industrial applicability) and sufficient description.

96 Section 3(i) excludes “any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings” from patentability.

97 Section 3(o) excludes the “discovery of any living thing or non-living substances occurring in nature” from patentability.

be considered ‘novel’ - i.e. it was inevitably obtained by applying the process already claimed in the original patent.99

It is pertinent to note in this context that Article 27 of TRIPs stipulates that “patents shall be available for any inventions… provided that they are new, involve an inventive step and are capable of industrial application.” This leaves some flexibility in the hands of member states to define these patentability criteria in a manner that suits their specific national interests. Member states have, in fact, refined patentability criteria in the context of specific fields of technology, taking into account the unique concerns posed by such technologies. For example, in 2001, the revised utility guidelines formulated by the United States Patent and Trademark Office (USPTO) were targeted towards biotechnology inventions. It is also pertinent to note that a provision has been enacted in Germany to ensure that the patent monopoly on a gene sequence is limited to the specific function disclosed and not to all functions.100

Opposition Mechanism

Apart from this, the robust opposition mechanism (pre-grant and post-grant) could be leveraged to filter out frivolous patents. Some mailbox applications have already been challenged under the pre-grant opposition procedure. Thus, for example, Natco Pharma Ltd, an Indian pharmaceutical company, has opposed an application by Novartis India Ltd pertaining to the anti-cancer drug imatinib mesylate on the ground that it lacks novelty. According to Natco, the Indian patent application merely claims a crystal form (beta) version of a drug that was already known in 1993.101 This challenge is bound to create considerable interest, as Novartis already owns an exclusive marketing right102

100 Supra note 37, p.36-37.
102 In accordance with Article 70.9 of TRIPs, Chapter IVA of India’s Patent Act (which has now been deleted by the 2005 Act) provided that till such time as a product patent regime for pharmaceutical inventions was established, limited rights known as ‘exclusive marketing rights’ would be granted to inventions that met certain criteria - the applicant had to have a patent issued in a foreign country and have procured marketing approval from the relevant authority in that country as well as from the relevant authority in India. As the name itself suggests, the crux of this concept is a limited right to exclusively market the drug or medicine in question. The exclusive marketing right lasts five years or until the issuance or rejection of a patent (Section 24B, Patents Act, 1970).
over this drug (which it sells under the name Glivec) and has injunctioned several generics on the basis of this exclusive marketing right.

**Price Control**

One of the main objectives of the pharmaceutical policy is to ensure availability of good quality essential pharmaceuticals at reasonable prices within the country for mass consumption. It will also help to create an environment conducive for channelising a higher level of investment into R&D in pharmaceutical sector with a particular focus on disease endemic to the country.

With a view to encouraging generation of intellectual property and facilitating indigenous endeavours in Pharma Research and Development (R&D), appropriate fiscal incentives have been provided in the policy. The pharmaceutical policy 2002 has allowed some exemptions from price control for new drugs patented under the Indian Patents Act.

(i) A manufacturer producing new drugs patented under the Indian Patent Act 1970 and not produced elsewhere, if developed through indigenous R&D, would be eligible for exemption from price control in respect of that drug for a period of 15 years from the date of the commencement of its commercial production in the country.

(ii) A manufacturer producing a drug in the country by a process developed through indigenous R&D and patented under the Indian Patents Act 1970 would be eligible for exemption from price control in respect of that drug till the expiry of patent from the date of commencement of its commercial production in the country.

(iii) A formulation involving a new delivery system developed through indigenous R&D and patented under the Indian Patents Act 1970, for process patent for formulation involving new delivery system would be eligible for exemption from price control from the date of commencement of its commercial production in the country till the expiry of the patent.\(^\text{103}\)

Two major apprehensions of adopting the TRIPs agreement in the pharmaceutical sector were regarding the higher prices of the patented products and their accessibility. By providing blanket exemption from price control the government is making the access

\(^{103}\) *Pharmaceutical Policy 2002.*
to drugs difficult. It appears that ‘who patents the product’ matters more for the government than what is patented. It has been opined that rather than exempting drugs from price control, providing easy access to credit, promoting venture capital funds and streamlining the procedures would help in promoting innovations.

Price control measures are generally intended to ensure that consumers are not unfairly treated on the price front through charging excessive prices, not commensurate with the costs of supply or the benefits accrued. It is imperative that any pricing policy should ensure that the patients should receive their medicines at the lowest possible price and at the same time producers make adequate returns for his investments and efforts. None of the Drug Price Control laws to date have been able to achieve these twin objectives of making drugs available at affordable price while ensuring profitable growth of the industry.

The pharmaceutical policy 2002 has attempted the price decontrol with the plea that this shall boost R&D expenditure in the pharmaceutical sector. When concerns were raised that amendment of the Indian Patent Act would result in rise in drug prices, the Ministry of Chemicals and Fertilisers had consistently claimed that any rise in prices would be kept in check through mechanisms in the DPCO. Price controls have already been diluted in the past decade and only 40% of the turnover of the industry was under price control. Any further dilution would mean virtual abandonment of price controls. If the Government considers this under grab of encouraging R &D, it will only substantiate earlier fears that a change in the Patent Act can only, lead to a spiralling rise in prices of drugs.\textsuperscript{104}

Act vis-a-vis patents for drugs and resulting monopoly and dominant position should be introduced.\textsuperscript{105}

6.5.2 Spurring an Innovation Culture in India

The multinational pharmaceutical industry argues that a product patent regime is essential for encouraging R&D in new drugs and catapulting the domestic industry into the innovative drug sphere. It needs to be noted however that basic reverse engineering skills (organic chemistry skills) are different from the skills required to arrive at new drugs (medicinal chemistry skills). Besides, the costs of researching upon and introducing a new drug into the market are colossal. It therefore remains to be seen whether incentives through a patent regime will achieve the desired results and whether Indian companies will be able to compete with global multinational companies on this turf. A commentator rightly notes that till recently, the emphasis has been “mainly on building a system of production and not on a system of innovation”.\textsuperscript{106}

However, over the last couple of years, Indian firms have been engaging in incremental modifications of pharmaceutical products developed in foreign (mainly Western) countries. Such modifications or incremental innovations that cater specifically to the public health needs of India (such as new drug delivery systems and formulations that are created to withstand tropical temperatures) are of immense value. An excellent example of such incremental innovation is that of Wockhardt Ltd., which developed humidity resistant salt forms and isomers of known anti-microbial substances. The original compounds had been patented by the Otsuka Pharmaceutical Company as potential antimicrobial agents against bacteria that were resistant to conventional antibiotics such as penicillin, ampicillin and streptomycin. The patented salts have better solubility characteristics and greater stability in the presence of high humidity climates than the original patented active substance. It is likely that the new regime will, at the very least, incentivize these kinds of incremental innovations - the extent to which it will do so will, of course, depend on how the patent eligibility and patentability requirements are interpreted by the Patent Office and courts.

\textsuperscript{105} \textit{Ibid.}

It is also likely that a product patent regime will encourage global multinationals to outsource some of their drug manufacturing and clinical trials to India and enter into appropriate partnerships with Indian companies.\textsuperscript{107}

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\textbf{6.6 Is Indian patent law TRIPs complaint?}
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The TRIPs agreement basically deals with countries which are developed, developing & less developed. Being the developed countries, USA, UK, Canada actually incorporated most of the TRIPs provisions but countries like India, Singapore, Bangladesh could not do the same because of it’s socio-economic conditions. Some countries have had much less amicable reactions to TRIPs. South Africa and Brazil stand out with regard to the health issue. Both countries have successfully attempted to chart out a new course, which goes much beyond what would have been deemed acceptable under TRIPs until recently. This is remarkable because both legal regimes were challenged and the challenge was abandoned in each case. But in reality, the patent law which was a model for other developing countries like Argentina, Mexico, Egypt, Brazil and Chile, has been replaced by the Indian Patents Act, 1999, which is modeled on the basis of the TRIPs (Trade-Related Aspects of Intellectual Property Rights) text. This amendment seeks to implement the obligations that India has taken in the field of patents by signing the TRIPs agreement. The bill generally aims at making the 1970 Patents Act as TRIPs compliant as possible.

The Patents Act, 1970 was amended again in 2002 and 2005. The Patents (Third Amendment) Act, 2005, extended product patents to products from all industry sectors, including pharmaceuticals. It also set the term of patent protection to 20 years to meet the TRIPs deadline for January 1, 2005. This closed the option of reverse engineering that largely contributed to the growth of the Indian pharmaceutical industry. It will not be possible to produce the patented product by adopting a different process. Some safeguard measures and flexibilities contained in the TRIPs agreement were introduced in the patent system to protect public health, such as the Commissions on TRIPs that included leading senior former government officials and experts as members and held public consultations that recollected the views of experts, NGOs, industry associations and government

officials. The reports produced by the People’s Commissions studied the debates in parliament on amendments to the Patents Act, 1970 and provided specific suggestions on changes to ensure the amended Act would prioritize the national interest and access to medicines.\(^{108}\)

The TRIPs agreement has widened the scope, duration, and strength of patent protection. India actually complied with some major provisions of the TRIPs agreement, i.e. Article 27.1,\(^ {109}\) Article 33,\(^ {110}\) and Article 31.\(^ {111}\) But provisions like Section 3(d) directly go into conflict with the TRIPs agreement. This is because the Section 3 (d) of the Patents Act narrowly defines ‘new use’ doctrine and excluded from patentability the new use of an old substance with intention of preventing ‘ever-greening’ of patents.

The law relating to computer software has been clarified. Although software per se is not patentable, software configured to achieve a particular technical result may be. Previous practice was to grant patents only to software coupled with hardware. Methods of treating plants are now patentable, although processes for treating human beings and animals are not. Micro-organisms are now patentable, whereas previously all forms of life had been excluded.

The present scenario is not altogether as disappointing as it was in the 1970s or 1990s; the scenario is better than it was before. The new amendment of the Indian Patent Act gave a crystal clear view of India’s progressive attitude and intention to enter in the arena of advancement. Since the amendment the Global Economic Competition welcomes India as a nation having huge prospect for investment. The Information era urges before India to wipe out the evils of social dilemma in regard to granting Patent right India must also take the convenient means to eradicate the lacunas in its Patent law (e.g., Section 3(d) of the Indian Patent Act) to cope up with the progress of other nations and achieve the tag of Developed Nation.


\(^{109}\) Subject to the provisions of paragraph 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.

\(^{110}\) The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.

\(^{111}\) Other use without authorization of the right holder.
The Indian Patent System has geared up to provide a level playing ground for all stakeholders. The recent amendments have brought the national IP Laws close to the TRIPs norms which were the real need to change the scenario prevailed in regard to Patent rights. The 40 years old system of limited term process patents for pharmaceutical products is getting abolished by virtue of the new Amendment. Multinational Companies are looking at the Indian market more seriously which will boost up Indian economy and progress. The patent law attempts to put India in compliance with its TRIPs obligations. In the process, it sets aside some of the most salient elements of the current legal regime which, together with other instruments such as the Drugs Price Control Order, have generally served well the interests of the country and its inhabitants. It is likely to bring about a legal regime that is less favorable from the point of view of access to drugs for the people of this country. Further, TRIPs cannot be implemented in isolation. India has a number of other international obligations, in particular in the field of human rights. As interpreted by UN human rights organs, the right to health requires that countries progressively take positive steps towards facilitating access. Dismantling the 1970 regime may constitute a violation of India's obligations under the covenant on economic, social and cultural rights.\(^\text{112}\)

6.7 Conclusion

The major changes introduced in the Indian Patent Act that were required to meet India’s obligations to international agreements and treaties. The new Patents Act (Patents Amendment Act 2005) has created a strong patent system in India. Overall the present Act has increased the scope of patenting and provides stringent safeguards to the patentee. The new Act would play a major role in creating a technology driven market. Firms would increasingly try to create monopoly based on their patented technology. Indian firms primarily those that are in high technology areas would face increasing pressure, as patented products would enter the market.

The pharmaceutical sector would face the maximum impact. On one hand newer drugs would enter the market, on the other hand drug prices are expected to rise as generic drugs for drugs patented post 1995 would have to withdrawn. A patented drug

provides the firm holding the said patent on it a monopoly and thus it can demand a very high price for the drug. It would be difficult for Indian firms to control the market. Mailbox’ filing shows the intention of foreign firms to bring in patented products in pharmaceuticals in the Indian market.

One of the ways for Indian firms would be to increase their own R&D and innovation activity to create patented products in pharmaceuticals. Patent trends show Indian firms are trying to become innovative firms. Product patents in pharmaceuticals were also obtained in the USPTO. However, it should be noted that through incremental modification of their products, changing dosage intensity and including minor features such as inert ingredients and the form, colour etc. it is possible to get product patents in pharmaceuticals in the USPTO. This may not be possible in the IPO, as patents would be granted only for any ‘new entity’ involving one or more inventive steps.

Indian firms can also gain advantage through compulsory license. The amendment now gives the option of exporting drugs to a country, which makes a request for a generic drug. The only condition would be that the country where it can be exported should have no or insufficient manufacturing facility.

The major changes made in the Indian Patent Act would have significant impact. The market would increasingly become technology driven. Indian firms would have to compete in the new scenario. The new Act provides little scope for firms to infringe upon products that are protected by patents.

Finally, the extent of the flexibility that is built into the TRIPs agreement is not clearly defined. Many provisions in the new patents regime are likely to be challenged in the near future since their compliance with TRIPs remains an open issue. This lack of clarity has to be resolved and, therefore, the system can benefit from the judicial analysis by unraveling the meaning of its new patent law.