Impact of TRIPS on Indian Pharmaceutical Industry

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After India became a founder member of WTO and acceded to the TRIPS Agreement, the product patent regime was reintroduced in India after a gap of 35 years. The significance of the new IP regime on pharmaceutical industry in India, the amendment to the Patents Act, 1970, in fulfillment of the obligations to comply with TRIPS, related developments in other fields of IP as well as enforcement of new IP/Patent regime on the pharmaceutical industry are comprehensively discussed herein. The regulatory interfaces of patents in the Indian and international context are also briefly dealt with.

The historical evolution of IP with specific reference to patent regime in India is dealt with. Significance of IP such as patents, trademarks, industrial designs, trade secret and data exclusivity are elaborated. The key elements of the TRIPS Agreement which led to the three consecutive amendments to the Patents Act, 1970 are highlighted. The significance of the patent amendments in 1999, 2002 and 2005 and their highlights as well as the need for such amendments in fulfillment of TRIPS obligations have been described herein. Finally, the impact of post-TRIPS scenario in Indian pharmaceutical industry with specific reference to the international operations and the regulatory interfaces has been analysed. The related fields like biodiversity and plant varieties are also touched with.

Keywords: TRIPS Agreement, pharmaceutical industry, compulsory licensing, data exclusivity, exclusive marketing rights, research exemptions, pre/post grant oppositions, patentability

Patents in India have their origin in the 1856 Act, which was consolidated into the Designs and Patents Act, 1911. After independence, relative inaccessibility and unaffordability or even non-availability of essential life saving medicines led the Government to appoint two Committees: the Tek Chand Patents Enquiry Committee (1948-50) and the Ayyangar Committee (1959). Consequent to the recommendations of these Committees, the Indian Patent Law was amended in 1970. The Patents Act, 1970 abolished product patents for food, pharmaceuticals and chemicals and restricted grant of patents in these fields only to process patents. The term of these process patents were restricted to 7 years from the date of application or 7 years from sealing, against 14 years from the date of application for others, in general fields. The compulsory licence exemptions were further reinforced by the introduction of the ‘licence of right’ provision, which is best defined as an automatic compulsory licence. This provision permitted anyone to freely practice invention in public interest; without fear of any infringement suit. Introduction of ‘licence of right’ virtually abolished any need to resort to compulsory licence during the tenure of the 1970 Act. As such, no compulsory licence applications were filed during the tenure of the un-amended Patents Act, 1970.

The Patents Act, 1970, consequently provided an impetus for the growth of the generic pharmaceutical industry in India. The Patents Act, 1970 incorporated very well-thought out, highly effective, safe-harbor provisions, though considered controversial in the global context for early generic introductions of patented New Chemical Entities (NCEs) in India and essential life saving medicine based on them. The amendments to the Patents and Designs Act, 1911, ushering in the Patents Act, 1970 would have remained only on paper, had it not been for the entrepreneurship and enthusiasm with which the Indian national pharmaceutical industry picked up the gauntlet and went about developing innovative

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processes and methods of standardization including bio-equivalence studies, for process development, manufacture, and marketing of generic equivalents which were therapeutically equivalent to the innovator products. This initiative had earned the label of 'reverse-engineering' for the Indian pharmaceutical industry, which has in post-TRIPS years proved to be a boon for moving into contract research and to an extent, even to the drug discovery research.

During 25 years from 1970-1995, the share of the national sector of the pharmaceutical industry recorded a growth from 15% to nearly 18% or near about. During this period, India became nearly self-sufficient in manufacture of medicines and a substantially large manufacturer and exporter of bulk drugs/active ingredients. India became net exporter of pharmaceuticals occupying the 3rd largest position in terms of volumes and 14th largest in terms of values.

The introduction of Intellectual Property Agenda during the Uruguay Round of GATT in 1986 evoked early fears and concerns for the Indian pharmaceutical industry. The early reaction of the Indian pharmaceutical industry to the Uruguay Round and the later Dunkel Draft had been one full of panic, the 'sky is falling' 'Doomsday' predictions from 'pharma pundits' were also in plenty. However, media and the consuming public (even a large sector of small-medium enterprise) remained unattacked and disinterested in the GATT/WTO/TRIPS emergence and developments, till stories on Basmati, Turmeric, Neem and the like, started making rounds.

Consequently, thereafter national debates opened up and many NGO’s and public interest groups commenced actively studying and contributing views, comments and suggestions which became helpful to the law makers to understand and appreciate different views as well as pros and cons of WTO/TRIPS emergence. This could not have been possible earlier, because the early air was polluted with myths and canards, the reason being poor level of understanding and appreciation of the IP/Patent system. Only after a few educationists, eminent lawyers and jurists and informed industry leaders joined hands to commence formal intellectual property (IP) and patent training institutions, demystification process and dissemination process for IP/patent education and training started in India. The post WTO/TRIPS emergence of India coincided largely to these national expertise developing efforts.

The impact of TRIPS on Indian pharmaceutical industry is being treated on the lines in which it evolved during emergence of TRIPS and the steps taken for compliance with the TRIPS by India. As the Patents Act, 1970 went through three amendments and product patent regime re-emerged in India, the Indian pharmaceutical industry was impacted. An analysis of this impact on this pharmaceutical industry and the Indian healthcare scenario is presented here.

**Significance of IPRs in Pharmaceuticals**

One of the most fundamental changes in global trade policy set out by the Uruguay Round of trade negotiations was the commitment by all the World Trade Organization (WTO) Members to comply with the requirements of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). TRIPS lays down minimum standards of protection for intellectual property rights (IPR) and their enforcement, which are mandatory for WTO member countries for implementation. However, it allows flexibilities within its overall provisions or articles, to take effective steps to meet the healthcare needs of the member countries, especially Least Developed Countries (LDCs) and developing countries.

The TRIPS Agreement, deals not only with patents, but also with other forms of IPR such as copyright, trademark, industrial designs, geographical indications and others. India has already been having a reasonably strong copyright, trademark and industrial design protection and enforcement, even prior to TRIPS.

Three dominant IPs which play important role in development and commercialization of pharmaceutical industry are patents, trademarks, and trade secrets. Apart from patents, other forms of IPs such as trademarks, copyright, designs and confidential information are also largely relevant to pharmaceutical industry. Use of these other forms of IPs in pharmaceutical industry is dealt here.

**Trademarks**

The widest and largest use of IPR in pharmaceutical industry is in the use of trademarks. Trademarks, though inherently protectable through common law, even if they are not registered, Statutory protection under the Trademarks Act becomes available consequent to registration of trademarks. In pharmaceutical industry, the registration of trademarks helps brand-building for value creation. Branded queries or medicines help the patients and medical profession to identify the manufacturer and potentially reliable quality inherent in the branded product. As such
trademarks in medicines help to build trust and confidence in the minds of the doctors and patients. Approximately 40,000 brand names are registered under Class 5 as trademarks in India.

One of the specific features of the Trade Marks Act, 1999 (Sec. 13) is that scientifically approved name (by the WIPO) for a pharmaceutically useful chemical or biological, is known as International Non-Proprietary Name (INN). Once WHO approves a name and a therapeutic category for a potential NCE, this INN or closely resembling names cannot be registered as Trademarks. However, in India (as in many developing countries) the practice of applying for and receiving grant of names closely resembling INNs are very prevalent and continues to be so.

Section 13 of Indian Trademark Act, 1999 states that ‘Words, which are declared by the World Health Organization and notified in the prescribed manner by the Registrar from time to time, as International Proprietary Names shall not be registered’. This prohibition stands against the generic name registration as trademark. In a recent case, where Dr Reddy’s challenged Torrent Pharmaceuticals against the registration of DOPAMINE, the Intellectual Property Appellate Board held that DOPAMINE cannot be registered as it is an international non-proprietary name allotted by WHO.

There have been innumerable Trademark related litigations in India, more in the Post-TRIPS era. With the introduction of the protection for ‘Well Known Marks’ in the latest amendments to the Trademarks Act, 1999, there is added scope for TM related litigations, which may increasingly lead to revocation of registered trademarks in India.

Copyright

Copyright protects the literary, artistic, dramatic or musical and cinematographic creations of author for an exclusive period of time. Competitors are prohibited from copying which constitutes infringement of copyright. In pharmaceutical industry, documents recording the researches, instruction manuals, dossiers and literature texts are protected through copyright. In case of non-prescription drugs and over-the-counter (OTC) drugs, various slogans or one-liners (jingles) are also protected through copyrights. All literature based on research findings are also copyrightable. Hence, researchers are careful in documenting the result at every step of research.

As copyright also protects the artistic creations, different drawings, pictures, graphic or colour combinations used on cartons, collapsible tubes, labels of pharmaceutical products are copyright protected. Violation of copyright or infringement of copyright by the competitors leads to litigation though they are very few in pharmaceutical sector.

Post-TRIPS, the practice of copying ‘product inserts’ of an innovator or ‘first-launcher’ is getting exposed to potential copyright infringement suits, which could lead to imprisonment and fine, unlike patent infringement suits. These practices which were widely prevalent before TRIPS, have now come under the scanner and have consequently come under control.

Industrial Designs

Designs Act protects shape or appearance, as applied to an article for commercial or industrial purpose. Design protections are available for outer packaging of bottles, shapes of medical instruments, designs over the tablet cover etc. In USA, designs are protected under Law of Design Patents, though design protection in India is through ‘Industrial Designs’. Use of design protection in Indian pharma sector is comparatively low, though biomedical devices, syringes, inhalers etc. have increasingly acquired protection under the Designs Act, 2000.

Trade Secret and Data Exclusivity

Though there is no specific Act for providing protection, trade secret protection is conferred to any formula, pattern, device, consumer lists etc. which are crucial information for trade and commerce, through common law. Pharma industry is accustomed to maintain trade secret protection during synthesis of active pharmaceutical ingredients (APIs) as well as in dosage form development. However, with the advantages of harmonization of GMP (Good Manufacturing Practices), GLP (Good Laboratory Practices), GCP (Good Clinical Practices), ICH (International Code of Harmonization) and CTD (Common Technical Dossiers), it has become essential to disclose all technical details for regulatory submissions and approvals. Therefore, it has become a necessity to protect crucial information under trade secret protection, before such submissions. But India still lacks a legislation to protect confidential information. Presently, however, trade secrets continue to have to seek protection through Law of Contracts and Torts.

One of the most controversial and widely debated topics, presently in India, related indirectly to
‘confidential information’ is the ‘data exclusivity’. Data exclusivity refers to a practice, whereby, for a fixed period of time, drug regulatory authorities do not allow the dossier or regulatory documents of an originator to be referred or used to register a therapeutically equivalent generic version of that product. Article 39 (3) of TRIPS specifically talks about protection of undisclosed test data (clinical data which is otherwise not in public domain) from unfair commercial use. India continues to deliberate on this form of ‘Data Protection’. Many committees appointed by the Government have deliberated and given their requests in the past, the latest being the Satwant Reddy Committee Report, in this regard. Even though an early solution does not seem to be in sight, the Office of the Drugs Controller General of India has recently assured the industry that the needful guidelines will shortly be put in place.

The Patents Act 1970 and TRIPS Agreement

There is a general perception that re-introduction of the product patent regime in India was the single-most significant contribution of the TRIPS Agreement. However, on a closer and finer analysis the abrogation/deletion of the licence of right provision (which was widely acclaimed as non-TRIPS compliant provision) from the Patents Act, 1970, could be viewed as the major factor in taking India to the global patent arena, where the protection of the patentee’s rights are truly and deservedly made available without dilution.

The TRIPS Agreement

The TRIPS Agreement was signed in Marrakesh, Morocco, on 15 April 1994, also linked to Paris Convention through Article 2 of TRIPS. Articles 7 and 8 of TRIPS deal with objectives and principles. The objectives of TRIPS are enshrined as promotion of technological innovation and transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations. The principles of TRIPS highlight that the members formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, in a manner consistent with the provisions of TRIPS Agreement.

Article 27 of Part II of TRIPS is the most relevant provision relating to pharmaceutical industry. Article 27.1 provides broad definition of patentable inventions, which states that patent shall be available to all inventions, whether products or processes, in all fields of technology, provided they are new, involve inventive step and are capable of industrial application. Article 27.2 describes exclusion criteria for patentable inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law. Under Article 27.3 (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals may be also excluded from patentability. Similarly, Article 27.3 (b) leaves an option for member countries to grant patents for plants and animals and biological processes, at their discretion. Further, grant of patents for product or processes for microorganisms have made compulsory. The option for granting protection for plant varieties either through patents or through UPOV (The International Union for the Protection of New Varieties of Plants) are also left at the discretion of member countries’. A uniform patent term extension of 20 years in return for disclosing the invention to the public in the patent application with sufficient details to enable a person skilled in the relevant technology to practice the claimed invention is also provided by TRIPS.

Option for providing exceptions to exclusive rights conferred by a patent is also enshrined in the TRIPS Agreement. In case of process patents, the provision for reversal of burden of proof is to be made available by the member countries. Other than these specific provisions relating to patents, TRIPS also provides protection for undisclosed information with specific reference to data against unfair commercial use under Article 39.3. This provision is being interpreted as ‘Data Exclusivity’.

Transitional arrangements and protection of existing subject matter during the transition phase (Article 70.8) are also dealt with under TRIPS. On signing of TRIPS, it became obligatory on member countries to comply with the provisions of TRIPS Agreement by making amendments to the national laws, wherever necessary.

The Patents Act, 1970 (as amended upto 2005)

Through the three amendments to the Patents Act, 1970, India has made the Indian Patent laws, TRIPS compliant, substantially.
The definition of patentable invention under Patents Act, 1970 was consequently amended as follows:

- Section 2(1) (j) defines ‘invention’ as a new product or process involving an inventive step and capable of industrial application [The Patent (2nd Amendment Act, 2002).
- Section 2 (1) (ja) defines ‘inventive step’ as 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 a person skilled in the art [The Patent (3rd Amendment) Act, 2005].
- Product patent have now been made available to all fields of inventions including pharmaceuticals, food and chemical [The Patent (3rd Amendment) Act, 2005].
- The license of right under the Patent Act, 1970 has been deleted [The Patent (2nd Amendment) Act, 2002].
- Reversal of burden of proof under Section 104-A has been inserted [The Patent (2nd Amendment) Act, 2002].
- Microorganisms are made patentable under Section 3(j) [The Patent (2nd Amendment) Act, 2002].
- Research exemption inserted under Section 107-A [The Patent (2nd Amendment) Act, 2002].
- Section 92-A has inserted provisions for compulsory licence for the export of patented pharmaceutical products [The Patent (3rd Amendment) Act, 2005].
- The transitional arrangements have been made through the Patent (1st Amendment) Act, 1999.

The Patent (1st 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 Patent Act, 1970, by proposing and introducing Exclusive Marketing Rights (EMR) provisions on 1 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 judgments from DSB, India successfully enacted in the 1st amendment introducing the EMR provision retrospectively from 1 January 1995. A non-obstante clause was introduced through subsection 2 of Section 5 of the Patents Act, 1970 and the same was linked to newly introduced Chapter IV A, Section 24 A to 24 F, thereof.

The EMR provisions have been linked to the filing of process patents as well as product patents relating to an invention after 1 January 1995. The product patent applications which were eligible for post-TRIPS inventions/molecules were to go into a ‘mailbox’ which would be opened only after product patent regime comes into force in India. Even though 8500 EMR applications were filed in India post 1 January 1995, only about 14 EMRs were filed/processed in India. During the early days of this period, there have been doomsday predictions by ill-informed experts that all the 8500 applications will become EMRs and will cause harm to the Indian pharmaceutical industry. Contrary to such predictions only 14 EMR applications were filed out of which large majority of them got rejected for non-fulfillment criteria including being pre-1995 molecules or being based on appropriate tests conducted before 1 January 1995.

The criteria for qualifying for EMR as per Chapter IV A were as follows:

(1) A patent application/specification with the claim for a patent for an invention covering an article or substance on the basis of appropriate tests conducted on or after 1 January 1995 is filed on the country where the invention has been claimed. The said country having a convention country status, vis-à-vis, India as on the date of filing.

(2) Filing a patent application for a patentable invention in India (as above) for the method or process of manufacture of the invention relating to the identical article or substance and obtaining a grant of a process patent in India.

(3) Granting approval to sell or distribute the article or substance from the appropriate authority in India.

(4) Applying for an EMR in India, attaching:
(a) details of the product patent granted in convention country;
(b) details of process patent granted in India;
(c) details of marketing approval granted in India; and
(d) copy of the product patent (mailbox) applications filed in India for an identical product for which process patent and marketing approval has been granted to the same applicant who has filed the same patent application.

**EMR Grant in India**

In view of the complex conditionalities majority of EMR applications were rejected. In most cases, appropriate tests were conducted prior to 1 January 1995 and in others there have been non-matching of applicant or subject matter or lack of convention status of the country of research and other technical grounds. One of the EMRs granted was stayed by Kolkata High Court and related product patent (mailbox application) was rejected thereafter, in post-2005 product patent examination (on pre-grant opposition). Another EMR which had been granted to an Indian company for a topical composition of known substances has also lapsed, thereafter the composition (product) patent application has been granted on the pre-grant opposition. A third EMR application filed by a Swiss based pharmaceutical corporation led to the grant of an EMR. The Swiss Pharmaceutical Corporation thereafter successfully obtained an injunction against majority of other Indian companies, post-2005, when the product patent (mailbox) application was taken up for examination, a large number of pre-grant opposition were filed and product patent applications were rejected, leading to the extinction of the EMR, thereof. An EMR for pesticide has been granted to an Indian company and was replaced by the grant of a product patent, post-2005.

**The Patents (2nd Amendment Act), 2002**

The Patents (2nd Amendment) Act, 2002 amended the definition for ‘invention’ as follows:

- Section 2(1) (j) defines ‘invention’ as a new product or process involving an inventive step and capable of industrial application.
- Microorganisms were made patentable under Section 3 (j) of The Patents Act, 1970 of the Act from this amendment.
- The patent term has been extended to 20 years for all fields of inventions from the date of filing of application through the substitution of Section 53.
- The Patents (2nd Amendment) Act, 2003, deleted the provision ‘licence of right’ from the compulsory licence options, for TRIPS compliance.
- Reversal of burden of proof under Section 104-A has been inserted.
- The Patents (2nd Amendment) Act, 2002 incorporated the research exemption under Section 107-A

**Research Exemptions**

Article 30 of TRIPS Agreement provides its member nations to include exemptions to the exclusive rights conferred by patents, provided that such exemptions do not unreasonably conflict with normal exploitation of patents and do not unreasonably prejudice the legitimate interests of the patent owners, taking account of the legitimate interests of third parties. A patent granted under the Patents Act, 1970 confers exclusive rights upon the patentee to prevent unauthorized third parties from making, using, selling or importing patented product in territorial jurisdiction of India. Any individual, who violates these exclusive rights of the patentee, faces liability for patent infringement. However, there are exemptions available under the Act against the exclusive rights conferred upon the patentee. Experimental/Research Exemptions are clearly provided under Section 47 (3) and 107 A (a) of the Patents Act, 1970. According to Section 47 (3), any person can use patented product or process for the purpose of experiment or research including imparting of instructions to pupils. This provision is merely for academic purpose and further research or experiment. This exemption can be used as a statutory defense against infringement where the patented invention has been used for research or experimental purposes. The amended Section 107 A (a) states that any act of making, constructing, using, selling or importing a patented invention solely for uses related to the development and submission of information does not amount to infringement of patent. Therefore, it enables the pharmaceutical companies to perform further research and development activities over the patented product for preparing for regulatory approval. This exemption is specifically useful for generic manufacturers to prepare generic version in advance of the patent expiry. When these two exemptions under Section 47 (3) and 107 A (a) are taken together, it appears to be extremely useful for experimental and research purposes of pharmaceutical sector. Research exemption is known as Bolar Provision in Canada which originated from Roche.
Products v Bolar Pharmaceutical. In US, this exemption is known as Hatch-Waxman Exemption or § 271(e)(1) exemption.

**Compulsory Licences**

The Indian Patent law empowers the Controller of Patents to issue compulsory licences to deal with the following extreme and/or urgent situations:

(A) Section 84–Compulsory licence can be granted if the following conditions are not met:
   (a) reasonable requirements of the public
   (b) drugs available to public at a reasonably affordable price
   (c) patented invention not worked in India.

(B) Section 84 and Sections 92–Liberal compulsory licence for
   (i) National emergency
   (ii) Circumstances of extreme urgency
   (iii) Public non-commercial use
   (iv) Patentee’s anti-competitive practices

(C) Section 84–Compulsory licences, further on the following grounds
   (i) refusal to grant voluntary licence on reasonable terms
   (ii) interests of manufacturing industry in India is prejudiced
   (iii) demand not adequately met at reasonable terms
   (iv) export demand not adequately met
   (v) establishment or development of commercial activity is prejudiced
   (vi) restrictive clauses or practices in licensing
   (vii) working on commercial scale is prevented or hindered

(D) Section 92 A–Compulsory licence for export against CL issued from overseas.

Sub-section (g) of Section 3 was deleted from the list of non-patentable inventions. Section 3 (g) reads as follows:

‘a method or process of testing applicable during the process of manufacture for rendering the machine, apparatus, or other equipment more efficient or for the improvement or restoration of the existing machine, apparatus or other equipment or for the improvement or control of manufacture’.

The deletion of this section, in a way, widened the scope of patentability of testing methods or processes which are being developed in support of manufacture in pharmaceutical industry. Processes for character-ization or standardization of herbal ingredients and medicaments could come under this category.

**The Patent (3rd Amendment) Act, 2005**

The Product Patent Regime as required under the TRIPS provision at the end of the 10 year pipeline grace period (5+5) as available and availed by a country such as India (being a developing country with no existing product patent regime) came into effect through the 3rd Amendment leading to the Patent (Amendment) Act, 2005. The examination of the mailbox application commenced thereafter.

- The Act has omitted Section 5 of the Indian Patent Act, as per only process patents for food, medicines and other drug substances, were to be eligible. Consequently, product patents became available in all fields of inventions.
- The Act also introduced Section 92 (A) of the Act which deals with compulsory licensing of pharmaceuticals for export purposes. This is meant to facilitate the Indian industry to continue supplying cheaper generic versions of patented drugs to those LDCs that do not have adequate domestic manufacturing capabilities.
- The Patent (Amendments) Act, 2005 has also omitted Chapter IV A and Sections 24 A to 24 F of the original Patent Act, discontinuing EMR provisions (as product patent regime has been made operational).

**Pre / Post Grant Oppositions**

Provision for opposition of an accepted patent application by any interested person was available under the Patents Act, 1970, before amendment. However, this opportunity was available only after publication of an examined and accepted patent application.

As per the notification of the 3rd amendment, it was proposed that patent opposition opportunity will be restricted to post-grant opposition only. However, the Parliamentary debate and consequent consensus in early 2005, led insertion of the additional provision for pre-grant opposition along with the provision for filing post-grant opposition, in the finally amended Act.

Pre-grant opposition can be initiated only during the period after the publication (18 months publication) of the patent application in the Official Journal of the Patent Office and before the grant of the patent. Section 25 (1) of The Patents Act, 1970
lays down the grounds on which a patent application can be opposed in India. Any person may file a pre-grant opposition or representation to the Controller with statement and evidence along with a request for hearing. The Controller shall consider pre-grant representation only when a request for examination of the application has been attached. On the other hand, the notice of post-grant opposition can be submitted to the Controller by any interested person at any time after the grant of patent, but before the expiry of the period of one year from the date of publication of grant of patent in the Patent Office Journal. The grounds for post-grant opposition are similar to those for pre-grant opposition. As far as pre-grant opposition is concerned, there is no prescribed form or prescribed fee for the submission of pre-grant opposition. Rule 55 A of the Patents Rules, 2003, states that post-grant opposition shall be made in Form -7 along with the prescribed fee of Rs 1500 for natural person and Rs 6000 in case of other than natural person to the Controller in duplicate at the appropriate office. Hearing is a mandatory relief in case of post-grant opposition, whereas in pre-grant opposition it is being granted only on request of the opponent or the applicant. Order of the Controller General is not appealable in the case of pre-grant opposition. On the contrary, the Order of the Controller General out of post-grant opposition can be appealed before the Intellectual Property Appellant Board.

Criteria of Patentability and its Enforcement

Criteria of patentability play a key role in determining whether an invention is patentable or not in India. Amendment of Section 3 (d) in its present form has become a major concern for the pharmaceutical industry, even though the Chennai High Court Judgment has put its seal on the Constitutional validity of Section 3 (d). Section 3 (d) now reads as follows:

“(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Explanation – For the purposes of this clause, salts, esters, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.”

This amendment of Section 3(d) was carried out by the Indian Parliament to control ‘evergreening’ and attempts to obtain product patent protection for Pre-1995 molecules in India (which otherwise do not qualify for a product patent in India). Consequently, the patent application for Gleevec (Imatinib Mesylate) was rejected (including on other grounds) which led Novartis to filing of a Writ Petition challenging validity of Section 3(d) amendment. The Constitutional Validity of Section 3 (d) was upheld by the Chennai High Court in the Gleevec case.

Impact of Post-TRIPS Scenario on Indian Pharmaceutical Industry

The advent of WTO and TRIPS regime has done wonders for the Indian pharmaceutical industry. Under the protected pre-1995 regime, Indian pharmaceutical industry had been floating complacently without direction and with no sense of urgency. Only after the emergence of TRIPS on the horizon, Indian pharmaceutical industry woke up to the challenges of new intellectual property regime. Truly, the Indian pharmaceutical industry became part of the knowledge industry consequent to TRIPS.

For the first time in many decades, the Indian pharmaceutical industry felt threatened in their home pitch. While a few visionary corporates like Dr Reddy’s started initiating actions to face the challenges of product patent regime for early 1990s by setting up a Drug Discovery Programme, most others took their time to set up research facilities and innovative research programmes. However, the real action phase has commenced post-2005. The intellectual property/patent awareness creation and absorption as well as keenness and enthusiasm for inculcating patent practices have largely helped the Indian pharmaceutical industry to find a new born to set in motion, new strategies not only for survival, but also for continuing the trend or dominance that the Indian pharmaceutical industry has been showing for the last few decades.

While a reasonable good number of Indian pharmaceutical corporations have set up research facilities of global standard and have initiated research programmes for New Drug Delivery Systems and also in some cases for Drug Discovery Programme, the overseas pharmaceutical corporations
(widely termed as ‘MNCs’) have not been as enthusiastic in the post-TRIPS regime in India. Very few overseas pharmaceutical corporations expanded their research facilities substantially in India, post-1995. This could very well be understood and appreciated in the light of the following analysis of the emergence of TRIPS and post-TRIPS scenario as envisaged globally.

When the Uruguay Round commenced in 1986 (or even earlier when the Intellectual Property Agenda was introduced into the GATT), the global corporations had great hopes of once again conquering the pharmaceutical markets lost to them over the years (however meager it may be) to the pharmaceutical manufacturers in the third world countries. The successful completion of Uruguay Round negotiations, culminating in the signing of WTO and TRIPS gave extraordinarily ‘great expectations’ of a very bright future in the emerging markets for the global corporations. However, effective use of the inbuilt flexibilities in the TRIPS Agreement by the member countries of the developing and emerging markets thwart these dreams of global pharmaceutical giants. Led by countries like India, Brazil, Argentina, South Africa and others, the post-TRIPS patent regime in the respective national jurisdictions has continued to enjoy the exemptions and strike an effective balance between public health requirement and patent protection. The failure of EMR regime in the transition phase has added fuel to the fire of their anxieties in the IP front, post-1995. The anxiety for early enforcement of IP/patent right through litigations initiated by ‘Bigpharma’ has been counterproductive. Not only did these initiatives meet with negative results in most cases, but also generated substantial media and public interest in persuading the Government to incorporate effective measures for protecting public health within available flexibilities of TRIPS.

During the post-TRIPS regime, there have been extreme concerns about misappropriation of traditional knowledge. The cases involving Neem, Turmeric, Basumati, including Geographical Indications in the latter case and many others alerted the law makers to include extreme safety measures to prevent misappropriation of traditional knowledge. The Government of India under the auspices of the Council of Scientific & Industrial Research (CSIR) through The National Institute of Science Communication And Information Resources (NISCAIR) came up with TKDL (Traditional Knowledge Digital Library) which is a compilation of indigenous knowledge and know-how in the field of indigenous knowledge wealth.

The enactment of Bio-Diversity Act, 2002, with benefit sharing mechanisms, measuring for patenting as well as exploitation is also a post-TRIPS development. Unlike USA who has opted for plant patents, India has enacted Plant Variety Protection Act in 2001 as PPVFR (The Protection of Plant Varieties and Farmers’ Rights Act, 2001). Even though India has great potential for developing modern medicines and discovering new drugs based on its vast herbal and natural resources, the over anxiety to prevent misappropriation has created hurdles and impediments in research and development of herbal products.

The Indian pharmaceutical industry which had commenced export of bulk drugs (active ingredients) and formulations to least developed countries in the late 70’s and 80’s, has now emerged as a major global player, post-TRIPS. The direction of India’s pharmaceutical exports have substantially changed course to the developed countries such as US and Europe in the post-TRIPS era. Initially forced by the TRIPS regime to comply with global intellectual property practices and later finding advantages of such practices to achieve greater success in the global markets, following voluntarily global IP practices such as freedom to market analysis and operations, patent mapping/landscaping and adoption of non-infringing processes for filing DMF (Drug Master File) and ANDAs (Abbreviated New Drug Applications) have greatly helped the Indian pharmaceutical industry to scale greater heights of market penetration and technological progress.

India has always been a treasure house of technically qualified people for the global research and knowledge driven manufacturing community. The post-TRIPS scenario further encouraged technical and legal professionals in pharmaceutical industry in India to incorporate IP/Patent practices in their knowledge upgradation and work culture. Consequently, the post-TRIPS knowledge driven pharmaceutical research environment in India has encouraged pharma professionals of Indian origin to be part of the reverse brain-drain.

The success of the Indian generic industry has been taken note of by other leading generic players of this arena. Almost all the major leading global generic
pharmaceutical corporations have set up research facilities in India and have also made major mergers and acquisitions, thereby making India the single largest pharma player in the world, post-TRIPS.

**Conclusion**

While the intellectual property practices including patent laws and practices are undergoing major changes globally, the Indian IP/patent laws are getting consolidated, more specifically, in the field of pharmaceuticals. The recent case laws in Gleevec and Tarceva extending to the High Courts of Chennai and Delhi respectively and the early appeals to IPAB are testing the Indian waters on pharma patent jurisprudence. While a few hundred product patent applications have been granted, post-2005, only a few of the 8000 plus product patent applications have been subjected to pre-grant oppositions. While it is too early to comment on compulsory licences, it appears that this provision will be sparingly used, at least in the next few years.

There is an increasing trend in awareness, public participation, patenting, patent-opposition and patent enforcement in India in the pharmaceutical field. There is a nearabout 30% share for pharma in filing and grant of trademarks and patents. The trend of PCT international filings are on the increase. Licensing (both in-licensing and out-licensing) of technologies have gained acceptance and the recent surge in filing of ANDAs in USA have provided an impetus to co-marketing, co-licensing alliances and networking of Indian pharma companies with Global Pharma Corporations.

There is increasing trend in IP/Patent training and education. Most of the universities, institutions and law campuses and colleges have commenced Post-graduate degree and diploma courses in IPR. A few institutes have been set up specifically to train professionals on patent law and practice. The global opportunities in this field are being extensively pursued and tapped by the local technically and legally trained manpower.

Indian pharma traditionally was against IPs in general in the 70’s and 80’s. The National Sector was pro-non-branded generics and anti-trademarks in the 70’s. The Indian dominance in the branded generics have made the National Sector extremely pro-trademarks. Similarly, Indian National Sector was anti-patents in the 70’s. Patent practice by Indian National Sector has commenced post-TRIPS. Once the Indian pharma industry starts participating in Innovative Research and Drug Discovery Programmes, a day is not too far, that India may move to the forefront of patent advocacy and all related practices (both good and bad).

**References**

3. 733 F.2d 858 (Fed. Cir. 04/23/1984).