CHAPTER-IV

WTO, INTELLECTUAL PROPERTY AND PUBLIC HEALTH

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WTO, INTELLECTUAL PROPERTY AND PUBLIC HEALTH

In 1994, the GATT introduced the agreement on Trade Related Intellectual Property Rights (TRIPs) which covers protection of intellectual property.

WTO policies on Trade-Related Intellectual Property Rights (TRIPS) have important implications for ‘knowledge-based’ industries and particularly affect Developing countries like India and China which have good technological Skills. An industry that is especially affected by TRIPS is pharmaceuticals and this has urgent implications for public health in developing countries. The argument for TRIPS is that pharmaceutical companies need Protection of patents to recover the high investments that new drugs require. Unless this protection is guaranteed, they will not produce new drugs and Welfare will be reduced. TRIPS offer opportunities not just for Western, but also for Indian, pharmaceutical companies.

A joint study of WTO and WHO suggests that the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology to the material 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.\(^1\) The

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\(^1\) WHO, WTO, Agreements and Public Health : A joint study by the WHO and the WTO Secretariat Press, 2002, paragraph 44 p-38,
article 8 enshrines the basic principles on which TRIPS Agreement is based. The article is as follows.

1. Members may in 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 provided that such measures are consistent with provisions of this Agreement.

   ➢ extends the scope of patentable subject matter to any invention whether products or process, in all fields of technology [Article 27.1];

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology,²

According to TRIPS Agreement, it,

   ➢ Enlarges the period of patent protection to 20 years [Article 33];
   ➢ Deems importation as equivalent to working of a patent [Article 27.1].
   ➢ Protects the right holder against discrimination on the grounds of place of invention, place of production, and field of technology [Article 27.1];

² Ibid, paragraph 45, pp-38-39,
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- Limits the scope of compulsory license, licensor of right, government third party use [Article 31];
- Reverses the burden of proof in some cases (Article 34).

The TRIPs Agreement provides relatively high minimum standards for each of the main categories of intellectual property rights. Establishes standards of protection and enforcement, and provides for the application of the WTO dispute settlement mechanism to resolve disputes between WTO members. It was suggested that high levels of intellectual property Protection, would encourage multinationals to market their newer Pharmaceuticals more quickly and intensively in the developing world; the offer of strong IP Protection would encourage local and multinational firms to establish R & D until these, promoting technological development; and finally, perhaps the most compelling argument was that the intellectual property standards in the developing world would give private firms an incentive to invest in the development of products of specific importance to consumers in those countries. Thus, arguably the TRIPS Agreement attempts to strike a balance between the longer term objective of providing incentives for future inventions and creations. It covers huge areas including pharmaceutical products, micro-organisms and micro-biological transformations. The TRIPs Agreement deals in following major intellectual property rights: (1) Copyright and related rights (2) patents (3) trademarks and service

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3 Chandiramani, Nilima, Legal Factors in TRIPS, Economic Political Weekly, Vol. 37, No.3, 19-25 Jan, p-201
marks, (4) geographical indications (5) undisclosed information or trade secrets (6) industrial designs (7) layout designs of integrated circuits.

Copyright: It helps in protecting the literary, musical, graphic, or other artistic form in which the author or the creator expresses intellectual concepts. The concept of copyright is grounded in principle of originality. Copyright can be applied to any ‘tangible form’ including literary works, dramas, pantomimes, and choreography, pictorial, graphic and sculptural works. It does not deal with ideas or facts. Protection extends to expressions only.

Patent: The law protects ‘inventions of all kinds’ and encourages new inventions, and research and development. Basically, it allows the inventor a monopoly and commercial exploitation for a limited and fixed period of time. Unlike copyrights patents provide the inventor exclusive rights in that specific area, barring it from public use. Patent is a reward, an inducement to the patent holder to bring forth a new, novel and useful invention which furthers human knowledge and benefits and develops the society at large. Patents are territorial, a patent holder has rights only in the territory in the patent was issued. In order to gain rights in other countries the inventor will require to file a patent application in other countries.

Trademark: it safeguards any word, name, symbol, logo, or device used to identify or indicate the source of goods or services, from cheap imitations. It helps in maintaining the integrity of products and

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diminishes the chances for ‘product confusions and unfair competition’.
The agreement defines what types of signs must be eligible for
protection as trademarks, and what the minimum rights conferred on
their owners must be Trademarks like patents, are territorial in
characteristic, and the seeker will require to apply to other countries.

**Geographical Indications:** Geographical indications are those
indicators, by which the quality of the product is assessed, specially
reflecting the characteristic of regional or local features geographical
indications are used to protect regional affiliation in the nomenclature of
a commodity such as champagne wine or Darjeeling Tea. Thus
geographical indicators definitely portray the regional/local
characteristic present in the product.

**Trade secrets:** It is primarily information like formula, pattern,
compilation, programme, method, technique, process, recipe etc. On
which the production of the product is based. This information is always
protected from public usage. Trade secret laws basically, protect trade
espionage and dissemination of the knowledge.

**Industrial Designs** – Industrial Designs seeks novelty in design in any
product, right from automobile engines to ball pens. Some sections of
industrial design require artistic flair. This law prevents gross imitation
leading to unfair competition and gives Philip to higher level of
sophistication and innovation in design.

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9 Supra Note 7.
10 Ghate, Utkarsh, Patenting Life Bio-diversity and Intellectual Property Rights,
Resonance, Feb 200. P. 52.
**Layout Designs of Integrated circuits**: It refers to mask works (topographies) of a semiconductor chip. The period of ten years is the minimum term given from the date of first commercial exploitation.

The TRIPs Agreement essentially establishes discrete rights and obligations for WTO Members. The Agreement has resulted into:

- An international law of substantive minimum standards for IP Laws; Minimum international criteria for national enforcement of IP rights through civil, criminal, and administrative proceedings.
- National IP standards and enforcement to the WTO dispute settlement system, thereby providing an international forum for enforcement of rights and resolution of disputes.
- Certain common procedural requirements that each national government must meet concerning the administration and the maintenance of IP rights.\(^{11}\)

It aims to harmonize various patent laws of different countries, in order to further regulate free international trade, grounded in the new liberal framework.

The substantive criteria that have to be met required by an invention in order to qualify for patent are (a) novelty (b) inventive step’ (c) and industrial applicability, similarly the agreement also provides distinct criteria on the basis of which it may be disqualified for the grant of a patent. Those standards which reasonably relate to public health are-

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- Inventions whose commercial exploitation needs to be prevented to protect human, animal or plant life or health,
- Diagnostic, therapeutic and surgical methods for treating humans or animals.
- Plant and animal inventions other than micro-organisms, and essentially biological process for the production of plants or animals other than non-biological and micro-biological processes.\(^\text{12}\)

**Developing Countries AND TRIPS**

TRIPS Agreement provide varied, specific time periods to implement the regulations of the Agreement by developing and least developed and least developed countries. The developing countries needed to comply with the regulations by 1\(^{\text{st}}\) January 2000 and Least Developed Countries (LDCs) by 1\(^{\text{st}}\) January 2006. Agreement specifically recognizes the 'economic, financial, administrative and technological constraints of the least developed countries,'\(^\text{13}\) Even though developing countries benefit form certain grace periods for full compliance with TRIPS Agreement, article 70.8 and 70.9 require that they must establish an administrative mean for preserving means and priority for patent application during the transitional period.\(^\text{14}\) Thus developing countries which complied to the TRIPS regulation by 2005 had two obligations.

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\(^{12}\) WHO.WTO. Agreements and Public Health : A joint study by the SHO and the TO, WTO Secretariat Press, 2002, paragraph 57 p43-44,

\(^{13}\) Ibid.


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(a) They must allow inventors to file patent applications from 1st January 1995, even though the actual decision on whether or not to grant any patent need not be taken until the end of the transition period. This provision was established because the date of filing is significant as it is used for assessing whether the application meets the criteria for patenting, including novelty ("newness" criterion).

(b) Second if the government allows the relevant, pharmaceutical or agriculture chemical products to be marketed during the transition period, it must subject to certain conditions provide the patent applicant an exclusive marketing right for the product for five years, on until a decision on a product patent is taken, whichever is shorter.\textsuperscript{15}

Despite the claims made by the advocates of TRIPs Agreement, it faced sweeping and severe criticisms from all over the world. The inclusion of intellectual property standards in the treaty establishing the WTO was deeply unpopular with the developing countries and the source of considerable friction during the negotiations. Lineout, Jean. O. and Macleod, Margaret observe that Pharmaceutical IPRs have been reduced to 'essentially a market distortion, a government sanctioned monopoly and subsidy.'\textsuperscript{16} The myth that Patents contribute to the stimulation of creativity and inventiveness and their absence to lack of creativity and ingenuity is based on an artificial construction of

\textsuperscript{15} Supra Note 12, P. 46-47.
knowledge being isolated in time and space, without being connected to
the social fabric and contributions from the past. According to
developing countries TRIPS Agreement will lead to monopolization and
inaccessibility of essential commodities like medicines and drugs etc.
and will dilute sovereign power of nations over their national
biodiversity\textsuperscript{17}.

**WTO Ministerial Declaration on TRIPS and Public Health (Doha
Declaration)**

In response to concerns like that of developing countries, the
WTO Ministerial Declaration on TRIPS and Public Health, was
thrashed out at WTO meeting in Qatar. It was an effort among
developing countries to clarify that TRIPS should not prevent member
nations from taking measures to protect public health. Though it is not a
relaxation of the agreement, the message was that TRIPS is not always
appropriate and that poor countries should design their IP system to fit
their particular circumstances, according to their levels of scientific and
technological development, IP protection should offer opportunities to
poor people, not a threat to their health.

If a sustainable and effective solution to combating diseases like
AIDS in the developing world is the goal, then a blanket application of
IP would be counter productive. A practical global IP system should be
a flexible one that takes different countries’ economic and social
circumstances into account and makes sensible compromises.

\textsuperscript{17} SHIVA, VANDANA, Protect or Plunder? Understanding Intellectual property
The Declaration notes that countries are free to determine the grounds on which compulsory licenses are granted, and the right to determine what constitutes a "national emergency or other circumstances of extreme urgency". The latter provisions reflect the shortcut in procedures allowed in these circumstances in Article 31(b) of TRIPS. Paragraph six refers to procedures for compulsory licensing in the pharmaceutical sector needed to address "public health problems especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics". It does not, as sometimes assumed, refer only to compulsory licensing in situations of emergency or urgency. Nor is it limited to a particular type of disease.

Some middle-income developing countries, such as India and China, with their industrial-scale copying of other people’s products, are sufficiently advanced to benefit from the sort of innovation that would be spurred by stronger patent protections. They should implement the IP protection required by TRIPS, for the sake of their own industry. But for the least developed countries where life-threatening disease - not just AIDS, but malaria, TB and other scourges - are rampant, there have to be ways to bypass patents. Not only should these countries be allowed to make cheap generic versions of patented drugs themselves, but they should also be permitted to buy generics made elsewhere if they do not have the capacity at home.

Growing concerns in developing countries regarding access to medicines at prices that their citizens could afford led to considerable divisions amongst the WTO members. The outcome of this process was the Ministerial Declaration adopted at the conclusion of the Doha

18 See for details, Doha Ministerial Declaration paragraph 5b, 5c.
Ministerial Conference held in 2001 on TRIPS Agreement and Public health.

The Doha Declaration constituted a milestone in the TRIPS Agreement history for two reasons: first, because it ensures balance between the right of the Members to implement policies intended to safeguard public health and patent right; second, because the Doha Declaration sets forth a clear preventive standard of the whole TRIPS Agreement, as well as some other specific rules of that Agreement, such as compulsory license and exhaustion of intellectual property rights.\(^\text{19}\)

The Ministers stated "TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and in particular, to promote access to medicines for all."\(^\text{20}\) The Doha Declaration determines, in general, that in applying "the customary rule of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles."\(^\text{21}\) The objectives of the Agreement of TRIPS provided in Article 7 states that protection and enforcement of intellectual property rights should among other things be "conducive to social and economic welfare, and to a balance of rights and obligations." Furthermore, Article 8 of the Agreement directs WTO Members to

\(^{20}\) Doha Declaration, para -4.
\(^{21}\) Doha Declaration, para -5(a).
adopt measures necessary to protect public health and nutrition while formulating or amending their laws and regulations relating to intellectual property. Thus, Articles 7 and 8 of the TRIPS Agreement require that WTO members must ensure that the laws relating to all forms of intellectual property rights covered by the Agreement give due consideration to issues like protection of public health and nutrition and do not merely serve the interest of the owners of intellectual property.

The second area of focus of the Doha Declaration was compulsory Licenses. With the product patent regime establishing itself following the adoption of a TRIPS –consistent patent regime by India, the future of the pharmaceutical industry in India would critically hinge on the ability of the producers to obtain licenses from the owners of proprietary technologies. For obtaining the license, from the owners of proprietary compulsory licenses, is an instrument that has been embedded in the patent system for preventing abuse of patent monopoly. The rounds for the grant of compulsory licenses include the refusal of the patent holder to exploit the patent commercially in the country granting the rights.\(^{22}\) At the same time, however, the prospective beneficiaries of the compulsory licensing system would have to demonstrate that they have “made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that

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\(^{22}\) The Paris Convention, which has set the global standards for patenting since it was adopted in 1883, provides in Article 5A that the signatories to the Convention have the “right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work”. It may also be mentioned that Article 2 of the TRIPS Agreement required that WTO Members are required to comply with the substantive provisions of the Paris Convention.
such efforts have not been successful within a reasonable period of time.

In some ways, the Doha Declaration goes well beyond the provisions of the Paris Convention. The Declaration states that every WTO Member has “the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted” irrespective of the fact that the terms and conditions in Article 31 of the TRIPS Agreement that govern the grant of such licenses, should always be observed.

The developments centering on the Agreement on TRIPS that have taken place during the past few years, call clear articulation of which was the Doha Declaration, bring home the point that the TRIPS-consistent patent laws have to take into consideration the interests of the public at large, besides of course granting patent rights on inventions that unambiguously represent advances in technology. This later point is particularly important given that the patent offices in some of the more advanced countries like the US, have been granting patents on the so-called incrementally modified drugs (IMDs), which could include new formulations, new combinations of active ingredients or new salts or esters of approved compounds. Recent studies have found that in the United States brand manufactures have flooded the market with IMDs, which “in 85% of the cases, do not provided significant improvement over currently marketed therapies. What is an advantage for the firms is

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23 Article 31(b) of the TRIPS Agreement.
24 Doha Declaration, para. 5(b).
25 It is considered as of strong economic incentives by the pharmaceutical firms. The development of an IMD is “safer, faster, and more cost effective for the developer as an incremental improvement rather than a original product.
usually a disadvantage for the consumers since these IMDs have contributed substantially to the rising prices of medicines.

These developments taking place in countries like the United States, which provide the most extensive patent rights, should be seen as useful guideposts for the policy makers in India while they are in the process of adoption of a TRIPS-consistent patent regime. In a country where access to medicines at affordable prices is a major area of concern, one hardly needs to labour on the point that adequate safeguards need to be provided to ensure that the country does not witness the specter of high medicines caused by the grant of IMD patents. What this implies is that strengthening of the rights of the patent holder, which is the cornerstone of the TRIPS Agreement, must be tempered by the inclusion of provisions that effectively address public interest concerns.


The Patent (Amendment Act, 2002) dealt with many issues relating to Pharma industry. One of the most debated questions is the impact of these amendments in the health sectors and more specifically on access to medicines. It is believed that it has a negative effect on people’s access to medicine. However, the present law adopted the restricted rights of holders of medical patents to foster the availability of cheaper medicines. While the TRIPS Agreement lays down a number of precise standards and rules it also introduces a number of exceptions and qualifications over the years. Several issues would need careful consideration as India Implements a TRIPS-compliant patent regime.
The following is a non-exhaustive list: (i) defining the scope of patentability to address among other issues, patents on IMDs, (ii) provisions for the grant of compulsory licenses, (iii) opposition proceedings, (iv) specific exceptions as for example “parallel imports” (v) protection of generic producers.  

_Salient features of the Patents (Amendment) Act, 2002 and the Patents Rules, 2003_

- Term of every patent which is in force including a patent restorable, U/S. 60 as on 20.5.2003 has now become 20 years from the date of filing.
- Time for restoration of a ceased patent, U/S 60 has now increased from 12 months to 18 months as such an application for restoration of a patent ceased on or after 20th May 2003 can be filed within 18 months from the date of ceasession.
- A new definition of "Invention" means a new product or process involving inventive step and capable of industrial application; has now come in force.
- A method or process of testing during the process of manufacture will now be patentable.
- Process defined, U/S 3(i) in case of plants, are now patentable while a process for diagnostics and therapeutics has now been considered as non patentable,
- A list of Authorized Depository Institutions have been notified in the Gazette Of India, Part II, Section 3 sub-section (ii) dated

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20.5.2003 for depositing the biological materials mentioned in the specification at the time of filing a patent application.

- The source of Geographical origin of the biological material used in invention is required to be disclosed in the specification.

- 18 months publication has been introduced, therefore, every patent, except in which a secrecy direction is given U/S 35 will now be published just after 18 months from the date of filing/priority and will be open for public on payment. As such the filing intimation being published in the Gazette immediately after filing has been stopped.

- A request for examination system has been introduced and therefore all the patent applications in which First Examination Report has not been issued on or before 19th May, 2003 will now be examined U/S 12 only after filing a request for examination.

- The applications for patent will now be examined in serial order in which the request for examination is filed.

- In case the application has been filed before the commencement of this Act, the request shall be made within a period of twelve months from the date of commencement of the Act i.e. 20th May 2003 or 48 months from the date of application, whichever is later.

- Provision for filing request for examination by any other interested person (other than applicant) also has been introduced.

- Provision for the withdrawal of application by applicant any time before grant has been introduced.
Time for putting the application in order for acceptance U/S 21 has now been reduced from 15/18 months to 12 months.

Section 39 in modified form prohibiting filing patent application outside India, inventions limited to the fields of defense purposes or atomic energy has been reintroduced.

Opposition Proceedings U/S 25 have been simplified and shortened, fixing hearing is not compulsory, if the applicant does not file reply statement and evidence, application will be deemed to have been abandoned.

Provision for allowing Paris Convention Priority has been extended to group or union of countries or inter governmental organizations, therefore, 12 month priority will also be available in certain cases.

(a) **Scope of patentability**

It is of critical importance to define the scope of patentability since in many jurisdictions, and in particular, those existing in developed countries the definitions are so open-ended that they have undesirable consequences as for instance, the grant on patents on IMDs. Narrowing down the scope of patentability, particularly in respect of pharmaceuticals should be seen as the first step for ensuring that the IMDs do not get patent rights in India. This required that the amended law provide appropriate definitions/clarifications in respect of the three criteria used for assessing whether or not a claimed invention is patentable, viz. novelty, inventive step and industrial application. It needs to be noted here that the TRIPS Agreement does not define any of these three criteria implying thereby that the WTO Member countries are free to adopt their own definitions.
Two issues are important in this context. These are the elaboration of the criteria for patentability and the issue of patentable subject matter. Four amendments were introduced in the Patents Act, and some of these require close examination.

The first is the elaboration of the definition of "inventive step", which was accepted as being coterminous with non-obviousness in the earlier versions of the Patents Act 1970. According to section 2(ja), "inventive step" means a feature of the invention that involves technical advance as compared to the existing knowledge or having economic significance or both..." How the Patent Office interprets this definition would be seen with interest on two counts. First, the extent of "technical advance" that would be considered sufficient for the grant of the rights could depend largely on the subjective judgment of a patent examiner. In other words, a patent examiner would require a clear set of guidelines further to ensure that incremental innovations of the kind that the IMDs represent are not granted patent rights. Secondly, assessment of the inventive step based on the "economic significance" of an invention could lead to erroneous outcomes. This problem could arise from the exaggerated claims regarding the economic value of the invention that the patent applicant would be tempted to take advantage of this provision.

The second amendment of this class that requires a re-look is the introduction of a new definition for "pharmaceutical substance". Section 2(ta) 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 terms ‘chemical’ should have been inserted so that the definition would be ‘any new chemical entity’.27

A third amendment tries to exclude discoveries or new use of a known substance from the ambit of patenting. Here again, the language used leaves for too much of an ambiguity. A good example of this is the exclusion of “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” from patentable inventions.

While answers to several of these issues may eventually be settled through the disputes including those that would be in the nature of opposition to the grant of patents, there is obviously a need to get legal certainty on this contentious issue. Reflecting this need, the Government of India had set up a five-member. “Technical Expert Group on Patent Law Issues” in April 2005 headed by Dr. R.A. Mashelkar, Director General, Council of Scientific and Industrial Research (CSIR). The Group was given the following terms of reference.28

(a) Whether it would be TRIPS (Trade-Related Intellectual Property Rights) compatible to limit the grant of patents for pharmaceutical substance to new chemical entity or to new medical entity involving one or more inventive step; and,

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27 NCE: according to 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.

28 Government of India - Mashelkar Report
(b) Whether it would be TRIPS compatible to exclude microorganisms from patenting.\(^{29}\)

As regards the patentable subject matter, the key change introduced was the mandatory requirement for removing the "process-patent-alone" regime in case of chemicals. This involved removal of Section 5(1) of Patents Act, 1970 which provides for process patents in this field. This has meant that from January 1, 2005 product patent applications are being accepted and examined.

It is vitally important that the scope of patentability, definition of pharmaceutical entity, is laid down in clear and unambiguous manner. This step would go a long way in reducing the number of patent litigations, which are threatening to increase. The obvious targets are patents that are being sought for drugs can be used for treating diseases like HIV/AIDS, cancer and TB. Presently, two significant developments have taken place. The first involved the Novartis patent on a drug used for the treatment of cancer, Gleevec. Product patent application for Gleevec was made using the "mailbox" provisions, which meant that Novartis could enjoy five-years of Exclusive Monopoly Rights on the basis of the application made. The EMRs were granted in November 2004, but the grant of the patent was opposed and the opposition was finally upheld in January 2006.\(^{30}\)

\(^{29}\) Later withdrawn.

\(^{30}\) Novartis case discussed in "Verdict of Novartis an F. Hoffmann La Roche Ltd : a judicial attempt to strike a balance of convenience."
(b) Protection of Generic Producers

Section 11A of the Patents Act, 1970, as amended, protects the interests of such generic producers whose business interests may be affected in the product patent regime. This section states that “the patent holder shall only be entitled to receive reasonable royalty from such enterprises which have made significant investment and were producing and marketing the concerned product” before January 1, 2005, and “which continue to manufacture the product covered by the patent on the date of grant of the patent”. In addition to this, it is provided that “no infringement proceedings shall be instituted against these enterprises.”

Although this provision is expected to provide success to the generic producers, it would have to face a number of imponderables. First, the threshold for assessing whether or not a given level of investment can be considered “significant” is not clear. This lacuna regarding the definition of “significant” poses threat of infringement suits as the patent holder may challenge any definition of “significant investment” that may be proposed to extract high royalty payments.

(c) Compulsory Licensing

A compulsory licence is a licence granted by the Government to a third party to use patents and other forms of intellectual property to limit patent and other rights in order to correct distortions in the exploitation of the patent by the holder and avoid the negative impact of such action on the consumer. Governments are authorized to issue compulsory licences to broaden access to products and technologies, and to achieve certain public good when it is threatened by the monopoly granted by
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the patent rights. The Paris Convention already had a provision which states that each country has the right to take legislative measures for the grant of compulsory licences to prevent the abuses which might result from the exclusive rights conferred by the patent e.g., failure to work the patent.31

(d) Grounds for Grant of Compulsory Licenses

The various grounds under which compulsory licences” could be granted are :- (i) Refusal to deal, (ii) Public Interest and Anti-Competitive Practices, (iii) Public Health Issues, (iv) Non-Commercial use, (v) Government Use, (vi) Use of Dependent Patents, (vii) Compulsory Licenses for Medicines. Therefore, the compulsory licensing system could be immensely useful for the firms in the Indian pharmaceutical industry for they can no longer meet their technology-requirement by taking recourse to reverse engineering.

Developments over the past few years indicate that the point of view of developing countries has been getting better support from the global community. Apart from para 31 of TRIPS, multilateral Agreements under NAFTA, the European Union and other trade blocks also have provisions to issue compulsory licenses through national legislations for broad bio-technology tools of research, dependent patent, unreasonable prices, anticompetitive practices and for non-commercial use e.g. in research. Even the US, the most patent-savy country in the world, has provisions for compulsory licenses under 28 USC 1498 for Government use, under which the US Government does not have to seek

a license or negotiate for use of a patent. In 2001, legal uncertainties in respect of the use of compulsory licensing provisions for public health concerns were effectively removed by the Doha Declaration on TRIPS Agreement and Public Health.

The Commission on Intellectual Property Rights (CIPR), which was instituted by UK Department for International Development, was equally supportive of the compulsory licensing system. In its report, “Integrating Intellectual Property Rights and Development Policy”, the Commission emphasized that “developing countries should establish workable laws and procedures to give effect to compulsory licensing and provide appropriate provisions for government use”.

Despite the above-mentioned developments, the compulsory license system provided by India in its amended Patents Act may not fully meet the requirements of the domestic pharmaceutical industry.

The Indian patents Act, provides that an application for the grant of compulsory licence can be made only after three years from the date of grant of the patent unless exceptional circumstances like national emergency or extreme emergency can be used to justify the grant of a license on an earlier date. Three broad grounds for the grant of the compulsory licences have been spelt out thus (a) reasonable requirements of the public with respect to the patented invention have not been satisfied, (b) the patented invention is not available to the public at a reasonably affordable price, and (c) the patented invention is not worked in the territory of India. The Patents Act sets out the

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32 Ibid.
33 Section 84 of Patents Act.
circumstances under which “reasonable requirements of the public” would not have been met. Such circumstances would arise if the patent holder refuses to grant a licence on reasonable terms, and which, in turn, affects: (i) development of new trade or industry in the country, and (ii) establishment or development of commercial activities in India, and (iii) development of the export market for a patented article manufactured in India. The last mentioned provision is aimed at ensuring that India has the option to export the products that have been produced using the licenses from the patent holders. The major impact of this provision could be felt in the pharmaceutical sector, where India could well emerge as a major supplier of pharmaceuticals to the developing countries that do not have sufficient domestic manufacturing facilities.

But while the above-mentioned conditions for the grant of compulsory licenses can be seen to be facilitating the grant of the licenses, the Act also stipulates that the relevant authority have to take into consideration four additional factors before the licenses can be granted, the sealing of the patent and the measures already taken by the patentee or any licenses to make full use of the invention; 9b) the ability of the applicant to work the invention to the public advantage; (c) the capacity of the applicant to undertake the risk in providing capital and working the invention, and (d) the efforts made by the applicant to obtain a licence from patentee on reasonable terms and conditions and that such efforts were not successful within a reasonable period.\(^{34}\)

\(^{34}\) The third amendment provided some crucial clarifications pertaining to this condition. The designated authority has been allowed to interpret the term “reasonable period” to mean a period not ordinarily exceeding six months [Section 84(6)].
Consideration of these factors for granting compulsory licences gives rise to several problems. First, the procedural requirements are too onerous and could consequently result in delay. Secondly, it is not clear whether the grant of a compulsory licence would automatically follow the refusal of a patentee to issue a voluntary license on reasonable commercial terms. Thirdly, the grounds for the determination of anti competitive practices have not been spelt out either in the Patents Act or in Competition Act. And, finally, there is no ceiling on the remuneration payable to the patent holder, which will inevitably lead to demand for excessive royalty and unnecessary litigations.

The remuneration that a patent holder could demand following the decision to grant compulsory license for the “working of patents in the country of grant may become a serious constraint for the smooth functioning of the compulsory licensing system. This situation arises because the Agreement on TRIPS provides the rights holder a distinctly superior bargaining position. Article 31(h) of the TRIPS Agreement\(^\text{35}\) provides the guideposts in this regard, this Article has the potential of rendering the cost of the license prohibitive for the drug majors have claimed that the average cost of bringing one new medicine to market is at least a billion US dollars.

Royalty payments would be a critical issue in the implementation of the compulsory licensing system as is provided in the Indian Patents Act. According to an OECD study, firms have reported that in some cases royalty payments can exceed 20% of their net sales. And, in South Africa, Glaxo Smith Kline demanded a royalty of 25% before the courts

\(^{35}\) Article 31(h) states that “the right holder shall be paid adequate remuneration.....taking into account the economic value of the authorization.
intervened. A higher royalty will increase the price of generic drugs and this, in the ultimate analysis would militate against the existence of the generic producers whose raison d'etre is to supply medicine at affordable prices.

The provisions in the Indian Patents Act relating to the payment of royalty and other remuneration for obtaining a licence do not address the above-mentioned problems. In fact, Section 90 provides that the remuneration would take into consideration the perspective of the patentee, which includes the expenditure incurred by the patentee for making and developing the invention and for obtaining and keeping the patent in force. It may be argued that these considerations for determining the royalty and other remuneration would enhance the already superior bargaining position of the patentee and that these would need to be tempered with public interest considerations as well.

In light of the above-discussion it can be concluded that India has not ensured that its compulsory licensing system can function in a manner that public interest concerns can be addressed. While the procedural complexities would delay the grant of licences, ambiguities on the methodology for determining remuneration to the patentee, can be a serious roadblock.

(e) **Opposition Proceedings**

Although the grounds for opposition available in the pre-grant stage have been restored, the right of appeal is available only for post-grant opposition. India has thus become the only country among the major patent granting ones, which provides for both pre-and post-grant
opposition in its patent legislation. It may well be argued that by so doing India has put that patent applicant in a disadvantageous position, an argument that can bring the entire procedure for opposition to the grant of patents before the courts.\footnote{25 of the Patent Act.}

However, effectiveness of the opposition proceedings depends upon the access to information on the mailbox applications. The Patent Office in 2005 has issued a notification in its official journal that inventions either filed or claiming priority on July 30, 2003 have been deemed to be published. However, no physical publications have been available to date. This lack of publication takes away the possibility of accessing information relating to the patent application and the ability to oppose the same. Lastly the Act refers to the publication of an application, but fails make the publication of the complete specification available to the public. This will greatly hamper opposition proceedings.

(f) \textit{The Two Exemptions}

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.

"\textit{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.
Section 271(e) (1) of the US patent law (35USC), 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 Life sciences, which was adjudicated upon by the US Supreme Court.\(^{37}\)

Following from the precedence set in the US, Canada took two significant steps to make carve outs in its Patent Act. Section 55.2(1), or the “regulatory review exception”, of the Canadian Patent Act allowed all activities related to the development and submission of information required to obtain marketing approval for pharmaceutical products carried out by a third party without the consent of the patent holder at any time during the patent term. Further, Sections 55.2(2) and (3), or the “stockpiling” exception, of the Patent Act together with the Manufacturing and Storage of Patented Medicines Regulations allowed manufacturing and stockpiling of pharmaceutical products during the six months immediately prior to the expiration of the 20-year patent term.

\(^{37}\) Dhar Biswajit : Post -2005 scenario in patent protection in the pharmaceutical sector : The case of the generic pharmaceutical industry in India at http://www.iprpatents.html.
The "Bolar exemption" 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.38

Although in its essentials, Section 107A(a) mirrors the provisions of the Canadian patent Act, it has one significant difference Included in the exception to the rights is the act of importation, which the Canadian patent Act does not provide. The implications of including the act of importation as a part of the "Bolar exemptions" are not immediately obvious. Nor is it clear as to how this exemption may in any way affect the applicability of Section 107A (b) that provides for parallel imports.

Parallel imports

The Agreement on TRIPS allows for the parallel imports, although the specific circumstances under which such imports can take place have not been defined. The Indian Patents Act, 1970 has taken the initiative to include the provision of parallel imports. The relevant provision, provided under Section 107(b) reads as follows:

"Importation of patented products by any person from a person who is duly authorized under the law to produce and sell or distribute

the product”. As has been explained by the Government this provision of parallel import of patented product was introduced for “ensuring availability of patented products at cheaper price to the consumers. In particular, reference to a person duly authorized under the law” to produce and sell or distribute the product seems to indicate that parallel imports may include products produced under compulsory license. OECD countries have traditionally excluded such possibility, limiting parallel imports to products marked abroad with the consent of the patent holder. The TRIPS Agreement is silent on this issue.

IPR, Prices of Medicines and Drug Development for Poor People

The importance of prices of medicines to poor consumers in developing countries is perhaps obvious. But it is worth emphasizing that if a sick person has to pay more for a pharmaceutical product as a result of a patent, it means that he or she will have less to spend on other essentials of life such as food or shelter. Alternatively, foregoing the medicine because it is unavailable or unaffordable may result in long term ill health, or death. That is why it is essential to consider the impact of the introduction of an IP regime on prices. While recognizing that the prices were affected by many factors. These include purchasing power, competition and market structure, responsiveness of demand to price and government price controls and regulations. In India nearly 95% of domestic demand for pharmaceuticals is met from domestic production. Apart from a few life saving drugs (anti-cancer, cardiovascular, antihypertension) almost everything is produced in India. As a
consequence, medicine in India is very cheap relative to the West and, relative to other developing countries which rely on imports.

The purpose of patents, is to provide a temporary monopoly to rights holders as a stimulus to inventions and their commercialization. However, it should also be noted that the monopoly right provided by a patent normally only excludes others from making, using or selling that particular invention. It does not prevent competition from other drugs, patented or not, that address the same medical conditions. Nevertheless, other things being equal there is a presumption that the producer of a patented product, through the ability to exclude copies, will attempt to earn a monopoly profit and charge higher prices that would otherwise be the case. That, indeed, is the basis of the system. The bargain with society is precisely that the benefits to society generated by the extra innovation induced (for example, a lifesaving drug which might not exist but for the patent system) should exceed the extra cost of the product.  

The prevalence of patents is very much higher in countries where there is a substantial market, and technological capacity. Thus in South Africa (which alone counts for over 17% of Africa’s HIV cases) 13 of the 15 drugs are patented. There are 6-8 patents for these drugs in Botswana, Zambia, Ghana, Kenya, Malawi, Sudan, Swaziland, Uganda, Zambia and Zimbabwe, which together account for another 31% of HIV cases in sub-Saharan Africa. This is of course true, but it does not follow that the patent system has no adverse effects. Even if patents do not exist for particular products and countries, the patent system may still

have an effect on access to medicines. Most low income developing countries have to rely on imports for their supplies. The existence of patents in potential supplier countries may allow the patentee to prevent supplies being exported to another country, particularly through controls on distribution channels. This is another reason why companies may selectively patent in countries such as South Africa because it is a potential supplier to its poorer neighbors in the rest of Southern Africa (or indeed elsewhere).

The two biggest killers in sub-Saharan Africa are AIDS (2.5 million deaths per year) and malaria (2 million deaths per year). Other killers are diarrhoea, tuberculosis and sleeping sickness. Between 1980 and 1995, malaria wiped $74 billion from the economies. The worst hit countries in Africa were: Gabon, Namibia, Zimbabwe, Botswana, Cameroon, Ghana. Outside Africa, the worst affected countries are India and Haiti. The bit difference between AIDS and malaria, on the one hand, and diarrhea, tuberculosis and sleeping sickness, on the other, is that the latter are the consequence of poverty. They result from unsafe drinking water, bad sewage, poor housing. So removing these conditions will eradicate these diseases.

There are two ways of attacking malaria: attack the carrier (Anophloes gambiae) or attack the parasite. Attacking the carrier is very difficult, especially as DDT is no longer used. But attacking the parasite needs research into vaccines. AIDS and malaria are not the consequence of poverty, but they are the cause of poverty. So to eliminate malaria it requires active medical; public health intervention. AIDS requires cheaper treatment for sufferers in Africa and both
malaria and AIDS require vaccines. But, left to the market, such treatments will never be developed.

44 out of 150 (29%) countries have severe malaria. 35 of these 44 are in Africa. The average GDP per head of malarial countries is $1526 compared to $8,268 for non-malarial countries. The only exceptions to malaria as a cause of poverty are Oman and Gabon which are oil-rich. Because there is no money to be made in saving, lives from AIDS and malaria. Instead the illness, that drug companies focus their research on are “rich country” illnesses: sexual dysfunction (Viagra); depression (Prozac); attention deficiency (Ritalin). EU has spent $5 billion in 2001 to fight mad cow disease which has claimed 80 lives but 17 million Africans who have died of AIDS could have been saved with that kind of money.\footnote{Ibid.}

So there is market failure: in terms of social welfare the world would benefit if AIDS and malaria were eliminated from Africa and other countries would also benefit but this does not seem to happen because private welfare to drug companies is too small.

Drug companies argue that if they can’t get protection in poor countries for their inventions, then there is no incentive to research remedies for the diseases plaguing poor countries. However, the brutal facts of the market indicate there is little incentive anyway. These countries are not rich enough to buy the new remedies – the Southern African News Features reported that the entire combined purchasing power of South Asia and Sub-Saharan Africa’s health budgets is the
same as the pharmaceutical drugs market in the United States just for the 15 million people who suffer from heart failure and angina.

It is estimated that less than 5% of the money spent worldwide on pharmaceutical R&D is for diseases that predominantly affect developing countries. Pharmaceutical research by the private sector is driven by commercial considerations and if the effective demand in terms of market size is small, even for the most common diseases such as TB and malaria it is often not commercially worthwhile to devote significant resources to addressing the needs. In 2002, the world drug market is valued at $406 billion, of which the developing world accounts for 20%, and low income developing countries very much less. In many pharmaceutical companies, research objectives are set by reference to threshold returns\(^1\).

Arguably, the large pharmaceutical companies are unwilling to pursue a line of research unless the potential outcome is a product with annual sales of the order of $1 billion. In view of the fact that private companies have to be primarily responsible to their shareholders, this necessarily leads to a research agenda led by the market demand in the markets of the developed world, rather than by the needs of poor people in the developing world, and thus a focus is mainly on non-communicable disease.

Regardless of the intellectual property regime prevailing in developing countries, in reality there is little commercial incentive for the private sector to undertake research of specific relevance to the majority of poor people living in low income countries. Accordingly,

\(^1\) Ibid.
little such work is done by the private sector. Total pharmaceutical R&D in the private sector has more than doubled in the last decade. Exactly what proportion of this is directed to diseases afflicting mainly developing countries is difficult to determine. However it has been estimated that of 1393 drugs approved between 1975 and 1999, only 13 were specifically indicated for tropical diseases. Where diseases are common to both developed and developing countries, the picture is different. Thus, there is significant private sector R & D on HIV/AIDS. This contrasts with the limited work on tuberculosis and malaria, and virtually none on diseases such as sleeping sickness. As regards HIV/AIDS, there are now 64 approved drugs in the US for treatment of the disease and opportunistic infections, and 103 in development.

In the case of public sector undertakings, such as The national Institutes of Health (NIH) in the US or Medical Research Councils (MRCs) in other developed countries. The situation is little different because their research priorities are principally determined by domestic considerations. Public sector spending on health research was estimated to be $37 billion in 1998, of which $2.5 billion was spent in low and middle income developing countries. In 2001 the US National Institutes of Health (NIH) alone accounted for over $20 billion. In addition, charitable foundations are estimated to have spent $6 billion. The WHO’s Special Programme for Research and Training in Tropical diseases (known as TDR) receives only about $30 million annually.

The exact proportion of public sector spending on diseases relevant to developing countries has not been authoritatively estimated, but seems unlikely to be higher than 10%. This situation is now being addressed through the WHO, the Global Forum for Health Research, the
initiative of Medicines Sans Frontiers on drugs for neglected diseases, additional funding by foundations and the development of several public-private partnerships to address specific diseases. But the overall level of funding for these new efforts is still very modest in relation to the scale of the problem and global R & D expenditure of about $75 billion, and the uncertain outcome.

So regarding the role IP protection plays in stimulating R & D on diseases prevalent in developing countries, all the evidence suggests that it hardly plays any role at all, except for those diseases where there is a large market in the developed world (for example, diabetes or heart disease). There is some weak evidence related to an increase in indicators of research activity in malaria since TRIPS was agreed, but the relation between cause and effect is not at all clear. The heart of the problem is the lack of market demand sufficient to induce the private sector to commit resources to R & D.