Chapter 4

Trade Related Intellectual Property Rights
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Chapter 4

Trade Related Intellectual Property Rights

The World Intellectual Property Organization (WIPO) defines intellectual property as “the legal rights which result from intellectual activity in the industrial, scientific, literary and artistic fields”. The WIPO Handbook on Intellectual Property gives two reasons for the protection of intellectual property. It says:

“Countries have to protect intellectual property for two reasons. One is to give statutory expression to the moral and economic rights of creators in their creations and the rights of the public in access to those creations. The second is to promote, as a deliberate act of Government policy, creativity and the dissemination and application of its results and to encourage fair trading which would contribute to economic and social development”.¹

It can be discerned from the above cited reasons for protection of intellectual property rights that protection of intellectual property is a means to an end. The end being achieving a balance between the rights of the inventors and the ‘rights of public in access to those inventions’ and between the promotion of creativity and the ‘dissemination and application of the results of those inventions which would contribute to economic and social development’.

But the protection envisioned for intellectual property rights in the WTO’s Trade Related Intellectual Property Rights Agreement (TRIPS) is concerned mainly with the rights of the intellectual property owners and the objectives of development stated in the treaty are of secondary importance.

The basic premise for the protection of intellectual property rights in the TRIPS agreement is the assumption that inadequate protection for intellectual property

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rights causes distortions and impediments to international trade. The establishment of a linkage between intellectual property rights and trade was a ploy to ensure monopoly income for the trans-national corporations (TNCs), who held and continue to hold most of the patents. TRIPS has proved to be an impediment for the developing countries in their developmental efforts by acting as a hindrance to the transfer of technology, protection of public health and the rights of indigenous and local people.

1. TRIPS in the Uruguay Round

An attempt to introduce intellectual property rights into the framework of General Agreement on Tariffs and Trade 1947 (GATT) was made during the Tokyo Round held from 1973-79 when the US and the European Communities (EC) supported by Japan and Canada, put forward a Draft Agreement on Anti-Counterfeiting Measures, in response to growing dissatisfaction among the holders of intellectual property rights. The members of GATT did not reach an agreement on this issue.

There was growing opinion among the TNCs of the US, who were engaged in manufacture of technologically intensive goods and services that the existing intellectual property regime was weak and had led to the proliferation of counterfeit goods. Besides, the private enterprises had been heavily investing in R&D and they wanted to be able to recover the cost. This would not have been possible without monopoly rights to produce and sell the product. Therefore the US renewed its efforts to include the issue in the Uruguay Round, though the issue of intellectual property was being governed by the WIPO and discussions were also going on in forums like Food and Agricultural Organization (FAO) and United Nations Economic and Social Council (UNESCO). The US chose GATT as a forum to introduce strengthened laws for intellectual property (IP) rights over WIPO because GATT was a place where developing countries could be made to give protection to the IP holders, in return for increased access (or otherwise) to their goods in developed countries’ market. The dispute settlement mechanism of the GATT could be used for the enforcement of IP laws and the wider membership of GATT meant that new laws could be enforced in more number of countries.
In 1985 a committee was established in GATT and was given a wide mandate to discuss new issues and this also included intellectual property. The US had already in place provisions to take unilateral actions against those countries which refused to provide protection to its intellectual property holders. The Trade Act of 1984 enabled them to use Section 301 of the Trade Act of 1974 to protect the rights of IP owners.

The developing countries refused to negotiate on the new issues and contended that there were several unresolved issues from previous GATT negotiating rounds which were important to them. As a response the developed countries threatened unilateral sanctions against them. The GATT itself had in it, provisions like Article XX – the General Exception clause, which allowed the contracting parties to take measures to secure compliance with laws for protection of patents, trademarks and copyrights and prevention of deceptive practices, not inconsistent with the provisions of GATT. Article IX: 6 also stipulated the Contracting Parties to co-operate with each other to prevent the misuse of trade names so as to misrepresent the true of origins of the product. It was the view of the Third World countries that these provisions did not create rules for protection of intellectual property but only made sure that trademarks, patent, copyrights and such other IP rights are not used as a barrier to restrict trade. Countries like India and Brazil averred that the task of formulating new laws and strengthening the existing ones was a complex issue and fell in the scope of WIPO’s jurisdiction.

The developed countries used outright threats to make the developing countries agree to negotiate on IP. In one instance, Paul Lyutens, the Deputy Director-General of the EC said that “the Third World should not abuse their patience” and that “the US and EC will be forced to take action outside the international framework if the developing countries do not end their reluctance to discuss the issue of Intellectual property in the GATT”. The developed countries were of the opinion that the Paris


Convention and laws dealing with patent and trade mark were inadequate. Under the
Paris Convention for protection of industrial property, the holders of trade mark and
patents could go to court to seek damages for infringements of their rights. But it
was opined by the developed countries that there was a requirement for rules which
would enable countries to prevent the entry of counterfeit goods at their customs
entry point rather than owners of intellectual property having to go to court.¹

Ultimately when the Uruguay Round was launched in 1986 in Punta Del Este, the
guidelines for subject matter of negotiations laid down in the Uruguay Round
agenda included TRIPS.

When the developing countries had agreed to the inclusion of TRIPS in the
negotiating agenda they had perceived the mandate to be a limited one, confined to
the existing provisions of GATT relating to the intellectual property and trade. Third
World countries like India and Brazil opined that the task of formulating new laws
and strengthening the existing ones was a complex issue and fell in the scope of
WIPO’s jurisdiction.

The US however interpreted the mandate in a broad way to include substantive
(defining rights and duties as opposed to giving the rules by which rights and duties
are established) issues as well. The US wanted the negotiating group to examine the
adequacy of the national laws regarding the protection of IP Rights. It was opined
that inadequate protection of intellectual property, limited scope and duration of
protection, misuse of compulsory license mechanism, lack of enforcement and
access to border enforcement, difficulties in gaining access to judicial and
administrative bodies and the burden of proof on IP holder rather than the
transgressor, were resulting in heavy losses for their enterprises and that GATT had
not dealt with these issues adequately. It had therefore stressed that the members
should take advantage of the ‘unique opportunity’ and creates rules in this area.⁵

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¹Ibid.
⁵IFDA/Chakravarthi Raghavan, “Far Reaching Proposal on IP Rights” SUNS, March 28, 1987,
www.sunsonline.org.
The differences between the developed and developing countries on this issue continued as negotiations progressed. The developing countries maintained that the IP standards and its enforcement were matters that fall in the jurisdiction of national laws to be formulated by the states. The developing countries raised the issue of conflict between IP rights and public welfare and development policies. Negotiations on these issues had been going on in other forums like the WIPO and FAO for a long time and it had not been possible to solve these issues as the developed countries had been blocking the discussions. In such a situation, the Third World countries opined that it would be detrimental to their interests if rules pertaining to intellectual properties are formulated in a short span of time without proper deliberations, and would prejudice the work taking place in other appropriate forums.

The US in the meanwhile had been mounting pressure on the Third World by way of ‘Special 301’ provision of ‘Omnibus Trade and Competitiveness Act’ of 1988 which had strengthened the powers of the US President to impose unilateral sanctions on those countries which had failed to provide protection to the IP holders. Under this law, the US had taken unilateral action against China, Brazil, India, Taiwan, Republic of Korea, Mexico, Saudi Arabia, Thailand and some countries of Latin America. Owing to these pressures, some developing countries like South Korea and Hong Kong changed their stance and showed support to the views of industrialised countries. Countries like India and Brazil which had held their ground so far, also gave in and agreed to the discussion on substantive issues. However the difference of positions on the details of the agreement continued and developing countries put forward their positions in various papers.

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1.1 The Position Adopted by Developing Countries

The developing countries had stressed that any formulation of rules should take into account the need to protect public welfare. In particular they wanted the agreement to:

- Refrain from imposing uniform standards of protection in view of the difference in the developmental status of the developed and less developed countries.

- Include a provision to enable the working of the patent in the country where the patent is granted – as opposed to importing the product which has been patented.

- Balance the rights and obligations of the patent holders.

- Enshrine conditions for making available the technology to the developing countries on reasonable terms.

- Prohibit the introduction of product patenting as it would hamper the chances of production of the patented product through the process of reverse engineering.\(^7\)

- Exclude plant variety rights as they were being dealt with under separate convention.

- Enable Third World countries to exclude certain products from patenting in view of their importance to public welfare.

- Make provision for the issue of compulsory license, in case of abuse of patent rights.

- Leave the duration of protection of patents to the discretion of the countries.

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\(^7\)The developed countries had denied product patenting for a long time in areas like chemicals and pharmaceuticals in the interest of public welfare. See “Standoff in TRIPS Discussion”, SUNS, July 18, 1989, www.sunsonline.org.
The developing countries did not want the agreement to prescribe a time frame for the implementation of the agreement, as they felt it was not possible to bring about developments within the deadlines.

The position of the developed countries was in contrast to these proposals. The Draft Final Act of 1991 (Dunkel Draft) proposed a compromise formula which sought to accommodate the interests of both the developing and developed countries. It accommodated the interests of the developed countries by providing for strengthened rules for intellectual property. The interest of the developing countries were claimed to have been accommodated by providing them greater transition period and special and differential treatment. The compromise solution was accepted and TRIPS agreement was concluded. But the agreement was accepted by the developing countries more as a result of the pressure exerted by the developed countries rather than as a result of negotiations.\(^8\)

It is said that the negotiations on intellectual property were the most non-transparent of all the negotiations.\(^9\) Discussions were initially held between five developed and developing countries and the outcomes were placed before an expanded group of ten developed and ten developing countries. Beyond this, there were no other countries that were involved. There were also no recordings of the negotiations that took place. The developing countries were at a disadvantage during negotiations because of lack of expert knowledge of the subject. Whether the compromise formula actually reflected the interests of the developing countries can be discerned by studying the various provisions of the TRIPS agreement.

2. **Provisions of the Agreement**

The TRIPS Agreement which was initially introduced as an agreement to regulate the trade related aspects of intellectual property rights, resulted in an agreement


primarily concerned with the protection of intellectual property. There has been a complete reversal of the intentions of the provisions of the GATT relating to intellectual property. The provisions of GATT were intended to make sure that the rules pertaining to the protection of intellectual property rights did not become a barrier to trade and the burden of proof was on those who imposed restrictions on trade citing the reason of infringement of IP rights.

In the TRIPS agreement, the main focus is on the enforcement of rules to protect intellectual property rights and the intention is to see to it that development objectives of the developing countries do not come in the way of protection of intellectual property rights. There is an assumption that lack of adequate protection to IP rights distorts trade.

The areas of intellectual property covered by TRIPS are patents, copyright, trademarks, geographical indications, industrial designs, layout designs of integrated circuits and undisclosed information. The TRIPS agreement sets minimum standards for protection in all areas of intellectual property. It subjects the disputes between members over TRIPS to the dispute settlement procedure of the WTO.

The Preamble of the TRIPS Agreement along with Article 7 of the Agreement enumerates the objectives. The principal objective is to promote effective and adequate protection to intellectual property with a desire of reducing distortions and impediments to trade and see to it that measures to protect IP rights by themselves do not constitute a barrier to trade. It recognizes the public policy objectives including developmental and technological objectives.

Article 7 says that protection and enforcement of intellectual property rights should contribute to

a) Promotion of technological innovation and transfer and dissemination of technology.

b) Mutuality of advantage for producers and users of technological knowledge.
c) Social and economic welfare.

d) Balance of rights and obligations.

Article 8 allows members to adopt measures to protect public health and nutrition, promotion of public interest in sectors of vital importance and prevention of abuse of intellectual property and practices which unreasonably restrain trade or adversely affect the international transfer of technology.

Of all the areas of intellectual property, patents have a far reaching impact on issues pertaining to developing countries. TRIPS deals with patents in Part II, Section 5 of the agreement.

Article 27, which outlines the patentable subject matter, says that patents shall be available for any invention, subject to the criteria that they are new, involve an inventive step and are capable of industrial application. Patents should be provided both to products and process, in all fields of technology, irrespective of the place of invention and whether they have been locally produced or imported.

The Article however, allows governments to exclude from patentability, the commercial exploitation of any invention, with respect to

a) Public order or morality

b) Protection of human, animal or plant life or health or prevention of serious damage to environment

c) Diagnostic, therapeutic and surgical procedures for the treatment of humans or animals

d) Plants and animals

e) Biological process for the production of plants and animals.
Though plants and animals and biological process for the production of plants and animals have been excluded from patentability, micro-organisms and micro-biological processes for the production of plants and animals have not been excluded which means members will have to provide patents for micro-organisms and micro-biological processes for the production of plants and animals. The agreement mandates that plant varieties have to be afforded protection either by patent or through sui generis system or by combination of both.

Rights of the patent holder have been enumerated separately in Article 28. The Article prevents anybody from making, using, offering for sale, selling or importing the patented product without the patent owners’ consent. The same applies to the products directly obtained from processes which have been patented. It also confers on the patent holder, the right to assign, right to transfer the succession of the patent and the right to conclude licensing contracts. The footnote to Article 28 says that the rights conferred under this Article with respect to use, sale, importing, or other distribution of goods are subject to Article 6 which relates to exhaustion principles.\footnote{According to the principles of exhaustion the IPR holder loses the rights over the product after the first point of sale. See “International Exhaustion and Parallel Importation”, http://www.wipo.int/sme/en/ip_business/export/international_exhaustion.htm.}

Article 6 relating to the exhaustion principles stipulates that nothing in the agreement will be used to address the issue of exhaustion of intellectual property rights which means that the exhaustion principles will be decided solely by national governments and they cannot be subject to dispute settlement mechanism.

Article 29 stipulates some conditions on the patent applicants. It requires the patent applicant to disclose the invention in sufficiently clear and complete manner and also indicate the best mode for carrying out the invention.

2.1 Compulsory License

Article 31 deals with the use of a patented product without the authorization of the patent holder. This is popularly known as issue of compulsory license (to be
distinguished from a voluntary license given by the patent holder himself). A compulsory license may be granted by the government to a third party or executed by itself. All methods of obtaining a voluntary license at a reasonable cost and in a reasonable time frame should have been exhausted before authorizing a compulsory license (Article 31(b)). This condition is waived in times of national emergencies, in case of extreme emergency or in case of public non-commercial use. In all cases the patent holder should be informed. The scope and duration of the compulsory license will be restricted to the purpose for which it was issued and will cease to be operative as soon as the conditions which warranted the license cease to exist. The use of compulsory license should be restricted to the domestic market of the member issuing the compulsory license. The agreement stipulates that adequate remuneration commensurate with the value of the authorization should be given to the patent holder in all cases. The legality of such authorization and the decisions over the remuneration can be subjected to judicial review or other independent review by a distinct higher judicial authority of the member which has issued the compulsory license. Article 31(k) stipulates that the requirements mentioned in 31 (b) and 31(f)\textsuperscript{11} need not be fulfilled when compulsory license is issued to remedy anti-competitive practices.

### 2.2 Term of Patent Protection

Article 33 mandates patent protection for 20 years from the date of filing of the patent. Article 34.1 says that in case of an infringement of the right of a patent holder, if the subject matter of the patent is the process for obtaining the product, the burden of proof shall be on the person who has produced the product without the consent of the patent owner, to prove that the product has been obtained from a process different from that which has been patented.

\textsuperscript{11} Article 31 (f) restricts the use of compulsory licensing to the domestic market of the member which has issued such license.
2.3 S&DT for Developing and Least Developing Countries

Special and differential treatment for the developing and least developed country members has been provided by way of greater transition periods of five and ten years and a provision of extension of the transition period for LDCs beyond ten years upon request (Art. 65 and 66).

Article 67 says that the developed countries shall provide technical and financial assistance to the developing and least developed country members to facilitate the implementation of the agreement.

2.4 Implications of the TRIPS Provisions for Developing Countries

Looking at the relevant provisions of the TRIPS Agreement it appears that, except for a few provisions the interests of the developing countries have been largely ignored. The developing countries did not want the imposition of uniform standards of patenting in view of the different developmental status of the developing and developed countries. But the TRIPS agreement stipulates minimum standard of patent protection for all the members.

The TRIPS agreement stipulates that patent protection should be provided, irrespective of the fact whether the products are locally produced or imported. This goes against the interests of the developing countries as the TNCs in most cases do not work their patents in the country in which they have obtained the patent.

The provision for product patent is disadvantageous to the developing countries as it prevents anybody else from manufacturing the product, even through a process different from the one followed by the patent holder.
It has been held that the burden of proof on the defendant in case of a process patent goes against the principle of equity and natural justice.\(^\text{12}\)

The developing countries opine that the duration of 20 years is too long. Such a long duration of patent protection will mean that they cannot hope for the transfer of technology to produce the product themselves without shelling out on royalty. They will lose considerable financial resources either through payment of royalty or through import of the product for such a long period.

The developing countries also wanted to be able to exempt certain technologies from patenting altogether – especially pharmaceuticals. But the provision of TRIPS agreement that patent protection shall be provided to all technologies prohibits any such move by the developing countries.

The developing countries were also dissatisfied with the limited transition period of five (for developing countries) and ten years (for Least Developed Countries)\(^\text{13}\) as they feel that it is too little a time for a country to reach a stage where it can do without dissemination or transfer of technology.

The inclusion of micro-organisms and micro-biological processes for the production of plants and animals in the ambit of patent was also opposed by the developing countries. Though it has been provided that members can formulate their own *sui generis* system for the protection of plant varieties, the developing countries are pressurized to adopt certain standards even in this area.

Although it appears that the concerns of developing countries have been taken care of by making provision for compulsory licensing in case of pharmaceutical patents, there are a lot of issues when it comes to their operation.


\(^{13}\) The transition period for LDCs with respect to pharmaceutical patents has been extended till 2016; therefore they have been exempted from providing patent protection for pharmaceuticals until the expiration of the transition period.
Inspite of the Agreement recognizing the importance of dissemination and transfer of technology for the developing countries, not much benefit has accrued to them.

The developing countries have been facing problems particularly in the areas of technology transfer, pharmaceuticals patent and biopiracy. These topics are dealt with in detail in the ensuing sections.

3. TRIPS and Transfer of Technology

Access to knowledge and acquisition of knowledge play an important role in the development of an economy. Transfer of technology has been defined as a “mechanism for shifting of information across borders and its effective diffusion into recipient economies.” The international rules pertaining to IP rights have a bearing on the transfer of technology and this has been confirmed by the Task Force of the UN Millennium Project on Science, Technology and Innovation. The Task Force recommends that there is a requirement for the international rules be reviewed to make them compliant with the objectives of transfer of technology to the developing countries.

The Task Force says that there is a “need to recognize that a rich body of scientific and technological information exists in patent databases and more needs to be done to increase access and analysis of that data to support innovation.” The Report also stresses that there is a requirement to increase international co-operation to “address the inequalities and bridging the gap in capabilities to access scientific data and information for development”.

Transfer of technology is important for the developing countries from the point of development of industries. Particularly important are the small and medium enterprises whose success depends upon the access to technology.

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15 Ibid., p.4. Emphasis added.
Access to technology is also important for food security as there is a need to increase food productivity through sustainable methods for a growing population. Efficient public health system depends among other things on access to medical and medicine technology. Transfer of technology assumes importance in the context of environment and climate change as there is growing emphasis on environmentally sound technologies for the production of goods.

Most countries of the world have borrowed technology from others at some point of time or the other. The developed countries in fact had not provided patent protection for a long time and were able to replicate the technology invented elsewhere. Even when they introduced patent laws, they were not as stringent as the TRIPS laws. The developed countries had also refrained from granting patent protection to pharmaceuticals. They could not have possibly attained the level of development they have today if they had to abide by such stringent IP laws.\(^{16}\)

The developing countries had, throughout the negotiating period of TRIPS, maintained the stand that the resulting agreement would hamper the chances of transfer of technology to the developing countries, as it would place emphasis on the rights of the patent holder to the detriment of the transfer of technology which was a vital component of their developmental programme. The TRIPS agreement has recognised the importance of dissemination and transfer of technology in Articles 7, 8, 40 and 66.

Article 7 says that protection and enforcement of intellectual property rights should contribute to the transfer of technology; Article 8 provides that national governments can take measures to prevent the abuse of intellectual property rights by patent holder or practices which adversely affect the international transfer of technology.

Article 40 enables the government to introduce measures to remedy the licensing practices that restrain competition and hinder transfer of technology. There is also a provision for consultation mechanism between a member whose national is an intellectual property holder and has engaged in restrictive practices that has hampered transfer of technology, and a member whose laws pertaining to anti-competitive practices have been violated.

Article 66.2 provides that the developed country members shall provide incentives to the enterprises and institutions in its territories for the purpose of promoting and encouraging transfer of technology to least developed country members. The agreement also enables the transfer of technology through disclosure of the invention and compulsory licensing mechanism.

How far these provisions have helped the transfer of technology to developing countries is a matter of debate. The developing countries contend that the TRIPS agreement was formed to protect the interests of the TNCs who wanted to prevent competition from other firms as they believed that technological and scientific system was too open and facilitated the imitation of technology owned by them. As TRIPS agreement protects the right of IP holder by way of barring anyone else from making, offering for sale, selling, or importing the product which is on-patent, without the authorization from the patent holder. This reduces the chances of developing countries to obtain technology in reasonable terms. The rights conferred by TRIPS has the propensity to increase monopolistic behavior of the TNCs who hold the majority of patents. TRIPS impedes the transfer of technology as the monopoly rights granted by it results in higher price of that product. High cost makes it difficult for least developed countries to acquire technology.

Another problem that is faced by the developing countries is regarding obtaining environmentally sound technologies. Of late lot of emphasis is being placed upon the use of environmentally sound technologies in the production of goods. Developed countries have formulated laws that ban the import of goods that do not fulfill this criterion. At the same time, developing countries are being denied access to environmentally sound technologies. One such instance is the difficulties
encountered by Indian companies in acquiring technology for ‘HFC134 A’ which was the replacement for chlorofluorocarbons (CFCs). It had been agreed under Montreal Protocol to phase out the CFCs as they were found to have caused the depletion of the ozone layer. The HFC134 A technology was on patent and the patent holders were not willing to transfer the technology, without control over ownership of the Indian company concerned.

The developed countries have not instituted any mechanism to facilitate transfer of technology to the least developed countries as stipulated in Article 66.17

There is a strong link between local production and transfer of technology. But the TRIPS agreement, by guaranteeing the right of patent irrespective of the fact whether the product is locally produced or imported has given a death blow to the chances of transfer of technology to developing countries. Developing countries had insisted on working of the patent in the country in which the patent has been obtained. But this was not taken into consideration because it would result in transfer of technology and result in loss of monopoly income for the TNCs.

Under the current regime of IP rights, the only way in which the developing countries can hope to access technology is by paying royalties for the use of technology, or by importing the product, both of which involves drain of financial resources. Another way is to wait till the expiration of the patent period of 20 years – by the time which the technology would have become obsolete.

The TRIPS agreement has no specific provision which makes it obligatory on the part of a patent holder to transfer the technology to developing country members. This has led to the exacerbation of the problem of technology-deficit for the developing countries.

17 South Centre, n.15, p. 8.
4. TRIPS and Public Health

One of the components of an efficient healthcare system is the availability of medicines, medical technology, diagnostic methods and vaccinations. This aspect assumes more importance in the case of developing countries which have not yet reached a stage where they are capable of developing the technologies necessary in the field of medicine. The developing countries require assistance in the field of healthcare, as diseases are rampant. The percentage of population which is vulnerable to diseases and which does not have access to healthcare and medicine is large. Therefore it becomes important that the people in developing countries have greater access to medicine and medical technologies. Most of these technologies are under patent and a majority of them are held by the TNCs.

The developed countries in their initial stages of development had excluded certain essentials from patenting, and pharmaceuticals were one of them. This means they were free to manufacture the drugs which were still under patent. With the advent of TRIPS this option is not available as it guarantees the patent rights in all fields of technology. Once a pharmaceutical invention has been granted a patent, persons other than the patent holders or those who have not been authorized by the patent holder cannot manufacture, sell, or import that particular medicine.

4.1 TRIPS and the Generic Drugs

Generics drugs could be interpreted in two ways: one is the dictionary meaning which means a drug that does not have a trade mark. The other meaning from patent point of view is that they are simply copies of patented drugs, or drugs whose patent has expired.\(^\text{18}\) Therefore, generic copies of patented drugs could be manufactured and sold:

- When a compulsory license has been issued;

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\(^{18}\) WTO Fact Sheet: TRIPS and Pharmaceutical Patents: “What Does “Generic” Mean?”, www.wto.org/english/tratop_e/trips_e/factsheet_pharm03
Flexible patent laws have played an important role in the development of generic drug industries which are capable of supplying the generic drugs at a much lesser cost than the TNCs who own the patents and sell the drugs at exorbitant prices. The Indian generic drug industry has been considered as the ‘poster boy’ of the world generic drug industry. Indian generic manufacturers have been supplying generic drugs at a much lesser cost than the original manufacturers of the drug. The Indian Patent Act of 1970, which replaced the patent law formulated during the British rule, enabled the development of a domestic drug industry in India. The highlights of the Indian Patent Act of 1970 was process patent as opposed to product patent, shorter patent term of five years from the grant of patent or seven years from the date of application, and a provision for issue of compulsory license after three years of granting of patent. As a result of these policies the share of domestic finance in production of bulk drugs doubled between 1975 and 1988. \(^{19}\)

India has been supplying low cost generic medicines worldwide. Indian generic drug industry has been instrumental in saving the lives of millions of people suffering from AIDS and other diseases. India has been supplying 70% of the HIV-AIDS drugs procured by UNICEF, the Global Fund and Clinton Foundation. It also supplies 75-80% of the drugs supplied by the International Dispensary Association to the developing countries.

However, the capacity of the generic drug manufacturers to supply cheaper drugs has been eroded as a result of the TRIPS agreement. India has had to modify its patent laws to make it TRIPS compliant. A patent period of twenty years and the obligation to grant product patent has made generic manufacture of a drug difficult. To top it, six Indian companies have been bought over by foreign firms. Organizations like UNAIDS, Doctors Without Borders and UNITAID have

expressed concern over the effects of these developments on the capacity of Indian generic industry to supply drugs to Africa and other developing countries.\textsuperscript{20}

The developed countries have been creating all sorts of hindrances to the exports of generic or off-patent drugs. The shipments of generic drugs destined to Ecuador from India were seized, once in 2008 and for the second time in 2009 while it was in transit in the territory of EC. India was engaged in a dispute settlement process with EC over this issue in the WTO.\textsuperscript{21}

Another issue is the attempts by the developed countries, led by the US and EC, to introduce Anti-Counterfeiting Trade Agreement (ACTA) in the WTO. Their argument in support of the Agreement is that counterfeit goods are no more restricted to luxury goods but also medicines and other products which are dangerous to health and safety. The Agreement which has been negotiated between eleven developed nations (US, EC, Australia, Japan, South Korea, Canada, Mexico, Switzerland, New Zealand, Morocco and Singapore) seeks to provide higher protection to IP rights and set up stringent standards for export, import and in-transit goods. The developing countries are of the view that such an agreement will further undermine the chances of poor people in developing countries to obtain generic drugs. It is said that, the ACTA, even if it is not introduced in the WTO, will be implemented through domestic laws, which will then be applied to all the countries through MFN clause.\textsuperscript{22}

Of late there have been instances of the passing or planning of Anti-Counterfeit law by several African countries, under pressure of global pharma companies whose profits are eroded by the export of generic drugs. These companies have created confusion by equating counterfeit drugs that are spurious, with generic drugs which are copies of patented drugs. One such country which has passed Anti-Counterfeit law owing to misconceptions is Kenya. Fortunately, the Kenyan Health Ministry has


\textsuperscript{22} “Developed Nations Take Up ACTA at WTO”, \textit{Economic Times}, Bangalore, 19 June 2010.
acknowledged that passing such an Act was a mistake and that the law was passed by the Ministry of Industry without realizing the ramifications for public health. This happened after the India’s efforts to sensitize the Kenyan Government to the possible effects of such a law over its capacity to import life saving cheap drugs. The Kenyan Health Ministry thereafter decided to make changes to the law so that it does not affect the import of cheap, life-saving generic drugs. According to the TRIPS Agreement the IP rights are protected only in the territories where the patent has been granted but the Kenyan law recognized IP rights protected in other territories as well. This would make the generics imported into or in transit in Kenyan territory illegal, if a patent exists anywhere else in the world. This law would be harmful to Kenya not only from the point of availability of generic drugs but from the point of its ability to define patentability criteria from a developmental perspective. 23 There have been reports of EC pressing for a similar bill in Uganda. Such laws are in the pipeline in countries like Nigeria, Zambia and Malawi. There are reports of a World Health Organization (WHO) Task Force seeking to define counterfeit products in such a way as to make trade of generic drugs illegal.

All this point to the fact that there is concerted effort by the developed countries, encouraged by their TNCs, to hinder the generic manufacturers based mostly in developing countries to supply generic life saving drugs to poor people all over the world. The implications of such moves are twofold; first they are detrimental to the interests of the poor and second, they have an impact on the export earnings of the developing countries.

4.2 Compulsory Licensing and Developing Countries

The TRIPS has made provision for the use of a patent without authorization by the patent holder either through direct use by government or by recourse to compulsory license (after failure to obtain voluntary license on reasonable commercial terms and within reasonable period of time). This provision assumes a lot of importance in the case of public health. However, the grounds on which compulsory license can be

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issued have not been explicitly mentioned. The grounds for issue of compulsory license could be broadly interpreted as cases of national emergency, extreme cases of emergency or for public non-commercial use, protection of public health and nutrition, socio-economic development and technological development and abuse of intellectual property. The absence of proper definition of grounds on which compulsory license can be issued has led to ambiguity. While it can be interpreted broadly as outlined above, it could also be interpreted as narrowly as possible. This is what the TNCs are trying to do in case of pharmaceuticals. There is an attempt by the developed countries in collusion with the pharma TNCs to limit the scope of compulsory license.

The power to issue compulsory licenses is important for developing countries in view of the monopolistic practices of the pharmaceutical companies which own the patents for several life saving drugs. The monopoly rights enable the pharma majors to jack up the prices of these drugs which are made available by the generic companies at a low price. The highly priced drugs are a problem even in developed countries which also has an economically weaker section which cannot afford high priced, patented drugs.

According to an UNCTAD paper on transfer of technology and global integration, the world pharma industry is dominated by few large TNCs; and only ten countries have (all of them industrialized) significant research base to discover new drugs and the rest of the industries are generic manufacturers. This means that only a few TNCs will hold patents rights and thereby enjoy the right to manufacture and sell the drugs worldwide. It also means that they will decide the price of those drugs, many of them life saving.

But the generic manufacturers cannot produce or sell these drugs without the permission of the patent holder as per the TRIPS agreement. The only other way is through the issue of compulsory license. But as mentioned before, the provision under TRIPS agreement for compulsory license is ambiguous in the sense that it does not clearly mention the grounds on which compulsory license can be issued. Besides, there is also a hitch as drugs produced under compulsory license will be only for the domestic market. Countries which do not have sufficient capabilities for the manufacture of drugs are left without hope, as they will have to depend on the import of drugs from the original manufacturers or licensed manufacturers who sell those drugs at a high price. This problem could be remedied by the issue of compulsory license to import the drug from a generic drug manufacturer. The developing countries made efforts to include this provision in the TRIPS Agreement and were successful in getting a declaration on TRIPS and Public Health that recognised the right for issuing compulsory license by those countries that do not have sufficient manufacturing capacities, but the global pharma majors are making all out efforts to restrict the scope of diseases in which compulsory licenses can be issued. WTO Declaration on TRIPS and Public Health is discussed in detail in the chapter on Doha Round of Negotiations.

Several countries have issued compulsory licenses for on-patent drugs for reasons other than just national emergencies. For instance, Malaysia was the first to issue a compulsory license for the import of drugs from India for treatment of AIDS patients. In the aftermath of the issue of compulsory licenses, the Health Ministry of Malaysia revealed that the government was able to treat more patients because the cost of imported medicine was only 1/7 of the price of the patented and branded products.

In Thailand, compulsory license was issued for four drugs used in the treatment of cancer, after governmental efforts to obtain voluntary license failed, even after Twelve Rounds of negotiations with patent holding companies. An official study showed that Thailand could save almost four billion baht in the period 2008-2012 through the use of generic drugs which were 4-30 times cheaper than branded drugs. One such drug was Docetexel, which was priced at 25000 Baht while the generic
version was offered for 4000 Bahts. There were attempts from foreign drug companies and US and EC to reverse the issue of compulsory license and the government contemplated the reversal of decision owing to pressure. But the protest by patient groups and NGOs forced the government to go ahead with the compulsory license.

Very recently, India issued its first compulsory license for the manufacture of a drug still under patent. The compulsory license was issued for the manufacture of the drug Naxevar (Sorafenib Tosylate) used in the treatment of kidney and liver cancer, to an Indian company called Natco which offered to sell the monthly dosage at Rs.8800 whereas Bayer, the company which used to import the drug into India was selling it at a price of Rs. 2, 80,400. This issue of compulsory license has given cancer patients some hope. Bayer has however appealed against the decision and is being backed by US which has placed India on a ‘Priority Watch List’ in a move to pressurize it to protect the interests of its company.

In addition to using the provisions of TRIPS to secure a monopoly rights for themselves, charging exorbitant prices for patented drugs and by trying to prevent the issue of compulsory license, the pharmaceutical majors have been making attempts at Evergreening their patents. The term Evergreening has been used to refer to the practice of the big pharmaceutical companies trying to get new patents on known drugs by making minor changes to them and claiming them to be new drugs. The pharma MNCs are doing this to ensure their profits for another 20 years as most of their drugs will be going off-patent soon and their inventions are drying up. Example of such an attempt to evergreen a patent is the case of Novartis filing a patent in India for ‘Glivec’, a cancer busting drug. The Supreme Court of India rejected Novartis patent application on the grounds that Glivec fell within the definition of ‘incremental improvement’ under the Section 3(d) of Indian Patent Act and hence not liable for patent. Section 3(d) of Indian Patent Act allows patent for new salts and chemical substances provided they result in the enhancement of efficacy. Section 3(d) says:

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Glivec’s key ingredient Imatinib was given patent in 1993 and under this patent all salt forms including Imatinib Mesylate were covered. Novartis was seeking patent for beta-crystalline form of the Imatinib Mesylate compound. The Supreme Court rejected the appeal of Novartis on the grounds that the beta crystalline form of Imatinib Mesylate did not result in enhanced efficacy. (The Supreme Court further clarified that efficacy in pharmaceuticals meant therapeutic efficacy). The SC has highlighted another important fact in the case. It has pointed out that when Glivec was marketed in India under the ‘Exclusive Marketing Rights’ (EMR) given to Novartis, pending the decision on patent, Glivec was marketed as Imatinib Mesylate and not Imatinib Mesylate in beta crystalline form. Therefore the SC is of the opinion that the case of Novartis appears as an attempt to obtain patent for Imatinib Mesylate which is a known drug and which already has a patent.

The cost of monthly dosage of Glivec is Rs.1.20 lakhs whereas generic versions are available in the range of Rs. 8000 to Rs. 10,000. Had Novartis been granted patent, generic manufacturers would have to stop the production of the drug. This will make the drug unaffordable to cancer patients not only in India but also in other developing countries. Other attempts at Evergreening of patents are Merck’s second patent application on its on-patent HIV drug Raltegravir. Merck has filed for a second patent on same drug which it claims the Raltegravir Potassium Salt. The first

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28 According to Article 70. 9 of TRIPS Agreement, where a product is subject of a patent application in a member country it shall be given EMR for a period of five years after obtaining marketing approval in that member or until a patent is granted or rejected, whichever period is shorter.

29 The Supreme Court of India, Civil Appellate Jurisdiction, Civil Appeal Nos. 2706 – 2716 of 2013, Novartis AG Versus Union of India and Others, With Civil Appeal No. 2728 of 2013 Natco Pharma Versus Union of India & Others And Civil Appeal Nos. 2717 – 2727 of 2013 M/S Cancer Patients Aid Association Versus Union of India and Others, Judgment, April 1, 2013, New Delhi.
patent on the drug expires in 2024. If its second patent is granted the patent could be extended till 2027.\textsuperscript{30}

The pharma majors are trying to book their profits by attempting to patent existing product by making minor changes to it and claiming them to be new. They want patent protection over and above what is provided by the TRIPS Agreement. The judgment given by the SC of India is a historic one, paving way for more such decisions in the interests of the people. The Section 3(d) of Indian Patents Act and therefore the judgment of the SC are in conformity with the TRIPS Agreement as Article 1 of the Agreement gives flexibility to the member countries to “determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice”.

In developing countries, the government health sector is able to cater to only a small percentage of the population and most of the people have to spend out of their own pockets on healthcare and medicines. In such a situation, high cost of drugs will push people into poverty. It has been found that medical treatment is the second most common cause of rural indebtedness and pushes 39 million into poverty every year in India.\textsuperscript{31} This is the case in many developing countries. In such a situation availability of affordable drugs plays a very important role.

5. TRIPS and Patent Protection for Life Forms

As discussed earlier, the TRIPS agreement allows the patenting of life forms and considers microorganisms and microbiological processes, for the production of plants and animals as patentable subject matter. It also stipulates that members are supposed to provide protection for plant varieties through patents or a \textit{sui generis} system or through a combination of both. These provisions have raised questions about the appropriateness of patents for life forms and processes in the first place,

\textsuperscript{30}Disputes on Medicines: What the Novartis Order Will Likely Affect”, \textit{The Hindu}, 7 April, 2013.

\textsuperscript{31}Dr. Gopal Dabade, “NEML Will Eliminate Unwanted Medicine”, \textit{Deccan Herald}, Bangalore, September 16, 2012.
and about the implications of granting patent protection to life forms on the rights of indigenous and local people.

It has to be noted that historically, patents were restricted to only industrial inventions and not to life forms. The US was the first to introduce patents for plants in 1930 and thirty years later plant breeder rights were introduced through the Union for Protection of New Varieties of Plants (UPOV).

The criteria for patentability under TRIPS agreement is that the inventions of products or processes should be new, involve an inventive step (non-obvious) and should be capable of industrial application (useful). It is contended that reproduction of life forms is essentially a biological process. Even if human intervention in the reproduction, results in a better offspring which is “useful”, it is restricted to identification of a particular trait and the invention of the technology to introduce that trait into the offspring. It is acknowledged that such a technology could be patented and the discovery of the trait be rewarded, as it requires considerable effort and skill. But it would be unethical to stipulate that the whole product (in case of a plant variety or seed) or the organism (in case of microorganisms) or gene could be patented. 32

Various problems have stemmed from the awarding of patents to plant varieties, microorganisms and genes. According to a study, 500,000 genes or partial sequences of genes had received patents up to the year 2000. Once a particular gene has been patented, it excludes other researchers from carrying on R&D activities on that particular gene and thereby increases the cost of R&D through licensing and royalty fees. It has implications for developing countries that could be late entrants in the field, which thereby are deprived of initiating R&D. One such example is the denial of access to BRCA1 and BRCA2 gene which is linked to susceptibility to breast cancer and ovarian cancer. The patent was held by a US based company called Myriad Genetics, which was given exclusive rights to conduct diagnostic tests on

the genes. This hindered others from developing alternative diagnostic tests and created a monopoly position for Myriad genetics which could charge high price for the tests. Recently, the New York Federal Court declared the patents as invalid, taking cognizance of its impact on medical research and public interest.  

5.1 Patenting of Plant Varieties

Farmers all over the world have been continuously engaged in bringing about improvements in plant and animal varieties. The progress in agriculture achieved hitherto, has been to a great extent the result of collective efforts by farmers. Plant breeding had not been a commercial activity and farmers did not derive any monetary benefits from the ‘invention’ of a new variety of plants. As pointed earlier, protection of plant breeders’ rights was instituted with the establishment of International Union for the Protection of New Varieties of Plants in 1961. This came about after the entry of the private sector into plant breeding in Europe. The Protection of Breeders Rights under UPOV recognised the rights of farmers to ‘save, re-sow, exchange and sell seeds of the protected varieties’. Hence there was a balance between the rights of farmers as well as rights of breeders. Though TRIPS does not prescribe standards for the protection of plant varieties, it mandates that plant varieties should be protected through patents or any other sui generis system. Though each member is free to constitute its own sui generis system for the protection of plant varieties, this has to be understood in the light of international pressure to follow a particular standard of protection and in this case it is the UPOV as amended in 1991. The amendment to UPOV has tilted the balance in favour of the plant breeders in that it extends the patent right for a new variety of plant to its harvest, reproduction, propagation, and conditioning and stocking as well. It also restricts the usage of the plant variety, obtained from the protected variety without the permission of the patent holder.

The proliferation of genetically modified crops is another dimension of the problem. Several agribusiness corporations are engaged in the production and sale of genetically modified crops and hold patents over these crops. When the farmers use these patented seeds, they forfeit their right to save the seeds for the next season. The agribusiness giant Monsanto has appointed investigators and encourage neighbouring farmers to report any act of saving the patented seeds. They had developed a technology called ‘terminator technology’ which produced sterile seeds that would not germinate. This demonstrates that the TNCs are so obsessed with their profits that they will go to any lengths to guard their profits. This has a huge impact on the food security of the people especially in the developing countries as farming is the main source of livelihood for the people. It is not a significantly commercial proposition and farmers have depended on traditional methods of cultivation, saving and exchanging seeds and breeding new plants by careful selection. With the advent of TRIPS, their right to save seeds has been jeopardized as their ability to grow crops now depends on their ability to pay for seeds. It is found that 67% of the proprietary seed market has been controlled by ten transnational corporations, with one corporation controlling a quarter of the market. In such a situation, they will have an oligopolistic control over the markets and there is every possibility that they will charge high prices for their products. The dominant market position of the agribusiness corporations combined with the patent laws will endanger the very livelihood of farmers especially in the developing countries.

5.2 TRIPS and Biopiracy

The provision to patent life forms and the absence of a clear distinction between discovery and invention in the TRIPS agreement has led to the proliferation of biopiracy. A huge portion of the knowledge pertaining to the natural world possessed by mankind today, could be attributed to the efforts of indigenous and local people over a period of several centuries. The world has come to benefit immensely from the collective knowledge which was transmitted to all parts of the

globe through the forces of globalisation, in its benevolent phase. In the period of colonisation, the Europeans were astounded by the knowledge of the local people regarding their environment and they assimilated such knowledge into their knowledge system. 35 No ownership was ever claimed by the indigenous people over the innovations and discoveries made by them. However, there has been an infringement of the rights of the indigenous and local people in the recent decades as a result of the activities of the TNCs that are involved in the commercialization of products which are based on biological resources. Such commercialisation is known as bio-prospecting. When bio-prospecting is done without the acknowledgement of the source and sharing of benefits, it is called biopiracy. A lot of discoveries claimed to be made by these TNCs can be labelled ‘prior knowledge’ which means knowledge that has existed for a long time, but which may not have been documented. Nevertheless, they have passed on from one generation to another through word of mouth. Since it is collective knowledge, there has been no claim of ownership. Indigenous people resent the commercialisation of such knowledge, since it was inventors intended to be used for common good.

In the past few years with the proliferation of the intellectual property regime, there has been an infringement of the rights of indigenous and local people. The TRIPS Agreement which provides for the patenting of micro-organisms, micro-biological and non-biological process and also plant varieties, has given scope for proliferation of patents for life forms in the past few years. The TNCs have tried to patent the traditional knowledge of the indigenous and local people with respect to biodiversity, claiming them to be inventions. The use of the indigenous knowledge for profit, without acknowledging the source, asking for permission or paying compensation to the rightful owners of the knowledge is intellectual property theft.

Indigenous people have developed their own system of medicine, by observing the patterns and symptoms of diseases and using the biological resources available in

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their vicinity. This medicine system is a great repository of knowledge, which is of immense importance to the indigenous and local people. There have been attempts to patent the traditional knowledge which has been put to use for several centuries. To patent such traditional knowledge as “new discovery” is a gross violation of the rights of the local community. The indigenous and local people will lose in three ways because of the commercialisation of the traditional knowledge. One, they might be deprived of the access to the medicines that they themselves had inherited two, they will not be given a share in the benefits accrued from the commercialisation of such medicines, and, three, there may be some medicine or medicinal system which may not be viable for commercialisation and hence may be lost in due course.

There are several instances where the TNCs belonging to developed countries have appropriated the traditional knowledge of the local and indigenous people without acknowledgement or sharing the benefits.

**a) Patent on Kombo Butter**

Rutgers University of New Jersey, US has filed for patent of ‘Kombo butter’ an extract from African Nutmeg tree (which is used as a traditional medicine in central and West Africa) and another plant *kinkeliba* a West African Shrub known for its medicinal properties. The patent is pending in the US patent office. The university has also filed application under Patent Co-operation Treaty and European patent office. Rutgers University claims that the discoveries with respect to medicinal properties of *kinkeliba* are its own, while *kinkeliba* has been widely used in West Africa in the treatment of diabetes. It has been found that not only there is absence of acknowledgement of the source of its discovery, the Rutgers University Access and Benefit sharing mechanism is also not up to the standards of Nagoya Protocol on Access and Benefit Sharing.

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b) Claims Over Asian Plant Species by Avon

Avon, a leading skincare company based out of US has filed patent for several Asian plant species which it has been using in the manufacture of skincare products. Avon has filed patents for plants like bignay, bai yanang, elephant foot yam, agathi, false daisy, alisma orientale, binh voi and soap nut. Till date Avon has been granted three patents in US and it is seeking patent rights in other countries also. All these plants over which Avon has been claiming patent rights have been well known for their medicinal properties in Asia and are being used in several Asian countries. Therefore it has become difficult for any one country to claim source of these plants.

c) Patent on Enola Bean

Larry Proctor, a US national obtained a patent on a particular yellow coloured variety of Enola Bean. Enola bean is cultivated in Mexico on a large scale and Larry Proctor had obtained ‘uniform and stable population’ of yellow beans by careful selection of yellow seeds from the seeds he had brought from Mexico, after planting them and collecting yellow seeds for several generations. He applied for the patent of yellow bean on the ground that it was not grown in US. A patent was granted, which gave him exclusive rights over the import and sale of yellow seeds in US. He also got another patent on the plant variety. With two patents in hand Larry Proctor filed lawsuits against those US companies which were importing and selling yellow beans in US. He also claimed royalty from the exporters of yellow beans from Mexico. This disrupted the trade of beans between the US and Mexico and caused inconvenience to farmers who were dependent on the export of the beans. This blatant misappropriation of the genetic resources of Mexico enraged not only the farmers and government of Mexico but also other people in US who were engaged in the cultivation, sale or import of the beans. Several challenges were filed against

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the patent. It was opined by experts that yellow beans were widely grown in Mexico and that the patent given to Larry Proctor was inappropriate as his finding was not unique. The patent was revoked only in 2009 following several challenges, but enough damage had been done to the farmers in these ten years as a result of lawsuits filed by Larry Proctor.

These instances of bio-piracy point towards the fact that TRIPS is grossly inadequate in protection of the rights of people. It has resulted in misappropriation of biological resources, as TRIPS has given scope for such acts by allowing plant varieties, micro-organisms and micro-biological processes to be patented. It gives importance to the rights of intellectual property holders over the rights of people. This is exemplified by the fact that there is no mechanism for acknowledgement of biological sources or benefit and access sharing mechanism in TRIPS.

Looking into these arguments it becomes very important to do a rethinking on the current system of protection of intellectual property rights as it is not suited to protect the rights of indigenous and local people. Even if these people are guaranteed recognition and compensation, the current system will fail to do justice to the huge repository of knowledge they possess or to the people themselves. This is because the current rules for intellectual property concentrate on protecting the rights of individual and commercial exploitation of a particular knowledge, as against the common good. Therefore it is a matter of prime importance that a sui generis system to protect the rights of indigenous and local people is adopted and adhered to by all nations.

The Convention on Biological Diversity (CBD) which came into being in 1992 recognized the sovereign rights of States over their own biological resources. It also recognised the dependence of indigenous and local communities over on biological resources and the desirability of equitable sharing of benefits coming from the use of traditional knowledge. Article 15.7 of the Agreement explicitly says that:

“Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and,
where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms”.

The Nagoya Protocol for Access and Benefit Sharing which was adopted in October 2010 aims to advance the objectives of Access and Benefit Sharing mechanism which is one of the main objectives of CBD. In the advancement of this objective the Nagoya Protocol stipulates among other things, that the parties to the Agreement:

- Take legislative and administrative measures to ensure that traditional knowledge associated with genetic resources are accessed with prior informed consent or approval and involvement of the indigenous and local communities who hold such knowledge, on mutually agreed terms.

- Take into consideration the indigenous and local communities’ customary laws, community protocols and procedures with respect to traditional knowledge in implementing their obligations under the protocol.

- Shall establish a Clearing-House to inform the potential user of traditional knowledge associated with genetic resources, about their obligations regarding the access to and fair and equitable sharing of benefits arising from the utilization of such knowledge.

- Shall ensure that utilization of traditional knowledge associated with genetic resources within its jurisdiction has been accessed in accordance with the prior informed consent of the indigenous and local communities who hold such knowledge, on mutually agreed terms as required by the legislative and

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regulatory requirements of the parties in which such indigenous and local communities are located.

- Shall take appropriate measures to address instances of non-compliance with measures adopted for ensuring fair and equitable sharing of benefits arising from the utilization of traditional knowledge associated with genetic resources and co-operate in cases of violation.

The indigenous people have made great contributions towards protecting the environment by developing practices which foster sustainable development, enriching the natural environment in which they live and enhancing the biodiversity. It therefore becomes a matter of prime importance to protect the rights of indigenous people.

6. From Singapore to Doha

By the time of the Singapore Ministerial in 1996, the adverse impact of TRIPS agreement was felt by the developing countries. This was evident from the statement of the Indian delegation during the Singapore Ministerial. The Indian delegate said:

“Concerns have been expressed in our country regarding the possible adverse effects of this Agreement on prices of pharmaceutical products and agro-chemicals. There is a feeling that the developing countries may have to incur heavy costs in implementing this Agreement by way of higher royalty payments, increased administrative costs and possible transnational monopolistic control in some sectors. I would hope that we will collectively find ways and means of addressing these concerns”.

The TRIPS agreement had mandated the review of the agreement through Article 71.1, after the expiration of the transition phase as provided in Article 65.2. Accordingly the developing countries wanted their concerns to be addressed during the review process. The developing countries had focussed on the review of Article 7, 8 and 27.3(b), and the issue of compulsory licensing.

The developing countries put forward their concerns regarding the TRIPS agreement in the proposals submitted during the preparatory process for the third ministerial conference.

Kenya, on behalf of the African Group, averred that the mandate for the TRIPS council was to review the substantive provisions of Article 27.3 (b) and it proposed that the review process should clarify that plants, animals and microorganisms are not patentable and all natural process for the production of plants, animals and other organisms are also excluded from patentability.

It also proposed that the review process should clarify that any sui generis system for the protection of plant varieties should provide for the protection of innovation and inventions of the indigenous and local people in accordance with the provision of CBD and the International Undertaking on Plant Genetic Resources. It called for the protection of farmers traditional rights to save and exchange seeds and sell their harvest and prevention of anti-competitive practices that threaten the food security of the developing countries.

In this direction, it was proposed that there should be harmonisation of the principles of the CBD and the International Undertaking on Plant Genetic Resources.41

Proposals echoing the above demands were also submitted by Bolivia, Colombia, Cuba, Dominican Republic, Ecuador, Egypt, El Salvador, Honduras, India, Indonesia, Malaysia, Nicaragua, Nigeria, Pakistan, Paraguay, Peru, Sri Lanka,

41 World Trade Organization, JOB(99)/4797/Rev.3 (6986), 18 November 1999, p.41-46
Uganda and Venezuela. It was additionally proposed by some countries that patents inconsistent with Article 15 of the CBD should not be granted and that this provision should become part of the TRIPS agreement and come into force by 1 January, 2004.

Cuba, Dominican Republic, Egypt, El Salvador, Honduras, India, Indonesia, Malaysia, Nigeria, Pakistan, Sri Lanka and Uganda proposed that Article 7 and 8 of the Agreement should be operationalised so as make transfer of technology possible from the developed countries to the developing countries on fair and mutually advantageous terms.

A group countries which included Jamaica, Kenya, Pakistan, Sri Lanka, Tanzania, Uganda, Zambia and Zimbabwe asked for the review of provision relating to compulsory licensing to make sure that governments, especially the least developed countries, are able to issue compulsory licenses to their domestic manufacturers, in case of abuse of patent rights, by charging exorbitant prices, especially those drugs which have been listed as essential drugs.

Apart from these substantive issues the developing countries also wanted the extension of the transition period in view of the financial and technical difficulties experienced by them in instituting administrative process, enacting laws pertaining to IP Rights and creating the required infrastructure to promote R&D. This was considered important for the developing countries to be able to develop technologies on their own, rather than depending on the developed countries for technology forever.

The filing of court case by the Pharmaceuticals Association of South Africa – an association of multinational corporations (MNCs) operating in Africa against the Medicines Act promulgated by the South African government – led to debates about the provision relating to compulsory license. Owing to severe protests by the developing countries and the intensity of the issues involved, it was decided that the issues of concern to the developing countries regarding TRIPS would be included in
its entirety in the agenda of the Doha Round of negotiations and that there would be a separate declaration on TRIPS and Public health.

The developed countries, propelled by the pharma MNCs wanted the debate on compulsory license to be limited to the issue of TRIPS and access to medicine only and not to public health as it would have involved larger issues. The developing countries had to negotiate hard for linking TRIPS with public health.

7. Summary

It can be discerned from the issues involved in the TRIPS Agreement that it is one of the blatantly unjust agreements to be included in the WTO. The issue of intellectual property clearly falls into the jurisdiction of other specialized organizations or treaties constituted for that purpose. The reason to include it in WTO was to ensure its enforcement through the dispute settlement mechanism that has the power to impose sanctions not only in the area of IP but also in other areas like goods and services. The developing countries were coerced to agree to the inclusion of intellectual property rights in the negotiating agenda by outright threats of sanctions. The Agreement has worked against the interests of the developing countries. The developing countries became aware of the hidden agenda of the TRIPS agreement only after the conclusion of the Uruguay Round and have been asking for redressal of the imbalances.

Whether the concerns of developing countries regarding TRIPS have been adequately addressed in the aftermath of the Doha Ministerial will be discussed in detail in the next chapter.