CHAPTER VI

WORLD TRADE ORGANIZATION
AND INDIAN INTELLECTUAL PROPERTY RIGHTS
INTRODUCTION

Trade-Related Aspects of Intellectual Property Rights (TRIPs) is a World Trade Organization (WTO) Agreement negotiated during 1986-94 Uruguay Round of international trade talks. The Agreement was instrumental in introducing Intellectual Property Rules into the multinational trading system for the very first time. The TRIPs Agreement, together with the 1968 Stockholm Conference that adopted the revised Berne and Paris Conventions and created the World Intellectual Property Organization (WIPO)\(^1\), is undoubtedly the most significant milestone in the development of intellectual property in the previous century.

Its scope is in fact much broader than that of the previous international Agreement dealing with intellectual property. It covers not only all areas already (sometimes only party) protected under existing Agreements, but also

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\(^1\)The World Intellectual Property Organization (WIPO) is a specialized agency of the United Nations. It is dedicated to developing a balanced and accessible international Intellectual Property (IP) system, which rewards creativity, stimulates innovation and contributes to economic development while safeguarding the public interest. WIPO was established by the WIPO Convention in 1967 with a mandate from its Member States to promote the protection of IP throughout the world through cooperation among states and in collaboration with other international organizations. Its headquarters are in Geneva, Switzerland which existed prior to the formation of the WTO.
giving new life to treaties that failed in protecting for the first time rights that did not benefit from any multilateral protection.

# TABLE 1

## MAJOR INTELLECTUAL CONVENTIONS ON INTELLECTUAL PROPERTY

<table>
<thead>
<tr>
<th>Year and Place of Convention</th>
<th>Subject-matter</th>
<th>Associated International Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Paris Convention (1883), 129 signatories, revised</td>
<td>Protection of patents, trade marks, service mark, industrial design. Allows for compulsory licensing. Updated periodically. Does not stipulate duration of patents or define what is patentable</td>
<td>WIPO</td>
</tr>
<tr>
<td>2. Berne Convention (1886), 111 signatories, revised in 1971</td>
<td>Basic copyright treaty based on principles of non-discrimination and national treatment (like Paris Convention)</td>
<td>WIPO</td>
</tr>
<tr>
<td>3. Madrid Agreement, 1891</td>
<td>Allows seizure on importation of goods bearing false origin</td>
<td>WIPO</td>
</tr>
<tr>
<td>4. Universal Copyright Convention, 1952, 57 signatories</td>
<td>Principle of non-discrimination and national treatment</td>
<td>UNESCO</td>
</tr>
</tbody>
</table>

2 Explicitly referred to in TRIPs Agreement. The IPIC Treaty had not yet entered into force as on March 1995
5. Rome Convention, 1961, 47 signatories
Protection of rights (performer producers of phonograms, broadcasting organizations) ILO, UNESCO, WIPO

6. Geneva Convention, 1971, 52 signatories
Protection of producers of phonograms against the making of duplicates in another country ILO, UNESCO, WIPO

7. IPIC Treaty 1989, 8 signatories
Treaty on IP in respect of integrated circuits WIPO


The WTO-TRIPs Agreement attempts to standardize 150 national laws dealing with Intellectual Property Rights and to apply common international rules for regulating intellectual property throughout the world.

Intellectual Property Rights are state created monopolies conferred on individuals or companies over the creations of their minds. Intellectual Property Rights can be broadly divided into three main categories (although there are additional types such as trade secrets, geographic indicators, integrated circuits, etc.):

1. **Copyright and Related Rights** – create rights of authors of literary and artistic work such as music, video, photos, and text. Very generally, copyright gives owners the exclusive right to reproduction, distribution, adoption, public display/performance of a creative work. There are important limitations to an author’s rights under copyright, such as fair use rights and first sale privileges. The rights granted under copyright have increased significantly in recent years, particularly in terms of the scope and duration of those rights, while the
number of limitations and exceptions that allow for flexibility and innovation are eroding.

2. **Trademarks** – create rights to distinctive signs, marks, logos, and geographical indications used in commerce. Trademarks are used to identify the origin of products and services in the stream of commerce. They were originally intended to protect consumers from confusion as to the source of products or services, but can be misused to prevent discussion and competition, particularly on the Internet.

3. **Patent Rights** – govern inventions and designs, processes or methods of doing business, and in the US, patents have been extended to regulate software.

TRIPs establish minimum levels of protection that each WTO Member nation must provide to the intellectual property of fellow WTO Members. The TRIPs Agreement therefore is often called a “minimum standards Agreement,” allowing Members to provide greater restrictions on the use of intellectual property if they so wish. The TRIPS Agreement covers five broad areas:

- Application of the basic principles of the trading system and other international intellectual property Agreements
- Adequate protection to Intellectual Property Rights
- Enforcement of Intellectual Property Rights adequately in their own territories
- Settlement of disputes on intellectual property between Members of the WTO
- Special transitional arrangements during the period when the new system is being introduced.

Non discrimination is a prominent feature of the TRIPs Agreement and among its most basic principles are included the National Treatment
requirement, and the Most Favoured Nation treatment requirement. In setting the Intellectual Property Rules that WTO Member nations must follow, TRIPs builds upon the international Agreements of the World Intellectual Property Organization (WIPO). The WTO-TRIPs Agreement also gives special emphasis to the Agreements of the Paris Convention for the Protection of Industrial Property (trademarks, patents, industrial designs, etc), the Berne Convention for the protection of literary and artistic works (copyrights), and the Rome Convention on broadcasting. The perceived problems with the above treaties dealing with Intellectual Property Rights were threefold:

(a) Some standards were weak and vaguely specified. The Paris Convention, for e.g., essentially required only National Treatment in each Member's patent laws and grant of priority rights.

(b) They provided no effective procedures for settling IPRs disputes and were therefore only statements of intention on the part of signatory nations. Departures from the Paris Convention guidelines covering compulsory licence issuance, for e.g., were common in national laws.

(c) It was difficult to renegotiate the Conventions rapidly and flexibly enough to handle new technologies, such as integrated circuits, software and electronic database, which were straining classical conceptions of intellectual property protection. Among many developed economies these technical advances were pushing forward changes in IPRs, which evolve dynamically in any event, but the WIPO

3treating one's own nationals and foreigners equally
4equal treatment for nationals of all 150 trading partners in the WTO
Conventions were seen as hardbound. Based on these perceptions, the negotiations in the Uruguay Round used the existing Conventions as a logical point of departure. As a first step, they looked at each one and decided which provisions should be included into the future TRIPS Agreement. All of the substantive provisions of Paris and Berne Conventions and IPIC Treaty were incorporated by reference. Some new necessary rights were added.

Because of United States dissatisfaction with the existing international intellectual property Agreements, the US was the prime mover to include the subject of intellectual property in the Uruguay Round. Inclusion of IPRS was strongly opposed by developing countries. In the end, it was agreed to include it into negotiations although with imprecise scope. When the negotiating structure for the Uruguay Round was established early in 1987, one of the negotiating groups was dedicated to TRIPS. By the time of the mid-term review of the Uruguay Round in Montreal in December 1988, substantial consensus appeared to have been reached, but with Brazil and India leading the opposition, intellectual property remained one of the areas on which Agreement had not been reached along with agriculture, textiles and safeguards. In 1990, the European Community was first to come forward with a draft of an Agreement, with US, Japan, Switzerland and then India on behalf of 14 developing countries followed the suit. The Chairman of the negotiating group produced a composite draft Agreement, but several important matters remained outstanding. Late 1990 saw the introduction of a comprehensive draft document by the negotiating group on which negotiations took place in 1991. The developed countries buried their differences while the developing countries also withdrew their categorical opposition. TRIPS require Member Governments to ensure that Intellectual Property Rights can be enforced under national laws and that the penalties of infringement are severe enough to deter further violations. The Agreement describes in detail how

enforcement should be handled, including rules for obtaining evidence, provisional measures, injunctions, damages and other penalties. The Agreement also suggests how each Member nation's courts should behave when faced with certain cases involving counterfeit or infringing goods. TRIPs further require Member Governments to ensure that Intellectual Property Rights owners receive the assistance of customs authorities to prevent imports of counterfeit goods. After the Uruguay Round, the GATT became the basis for the establishment of the World Trade Organization. Because ratification of TRIPs is a compulsory requirement of World Trade Organization membership, any country seeking to obtain easy access to the numerous international markets opened by the World Trade Organization must enact the strict intellectual property laws mandated by TRIPs. For this reason, TRIPs is the most important multilateral instrument for the globalization of intellectual property laws. States like Russia and China that were very unlikely to join the Berne Convention have found the prospect of WTO membership a powerful enticement. Furthermore, unlike other treaties on intellectual property, TRIPs has a powerful enforcement mechanism. States can be disciplined through the WTO's dispute settlement mechanism.

OBJECTIVE OF THE TRIPs AGREEMENT

The TRIPs Agreement constitutes the most significant strengthening ever of global norms in the intellectual property area. TRIPs are intended to maximize the contribution of intellectual property systems to economic growth through trade and investment by:

- establishing minimum standards for Intellectual Property Rights protection in the national systems of WTO Members
- prescribing agreed elements of an effective mechanism for administration and enforcement of Intellectual Property Rights

See generally Daniel Gervais, The TRIPs Agreement Drafting History and Analysis, Sweet & Maxwell (1998)
• creating a transparency mechanism - each WTO Member is required to provide details of their national intellectual property laws and systems, and to answer questions about their intellectual property systems
• creating a predictable, rules-based system for the settlement of disputes about trade-related intellectual property issues between WTO Members
• allowing for mechanisms that ensure that national intellectual property systems support widely accepted public policy objectives, such as stamping out unfair competition, facilitating transfer of technology, and promoting environmental protection.

The Preamble to the Agreement, which talks about the objective of the Agreement, is an integral part of it. It draws heavily upon the two Ministerial Declarations, which preceded the Brussels meetings, i.e., the Punta-del-Este Declaration, which launched the Round and the Mid-Term Review Decision of April 1989. The second and third paragraphs constituting the Preamble in fact contain the summary of the negotiating mandate. The Preamble declares Intellectual Property Rights as private rights. This was done to reaffirm that states are not, as a general rule, obliged to take action *ex officio* against violations of Intellectual Property Rights, but that such matters should in principle be resolved between the private parties involved. This rule is particularly relevant in respect of criminal sanction.

The Agreement on TRIPs also reflects on the need to cater to the special needs of the developing and LDCs and also reflects on the need to cater to the special needs of the developing and LDCs. Indeed, for many of them, full protection of Intellectual Property Rights, including effective enforcement before national courts and administrative bodies will necessitate changes not only to their laws but also to well-rooted practices involving additional expenses. In that light, the contracting parties recognized the need for flexibility and the need to take into account the developmental objectives of these countries. The TRIPs Agreement talks about the need to establish mutually supportive relationship between the WTO and WIPO as well as with other relevant international organizations. TRIPs take into account, *inter-alia,*
The whole Agreement contains 7 Parts and 73 Articles covering all aspects of IPRs, their enforcement and institutional arrangements. The key provisions are listed hereunder in the Table 2 with certain relevant comments.

**TABLE 2**

**SUBSTANTIVE REQUIREMENTS OF THE TRIPS AGREEMENT IN THE WTO**

<table>
<thead>
<tr>
<th>GENERAL OBLIGATIONS</th>
<th>COMMENTS</th>
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<tbody>
<tr>
<td>1. National Treatment</td>
<td>Applied to persons</td>
</tr>
<tr>
<td>2. Most-favoured-nation principle</td>
<td>Reciprocity exemptions for copyright; prior regional/bilateral allowed</td>
</tr>
<tr>
<td>3. Transparency</td>
<td></td>
</tr>
<tr>
<td><strong>Copyright and Related Rights</strong></td>
<td></td>
</tr>
<tr>
<td>4. Observes Berne Convention</td>
<td>Does not require moral rights</td>
</tr>
<tr>
<td>5. Minimum 50-year term</td>
<td>Clarifies corporate copyrights</td>
</tr>
<tr>
<td>6. Programmes protected as literary works</td>
<td>A significant change in global norms</td>
</tr>
<tr>
<td>7. Data compilations protected similarly</td>
<td></td>
</tr>
<tr>
<td>8. Neighbouring right protection for Phonogram producers, performers</td>
<td>A significant change in global norms</td>
</tr>
<tr>
<td>9. Rental rights</td>
<td></td>
</tr>
<tr>
<td><strong>Trademarks and Related Marks</strong></td>
<td></td>
</tr>
<tr>
<td>10. Confirms and clarifies Paris Convention</td>
<td></td>
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</tbody>
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<tr>
<th></th>
<th></th>
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<tbody>
<tr>
<td>11.</td>
<td>Strengthens protection of well-known marks</td>
<td>Deters use of confusing marks and speculative registration</td>
</tr>
<tr>
<td>12.</td>
<td>Clarifies non-use</td>
<td>Deters use of collateral restrictions to invalidate mark</td>
</tr>
<tr>
<td>13.</td>
<td>Prohibits compulsory licensing</td>
<td></td>
</tr>
<tr>
<td>14.</td>
<td>Geographical indications</td>
<td>Additional protection for wines and spirits</td>
</tr>
<tr>
<td><strong>Patents</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15.</td>
<td>Subject matter coverage</td>
<td>Patents provided for products and process in all fields of technology</td>
</tr>
<tr>
<td>16.</td>
<td>Biotechnology</td>
<td>Must be covered but exceptions allowed for plants and animals developed by traditional methods</td>
</tr>
<tr>
<td>17.</td>
<td>Plant breeders’ rights</td>
<td>Patents or effective and <em>sui generis</em> system required</td>
</tr>
<tr>
<td>18.</td>
<td>Exclusive right of importation</td>
<td></td>
</tr>
<tr>
<td>19.</td>
<td>Severe restrictions on compulsory licenses</td>
<td>Domestic production can no longer be required; non-exclusive licenses with adequate compensation</td>
</tr>
<tr>
<td>20.</td>
<td>Minimum 20-year patent length from Filing date</td>
<td></td>
</tr>
<tr>
<td>21.</td>
<td>Reversal of burden of proof in process Patents</td>
<td></td>
</tr>
<tr>
<td>22.</td>
<td>Industrial designs</td>
<td>Minimum term of protection: 10 years</td>
</tr>
<tr>
<td><strong>Integrated Circuits Designs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>23.</td>
<td>Protection extended to articles incorporating infringed design</td>
<td>Significant change in global norms</td>
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<tr>
<td>24.</td>
<td>Minimum 10 years protection</td>
<td></td>
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<tr>
<td><strong>Undisclosed information</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>25.</td>
<td>Trade secrets protected against unfair methods of disclosure</td>
<td>New in many developing countries</td>
</tr>
<tr>
<td><strong>Abuse of IPRs</strong></td>
<td></td>
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<tr>
<td>26.</td>
<td>Wide latitude for competition</td>
<td>Cannot contradict remainder of WTO</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Policy to control competitive abuses</td>
<td>Agreements</td>
<td></td>
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<td>--------------------------------------</td>
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<td></td>
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<tr>
<td><strong>Enforcement Measures</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>27. Requires civil, criminal measures and border enforcement</td>
<td>Will be costly for developing countries</td>
<td></td>
</tr>
<tr>
<td><strong>Transitional Arrangements</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>28. Transition periods</td>
<td>5 years for developing and transition economies; 11 for poorest countries</td>
<td></td>
</tr>
<tr>
<td>29. Pipeline protection for pharmaceuticals</td>
<td>Not required but a provision for maintaining novelty and exclusive marketing rights</td>
<td></td>
</tr>
<tr>
<td><strong>Institutional Arrangements</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30. TRIPs Council</td>
<td>Agreement to be monitored and reviewed</td>
<td></td>
</tr>
<tr>
<td>31. Dispute settlement</td>
<td>Standard approach with 5-year moratorium in some cases</td>
<td></td>
</tr>
</tbody>
</table>

**GENERAL PROVISIONS AND BASIC PRINCIPLES**

**NATURE AND SCOPE OF OBLIGATIONS**

Part I of the Agreement contains general provisions and basic principles. It further clarifies the relationship of the Agreement with the Paris and Berne Conventions and other Agreements on intellectual property. The TRIPs Agreement sets minimum standards. It places no obstacles in the way of countries which may wish to go beyond TRIPs, it explicitly permits them to do so. The only condition imposed is that any additional level of protection must not contravene the provisions of the TRIPs Agreement. In Article 1 the implementation framework is set out for Members. Governments commit themselves to minimum standards, for which compliance is mandatory.

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Part I (Articles 1-8)

Article 1
Governments are free to increase additional Intellectual Property Rights (IPR) protection or to decide how such protection should be adopted in their own legal system and practice, provided such protection does not contravene the provisions of the Agreement.

Article 1.2 of TRIPs Agreement defines intellectual property in a pragmatic way. It comprises the forms of intellectual property covered in the Agreement namely copyrights and related rights, trademarks, geographical indications, industrial designs, patents, layout designs of integrated circuits and the protection of undisclosed information. This excludes from general TRIPs obligations forms of intellectual property not covered by TRIPs. It is also important to note that contrary to the Paris Convention, TRIPs does not cover protection against unfair competition.

WTO membership is the fundamental element in the definition of 'nationals' to whom the treatment provided for in the Agreement in the nationals of other Members. It goes on to the say that nationals are to be understood as those natural or legal persons who would meet the criteria for eligibility for protection provided under the Paris Convention, the Berne Convention, the Rome Convention or the Treaty on Integrated Circuits. The benefits of the protection under TRIPs Agreement are meant to be given to private persons. In other words, when implemented, the protections are meant to give rise to enforceable property rights, but the individuals must be nationals of the Members of the WTO. However, with so many countries becoming Members of the WTO, the need to determine nationality is not a big issue now.

**INTELLECTUAL PROPERTY CONVENTIONS**

Earlier treaties on IPR were not meant to be abrogated by TRIPs. Negotiating parties therefore included substantive provisions to this effect in

\(^{10}\text{Article 2}\)
Article 2. As a result, the Paris Convention for the Protection of Industrial Property, the Berne Convention for the Protection of Literary and Artistic Works and the Rome Convention (International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations), as well as the Treaty on Intellectual Property in Respect of Integrated Circuits became part of the aspects to be considered in the implementation process.

NATIONAL TREATMENT AND MOST FAVOURED NATION

The general principles of the GATT Agreement, employed as a framework for the Uruguay Round negotiations, are reflected in the TRIPS general provisions found in Articles 3 and 4. Since the inception of the Paris and Berne Conventions, the National Treatment principle has been the standard in the field of intellectual property. Article 3.1 of the Agreement provides for the National Treatment. It requires Members to accord to the nationals of other Members' treatment no less favourable than it accords to its own nationals with regard to the protection of intellectual property. National Treatment permits countries, provided they do not discriminate between foreigners and locals to vary the level of protection they give to intellectual property according to what they see as their needs at anyone time or in anyone sector. Yet, to the country which does provide protection, it may seem like an onerous requirement if one's own nationals do not receive the corresponding level of substantive protection in the foreigner's home country. The requirement of National Treatment goes beyond those 'matters affecting the use of Intellectual Property Rights specifically addressed in the Agreement'. It also applies to the matters which a Member country embraces generally 'affecting the availability, acquisition, scope maintenance and enforcement of Intellectual Property Rights'.

In short, Members are compelled to respect the principle of "National Treatment" under which nationals of other countries are to be granted
treatment no less favourable than that accorded to the Member’s own nationals with regard to the protection of IP.

The requirement of National Treatment under Article 3 is subject to the exceptions provided by WIPO Conventions. In addition, an explicit exception to the broader coverage for National Treatment is also made in respect of the rights to performers, producers of phonograms and broadcasting organizations. However, Article 3.2 says that, these exceptions can only be used where they are necessary to secure compliance with laws and regulations which are not inconsistent with the provisions of the Agreement and where such practices are not applied in a manner which would constitute a disguised restriction on trade.

Likewise, the "Most-Favoured-Nation" (MFN) commitment of Article 4 must be considered. Most favoured nation principle is a new element introduced in TRIPs under Article 4. According to this, an advantage conferred on any country must be extended to all Members. This is a novelty in the field of intellectual property.

**GENERAL OBLIGATION**

In other words, under this system, well known in the multilateral trade arena, any advantage, favour, privilege or immunity granted to nationals of any other country must be accorded to nationals of all WTO Members. The purpose of this rule is to ensure uniformity of the multilateral trade environment. The obligation of MFN to multilateralise extends to the benefits granted to any other country and not just Members of the WTO, though the obligation itself is only owed to nationals of the Members. Like the national treatment provision, it applies to member’s protection of Intellectual Property Rights specifically addressed in the Agreement.

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12 Article 3
13 Article 5
Like National Treatment, MFN also has certain exception. The principle is exempted for any advantage, favour, privilege or immunity accorded to any Member. Firstly, from any international Agreements on judicial assistance or law enforcement of a general nature. This exception is not particularly confined to the protection of Intellectual property. Secondly, the exception is allowed if any advantage, favour, privilege or immunity granted is in accordance with the provisions of the Berne or Rome Convention to any Member. Thirdly, any advantage, favour, privilege or immunity is related to the rights of performers, producers of phonograms and broadcasting organizations that are not provided under the Agreement, the principle will not be applicable. Lastly, a particularly significant exception from the most-favoured-nation clause is that regarding international Agreements related to the protection of intellectual property, which entered into force prior to the entry into force of the Agreements establishing the WTO.

**EXHAUSTION OF RIGHTS**

Article 6 of the Agreement is important due to its stress that the principle of exhaustion of rights is a necessary ingredient in balancing exclusive rights and needs of the markets. It is generally accepted in law that the holder of Intellectual Property Rights in product exhausts those rights over the further distribution in a particular market once he has sold the product. The TRIPs Agreement states that whatever a Member does in this respect cannot be challenged under WTO dispute settlement procedures, provided that the TRIPs National Treatment and MFN obligations have been complied with.
OBJECTIVES

Article 7 states that, the protection of Intellectual Property Rights should aim at promoting technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge, in a manner conducive to social and economic welfare; it should also aim at a balance of rights and obligations.

PRINCIPLES

With respect to the enactment or Amendment of their national laws, Members may adopt measures necessary to protect public health and nutrition and to promote public interest in sectors of vital importance for their socio-economic and technological development, provided that such measures conform to the TRIPs Agreement. Moreover, Governments are entitled to provide for measures to prevent the abuse of IPR by right holders or to contest practices which unreasonably restrain trade or adversely affect the international transfer of technology, again consistent with the provisions of the Agreement.

SUBSTANTIVE STANDARDS

Part II of the Agreement addresses, in its various sections, the different kinds of IPR and establishes standards for each category.

\(^{15}\text{Article 7}^{16} \text{Article 8}^{17}\text{Part II Article 9-40 of the Agreement}\)
SECTION 1: COPYRIGHT AND RELATED RIGHTS
(NEIGHBOURING RIGHTS)

According to the Article 9.2 of the Agreement, copyright protection shall extend to expressions and not to ideas, procedures, and methods of operation or mathematical concepts as such. Copyright is granted to literary work, musical work, dramatic work, pictorial work, sculptural work, architectural work, choreographic work, graphic work, motion picture, sound recording, audiovisual work, computer programmes, etc.

The TRIPs Agreement for the first time lists the exclusions from copyright. It thus helps to delineate the scope of the Berne Convention. The Agreement obliges countries to protect all 'expressions' as a synonym of the term 'literary and artistic works'. Similarly, all computer programmes whether in source or object code has been protected as literary works. Databases, whether in machine readable or other form, which by reason of selection or arrangement of their contents constitute intellectual creations are also protected as literary works. Such a copyright protection, however, does not cover the data or material itself and it will not affect any copyright subsisting in the data or material itself.

The owner of a copyright has the right to exclude others from reproducing, distributing, preparing derivative works, performing, displaying, or using the work covered by copyright for a specific period of time. The essence of copyright is originality, which implies that the copyright owner or claimant originated the work. However, a work of originality need not be novel. Originality does not imply novelty in copyright law; it only implies that the copyright claimant did not copy from someone else.
BERNE CONVENTIONS AND TRIPs AGREEMENT

The principal copyright standards under the TRIPs Agreement are those set by the Berne Convention. Article 9 of the TRIPs Agreement requires from the WTO Members to comply with Article 1 to 20 of the Berne Convention with its Appendix also. An exception to the obligation to comply with the substantive provisions of the Berne Convention is that the TRIPs Agreement does not in it give rights or set obligations with respect to Article 6 bis of the Convention, which deals with what are known as 'moral rights'. These are the rights of authors to have their authorship acknowledged and to prevent their work from being changed in ways that distort or mutilate it. In United States - Section 110(5) Act case the Panel made a finding on the relationship between the TRIPs Agreement and the Berne Convention (1970) and affirmed that the Berne Convention had become the part of the TRIPs Agreement and as provisions of that Agreement have to be read as applying to WTO Members', one should avoid interpreting the TRIPs Agreement to mean something different than the Berne Convention except where this is explicitly provided for.  

The Agreement on TRIPs provided the teeth to the Berne Convention by bringing most of the provisions of the Convention under WTO dispute settlement mechanism. Earlier the Convention was lacking of an authority with the power to interpret the provisions. The inclusion of the Appendix avoids a possible conflict between the Convention and the TRIPs Agreement.

The main additions or clarification in the Agreement from Berne Conventions are:

(a) a requirement to protect computer programmes as literary works under the Berne Conventions, and also to protect

databases or other compilations whose arrangement or selection make them intellectual creations, even when the individual elements are not protected by copyright;19

(b) a requirement to give authors of computer programmes and films the rights to authorize or prohibit commercial rental of their copyright works;20

(c) a requirement that limitations or exceptions to exclusive rights be limited to special cases that do not conflict with normal exploitation of the works concerned or unreasonably prejudice the right-holder's legitimate rights.21

For the first time at the international level, rental rights for phonograms, films and data compilations and minimum standards of protection for works not belonging to natural persons are being granted.22 In the area of copyright, TRIPs brought the minimum standard of protection under the Berne Convention. For most countries, there was, therefore, no change, but it has been established that 33 countries were not party to the Berne Convention. In addition to clarifying certain issues (such as the calculation of the term of protection of works not belonging to natural persons)23, TRIPs made headway in the field of software and data compilations. Article 10.1 stipulates that computer programs are to be protected as literary works under the Berne Convention. This was important as the TRIPs solution emphasized the role of copyright as the basic instrument of software protection and, at the same time, required that the term of protection be the same as in the case of literary works. Article 10.2 of TRIPs contains the origins of the database right since it clarifies that databases and other compilations of data or other material must

19 Article 10
20 Article 11
21 Article 13
22 Article 11
23 Article 12
be protected as such under copyright, even if they include data that, as such, are not protected under copyright. TRIPs protect databases only on the condition that they are intellectual creations and choose the "usual" copyright regime. Still, it has highlighted the importance of database protection.

Important provisions concerning related rights were placed in Article 14. For example, Article 14.5 expanded the 20-year term of protection required under the Rome Convention to 50 years.

**LIMITATIONS AND EXCEPTIONS**

Article 13 of the Agreement on TRIPs provided that limitations and exceptions have to be confined to certain special cases, which do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the right holder. In interpreting Article 13, the Panel in US - Section 110(5) Copyright Act case outlined its interpretive approach to this provision, specified the conditions for limitations or exceptions to exclusive rights and found that these conditions apply cumulatively. The Panel felt the need for giving a distinct meaning to each of the three conditions and to avoid a reading that could reduce any of conditions to 'redundancy of inutility'. The three conditions apply on a cumulative basis, each being a separate and independent requirement that must be satisfied. Failure to comply with anyone of the three conditions results in the Article 13 exception being disallowed.24

**SECTION 2: TRADEMARKS**

According to Article 14 of Part II of the Agreement, any sign, or any combination of signs, capable of distinguishing the goods or services of one undertaking from those of other undertakings, any sign including personal names, letters, numerals, figurative elements and combination of colours as

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well as any combination of such signs are eligible for registration as trademarks. Where the signs are not inherently capable of distinguishing the relevant goods or services, the registrability of such trademarks is also required but may be made dependent on a distinctiveness acquired through its use. In addition, registrability may be limited to visually perceptible marks, thus probably excluding from mandatory registration of factory and sound marks.

Apart from the ground of refusal contained in Article 15(1) of the Agreement, the grounds mentioned under the Paris Convention can also be used. The registrability of a trademark to be made dependent on use, but not filing of an application. In addition, failure to use may not be a ground for refusal before the expiry of three years from the date of application. Article 15(1) of the Agreement states that the nature of goods and services in no case should prevent registration of a mark. The language is similar to Article 7 of the Paris Convention. The principle underlying this provision is that intellectual property protection should not depend on whether the goods or services can legally be sold or provided within a country.

The Agreement on TRIPs requires from each Members to publish trademark either before registration or promptly thereafter in order to allow third parties to oppose registration or obtain its cancellation. The Agreement introduces the first international requirement to provide for such opposition and cancellation procedures. Since the nature of the procedure has not been mentioned in the Agreement, it all depends on the national law of each WTO Member.

In the area of trademarks, TRIPs generally confirms the standard of protection resulting from the Paris Convention. The most important features of the TRIPs regulation are the following: the nature of goods or services to which a trademark is to be applied cannot be an obstacle to registration; actual use of a trademark cannot be a condition for filing an application for registration; service marks must be protected in the same way as marks
distinguishing goods, the protection of well-known marks is strengthened in that Article 6 bis of the Paris Convention must be also applied to services and the protection of registered well-known marks must extend to goods or services which are not similar to those in respect of which the trademark has been registered, provided that use of that trademark in relation to those goods or services would indicate a connection between those goods or services and the owner of the registered trademark and provided that the interests of the owner of the registered trademark are likely to be damaged by such use; Article 16.3 deals with the use of certain well known marks in relation with goods and services other than those for which the mark is registered, subject to two cumulative conditions: (a) that a link be made to the owner of the well known mark and (b) that there be likely damage to the interests of the well-known mark. The term of protection between registration and renewal must not be less than seven years; indefinite renewal must be allowed as long as conditions for renewals are met.

Lastly, cancellation of a mark on the grounds of non-use cannot occur until there have been three years of uninterrupted non-use, unless the trademark owner shows valid reasons based on the existence of obstacles to such a use.

LICENSING AND ASSIGNMENT

The TRIPs Agreement prohibits compulsory licensing of trademarks. While compulsory licensing of patents is justifiable on the ground of public interest, it is not so with trademarks. The purpose of a trademark being its ability to distinguish the goods or services of one undertaking from those of another, it would not be proper to let the third party use that link without the consent of the trademark owner. The WTO Members are free to determine their own conditions on the licensing and assignment of trademark. They also

\[\text{Article 16.2}\]
\[\text{Article 19}\]
retain the right to determine their own conditions of transfer and assignment, including possible registration requirement.

SECTION 3: GEOGRAPHICAL INDICATIONS

Geographical indications identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin. Several commercial products are traditionally produced in a specific geographically definable region. Where these products are accredited specific criteria essentially attributable to their geographical provenance, the geographical indication becomes, in trade relations, the reliable "carrier" of qualifying product characteristics. Geographical indications are then ascribed the function and importance of trademarks and are entitled to legal protection.

Section 3 incorporates the principles of the Lisbon Agreement for the Protection of Appellations of Origin and their International Registration signed in 1958 and revised in 1967, although without explicit reference in the text.

Under the Agreement, Members are committed to adopt legislation which prevents the use of indications likely to mislead the public as to the geographical origin of the goods or to constitute an act of unfair competition. Members should also refuse or invalidate the registration of a trademark which contains or consists of a geographical indication with respect to goods not originating in the territory indicated, if use of the indication in the trademark is of such a nature as to mislead the public as to the true place of origin. It also prohibits the use of a geographical indication which although correctly reflects the origin of the goods nonetheless falsely represents to the public that the good originates in another geographic location.
SPECIAL PROTECTION FOR WINES AND SPIRITS

More restrictive provisions have been developed for wines and spirits. Here, Members shall provide the legal means for preventing the use of a geographical indication identifying wines or spirits as not originating in the place indicated by the geographical indication in question, even where the true origin of the goods is indicated or where the geographical indication is accompanied by corrective supplements such as "kind", "style", "imitation" or "similar". The holder of the right does not have to show that there is a likelihood of confusion or that there is unfair competition; the use of an identical or similar indication of origin is itself an infringement.

EXCEPTIONS TO GEOGRAPHICAL INDICATIONS RULE

Section 3 also comprises exceptions to given provisions.27 Previously existing protection of rights may not be diminished because of the Agreement. Members may refuse protection of geographical indications, which have become generic terms of product description in that Member. Just to give an example related to wine and spirits, Article 24.4 of TRIPs states that, Members are not required preventing continued and similar use of a particular geographical indication of another Member when identifying wines or spirits in connection with goods or services by any of its nationals or domiciliary who have used that geographical indication in a continuous manner with regard to the same or related goods or services in the territory of that Member either for at least 10 years preceding 15 April, 1994 or in good faith preceding that date.

The implementation process must avoid distortion of prior trademark rights. Where a trademark right has been applied for or registered in good faith, or where rights to a trademark have been acquired through use in good faith either before the date of application of the Agreement in that Member or before the geographical indication is protected in its country of origin,

27Article 24
implementing measures should not prejudice eligibility for or the validity of the registration of a trademark, or the right to use a trademark, which is identical with, or similar to, a geographical indication. Members are not obliged to protect geographical indications which are not or cease to be protected in their country of origin, or which have fallen into disuse in that country.

FURTHER NEGOTIATIONS ON GEOGRAPHICAL INDICATION MARK

Articles 23 and 24 of the TRIPs Agreement provide for further negotiations on the subject. The Council on TRIPs, established under Article IV of the WTO Agreement, will oversee negotiations on a multilateral system of notification and registration of geographical indications for wines. Member countries will also negotiate on increased protection for individual geographical indications for wines and spirits.

SECTION 4: INDUSTRIAL DESIGN

The Agreement on TRIPs require from each Member country to provide protection for independently created industrial designs that are new or original. A patent-like requirement of inventiveness or non-obviousness is not required. Parties may provide that designs are not new or original if they do not significantly differ from known designs or combinations of known design features. The Agreement permit the parties to provide protection that shall not extend to designs dictated essentially by technical or functional considerations.

Article 25 of the Agreement of TRIPs explicitly requires Governments to provide protection for textile designs, either under an industrial design law or through copyright law. Textile designs, which typically have a short life cycle, exist in large numbers and are subject to copying, are given special attention. For obtaining protection, each Member is obliged to ensure that cost, examination or publication do not unreasonably impair the opportunity to
seek and obtain such protection. Industrial design grants to the right holder the right to prevent third parties from making, selling or importing articles bearing or embodying a design which is a copy, or substantially a copy, of the protected design, without his consent when such acts are undertaken for commercial purposes.

The Members may provide exceptions to the protection of industrial designs if such exceptions do not unreasonably conflict with normal exploitation of protected industrial designs and such measures do not unreasonably prejudice the legitimate interest of the owner of the protected design. The Agreement explicitly specifies that, the protection available shall be at least ten years. The owner of a protected design must be able to stop unauthorized third parties from making, selling or importing for commercial purposes, products which copy the design.

Also based on the Paris Convention, yet going far beyond that, the duration of protection shall "amount to" at least 10 years - the use of the word "amounts" is of relevance since this wording of Article 26.3 of TRIPs allows the division of the term, e.g. into two five-year periods.

SECTION 5: PATENTS

The provisions on patents probably constitute the most important substantive part of TRIPs. Since TRIPs clearly introduces higher standards of protection than the Paris Convention. A patent is an IPR granted to inventors. The inventor, as owner of the patent, has the right to exclude any other person from making, using, selling or importing the invention protected by the patent, for a certain period of time in a given territory.

Before the adoption of the Agreement, countries were free to determine the terms for patentability, the rights conferred to patent holders and the duration of patent protection. The establishment of areas of non-patentability
was also left to countries' own discretion. It is not surprising that patent law was thus tailored to follow countries' own economic interests. This resulted in diverging standards among Members, which inevitably caused substantial tensions in global trade relations.

Before TRIPs, there were three major problems with international patent protection: the protection was often available only for a limited scope of products and processes (i.e. some were excluded); the terms of protection were inadequate; and compulsory licensing was excessive. TRIPs address all those issues. The key provision is Article 27, which stipulates that “patents shall be available for any inventions, whether products or processes, in all fields of technology, without discrimination as to the place of invention and whether products are imported or locally produced, provided that they are new, involve an inventive step and are capable of industrial application.” Interestingly, TRIPs does not define the term “invention”. But footnote to Article 27 of the TRIPs Agreement makes it clear that whatever distinction one might have found in the past, the terms, ‘useful’ and ‘non-obvious’ corresponds to the later two. In determining the eligibility of an invention to be patented and enjoyment of Patent Rights the TRIPs Agreement prohibits discrimination based on whether the invention is locally produced or imported. Mandatory terms of application comprise complete and sufficiently clear disclosure of the invention as to the method of use and production. As a result, there can be no doubt that patent protection must be available for food, pharmaceuticals products, chemical products and processes, etc. It should be reminded that patent laws of many states had to be revised as a result since it was, for example, not uncommon to deny patent protection to pharmaceutical products (as opposed to processes).

^Article 27.1

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EXCEPTIONS

The Agreement states three exceptions, those countries may rely on to exclude otherwise patentable subject matter. These include:

1. Inventions which are contrary to order public or morality, i.e. inventions which are dangerous to human, animal or plant life or health or seriously prejudicial to the environment. (Article 27.2)
2. Diagnostic, therapeutic and surgical methods for the treatment of humans or animals (Article 27.3(a)).
3. Plants and animals other than microorganisms and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. Any country excluding plant varieties from patent protection must provide an effective *sui generis* system of protection (Article 27.3 (b)).

The interpretation of this last clause has been extremely contentious. The term *sui generis* (Latin for 'of its own gender/genus') is not defined in the Agreement, but it is generally believed that it enables Member countries to fashion their own protection scheme for plants. Possible protection mechanisms include the Plant Breeder's Rights system offered by Union for the Protection of New Varieties of Plants (UPOV Convention), plant patents or a licensing regime. More than one form of plant protection can be implemented in a given Member country.

One of the controversies of Article 27.3 focuses on the meaning of *sui generis* and exactly what is considered an 'effective' form of plant variety monopoly right. In part because of the difficulties with this provision, Article 27.3 was to be reviewed in 1999, four years after the entry into force of the Agreement. The review has never been completed, and this Article remains a hot issue. To date, some 30 countries are calling for further discussion on Article 27.3, and some have proposed:
1. Rewriting the Article to exclude patents for any organisms or genetic material (although ostensibly countries could achieve this by defining these subjects matters as "discoveries" and not "inventions");
2. Defining in detail what an effective plant variety development right system is;
3. Extending exclusionary rights of some sort to traditional or indigenous knowledge; and
4. Making explicit linkages with obligations for the conservation and use of biodiversity, including mandatory disclosure of the source of genetic materials used in a patented invention, and creating obligations to record arrangements for access to genetic resources as evidence of prior informed consent.

It remains to be seen whether any of these proposals will be adopted. Patent protection within TRIPs standards must confer on the right holder exclusive rights of making, using, offering for sale, selling and importing. Process patents must additionally extend these rights over products obtained directly by the process in question. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

The Agreement of TRIPs put stringent conditions on use of a patented invention without the authorization of the right holder. This includes situations involving use of the invention by the Government or use by a third party authorized by the Government under a compulsory licence. These conditions, including special conditions applicable to semiconductor technology, will also apply to compulsory licensing of rights protecting integrated circuit and layout designs. Many WTO Members will be required to eliminate provisions that now subject patents to compulsory licences if the patented invention is not produced locally.
Article 30 of the TRIPs Agreement provide limited exceptions to the exclusive rights conferred by a patent, provided such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner by taking into account the legitimate interests of the third parties. In Canada-Pharmaceutical Patent Case\(^29\) the Panel addressed the basic structure of Article 30 and outlined the conditions for its application and then found that, these conditions apply cumulatively. Article 30 establishes three criteria that must be met in order to qualify for an exception:

(i) the exception must be limited;
(ii) the exception must not unreasonably conflict with the normal exploitation of the patent;
(iii) the exception must not 'unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties. All the three conditions are cumulative, each being a separate and independent requirement that must be satisfied. Failure to comply with any of the three conditions results in the Article 30, exception being disallowed.

Section 5 contains a "reversal of burden of proof". Provided the patent's subject matter is a process for obtaining a product, judicial authorities have the right to call the defendant to prove that the process, by which an identical product is produced, substantially differs from that which benefits protection.

The rights obtainable by patentees are clearly outlined in Article 28. The Article also provides that rights are conferred for products which are directly obtained by a patented process or method. For e.g., if a patent is issued for a novel method of manufacturing snow skis, the skis produced will also be protected by the patent. The TRIPs Agreement provides that inventions must be disclosed by publication (Article 29), the term of protection available for a patent under the TRIPs Agreement must be at least 20 years from the filing of the application. The Agreement does not explicitly deal with one well known difference national patent systems, the adoption by some countries of the date of invention rather than the filing date as the date for determining priority between two claims for the same invention. The Members should not discriminate according to the place of invention in the patent protection they give. In case of any revocation or of forfeiture of the registered patent an opportunity for judicial review are available according to the standards as contained in Part III of the Agreement.

RULES FOR COMPULSORY LICENSING

The conditions for compulsory licensing have been listed in Article 31 (though TRIPs does not use the term compulsory licensing - instead it refers to "use without authorization from the right holder"). The most important requirements are the condition that the licence can be granted only if an unsuccessful attempt has been made to acquire a voluntary licence on reasonable terms and within a reasonable period of time and the requirement to pay adequate remuneration. In other words, where patentee and licence applicant have failed to agree on commercial terms and within a reasonable period of time, provisions are included to allow for the issuance of compulsory licences under defined conditions, and which require the payment of adequate
remuneration to the patentee in each case. Governments are equally subject to the terms of licensing.

There are 12 principles listed in 31 Article. They are:

(a) Licences must be granted only on a case by case basis;
(b) When ordering for compulsory licensing there must be prior consultation with right holder. However, in the case of national emergencies and non-commercial use, the need for prior negotiation does not apply;
(c) A compulsory licence should be liable to be revoked as soon as the purposes for which it was granted no longer justify the licence and are unlikely to recur;
(d) The scope of a compulsory licence must be proportional i.e., limited to the purposes for which it was granted;
(e) Compulsory licences may only be granted for public non-commercial use or to remedy an anti-competitive practice;
(f) Compulsory licensing shall in all cases be non-exclusive;
(g) Rights derived from Compulsory licensing cannot be transferred to a third party except for those cases in which the two parties jointly engage in business;
(h) Compulsory licensing for all practicable purposes should remain confined to ensure predominantly the supply of the domestic market of the WTO Member granting the licence;
(i) When the situation that led to the setting of compulsory licensing has ceased to exist and there is no likelihood of recurrence, compulsory licensing shall be trimmed, provided the legitimate benefit of the licence shall be protected;
(j) The owner of the right shall be given an appropriate compensation;
(k) Decisions to grant, continue, renew compulsory licences as well as decisions concerning the level of the adequate remuneration of the patent owner must be subject to judicial review;
(I) Where a compulsory licence is given for exploiting a patent (the second patent), which cannot be exploited without informing another patent (the first patent), the invention claimed in the second patent shall involve an important technical advance. The owner of the first patent is entitled to a cross-licence on reasonable terms of the second patent and the authorized use for the first patent shall be non-assignable without including assignment of the second patent.

Article 31 of the TRIPs Agreement tries to strike the balance between two opposing interests - the interests of inventors and of technologically advanced countries and those of licences and of technologically less advanced countries.

**SECTION 6: LAYOUT- DESIGNS (TOPOGRAPHIES) OF INTEGRATED CIRCUITS**

In Section 6 of Part II of the Agreement, Members agree to provide protection to the layout-designs (topographies) of integrated circuits. Authorization of the right holder is necessary for importing, selling, or otherwise distributing for commercial purposes a protected layout-design, an integrated circuit in which a protected layout-design is incorporated, or an article incorporating such an integrated circuit only in so far as it continues to contain an unlawfully reproduced layout-design.

As regards the Treaty on Intellectual Property in Respect of Integrated Circuits, the TRIPs Agreement gives additional terms of protection for this subject matter, i.e. minimum protection for ten years, but protection may lapse after fifteen years and provides for minimum penalties for infringements. In the field of layout designs of integrated circuits, TRIPs adopts some provisions of the 1989 Washington Treaty on Intellectual Property in Respect of Integrated Circuits. However TRIPs goes beyond this standard of protection in that it is
also available for products containing the infringing integrated circuits and that innocent infringers are liable to pay a sum equivalent to a reasonable royalty.

SECTION 7: PROTECTION OF UNDISCLOSED INFORMATION

Only one Article of TRIPs (Article 39) deals with the protection of undisclosed information. TRIPs do not require that trade secrets be treated as IP rights sensu stricto (i.e. exclusive rights such as patents or trademarks). It is sufficient to adequately protect undisclosed information in unfair competition law. Recognizing the commercial value of trade secrets and non patentable "know-how", TRIPs requires Members to develop national legislation to protect such information from being disclosed to, acquired by, or used by persons without the consent of the person who is lawfully in control of it, in a manner contrary to honest commercial practices. To be awarded protection, such information must be secret, have commercial value because it is secret, and have been subject to reasonable steps to keep it secret.31 The footnote attached to Article 39.2 relating to the phrase 'a manner contrary to honest commercial practices', is nonetheless useful as it provides clear example of cases which must be considered as falling into the category of dishonest commercial practices. This is compatible with the traditional interpretation of Article 10 bis (2) of the Paris Convention.

Likewise, these provisions are valid, under defined circumstances, for information submitted to Governments (i.e. undisclosed tests or other data submitted as a condition of approving the marketing of pharmaceutical or agricultural chemical products), giving protection against unfair commercial use.

31 Article 39.2
SECTION 8: CONTROL OF ANTI-COMPETITIVE PRACTICES

DEFINITION OF ABUSE

In the last section of Part II of the Agreement, Members agree that some licensing practices or conditions pertaining to IPR which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology. The provision concerning the control of anti-competitive practices in contractual licences must be read as acknowledgment of the fact that IPRs may be used in a way that is harmful to the economy and thus do not deserve protection. From this perspective, Article 40, TRIPs is more important because of the link it establishes between IP law and competition law than because of its precise content.

Article 40 of TRIPs also creates a platform for negotiations and consultations between Members in matters concerning alleged abuse of IPRs and competition law concerns. The section provides for consultations between Governments where there is an abuse of IPR resulting in an adverse effect on competition. The Agreement obliges the parties to give full and sympathetic consideration or requests from other parties for assistance to deal with anti-competitive practices of their nationals.

ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS

Sufficient protection for IPR would be worthless unless the right holders have the opportunity to claim their rights and infringers can be prosecuted. These issues are dealt with in Part III of the Agreement, which commits Members to the development of remedies and procedures under domestic law.

30 Article 40
32 Article 40.3, 40.4
34 Part III, Article 41-61 of the Agreement
to ensure that IPR are effectively enforced for both national and foreign right-holders. The implementation should comprise procedures for effective action against infringement of IPR, ensuring that they are fair and equitable, not unnecessarily complicated or costly, and do not entail unreasonable time limits or unwarranted delays.

Without being obliged to put in place a judicial system distinct from that for the enforcement of domestic law in general, Members have to allow judicial review of final administrative decisions and initial judicial decisions. The provisions on enforcement are contained in Part III of the Agreement, which is divided into five sections.

The Agreement makes a distinction between infringing activity in general, in respect of which civil judicial procedures and remedies must be available, and counterfeiting and piracy — the more blatant and egregious forms of infringing activity — in respect of which additional procedures and remedies must also be provided, namely border measures and criminal procedures. For this purpose, counterfeit goods are in essence defined as goods involving slavish copying of trademarks, and pirated goods as goods which violate a reproduction right under copyright or a related right.

**GENERAL OBLIGATIONS**

The general obligations relating to enforcement are contained in Article 41. Paragraph 1 requires that enforcement procedures must be such as to permit effective action against any act of infringement of Intellectual Property Rights, and that the remedies available must be expeditious in order to prevent infringements and they must constitute a deterrent to further infringements. On the other hand, these procedures must be applied in such a

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35 Article 41
manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse.

The following three paragraphs contain certain general principles, the aim of which is to guarantee due process. Paragraph 2 deals with enforcement procedures. Such procedures must be fair and equitable, and they may not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays. Paragraph 3 concerns decisions on the merits of a case. Such decisions shall preferably be in writing and reasoned, and they shall be made available at least to the parties to the proceeding without undue delay. Decisions on the merits of a case shall be based only on evidence in respect of which parties were offered the opportunity to be heard. Paragraph 4 requires that parties to a proceeding shall have an opportunity for review by a judicial authority of final administrative decisions and, subject to jurisdictional provisions in a Member's law concerning the importance of a case, of at least the legal aspects of initial judicial decisions on the merits of a case. However, there is no obligation to provide an opportunity for review of acquittals in criminal cases.

According to Paragraph 5, it is understood that the provisions on enforcement do not create any obligation to put in place a judicial system for the enforcement of Intellectual Property Rights distinct from that for the enforcement of law in general, nor does it affect the capacity of Members to enforce their law in general. In addition, it is stated that nothing in these provisions creates any obligation with respect to the distribution of resources as between enforcement of Intellectual Property Rights and the enforcement of law in general. However, a number of countries have found it helpful to establish special enforcement units that pool together required experience needed to effectively fight against counterfeiting and piracy. Moreover, some countries have centralized certain types of intellectual property issues in one or a limited number of courts in order to ensure the availability of necessary expertise.
The Second Section requires that civil judicial procedures must be available in respect of any activity infringing Intellectual Property Rights covered by the Agreement. The provisions of the section elaborate in more detail basic features that such procedures must provide for.

Article 42 of the TRIPs Agreement obliges Members to make civil judicial procedures available to right holders to enforce their Intellectual Property Rights covered by TRIPs and in doing so, requires Members to provide what is generally referred to as ‘due process’. The procedure includes:

- defendants must be given timely and detailed written notice of the basis of the claims against them;
- all parties should be permitted to be represented;
- overlay burdensome requirements for mandatory personal appearances may not be imposed;
- all parties must be permitted to substantiate their claims and present all relevant evidence; and
- confidential information must be protected unless contrary to constitutional requirement.

Article 43 deals with how the rules on evidence should be applied in certain situations. In a situation where evidence that is likely to be important for one party is in the possession of the opposing party, the court must be empowered, provided that certain conditions are met, to order the latter party to produce that evidence. In addition, courts may be authorized to make their decisions on the basis of information presented to them, if a party refuses without good reason access to evidence that is in his or her possession, subject to providing the parties an opportunity to be heard.

^Articles 42-49
The section contains provisions on injunctions, damages and other remedies. Article 44 requires that, the courts be empowered to order injunctions, i.e. to order a party to desist from infringements, including the possibility to prevent imported infringing goods from entering into domestic distribution channels. Members are not obliged to provide that authority where a person has acted in good faith. Article 45 provides that the courts must be empowered to order an infringer, at least if he or she acted in bad faith, to pay the right holder adequate damages. They must also be authorized to order the infringer to pay the right holder's expenses. These expenses may include appropriate attorney's fees. In appropriate cases, the courts may be authorized to order recovery of profits and/or payment of pre-established damages even where the infringer acted in good faith.

In order to create an effective deterrent to infringement, Article 46 requires that the judicial authorities must have the authority to order infringing goods to be disposed of outside the channels of commerce; or, where constitutionally possible, destroyed. Similarly, it must be possible to dispose of materials and instruments predominantly used in the production of the infringing goods. In considering such requests, the courts must take into account proportionality between the seriousness of the infringement and the remedies ordered as well as the interests of third parties. In respect of counterfeit trademark goods, it is clarified that the simple removal of the trademark unlawfully affixed shall not be sufficient, other than in exceptional cases, to permit release of the goods into the channels of commerce.

The judicial authorities may be authorized to order the infringer to inform the right holder of the identity of third persons involved in the production and distribution of the infringing goods or services and of their channels of distribution (Article 47). This option is aimed at assisting the right holders to find the source of infringing goods and to take appropriate action against other persons in the distribution channels. This provision must be applied in a way that is in proportion to the seriousness of the infringement.
The section contains certain safeguards against abuse of enforcement procedures. Article 48 provides that the judicial authorities must have the authority to order the applicant who has abused enforcement procedures to pay an adequate compensation to the defendant who has been wrongfully enjoined or restrained to cover both the injury suffered and expenses. Such expenses may include appropriate attorney's fees. Public authorities and officials are exempted from liability to appropriate remedial measures only where actions are taken or intended in good faith in the course of the administration of that law.

Article 49 provides that, to the extent that any civil remedy can be ordered as a result of administrative procedures on the merits of a case, such procedures shall conform to principles equivalent in substance to those set forth in the section.

PROVISIONAL MEASURES 37

Article 41 requires that enforcement procedures must permit effective action against infringements and must include expeditious remedies. As these judicial procedures may take a fair amount of time, it is necessary for the judicial authorities to be empowered to provide provisional relief for the right holder in order to stop an alleged infringement immediately. The provisions on provisional measures are contained in Article 50. It requires each country to ensure that its judicial authorities have the authority to order prompt and effective provisional measures. Such measures must be available in respect of any Intellectual Property Right. Provisional measures have to be available in two situations. One is where they are needed to prevent an infringement from occurring, and to prevent infringing goods from entering into the channels of commerce. This includes preventing imported infringing goods from being dispersed into domestic distribution channels immediately after

37Article 50
customs clearance. The other situation is where such measures are needed to preserve relevant evidence in regard to the alleged infringement.

Effective use of provisional measures may require that action be taken without giving prior notice to the other side. Therefore, the judicial authorities must have the authority to adopt provisional measures in audita altera parte, i.e. without prior hearing of the other side, where appropriate, in particular where any delay is likely to cause irreparable harm to the right holder or where there is a demonstrable risk of evidence being destroyed (Paragraph 2).

The courts may require the applicant to provide any reasonably available adequate evidence that the applicant is the right holder and that the applicant's right is being infringed or that such infringement is imminent (Paragraph 3). The applicant may also be required to supply information necessary for the identification of the goods (Paragraph 5). Where provisional measures have been adopted in audita altera parte, the parties affected must be given notice, without delay after the execution of the measures at the latest. The defendant has a right to review with a view to deciding, within a reasonable period after the notification of the measures, whether these measures shall be modified, revoked or confirmed (Paragraph 4).

The provisions on provisional measures contain certain safeguards against abuse of such measures. The judicial authority may require the applicant to provide a security or equivalent assurance sufficient to protect the defendant and to prevent abuse (Paragraph 3). Provisional measures shall, upon request by the defendant, be revoked or otherwise cease to have effect, if the applicant fails to initiate proceedings leading to a decision on the merits of the case within a reasonable period to be determined by the judicial authority ordering the measures. In the absence of such a determination, this period may not exceed 20 working days or 31 calendar days, whichever is the longer (Paragraph 6). Where the provisional measures are revoked or where they lapse due to any act or omission by the applicant or where it is
subsequently found that there has been no infringement or threat of infringement of an Intellectual Property Right, the judicial authorities shall have the authority to order the applicant to provide the defendant appropriate compensation for any injury caused by these measures (Paragraph 7).

The above principles apply also to administrative procedures to the extent that any provisional measure can be ordered as a result of such procedures (Paragraph 8).

SPECIAL REQUIREMENTS RELATED TO BORDER MEASURES

The TRIPs Agreement contains special requirements on border measures aimed at preventing imports of goods, which bear counterfeit trademarks or represent piracy of copyright material. Counterfeiting and piracy are the most blatant form of infringement of Intellectual Property Rights. The border measures provisions apply, as a minimal international norm to counterfeit trademark and pirated copyright goods. Article 51 of TRIPs obligates Members to adopt procedures under which a right holder may apply in writing to either administrative or judicial authorities to suspend release by the customs authorities of counterfeit trademark and pirated copyright goods. The preferred means of dealing with both is to attack the problem at source, by catching the counterfeiters and pirates where they produce the goods.

However, action to seize goods at the border, using the resources of customs authorities, offers a back-up method of fighting this illegal trade when the products concerned are exported from one country to another. Members may adopt similar procedures for infringement of other Intellectual Property Rights and adopt corresponding procedures concerning the export of infringing goods.

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38 Article 51-60
A right holder wishing to initiate procedures to suspend release of goods by customs authorities is required to provide adequate evidence to make a *prima facie* case showing an infringement of his Intellectual Property Right. A right holder who suspects the counterfeit or pirated goods are about to be imported must apply in writing for action to be taken, giving *prima facie* evidence of infringement and providing enough information for the customs authorities to identify the goods concerned. For their part, the authorities must inform the right holder of their nature of action. The remedies available must not do any harm to the right holder. The measure adopted should not in any manner be used to legitimate trade. If any injury is caused to the right holder, a reasonable compensation is paid to him.

**CRIMINAL PROCEDURES**

Because the profit margins to be realized by producers of trademark counterfeit goods and pirated copyright goods are so enormous, monetary damages are frequently are insufficient to deter such activity. Accordingly, Article 61 of the TRIPs Agreement requires that criminal procedures and penalties must be at least applied to willful trademark counterfeiting and to copyright piracy on a commercial scale. Imprisonment or monetary fines must be consistent with the level of penalties applied for crimes of corresponding gravity and must be applied as a deterrent. The remedies for willful trademark counterfeiting and copyright piracy on a commercial scale must include seizure, forfeiture and destruction of the infringing goods and of the materials and equipment used in their manufacture.

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39 Article 61
Article 62 of the TRIPs Agreement fills a lacuna of the intellectual property framework. Although the existing Conventions in this field did contain rules for facilitation of the acquisition of right in third countries, there were no general rules for their application. Article 62(1) can be considered a **Chapeau** to the whole Article. It says that acquisition rules apply to all rights protected in Sections 2 to 6 of Part II. Copyright and other related rights have been excluded owing to widespread absence of mandatory registration. Undisclosed information has also been excluded due to the variety of the forms of protection that apply to it and also due to absence of registration. As regards other rights, the rules set out in Article 62 apply where reasonable procedures and formalities are required as a condition for the acquisition or maintenance of such rights.

Article 62(2) of the Agreement obliges WTO Members to proceed expeditiously, with grant and registration procedures. While no fixed time is provided, a result oriented benchmark is provided: the procedure should constitute an ‘unwarranted curtailment of the period of protection’. Article 63(3) applies the rules of Article 4 of the Paris Convention (concerning the right of priority) to service marks. In other words, the other provisions of the Paris Convention relating to rights acquisition and maintenance do not apply to service marks. Article 62(4) establishes important principles that apply to all acquisition, maintenance, revocation, opposition and cancellation. All such procedures must be fair and equitable, not necessarily complicated or costly or entail unreasonable time limits or unwarranted delays. All administrative decisions are subject to review by judicial or quasi-judicial authority.

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40Part IV, Article 62,63 of the Agreement
The Agreement begins to assure compliance by requiring transparency. This obligation has the potential to require Members to conform a rule-based system of intellectual property. The Agreement requires the publication of all laws, regulations, final judicial decision and administrative rulings of general application. If publications are not practicable, they must be made publicly available. While notifying the obligation the Members must communicate all information in accordance with Article 6 of the Paris Convention. The Agreement directs WTO Members to be prepared to supply laws, regulations, final judicial decisions and administrative rulings of general application and bilateral Agreements to other Members upon written request and to be given access to other Members to specific judicial decisions, administrative rulings or bilateral Agreements. The Agreement further allows WTO Members to protect confidential information when disclosure could impede law enforcement or otherwise be contrary to the public interest or would prejudice the legitimate commercial interests of specific enterprises, whether public or private.

The provisions of the TRIPs Agreement as such cannot be the direct and sole basis of a claim by a private party, that is, it has not been conceived as a self-executing instrument. An action which charges non-compliance with the rules of the TRIPs Agreement can only be taken by other WTO Members and not by individuals or firms.

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41Part V, Article 64 of the Agreement
Non-compliance with the new rules, once adopted, would give rise to a dispute settlement procedure under the WTO rules and, possibly, to retaliatory commercial measures in any field (not only in IPRs) by the country whose nationals are affected by such non-compliance. Since, within the WTO, adherence to the new IPRs universal standards will be monitored by the Council for TRIPs, the possibility of deviations from those standards is drastically reduced, unless a non-complying country is prepared to bear the costs of any trade restrictions that may be imposed.

The new WTO "Understanding on Rules and Procedures Governing the Settlement of Disputes" provides a limited time frame and considerable automaticity for the settlement of disputes. It creates a Dispute Settlement Body (DSB) composed of all WTO Members and stipulates a 'negative consensus' rule for the establishment of Panels, the adoption of their reports and the authorization of retaliatory measures. Such a rule means that the Panel process will be instituted if at least one country favours this course.

The adoption of this understanding also means that unilateral actions, such as action under Section 301 of the US Trade Act, cannot be imposed before the DSB has verified the existence of a case of non-compliance and authorized retaliatory action. Any unilateral action taken before or outside such a procedure would be illegal under the WTO Agreement. Precisely, Article 64 of the TRIPs Agreement makes it clear that disputes arising under the Agreement on TRIPs are to be settled under the terms of the WTO Dispute Settlement Understanding. However, as in the case of disputes involving trade in goods or service, it is only when a dispute reaches the stage of formal consultations, at which a subsequent request for a Panel is clearly likely, that it moves beyond the area of responsibility of the specialized Council concerned which in the case of TRIPs is the Council of TRIPs.

As regards, the new dispute settlement system, the principal provisions relating to the settlement of disputes is summarized in the following table:
### TABLE 3

**THE PRINCIPLES RELATING TO THE SETTLEMENT OF DISPUTES**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>CONSULTATIONS</td>
<td>(role of the Director-General’s good offices and mediation)</td>
</tr>
<tr>
<td>(60 DAYS)</td>
<td></td>
</tr>
<tr>
<td>ESTABLISHMENT OF PANEL</td>
<td>(by Secretariat-composed of 3 to 5 members)</td>
</tr>
<tr>
<td>PANEL ENQUIRY</td>
<td>(hearings and written submissions)</td>
</tr>
<tr>
<td>(6-9 MONTHS)</td>
<td></td>
</tr>
<tr>
<td>PANEL REPORT</td>
<td>(to parties and Dispute Settlement Body (DSB))</td>
</tr>
<tr>
<td>IF NO APPEAL</td>
<td>IF APPEAL</td>
</tr>
<tr>
<td>(20-60 days)</td>
<td>(60-90 days)</td>
</tr>
<tr>
<td>ADOPTION BY DSB</td>
<td></td>
</tr>
<tr>
<td>INDICATION OF INTENTIONS BY MEMBERS CONCERNED</td>
<td></td>
</tr>
<tr>
<td>NEGOTIATION OF INTENTIONS BY MEMBERS CONCERNED</td>
<td></td>
</tr>
<tr>
<td>POSSIBLE SUSPENSION OF CONCESSIONS BY DSB (if no compensation agreed)</td>
<td></td>
</tr>
<tr>
<td>IF NO</td>
<td>IF</td>
</tr>
<tr>
<td>ARBITRATION</td>
<td>ARBITRATION</td>
</tr>
<tr>
<td>(30 days from)</td>
<td>(60 days from)</td>
</tr>
</tbody>
</table>
The following table lists the disputes in which Panel or Appellate Body Reports have been adopted where the provisions of the TRIP were invoked:

**TABLE 4**

<table>
<thead>
<tr>
<th>S. NO.</th>
<th>CASE NAME</th>
<th>CASE NUMBER</th>
<th>INVOKED ARTICLES</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>India-Patents (US)</td>
<td>WT/DS 50</td>
<td>Articles 27, 63, 70.8 and 70.9</td>
</tr>
<tr>
<td>2.</td>
<td>Indonesia-Autos</td>
<td>WT/DS 54</td>
<td>Articles 3, 20, 65</td>
</tr>
<tr>
<td>3.</td>
<td>Canada-Pharmaceutical Patents</td>
<td>WT/DS 114</td>
<td>Articles 27, 30, 33, 70</td>
</tr>
<tr>
<td>4.</td>
<td>US-Section 110(5) Copyright Act</td>
<td>WT/DS 160</td>
<td>Articles 9.1 and 13</td>
</tr>
<tr>
<td>5.</td>
<td>India-Patents (EC)</td>
<td>WT/DS 79</td>
<td>Articles 70.8(a) and 70.9</td>
</tr>
<tr>
<td>6.</td>
<td>Canada-Patent Term</td>
<td>WT/D 170</td>
<td>Articles 33, 62.1, 62.4, 65, 70.1 and 70.2</td>
</tr>
</tbody>
</table>
TRANSITIONAL ARRANGEMENTS

Part VI of the Agreement lays down transitional arrangements, in particular as regards the obligation to apply the provisions of the Agreement. The deadlines for implementation are to be counted from the date of entry into force of the Agreement. The length of the period granted to ensure compliance depends on the level of development of Members as recognized by the United Nations.

Developed countries must comply with all the Agreement provisions within one year, i.e. by 1 January 1996. All Members, including those availing themselves of longer transitional periods, must comply with the provisions concerning "National Treatment" and the "MFN" commitment.

Developing countries are required to bring legislation and practices in conformity within a transitional period of five years, i.e. by 1 January 2000; and in some cases of product patents, they are given a further period of five years. Countries in the process of transition from a centrally-planned to a market economy are given the same privileges as to terms of implementation as developing countries, provided they are planning a structural reform of their IP system and encounter special problems in the preparation and implementation of the latter within domestic law.

In view of their special needs and requirements and the various obstacles that might deter rapid implementation, least developed country Members are given a transitional period of eleven years, i.e. by 1 January 2006. This transitional period is subject to a possibility of extension upon duly motivated request. Countries availing themselves of a transitional period are compelled, since entry into force of the Agreement, to comply with the so-called "non-backsliding" clause and the "mail-box" provision. As to the former, during the period of transition, Members are not allowed to reduce the level of

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Part VI (Articles 65-67)
protection of IP to a level below that which is provided by the Agreement. As to the latter principle, developing country Members which do not provide for patent protection for pharmaceutical and agricultural chemical products at the date of entry into force of the WTO Agreement are compelled to accept the filing of patent applications for such products as from that date.

INSTITUTIONAL ARRANGEMENTS

COUNCIL OF TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS

The Council for TRIPs has been established to monitor the operation of the TRIPs Agreement. The TRIPs Council while doing its function may seek assistance and information from any source it deems appropriate. The Council is also obliged to give assistance to the Members in the context of dispute settlement procedures. The Council works only on a consensus basis and the issues on which consensus cannot be reached shall be sent to the WTO General Council. The Council has provided certain international institutes i.e., FAO, IMF, UPOV, OECD, UN, UNCTAD, WIPO, etc. as the observer status. The Council has also conferred ad-hoc observer status to WHO.

INTERNATIONAL CO-OPERATION

The TRIPs Agreement stresses the importance of the exchange of information on infringing goods, particularly as regards professional infringes. The Agreement expressly mentions the exchange of information between customs authorities with regard to stoppage of trade in counterfeit trademark goods and pirated copyright goods.

49Part VIII (Articles 68-73) of the Agreement
CONTROVERSIES IN TRIPs

Since TRIPs came into force it has received a growing level of criticism from developing countries, academics, and non-governmental organizations. Some of this criticism is against the WTO as a whole, but many advocates of trade liberalization also regard TRIPs as bad policy. TRIPs' wealth redistribution effects (moving money from people in developing countries to copyright and patent owners in developed countries) and its imposition of artificial scarcity on the citizens of countries that would otherwise have had weaker intellectual property laws are a common basis for such criticisms.

ACCESS TO ESSENTIAL MEDICINES

The most visible conflict has been over drugs for AIDS in Africa. Despite the role which patents have played in maintaining higher drug costs for public health programmes across Africa, this controversy has not led to a revision of TRIPs. Instead, an interpretive statement, the Doha Declaration, was issued in November 2001, which indicated that TRIPs should not prevent states from dealing with public health crises. After Doha, the United States and to a lesser extent other developed nations began working to minimize the effect of the declaration.

A 2003 Agreement loosened the domestic market requirement, and allows developing countries to export to other countries where there is a national health problem as long as drugs exported are not part of a commercial or industrial policy. Drugs exported under such a regime may be packaged or coloured differently to prevent them from prejudicing markets in the developed world.

In 2003, the Bush Administration also changed its position, concluding that generic treatments might in fact be a component of an effective strategy
to combat HIV. Bush created the President's Emergency Plan for AIDS Relief Programme (PEPFAR), which received $15 billion from 2003-2007, and was reauthorized in 2007 for $30 billion over the next five years. Despite wavering on the issue of compulsory licensing, PEPFAR began to distribute generic drugs in 2004-2005.

SOFTWARE AND BUSINESS METHOD PATENTS UNDER TRIPs AGREEMENT

Another controversy has been over the TRIPs Article 27 requirements for patentability "in all fields of technology", and whether or not this necessitates the granting of software and business method patents.

EMERGING ISSUES

Just as Intellectual Property Rights vary on functional grounds, their importance differs greatly among economic sectors. In order to understand the sources of pressure for change in global protection it is useful to discuss the dependence of critical sectors on various forms of Intellectual Property Rights. Most of the emerging issues that led to the criticism of the Agreement are related with the relationship between the developed and developing countries. These issues are fundamentally affecting the pace of globalization and need to be urgently addressed.

TRIPs AND BIODIVERSITY

The issue arises from the interaction between International Environmental Law with respect of biodiversity and Intellectual Property Law. One aspect of this issue that is not yet explicitly addressed by international legal rules is the use for patentable technology that exploits genetic resources found in the nature in developing countries. There is a concern that, these
The provision of the UN Convention on Biological Diversity 1992 (CBD) on Intellectual Property Rights have been subject to heated debate both at WTO and the Conference of the Parties to the Convention. The main reason for becoming the issue so critical is that TRIPs Agreement classifies micro-organisms, micro-biological and non-biological processes as patentable but lacks clear provisions on bio-piracy. This has led to wide scale piracy of genetic wealth from developing countries. As a result of this rampant piracy, the developing countries are asking for the harmonization of TRIPs Agreement with provisions of Convention on Biological Diversity. The developed countries like EU and US are opposing vehemently to this demand.

TRIPs AND TRANSFER OF TECHNOLOGY

Like Bio Diversity Convention and its relationship with TRIPs, the issue of transfer of efficient and sustainable technology transfer to technology

44See Environment and TRIPs WT/CTE/W/8, paras 76-8
deficient countries is a hot and debatable issue at the WTO level. The developing and LDCs are quite vocal on the issue of transfer of technology from multinational corporations of developed countries to developing countries. The developed countries are very reluctant in transferring their technologies to the less advanced countries, as they do not want to end their monopoly, which they command due to their superior technology. The TRIPs Agreement provides for the transfer of technology to help the developing countries. Articles 7 and 8.2 of the Agreement clearly provides for the transfer of technology to the less developed countries.

However, even after having explicitly mentioning TRIPs Agreement about the transfer of technology, this is still far from becoming a reality. The reason for this difficulty is that the relevant WTO provisions are voluntary and in the spirit of best endeavour. The developed countries under the WTO Agreement are not bound by any statutory obligation to transfer technology to the developing countries. North-South technology transfer still remains an unrealized objective. The developing country industry is now calling for technology access and not Market Access through WTO.

**TRIPs AND UNILATERAL ACTION**

The continuing use by the United States of unilateral trade action, particularly under Sections 301, to deal with complaints about inadequate protection of Intellectual Property Rights in developing countries in some instances simultaneously with the pursuit of dispute settlement in the WTO is one issue which has wide consequences and need to be addressed. It is arguable that, even if unilateral action does not violate any specific provision of the GATT or the TRIPs Agreement, it may be in contravention of Article 23 of the DSU. This would seem to preclude unilateral action without reference to WTO dispute settlement, where the subject matter is covered by the TRIPs Agreement.
IMPLEMENTATION IN DEVELOPING COUNTRIES

The obligations under TRIPs apply equally to all Member States, however developing countries were allowed extra time to implement the applicable changes to their national laws, in two tiers of transition according to their level of development. The transitional period for developing countries expired in 2005. The transitional period for least developed countries was extended to 2016, and could be extended beyond that.

Developing countries are massive net-exporters of copyright, patent- and trademark-related royalties. It has therefore been argued that, the TRIPS standard of requiring all countries to create strict intellectual property systems will be detrimental to poorer countries' development. Many argue that it is, prima facie, in the strategic interest of most if not all underdeveloped nations to use any flexibility available in TRIPs to write the weakest IP laws possible.

This has not happened in most cases. A 2005 Report by the WHO found that, many developing countries have not incorporated TRIPs flexibilities (compulsory licensing, parallel importation, limits on data protection, use of broad research and other exceptions to patentability, etc) into their legislation to the extent authorized under Doha.

This is likely caused by the lack of legal and technical expertise needed to draft legislation that implements flexibilities, which has often led to developing countries directly copying developed country IP legislation, or relying on technical assistance from the World Intellectual Property Organization (WIPO), which, some say, encourages them to implement stronger intellectual property monopolies.
POST-TRIPs EXPANSIONISM

The requirements of TRIPs are, from a policy perspective, extremely stringent. Despite this, lobbyists for the industries that benefit from various intellectual property laws have continued since 1994 to campaign to strengthen existing forms of intellectual property and to create new kinds:

• The creation of anti-circumvention laws to protect Digital Rights Management Systems. This was achieved through the 1996 World Intellectual Property Organization Copyright Treaty (WIPO Treaty) and the WIPO Performances and Phonograms Treaty.
• The desire to further restrict the possibility of compulsory licences for patents has led to provisions in recent bilateral US trade Agreements.
• It is one thing for states to have intellectual property laws on their statutes, and another for Governments to enforce them aggressively. This distinction has led to provisions in bilateral Agreements, as well as proposals for WIPO and European Union rules on intellectual property enforcement. The 2001 EU Copyright Directive was to implement the 1996 WIPO Copyright Treaty.
• The wording of TRIPs 27 of non-discrimination is used to justify an extension of the patent system.
• The campaign for the creation of a WIPO Broadcasting Treaty that would give broadcasters (and possibly web casters) exclusive rights over the copies of works they have distributed.

CONCLUSION

Under the Agreement on Trade-Related Intellectual Property Rights which was negotiated during the Uruguay Round states have committed themselves to enshrining in national law minimum standards for each area of Intellectual Property Rights. These minimum standards are those laid down under various international Conventions plus a number of other obligations to
increase the protection given. In essence the TRIPs Agreement aims to bring Intellectual Property Rights protection standards in developing countries up to the standard and pattern established in the advanced industrial countries. Furthermore, in order to enable the holders of Intellectual Property Rights to enforce protection, complaints procedures and remedies must also be enshrined in national law.

The implementation of the Agreement will introduce major changes in the way that developing countries deal with intellectual property matters. It drastically limits the freedom of countries to shape their intellectual property systems in accordance with national objectives and degrees of development. Nevertheless, as a legal text, the TRIPs Agreement contains many ambiguities and loose definitions which leave scope for differing interpretations to be incorporated in national legislation. Moreover, there are other aspects of the Agreement which also provide scope for determining the content of national legislation as follows:

First, developing and least developed countries have been granted transitional periods of 4 and 10 years respectively, in which to incorporate and adapt to the new standards and procedures, a further delay of five years is also granted with respect to the introduction of product patents. However, this additional leeway may be more apparent than real in the important fields of pharmaceutical and agricultural chemical products due to the fact that a TRIPs clause allows product and process patent protection from the date of filing an application, which may be shortly after the date of entry into force of the WTO Agreement.

Secondly, developing countries can develop and apply effective compulsory licensing systems in order to ensure a reasonable degree of competition and to ensure that medicines and other essential goods and services are available to the population. However, there are specified conditions to be filled which once again may limit the extent to which resort can be made to compulsory licensing.
Thirdly, the international exhaustion of rights and other exceptions to exclusive rights can be established in order to prevent the accumulation of excessive market power by certain entrepreneurs and to promote research and development in developing countries.

Finally, in particular areas developing countries may provide for specific solutions or design appropriate approaches. For example, nothing in the TRIPs Agreement excludes legitimate reverse engineering of semiconductors and software, a crucial means of generating competition and encouraging innovation. *Sui generis* regimes of protection rather than patent protection may be developed for plant varieties, ensuring farmers' rights to re-use seeds and ensuring the availability of protected varieties for the purposes of breeding new varieties.

In drafting national legislation, developing countries and LDCs should need to make full use of available legal skills and resources in order to minimize the potential economic and social costs of the reinforced and expanded protection of intellectual property they have to introduce, designing and executing national policies for promoting competition, local innovation and production and widespread access to essential goods. In reformulating their IPRs systems in a manner compatible with their own conditions and needs, developing countries would benefit from consultation and co-operation among themselves to develop and subsequently implement model laws. They could also collaborate on the training of public officials on these matters.

Such co-operation could also extend to considering the development of regional approaches to implementing TRIPs legislation as well as to complementary legislation with respect to appropriate competition policies. They might also consider formulating common strategies to support the adaptation of industries adversely affected by the new IPRs regime.
It is important to appreciate that, the rules regarding the protection of intellectual property not only influence matters related to cross-border trade but will also have a direct bearing on the framework affecting foreign direct investment and innovation. From the point of view of the pace and content of development in the South, the TRIPs Agreement leaves much to be desired. At a general level, one can question whether an Agreement which strengthens Intellectual Property Rights in the manner prescribed by the TRIPs Agreement is the most effective means of encouraging invention, technological innovation and development of a national production capacity in developing countries. They claim that, TRIPs will encourage foreign investment is also questionable. But, as argued elsewhere by the South Centre, developing countries need to be vigilant concerning the level and content of FDI entering their economies.

Developing countries individually and as a group will therefore need to monitor their experience in the implementation of the Agreement very carefully to assess the impact on the transfer of technology, on national efforts to promote technological adaptation and innovation and on the development of a national production capacity.

If developing countries are to avoid the profound North-South imbalance in negotiating positions manifested in the TRIPs negotiations during the Uruguay Round, and if they are to make an effective contribution to the pending reviews of the TRIPs Agreement, they will need to put forward joint views on the revisions needed in TRIPs in order to promote their own socio-economic developmental interests. Similarly, developing countries would also benefit from establishing a common strategy and co-ordinating their action at the Council for TRIPs and other bodies of the WTO dealing with IPRs.

Whether increased protection for intellectual property will generate a higher rate of transfer of technology to developing countries through licensing or through foreign direct investment or whether it will limit the diffusion of
technology and innovation in developing countries is yet to be seen. There is a possibility that, in a globalize economy, with low tariff barriers for manufactured products, the current changes in the intellectual property system could encourage the concentration of innovation and production in industrialized countries, the innovations being disseminated largely through trade, i.e. already incorporated in products and services. These are important matters affecting the balance of North-South relations and as such merit careful study and discussion in institutions within the United Nations system, such as UNCTAD.
SECTION B

INDIAN INTELLECTUAL PROPERTY RIGHTS

INTRODUCTION

India has a long history of patent policy which was defined after enormous study. But India’s approach to patents differs from those of industrialized countries in that India sees patents as a tool of public policy. India’s policy is being challenged by the demand to reform IPR laws to conform to TRIPs.

INDIA’S PATENT POLICY PRE-TRIPs

India’s patent policy focused on balancing developmental concerns with the need for promoting innovations. India viewed patents as a tool for economic development and restricted the scope and term of patents. The sentiment in India on the issue of patents, especially on pharmaceuticals, is illustrated by an oft-quoted statement made by Indira Gandhi at the World Health Assembly in 1982: “The idea of a better-ordered world is one in which medical discoveries will be free of patents and there will be no profiteering from life and death”. Unfortunately, she had not foreseen the Treaty like TRIPs in the world arena and Indian Patents Amendment Act, 2005 in India.

Patent policy has a long history in India, dating back to 1856, but the actual attention of policymakers towards patents began right after Independence. Two expert committees were established in independent India to study patents and provide suggestions on the type of patent system that India should implement. These committees conducted an extensive survey of patents in India. The Patent Enquiry Committee (1948-50) reported that, “the Indian patent system has failed in its main purpose, namely to stimulate inventions among Indians and to encourage the development and exploitation
of new inventions for industrial purposes in the country so as to secure the benefits thereof to the largest section of the public." The second committee known as the Ayyangar Committee (1957-59) noted that foreign patentees were acquiring patents not "in the interests of the economy of the country granting the patent or with a view to manufacture there but with the object of protecting an export market from competition from rival manufacturers particularly those in other parts of the world". Thus India is deprived of getting, in many cases, goods at cheaper prices from alternative sources because of the patent protection granted in India. The reports concluded that, foreigners held 80-90% of the patents in India and were exploiting the system to achieve monopolistic control of the market. The committees therefore suggested that, a patent system that focused on access to resources at lower prices would be beneficial to India. This was in tune with the science and technology mission of developing indigenous technology and fostering R&D activities in areas of national significance.

The Patent Act of 1970, the current legislation on patents in India, was based on the recommendations of these committees. The main aim in India was to ensure that, patents did not lead to monopoly by foreign companies nor lead to high prices for medicines and food items. The Patent Law of 1970 (the current law) restricts the field of patentability, only grants process and not product patents in food, pharmaceutical and chemical fields, restricts the term of patents and has an elaborate system of licences to ensure that patents are worked in India. The act found support among domestic firms and various political parties in India.

THE INDIAN PATENTS ACT, 1970

The Indian Patents Act has been hailed as model legislation for developing countries. It seeks to balance both the need for granting rewards for inventors while ensuring that India's developmental needs are not ignored. The following essential features of the Act reveal the basic patents policy of India:
1. **General Principle of Patent Grant** -
(a) that patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without under delay; and

(b) that they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article.

2. **Principle of National Treatment** - no limitations or restrictions on foreigners in applying for or obtaining patents in India.

3. **Inventions Not Patentable** - The following are not patentable:
(a) An invention which is frivolous or which claims anything obviously contrary to will established natural laws;

(b) An invention, which is primary or intended use of which would be contrary to law or morality or injurious to public health;

(c) The mere discovery of a scientific principle or the formulation of an abstract theory;

(d) The mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant;

(e) A substance obtained by a mere admixture resulting only in aggregation of the properties of the compounds thereof or a process for producing such substance;
(f) The mere arrangement or re-arrangement or duplication of known devices, each functioning independently of one another in a known way;

(g) A method or process of testing applicable during the process of manufacture for rendering the machine, apparatus, or other equipment more efficient or for the improvement or control of manufacture;

(h) A method of agriculture or horticulture;

(i) Any process for the medicinal, surgical, curative, prophylactic or other treatment of human beings or any process for a similar treatment of animals or plants to render them free of disease or to increase their economic value or that of their products.

4. Search for Novelty - compulsory search is required extending to prior publications not only in India but also in any other part of the world.

5. Patentability of Inventions in the Area of Chemicals, Food and Drugs - In case of inventions relating to substances intended for use as food, drug or medicines or substances produced by chemical process, patentability will be limited to claims for the methods or processes of manufacture only.

6. Term of Patent - The term of the patent in 14 years from the date of patenting, i.e., the date of filing the complete specification. In the case of inventions in the field of food, drug or medicine, the term will be 7 years from the date of filing or 5 years from the date of sealing, whichever is shorter.

7. Licensing Provisions - 2 types of licences: compulsory licences and licence of rights. Compulsory licences enabling another party to work the patent can be applied for any time after the expiry of three years from the date of sealing of the patent. In the area of food, drug, medicine or chemical, after the expiry of three years from the date of patent grant, they shall be endorsed
with the word "Licence of Right". These enable any interested person as a matter of right to be entitled to work such patents.

8. Royalties - In the case of patents related to food, drug or medicines, the royalty reserved to the patentee under a licence shall not exceed 4% of the net ex-factory sale price in bulk of the patented article.

9. Use of Patented Inventions by the Government - In order to ensure that scarcity of a patented article doesn't arise and lead to high prices, the Government is vested with powers to make use of or exercise any patented invention merely for its own purpose.

10. Appeals - In all cases, appeals will be only with the High Court.

INDIA'S PATENT POLICY AND TRIPs

The philosophy of India's Patents Act of 1970 varies enormously from the framework being established under TRIPs. There are several knowledge and areas of information, which India considers un-patentable. India has a large community of scientists and researchers among whom publication rather than gaining patents has been a concern. G.V. Ramakrishna, Chairman of the Disinvestment Commission, points out that in India, "We (Indians) are accustomed to the notion that knowledge is free. Our whole orientation has to change from one that stresses intellectual attainment to one that protects intellectual property." Industrialized nations conceive of patents as a Fundamental Right comparable to the right of physical property, whereas developing nations view it as fundamentally as an economic policy question. From the perspective of developed countries, intellectual property is a private right that should be protected as any other tangible property, but for developing nations, intellectual property is a public good that should be used to promote economic development. The following table illustrates the basic differences between India's patent system and TRIPs:
### TABLE 5

**COMPARISON OF INDIA’S PATENT ACT AND TRIPs**

<table>
<thead>
<tr>
<th><strong>INDIAN PATENT ACT OF 1970</strong></th>
<th><strong>TRIPs</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Only process not product patents in food, medicines, chemicals</td>
<td>Process and product patents in almost all fields of technology</td>
</tr>
<tr>
<td>Term of patents 14 years; 5-7 in chemicals, drugs</td>
<td>Term of patents 20 years</td>
</tr>
<tr>
<td>Compulsory licensing and licence of right</td>
<td>Limited compulsory licensing, no licence of right</td>
</tr>
<tr>
<td>Several areas excluded from patents (method of agriculture, any process for medicinal surgical or other treatment of humans, or similar treatment of animals and plants to render them free of disease or increase economic value of products)</td>
<td>Almost all fields of technology patentable. Only area conclusively excluded from patentability is plant varieties; debate regarding some areas in agriculture and biotechnology</td>
</tr>
<tr>
<td>Government allowed to use patented invention to prevent scarcity</td>
<td>Very limited scope for Governments to use patented inventions</td>
</tr>
</tbody>
</table>


These differences in patent systems led to disputes in the GATT negotiations on the inclusion of IPRs in the WTO. The type of patent system that India established was clearly against the global IP regime promoted by the US. The main objection of the US is to the provision in India’s patent law that allows for process but not product patents in the area of food, drug or medicine. The United States terms the activities of India to find alternative processes as “piracy”. According to the US, Indian firms are copying technology developed by advanced nations. This is leading to large-scale...
losses for the US. The Pharmaceutical industry in the US has been especially vocal on this issue. Pharma, the association that represents US based pharmaceutical companies points out, "Based on the refusal of the Government to provide pharmaceutical patent protection, India has become a haven for bulk pharmaceutical manufacturers who pirate the intellectual property of the world’s research-based pharmaceutical industry."

INDIA’S NEGOTIATIONS ON TRIPs

India’s negotiating position within TRIPs and its policy on patents have undergone enormous shifts. India was one of the most vocal opponents of TRIPs and there was strong domestic support for India’s restricted system of patents for decades. Recently, India has revised its patent policy to conform to TRIPs and agreed to include IPR in the WTO. External trade threats were one of the factors that promoted this change, but the policy shift took place only with changes among actors within India. An interplay of domestic and international factors influence India’s ability to promote its interests in international negotiations. In order to formulate strategies for the future, it is important to analyze the role of these factors in prior negotiations.

OPPOSING IPRs IN GATT

India and Brazil played a key role in the initial stages in preventing the inclusion of IPRs in GATT. The United States had attempted to promote the inclusion of Intellectual Property Rights through a proposal for an anti-counterfeiting code within the GATT Framework Right from 1982. India along with Brazil was able to counter this move to some extent by arguing that GATT’s jurisdiction was limited to tangible goods and that GATT lacked the legal competence to address an issue within the IP area. They contended that, counterfeit goods belonged to the exclusive jurisdiction of WIPO. Although in 1988, India and Brazil could not prevent the inclusion of IPRs in the Ministerial Declaration, until 1988 they could ensure that no substantive IPRs were part of GATT.
Several developing countries argued vehemently that, not only were counterfeit trademarked goods beyond the GATT's authority, but also GATT could not extend itself to issues regarding copyrights and patents because these protections covered intangible objects. Brazil submitted a proposal on behalf of nine other countries including India for the new round of negotiations specifically excluding IPRs and Services. Their inability to prevent the inclusion of IPRs in the Ministerial Declaration arose from the fact, the US and Japan began promoting IPRs even more strongly and the US. In 1985 US first initiated action against Korea, and according to one author, one objective of this was to separate Korea from joining developing country opposition to the GATT initiative on IPRs. In addition as recounted by Jayashree Watal, a negotiator for India, the 25 hardliner developing countries shrank to 10. Developing nations agreed to the Ministerial Declaration with the expectation that they could limit negotiations to trade in counterfeit goods and other trade-related aspects.

But right until 1988, India and other developing countries were able to prevent a major role for IPRs in GATT. India, Brazil and other developing nations continued to assert that only trade in counterfeit goods should be the focus of discussions in the GATT meetings in 1987 and 1988. Right up till this mid-term meeting, India and Brazil were the leading opponents against negotiation of substantive aspects of IPRs. In fact, India and Brazil were key actors in blocking an Agreement on discussing substantive Intellectual Property Rights at the Mid-Term Meeting. Muchkund Dubey, a member of the Indian Delegation during these meetings, explained the stance of India and developing nations in the following manner, "During the initial years India played a leading role in resisting the move to launch the new round and withstanding Northern pressure. The tenuous unity of the developing countries was maintained almost until the end of the mid-term review in Montreal in December 1988. India until the last days of the resumed mid-term review session firmly adhered to the position that GATT wasn't the forum to discuss norms and standards of IPR protection nor could higher level of IPR be part of a liberal multilateral trading system."
It is important to understand how developing countries were able to some extent to assert their interests in these years. One factor was the unity among developing countries at this time. Another important factor that one must focus on is that in India's case there was a strong domestic constituency that supported India's Patent Act of 1970. Indian Industry to a great extent wanted to retain the essential features of India's Patent Act and even opposed India joining the Paris Convention in spite of trade pressure. India resisted attempts in the 80's by the US to place pressure on India to join the Paris Convention and industry bodies were of the view that India should not join the Convention. In 1986 India debated the option of joining the Paris Convention.

At this time, reportedly IDMA (Indian Drug Manufacturers Association) played an important role in pointing out the negative impact of the Convention on India. In 1988 a reference to India joining the Paris Convention provoked reactions in Parliament on the negative implications for industrial development if India became a party to the treaty. The stance of industry bodies was also made clear in Parliament when the Minister of State for Industrial Development pointed out that FICCI (Federation of Indian Chambers of Commerce and Industry), the most influential representative of Indian industry at the time, had taken the position in 1986 that India should not join the Paris Convention. ASSOCHAM (Associated Chambers of Commerce and Industry), another industry body in India, however, took the view in 1986 that India should join the Paris Convention reflecting internal changes that took place within ASSOCHAM. In 1986, ASSOCHAM underwent enormous transformations from being a representative not only of industry but also trade interests and opened itself up for the first time to overseas membership. The beginning of such fissures to some extent could explain a weakening of India's position in 1988.

**SHIFT IN INDIA'S NEGOTIATING POSITION**

In 1989 India made a surprising move gave up its opposition to including IPRs in the negotiations. On April meeting in Geneva in 1989, India
made a shift in policy and agreed to include IPRs in the negotiations. India's about turn on the issues was due largely in part to pressure from the US. Analysts have drawn linkages between the threat of US Special 301 law against India and India's charge of stance on the issue in GATT. At the time when India made the switch over, the Times of India reported that, "India reportedly decided against taking a firm stands on issue lest the United States invoked Article 301 to retaliate." In one of the article of the Economic and Political weekly, it is written that, India compromised its position on IPR in the hope that it would case the direct US pressure on which India food being designated "unfair trader" in the Super 301 process. Eric Wolfhard said, in retrospect India's April accession seems merely strategic. Elaborating on the reasons for India's change of position he points out that, at the time India was a victim of a series of unilateral measures introduced by the US to deal with some of the major developing countries. He also notes that, India required support from US to borrow from IMF and World Bank to meet the depleting foreign exchange crises caused during the Gulf War.

Trade pressure through Special 301 is an important factor that explained India's shift in position. US trade pressure also led to divisions within developing countries. Several related explanations have also been forwarded as reasons for India's change in position. Ms. Jayashree Watal, who was part of the negotiating team for India in TRIPs, explained that at the time the U.S. questioned India's needs to block the negotiations. The US position was that India could object to any aspect of the Treaty, but did not need to refuse discussing the issue of IPRs altogether. This appeared at the time to be rational to Indian leaders. She explained that, India was isolated during the negotiations and had to agree to the discussions. Muchkund Dubey stated, "Unity collapsed at the resumed mid-term review of negotiations in Geneva in April 1989." Developing countries also believed that they could get concessions in other fields such as textiles. As the Uruguay Round included an entire host of issues such as Services, Agriculture and many others, developing nations were hard pressed to negotiate strongly on all aspects, and could not ignore an Agreement that covered such extensive aspects.
India and other developing nations also felt multilateral forum may be better than dealing bilaterally with the U.S.

It is important to note that divisions domestically also began at this time. Watal also points out that, business interests within India became sharply divided, with industry associations dominated by MNCs demanding Amendments in India's patent laws and others rejecting any suggestion of India even joining the Paris Convention. The shift was perceived in India as "surrender" to US interests. Domestic criticism within India was sharp against this policy change on the part of India.

DOMESTIC OPPOSITION TO CHANGE

Though there was shift in India's negotiations globally, there was no change in India's domestic policy on patents. This opposition existed in spite of trade pressure. The Government tried to pacify domestic criticism by asserting that only certain aspects of IPRs would be focused upon and that there wasn't a change in India's position. Dinesh Singh, then Minister of Commerce, explained in the debate on the issue in Parliament, "Our stand has been that only the trade related aspect should be discussed and that position has been maintained by India. A discussion in the Uruguay Round does not commit us to anything. There has not been a shift in our position, but there has been a shift in the negotiating stand." In order to explain its stance on the Uruguay Round negotiations, the Indian Government took the position that, talks in Uruguay would be listed to "trade-related Intellectual Property Right" which comprises only the restrictive and anti-competitive practices of the Intellectual Property Rights.

In spite of India's turn around in GATT India attempted to ensure that there would only be a narrow focus on IPRs. India was the first developing country to submit views on each of the substantive issues and in this document attempted to stress that only trade related aspects would be discussed. It emphasized that only restrictive and anti-competitive practices
could be considered trade related. The submission expressed the view that only those practices that distorted international trade should be the subject to negotiation. India emphasized the need for more favourable treatment for developing countries in the area of patents and trademarks; and proposed that such countries should remain free to adapt their domestic legislation to their economic development and public interest needs. India also argued that concepts such as Most Favoured Nation and National Treatment could not apply to intellectual property because these concepts were applicable to goods rather than the right of persons, rights that the Intellectual Property Conventions protect. Submissions were made by several other developing and developed countries, resulting in numerous proposals by the end of 1989. Developing nations were able to gain one concession at this time as consensus was reached that less developed countries should be allowed time to make transitions to conform to TRIPs.

In spite of bilateral and multilateral trade pressure, India did not revise its patent laws according to TRIPs from 1994-1998 due to opposition from actors that benefited from the existing patent structure. The Government, under external pressure and the force of actors that favoured change, attempted to pass legislation at this time to raise patent protection in India in the form of a Patent Amendment Bill in 1994-95. However, this move failed due to the enormous resistance that emerged against patent reform. Domestic industry in India began to mobilize to counter India's policy shift in global negotiations on IPRs. Pharmaceutical companies and other interests established an organization to lobby the Government against changing patent laws. In 1988, the National Working Group on Patent Laws was established in India. Composed of experts from science, law and health industries, the lobby was supported by certain industry groups and was influential at the governmental level in fostering resistance against change. It effectively pointed out the implications of raising patent standards on drug prices, health care and domestic industrial development. India therefore conformed to US trade pressure in terms of negotiating on IPR in GATT, but there was no major domestic constituency that favoured change at this time.
DOMESTIC POLICY CHANGE

A domestic policy shift enabled India to revise its patent laws in 1998-99. The change occurred on various levels. Firstly, the impact of liberal ideas regarding economic reforms slowly led to a greater westernized notion of Intellectual Property Rights on the part of political parties and industry groups. With the initiation of economic liberalization in 1991, sections of the Congress Party began favouring changes in patent laws. The BJP after coming to power in 1998 abandoned its opposition to patent reform and adopted a pro-patent position. Although opposition to reform existed within both the parties, the BJP and the Congress eventually ensured the dominance of groups within their parties and affiliations that favoured change on patents. Closely related to this pro-reform element with political parties was the rise of a more “modern” and professionally managed segment of industry in India. The gradual emergence of a technologically more advanced segment among industrial companies was an important factor in promoting economic liberalization in India. In tune with this pro-reform policy, important industry bodies in the 1990s began to advocate the need for greater patent protection in India. The Confederation of Indian Industry (CII) took the position in its statements before the Gujral Committee that India was not able to get relevant technology due to the absence of product patents. ASSOCHAM (Associated Chambers of Commerce and Industry) stressed before the Gujral Committee that India needed to strengthen patent laws in order to attract foreign direct investment. The industry bodies began to support the bill to amend patent laws in conformity with TRIPs. The CII, placed on its ‘wish list’ for the Government the passing of the patent bill to conform to TRIPs. In 1997, the Federation of Indian Chambers of Industry and Commerce (FICCI) established the International Institute of Intellectual Property Development (IIPD). This institute aims at promoting the patenting culture amongst the scientific and technical community and use IPR as a strategic tool in forwarding business interests. It loudly promotes the slogan “Patent or Perish”.

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45 A committee established by the Indian Parliament to solicit views and prepare a report on the impact of the WTO Agreement on India
A component of this change within industry bodies arose from some domestic firms who prospered under the existing patent structure, but came to visualize significant avenues for profit from the new patent regime. Dr. Reddy's Laboratories, which has been preparing for the change in patent policy since 1984, believes that it has a competitive edge in new drug discovery which will lead to its growth under the revised policy. Industry heads from Ranbaxy, a major pharmaceutical firm expressed that, "India currently has a deficient system as far as providing intellectual protection goes, therefore we see the need for a radical change. It is a myopic view that multinationals will dominate the industry, as players are emerging at all levels". Interviews with several Indian and MNC subsidiary firms and two industry associations conducted by Lanjouw revealed a shift in the debate on patents in India around 1997-98. Compared to just a year before she said, no one any longer expressed doubt that India would, in fact, be in compliance with WTO intellectual property requirements when deadlines were reached and that, recent interviews indicated that there was an entirely new debate underway in the country on whether India should voluntarily skip the end of the period under Exclusive Marketing Right (EMR) and go straight for product patents.

Another domestic constituency promoting change emerged from top Indian research and scientific institutes that felt they could benefit from patents rather than publications. The Council of Scientific and Industrial Research (CSIR) with its chain of 40 laboratories reflects this more globally market oriented position focusing on acquiring patents. Prime Minister Atal Behari Vajpayee in January 1999 stated, "I compliment CSIR for creating an intellectual climate supportive of the early passage of the bill to amend the Patents Act". This atmosphere emerged both from CSIR's role in promoting patent activity and from countering the bio-piracy argument against increasing patent protection in India". Anji Reddy, chairman of Dr. Reddy's Labs, states that Mashelkar, head of CSIR, "...not only inspired scientists in CSIR to create wealth by harnessing intellectual property, but was also an inspiration for all of us in the industry." The CSIR's instrumental role in defeating the US patent on
turmeric turned around the debate on the implications of patents on traditional knowledge, and this was crucial for promoting changes in patent policy. This shift enabled various domestic policy changes. India also changed its negotiating strategy within TRIPs.

**AMENDMENT OF INDIAN PATENTS ACT, 1970**

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

India had to provide a means by which patent applications could be filed during the transitional period. The "mailbox provision" allowed applicants to file for patents, thereby establishing filing dates, while at the same time permitting member countries to defer granting product patents. In addition, India also had to provide Exclusive Marketing Rights (EMRs) in exchange for permission to delay the granting of product patents until January 1, 2005. EMRs are supposed to apply where a patent is granted for the same product in another WTO member country after 1995 (the date of entry into force of TRIPs), provided the other member country obtained marketing approval for the product.

Therefore to provide all these, in 1999, the first Amendment of the Patent Act, 1970 introduced the requirements under the "transitional arrangements through Section 5(2), which allowed product patent applications to be filed through a 'mailbox', while Chapter IVA provided for the grant of Exclusive Marketing Rights (EMRs) if certain conditions were fulfilled." In 2002, the second Amendment of the Patent Act provided for changes in the
scope of patentable inventions, grant of new rights, extension of the term of protection, provision for reversal of burden of proof in cases of process patent infringement, and conditions for compulsory licences. This Amendment was one more step in India's journey towards TRIPs compliance. The final step was a requirement to introduce product patents in the area of chemicals, pharmaceuticals, and agricultural chemicals and food. The deadline for compliance was January 1, 2005.

THIRD PATENT AMENDMENT ACT, 2005

On December 26, 2004, India issued a presidential decree (hereinafter "the Ordinance") to amend its law and meet this final deadline. The Ordinance, in addition to introducing product patents, also introduced many other substantial amendments. The Patent (Amendment) Act of 2005 (hereinafter "the Act"), passed by the Indian Parliament, replaced that Ordinance. Several Amendments were made to the Ordinance in the Act, and some contentious issues pertaining to patentability of new chemical entities and micro-organisms were referred to a technical panel.

One of the major changes that the third Amendment brought about was India's recognition of product patents for 'food', 'drug', and 'pharmaceuticals' on January 1, 2005. The Act repealed the controversial Section 5(1) of the Patents Act, 1970, which provided for process patents in this field, and also removed the definition of food. The major Amendments brought by the Third Amendment Act are discussed below:

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46 Patents Act, 1970 (The Act only recognized process patents for pharmaceuticals, food, agrochemicals, etc.)
47 Id, S.5 (1), 2(1) (g)
A. SCOPE OF PATENTABILITY

The Act amended the definition of “patent.” Under the Patent Act, 1970, “patent” was defined to mean “a patent granted under this Act.” The amended law defines “patent” as “a patent for any invention granted under this Act.” With reference to the inventive step, the Act states: ‘inventive step’ means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both that makes the invention not obvious to a person skilled in the art.

In the Patent Act, 1970, “inventive step” was defined as “a feature that makes the invention not obvious to a person skilled in the art.” The new definition for “inventive step” aims to raise the standard for an inventive step. For patent eligibility, an invention must involve an inventive step and technical advances as compared to existing knowledge, or it must have economic significance, or both. The use of the expression “economic significance” in the new law is interesting; it is neither a classical patentability criterion nor does it have anything to do with inventions. The Patent Controller is now required to independently assess the economic significance of an invention based on data furnished by the patent applicant himself.

While Section 2(1) (j) retains the old definition of “new invention,” a new definition for “new invention” has been added in Section 2(f). “New invention” is defined as any invention or technology which has not been anticipated by the publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e. the subject matter has not fallen in public domain or that it does not form part of the state of the art.
The interpretation of “invention” in Section 2(1) (j) depends on this new definition for “new invention.” The above exhaustive definition puts the onus on the patent applicant to clarify the novelty and patentability of a newly claimed invention. This Amendment presents a check on the granting of patents with frivolous claims.

Lastly, the Act also provides a new definition for a “pharmaceutical substance” as “any new entity involving one or more inventive steps.” The above definition is quite broad, and definitely has a bearing on determining patentability for pharmaceuticals. Ideally, “new entity” should have been stated clearly as a “new drug molecule” for specificity.

B. EXCEPTIONS TO PATENTABILITY

With regards to what is not patentable, the Act dropped the earlier provision contained in the Ordinance; that provision created the possibility for the grant of a patent on a second medical use of a known drug. The amended Section 3(d) reads thus: “The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least employs one new reactant.”

Explanation - For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substances shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy. It follows from the above statements that patents would not be available on the following grounds:

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53 Id. at S.2(1)(ta)
54 S.3(d), Patents (Amendment) Ordinance (2004)
55 S.3(d), Patents (Amendment) Act (2005)
• the mere discovery of a known substance which does not result in the enhancement of the known efficacy of that substance.
• the mere discovery of any new property or new use for a known substance;
• the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least employs one new reactant.

One can argue that, a minor alteration to an existing drug molecule, resulting in “enhancement of its known efficacy” could lead to the grant of a patent on that molecule. The word “mere” has been deleted from qualifying “new use,” patents available only in instances where the discovery is not mere. With reference to the lengthy explanation accompanying the above provision, the Act states that, patents would not be available on new forms of a known substance unless it “differ[s] significantly in efficacy.” Efficacy will thus be the important deciding factor for grants of patents on drug molecules. This would help both domestic and foreign pharmaceutical companies secure patents on “genuine innovations” only, and would reduce the opportunity for companies to extend their patent monopoly through minor modifications or “fence patents” around a drug molecule. While the onus of passing the “efficacy” test has been put on the patent applicant, a lot would depend upon the specifications and the claims therein.

C. COMPULSORY LICENSING

Compulsory Licensing is a procedure whereby a Government can allow any company, agency or designated person the right to make a patented product, or use a patented process under licence, without the consent of the original patent holder. Under Section 84(1) of the amended Act, an application can be made for compulsory licence three years after the grant of

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56 S.3(d), Patents (Amendment) Ordinance (2004)
57 S.3(d), Patents (Amendment) Act (2005)
a patent: “At any time after the expiration of three years from the date of the grant a patent, any person interested may make application to the Controller for grant of compulsory licence.”\(^{59}\) A reasonable time period extending up to six months has been introduced, allowing the Controller to grant compulsory licences in those cases where the applicant has made efforts to obtain a licence from the patentee on reasonable terms and conditions without any success.\(^{60}\)

This time period for issuance of a compulsory licence remains a cause of concern. As per the Act, applications for compulsory licences can only be made after a period of three years once the patent has been issued.\(^{61}\) In addition, the six month time-frame could result in further delay in the issuance of a compulsory licence. With respect to exporting drugs to a country which makes a request for a generic drug, the Act has simplified the compulsory licensing procedure; countries that put in a request for generic drugs do not have to issue a compulsory licence.\(^{62}\) Compulsory licence shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory licence has been granted by such country or such country has, by notification or otherwise, allowed importation of patented pharmaceutical products from India.\(^{63}\)

D. MAILBOX APPLICATIONS

The Act in Section 11A introduced a new proviso: provided also that after a patent is granted in respect of applications made under sub-Section (2) of Section 5, the patent-holder shall only be entitled to receive reasonable royalty from such enterprises which have made significant investment and were producing and marketing the concerned product prior to the 1st day of

\(^{59}\) S.84 (1) (c) of the Act
\(^{60}\) Id. at S.84(6) (The explanation has been inserted at the end of S.84 (6) of the Act)
\(^{61}\) Id. at S.84(1)
\(^{62}\) S.92A. (1)
\(^{63}\) Id. at S.92A(1)
January, 2005 and which continue to manufacture the product covered by the patent on the date of grant of the patent and no infringement proceedings shall be instituted against such enterprises.\textsuperscript{64}

Indian generic drug manufacturers have been manufacturing generic versions of branded drugs. Under the Act, such generic drug manufacturers that had made significant investment and were marketing the product before January 2005 can continue marketing the product in the new regime. The Act grants them immunity from infringement suits from patent holders. They would only have to pay a reasonable royalty to the patentee.

A majority of 7,520 patent applications in the mailbox belong to Multi National Companies (MNCs), while Indian drug companies have filed 1,406 applications.\textsuperscript{65} Compared to these numbers, the US Food and Drug Administration (USFDA) approved only 297 New Chemical Entities (NCEs) in the period from 1995-2004.\textsuperscript{66} The unusually large number of patent applications filed by MNCs points to the fact that they are not related to NCEs, and involves either frivolous or preventive pleas. While the law has stated that, the generic manufacturers would have to pay a "reasonable royalty" to the patent holder, it has not defined "reasonable.\textsuperscript{67} Ideally, the royalty rate should have been fixed at 4%, following the practice adopted by Canada for many years, or at 5% following South Africa.\textsuperscript{68}

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\textsuperscript{64}Id. at S.11A
\textsuperscript{67}S.11A (The Act has mentioned that a "reasonable royalty" needs to be paid to the patent holder. However, it has not specified the rate to be paid)
\textsuperscript{68}GSKandBlIssueAnti-retroviralLicences, http://www.compcom.co.za/resources/Comp%20Comm%20March%20HTML/1%20GSK&Bl.html (Oct. 21, 2005) (South African Competition Commission in 2003 found GlaxoSmithKline (GSK) and Boehringer Ingelheim (Bl) guilty of excessive pricing for AIDS drugs. The royalty rates were reduced from 30% to 5% in the case of GSK, and from 15% to 5% in the case of Bl)
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E. OPPOSITION TO A PATENT

Chapter V which concerns opposition was given a new chapter heading: "Opposition Proceedings to Grant of Patents." Section 25(2), introduced by the Ordinance, and was deleted with an objective of strengthening pre-grant opposition. In the Ordinance, the post-grant opposition system had been introduced, and grounds pertaining to pre-grant opposition had been considerably reduced to two. The Act now provides for two different stages of patent opposition: pre-grant, upon the publication of the application; and post-grant, upon the grant of a patent. All 11 grounds for pre-grant opposition have been restored in Section 25 of the Patents Act. While an interested person can initiate post-grant opposition, the Act allows any person to institute a pre-grant opposition on the same grounds as the post-grant opposition. In addition, a minimum period of six months has been introduced for making representation from the date of publication, as compared with the earlier timeframe of three months.

F. PUBLICATION

The Act amends Section 11A of the Patents Act, which prescribes the initial publication requirement. The Act states that, "the applicant shall have the like privileges and rights as if a patent for the invention had been granted on the date of publication of the application." There are two points for concern pertaining to Section 11A. First, the patent applicant's option to demand an early publication of the patent application permits him to prevent research and development by other companies on pre-patent information.

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69Chapter V, Patents (Amendment) Act, 2005. (In the Patents Act, 1970, Chapter V was entitled "Opposition to Grant of a Patent")
70Patents (Amendment) Ordinance, 2004. (Section 25(2) of the Ordinance denied a person making an opposition representation the right of becoming a party to any proceedings under the Act, a provision viewed as restrictive to the scope of opposition)
71ld. at S.25(1)
72ld. at S.25(2)
73ld. at S.25(1)
74Rule 55(1A), of the Patent (Amendment) Rules, 2005
75S.11A, Patents (Amendment) Act, 2005
76ld. at S.11A(7)
Secondly, the Act does not make the publication of the complete specification available to the public. Fears have been expressed that this could "greatly hamper opposition proceedings."77

G. DATA EXCLUSIVITY

Pharmaceutical companies have to submit test and clinical data to the national health authorities to obtain marketing approval for a new drug.77 The national health authorities keep the innovator data confidential against "unfair commercial use" for a certain time period,78 thus barring generic manufacturers from using the submitted innovator data for the stipulated period. The US and EU grant "data exclusivity" for five years79 and eleven years,80 respectively. Most often, companies use data exclusivity provisions to seek a period of monopoly in a country even if it does not have any patents on the product in the country. As such, data exclusivity provisions have considerable implications for developing countries like India.

So far, India has not introduced provisions pertaining to data exclusivity in the three Amendments to the Patents Act, 1970. India is now considering Amendments to the Drugs & Cosmetics Act, 1940 and the Indian Insecticides

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Act, 1968 incorporating provisions for data protection. Once data exclusivity is introduced, generic companies would have to do their own safety and efficacy tests. The huge cost involved in this exercise could result in generic companies being barred from producing a generic version of a product for a period extending effectively beyond 20 years. It may also result in the ineffective use of a compulsory licence due to data exclusivity provisions, were such a licence issued to a generic manufacturer.

H. "BOLAR" PROVISION

The "Bolar" provision is the best known of the many limited exceptions to the patentee's exclusive rights under Article 30 of the TRIPS. The amended Patent Act provides for "Bola" exception in Section 107A (a): any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product.

This would allow a generic drug manufacturer to produce or import patented drugs for the purpose of development and submission of information for regulatory trials before patents expire. In other words, but for the "Bolar" exception in Indian patent law, generic manufacturers would be forced to wait

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83 Agreement on Trade-Related Aspects of Intellectual Property Rights Annex 1C, Art. 30 (entered into force 1994), http://www.wto.org/english/tratop_e/traps_e/t_agm2_e.htm (countries "may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties")
84 S.107A(a), Patents (Amendment) Act, 2005.
for the patents to expire before embarking on the mandatory tests necessary for regulatory approvals. This would allow Indian generic manufacturers to compete among themselves, ensuring the continued availability of medicines at low costs for domestic, as well as international, consumers.

I. PARALLEL IMPORTS

Parallel imports occur when patented medicines produced or sold abroad with the consent of the patent owner are subsequently imported into the domestic market at cheaper prices without the consent of the owner. Parallel importation works on the principle that the patent owner’s rights have been exhausted through the first sale. In the Patent Act, 1970, Section 107A (b) contained a provision regarding parallel imports. This has since been streamlined further to avoid unnecessary delays. Section 107A (b) of the amended Act now 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, shall not be considered as an infringement of patent rights.

J. EXCEPTIONS FOR EXPERIMENTAL OR EDUCATIONAL PURPOSES

The Patent Act provides an exception for research and development from the ambit of patents, including for the purposes of research, experiments or education. Section 47(3) of the Patent Act addresses the experimental use of a patented invention, solely for the purpose of research or education.

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85 Agreement on Trade-Related Aspects of Intellectual Property Rights Annex 1C, Art. 28 (entered into force 1994), http://www.wto.org/english/tratop_e/trips_e/trytop_e.htm (patent owner cannot legally prevent the importation of patented products from another country. Parallel imports are subject to Article 6 (of TRIPS) on “exhaustion”)
86 S.107A (b), Patents (Amendment) Act, 2005 (requiring that the foreign exporter was “duly authorized by the patentee to sell and distribute the product”. This has now been amended to read “duly authorized under the law”)

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including "imparting of instructions to pupils": any machine, apparatus or other article in respect of which the patent is granted, or any article made by the use of the process in respect of which a patent is granted, may be made or used, by any person, for the purpose merely of experiment or research including the imparting of instructions to pupils.

BIOPIRACY CASE STUDY – I: TURMERIC

The Indian Council for Scientific and Industrial Research (CSIR) filed a case with the US Patents Office challenging the patent (5,402,504) granted to turmeric on the ground of "prior art". The CSIR stated that, turmeric has been used in India for thousands of years for treatment of wounds and rashes. Its use as a medicine was known and was not a new invention. The American Patent Office upheld the objection and cancelled the patent.

BIOPIRACY CASE STUDY – II: NEEM

Again India has made a complaint to the WTO's dispute resolution mechanism against 70-odd patents granted on products from the neem trees, suggesting that dried neem leaves have been used for centuries in India to protect clothes and grains against fungus. Some patents have been cancelled and some are in the process of investigation.

BIOPIRACY CASE STUDY – III: BASMATI

There was a clear case of biopiracy and theft with regard to the way Basmati Patent was obtained in 1997 by the Texas-based Rice Tec Inc. The Texas Company was already tracing in basmati rice with such brand names as temati, jusmati and kasmati. The American Patent Office declared: "The
invention relates to novel rice lines and to plant and grains of these lines and to a method for breeding these lines. The invention also relates to a novel means for determining and starch properties of rice grains and its use in identifying desirable rice lines."

The Texas Company claimed a patent on basmati variety of rice on the ground that it was derived from Indian Basmati crossed with semi-dwarf varieties, including Indica varieties. The patent is for a variety essentially derived from a farmer's variety – a simple case of cross breeding. It had to be treated as a false claim for an invention. The Indian Research Foundation pointed out that basmati, covers about 15 per cent of the area under rice cultivation and that the country exported large quantities of Basmati rice earning foreign exchange of Rs. 1,100 Crore in 1996-97. It is unique to Punjab in the same way that champagne is unique to certain areas in France. The patent represented a theft of collective intellectual biodiversity heritage of Indian farmers – an act of stealing markets for Indian aromatic rice varieties and a theft of the name Basmati itself. The patent was cancelled.

**BIOPIRACY CASE STUDY – IV: BITTER GOURD (KARELA)**

Indian scientists have been pointing out how the American Patent Law never takes into account the use of technology elsewhere in the world and encourages biopiracy. A New Jersey-based company, Cromak Research Inc, obtained an American patent for an edible herbal mixture comprising Karela, Jamun, Gurmar and Brinjal. Karela juice has long been in use in India as an anti-diabetic mixture.

In its meeting held in Geneva on 30th August, 2003, the WTO approved a resolution to ensure poor countries to have access to cheap medicines to combat killer diseases. Due to this concession, the developing countries like India, China and Brazil would stand to gain from the provision of
compulsory licensing as only they have the capacity to manufacture cheaper
generic copies.

But the Cancun (Brazil) Ministerial Meeting held in the month of
September, 2003 has ended without any consensus on contentious issues
like subsidy and investment. The developing countries, led by India,
demanded that, developed countries must put an end to the practice of
subsiding their agricultural products. As both the parties struck to their
respective positions, the meeting failed.

Let us see how these Amendments had influenced Indian health sector.

TRIPs AND INDIAN HEALTH SECTOR

TRIPs, the intellectual property component of the Uruguay Round of
the GATT Treaty, have given rise to an acrimonious debate between the
developed countries and less developed countries (LDCs). Business interests
in the developed world claimed large losses from the imitation and use of their
innovations in LDCs. They also asserted that IPRs would benefit the
developing countries by encouraging foreign investment, by enabling transfer
of technology and greater domestic Research and Development (R&D). On
the other side, developing countries and LDC Governments were worried
about the higher prices that stronger IPRs would entail and about the harm
that their introduction might cause to infant high tech industries. India was
very actively involved in opposing the TRIPs component of the GATT
Agreement, especially the proposal for product patents on pharmaceutical
innovations.

The Act which seeks to formalize product patents in pharmaceutical
and agricultural inventions effectively reverses 35 years of India’s drug policy
and it is therefore imperative for us to locate the Act within a larger history of
health infrastructure in India. At the time of Independence, India only controlled ten per cent of its pharmaceutical market and its drug prices were among the most expensive in the world as a result of the patent monopolies that allowed large corporations absolute control over the market. The Government of India then appointed the Ayyangar Committee in 1957 to recommend reforms to India’s patent law to tackle this problem.

The Ayyangar Committee found that, 80-90 per cent of the patents in India were held by Multi National Companies, and that more than 90 per cent of these patents were not even being exploited in India. The Committee stated that, the existing patent regime system was being exploited to achieve monopolistic control over the market in vital industries such as food, chemicals, and pharmaceuticals, resulting in medicines being unaffordable. The suggestions made by the Ayyangar Committee went on to form the basis for the Patents Act, 1970. India passed the Indian Patents Act of 1970 which attempted to assist in the development of the pharmaceutical industry by making new medicines at affordable prices and by making those medicines readily available to the public ensuring its national development at the expense of foreign corporations. The 1970 Act only allowed for ‘process patents’ for pharmaceutical patents but not the end product itself. This essentially meant that, an Indian pharmaceutical company could find an innovative or new way to make an existing drug through the process of reverse engineering.

During this period, Indian pharmaceutical companies were able to reproduce existing drugs rapidly and at a low cost, thereby making them competitive in both foreign and domestic markets. There has been a dramatic improvement in health infrastructure in India from 1947 till date and India is currently one of the cheapest countries for drugs. By 1991, Indian firms accounted for 70% of the bulk drugs and 80% of formulations produced in the country and in 19996 of the top ten firms by pharmaceutical sales; six are now Indian firms rather than the subsidiaries of foreign multinationals. Domestic firms now produce about 350 of the 500 bulk drugs consumed in the country.
There are over 250 large pharmaceutical firms and about 9,000 registered small-scale units, and the Indian Drug Manufacturers' Association (IDMA) estimates that, there another 7,000 unregistered small-scale units producing drugs. The generic drug industry has been vital in ensuring that drugs are available at readily at an affordable price. For instance there are at least 50 firms offering the important drug Ciprofloxacine.

In recent times, the most striking success of Indian pharmaceutical companies has been their ability to provide access to HIV/AIDS drugs at an affordable price. Till 2000, Anti Retroviral (ARV) drugs were not accessible to the vast majority of People Living with HIV/AIDS (PLHA) all over the world because of the high price. Multinational drug companies priced ARV drugs between US$12-13,000 annually per person. From 2000 the prices started falling after manufacturers from India introduced generic versions of ARV drugs. These generic drugs are currently provided to patients for as low as US$140 annually per person. This was possible because of the absence of a product patent regime in India.

Further, the absence of product patent protection up to 2004 has also facilitated the introduction of Fixed Dose Combination (FDC) of ARV drugs. A three-in-one cocktail pill introduced by the generic manufacturers substituted two pills for six pills per day. Thus the FDCs increased the accessibility as well as availability of ARV drugs. The introduction of FDCs became possible only because of the absence of product patent protection in India. The introduction of a product patent regime will prevent generic companies in India from manufacturing these FDC’s.

The Affordable Medicines Treatment Campaign (AMTC) notes that, the impact of monopoly on access to medicines is already being felt in India. The Controller of Patents has granted an Exclusive Marketing Right (EMR) to Novartis AG, for the drug called Gleevec used for the treatment of patients suffering from Chronic Myeloid Leukaemia (CML), a life threatening form of cancer. EMR is granted as a transitional arrangement before providing
product patent protection. Gleevec is sold by Novartis AG at Rs. 1, 20,000 per month. The generic version of the drug was otherwise available to CML patients at Rs. 9,000-12,000 per month. The EMR resulted in the withdrawal of generic version of Gleevec from the market. Consequently, the overwhelming majority of patients that suffer from CML every year in India denied access to this life saving drug. While it is true that as a signatory to the TRIPs Agreement, we have already introduced product patent in relation to pharmaceutical industries in India, and nothing can be done to withdraw it. It is however vital that we ensure that, the Patent Act should not compromise on the Fundamental Right to health or endanger the right to access medicines at an affordable price. The national Working Group on patents has stated that there may be a full review of the TRIPs process that is required given the seriousness of the crisis.

POSITIVE EFFECTS OF AMENDED ACT

Over a period of time Indian drug companies will lose the opportunity to develop processes for patent protected drugs in the country. Indian drug companies might become dependant on MNCs for technology to produce new drugs. However, among existing drugs say about 10 per cent of the marketed drugs are likely to become expensive due to Amendments made in new patents act. However, the existing 90 per cent of the old drugs will not be affected by this Act. While this is true, it must be understood that, the rate of obsolescence of old drugs is extremely fast today.

It was feared most that, technological dependence on MNCs will lead to establish their dominance over the Indian drug market. MNCs once again may start charging exorbitant prices for drugs in the Indian market. In product patent regime the drugs showing fastest growth would have been priced way beyond the capacity of the average consumer. The new rules do not apply to drugs patented before 1995 so companies like Cipla can continue selling its widely distributed version of the HIV treatment AZT. Even copies of drugs
patented between 1995 and the introduction of the law are not likely to be withdrawn. India, which has more than 70 US FDA-approved manufacturing plants, could become a production hub because of its cheap and skilled labour. As of now pharmacy companies in India were thriving on reverse engineering but the rule of the game is likely to change and most firms belonging to the organized sector are fully geared to face the upcoming challenges. It must be noticed that, outside the USA, maximum number of US FDA-approved plants are in India, which in itself is a testimony to the preparedness on the Indian industry.

With patent protection, India could be ideal centre for activities of research and development and clinical studies. The contract research organizations of domestic and global are viewing as the hotbed for clinical research. The proficiency in English and skilled manpower, and availability of huge patient volunteers with this new Amendment is going set phase for unprecedented opportunities for domestic manufacturers.

Domestic manufacturers along with MNCs may also find it profitable to discover novel drugs for diseases of developing countries. The diseases like Malaria, Tuberculosis need to be addressed urgently. There seems to be stimulation in activities in this neglected field of diseases. The Amendment made in the Act promises to safeguard the interest of the nation by Amendments like the Act does not applicable to molecules marketed by Indian companies prior to 2005. Provisions regarding the exclusive marketing rights included in the Act have removed the doubts from manufacturers’ minds that are willing to develop technologies that would bring the cost of the recently patented drug to a developing country. Hence the drug can be made available to the poor countries at an affordable price. The inventor is able to earn higher profits and therefore would likely invest more in R&D and drug discovery and testing, in turn increasing consumer welfare. Also, patent laws require specifications to be disclosed to all and therefore information about new technologies becomes more quickly available to others as an input into their own R&D. Moreover the innovating firm is able to reveal its innovation
without losing control and hence can sub-contract parts of the developmental work at lower cost to countries like India. Precisely, the three main arguments given by the proponents of strong patent regime in India are:

1. Weak patent regime discourages launch of new drug (by the original innovator) and therefore reduces patient’s welfare (so called).

2. Globally, the cost of R&D has gone up manifolds and therefore it is absolutely necessary to give more protection.

3. India will not suffer since majority of drugs in India are off-patent and so prices will not be affected much. This argument contradicts the spirit of argument 1. If old drugs are sufficient to treat Indian patients then why seek strong patent on grounds of argument 1?

Let us see, one by one whether these three arguments are really beneficial to Indian pharmaceutical sectors and protecting health of the poor in India.

**DELAY IN LAUNCH OF NEW DRUGS?**

The first argument essentially tells us that weak patent regime discourages innovating firms to launch new drugs in India, and therefore causes loss of welfare to Indian patients by denying access to newer and better treatment of their diseases. While this argument may hold some water for countries with low or no reverse engineering capabilities, it certainly a far fetched one in the context of India. In fact, the delays in launch of new drugs have considerably declined over the past decades, much due to strong reverse engineering R&D capabilities of Indian firms. It becomes evident from some examples of blockbuster drugs a drug qualifies for blockbuster status when its annual global sale is more than one billion dollars. Blockbuster drugs
are assumed to derive much of their popularity in the market due to some "major therapeutic gains". 87

Let's take the cases of specialized rheumatic analgesic blockbuster drugs, Celecoxib and Refecoxib, which were globally launched in 1999. 88 Both drugs were launched in India in 2000 by leading domestic firms, Sun Pharma and Torrent respectively, with a delay of less than two years. The pattern is also very similar for other blockbuster drug like Sildenafil Citrate 89 for erectile dysfunction, globally launched by Pfizer in 1998. It was introduced in India by domestic firms 90 in 2001, within three years of its global launch 91. Likewise, cardiovascular (heart related) blockbuster drug Atorvastatin, globally launched by Pfizer in 1997, was also introduced in India by a few domestic firms 92 within three years. More striking is the example of the anti-diabetic drug Rosiglitazone Maleate that was imitated and launched by leading domestic firms 93 within the first year of its global launch in 2000. Thus, these empirical examples suggest that, new blockbuster drugs were launched almost simultaneously or some minor delay in India even during the weak patent regime. Thus, imposition of strong patent would serve very little objective in shortening the delay of launch. On the other hand, with the introduction of patent, the inventor is trying to maximize his profits and therefore price his drug higher than if there were no patents. Correspondingly the consumption of the drug will be lower. This represents an indirect welfare loss to Indian consumers because of higher prices associated with introducing product patents. In addition to this are the direct costs of administering the patent system and enforcing patentee rights through the courts in case there are infringement disputes.

87Indeed, surprisingly although, major therapeutic gains are rare qualities among newly discovered drugs! According to US Food and Drug Administration only about 10 per cent of new drugs are considered to bring about critical improvement in medical treatment. All other new drugs only brought about marginal gains over existing drugs, although with higher prices
88Celecoxib by Pfizer and Refecoxib by Merck
89Popularly known as Viagra
90Ranbaxy, Cadila
91launch was delayed mainly because of legal court cases by Pfizer India
92Ranbaxy, Zydus Cadila, Sun Pharma
93DRL, Sun Pharma, and Torrent
The benefit in the form of increased consumer welfare from patent rights in India might turn out to be a cost. Substantial research has been carried out by national and international organizations on the potential effects of TRIPs on drug prices within India and other developing countries. Phrases ranging from "medical apartheid" to "national health disaster" have been used to describe the impact of the new patent regime being forced by the multinational pharmaceutical giants via the WTO and TRIPs. A study carried out by the International Monetary Fund (IMF) economist A. Subramanian, an organization which has never been a true friend of the poor and developing countries; found that drug prices in Malaysia, where patent protection for pharmaceutical products already exist, were from 20% to 60% higher than India and reflected a profit-maximizing behaviour by the pharmaceutical companies based on what the market can bear. Even the findings of the British Government's Commission for Intellectual Property Rights, set up to review the effects and impact of TRIPs and IPRs on developing countries, has stressed that Governments of developing countries should use what available checks and balances there are within TRIPs to ensure that any new legislation implemented around patents does not exacerbate a healthcare disaster which is likely to occur as a result of developing countries having to change their patent laws.

Moreover, all profits accrue to foreigners and funds are going out of India. Foreign patentees earn income from patents in two ways:

1. In the form of royalties if production remains under licence in India
2. In the form of export profits if the drugs are imported.

In the case of imports India faces further costs in terms loss of employment. Forex outflow and loss of self-sufficiency i.e. if strategies shift from imitative R&D to directly purchasing technology. A comparison between their international (in most cases in US) monopoly prices and Indian prices are given in the table below.
TABLE 6

<table>
<thead>
<tr>
<th>NAME OF THE MEDICINE</th>
<th>PRICES IN US</th>
<th>PRICES IN INDIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Celecoxib (CELEBRAX)</td>
<td>$3 per tablet</td>
<td>Calcibra (Ranbaxy) 100 mg Rs 40 per strip of 10 caps</td>
</tr>
<tr>
<td>Refecoxib (VIOTXX)</td>
<td>$3.5 to $4.5 depending on dosage</td>
<td>Rofibag (Ranbaxy) 25 mg Rs 41.50 per strip of 10 tablets</td>
</tr>
<tr>
<td>Sildenafil Citrate (VIAGRA)</td>
<td>$10-$12 depending on dosage</td>
<td>Penigra (Cadilla) 50 mg Rs. 77.83 per strip of 4 tablets</td>
</tr>
<tr>
<td>Atorvastatin (LIPITOR)</td>
<td>$2 TO $3 depending on dosages</td>
<td>Atorva (Dr. Reddy's) 10 mg Rs. 54.90 per strip of 10 tablets</td>
</tr>
<tr>
<td>Roseglitazone Maleate (AVANDIA)</td>
<td>$3 to $5 depending upon the dosages</td>
<td>Rezult (Sun Pharma) 2 mg Rs. 35.50 per strip of 10 tablets</td>
</tr>
</tbody>
</table>

What will be the implications of the new Act? Over a period of time Indian companies will lose the opportunity to develop processes for patent protected drugs in the country. India will become dependant on MNCs for technology to produce new drugs. Votaries of the new Patents Act argue that old drugs will not be affected by this Act. While this is true, it must be understood that the rate of obsolescence of old drugs is extremely fast today. Further, technological dependence on MNCs is the proverbial “thin edge” which will be used by the MNCs to establish their dominance over the Indian drug market once again (a position they had lost after the mid seventies). They will then again start charging exorbitant prices for drugs in the Indian market. Since the early eighties, the categories of drugs which show the maximum rise in sales are categories which include overwhelming majority of drugs still under product patent or whose product patents have expired recently. In other words as we have a product patent regime today, the drugs showing fastest growth would have been priced way beyond the capacity of the average consumer. Not only that, today Indian companies are the largest

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suppliers of low cost drugs to developing countries. For example, an estimated 60% of drugs to treat HIV-AIDS come from India. The new law is making this impossible, thereby threatening the lives of hundreds of thousands – not only in India, but across the globe.

The new patent regime would either raise the prices of new drugs to the international level or would make the Indian population wait until the patent expires and drugs become cheaper. In that case they will be consuming "old drugs" any way, and the purpose of getting quicker access to new drugs will be defeated. So actually prices would increase without much welfare gains in terms of access to new drugs. And, moreover, why such a big hue and cry about the welfare of Indian patients when only 13 of 1373 new molecules developed during the last 30 years target diseases of tropical countries like India?

**IS HIGHER COST OF R&D JUSTIFIED?**

In so far as the second argument is concerned, it is true that cost of R&D has gone up. But it has increased more due to the use of highly automated R&D machines to come out with potent molecules. In the good old days, companies used to rely on "scientific acumen" of their scientists. Instead, now they like to buy machines which run random experiments with hundreds and thousands of molecules (called high throughout screening) in order to increase the possibility of getting a potent drug. But recent studies have shown that use of such highly automated costly machines have done little or no good in terms of R&D productivities of the pharmaceutical industry. Pharmaceutical drug inventions can broadly be divided into two broad groups (a) research and (b) development. While research stage consists of synthesis and screening of chemical compounds, developmental stage comprises various clinical trials and approval of drugs for marketing. It has been shown that after automation in the last decade the share of screening and synthesis

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"which is argument 1"
costs in total R&D costs has gone up from 4-5 per cent to around 14 per cent. In addition, recent NBER (National Bureau of Economic Research, USA) study by famous industrial economist Ian M. Cockburn shows that, average research productivity has gone down by more than 60 per cent. While in 1980s the industry used to spend an average of $318 million for one new molecule, it paid around $806 million in the last half of 1990s. He attributes much of this decline in productivity to what he calls “re-tooling in response to innovation in method of invention”. Thus, it perhaps makes sense to seek the justification behind such an economically wasteful expenditure before justifying the imposition of TRIPs on grounds of higher R&D costs!

**ONLY MARGINAL IMPACT IN INDIA**

The third argument is the most mischievous one, making the entire argument stand on its head. It should be remembered that, patients do not choose medicines; they have to buy whatever is being prescribed by their doctors. In a world where most medical practitioners depend on company sales representatives for information about drugs and their efficacy; is it not foolish to assume that doctors would be supplied with unbiased and truthful information on old, cheap medicine where new medicines can fetch higher profits to firms. At another level, monopolies in new products would enable firms to provide greater incentives, pecuniary or otherwise, to medical practitioners for prescribing newer drugs. Moreover, even if we assume that the imposition of TRIPs would not hurt the majority of Indian patients at present, it is bound to hit hard in the longer run, as share of new drugs compared to older ones will increase in the market. After all, we do not intend to impose TRIPs only for the next one year?

The impact will even be more pronounced in the markets for antibiotic drugs. People (or more appropriately the pathogen!) develop resistance to antibiotic drugs and therefore require newer version of stronger antibiotics.

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96 see some recent work by Amit S Ray for the Independent Commission of Health in India
Indian people are more prone to infective diseases compared to the westerners and tend to consume more antibiotic. They, therefore develop resistance to antibiotics quicker and need stronger, newer version of antibiotic with shorter delay compared to western people. Some studies suggest that, while the first generation antibiotic drugs are sufficient for 90 per cent people in the US, it can cure only a meagre 10 per cent people in India primarily because of higher level of resistance to antibiotics among Indian population. Assuming a new antibiotic is developed and sold by the innovator in India under strong patent. Since older drugs would not work, Indian patients will have to buy the newest antibiotic paying the monopoly price! Even a ciprofloxacin tablet for which patent has recently expired costs around 2 dollar per tablet in US and something between 0.05 and 0.2 US dollar in India, one can imagine the impact of strong patent on prices of antibiotics and the health care expenditure of Indian people.

**STRONG PATENT AND TECHNOLOGICAL ADVANCEMENT**

Finally, a strong patent regime has often been found detrimental to the process of industrial development in particular and scientific advancement in general. Let's look at the evolution of the patent regime in many of today's industrialized countries.

India or rather the British-India adopted a strong patent regime as early as in 1911, which was in force till 1970. So, the weak patent regime in India is only about three decades old. This is rather small a duration to expect any technological catch-up process to be successful. In fact, many of today's developed and industrialized countries had weak patent protection for a much longer period, and some of them even had weak or no patent protection when India possibly more underdeveloped than at present was under strong protection! Netherlands did not have a patent regime till 1912. Germany

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Ciprofloxacin is a 4th generation antibiotic sold in the name of Cifran by Ranbaxy

we must also remember that we have weak patent protection only in a handful of sectors, which includes pharmaceuticals
introduced the system of patent in 1877, but continued to have only a very weak patent protection until as late as 1956, and shifted to a strong one only after developing indigenous technological competence in industries like pharmaceutical and synthetic dye. The case of Japan is well known to many. After developing the patent law along the US line in 1885, Japan adopted the German model since 1905, by considerably weakening the definition of "inventiveness". This change was especially meant for protecting small inventions at a time when Japan’s technology lagged behind that of many western nations. This law^6 supplements Japan's major patent law^8. It reformed the patent regime only at the time of Uruguay Round of GATT negotiation in 1995. It should be noted that, whether a patent regime is weak or strong depends on multiplicity of factors such as length of protection (number of years), breadth of protection (product or process or both, even within a product or process there can be narrower definition of newness allowing more inventing around and therefore considered as less protective), definition of inventiveness and various enforcement mechanisms. While Germany only allowed for process patent with duration of 3 to 7 years, Japan had both product and process patents for 5 to 15 years but had allowances for small inventions built-in in the definition of inventiveness and various tax enforcement measures.

Moreover, TRIPs may prove to be a breeding ground for cost inefficient process technologies. Suppose there are two different processes to make a product. Under an Intellectual Property Rights regime, which only grants patents to a particular process (let’s assume that is a high cost one), there are no incentives for investing on R&D to find out another more cost-efficient way to prepare the same product. After all, the proponents of liberalization de-regularized Indian industries ostensibly to make the Indian industry more cost efficient and internationally competitive! Ironically, TRIPs could lead to somewhat similar situations; where an innovator will have less or no incentive to search for cost efficient processes once they can establish a monopoly in

^6now known as Law No. 123, 1959
^8Law No. 121, 1959

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the product market for a duration of 20 years. Historically, declining competitiveness of the US and British synthetic dye industries vis-à-vis the Germans in the early 20th century and US automobile industry vis-à-vis the Japanese in the mid-20th century have primarily been attributed to the cost inefficiency of those countries under strong product patent regime. The consumer may therefore have to pay high prices for inefficient processes of novel drugs under TRIPs, which is in sharp contrast with the stated objectives of the WTO to raise global cost efficiency and, thereby, consumer welfare.

It proposes to extend the scope of patentability by allowing patent protection for the new use of known drugs, otherwise known as “ever greening”. Therefore, if a particular patented product used for treating disease X is also found to be useful for treating disease Y, then a patent can be granted for its new use. This will enable pharmaceutical companies to extend for a further 20 years the monopoly over the initial patent for the product relating to disease X once it is close to expiration. As a result, this type of provision blocks the commercialization of such products and will never fall into the public domain where they can be copied and sold at more affordable prices. TRIPs do not require its Member States to extend the scope of protection for existing patents. However, by including such a provision in the Act, the Government is increasing the powers of the pharmaceutical giants to control the drugs market.

The Act fails to provide a provision, as allowed under TRIPs, which enables any organization or member of the public to oppose a patent application which should not be considered patentable for lack of invention or newness. Such a provision is key in order to put a check on the ever greening of existing patents, in particular where it relates to medicines, as well as other trivial applications. Moreover, considering the lack of resources of the Indian Patent Office to examine thoroughly applications under new patent laws, an opposition procedure to protect public interest is imperative. As a result this is

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100TRIPs And Its Impact On Drug Prices And Health Care In India: Saradindu Bhaduri and Abhay Kumar

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likely to result in several invalid patents being granted without challenge and any attempt to invalidate such patents during an infringement action will prove costly and burdensome as the burden of proof would lie with the infringer as opposed to the owner of the patent as was the case previously. It is somewhat surprising to see the Government avoiding the inclusion of such a provision when countries like Australia, Brazil, Canada, China, France and the UK, all offer an opposition process.

In the Act compulsory licence provision is loaded with cumbersome procedural formalities and is unlikely to serve as a way of curbing the patent monopolies. TRIPs sets out a none exhaustive list which allows for Member States to seek a compulsory licence from the patent holder where there is, for example, a national emergency or other circumstances of extreme urgency and the need to reproduce a patented product. This is often the case with life saving drugs such as antiretroviral for HIV/AIDS treatment. However, the amended Act fails to take advantage of the ability to offer compulsory licences where the patent holder fails to respond or refuses to deal with the request in a stipulated time. Argentina, Brazil and China have all included such a provision in their patent laws. Furthermore, the Act fails to incorporate entirely the decision of the TRIPs General Council passed on 30 August 2004 allowing the grant of compulsory licences for export purposes to countries with no or insufficient manufacturing capacity in the pharmaceutical sector. This could have severe effect on countries which depend on India’s ability to generic life saving drugs.

India fought for the passage of the historic Doha Declaration on the TRIPs Agreement and public health, which reaffirmed countries’ rights to use flexibilities in WTO rules to prioritize access to affordable medicines101. However, the changes the Government of India is considering are “TRIPs-plus”—they do not make full use of the flexibilities TRIPs provides, and in some cases they exceed the standard of patent protection that TRIPs

101 "Declaration on the TRIPs Agreement and public health,” WT/MIN(01)/DEC/2, 20 November 2001
Civil society groups in India, and in importing countries around the world, led by the Affordable Medicines and Treatment Campaign (AMTC), are demanding that the Indian Government alter the Patents Act in the following, pro-public health manner:

- **Simplify and streamline India's compulsory licensing procedure.** Routine issuance of compulsory licences after January 1, 2005 in India is critical if the rapid entry of generic versions of important pharmaceuticals is to continue. But compulsory licensing in India is considered cumbersome. The process must be changed to facilitate routine and expedited compulsory licensing of important medicines. A strictly enforced deadline of one to three months should be established for the grant of a compulsory licence, and rights of appeal should not include permission for injunctive relief that would impede the use of the licence.

- **Retain India's pre-grant opposition procedure.** India’s pre-grant opposition procedure permits opposition to potentially frivolous patent applications, protecting consumers against high prices on non-innovative pharmaceutical products under consideration for patent protection.

- **Remove draft provisions for new-use or second-use patents,** currently described in Section 3(d) of the Patents Act. TRIPs do not require the granting of additional patents for new uses or new dosage forms for known medicines. New use or second use patents do not reward or encourage true innovation; they will however increase the cost of important medicines, compromise patient access, and extend monopolies over a longer period of time.

- **Fully implement the decision of the WTO General Council on the implementation of Paragraph 6 of the Doha Declaration for countries that lack sufficient domestic pharmaceutical manufacturing capacity (the “August 30th Decision”).** The Patents Amendment Act, 2005, would
not permit export of compulsorily licensed medicines from India without a compulsory licence granted in the importing country. If the importing countries do not have a patent for the compulsorily licensed medicine in force, it would not be allowed to import compulsorily licensed medicines exported by India, even though the August 30 Decision clearly permits this. Despite its flaws, the August 30 decision should be implemented in as complete a manner as possible.

**TRIPs AND INDIAN FARMERS**

A trip is a clearly anti-developing country Treaty. Its provisions seriously threaten self reliance in agriculture and the livelihoods of farmers, by seeking to establish a monopoly for the Life Science Corporations on seed production and sale. TRIPs do not allow for the exercise of national sovereignty over biodiversity as mandated by the Convention on Biological Diversity because it obliges countries to enact Intellectual Property Rights on plant varieties which are a part of biodiversity. TRIPs do not contain any elements of equity or benefit sharing. It does not allow countries to claim a share of benefits from companies who breed new varieties using farmers' varieties as the base since there is no provision requiring disclosure of the country of origin from where base materials have been taken. A TRIPs does not require users of biodiversity like traditional plant varieties and land races to fulfill access obligations like Prior Informed Consent and Material Transfer Agreements. It therefore condones and facilitates biopiracy, respecting neither the ownership of communities over bioresources nor the indigenous knowledge that goes into maintaining and refining biological resources. The pre-Seattle developments indicated clearly that the US is pushing for compliance on the *sui generis* option for protecting plant varieties within the framework of the Union for the Protection of New Plant Varieties (UPOV). A number of influential bodies, including the WTO itself, are pushing for a narrowing of the *sui generis* option to this one legislative model. This is unfair and uncalled for. UPOV is not mentioned in the TRIPs Agreement when other relevant IPR Treaties like the Patent Cooperation Treaty are. Independent
legal and economic experts have reiterated that, UPOV should not be accepted as an effective *sui generis* system for TRIPs and that there is ample scope for manoeuvre, flexibility and national discretion in interpreting the *sui generis* option. Implementing a UPOV derived *sui generis* system will have an all round negative impact. This will include exacerbating genetic erosion, limiting the growth of research and hurting farmers economically. UPOV introduces legal and economic restrictions on farmers' livelihood practices. Farmers' rights are reduced by law to a mere exemption which will be subject to compliance of the seed company under the 1991 Treaty.

As a general principle, access to genetic resources declines through their privatization and becomes subject to restrictive terms, whether for production or breeding purposes. Although farmers are responsible for 80-90% of the seed supply in the countries of the South, this will massively shift to private control under plant variety rights regimes. Contrary to what many people assume, corporate breeders very much take farmers to court for alleged piracy of proprietary seed. This has happened in the US. In fact corporations are actively pursuing more powerful means such as contract law governing purchase Agreements, “terminator” type sterile seed technologies and hybridization to prevent farmers from saving seed out of their harvests for another planting. UPOV is biased towards the needs of industrial agriculture, especially through its DUSN (Distinct -Uniform - Stable - Novel) criteria; the uniformity criterion alone has been singled out as favouring, for example, pure lines as opposed to varietals mixtures on the market. By allowing companies to collect royalties on seed sales, UPOV stimulates the corporate take-over of plant breeding which means fewer actors supplying the market. Corporations are not in the business of genetic conservation or genetic diversity and tend to work with highly stabilized elite material with wide adaptation. These highly marketed varieties tend to replace more diverse traditional materials, and consequently the diversity being used by farmers' declines. Impact studies conducted in one UPOV Member State, the USA; report a decline in the flow of germ plasm among breeders, a decline in the sharing of scientific information and a decline in the rate of progress in plant breeding. It is
Noteworthy; however, that UPOV was obliged to revise its Treaty in 1991 in order to address an important dysfunction in its own system: instead of providing an incentive for innovation (breeding truly novel varieties), UPOV was providing an incentive for plagiarism (making slight changes on existing varieties and calling them "new" and worthy of protection). Gene Campaign has consistently opposed India joining the UPOV since this model does not address the needs of India and other developing countries. The reasons for this are several. The UPOV system is not suited for developing countries because it embodies the philosophy of the industrialized nations where it was developed and where the primary goal is to protect the interests of powerful seed companies who are the breeders. In the UPOV system, rights are granted only to the breeder, there are no rights for the farmer. In India the position is very different. We do not have big seed companies in essential seed sectors and our major seed producers are farmers and farmers' cooperatives. Logically, our law will have to concentrate on protecting the interests of the farmer in his role as producer as well as consumer of seed. Once we are in the system, we shall be forced to go in the direction that UPOV goes if not today then tomorrow. The writing on the wall in UPOV is clear. It is a system headed towards outright patents.

Starting with its first Amendment in 1978 when limited restrictions were placed on protected seed. The 1991 Amendment brought in very strong protection for the plant breeder. In this version, breeders are not exempt from royalty payments for breeding work and the exemption for farmers to save seed has become provisional. UPOV now also permits dual protection of varieties that means in the UPOV system, the same variety can be protected by Plant Breeders Right (PBR) and patents. It would seem obvious that UPOV is ultimately headed towards patent protection for plant varieties. It would be wise for India to stay out of a system which has plant patents as its goal since that is neither our goal nor our interest. UPOV laws are formulated by countries which are industrial, not agricultural economies. In these countries the farming community is by and large rich and constitutes from 1 to 5% of the population. These countries do not have the large numbers of small and
marginal farmers like we do. UPOV laws are framed in countries with a completely different agricultural profile to ours. These are countries where subsidy to agriculture is of a very high order unlike India. Because they produce a massive food surplus, farmers in industrialized countries get paid for leaving their fields fallow. The UPOV system does not have to protect the farming community of Europe in the way that our seed law will have to protect ours.

In Europe, agriculture is a purely commercial activity. For the majority of Indian farmers however, it is a livelihood. These farmers are the very people who have nurtured and conserved genetic resources. The same genetic resources that breeders want to corner under Breeders Rights. We must protect the rights of our farmers and these rights must be stated unambiguously in our *sui generis* legislation. Almost all agricultural research and plant breeding in India is financed with the taxpayers’ money. It is conducted in public institutions like agricultural universities and institutions of the Indian Council of Agricultural Research (ICAR). This research belongs to the public. The laws of UPOV on the other hand are formulated by societies where seed research is conducted more in the private domain than in public institutions; where big money is put into breeding using recombinant DNA technology which is expensive. Because they invest in expensive breeding methods and need to secure returns on their investments, seed companies in Europe seek market control through strong IPRs. These conditions do not apply in India. The UPOV system is far too expensive. The costs of testing, approval and acquiring an UPOV authorized Breeders Right certificate could be in thousands, even lakhs. Such rates will effectively preclude the participation of all but the largest seed companies. There certainly will be no space in such a system for small companies, farmers’ co-operatives or farmer/breeders. Farmers play a significant role as breeders of new varieties. They often release very successful varieties by crossing and selection from their fields. These varieties are released for use as such. In addition, in almost all cases, these varieties are taken up by agriculture universities as breeding material for producing other varieties. Such farmer/breeders would not be able
to participate in an expensive system like UPOV. Their material along with their labour and innovation would be misappropriated by those with the money to translate such valuable germ plasm into money-spinning varieties registered in UPOV. Poor farmers unable to pay the costs of getting an UPOV certificate would tend to sell their varieties for small sums to larger seed companies. This will be the ultimate irony, creating an institution that will snatch away from the farmer his material and his opportunities. Since the Ministry of Agriculture refused to take any action in developing alternatives to UPOV, Gene Campaign together with the Centre for Environment and Development drafted a developing country alternative to UPOV called the Convention of Farmers and Breeders (CoFaB). This proposed Treaty is designed to protect Farmers and Breeders Rights in the germ plasm owning countries of the South, to secure their interests in agriculture and to fulfill the food and nutritional security goals of their people. The salient features of CoFaB are an unambiguous and well defined Farmers Rights which recognizes the farmers' sophisticated knowledge of germ plasm, their contribution to the conservation of this germ plasm and their role in breeding and selecting well adapted, effective varieties of food and cash crops. Breeders Rights in CoFaB are protected without granting exclusive monopolies as in UPOV. CoFaB provides for strong and reasonable Breeders Rights which fully rewards their labour and innovation. It also places on them part of the responsibility of working towards the common goal of food and nutritional security. In its Human development Report of 1999, the UNDP has commended CoFaB as an alternative to UPOV. It has described CoFaB as a "strong and co-ordinated international proposal" which "offers developing countries an alternative to following European legislation by focusing legislation on needs to protect farmers' rights to save and reuse seed and to fulfill the food and nutritional security goals of their people".

Unfortunately, the Government is keener to toe the TRIPs and UPOV line than do any pro active thinking on how to protect Indian agriculture and the Indian farmer. Despite widespread acknowledgement at the national and international level that UPOV is detrimental to the interest of developing
country agriculture and an acceptance that CoFaB is a suitable alternative. The Ministry of Agriculture has enacted a *sui generis* legislation conforming fully to TRIPs and UPOV. This mindless if not perverse action is difficult to explain since a debate against UPOV has been conducted nationally and internationally for a long time. In fact, several countries in Asia, Africa and Latin America are strongly urging the rejection of UPOV as a model for the *sui generis* system in the WTO. The Act, called the Protection of Plant Breeders and Farmers Rights Act, 2001 is a flawed legislation. The philosophy and language is not Indian. It is anchored in the WTO and UPOV. The Preamble itself states that, this Act is being drafted in order to comply with the requirements of the TRIPs regime. In fact the Act opens with the text to provide for the establishment of an authority to give an effective system for protection of the Rights of Plant Breeders and Farmers, and to encourage the development of new varieties of plants and to give effect to sub-Paragraph (b) of Paragraph 3 of Article 27 in Part II of the Agreement on Trade Related aspects of Intellectual Property Rights. The purpose of the Act is to encourage the development of new plant varieties, as it is in UPOV, not to provide conditions to ensure food security.

The Indian Act also sets out to essentially protect the Rights of the Breeder as in UPOV. Farmers' Rights found mention in the Act only after aggressive campaigning by groups concerned with agriculture, food security, the issues of agriculture and Intellectual Property Rights. Gene Campaign and others who lobbied to get the original Bill re-examined and introduced suggestions for strengthening Indian interests, were consistently opposed by the lobby of the seed industry which had just as much interest in keeping the Act weak on issues like Farmers' Rights and strong on Breeders Rights. It was certainly reflected in the tug of war within the Ministry of Agriculture over the formulation of important clauses relating to the scope of Farmers' Rights and restrictions on Breeders Rights. The current version of the Act has essentially three major flaws of which the most alarming is the weak Farmers' Rights, the second is the irrational conditions for operationalising compulsory licensing and the third is the thoroughly inadequate, bureaucratic authority
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constituted to oversee the implementation of the Act. The diluted Farmers' Rights in the Act strikes at the very root of food security and hence it should not be accepted under any circumstances. What the Act contains under Section 31 which spells out Farmers' Rights is, "Nothing contained in this Act shall affect the right of a farmer to save, use, exchange, share or sell his farm produce of a variety protected under this Act. Provided that a farmer shall not be entitled for such right in case where the sale is for the purpose of reproduction under a commercial marketing arrangement."

Simply stated this means that, once the farmer plants a variety of seed on which someone has a Breeders Right, Farmers' Rights will allow that he or she can sell the produce of the farm. The farmer will also have the right to save this seed; it could be interpreted, to sow the next crop, although this is left ambiguous in the language. The Farmers' Right does not clearly spell out that the farmer has the unequivocal right to save his farm produce in the form of seed for him, to sow the next crop. The new law also allows the farmer to exchange and share his farm produce with others.

However, what the farmer can not do, according to the new law, is sell seed. And this is really the most devastating blow to the rights that farmers have today. According to Section 31, the farmer is not entitled to sell any part of his farm produce for reproduction that is for the purpose of seed. Any lawyer can explain that prohibiting sale of seed under 'commercial marketing arrangement' means a complete denial of the right to sell, whether the sale is of one kilogram or 1000 kilograms. It is clear that under the new law, sale of seed is prohibited to the farmer. When confronted with this, the babus in the Ministry of Agriculture have waffled endlessly and unconvincingly, that the wording denying sale under 'commercial marketing arrangement' does not impinge on the Farmers' Right to sell seed. It only restricts they argue, the farmer selling seed branded with the Breeders registered name. The obvious question then is, if that is what is truthfully intended; why not just make the wording of the Act clear and unambiguous? Why do it in such a complicated way, saying one thing but meaning something else? The second portion can
quite easily read - “Provided that a farmer shall not be entitled for such right in case where the sale is for the purpose of reproduction under a branded marketing arrangement.” Or another version could be “...not be entitled to such a right where the sale is in the form of packaged and labeled seed.” These formulations would protect the Rights of the Breeder over his/her certified variety. They would also protect the rights of the farmer to sell seeds of a variety protected by a Breeders Right but the special advantage conferred by the registered name would be available only to the breeder, not the farmer. The breeder would be monetarily compensated by the royalty payment included in the price of the first sale but would not be allowed to perpetuate this royalty in every sale. The farmer having the right to sell seed is an essential component of our food security and simply can not be trifled with. The consequences of denying the farmer the right to sell seed will lead to impoverishment and dependence for farming communities. It will also impact on national security in a quite dangerous way. The denial of the right to sell will lead to loss of income for the farmer, from seed sale. Far more worrying is that, it will lead to the farming community losing control over seed production. This will ultimately threaten self reliance in agriculture. There is a real danger that farmers could become dependent on multinational seed companies for seed supply, with all the implications that this could have.

However, none of the three Acts (the Patents Amendment Acts, 2005, the Protection of Plant Breeders and Farmers Rights Act, 2001 and the Conservation of Biodiversity Act, 2002) give legal status or legal protection to collective and cumulative innovation embodied in the traditional knowledge. Traditional medical practitioners and traditional farmers are thus left vulnerable to continuing biopiracy and erosion of their knowledge, practices and livelihoods. In fact all three laws facilitate monopolies and undermine Farmers’ Rights to seed, Peoples’ Rights to Medicine and our collective rights to our biological and intellectual heritage.

Therefore, the question arises: what are the implications for India of these curtailed Farmers’ Rights? The short answer to i.e., a compromise with
national security. Food security, as we are all aware, is a critically important part of national security. A nation that does not produce its own seed and its own food can not be a secured nation. Today, India plants over 60 lakh tons of seeds every year into its fields. The National Seeds Corporation and the various State Seed Corporations together produce less than 15% of this requirement. Over 85% of the seeds amounting to roughly 52 lakh tons that are planted in Indian fields every year are supplied by the farming community. In other words, India's largest seed producer is the Indian farmer. This right and freedom to function as the biggest, most de-centralized supplier of locally well-adapted seeds has helped India to make the transition from a grain deficient to a grain surplus nation, even if it is a precarious surplus. As we are taking the Farmers Rights to sell seeds, the shortfall in the market of 50 to 52 lakh tons of seed will be filled by MNCs. If that happens, India will lose control of its seed production, its agriculture and its food security.

Given that India's food security is monsoon dependent and uncertain and given that India has just about emerged from the humiliation of food imports, it is amazing that the Ministry of Agriculture have the nerve to put out legislation with such a threatening component for food security. What then needs to be done so that our genetic resources are not plundered and our agricultural security is not harmed? At the national level, civil society must mobilize public opinion against the damaging clauses concerning Farmers' Rights in the new legislation. Concerned citizens must demand a fully protective Farmers' Right and a rejection of the UPOV. At the international level, in the WTO, India must lobby for establishing a linkage between the Convention on Biological Diversity (CBD) and TRIPs, stating that it is the CBD which must have primacy over the TRIPs and not the other way round. Demanding primacy for the CBD is justified and supported by Article 22 of the CBD which says – The provisions of this Convention shall not affect the rights and obligations of any Contracting Party deriving from any existing international Agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity. It is clear that the implementation of TRIPs is detrimental to the health of biological
diversity and therefore its implementation must be made subservient to the conditions of the CBD.