

# **TRIPS: ISSUES, IMPACT AND THE WAY FORWARD FOR DEVELOPING COUNTRIES INCLUDING INDIA**

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## **I. Introduction:**

The Conclusion of the Uruguay Round (UR) and the signing of the agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) by member nations under the multilateral trade negotiations is a major landmark in the discipline and development of international law. However, many member countries of the WTO are faced with many difficult questions in defining their respective national intellectual property strategy and policy and designing intellectual property rights legislation in conformity with those policies and requirements of the TRIPS Agreement

The extent of protection and enforcement of intellectual property rights varied widely around the world and these differences became a source of tension in international economic relations. At the same time, they have been recognized as a development issue. It seems that TRIPS agreement is an attempt to narrow the gaps in the way these rights are protected around the world, and to bring them under common international rules. The Ministerial Meeting in Doha issued a Declaration, which stressed the need for TRIPS Agreement.<sup>2</sup>

The main objective of this policy draft is to provide better understanding of the economics and content of the TRIPS agreement and suggest the way forward to those countries who are in the process of designing the fine print of the IPR code and also for those which have already adopted legislation in this area. This draft has reviewed the implications of the TRIPS agreement based on the issues raised by the developing countries. It provides an overview of the relationship of intellectual property rights with various development dimensions of the economy. The policy draft also analyses provisions on copyright and related rights in TRIPS and in the relevant provisions in the Berne Convention and discusses the new World Intellectual Property Organization (WIPO) treaties and the unresolved issues on databases and audiovisual works. The policy draft also discusses the patent regime of India and examines the impact of the new TRIPS regime beyond 2005.

Contrary to popular perceptions many developing countries were already in compliance with many of the specific provisions of TRIPs. For example, many developing countries have a long tradition of protecting copyright, having continued and even further strengthened national laws instituted in the late nineteenth

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<sup>2</sup> The Ministerial Declaration adopted on 14th November, 2001 at the Doha meet on TRIPS stressed the importance of implementation and interpretation of the Agreement in a manner supportive of public health, by promoting both access to existing medicines and research and development. Further, it notes the extension of geographical indications to products other than wines and spirits and instruct the council for TRIPS to examine the relationship between TRIPS agreement and convention on Biological Diversity and the protection of traditional knowledge and folklore.

century<sup>3</sup>. However, in certain areas they are unlikely to give up limited flexibility available in TRIPs to alleviate any perceived ill effects of such protection or to balance the interest of third parties.

## II. Economics of IPRs

Economic theory provides rationale for protecting IPRs. Patents are perhaps the most important legal instruments for protecting intellectual property rights. The production and dissemination of new knowledge is fraught with market failures because knowledge is a public good. Patents provide a second-best solution to the resulting appropriability problem. Economic models can show that patents play an important role in providing incentives for innovation, in promoting the dissemination of knowledge, and in helping technology transfer and commercialization of new technology. As such, the patent system contributes to solving a problem but comes with shortcomings of its own, mostly because it creates market power positions that can adversely affect the economic performance of the system. In fact, for most of the nineteenth century, the patent system was under considerable criticism by the same economics profession that now provides the most valuable insights for its defense. This change is due to the increased appreciation for the critical role that innovations play in stimulating economic growth. The possibility of protecting discoveries through patents, for example, is credited for bringing about crucial technical improvements in the industrial revolution (Dutton 1984).

Langiner and Moschini (2002) notes that *ex post* inefficiency of the patent system can be viewed as the necessary downside in providing enough inducement to undertake desirable R&D projects. The size of the inducement depends on the length and scope of the patent right. Ideally, such an inducement should be proportional to the cost of the R&D project, which means that the length, breadth, and height of a patent<sup>4</sup> should be tailored to each particular innovation. In addition to the cost of the project, such a tailored patent should also reflect the particular market conditions of the new product and/or process. Clearly, the patent system does not do that, and arguably it cannot do that. These limitations suggest that continued efforts are required to improve the workings of the patent system. An understanding of its complex (and sometime subtle) economic implications, is required.

The main justification for patents is to foster innovation in a market economy, but the patent system is not the only method for encouraging innovation. Copyrights and trademarks, are additional instruments for intellectual property right protection that typically apply in contexts where patents do not. Trade secrets, on the other hand,

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<sup>3</sup> For example, Latin American countries like Bolivia, Chile, Columbia, Ecuador, Guatemala, Haiti, Mexico, Peru and Venezuela. Others like Argentina, Brazil and Egypt protected such rights under their civil, criminal or press laws. Yet others became members of the Berne Convention as colonies, e.g., India in 1887., it was the US that joined as late as 1988.

<sup>4</sup> Whereas the length of the patent protection characterizes the duration of the monopoly power, the scope of a patent bears on the intensity of the induced monopoly power (Merges and Nelson 1990). The breadth of a patent defines the range of products that are encompassed by the claims of the patent and therefore protects the patent holder against potential imitators. In general, the less specific the claims of the patent are, the broader the patent. The height of a patent, on the other hand, confers protection against improvements or applications that are easy or trivial. The value of a patent to a firm depends on how effective its protection is in these two dimensions (breadth and height), in addition to being related monotonically to the patent length.

can apply to patentable innovations and can provide effective protection against another party's discovery by inappropriate means (although a trade secret offers no protection against independent discovery or reverse engineering). Certain biological innovations are also afforded *sui generis* protection by such means as plant patents and plant variety protection certificates (Barton 1998).

More generally, alternatives to patents include rewards or prizes, procurement contracts, and public production of new knowledge. With the reward system, the government specifies a fixed sum of money for a well-defined research goal and then awards this "prize" to the first firm to achieve the desired result. Asymmetric information between researchers and the government can make it difficult to implement the reward mechanism (Wright 1983). Specifically, to be effective, the government must know about the feasibility of various research projects as well as be able to assess the demand for various potential innovations. But firms are likely to be better informed than the government on such matters, and a decentralized solution such as the patent system may be superior.

With the procurement system, the government picks the firms that will be involved in the research project and specifies the terms of the project (such as expected research output and compensation terms) in a binding contract (Laffont and Tirole 1993). Unlike the prize system, this method can eliminate unwanted duplication of research efforts. But again, for this system to be efficient, the government must be quite knowledgeable about the costs and benefits of research ventures. More generally, innovations can be stimulated by the government's direct involvement in the production of new knowledge. Much of the research carried out at public institutions, and sponsored by public funds, is an example of such knowledge production. This structure, together with the complex social milieu characterizing academic institutions, has made possible the "open science" environment that can take substantial credit for many scientific and technological breakthroughs (Stephan 1996; David 1998). The tension between the behavioral standards of open science and the privatization of new knowledge made possible by patents is readily apparent. The concern is that the increased reliance on intellectual property right mechanisms may be eroding the domain of public information and access to research tools, which could have serious long-term consequences for the vitality of the community of science (David 2000).

### **III. Intellectual Property :Technology Development &Transfers and International Trade**

#### **III.1 Technology Development and Transfers**

The issue of technology transfer is possibly one of the most important area of interest to developing countries. It was precisely because of this concern that many developing countries were originally opposed to a GATT-driven accord on intellectual property rights. Indeed, one of the most important changes in international intellectual property embodied in the TRIPS agreement is the extension of the scope of protection to all types of technologies. Article 27 on patentable subject matter provides that "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced." This provision brought under the scope of the agreement technological fields such as pharmaceuticals products that were previous excluded from patentability by

many countries. It is therefore a surprise that one of the first disputes to be dealt with by WTO was on pharmaceutical products.

Since one of the aims of intellectual property protection is to stem unlicensed technology spillovers it is expected the countries that are most affected will call for alternative mechanisms to address this issue under the TRIPS agreement. It is not a surprise that India for example is calling for the establishment of working group on technology transfer (WTO, 1994). The call takes into account the implications of other agreements under WTO such as the General Agreement on Trade in Services (GATS), the Technical Barriers to Trade (TBT) agreement and Sanitary and Phyto-Sanitary agreement. India envisages the working group to "foster access to technologies; cooperate in the development of scientific and technical resources including the creation and growth of national innovations system; grant credits for financing the acquisitions of technology; provide assistance and cooperation in the development and administration of laws and regulations likely to facilitate (technology transfer); strengthen the negotiating capacity for (technology transfer) transactions; and assist in the protection and commercializing local innovations. In addition the working group would also study the design of incentives that industrialized countries could grant to enterprises and institutional in their own countries to facilitate transfer of technology to developing countries.

The call by India arises from Article 7 on the objective the TRIPS agreement under which intellectual property protection should contribute "to the promotion of technological innovation and to transfer and dissemination of technology, to the mutual advantage producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to balance of rights and obligations". With the growing technological gap between the developed and developing countries, the developing countries are likely to increasingly call for creation of mechanisms that promote technology transfer and dissemination.

Many of the technology related arguments are linked to the public interest provisions of the TRIPS agreement and the perception that these were being eroded. One of the areas that has received much attention recently is the impact of intellectual property on the health care in the developing countries.

### **III.2 IPR and International Trade**

The debate on the relationship between intellectual property and international trade is a continuation of divergent interests of developed and developing countries in regard to access to technology (For the review of the issues see The South Centre; 1997, 1998).

Nations that generate technology have always sought to protect it while those that import it have pursued avenues that maximize access to the available technology (see Yusuf, A.A. 1998). The technological imitation and learning strategy has guided the development strategies of most industrialized nations. For example, when "the US was still a relatively young and developing country... it refused to respect international intellectual property rights on the grounds that it was freely entitled to foreign works to further its social and economic development (Office of Technology Assessment, 1986). The history of intellectual property protection in pharmaceutical products demonstrates this point. Many of the industrialized countries introduced patent

legislation in this field after they had attained a certain level of technological competence and international competitiveness.

More recently, technological learning has provided the policy basis for rapid industrialization among developing countries (Kim, 1997). Developing countries have favored policies and laws that promote the local working of patents, parallel imports, compulsory licensing and exclusion from patentability for certain classes of technologies. Much of the debate over the loosening of patent and copyright protection to allow for greater developing country access to technology occurred in the World Intellectual Property Organization (WIPO). For example, Berne Convention for the protection of literary and artistic works was substantially expanded in 1971 to include an annex on "special provisions regarding developing countries". The annex allows a country to "grant non-exclusive, non-transferable licences to its national for the reproduction or translation of foreign owned copyright works for educational or research purposes". These revisions were justified on the basis of national public interest and similar revisions were attempted in other intellectual property regimes.

The TRIPS agreement provides flexibility to developing countries to pursue their economic and social goals. Article 8 states countries "may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement." The agreement (in Article 8.2) provides countries with freedom to adopt measures that "may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology." This prevention of abuse clause deals primarily with measures that undermine competition. However, Maskus (1999) argues that TRIPS agreement needs amendment to protect the interest of developing countries. This issue arises from Article 40 of the TRIPS agreement which deals with "licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights have an adverse effect on competition in the relevant market. The study has proposed that this could be remedied by the adoption of a Trade Related Anti-trust Measures Agreement (TRAMs) which "would focus on basic principles, cooperation in procedures, and disciplines against clearly anticompetitive measures such as tolerance of export cartels and domestic exclusionary agreements and the protectionist use of anti-dumping rules." However, to achieve this may be difficult because of certain tradeoffs involved.

Although the agreement provides the leeway for developing countries to formulate laws that promote public interest goals, such laws must be consistent with the overall spirit of development. The success of initiatives taken by individual countries will therefore be viewed by other members of WTO in the context of the overall implementation of the agreement. This includes the way other countries seek to enforce the provisions of the agreement.

#### **IV. IPR and Health**

Without the incentive of patents it is doubtful the private sector would have invested so much in the discovery or development of medicines, many of which are currently in use both in developed and developing countries. But the evidence suggests that the IP system

hardly plays any role in stimulating research on diseases particularly prevalent in developing countries, except for those diseases where there is also a substantial market in the developed world (e.g. diabetes or heart disease). Nor is it likely that the globalization of IP protection will lead to greater investment by the private sector for the development of treatments for diseases that primarily affect developing countries. The evidence also suggests that patent protection has an effect on the prices charged for medicines. In developed countries, generic competition causes prices to fall quite sharply, particularly if the market is large enough to support a number of generic competitors. In the absence of patents in developing countries, more people would be able to afford treatments they need. When TRIPS comes fully into force after 2005, particularly when countries such as India have to introduce patent protection, the existing competition from generic suppliers will diminish.

The IP system is one factor among several that affects poor people's access to healthcare. Other important constraints to access to medicines in developing countries are the lack of resources, and the absence of a suitable health infrastructure (including hospitals, clinics, health workers, equipment and an adequate supply of drugs) to administer medicines safely and efficaciously. Moreover, developing countries may adopt other policies, for example, taxes on medicines, which adversely affect access.

As intellectual property rights are strengthened globally, the cost of medicines in developing countries is likely to increase, unless effective steps are taken to facilitate their availability at lower cost in developing countries. There are a number of IP policies that both developed and developing countries can adopt to promote cheaper prices for medicines in developing countries which will adversely affect the incentives for research on relevant diseases. One means of obtaining medicines at lower prices, amongst others discussed in this policy draft is for countries to use a mechanism called "compulsory licensing." This allows countries to license the manufacture of patented medicines to other manufacturers if there are good reasons to do so (e.g. when the government considers the price of a medicine is unjustifiably high). It can also be useful as a bargaining tool in price negotiations with producers of patented medicines. For instance, the US envisaged this possibility when negotiating the price of Cipro following the anthrax attacks last year. The importance of the IP system being used to improve access to medicines and public health was emphasized in a Declaration on TRIPS and Public Health at the WTO Ministerial meeting in Doha last year<sup>5</sup>.

A major issue at Doha was how countries without the capacity to manufacture medicines could procure them under the existing rules for compulsory licensing. There are a

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<sup>5</sup>Adopted on November 14, 2001 at the Fourth WTO Ministerial Conference in Doha. It stresses the importance of intellectual property protection for the development of new medicines, but recognizes the need for flexibility for the protection of public health. For example, paragraph 5.(c) recognizes each Member's right to determine what constitutes a national emergency or other circumstances of extreme urgency understanding public health crises such as HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency. Section (d) further states that the effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge.

number of ways this can be achieved. A crucial issue is how this can be effected in such a way that it provides appropriate incentives for the potential suppliers of medicines and cheaper prices than the patentee is able to offer.

Apart from international measures to facilitate access to medicines, developing countries need to adopt IP rules in their legislation and practices that limit the extent of patenting and facilitate the introduction of generic competition. Doha also allowed Least Developed Countries (LDCs) to exempt pharmaceutical products from patent protection until at least 2016. But most LDCs have already provided such protection and would need to amend their legislation accordingly.

- Because the IP system does little to stimulate research on diseases that particularly affect poor people, public funding for research on health problems in developing countries should be increased. This additional funding should seek to exploit and develop existing capacities in developing countries for this kind of research, and promote new capacity, both in the public and private sectors.
- Countries need to adopt a range of policies to improve access to medicines. Additional resources to improve services, delivery mechanisms and infrastructure are critical. Other economic policies need to be in harmony with health policy objectives. But so also does the IP regime. Countries need to ensure that their IP protection regimes do not run counter to their public health policies and that they are consistent with and supportive of such policies.
- The IP system can help to establish differential pricing mechanisms, which would allow prices for drugs to be lower in developing countries, while higher prices are maintained in developed countries. If differential pricing is to work, then it is necessary to stop low priced drugs leaking back to developed countries. Developed countries should maintain and strengthen their legislative regimes to prevent imports of low priced pharmaceutical products originating from developing countries and to help maintain the price differential. However, developing countries should aim to facilitate in their legislation their ability to import patented medicines if they can get them cheaper elsewhere in the world. TRIPS allows countries to set their own rules on what are technically called “parallel imports.”
- Developing countries should establish workable laws and procedures to allow them to use compulsory licensing. They should also make similar provisions for what is called “government use.” Many developed countries have such laws that allow their governments to make use of patented inventions without infringing a patent under a wide range of circumstances.
- How the issue of facilitating compulsory licensing for developing countries with inadequate manufacturing capacity is to be resolved is currently being debated in the TRIPS Council. It raises a number of quite detailed legal and practical matters. A way needs to be found to reconcile the nature of the solution adopted with the objective of providing medicines of the appropriate quality at the lowest possible

cost. If that cannot be achieved, the solution will have little practical reality. Nor will the option of compulsory licensing be effective as a negotiating tool with companies. Whatever the solution adopted, it should be capable of quick and easy implementation to ensure that the real needs of poor people in developing countries are given priority. And it should establish conditions that provide potential suppliers with the necessary economic incentive to export medicines that are needed by these countries.

- TRIPS allows considerable flexibility in how countries may design their patent systems. Since most developing countries do not have a significant research capability, they have little to gain by providing extensive patent protection as a means of encouraging research, but they stand to lose as a result of the impact of patents on prices. Therefore developing countries should aim for strict standards of patentability to avoid granting patents that may have limited value in relation to their health objectives. Such systems should aim to promote competition, and provide safeguards in the event of abuses of the patent system.
- For instance, most developing countries should exclude diagnostic, therapeutic and surgical methods from patentability, including new uses of known products, as permitted under TRIPS.
- Developing countries should also make provisions in their law that will facilitate the entry of generic competitors as soon as the patent has expired on a particular drug. One of these provisions (the “Bolar exception”) allows generic companies to develop their versions of patented drugs during the term of the patent without infringing it. Another one would be to make it easier and cheaper for generic companies to get regulatory approval for drugs similar to registered drugs, while providing for the protection of test data (e.g. clinical trials data companies require to get approval from regulators such as the FDA in the US) against unfair commercial use.
- Those LDCs which already provide pharmaceutical protection should consider carefully how to amend their legislation to take advantage of the Doha Declaration. The TRIPS Council should review the transitional arrangements for LDCs, including those applying to join the WTO, in all fields of technology.

These suggestions are in conformity with the recommendations made by the UK Commission on IPR(2002)

## **V. Copyright, Internet Material and Related Rights**

### **V.1 Copyright Provision of TRIPS and Internet Material**

Copyrights law protects the right of Intellectual creators with respect to their original work. The subject matter of copyright is literary and artistic works. All such works are protected as long as these are original expressions of an idea. The idea/expression dichotomy enables others to express the same or similar idea and receive copyright

protection as long as the expression satisfies the test of originality. Therefore, unlike product patents, copyright does not give the rightholder any monopoly over commercially viable ideas. The Berne Convention for the protection of Literary and Artistic works, as revised up to 1971, provided the highest level of international legal protection for copyright, prior to TRIPS.<sup>6</sup> Generally, copyright protection begins automatically from the date of creation, usually without being subjected to any formalities. Copyright protection lasts for the life of the author plus fifty years after the death of the author<sup>7</sup>. Although the traditional focus of copyright law has been books, music, painting or films, copyright protection now extends to computer software and compilations of data.

The most fundamental right conferred by copyright is the right to exclude unauthorized reproduction of the copyrighted work. Most copyrights laws also prohibit certain acts such as performing the work in public, making a sound or audiovisual recording of the work, making a motion picture of the work and translations or adaptations of the work. In addition to these economic rights, most copyright laws recognize moral rights, which normally include the author to claim authorship and to protect the work from mutilation or distortion.

Like patent law, copyright law seeks to balance the rewards to creators with the public interest in gaining access to the work. Copyright laws recognize much wider limitations to the exclusive rights granted to the right holder than in any category of IPR. In recent years the control of piracy in copyrighted works is becoming a more pressing issue, particularly with the rapidly advancing technologies that facilitate cheap and easy dissemination of these works. The boom in Internet sales of pirated music or software continues to grow unabated. New technologies are extending this kind of piracy to audiovisual works and books.

Despite the substantive progress made in WIPO on improving copyright protection in the new digital environment, the real problem lies in the fact that some music software companies allow to download music free of cost from their site particularly when the same is available in the market for a price. On the other hand it allows authors and performers an opportunity to sell their music or products directly to the consumers. At present no standard digitally secure format exists to download these works legally, protecting copyright owners. Moreover, there are legal difficulties in applying copyright notions such as 'publication' or 'country of origin' or 'reproduction' and questions arise whether copyright owners need new rights or exceptions to such rights or new ways of managing such rights. With increasing access to the Internet in developing countries these problems are likely to affect local copyright and related owners as much, if not more than, than foreign owners. It is thus in the interest of developing countries to keep abreast of such developments and participate fully in any future international agreements. International cooperation is required to tackle problems of piracy in this 'borderless' world. Members of the WIPO concluded a new WIPO Copyright Treaty (WCT) in December 1996. This treaty was intended to resolve the difficulties arising out of new

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<sup>6</sup> The Universal Copyright Convention administered by UNESCO is considered to provide a lower level of protection.

<sup>7</sup> In case the author is a corporation or other legal entity the duration usually begins from the date of first publication. This is the minimum requirements in the Berne Convention but many countries go further. India for instance grants "life" plus sixty while in Europe and the US this is "life" plus seventy years.

provisions of TRIPS into international copyright law as administered by WIPO, this treaty provides for some TRIPS-plus provisions, notably:

1. Owners of copyright are given an exclusive right of distribution (article 6)
2. The right of communication to the public is made explicit to cover the right to authorize any communication to the public, by wire or wireless means, including 'in such a way that members of the public may access these works from a place and at a time individually chosen by them', i.e. online interactive communication through the internet.
3. An obligation to provide adequate legal protection and effective remedies the circumvention of effective technological measures used by authors to exercise their copyright. This would cover encryption or water marking technologies that protect such works on the Internet.
4. An obligation to provide adequate and effective legal remedies against any deliberate unauthorized removal or alteration of any electronic rights management information (RMI) that identifies the work or its authors/owners such as those necessary for licensing, collecting royalties (Article 12).

The directive does not extend the right of communication, as required by Article 11 of the WCT, to broadcasting, including new forms such as pay-TV or video-on-demand, as these are not the same as on demand services for digitally formatted material.

There are however exceptions to the above which allows for certain technical copying such as that done during internet transmissions and are limited to the following:

- use for the sole purpose of illustration for teaching and scientific research
- non-commercial uses for the benefit of visually -impaired or hearing-impaired people;
- use of excerpts in connection with the reporting of current events
- quotation for criticism or review;
- use for the purpose of public security or proper performance of an administrative or judicial procedure.

Members can continue with existing exceptions on private copying, reprography or use of libraries.

However, the 1996 WIPO Copyright Treaty contains elements which may restrict the access of developing countries to information. Therefore,

- Publishers, including those on-line, and software producers should review their pricing policies to help reduce unauthorized copying and to facilitate access to their products in developing countries. Initiatives being undertaken by publishers to expand access to their products for developing countries are valuable and we encourage an expansion of such schemes. The extension of free on-line access initiatives for developing countries to cover all academic journals is a good example of what could be done.
- In order to improve access to copyrighted works and achieve their goals for education and knowledge transfer, developing countries should adopt pro-competitive measures under copyright laws. They should be allowed to maintain or adopt broad exemptions for educational, research and library uses in their national copyright laws. The implementation of international copyright standards in the developing world must be undertaken with a proper appreciation of the continuing high level of need for

improving the availability of these products, and their crucial importance for social and economic development.

- Developing countries and their donor partners should review policies for procurement of computer software, with a view to ensuring that options for using low-cost and/or open-source software products are properly considered and their costs and benefits carefully evaluated. In order that software can be adapted to local needs, developing countries should ensure that their national copyright laws permit the reverse engineering of computer software programmes, in ways that are consistent with relevant international treaties which they have signed.
- Internet users in developing nations should be entitled to fair use rights such as making and distributing printed copies from electronic sources in reasonable numbers for educational and research purposes, and using reasonable excerpts in commentary and criticism. Where suppliers of digital information or software attempt to restrict “fair use” rights by contract provisions associated with the distribution of digital material, the relevant contract provision may be treated as void. Where the same restriction is attempted through technological means, measures to defeat the technological means of protection in such circumstances should not be regarded as illegal. Developing countries should think very carefully before joining the WIPO Copyright treaty. In the USA, recent legislation (the Digital Millennium Copyright Act - DMCA) forbids the circumvention of such technological protection, even when the purpose of circumvention does not contravene copyright laws. The EU has introduced a special form of protection of databases (the “Database Directive”), which rewards investment in the creation of databases, and which may restrict access to data by scientists or others, including in developing countries. Countries should also not follow the lead of the US and the EU by implementing legislation on the lines of the DMCA or the Database Directive.

.It is only upon ratification by member countries that the WCT enters into force. Once it has entered into force, the treaty binds a country soon after ratification. Many developing countries may prefer to amend their copyright laws to make these changes before ratification, particularly those where international treaties are not self-executing. The possibility of incorporating the new WIPO treaties into TRIPS has already been raised in the TRIPS Council and will, doubtless, be reiterated once these treaties enter into force and are widely ratified. Most developing countries WTO members participated actively and supported these new WIPO treaties.

There are examples of developing countries, which have benefited from copyright protection. The Indian software and film industry are good examples. But other examples are hard to identify. Many developing countries have had copyright protection for a long time but it has not proved sufficient to stimulate the growth of copyright-protected industries. Because most developing countries, particularly smaller ones, are overwhelmingly importers of copyrighted materials, and the main beneficiaries are therefore foreign rights holders, the operation of the copyright system as a whole may impose more costs than benefits for them. As mentioned above there are flexibility's in copyright which exist in international treaties (such as the Berne Convention) to allow

copying particularly for personal and education use. These are known variously as “fair use” or “fair dealing” provisions. These have generally not proved adequate to meet the needs of developing countries, particularly in the field of education.

Developing countries need to put in place effective systems for enforcing rights. However, in many cases (e.g. software) the absolute scale of estimated losses from illicit copying is higher in developed countries. And weak levels of enforcement have undoubtedly had a major impact in some areas on the diffusion of knowledge and knowledge-based products in the developing world. Indeed, many poor people in developing countries have only been able to access certain works through use of unauthorized copies available at a fraction of the price of the original. An inevitable impact of stronger protection and enforcement, as required by TRIPS, will therefore be to reduce access to knowledge-related products in developing countries, with potentially damaging consequences for poor people. For instance, the cost of software is a major problem for developing countries, and the reason for the high level of illicit copying. Copyright can also be a barrier to the further development of software which is specifically adapted to local needs and requirements.

Access to the Internet in developing countries is limited, although growing rapidly in most countries. But the Internet provides an unrivalled means of low cost access to knowledge and information required by developing countries, when their access to books and journals is severely restricted by lack of resources. But the application of copyright rules to the Internet is problematic. And historic “fair use” rights may be restricted by forms of technological protection, such as encryption, which restrict access even more stringently than copyright.

## **V.2 Copyright Related Rights**

. Copyright has some closely related rights that follow similar principles of protection. These are called related rights or neighboring rights. These rights protect persons, other than the creators, who are involved in the dissemination of copyrighted works. The use of this term is usually confined to three specific categories of persons: performers, producers of phonograms and broadcasting organizations. In some countries such rights may be part of the copyright law<sup>8</sup>, while in others there is different legislation to cover these rights. Interestingly, unlike the case of other IPRs, it was an international agreement to provide such protection, the Rome Convention, 1961,<sup>9</sup> that triggered protection under national laws. The term of Protection in laws on related rights begins from the date of fixation, performance or broadcast, again without being subject to any formalities, and usually lasts for twenty years from this date. Protection of related right also serves to encourage creativity and the dissemination of creative works.

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<sup>8</sup> For instance, in countries with a common law tradition, like the US or India, the rights of producers of phonograms are covered under copyrights.

<sup>9</sup> The International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations, 1961. Subsequently, two new international agreements, the Convention for the Protection of Producers of Phonograms Against Unauthorized Duplication of Their Phonograms, 1971 (commonly known as the Phonograms Convention) and Convention Relating to the Distribution of Programmes Carrying Signals Transmitted by Satellite, 1974 (commonly known as the Satellites Convention) were conducted under the auspices of the WIPO.

With the conclusion of TRIPS under the Uruguay Round of multilateral trade negotiations, Protection of copyright and related rights became, for the first time, a subject covered by international trade law. Indeed, it was the wide scale sale and export of pirated sound recordings, films and software that set off the demand for worldwide protection of IPRs in GATT by the US and EU.<sup>10</sup> Even the US linked such protection to trade, there have been such historical precedents. In the mid-nineteenth century a new commercial treaty was finalized between France and Belgium only when Belgium agreed to the protection of the rights of France's authors<sup>11</sup> and publishers.

Copyright and related rights form an integral part of intellectual property rights. Article 9 to 13 of TRIPS specify the minimum standards for the protection of copyright. Although TRIPS goes beyond the preexisting international conventions on copyrights, there has been relatively marginal nature of additions testified by the fact that the North South negotiations on this subject have been less contentious as they were in the area of patents. Many developing countries have a long tradition of protecting copyright, having continued and even further strengthened national laws instituted in the late nineteenth century. In general, the Berne convention, as modified upto 1971 took into account the special needs of developing countries. The changes introduced by TRIPS are mostly in the nature of legalistic clarifications and do not represent a dramatic increase in the level of protection.

Article 9.1 of TRIPS establishes that WTO members must comply with Articles 1 through 21 of the principal pre-existing international agreement on copyright, the Berne convention (1971), including the Appendix thereto. During the TRIPS negotiations no developing country expressed any reservation on this.

The only exception to adherence to the Berne Convention in the TRIPS text was the result of an objection raised by the US to Article 6bis of that Convention which obliges members to protect the moral rights of authors. Article 6bis, paragraph (1) of the Berne Convention states:

Independently of the authors economic rights, and even after the transfer of the said rights, the author shall have the right to claim authorship of the work and to object to any distortion, mutilation or other modification of, or other derogatory action in relation to, the said work, which could be prejudicial to his honor or reputation.

Thus, under Article 6bis the authors of copyrighted works retain their prerogative to claim paternity of the work even after they have authorized reproduction or use. The prerogative of objecting to any modification of the work that authors consider derogatory to the works or prejudicial to themselves is also retained. The US objection to this may be that it would give owners of copyright the right to unjustifiably interfere in the adaptation of their copyrighted works even after authorizing such use.

It may be noted that normally moral rights may not apply to computer programmes in the way that they do to other copyrighted works. Some developing countries have sought to restrict the moral rights of authors of computer programmes in their recent

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<sup>10</sup> Nevertheless, it was recognized that some developing countries had long traditions of protecting copyright in their own domestic interests. See Gadbow and Richards (1988), p.16. These authors particularly noted the high level of copyright standards in Argentina, Brazil, India and Mexico.

<sup>11</sup> See Nimmer and Gellers (1998) at INT-37. See also Ricketson (1987), pp.35-6 wherein it is stated that existed prior to the Berne Convention were linked to some broader trade treaty and contained "most-favoured-nation" clauses for copyright.

legislation. While this is compatible with TRIPS, it may not be compatible with the new WIPO Copyright Treaty. India exempts adaptations made in order to utilize a computer programme for the purpose it was supplied. Further, while moral rights are available to producers of sound recordings, they do not extend to performers or broadcasting organizations.

Even in the pre-Uruguay Round period almost all countries protected copyright and many were members of the Berne Convention. Since its very inception in 1886 this convention required members to accord national treatment to foreign under the domestic law. Article 3(1) of the Berne Convention calls for the protection of all authors in member countries, irrespective of the nationality of the author or place of publication. In addition, Berne automatic protection immediately to foreign authors upon creation without subjecting such works to any formality. Some important exceptions applied to national treatment, notably the application of the rule of the shorter term. Under this rule, a Berne member faced with an author of work protected by another member that has a shorter term of protection in its copyright law (but the minimum required under Berne), may apply the shorter of two terms to such works. This exception is carried over the TRIPS through its requirement to adhere to the Berne Convention.

Copyrights protect creative expression and not ideas. This is generally acknowledged in Article 2(1) of the Berne Convention though not in explicit terms<sup>12</sup>. TRIPS now extends and elaborates this concept in specific terms by stating in Article 9.2 that copyright protection must cover expressions but not ideas, procedures, method of operation or mathematical concepts.

The council for TRIPS shall examine and report on the intellectual property issues arising in connection with electronic commerce. The issues to be examined shall include: Protection and Enforcement of Copyright and Related Rights; Protection and enforcement of trade marks; New technologies and access to technology

For developing countries, access at reasonable prices to foreign copyrighted works has to be balanced against adequate remuneration and incentives to domestic performers and copyright and related right owners. Unlike in other IPRs, developing countries are creators of a large amount of copyrighted works themselves and have important domestic lobbies seeking stronger and more effective protection in such rights.

Copyright only gives authors the right to prohibit copying or reproduction and use of protected work in certain ways. There is generally no right to prevent use of the work once it has been legitimately placed on the market. The work can, thus, be resold or commercialized. This is widely accepted principle of exhaustion of IPRs after the first sale. Rental rights i.e the right of authors to authorize or prohibit rentals of the work, were introduced for the first time in international copyright law under the TRIPS regime. This concept was primarily directed at computer programmes and sound recordings where it was perceived that a single act of rental could result in the private copying of the work, an act not prohibited under copyright or related rights. Once rentals are allowed, wide scale private copying is not easy to prevent, thus affecting the legitimate interest of the right

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<sup>12</sup> In the commentary to Article 2(1) the WIPO's Guide to the Berne Convention states: 'A fundamental point is that ideas, as such, are not protected by copyright. It is the patent rather than copyright laws to which one must look for protection.'

holder. Such a right may not have been necessary earlier as the technology for good quality or easy private copying had not yet developed.<sup>13</sup>

The real problems for developing countries in implementing section on copyrights in the TRIPS agreement may not arise from amending the legislation on the subject to incorporate new international commitments but in the enforcement of such rights. Even if the procedural requirements laid down in Part III of TRIPS are met, there would be questions on interpretation of the terms 'unreasonable time limits' or 'unwarranted delays'. Although there are not obligations on ex-officio action and a civil suit has to be initiated by the right holder in defending his IPRs, the state has an obligation to institute criminal remedies and border measures on copyright piracy. Preventing copyright piracy in the digital environment will be a stupendous task for countries with fewer resources to do so.

## **VI. Agriculture and Genetic Resources**

The amount of public resources from developed countries going into funding research relevant to poor farmers in developing countries is stagnant or declining, the dynamic element is private sector research, supported by IP protection and the demand from farmers in developed countries, and the commercial sectors of a few developing countries. This combination of trends poses the danger that research priorities overall will be increasingly less relevant to the needs of poor farmers in developing countries. Moreover the stagnation in public funding threatens, inter alia, the maintenance of national and international gene banks which are the principal source of the genetic material for future breeding efforts of relevance to poor farmers. While in recent years the IP rights of breeders have been increasingly strengthened, as required by TRIPS, little has been done in practice to recognize the services of farmers in the selection, development and conservation of their traditional varieties on the basis of which modern breeding techniques have built. The recently agreed FAO Treaty on Plant Genetic Resources seeks to protect the material in gene banks covered by the treaty from being directly patented, and also encourages countries to protect Farmers' Rights.

Under TRIPS countries must apply some kind of IP protection to plants, either patents or other kinds of protection of plant varieties (called *sui generis*). They must also allow microorganisms to be patentable. There is empirical evidence for some countries which suggests that *sui generis* systems of plant variety protection (PVP) have not been particularly effective at stimulating research on crops in general, and particularly for the kind of crops grown by poor farmers. Systems of PVP designed for the needs of commercial agriculture in the developed countries (such as provided for in the UPOV Convention) also pose a threat to the practices of many farmers in developing countries of reusing, exchanging and informally selling seeds, and may not be appropriate in developing countries without significant commercial agriculture. Patents are commonly used in developed countries both to protect plant varieties, and to protect genetic material incorporated in plants. Because they offer a stronger form of protection than most PVP

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<sup>13</sup> See WIPO(1995) Guide to the Berne Convention, pp 55-7. The Internet has now made private copying even easier but this has nothing to do with rentals.

systems they may offer a stronger incentive to research, particularly in developed countries, and the multinational agrochemical companies regard them as important. However, patents also pose a threat to farmers' traditional practices of reuse and exchange. Moreover the proliferation of genetic patents owned by different companies has led to costly disputes, and difficulties in pursuing research without infringing other companies' patents. There is evidence that patents are one factor contributing to the rapid concentration in the agricultural biotechnology field, with adverse effects on the degree of competition.

- Because of the restrictions patents may place on use of seed by farmers and researchers, developing countries should generally not provide patent protection for plants and animals, as is allowed under TRIPS. Rather they should consider different forms of sui generis systems for plant varieties.
- Because they are unlikely to benefit from the incentives to research offered by the patent system, but will have to bear the costs, developing countries with limited technological capacity should restrict the application of patenting in agricultural biotechnology, in ways that are consistent with TRIPS. For similar reasons they should adopt a restrictive definition of the term "microorganism".
- However, countries that have, or wish to develop biotechnology-related industries may wish to provide certain types of patent protection in this area. If they do so, specific exceptions to the exclusive rights, for plant breeding and research, should be established. The extent to which patent rights apply also to the harvested crop also needs to be carefully examined. It is important that a clear exception to the patent right is included in legislation to allow for farmers' reuse of seed.
- The review of the relevant provisions in TRIPS which is currently taking place in the TRIPS Council, should preserve the right of countries not to grant patents for plants and animals, including genes and genetically modified plants and animals. It should also permit countries to develop sui generis regimes for the protection of plant varieties that suit their agricultural systems. Such regimes should permit access to the protected varieties for further research and breeding, and provide for the right of farmers to save and plant-back seed, including the possibility of informal sale and exchange.
- Because of the growing concentration in the seed industry, it is important that public sector research on agriculture, and its international component, should be strengthened and better funded. The objective should be to ensure that research is oriented to the needs of poor farmers, that public sector varieties are available to provide competition for private sector varieties, and that the world's plant genetic resource heritage is maintained. In addition, this is an area in which nations should consider the use of competition law to respond to the high level of concentration in the private sector.

- Developed and developing countries should accelerate the process of ratifying the FAO Treaty on Plant Genetic Resources for Food and Agriculture and should, in particular, implement the Treaty's provisions relating to not granting IPR protection on genetic material in the form received from gene banks protected by the Treaty. They should also implement at national level, measures to promote Farmers' Rights. These include the protection of traditional knowledge relevant to plant genetic resources; the right to participate in sharing equitably benefits arising from the utilization of plant genetic resources for food and agriculture and the right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources.

These suggestions are in conformity with the recommendations made by the UK Commission on IPR(2002)

## **VII.Traditional Knowledge, Access and Benefit Sharing, and Geographical Indications**

### **VII.1 Traditional Knowledge**

There are a number of motives for protecting and promoting traditional knowledge. These include the erosion of traditional lifestyles and cultures through external pressures, misappropriation, the preservation of biodiversity and the promotion of its use for development purposes. Some wish to conserve traditional knowledge, and protect it against commercial exploitation – others wish to ensure that it is exploited in an equitable manner for the benefit of its holders. Underlying the debate on the protection of traditional knowledge may be much bigger issues such as the position of indigenous communities within the wider economy and society of the country in which they reside, and their access to, or ownership of, land they have traditionally inhabited. Given the varied reasons for protecting it and the broad nature of the subject matter, there is no one way in which it can be protected or promoted. A multiplicity of complementary measures, many of which will be outside the field of intellectual property, will be necessary. For example the type of measures required to prevent misappropriation of traditional knowledge may not be the same, indeed may not be compatible with, those needed to encourage its wider use. There is room for continued debate to clarify these complex issues.

Protection for traditional knowledge may be obtained both within the existing IP system and through the establishment of new or sui generis forms of protection. There have recently been a number of well-publicized cases of patents being granted for traditional knowledge that was already publicly known. To prevent the misappropriation of traditional knowledge through patents being taken out on such knowledge, efforts are being made to catalogue traditional knowledge in digital databases which will be accessible to examiners in all patent offices. In other cases, patent laws and practices may allow patents on “inventions” which are little more than discoveries. Some countries do not recognize the use of knowledge in other countries, as opposed to their own, as a reason for not granting patents. For example, use elsewhere might demonstrate that the claimed invention is not novel, or is obvious, even though it has not been used

domestically. Even if patents are granted for valid inventions derived from genetic resources or traditional knowledge, it may be that the communities that provided such resources or knowledge did not give their informed consent, and no arrangements for sharing any benefits from commercialization were agreed upon.

### **VII.2 Access to Genetic Resources and Benefit Sharing**

The Convention on Biological Diversity (CBD), which most countries have signed, seeks to encourage access to the world's genetic resources provided that it is done with the informed consent of the holder of the resource and that any benefits deriving from the access are shared in an equitable manner. The extent to which the IP system should be supportive of the CBD has been the subject of much debate. At the heart of this has been the question of whether patent applicants should disclose in their applications the source of any genetic resource used in their invention.

### **VII.3 Geographical Indications**

A further debate in the WTO's TRIPS Council centres on whether the protection afforded under TRIPS to geographical indications (that is indications that identify the origins of a product as a mark of quality and provenance) should be increased through either the establishment of an international register of protected indications or through the extension of the additional protection currently available for wines and spirits to other products. Lacking in this debate however is any real economic assessment of the impact of such proposals for developing countries.

### **VII.4 Some Suggestions**

- At this early stage in the debate on traditional knowledge, there is much to gain by considering the issue in a number of fora, while ensuring coherent approaches are developed and that effort is not duplicated.
- With such a wide range of material to protect and such diverse reasons for “protecting” it, it may be that a single all-encompassing sui generis system of protection for traditional knowledge may be too specific and not flexible enough to accommodate local needs.
- The digital libraries of traditional knowledge that are now being created, should, as soon as it is practical, be incorporated into the minimum search documentation lists of patent offices therefore ensuring that the data contained within them will be considered during the processing of patent applications. Holders of the traditional knowledge should play a crucial role in deciding whether such knowledge is included in any databases and should also benefit from any commercial exploitation of the information.
- Countries that only include domestic use in their definition of prior art should give equal treatment to users of knowledge in other countries. Account should be taken of the unwritten nature of much traditional knowledge in any attempts to develop further the patent system internationally.

- The principle of equity dictates that a person should not be able to benefit from an IP right based on genetic resources or associated knowledge acquired in contravention of any legislation governing access to that material.
- In such cases the burden should generally lie with the custodian of the knowledge to prove that the IP holder has acted improperly. But this requires that the custodian is aware of what has been done.
- For this reason, all countries should provide in their legislation for the obligatory disclosure of information in the patent application of the geographical source of genetic resources from which the invention is derived. This requirement should be subject to reasonable exceptions as, for example, where it is genuinely impossible to identify the geographical source of material. Sanctions should be applied only where it can be shown that the patentee has failed to disclose the known source or where he has sought to deliberately mislead about the source. The Council for TRIPS should consider this in the light of the review of this issue recommended in the WTO Ministerial Declaration at Doha.
- Consideration should also be given to establishing a system whereby patent offices examining patent applications which identify the geographical source of genetic resources or traditional knowledge pass on that information either to the country concerned, or to WIPO. WIPO may act as a depository for patent related information of this nature. Through these measures it will be possible to monitor more closely the use and misuse of genetic resources
- In respect of geographical indications, further research should be undertaken by a competent body, possibly UNCTAD, to assess the benefits and costs to developing countries of the existing provisions under TRIPS, what role they might play in development, and the costs and benefits of various proposals to extend geographical indications and establish a multilateral register.

These suggestions are in conformity with the recommendations made by the UK Commission on IPR(2002)

### **VIII.IPR and Innovation**

The debate on intellectual property protection relates to the growing recognition of the role of science and technology in international competitiveness over the last three decades(Porter and Stern,1999).Most of the industrialized countries have designed national innovation systems that aim at harnessing science and technology for economic growth and market competitiveness.The knowledge-based systems of innovation place particular emphasis on the protection of intellectual assets,a feature that is reflected in fact that bulk of world's patent activities occur in the trial of US,Europe and Japan(Table I)

Table I:Sources of Patent Cooperation Treaty Patent Applications,1997.

Region	Country	Number of Patents	Percentage of Total
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		Filed	
North America	United States	22,736	41.8
	Canada	1,075	2.0
Total North America		23811	43.75
Western Europe/EU	Germany	7436	13.7
	United Kingdom	3939	7.2
	France	2496	4.6
	Sweden	2188	4.0
	Netherlands	1749	3.2
	Switzerland	1101	2.0
	Finland	873	1.6
	Italy	797	1.5
	Denmark	642	1.2
	Austria	373	0.7
	Norway	367	0.7
Total Western Europe/EU		22,828	41.95
East Asia and China	Japan	4845	8.9
	South Korea	304	0.6
	China	157	0.3
Total East Asia and China		5306	9.75
Eastern Europe	Russia	419	0.8
Total Eastern Europe		732	1.35
Australasia	Australia	881	1.6
	New Zealand	166	0.3
Total Australasia		1047	1.92
All Other Regions		698	1.28
Total Number of Applications		54,422	100.0

Source:Dutfield(1997)

The concept of "national systems of innovations" has been developed to promote a better understanding of the linkages among the key actors in innovation. The basis of this approach is that understanding the linkages is essential for enhancing technological performance, which in turn is viewed as being critical to the process of national competitiveness. Technical change and innovation are a result of a complex and dynamic set of relationships involving actors producing, distributing and using various kinds of knowledge(OECD,1997). Essentially, the approach introduces the use of systems approaches in understanding the process of national competitiveness and its implications for the global economy. Changes in the intellectual property protection systems are part of

the transformation of national systems of innovation that has been taking place in the industrialized countries in the last three decades.

National innovation systems in developing countries including India are marked by greater concern for building basic scientific and technological capacity. Most of them are trying to integrate with the global economy in a way that allows them to benefit from international knowledge flows. These countries are often not in a position to use state-of-art technologies and lack policy infrastructure needed to place science and technology the core of development. Their needs, however, may help define the direction and pace of R& D in other part of the world.

A better understanding of the national systems of innovation in the various regions of the world and how they affect the direction and pace of technological innovation is a critical component in defining policies that take into account public interest issues in areas such as health, nutrition, energy, environment and communications. The rapid pace of globalization is also raising questions about the place of national systems of innovation in an international market. The emergence of regional systems of innovations and even global systems of innovation raises new issues related to the generation, distribution and use of knowledge. One of such issues is the relationship between intellectual property protection and development goals.

## **IX. Concerns of Members regarding TRIPS Agreement and International Policy Options**

### **IX.1 Concerns of WTO Members With Special Reference to Developing Countries**

There are several sets of problems that the agreement poses. At a general level there is concern that the efficiency losses resulting, for example, from significantly increased prices from pharmaceuticals would exceed any dynamic gains resulting from increased research and development or larger flows from foreign direct investment (Correa, 1996, Dearing, 1992). Or the length of time provided for patent protection is excessive. There is also general concern that the agreement does not provide for reasonable balance between the rights of producers and users of knowledge and technology; and that it is based on an outdated concept of "knowledge" which does not take into account the externalities of knowledge dissemination. But there is little agreement on how these broad issues can be addressed.

The patent system itself poses a variety of problems for a number of the poorer developing countries with an agricultural based economy. First, the patent system is unlikely to work as an incentive to local innovations, except in countries with a significant private scientific and technological infrastructure. At the same time the Agreement by not recognizing community property rights to traditional knowledge has led commercial firms in developed countries seeking to obtain property rights to traditional or product varieties (basmati rice and the bark of the neem tree are the known examples). The Agreement may also result in constraints on farmers use of their own seeds saved from harvest for replanting; and it is tended to encourage patents in process involving biotechnology aimed at providing substitutes for existing developing country exports. Also, developing countries have experienced difficulties in implementing the procedural and legal commitments required by agreement (UNCTAD, 1998, WTO, 1997-98).

Changing the number of these provisions to make the agreement more development friendly will not be easy due to the strength of the commercial and vested interests in developed countries; but it is certainly worth the effort for developing countries to suggest changes in the most detrimental aspects of the agreement .

Some argue strongly, particularly in business and government in developed countries, that IPRs help stimulate economic growth and reduce poverty. They say there is no reason why what works so well for developed countries could not do the same in developing countries. Others, particularly from developing countries and NGOs, argue the opposite equally vehemently. IP rights can do little to stimulate invention in developing countries, because the prerequisite human and technical capacity may be absent. Moreover, they increase the costs of essential medicines and agricultural inputs, hitting poor people and farmers particularly hard.

During the last 20 years or so, the level, scope, territorial extent, and role of IP protection have expanded at an unprecedented pace. Genetic materials have become widely patented. IP rights have been modified or created to cover new technologies, particularly biotechnology and information technology. Technologies produced in the public sector are routinely patented. The World Trade Organisation (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) has extended minimum standards for IP protection globally. There are continuing discussions in WIPO aimed at further harmonisation of the patent system, which may supersede TRIPS. Moreover, bilateral or regional trade and investment agreements between developed and developing countries often include mutual commitments to implement IP regimes that go beyond TRIPS minimum standards. Thus there is sustained pressure on developing countries to increase the levels of IP protection in their own regimes, based on standards in developed countries.

The functioning of IPR systems raises genuine concerns, even in developed countries. The submission of patent applications has increased tremendously in recent years – as has the perception that many patents of “low quality” and broad scope are being issued. Companies may incur considerable costs, in time and money, determining how – or whether - to conduct research without infringing upon other companies’ patent rights, or defending their own patent rights against other companies. This raises questions as to whether the substantial costs involved in patent litigation are a necessary price to pay for the incentives offered by the patent system, or whether ways can be found to reduce them. How does this proliferation of patents affect competition and research?

The concerns about the impact of IP in developed countries are important for developing countries as well. Developing countries can learn from the experience of developed countries in devising their own systems. In addition, the IP system in developed countries has had direct impacts on developing countries. Restrictions on access to materials and data on the Internet can affect everyone. IP rules and regulations may be hampering research on important diseases or new crops that affect developing countries but that is actually carried out in developed countries. Developing countries may not be

sharing appropriately in the benefits from commercialization of their knowledge or genetic resources when they are patented in developed countries.

## **IX.2 International Policy Options For Developing Countries**

Developing countries have raised issues regarding implementation of the TRIPS agreement. The different provisions have different institutional implications that need to be taken into account. The assessment points to the call for special and differential treatment of the developing countries on a case by case basis. This principle is already incorporated into the functioning of WTO and is expressed in many of its clauses. Part of this is a result of the negotiations that took place under the agreements that provided special treatment to developing countries on public interest issues such as education.<sup>14</sup> There are other issues, however, whose discussion include reopening the agreement for revisions. These include the review of the TRIPS. It is unlikely, and possibly undesirable, to reopen an agreement in the early stages of its implementation. Reopening a part of the agreement means that the entire document is subject to revision unless clear procedures and terms of reference are set out. What is more likely, however, is a discussion on the need to extend the review period as well as the moratorium on non-violation. Another area of diplomatic interest is the establishment of new working groups under WTO to address some of the key concerns of the developing countries. One of these is the proposal on a working group on technology transfer. Developing countries have put forward a number of proposals to set up working groups. These include working groups on biotechnology and labor proposed by Canada and the United States respectively. Discussions on working groups on issues of interests to developing countries will need to consider in the context of a wider context that includes requests for other working groups.

But many of the technology transfer issues are not likely to be considered in the context of multilateral agreements but will be dealt with in the context of bilateral arrangements. This, however, does not preclude the establishment of incentive mechanisms for technology transfer and cooperation in specific areas of mutual advantage. This could be in areas of national interest such as health, nutrition, energy and environmental management. But such bilateral arrangements will only address the interests of the more advanced developing countries, leaving the rest to promote their interest the multilateral system.

Developed countries have a wide range of policy instruments and incentive schemes that can be used to address some of the issues raised by the developing countries. For example, many of the developing countries do not have the requisite technological capacity to use state-of-the-art technologies. But they could benefit from using inventions

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<sup>14</sup> Article 9.1 of the TRIPS agreement requires members to comply with the Appendix of the Berne Convention (1971) which contains special provisions for developing countries. These provisions provide developing countries, inter alia, with some flexibility in the area of compulsory licenses for translations and reproductions subject to a number of notification procedures. They are not used extensively. They have been invoked under the TRIPS agreement by one WTO member. They are currently used by five countries under the Berne Convention, of which four are WTO members but still benefiting from the transitional period. However, these provisions may have made use of translations and reproductions in developing countries more affordable in the area of education. The possibility of using them may encourage publishers to make licensing for translation and reproduction available in developing countries on reasonable conditions (Youssef, 1999)

that are already in the public domain. To do this may require additional institutional arrangements that promote the transfer of such technologies to the developing countries.

For example, there may be a role for a new generation of charitable organizations that focus on promoting the use of public domain technologies to solve tropical problems in fields such as health, agriculture, environment and energy. One option that could be considered is the creation of charitable institutions that hold intellectual assets that could include donated inventions of relevance to the developing countries.

The history of the Consultative Group on International Agricultural Research (CGIAR) offers lesson that could inspire institutional innovations in other fields of technology. The CGIAR has been a custodian of genetic resources used to breed new varieties for tropical agriculture. Similar networks could be established to serve as custodians for inventions that could be used for addressing tropical challenges. But such a system would need a programmatic focus around specific technologies and would not function well as a general library of inventions; this is already being done by global network of national and regional patent offices.

Other approaches include the creation of incentives that promote the mobilization of scientific knowledge in the industrialized countries to address specific challenges such as the development of vaccines for tropical diseases. Such initiatives would require new form of R&D and commercial partnerships. Much of this will need to be discussed in the context of specific programmes such as research on tropical diseases, foreign direct investment linked to technology transfer in fields such as communications, collaborative research using genetic resources in the developing countries and others. The field of drug development based on the screening of genetic material from the developing countries is likely to become a key area of international trade conflicts.

One way to add value to genetic resources is investing in their identification and monitoring. So far little attention is paid to this task as illustrated by the low level of support for taxonomic work. Current estimates show that only about 1.7 million species have been documents out of an estimate of 40-50 million. In order to play a key role in strategic research programme involving modern biotechnology, developing countries will need to invest more in the identification and monitoring of biological diversity (covering genes, species and ecosystems). Undertaking this task would be in line with the provisions of Article 7 of the Convention on identification and monitoring of biological diversity. This work will be in keeping with the requirements of Article 7 of the CBD which calls upon governments to identify and monitor "Species and communities which are: threatened; wild relatives of domesticated or cultivated species; of medicinal, agricultural or other economic value; or social, scientific or cultural importance; or importance for research into the conservation and sustainable use of biological diversity, such as indicator species." This work should also include the identification and documentation of innovations by local and indigenous communities."

The current scenario can be turned into a series of collaborative research arrangements that offer mutual advantage to the developed and developing countries. Many of the practical details related to access to technology, capacity building, benefit-sharing and the related intellectual property issues can be addresses through such collaborative partnership. The lesson learnt from the process can help to inform further negotiations under WTO and other agreements such as CBD.

## **X. TRIPS and Welfare**

In retrospect, the decision of the Uruguay Round to bring intellectual property (IP) issues into the WTO through the TRIPS agreement seems to have been a mistake. Since the World Intellectual Property Organization (WIPO) already existed for dealing with IP issues, there was no need to bring them into the WTO by calling them trade related, rather than deal with any problems of enforcement of IP rights and create any new disciplines needed in the WIPO. The reason for bringing them into WTO seems to be the availability of the WTO's dispute settlement and trade sanctions mechanism for enforcing IP rights. The very same motive lies behind the persistent demand by some developed countries for inclusion of labour and environmental standards in the WTO. However, now with lot of bilateral treaties coming up there is a possibility of setting standards which are TRIPS plus standards on protection. It would mean that signing TRIPS has become imperative for countries and the challenges are domestic in the sense of using flexibilities under TRIPS to deal with the egregious impact of the TRIPS. Although the World Intellectual Property Organization (WIPO) already existed for dealing with IP issues it is also now talking of harmonization of standards and not having minimum standards like TRIPS.

TRIPS imposes a uniform life of at least 20 years from the filing date for all patents regardless of the nature of invention and protection for copyrights is for a much longer period. Products as well as processes can be patented. Bhagwati (2001) points out that unlike traditional trade liberalization, in which a liberalizer and its trading partners gain, TRIPS involves an unrequited transfer of royalties from user (poor) to producer (rich) countries. Maskus (2000, Table 6.1) estimates a transfer of \$8.3 billion to just four rich countries. Still, to be fair, "TRIPS provides a great deal of latitude in terms of how countries implement it. A variety of policies can be pursued to reduce the magnitude of the income transfer from South to North that will be associated with the implementation of TRIPS" (Hoekman, 2001, p.231).

TRIPS agreement recently attracted much criticism on the ground that monopoly rights conferred by patent protection raise the prices of life saving drugs (e.g. AIDS drugs) and put them out of reach of millions of those who need them in poor countries. Although, the compulsory licensing provisions of the TRIPS can be read as permitting rights of patent holders to be overridden in a national health emergency, this was challenged by multinational pharmaceutical companies. The failure of these companies to win their case in South African courts, the recent decision of the US not to challenge the Brazilian production of AIDS drugs as violation of TRIPS, and also the substantial reduction by drug companies of the prices of AIDS drugs sold in poor countries, were not enough to prevent the interpretation of TRIPS provision relating to public health from becoming almost a 'deal breaker' at Doha. Rich countries particularly the US, were accused of double standards in their insistence on poor countries respecting patent rights, while the US government itself threatened to override patents on the antibiotic CIPRO during the outbreak in October 2001 of anthrax infections attributed possibly to terrorist actions. In the debate over the pros and cons of the TRIPS agreement, three separate issues are being confounded.

**First, is the fundamental question: Is granting monopoly rights through patent protection the most cost-effective way of promoting innovation and invention of new drugs?**

**Second, what is the least cost way of producing the patented product to meet world demand?**

**Third, what is the appropriate mechanism for ensuring that the individuals deemed poor according to some accepted criteria have access to the drugs they need?**

On the first and basic question, the empirical evidence in favour of a strong link between patent rights and innovation does not exist. In the absence of such a link, patent protection is not even a means of promoting innovation, let alone being the most cost-effective means. Lerner (2001) cites Edith Penrose (1951) as noting, "If national patent laws did not exist, it would be difficult to make a conclusive case for introducing them; but the fact that they do exist shifts the burden of proof and it is equally difficult to make a really conclusive case for abolishing them."

In his own examination of 177 patent policy changes across 60 countries over a 150 year period, using patent based measures of innovative output, Lerner found, that adjusting for overall patenting, the impact of patent protection-enhancing shifts on applications by residents was actually negative" (Lerner, 2001, p.30). While noting the limitations of his study for not allowing for possible interactions between patenting and other forms of technology policy, and for the crudeness of his patent-based measures of innovative output, he concludes, that despite these limitations, "The failure of domestic patenting to respond to enhancements of patent protection, and the particularly weak effects seen in developing countries, were quite striking" (ibid, p.31). Jaffe (2000) also found that robust conclusion regarding the empirical consequences for technological innovation of changes in patent policy are few.

The Rand Journal of Economics published a symposium on the Patent System and Innovation in its Spring 2001 issue. Two of the papers in the symposium seems to be Interesting. Sakakibara and Branstetter examine the responses to Japanese patent reform of 1988, which significantly expanded the scope of patent rights. They econometrically analyzed US and Japanese patents data on 307 Japanese firms, and found "no evidence of an increase in either R&D spending or innovative output that could plausibly be attributed to patent reform (Sakakibara and Branstetter, 2001, p.98). Hall and Ziedonis examine the patenting behavior of firms in the semi-conductor industry in which the propensity of firms to patent has apparently increased dramatically since the mid 1980s. Yet they cite survey evidence suggesting that "firms in most industries have not increased their reliance on patents for appropriating returns to R&D over the decade of the 1980's "(emphasis in original) and ask "If firms in most industries do not rely heavily on patents to profit from innovation, then why are the patenting aggressively?" (Hall and Ziedonis, 2001, p.102).

Their answers to this "patent puzzle" for the semiconductor industry are two: "stronger patent rights may have facilitated entry by specialized firms and contributed to the vertical disintegration of the industry. But these positive effects coincide with a process whereby firms a mass vast patent portfolios simply as "bargaining chips", leading to portfolio races "(ibid, p.125).

Since holding a patent confers a legal right to exclude, the authors argue that "for firms engaged in rapidly changing, cumulative technologies, building larger portfolios of their own" legal rights to exclude" may reduce the hold up problems fixed by external technologies on favorable terms" (ibid, p.1281).

On the second question, it should be evident that the unit cost of production need not

necessarily be minimized if the patent holder itself produces the product, rather than licensing others to produce. And indeed, if the licensing activity was not constrained by government interventions, normal profit calculation would lead the patent holder to license others to produce (if it is more profitable to do so).

The answer to the third question is also clear. For ensuring the access of the poor to life saving drugs, no intervention in the markets for drugs are called for as long as they are or could be made competitive. What are needed are income transfers to the poor individuals and households (and not necessarily to governments of the countries in which they live). Of course allowing segmentation of markets in which most of the potential buyers are poor from those in which the buyers are rich, and enforcing the segmentation through a prohibition of so called “parallel” imports into rich markets of lower priced drugs from poor markets, could (though not necessarily would) enable producers to sell drugs at a lower price in poor markets, and thus make them affordable to the poor. However, compared to a policy of income transfers to the poor to enable them to buy drugs at a common world price, market segmentation is an inferior policy.

Unfortunately by accepting without question the efficacy of patents as a means of encouraging innovations, and worse still imposing a uniform patent life for all innovations, and forcing DCs to enact or amend patent laws, TRIPS agreement has imposed an avoidable burden, particularly on poor countries.

#### **XI: TRIPS AND INDIA**

In a move designed to make India’s patent legislation conform with the World Trade Organization’s *Trade Related Intellectual Property Rights* (TRIPS) patent regime, the United Progressive Alliance (UPA) government has pushed a patent amendment bill through India’s Parliament with the support of the Left Front. The patent amendment covers the food, pharmaceutical and agribusiness sectors and can be expanded over time to other sectors.

The Indian government became a signatory to TRIPS after it joined the WTO in 1995. Developing countries were given a “transition” period of 10 years to bring their national laws in accordance with TRIPS. The previous Bharatiya Janata Party (BJP)-dominated government passed two amendments, one in 1999 and the other in 2002, to the 1970 Indian Patent Act to prepare the groundwork for full implementation of TRIPS rules. In December 2004 the Indian Congress-led UPA government issued a presidential ordinance to bring the country into mandatory compliance with TRIPS by January 1, 2005. The government had six months to codify this ordinance by obtaining the approval of the parliament. This was done on March 23, when, after virtually no public debate, India’s parliament passed the third amendment to India’s 35-year-old patent act.

The latest amendment can be called TRIPS-plus because it actually goes beyond WTO requirements. For instance, the new legislation allows a pharmaceutical company to obtain additional patents when one of its already-patented drugs is discovered to be of use in combating other illnesses and conditions, thus extending the number of years over which the company will exert proprietary control over the said drug’s production and marketing.

Similarly, the new legislation goes beyond TRIPS in the obstacles it places on the Union government authorizing the production of patented drugs by generic manufacturers to meet public health emergencies.

Indian companies that are now producing generic versions of drugs for which patent applications were submitted between the signing of the WTO agreement in 1995 and January 1, 2005 will be allowed to continue doing so only if they pay a “reasonable” royalty to the patent holder.

With the adoption of this bill the Indian government has overthrown a key tenet of the 1970 Indian Patent Act that restricted patents to manufacturing processes rather than end products. Under the old patent regime, drugs patented in other countries could be analyzed and manufactured without paying royalty. This provision served to nurture the development of an indigenous pharmaceutical industry and by the 1990s Indian drug companies had become the fourth largest in the world when ranked by volume of drugs produced.

Product-patents granted under India’s new TRIPS-plus regime will remain in force for twenty years. During this time the patent-holder will have exclusive rights over the manufacture and sale of the drug.

The Indian drug industry has been instrumental in supplying cheaper generic drugs to the world market, especially the antiretroviral (ARV) drugs that have proven beneficial to persons infected with HIV/AIDS. At a time when western pharmaceutical companies were charging over \$1000 per month per patient for such drugs, the Indian drug industry was able to develop generic versions which were marketed for about \$12 per month. With the adoption of TRIPS-Plus the monopoly rights of the transnational drug companies have been reinforced, making the development of such life-saving generics increasingly problematic and ensuring, at the very least, that the price of such drugs may rise.

Although the impact of India’s new patent regime on the availability of cheaper generic drugs has received the greatest attention, it could also have immense consequences for Indian agriculture, which provides two-thirds of all Indians with their livelihood. Critics of the legislation warn that its ambiguous wording could open the door for transnational agribusiness companies to seek patents over common seeds or only slightly modified versions of common seeds and thereby appropriate seed-types that have been rendered resistant to cold, salt and drought through thousands of years of agricultural practice. Currently 80 percent of the seeds used in planting in India are supplied by the farmers themselves from seeds saved from previous crops. Farmers also have the right to barter seeds among themselves, thus enabling them to obtain seeds at little cost and without too much difficulty.

India was given ten year transition period from January 1, 1995 to make her laws TRIPS compliant<sup>15</sup>. India has complied with all the TRIPS provisions since January 1, 2005<sup>16</sup>.

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<sup>15</sup>TRIPS is divided into seven parts containing 73 articles 1)Basic Provisions 2)Different Standards of IPR 3)Enforcements 4)Acquisition and Maintenance of IPRs 5)Dispute Settlement Process 6)Transitional Arrangements 7)Institutional Arrangements

<sup>16</sup> Developing countries generally had until 2000 to comply. However, in order to accommodate differing economies and the fact that a number of developing countries did not grant product patents in a particular area of technology (i.e. pharmaceutical products), a special transitional rule was included in the TRIPS Agreement: if a developing country did not provide product patent protection in a particular area of technology when the TRIPS transitional period for developing countries ran out, it had a further five years (until 2005) to introduce protection in that area (TRIPS Art. 65.4)

This was done through series of amendments in its Patent Act 1970, first in 1999<sup>17</sup>, then in 2002 and finally in 2005. However, in the intervening period, India in accordance with the “mailbox” provisions in TRIPS Art. 70.8, had to provide a means by which patent applications in drugs & pharmaceutical substances and agrochemicals could be filed during the transitional period. The mailbox provision allowed applicants to file for patents and thereby establish filing dates, while at the same time permitting India to defer the granting of the patent for pharmaceutical products. The date of filing (or, in some cases, the date of priority) is important, as it is used to assess whether or not the application meets the necessary conditions for patenting a product, i.e. novelty, inventiveness and being capable of industrial application. The apprehension and the concern are that once the patent applications is reviewed for acceptability after January 1, 1995, the new product-process regime may put access to life-saving drugs for diseases like AIDS, life saving drugs, drugs on essential drug lists and anti-cancer drugs out of the reach of poor people both in India and elsewhere in the world. According to France-based Medicines Sans Frontieres, "People who rely on low cost medicines will have to wait three years before a generic company can even make an application for a right to produce the drug, whereas people in wealthy countries will have access to new medicines immediately, when they are proved safe and effective."

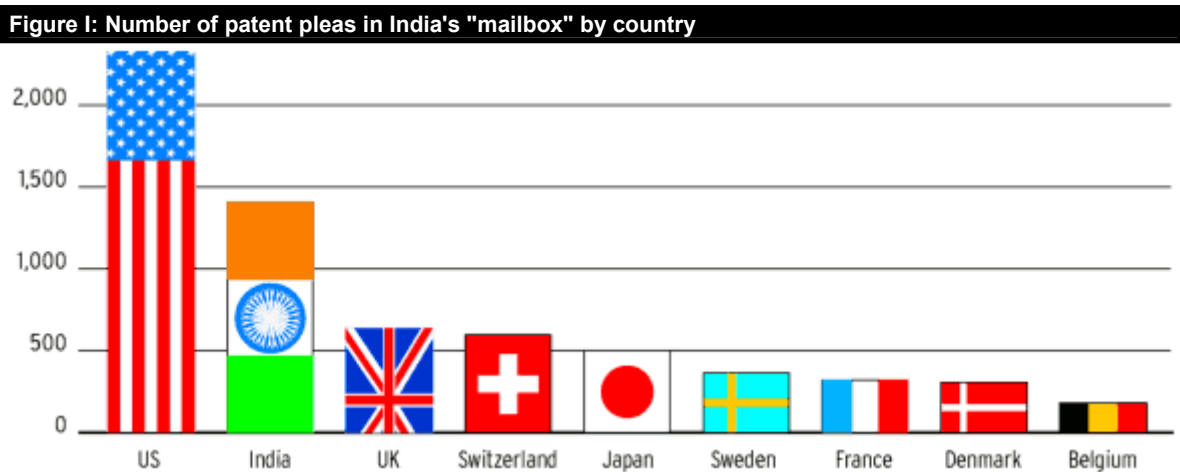
Estimates of the current number of pending patent applications range from 4,700 to 12,000 in which nearly 80% are foreign applications (refer to Figure I below). Since patents are often filed at an early stage in the development of medicines, the majority of patent applications pending in the mailbox are likely to relate to medicines not yet marketed, or only recently marketed, i.e. medicines for which generic firms have not yet produced their own versions. Most of the new launches are expected to come from R&D innovation like line extensions, combination drugs and improved dosage forms of drugs<sup>18</sup>. While, Pfizer has the highest number of patent applications among all companies (Figure II), Dr Reddy's Lab leads among the Indian companies (Figure III). 31 patents have been granted by the patent offices in India after January 1, 2005 till date. While there is an explicit mention of limiting the scope of patent (Mashelkar Report, November, 2006) the definition of New Chemical Entity (NCE) has surely broadened the

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<sup>17</sup> Provisions with respect to the mailbox were incorporated in the Indian Patent Act, 1970 vide the Patents (Amendment) Act, 1999. In addition, the Patents (Second Amendment) Bill, 1999 has provided for an appeals process, before an Appellate Board, on any decisions by the Controller of Patents including a grant of compulsory license (, non-voluntary licenses granted by the government to third parties to make the patented product, Clause 54) before approaching the Indian Courts. The Patents Law provides for compulsory license to avoid excessive pricing of products and to ensure that its is available adequately for public consumption. Government may use the threat of compulsory licences as leverage in litigation against a patent owner – particularly in the case of drugs for the treatment of AIDS, cancer, certain cardiovascular diseases, ebola and other fatal diseases. This provision meets a larger public interest, keeping in mind the specific Indian conditions and are in compliance with Article 31 of TRIPS

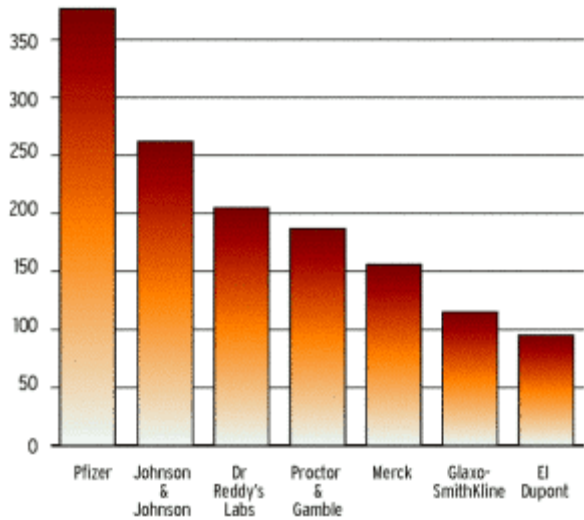
<sup>18</sup> Only 274 new chemical entities received marketing approvals from the US FDA between 1995-2003. This is a clear indication that many of the applications in the mailbox are for patenting of products with frivolous or marginal changes and, therefore, fall outside of the requirement of protection required for patents by TRIPS. Also, a new use of a known substance remains unpatentable. The relevant Section of the Indian Patents Act, 1970 has been amended to include a further explanation indicating that salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of a known substance would also be considered to be the same substance, unless they differed significantly in efficacious properties. Pre-grant opposition is also introduced in the new act. Overall, the policy is to limit the scope of patentability.

scope of patentability. NCE has to be new, involve an inventive step and should have useful industrial application. ‘Incentive step’ as defined in our patent laws is anything “which is technologically superior or of economic significance or both” and therefore not obvious to anyone which is skilled in the area. This” or” would mean that if the pharmaceutical companies can prove that their investments have been of economic significance then there application will be entertained and maybe granted patents and there is a possibility that “ me too” drugs or drugs with different dosages or drugs delivered through different delivery mechanism are granted patents after January 1,2005.. India need to make necessary amendments to the Indian Patent Law and define “ Inventive Step” as anything “ which is technologically superior and of economic significance and not obvious to anyone skilled in the area.”



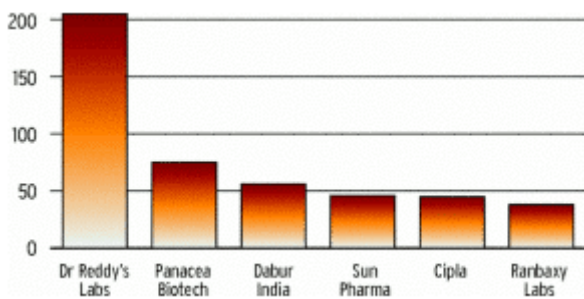
**Source:** Narendranath, *The Financial Express*, March 21 2005

**Figure II: Number of Patent Pleas in Indian Mailbox by All Companies**



Source : Narendranath, *The Financial Express*, March 21 2005

**Figure III: Number of Patent Pleas in Indian Mailbox by Indian Companies**



Source : Narendranath, *The Financial Express*, March 21 2005

Patent protection will be of 20 year duration. It will give an inventor the right for the above period to stop others from making, using or selling an invention without the permission of the inventor. TRIPS provides for patent protection for any inventions provided that they are new(not a prior art), involve an inventive step( is of economic significance or technologically superior or both and that makes the invention not obvious to a person skilled in the art) and are capable of industrial application. The apprehension is that 20-year monopolies will drive up the price of treatment in India and in hundreds of importing countries—the world’s source of supply of generic HIV medicines may disappear. For drugs like Gleevec (imatinib mesylate), a life-saving treatment for chronic myeloid leukemia (CML), the exclusion of generic competitors from the market through application of exclusive marketing rights (EMRs) increased the price from \$200 for a generic product to \$2000 per month for Novartis’ drug. Gleevec access in India is an important illustration of the likely impact of India’s Patent Act amendments.

TRIPS compliance would require patents to be granted to products, while India's previous patent regime established by the Indian Patents Act 1970 only required patents to be granted to the chemical processes that resulted in the production of a particular drug. This distinction between "process patents" and "product patents" in line with international patent practice before the 1995 TRIPS Agreement allowed for the development of a huge generic drug industry built on reverse-engineering brand-name drugs through slightly modified processes investments<sup>19</sup>. The following chart indicates how the prices of medicines in India are the lowest as compared to those in other countries. . This is due in part to the prevalence of alternative healing methods in India, such as ayurvedic medicine and homeopathy, but also because prices for drugs have been kept artificially low by the strict regulations . TRIPS Agreement though is silent about the price control of patented products .

Comparison of International and Indian Prices Prices Indian Rupees					
Drugs	India	Pakistan	Indonesia	UK	USA
Ciprofloxacin HCL 50 mg 10's tabs	29	424	393	1186	2353
Times Costlier		15	14	41	81
Diclofenac Sodium 59 mg 10's tabs	4	85	60	61	675
Times Costlier		21	15	15	169
Ranitidine 150 mg 10's tabs	6	74	178	247	864
Times Costlier		12	30	41	144

source: National working group on patent laws

However, drugs with patent priority dates before 1995 are not affected by the Patent Law. Also, the new law states that a currently marketed generic product can continue to be commercialized once the branded original has been granted patent protection, provided that domestic generic manufacturers pay 'reasonable' royalties to the patent holders, the generic firm had marketed the product prior to 1 January 2005, and the generic firm has made significant investment. In the case of HIV treatment, though generic production only of older, pre-1995 generic versions of medicines is not enough to satisfy the

<sup>19</sup> The R&D in diseases prevalent in India like Gonorrhoea, Dengue, Malaria, Tuberculosis, Hepatitis C, among others, suffered.

treatment needs of people in developing countries. Generic competition is needed to drive down the costs of newer “second-line” antiretroviral treatments that can cost as much as 26 times more than older, “first-line” generic combinations. These are precisely the medicines that will be considered for patent protection in India.

The Doha Declaration<sup>20</sup> also has given the members right to protect public health. It has also been clarified that the members have right to grant compulsory licenses and freedom to determine the grounds for issuing the same. Further it has also been clarified that each provision of TRIPS could be read in the light of its objectives (in Article 7) and principles (in Article 8). The main features of the Doha Declaration on Public Health are

- (a) Addressing public health problems for developing & least developed countries especially for HIV/AIDS, Tuberculosis, Malaria and other epidemics.
- (b) Recognition of IPR protection with simultaneous consideration of unaffordable prices of patented medicines.
- (c) Implementing measures for protection of public health and promotion to access medicines subject to respecting Most Favoured Nations (MFN) treatment to nationals and non-nationals.
- (d) Rights of members to determine grounds of compulsory licenses, define national emergencies & exhaustion rights.
- (e) Methodology to assist countries with no technological capabilities.

The Patent Act aims to curb ‘me-too’ product patent applications by requiring one or more inventive steps and excluding derivatives such as salts, esters, ethers, polymorphs and similar forms and combinations of known substances, unless their properties differ significantly in the context of efficacy. On the one hand, this would decrease the likelihood of evergreening. On the other hand, the inexactness of some of the language leaves scope for interpretation and therefore expensive and time-consuming litigation is likely to ensue.

Article 39.3 of the TRIPS which talks of unfair commercial use of the pre-clinical and clinical data has ramifications for the India pharmaceutical companies investments. While the big MNCs and now the Indian companies want data exclusivity for the same data, this is not a requirement according to TRIPS. Therefore, Indian generic companies should judiciously use Bolar provisions for their requirement and bring out the generic counterpart to the patented drug once the patent protection period is over. This will bring in competition and reduce prices of drugs which have become off patented.

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<sup>20</sup> The Ministerial Declaration adopted on 14th November, 2001 at the Doha meet on TRIPS stressed the importance of implementation and interpretation of the Agreement in a manner supportive of public health, by promoting both access to existing medicines and research and development. However, significantly, the Doha Declaration does not define the term ‘public health’. A narrow interpretation of the term would clearly render many public health initiatives futile.

## **PATENT SYSTEM IN INDIA**

The history of patents in India actually dates back to 1856, but policy-makers turned their attention seriously towards patents only immediately 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. The Patent Enquiry Committee (1948-50) and the Ayyangar Committee (1957-9) 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 S&T mission of developing indigenous technology and fostering R&D activities in areas of national significance. The Patent Act of 1970, the previous legislation on patents in India, was based on the recommendations of these committees. The main aim in India was to ensure that patents should not lead to monopoly by foreign companies or to high prices for medicines and food items. India sought to ensure this in its Patent Act by granting only process and not product patents in food, pharmaceutical, and chemical fields, restricting the term of patents, and formulating an elaborate system of licences to ensure that patents are worked in India. In tune with this policy, India refused to join the main international treaty on patents—the Paris Convention—as it stipulated higher standards of patent protection.

The statement by Indira Gandhi at the World Health Assembly in 1982 that, '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, symbolized India's stance on patents. In India, patents were seen more as a tool for economic development. Industrialized nations conceive of patents as a fundamental right comparable to the right of physical property, whereas developing nations view it '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 (Stewart 1993).

India's philosophy on patents underwent a revision with the Patent Amendment Acts of 1999 and 2002. India also joined the Paris Convention and the Patent Cooperation Treaty in 1998. The amendments led to revisions in India's policy on granting only process and not product patents in pharmaceutical and agro-chemical fields, increasing the term of patents to 20 years as demanded by TRIPs, and restricting the system of licences found in India's Patent Act. Table at the end outlines the major changes resulting from the amendments.

Provisions were also included to protect the Indian systems of medicine and to protect public health. The amendments essentially pave the way for full product patents in pharmaceuticals and agro-chemicals, which must be granted according to TRIPs, from 2005.

India's patent system is based on the Patent Act of 1970. The major features of the Indian Patent Act of 1970 are

Patentability of inventions relating to substances intended for use as food, drug, medicines, or substances produced by chemical process will be limited to claims for the methods or processes of manufacture only;

Compulsory licences and licence of rights can be granted. 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 chemicals, after the expiry of three years from the date of patent grant, they shall be endorsed with the word 'License of Right'. This will enable any interested person to be entitled to work such patents as a matter of right;

Certain types of inventions will not be patentable. They included:

- (a) an invention which is frivolous or which claims anything obviously contrary to establish natural laws;
- (b) an invention, the 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; and
- (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'.

Term of patent will be 14 years from the date of patenting, that is, the date of filing the complete specification. In the case of inventions in the field of food, drug, or medicine, the term will be seven years from the date of filing or five years from the date of sealing, whichever is shorter.

The Patent Act of 1970 was amended in 1999 and 2002 resulting in changes in some of these provisions. The Controller General of Patents, Designs, and Trademarks under the Department of Industrial Development, Ministry of Industry, is the administrative authority on patents in India. Patent Offices are located in New Delhi, Mumbai, and Chennai with the head office being based in Kolkata. The patent application must be filed in the appropriate Patent Office and the process" consists of several stages. The inventor must first ensure that his/ her invention meets the criteria of novelty and non-obviousness and conduct a search to establish the state of knowledge relating to the invention (known as prior art). The inventor then files a patent application with provisional specification before any public disclosure of the invention . The Patent Act of 1970 laid down the following procedures in relation to patent applications and some of these provisions may be modified with the Amendments to the Patent Act in 1999 and 2002. The provisional specification contains the broad aspects of the patentable invention and the inventor has 12 months (extendable to 15 months with a fee) to file a complete specification . The

patent application should contain the title, the inventor's name and address, the abstract, and a text defining the claims made. The text may also contain tables, drawings, etc. to support the claims. A technical examination of the application is conducted by the Patent Office and, if accepted, it is published in the Gazette of India, which is published weekly from New Delhi. Interested parties who consider that the patent has been wrongfully granted can oppose the patent within four months from the date of advertisement of the acceptance of the complete specification. If no opposition is filed, the patent is granted and the inventor must file for the sealing of the patent no later than six months from the date of advertisement of the acceptance of the complete specification. The patent is then granted and the inventor must pay annual renewal fees to keep the patent in force. The table below give the major changes to India's Patent Law.

#### Major Changes to India's Patent Law

India's Patent Act of 1970	Amendments to Patent Act, 1999, 2002
Only process and not product patents allowed on medicines, food, agro-chemicals	Applications allowed for product patents in medicines, food, agro-chemicals and Exclusive Marketing Rights introduced
Term of patents 14 years; 5-7 in chemicals, drugs	Term of patents 20 years
Compulsory licensing and licence of right (these provisions allow governments to issue licences to allow other companies to make a patented product or use a patented process without the consent of the patent owner under certain circumstances)	No licences of right; Compulsory licensing allowed but more restricted
Government allowed to use patented invention to prevent scarcity and included 'right to sell goods' Government had to notify the patentee of use "unless it appears to the Government that it would be contrary to the public interest to do so' Royalty payment not to exceed 4 per cent of price	Right of government restricted to 'right to sell on non-commercial basis' Government must notify patentee of use 'except in the case of national emergency or other circumstances of extreme emergency or for non-commercial use' Not more than adequate remuneration taking into account economic value of patent

On December 27, the Central government issued the Patents (Amendment) Ordinance, 2004. The ordinance amends the Indian Patents Act, 1970 for the third time with a view to introducing product patents for drugs, food and chemicals. With this, India claims to have conformed to the Trade-Related Intellectual Property Rights (TRIPs) Agreement of the World Trade Organisation.

In continuance of the ordinance The Parliament of India recently has approved the third Patents (Amendment) Bill 2005 with the Rajya Sabha passing it on March 23, 2005. Earlier, the Lok Sabha passed the Bill after the Government incorporated several amendments.

In summary, India has introduced a new product patents regime, covering drugs, foods and chemicals. This is in compliance with the Trade-Related Intellectual Property Rights (TRIPS) agreement of the World Trade Organisation (WTO). India has an enviable record of fully adhering to its international obligations. Moreover, strong patent laws are expected to encourage foreign investment in research and development projects and consequently benefit the Indian economy.

India carried out three amendments to its Patents Act 1970 in 1999, 2002 and 2005 to comply with the TRIPS obligations. The first amendment introduced exclusive marketing rights (EMR) as part of transitional arrangements. The 2002 amendment ensured compliance with all TRIPS obligations except the product patent regime. Product patent was introduced through an Ordinance in December 2004 and later incorporated as an amendment in 2005. In 2000 Pakistan replaced its old Patent and Design Act 1911 with the Patent Ordinance 2000. This Ordinance was further amended in 2002. Sri Lanka replaced its old legislation with a new Intellectual Property Act in 2003. This legislation follows the WIPO model law. Further it reflects the spirit of the US-Sri Lanka Bilateral Agreement on protection of intellectual property, which was concluded in 1991.

**The summary of 2005 TRIPS Act includes**

1) Indigenous manufacturers are allowed to manufacture patented products even after a patent is granted, in respect of mailbox applications, on payment of a reasonable royalty to the patent holder, if they had been producing and marketing the concerned product since prior to 1/1/2005. This provides a level playing field for domestic players who have already made substantial investments and have been manufacturing the products for which applications for patents have been received in the mailbox. This provision ensures the smooth transition from pre patent era to post patent era. There can be a marginal rise in the existing drugs as the licence to the marketed products will be nominal in most of the cases. There can be negotiations with the patent holder on price and technology transfer.

(2) The system provides for both pre-grant and post-grant opposition avenues, and reduces the timeframe for grant of patents in a cost-effective manner, while taking care of public interest. In fact, pre-grant opposition to patents has been strengthened and all the 11 grounds for pre-grant opposition to patents have been specifically listed in the Act, in the same way as before the Ordinance of December 2004. This provision is aimed at establishing a mechanism by which system of patent protection and provide avenues for the patent holders to challenge violation of their intellectual property rights by unfair means.

(3) In order to prevent "ever greening" of patents for pharmaceutical substances, provisions listing out exceptions to patentability (or what cannot be patented) have been suitably amended so as to remove all ambiguity as to the scope of patentability. This is very important in Indian context as it is very rich in traditional knowledge and heritage. The clear-cut instructions regarding what can not be patented would help public at large in a long run. The healing techniques of well established in ethnic system of medicines such as Ayurveda, Siddha and Unani system and formulations there in can not be patented.

(4) Conditions for obtaining compulsory licence have been clarified in order to facilitate export of patented pharmaceutical products by Indian companies to countries that do not have adequate production capacities such as least developed countries. The compulsory licensing is an instrument that the TRIPs allows by which governments can allow domestic manufacturers to manufacture patented products within 3 years of their introduction. The provision of this would be an opportunity for indigenous manufacturers to export the medicines to third world countries which can not manufacture their own drugs. There are many countries in Africa, Asia and South America which are in need of cheap drugs due to poor economic development in this area. It will be a boon for basic and formulation manufacturers as the market to this segment will definitely promotes opportunities. India being rich in cost effective and intellectually competitive manpower and other resources would definitely emerge as world leader as far as export of drug is concerned.

(5) 'Reasonable period' for negotiations between the patent holder and companies seeking compulsory licence has been fixed at six months. This provision of the Act would ensure positive dialogues and negotiations to happen between indigenous manufacturers to arrive at deals leading to win situations. In due course of time a better understanding of the situations and conditions in the needy poor nations would resolve the conflicts as the patent holders would also appreciate the efforts of the indigenous manufacturers efforts to sell drugs at a cheaper price. The patent holder will not be interested to sell the drugs to the poor nations as he would find practically obstacles and considerations are not cost effective for him.

(6) Exemption of research and development from the ambit of patents, including experimental and educational purposes. The basic research and education are the pillars of applied research. The education and research methodologies are the tolls for developing science and technology. Barring this area from the patent, government wants to ensure availability of trained manpower for sustained growth.

### **Implications of the New TRIPS regime: Beyond 2005**

What will be the implications of the new 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 organised 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 organisations 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 who 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 domestic industry controls 77 percent of the pharmaceutical market in India. However, there are five MNCs among the top 20 pharmaceutical companies in India. This shows the strong presence of pharmaceutical MNCs in the region. In such a context, the introduction of a product patent would eliminate competition in most of the new drugs and increase the share of MNCs in the South Asian pharmaceutical market.

Presently, the Indian pharmaceutical industry is one of the largest generic pharmaceutical industries in the world. Absence of product patent protection played a significant role in this phenomenal growth. In the recent years India emerged as the major

supplier of generic drugs (bulk drugs and formulations) for certain new and critical diseases like HIV/AIDS. The generic version reduced the price of Antiretro Viral (ARV) drugs from US\$ 10,000 to US\$ 140. According to Medicine Sans Frontieres (MSF), 50 percent of the people who access ARV treatment for HIV/AIDS in developing countries depend on generic drugs from India. As one of the most underdeveloped regions, public spending in health is very low in South Asia. As a result, the majority of people spend their private savings for health care. For instance, private expenditure on total health care spending in India and Pakistan is 84 percent and 77 percent respectively. Hence, any increase in the prices of medicines would have a direct impact on personal savings of the people. In other words, any rise in the price of medicines would result in the denial of access to medicines. There is already an acute crisis with regard to access to medicines in the region. In India alone 6,00,000 people need ARV treatment for HIV/AIDS and the central government is targeting 1,80,000 people under its free treatment plan by 2010. In the normal course, introduction of product patents restricts the manufacturing activities of local companies to non-patented drugs. Since most of the new drugs would be under patent protection a generic version of these drugs cannot be produced without resorting to compulsory license or government use. Compulsory licensing with the new competition policy can take care of the egregious impact of the TRIPS agreement. Also, at present 97 % of the drugs in India are off patented and therefore the impact on prices will be negligible. However, if the domestic companies are not able to increase their R and D in future we could see increase in prices in future. Government institutions with private partnerships need to increase R and D expenditure in finding new molecules of the drugs with focus on diseases prevalent in developing economies like India..

The Indian Patents Act attempts to limit the scope of patentability. Criteria for patentability are defined in the Act and it is linked to a web of definitions. According to the Act, a patent means a patent for any invention granted under this Act. The word invention is defined as a 'new product or process involving an inventive step and capable of industrial application. Thus a patent is granted only to a new product or process involving an inventive step and capable of industrial application. However, the Act defines inventive step as feature of an invention that involves technical advances as compared to the existing knowledge, or having economic significance, or both, and that makes an invention not obvious to a person skilled in the art. According to this definition to satisfy the inventive step test the invention has to satisfy any of the three conditions viz. advances over existing technical knowledge or economic significance or both. Generally speaking, economic significance should not be a sole criterion for evaluating the inventive step of the invention. Economic significance of an invention depends on many other factors and it is not the purpose of patents to recognise inventions only on that basis. However, the new definition makes the economic significance criteria as substitutable criteria to technical effect. As a result, the new definition of inventive step is a diluted one among the basic requirements of inventive step. At the same time TRIPS uses economic significance in a different context. Under Article 31 (1) (ii) of TRIPS states that compulsory license for dependent patents should look at whether the second patent should involve an important technical advance of considerable economic significance in relation to the invention claimed. Therefore economic significance could have been used along with the technical effect to judge the inventive step but not as the sole criteria.

Further, the Act now included two new definitions, viz., new invention and pharmaceutical substance, with the intention of limiting the scope of patentability. New invention means 'any invention or technology, which has not been anticipated by publication in any document or been 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. Hence, to qualify as a new invention, the invention in question should not have been either published in any document or used in India or anywhere in the world before the filing of the patent with complete specifications. It means the subject matter has not fallen either in the public domain or became part of the state of art. The notable omission here is that the publication does not include oral publication. As a result, it fails to recognize oral knowledge as an element in the definition. Further, this definition makes a difference between invention and technology. The common understanding is that invention in the patent context is related to the technology and therefore this differentiation does not make any sense. Hence, it does not serve any purpose. The meaning of definition reflects that it is intended to define the word anew. Likewise, the definition of pharmaceutical substance is not linked to the patentability of pharmaceuticals. The term pharmaceutical substance' is defined as any new entity involving one or more inventive step. Thus the definition expands the scope of pharmaceutical substance and encompasses every type of pharmaceutical entity, including, but not limited to, formulations, pharmaceutical salts, isomers, polymorphs and their combinations. Nevertheless, both definitions have not been linked to other provisions of the Act. Therefore, these definitions are stand-alone and provide some kind of incoherence to the statute. If they were used to interpret the patentability criteria these definitions would dilute the threshold levels of patentability criteria.

Section 3 of the Act excludes 16 types of inventions from the patent protection because they are not considered inventions within the meaning attributed to invention. There are a few exclusions having implications for the patentability of pharmaceutical substances. However, the most important exclusion is in sub-section (d), which states: '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 one new reactant.'

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 substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy'. This provision excludes new forms of a known substance, discovery of new property known substance, new use of a known substance. Further, it treats salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and other derivatives of a known substance would be considered as the same substance. Therefore subsequent patenting in any of the above mentioned forms is prohibited.

However, the exclusions in sub-section (d) do not prohibit patenting of known substances in all circumstances. Exclusions are qualified with words 'mere' and the phrase 'which does not result in the enhancement of the known efficacy'. These words and phrases are ambiguous, too broad and potentially allow new forms of existing substances to be patented. For instance, what is banned is the mere discovery of a known new form of a known substance and not the patenting of new forms of a known substance per se. Further, a minor amendment to an existing form can satisfy the requirement of 'result in enhancement of efficacy' and able to get around the provision as it stands. In addition, the phrase 'mere discovery' conveys that discoveries are patentable if they are not mere discoveries. The mandate under TRIPS is to provide patent protection to only inventions and discoveries.

These qualifications offer an entry point in favour of the patentee to claim patents on all those mentioned in the explanation. Furthermore, the Patent Office is not equipped like a science lab to examine whether the claimed invention differs significantly in properties with regard to efficacy. These flaws result in the expansion of scope of patentability. The Patents Act stand today does not insulate itself in dealing with evergreening of patents. Provisions pertain to the scope of patentability i.e. definitions on the criteria of patentability and the exclusions of patentability provide enough space for pharmaceutical companies to come around the exclusions and obtain patents for a known substance. This would delay the introduction of generic drug in the market even after the expiry of original patent and compromises the access to medicines.

India has also given due farmers rights to save ,exchange and sell seeds through the introduction of the Plant Variety Protection and Farmer's right bill 2001. The bill adequately defines the Plant breeders and Researchers right as well. Indian Biodiversity bill takes care of the rich biodiversity of the Indian region by documenting the same and also talks of benefit sharing and prior informed consent between the parties. It adapts to the Convention on Biological diversity Act. However, The WTO's TRIPS agreement and the TRIPS agreement which is adopted by many countries seems to be quiet about the issue of benefit sharing and PIC. India has adopted Sui-generis system in Agriculture by protecting new plant and animal varieties and also for protection of Traditional knowledge. India is also calling for widening the scope of Geographical indications to products besides wines and beer. These include giving due recognition to

Basmati Rice

Darjeeling Tea

Kanchipuram Silk Saree

Alphanso Mango

Nagpur Orange

Kolhapuri Chappal

Bikaneri Bhujia

Agra Petha

Goa Feni

among others. The fear is that now microorganism including genes, viruses can be patented.

**TRIPS AND PUBLIC SECTO RESEARCH:FUTURE POTENTIAL**

The patent activity of many public sector research institutions in India has increased in recent years. For decades, public sector institutions in India have focused on building indigenous capabilities and disseminating it cheaply to industry rather than patenting inventions and exercising ownership rights. This accounted for a low level of patents acquired by public sector research institutions. Patents granted from 1972-94 show that a majority of patents in India were awarded to transnational companies and about 80 per cent of the patents went to foreigners. Even among the domestic actors, the private sector had a greater share than the public sector

The CSIR, the Department of Biotechnology (DBT), and the ICAR are some of the public sector research institutions that have begun filing patent applications both in India and abroad. The below given table gives the patenting record of the CSIR in India 1990-1 to 1998-9.

Patenting Record of the CSIR in India 1990-1 to 1998-9

Year	Filed	Granted	Success rate (%)
1990-1	202	55	27.23
1991-2	230	66	28.70
1992-3	232	38	16.38
1993-4	198	80	40.40
1994-5	241	104	43.15
1995-6	260	106	40.77
1996-7	209	92	44.02
1997-8	264	155	58.71
1998-9	310	134	43.23

*Source: Adapted from Mani, S. (2002) Government, Innovation and Technology. Policy: An International Comparative Analysis, UNU, Tokyo, p. 246.*

## **XII. Summary and Conclusions**

This draft has reviewed the implications of the TRIPS agreement based on the issues raised by the developing countries. It provides an overview of the relationship between development and intellectual property rights and notes that the debates on TRIPS were part of broader issues of the role of technology in development and could not be addressed in narrower legalistic terms pertaining to enforcement. The policy draft outlines

specific issues raised by developing countries and concludes that they are related to implementation, among others. It calls for the need for flexibility and innovation in property rights systems to accommodate the interest of the developing countries. The draft offers a number of domestic and international policy options that could be pursued in addressing concerns of the developing countries.

The patent system, at least for developed countries, has emerged as the central institution for asserting intellectual property rights in many crucial fields of science and technology. From an economic point of view, patents offer a second-best solution to the market failure arising from the public good nature of knowledge. As such, the patent system contributes to solving a problem but comes with shortcomings of its own, mostly because it creates market power positions that can adversely affect the economic performance of the system. However, this perception may change if empirical results can support the theoretical result - innovations play an important role in stimulating economic growth.

However, even if patents do not stimulate innovation, policies that promote strong patents may be justified. A second purpose of patents is to promote disclosure, a benefit that remains intact under the modern dynamic theory of patents. Inventions that would be kept secret without patents are more likely to be revealed when under patent protection, making them freely available after the patent expires. This benefit of patents must be balanced against the social costs that arise because the disclosed inventions are not freely available during the patent term: patented inventions will be used too little, may hold up subsequent research on related inventions and may generate substantial transaction costs from costly legal challenges about possible infringement. But if patents facilitate a market for technological change licensing and other arrangements that permit the use of technology during the life of a patent may mitigate these costs.

TRIPS allows considerable flexibility in how countries may design their patent systems. Since most developing countries do not have a significant research capability, they have little to gain by providing extensive patent protection as a means of encouraging research, but they stand to lose as a result of the impact of patents on prices. Therefore, developing countries should aim for strict standards of patentability to avoid granting patents that may have limited value in relation to their health objectives. Such systems should aim to promote competition, and provide safeguards in the event of abuses of the patent system.

The adoption of the TRIPS agreement was followed by a period of the translation of its provisions into domestic law. The successful integration of the provisions of the agreement into domestic law depends on (a) the degree to which the provisions required changes in domestic legislation; (b) the degree to which the required changes conflict with existing laws of obligations under other agreements; and (c) the ability of the developing countries to adjust their institutions where the two issues outlined above do not hinder the implementation process.

The issue of technology transfer is possibly one of the most important areas of interest to developing countries. It was precisely because of this concern that many developing countries were originally opposed to a GATT-driven accord on intellectual property rights. With the growing technological gap between the developed and developing countries, the developing countries are likely to increasingly call for creation of

mechanisms that promote technology transfer and dissemination. This may be possible if the Article 27 of the TRIPS agreement on patentable subject is extended to protect all types of technologies.

As intellectual property rights are strengthened globally, the cost of medicines in developing countries is likely to increase, unless effective steps are taken to facilitate their availability at lower cost in developing countries. There are a number of IP policies that both developed and developing countries can adopt to promote cheaper prices for medicines in developing countries which will adversely affect the incentives for research on relevant diseases. One means of obtaining medicines at lower prices, amongst others discussed in this policy draft is for countries to use a mechanism called “compulsory licensing.” This allows countries to license the manufacture of patented medicines to other manufacturers if there are good reasons to do so (e.g. when the government considers the price of a medicine is unjustifiably high). It can also be useful as a bargaining tool in price negotiations with producers of patented medicines.

The review of the relevant provisions in TRIPS which is currently taking place in the TRIPS Council, should preserve the right of countries not to grant patents for plants and animals, including genes and genetically modified plants and animals. It should also permit countries to develop sui generis regimes for the protection of plant varieties that suit their agricultural systems. Such regimes should permit access to the protected varieties for further research and breeding, and provide for the right of farmers to save and plant-back seed, including the possibility of informal sale and exchange.

Developed and developing countries should accelerate the process of ratifying the FAO Treaty on Plant Genetic Resources for Food and Agriculture and should, in particular, implement the Treaty’s provisions relating to not granting IPR protection on genetic material in the form received from gene banks protected by the Treaty. They should also implement at national level, measures to promote Farmers’ Rights. These include the protection of traditional knowledge relevant to plant genetic resources; the right to participate in sharing equitably benefits arising from the utilization of plant genetic resources for food and agriculture and the right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources.

The Convention on Biological Diversity (CBD), which most countries have signed, seeks to encourage access to the world’s genetic resources provided that it is done with the informed consent of the holder of the resource and that any benefits deriving from the access are shared in an equitable manner. The extent to which the IP system should be supportive of the CBD has been the subject of much debate. At the heart of this has been the question of whether patent applicants should disclose in their applications the source of any genetic resource used in their invention.

A further debate in the WTO’s TRIPS Council centres on whether the protection afforded under TRIPS to geographical indications (that is indications that identify the origins of a product as a mark of quality and provenance) should be increased through either the

establishment of an international register of protected indications or through the extension of the additional protection currently available for wines and spirits to other products. Lacking in this debate however is any real economic assessment of the impact of such proposals for developing countries. Consideration should also be given to establishing a system whereby patent offices examining patent applications which identify the geographical source of genetic resources or traditional knowledge pass on that information either to the country concerned, or to WIPO. WIPO may act as a depository for patent related information of this nature. Through these measures it will be possible to monitor more closely the use and misuse of genetic resources

There are a number of motives for protecting and promoting traditional knowledge. These include the erosion of traditional lifestyles and cultures through external pressures, misappropriation, the preservation of biodiversity and the promotion of its use for development purposes. Some wish to conserve traditional knowledge, and protect it against commercial exploitation – others wish to ensure that it is exploited in an equitable manner for the benefit of its holders. Underlying the debate on the protection of traditional knowledge may be much bigger issues such as the position of indigenous communities within the wider economy and society of the country in which they reside, and their access to, or ownership of, land they have traditionally inhabited. Given the varied reasons for protecting it and the broad nature of the subject matter, there is no one way in which it can be protected or promoted. Protection for traditional knowledge may be obtained both within the existing IP system and through the establishment of new or sui generis forms of protection.

This policy draft analyses provisions on copyright and related rights in TRIPS and in the relevant provisions in the Berne Convention and discusses the new WIPO treaties and the unresolved issues on databases and audiovisual works.

Digitalization and the potential for instant, low-cost global communication have opened tremendous new opportunities for the dissemination and use of scientific and technical databases in developing countries, as elsewhere in the world. Indeed, the ability to access existing databases and to extract and recombine selected portions of them for research has become a key part of the scientific process. However, commercially-owned private sector databases typically seek to control unauthorized access in order to maximise revenues from subscriptions, even when some of the data they contain may be in the public domain or collected through publicly funded research. The central concern here, therefore, is that a strengthening of IP protection for databases at the international level, whilst encouraging more investment in new commercial database products and services, may at the same time greatly reduce the access of scientists and researchers in developing countries to the data they contain because they will often lack the financial means to pay for the necessary subscriptions.

It is clear that the issues surrounding access to information and knowledge over the Internet are still emerging. In some respects, they are of limited immediate importance in many developing countries, given these nations' limited Internet connectivity. However, Internet issues are crucial to universities and scientific research in the developing world, and may soon be central to secondary and even primary education in developing nations

since Internet access will be much less expensive than the construction and stocking of libraries. The Internet has remarkable potential for development and it is imperative that this is not lost.

More analysis needs to be undertaken about the best means of protecting digital content and the interests of rightsholders, whilst at the same time honoring principles that ensure adequate access and “fair use” for consumers. More specifically, policymakers need to gain a better understanding of the impacts of the trend towards on-line distribution and technological protection of content on developing countries. There is a possibility that much such material will be protected technologically or through contractual provisions that are imposed as a condition of accessing the material. And it is not clear how reasonable requirements of “fair use” will be guaranteed in such an environment.

Bearing in mind this considerable level of uncertainty, we conclude that it is premature at the present time for developing countries to be required to go beyond TRIPS standards in this area. We believe developing countries would probably be unwise to endorse the WIPO Copyright Treaty, unless they have very specific reasons for doing so, and should retain their freedom to legislate on technological measures. It follows that developing countries, or indeed other developed countries, should not follow the example of the DMCA(Digital Millennium Copyright Act) in forbidding all circumvention of technological protection. In particular, we take the view that legislation such as the DMCA shifts the balance too far in favour of producers of copyright material at the expense of the historic rights of users. Its replication globally could be harmful to the interests of developing countries in accessing information and knowledge they require for their development. Similarly we have concluded that the EU Database Directive goes too far in providing protection for assemblages of material and will restrict unduly access to scientific databases required by developing countries.

Users of information available on the Internet in the developing nations should be entitled to “fair use” rights such as making and distributing printed copies from electronic sources in reasonable numbers for educational and research purposes, and using reasonable excerpts in commentary and criticism. Where suppliers of digital information or software attempt to restrict “fair use” rights by contract provisions associated with the distribution of digital material, the relevant contract provision may be treated as void. Where the same restriction is attempted through technological means, measures to defeat the technological means of protection in such circumstances should not be regarded as illegal. Developing countries should think very carefully before joining the WIPO Copyright Treaty and other countries should not follow the lead of the US and the EU by implementing legislation on the lines of the DMCA or the Database Directive.

In retrospect, the decision of the Uruguay Round to bring intellectual property (IP) issues into the WTO through the TRIPS agreement seems to have been a mistake. However, now with lot of bilateral treaties coming up there is a possibility of setting standards which are TRIPS plus standards on protection. It would mean that signing TRIPS has become imperative for countries and the challenges are domestic in the sense of using

flexibilities under TRIPS to deal with the egregious impact of the TRIPS. Although the World Intellectual Property Organization (WIPO) already existed for dealing with IP issues it is also now talking of harmonization of standards and not having minimum standards like TRIPS. The only reason for bringing them into WTO seems to be the availability of the WTO's dispute settlement and trade sanctions mechanism for enforcing IP rights. The very same motive lies behind the persistent demand by some developed countries for inclusion of labour and environmental standards in the WTO. However, given that most of the developing countries including India are signatories to the TRIPS agreement, the study concludes that instead of watchfully waiting to support meaningful proposals originating from other countries it is time that they should take initiative to evolve and design beneficial policies on their own.

Implementation of the product patents regime in India with strong generic industry may hamper the global supply of generic drugs. Therefore there is legal and moral obligation on India to use the TRIPS flexibility to the optimum level. The immediate impact on prices would be negligible as only 3 % of the drugs are on patents. However, if the government is not able to step up and facilitate increase of R& D expenditures surely prices of drugs will be impacted in future. The government has priority to provide accessibility of cheap drugs to all. Compulsory licensing along with competition policy can take care of the egregious impact of the TRIPS agreement. The compulsory licensing provisions should be amended to remove cumbersome procedural amendments.

According to a National Institute of Health Care Management (NIHCM) study, the US Food and Drug Administration (USFDA) approved 1035 drugs between 1989 and 2000 and only 365 drugs i.e. 35 percent approved were new molecular entities i.e. drugs containing new active ingredients. Active ingredients of other 65 percent, were already available in the market and the differences were in terms of dosage, route of administration, and combination of active ingredients. Hence, there is no direct link between patent protection and therapeutic quality of a drug. Often, the patent is used as an instrument to maintain the market monopoly. Further, data shows that between 1995-2004 the USFDA had approved only 297 new chemical entities. However, the number of patent applications in the Indian mailbox is 8,926. This is a clear indication that many of these patent applications may be claiming patent protection for known pharmaceutical substances. The subsequent patenting of a known substance would result in the delay of introduction of generic version in the market and may hamper the access to medicines. Limiting the scope of patentability to new chemical molecules (for which R&D becomes essential) would bring down the number of patent monopoly in the market. Hence, limiting the scope of patentability to new chemical molecules may be essential for South Asian countries to ensure accessibility and availability of medicines. However, the moot question is whether limiting the scope of patent protection only to new chemical entities would violate the TRIPS obligation of non-discrimination and flexibilities provided by the TRIPS agreement.

**It summary, more research is needed to understand the implications of various articles and clauses of the TRIPS agreement. These can be taken up for discussion by economists in conjunction with lawyers, policy makers, administrators and other social scientists.**

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