

ECONOMIC AND SOCIAL COMMISSION FOR ASIA AND THE PACIFIC

Institutional Capacity-Building to Deal with the Implications of  
TRIPS for Industrial and  
Technological Development: Case Study of India



United Nations

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## Preface

In today's globalized society, technological innovations are in continuous demand to cope with the major problems faced by human beings, such as food shortage, incurable diseases such as human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS), and environmental deterioration such as depletion of the ozone layer and global warming. A large number of technological innovations and resulting marketable processes and products to mitigate these problems have entered the world market, largely from developed economies where research and development facilities and other requirements are adequate. Any scientific or technological innovation of a nation are its intellectual property and the country can protect them by formulating and implementing the appropriate laws, such as patent laws. However, the lack of a proper treaty and/or agreement between nations could limit the flow or transfer of such a technology to another nation by means of trade and investment. It could also lead to technology transferred or goods and services imported into a nation being expensive.

Trade-related aspects of intellectual property rights (TRIPS) Agreement have played important roles in such issues. During the Uruguay Round discussions, the developing countries argued that stronger intellectual property rights (IPRs) would have adverse effect on the technological development of developing countries. On the other hand, developed countries argued that stronger protection of intellectual property rights would not only result in better technology transfer but would stimulate technological development in developing countries. Indian experiences indicate that stronger IPRs protection encourages foreign investment in research and development activities, such as biotechnology, and technological development, if technology transfer occurs. However, prices of some of life-saving pharmaceutical products, such as those for HIV/AIDS and other acute diseases, that are the results of technological innovation and years of research and development activities and that have mostly come from developed countries into the world market, could go up in developing countries because of strong IPR protection in developed countries. The experiences of Japan and the Republic of Korea in the areas of pharmaceuticals and chemicals have demonstrated that introduction of effective IPR protection has eventually led to increased research and development activities and to improved economic performance of those countries.

The fourth session of the recent WTO Ministerial Conference, held at Doha from 9 to 14 November 2001 has given direction to the TRIPS council to continue its examination of the scope and modalities for complaints of the types provided for under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 and make recommendations to the ministerial conference. at its fifth session. It was reaffirmed that the provisions of Article 66.2 of the TRIPS Agreement were mandatory and it was also agreed at the Conference that the TRIPS council should put in place a mechanism for ensuring the monitoring and full implementation of the obligations in question. To that end, developed-country members should submit prior to the end of 2002 detailed reports on the functioning of the incentives provided to their enterprises for the transfer of technology in pursuance of their commitments under Article 66.2. Those

submissions should be subject to a review in the TRIPS council and information should be updated by members annually. The Ministerial Declaration also stressed the importance of implementation and interpretation of the TRIPS Agreement in a manner supportive of public health, by promoting both access to existing medicines and research and development into new medicines. Thus, the Ministers expressed concerns about the effect of IPP on prices while indicating that IPP held the key to the development of new medicines. Such an agreement among the Ministers on the impact of prices of medicines resulting from IPP should be considered as the major achievements of the developing countries.

The present study mainly deals with the implications of TRIPS for industrial and technological development of the developing countries of the region by building institutional capacity of those countries. The case study of India in this area is presented.

It is hoped that this publication will provide important information to the developing countries of the region for building the capacity of their institutions so that they can adopt and implement the proper laws relating to IPRs and help promote technology transfer and build up their technological capabilities by the proper implementation of the TRIPS Agreement.

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## Abbreviations

AIDS	Acquired Immune Deficiency Syndrome
CAT	Central Administrative Tribunal
CBD	Convention on Biological Diversity
DSB	Dispute Settlement Body
DSM	Dispute Settlement Mechanism
EDV	Essentially Derived Variety
EMRs	Exclusive Marketing Rights
EPO	European Patent Office
FCS	Flexible Complementing Scheme
FDI	Foreign Director Investment
GATT	General Agreement on Tariffs and Trade
HIV	Human Immune Deficiency Virus
IPP	Intellectual Property protection
IPR	Intellectual Property Right
IPRs	Intellectual Property Rights
IUPOV	International Union for the Protection of Plant Varieties
LDCs	Least Developed Countries
NTCNET	National Informatics Centre Network
PCT	Patent Cooperation Treaty
PIS	Patent Information System
PPVFR	Protection of Plant Varieties and Farmers' Rights Act
PVP	Plant Variety Protection
R&D	Research and Development
TRIPS	Trade Related Aspects of Intellectual Property Rights
UCC	Universal Copyright Convention
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

## I. INTRODUCTION

The Ministerial Meeting of the General Agreement on Tariffs and Trade (GATT), held at Punta del Esté, Uruguay in September 1986 had an ambitious agenda for a new round of negotiations. The developing countries at that Meeting were more worried about the inclusion of services to be negotiated in a new round. They concentrated their efforts to oppose its inclusion. They did not notice another important item on the agenda, trade-related aspects of intellectual property rights (TRIPS). As it turned out the Punta del Esté Declaration launching the Uruguay Round contained TRIPS as an item of negotiations and covered a broad mandate, which read as follows:

In order to reduce the distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights (IPRs), and to ensure that measures and procedures to enforce IPRs do not themselves become barriers to legitimate trade, the negotiations shall aim to clarify provisions and elaborate as appropriate new rules and disciplines.

Negotiations shall aim to develop a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods, taking into account work already undertaken in the GATT.

These negotiations shall be without prejudice to other complementary initiatives that may be taken in the World Intellectual Property Organisation (WIPO) and elsewhere to deal with these matters.

Quite evident from the mandate was the fact that GATT was called upon to evolve a distinct set of rules and procedures for intellectual property protection (IPP) to be adopted as a standard by all the Contracting Parties. The wide scope of the GATT initiative becomes at once clear if the proposals that were put forth by the developed countries to the negotiating group considering the issue of IPRs are considered.

When the Uruguay Round negotiations started in Geneva in February 1987, developed and developing countries had different interpretations of the negotiating mandate. While developed countries argued that the negotiations should consider the norms and standards of IPP, developing countries argued that norms and standards should not be negotiated because they did not fall within the ambit of GATT. This stalemate continued until April 1989 when after the Mid-term Ministerial Meeting at Montreal, developing countries agreed to discuss norms and standards of IPP.

India was one of the countries which opposed the discussion of norms and standards of IPP under GATT. It stuck to this position until April 1989 at which time it agreed to discuss norms and standards of intellectual property protection. After this, its attempts to bring any developing country concerns to the TRIPS Agreement did not succeed to a large extent (Rao,1989a). The role of non-Governmental organizations in bringing the issues relating to IPRs into public debate in India was very important.



### **A. Objectives of the negotiations**

The developed countries, represented primarily by the United States of America, the European Community and Japan, spelt out quite unambiguously the framework within which GATT negotiations on IPP should take place. The key element of the proposed framework was the extension of the discussions on this issue beyond the limits set by the GATT articles. According to the developed countries, the GATT articles were not broad enough to enable formulation of a code on IPP. Amendment of the GATT articles was, therefore, not considered useful for evolving an effective code for IPP and it was suggested that a separate exercise be undertaken for structuring a code underlying the GATT-based approach to IPP.

Protection of intellectual property within the GATT framework, in view of the developed countries, were required to include four major issues:

- (a) Setting adequate and substantive standards for the protection of intellectual property,
- (b) Effective border and internal enforcement measures aimed at preventing infringement of intellectual property rights,
- (c) A dispute settlement mechanism,
- (d) Provisions drawn from other GATT principles and adapted to intellectual property.

### **B. The developing country perspective**

Two features of the developing country position on TRIPS during the Uruguay Round negotiations need to be pointed out at the outset. One, the position of the developing countries in the GATT negotiations on intellectual property rights were clearly articulated in the submissions made by Brazil and India. And, two, the substantive points that were made by these countries related essentially to one form of intellectual property rights, patents rights.

Brazil raised three issues in the context of the strengthening of protection to IPRs that has been suggested by the developed countries. These were:

- (a) The effect of excessive protection provided to IPRs on the developing countries' access to latest technology.
- (b) The distortions and restrictions brought on the international trade consequent upon abusive use of intellectual property rights, and,
- (c) The effect of intellectual property on trade liberalisation.

In raising the point about the effect of excessive protection to IPRs on developing countries access to technology, Brazil commented on the imbalance in the nature of discussions that were then taking place in the Uruguay Round where prominence was being given to the rights of the intellectual property owners while the interests of users of intellectual property, which included the developing countries, was given a short shrift. According to Brazil, the discussions had to consider the obligations of the owners of intellectual property in addition to the question of the rights of the owners. The objectives of the obligations on the intellectual property owners, in view of Brazil, should be to allow developing countries greater access to technological innovations taking place globally.

Brazil, in its submission to the Negotiating Group dealing with the intellectual property issues argued that a stronger protection provided to intellectual property rights would tend to create a rigid monopoly situation which would favour the intellectual property owners who were mostly from the developed countries. The intellectual property owners could use the monopoly powers to deny developing countries access to latest technology. Consequently, a situation could arise where by accepting a higher degree of IPP, developing countries would not be able to freely acquire and adapt foreign technology, and they also would not be able to import new products and process from alternative foreign sources. Developing countries, which needed to adopt foreign technology and also have continued access to imported technology, would thus be seriously affected if they were asked to accept a strong regime of patent protection of the kind suggested by the developed countries.

In its submissions, Brazil suggested that flexible system of protection of IPRs should be adopted, as this would be most conducive to the needs of the developing countries. Flexibility should include specific exclusions of protection of intellectual property rights. This suggestion was in keeping with the standard of the Paris Convention for the Protection of Industrial Property by which exclusions and patentable subject matter were allowed to signatory countries.

Apart from the specific needs of the developing countries in the light of which Brazil argued for a flexible system of IPP, another detrimental effect of a rigid system was also mentioned, namely the abusive or anti-competitive use of intellectual property rights. Brazil suggested that measures had to be taken to check restrictions on international trade and flow of technology that could arise as a consequence of the exercise of excessive rights granted to the owners of intellectual property.

The Brazilian submissions, in essence, questioned the position taken by the developed countries regarding the influence of a strong regime of patent protection on international trade. While it raised some important issues, however, the submission did not question the justification of including the issue of IPRs in the Uruguay Round negotiations. This was a major point of contention and on this issue Brazil appeared to go along with the developed countries' position on the justification of discussing trade related aspects of IPRs in the Uruguay Round of GATT.

While Brazil restricted itself to countering specific issues that have been raised by the developed countries which bring in the question of IPRs in the Uruguay Round, India took a

position that covered a much larger spectrum of issues. At the same time, however, India, and Brazil, did not present its views on the trade relatedness of IPRs in the submissions to the Negotiating Group.

The essentials of the position taken by India in the GATT negotiations reflected a view of patent protection that could be found in the country's patent law. India was able to develop its own standards for patent protection, as it was not a member of the Paris Convention to the protection of Industrial Property when the Uruguay Round negotiations were in progress. The patent law adopted by the country, consequently, contained a few significant deviations from the Paris Convention standards. India, in its submissions, argued for the adoption of some of the features of its own patent law in arguing for a more flexible patent regime.

Three main features of the Indian Patent Act were highlighted in the Indian submission to the negotiating group. These were: (a) coverage of patentable subject matter, (b) duration of patent protection, and, (c) working of patents by using the provisions of compulsory licenses and licenses of right.

India argued that the process patent system, one of the principal elements of its Patents Act, provided encouragement to the development of more efficient and economical processes for the manufacture of an existing patented product. The developed countries utilized this important instrument of promoting innovativeness in the early stages of their industrialization, it was argued. In India's view, developing countries could derive similar benefits from the process patent system and two of these advantages were specifically mentioned in the country's submission to the negotiating group:

(a) First, these countries could build their own technological capabilities by developing new processes for manufacturing. Second, development of new processes could end the monopoly that the patent system gives to the inventor of the product and introduces new producers and this in turn could have its effect in lowering the price of the product through competition. Reduction of the price level, particularly in the case of essential products, was an important consideration for low-income countries.

(b) India has argued against a uniform standard for patent terms for all countries. The important point made in the submission is that developing countries should adopt a patent term that is significantly lower than that adopted by the developed countries.

(c) Working of the patent in the country of grant was a contentious issue, and this was established most effectively in the diplomatic conference that was held for the revision of the Paris Convention for the protection of industrial property in the early 1980s (Rao,1989b). On this issue, India's position was that adequate mechanisms had to be created to ensure that a patent is worked in the country of grant. India argued that although the Paris Convention allowed for the use of compulsory licensing and most countries acceding to this multilateral arrangement had incorporated this mechanism in their own patent laws, in actual practice, this mechanism was not found to be very effective in making the patentee work his patent. India suggested that to ensure working developing countries should be free to provide for automatic grant to compulsory licenses in sectors of critical importance such as food, pharmaceutical and

chemicals. These "licenses of right", once issued, should not be brought under any administrative scrutiny and while the country of patent grant gained from using the invention, the patentee should be compensated according to the host country's law.

It can thus be said that the submissions made by India gave important suggestions for introducing flexibility in the patent system. The suggestions far much beyond the Paris Convention standards, particularly in regard to the mechanism suggested for working the patent, that is, the license of right. India's suggestion on this issue was important, considering that while non-nationals were given patent protection by developing countries, the patent holders on their part were not interested in working the patent in the country of grant and, therefore, dissemination of technology did not take place. India thus suggested ways of increasing the obligations of the patent holder in order to balance the rights that the developing countries gave them to operate in their territory. This position was quite in keeping with the Brazilian view, which held that obligations on the patent holder should be brought in the patent laws.

At the formal end of the multilateral negotiations in the Uruguay Round at Brussels in 1992, there was no agreement on the final text of the TRIPS Agreement. The text at that time contained both the proposals of the developed and developing countries in square brackets. A reading of that text conveyed the idea that the differences of perception between developed and developing countries was indeed large.

The Brussels ministerial meeting was not conclusive and ended in a failure, one of the reasons being the TRIPS text. After this the formal negotiations were suspended and the negotiations moved on to a non-formal and secretive phase. One does not have access to documents to see what happened but the final text released in December 1993 (the so-called Dunkel Draft) contains most of the suggestions made by the developed countries and very few of the suggestions of developing countries (Dhar and Rao, 1992).

The Ministerial Meeting held in Marakkesh, Morocco in April 1994 adopted the final text of the Uruguay Round of negotiations, which contains the TRIPS Agreement. This meeting also launched the World Trade Organization (WTO).

The performance of the developing countries in these negotiations left much to be desired. First of all, these countries did not act as a block either formally or informally. There were differences of opinion between many of them. Many of them just did not bother about TRIPS. Some were put under pressure to accept the agreement.

Only few of the developing countries were convinced that the strengthening IPP would be beneficial to them. While a strong IPP worldwide may benefit them indirectly through a large flow of inventions, they were worried about the immediate problem of abuse of this monopoly. They apprehended that the TRIPS Agreement does not contain the necessary mechanism to check this. Between 1986 and 1993 when the discussions on the TRIPS agreements were going on many developing countries succumbed to unilateral pressure and changed their Intellectual Property laws. A post-Uruguay Round reality is that all the countries have to have strong IPP. The first task before the developing countries is to interpret the

TRIPS provisions to see whether some safeguards can be put in place. The other is to try to improve their technological capability to get the best out of the TRIPS agreement.

## II. THE INDIAN EXPERIENCE IN THE IMPLEMENTATION OF TRIPS

The TRIPS Agreement explicitly mentions seven areas of intellectual property in which a country has to provide protection. These are patents, designs, trademarks, copyright and neighbouring rights, plant variety protection, layout designs and geographical indications.

While India had to amend its laws related to patents, designs, trademarks and copyright, it had to enact fresh legislation with regard to plant variety protection, layout designs and geographical indications.

A part of the period during the negotiations and most of the period of the actual implementation of the TRIPS agreement, India faced frequent elections. This meant dissolution of the eleventh and twelfth Lok Sabhas<sup>1</sup> within less than two years. This had the consequence of bills being passed by the Lok Sabha but not by the Rajya Sabha, which expired at the time of the dissolution of the Lok Sabha.

Recently, India enacted new legislation on designs, trademarks, plant variety protection, layout designs and geographical indications. It amended its copyright law and is in the process of amending its patent law. While the changes to the designs, trademarks, and copyright laws were marginal and enacting new legislation in layout designs and geographical indications was non-controversial, those relating to plant variety protection and patents raised a lot of controversy.

One interesting feature of the new legislation is that infringement of rights has been treated as a criminal offence in all the laws except those for patents and designs. While trademarks and copyright infringements were traditionally treated as criminal offences those relating to plant variety protection and layout designs raise some uncomfortable questions.

The obligations under TRIPS meant that new institutions to grant rights had to be established in case of new laws, and institutions strengthened in the case of patent, designs, trademarks and copyrights. There is no obligation to 'strengthen' internal enforcement machinery in the TRIPS agreement (Article 41 (5)), but India chose to create new institutions for reviewing decisions to authority in all the intellectual property laws except designs.

Article 40 of the TRIPS Agreement provides for control of anti-competitive practices in contractual licenses. Only Patent (Amendment) Bill, 1999 and Designs Act, 2000 provide for

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<sup>1</sup> The Indian Parliament consists of two houses: Lok Sabha and Rajya Sabha. The Lok Sabha is the house of people, and each member of the Lok Sabha is directly elected by the people from a constituency. Election takes place every five years unless it is dissolved. A ruling coalition has to have at least a working majority. The Rajya Sabha is the council of States. State legislatures elect the members of the Rajya Sabha. It is a permanent house with one third of its members retiring every two years.

prohibition of anti-competitive practices in contractual licenses involving these IPRs. The Trademark, Copyright, Plant Variety Protection, Layout Design and Geographical Indications Acts do not have any provision prohibiting the use of anti-competitive practices in contractual licenses.

## **A. Legislative developments**

### **1. Intellectual property rights**

#### Patents

The law in force is the Patents Act, 1970, in effect from April 1972. India joined the Paris Convention on 7 December 1998.

The patentability criteria for inventions are new (novel, Sec. 2 (1j)) and useful (industrial applicability, Sec. 2 (1j)). Non-obviousness (inventive step) is not a criterion for patentability, hence it is not examined for by the examiner. Under Sec. 25, interested parties can initiate proceedings on the grounds that the invention is obvious. The examination is of form as well as substantive. The novelty criteria are anything new in the world. Opposition is possible under Sec. 25.

The following are excluded from patentability: (1) Inventions contrary to law or morality or injurious to public health (Sec. 3(b)); (2) Scientific principles (Sec. 3(c)); (3) Method of agriculture or horticulture (Sec. 3(h)); and (4) Medicinal, surgical, curative, prophylactic, or other treatment of humans, plants or animals (Sec. 3 (i)). Atomic inventions are not patentable (Sec 4). Food, medicine, drug and chemical inventions are given only process patents (Sec 5).

Whether the Act provides protection to other plant biotechnology inventions is a controversial issue. The Patents Act explicitly excludes some areas of technology. The absence of plant biotechnology inventions in the exclusions has given rise to interpretations as to whether they can be patented. Some claim that indeed is the case. Others argue that even if they are not explicitly excluded, the spirit of the Act is against patenting plant biotechnology inventions. One reason for this confusion is that when the Act was drawn up some time in the late 1960s biotechnology had not established itself. In the early 1980s, the Patent Office rejected applications involving plant biotechnology. The Patent Office also used Sec. 27 (rejections without opposition) after the specifications were accepted, but lately many plant biotechnology applications were granted patents. The infamous among these is the Agreetus patent on cottonseed, which was granted as a chemical process patent. Hence, there was a change in the way the Patent Office interpreted the Act.

For food, drug and medicine patents the length of the term is five years from sealing or seven years from the date of application, whichever is shorter. For all others it is 14 years from the date of application.

Compulsory licenses can be granted under some circumstances. Food, drug, medicine and chemical patents come under licenses of right at the end of three years from the date of sealing.

## 2. Mail box and exclusive marketing rights

The countries that have a process patent regime for pharmaceutical and agricultural chemicals as of 1 January 1995 can choose to delay the introduction of product patents for these fields for 10 years. This 10-year transition period for providing pharmaceutical and agricultural chemical product patents comes with a catch. Those countries that choose this transition period for pharmaceutical and agricultural chemical product patents have to provide a means to accept product patent applications for pharmaceuticals and agricultural chemicals from 1 January 1995 (Article 70 (8)) and also provide the so called Exclusive Marketing Rights (EMRs) during this period (Article 70 (9)). The acceptance of applications for product patents and provision of EMRs reduces this transition period to nothing. Thus the developed countries have made this 10-year transition period for pharmaceutical and agricultural chemicals unattractive, hoping that the developing countries will shift to a product patent regime before the TRIPS Agreement comes into force.

The stipulation under Article 65 of the TRIPS Agreement that applications for product patents for pharmaceuticals and agricultural chemicals should have to be accepted from 1 January 1995 and the provision of EMRs for these necessitated an immediate change in the law.

The Government of India chose the 10-year transition period to provide product patents for pharmaceuticals and agricultural chemicals. It had sufficient time (more than a year) to amend its Patents Act by the time the TRIPS Agreement came into force on 1 January 1995. Instead of utilizing this time to evolve a consensus on amending its Act to make it compatible with the TRIPS Agreement, it chose to amend the Act by the Patents (Amendment) Ordinance, 1994 (hereafter the Ordinance) promulgated on 31 December 1994 literally at the eleventh hour, after ratifying the WTO agreement on 30 December 1994.

Under the 10-year transition period for providing product patents for pharmaceuticals and agricultural chemicals the TRIPS Agreement required 2 major changes in the Act one providing a so-called 'mail box' facility for product patent applications for pharmaceutical and agricultural chemicals; and the other the provision of EMRs for pharmaceutical and agricultural chemical products.

The Government has set up an expert group, which was entrusted the task of suggesting specific amendments necessary to the Patents Act to comply with India's obligations. On the basis of the recommendations of this expert group an Ordinance was promulgated. The Ordinance stipulated that applications for product patents for pharmaceutical and agricultural chemical products would be accepted from 1 January 1995 and also laid down the procedure for granting EMRs.

Since 1 January 1995 the Patent Office has been accepting applications for pharmaceutical and agricultural chemical product patents. The Patent (Amendment) Rules, 1994 stipulated that these applications have to be submitted in Form 63, 63A, 63B, 63 AB, 64, 64A, 64B or 64 AB, as applicable. According to reports there were in all about 4,000 applications for product patents for pharmaceutical and agricultural chemicals since 1 January 1995.

Even after the Ordinance lapsed such product patent applications for pharmaceutical and agricultural chemical inventions were still being made, in anticipation that a future law had to be made effective retrospectively in accordance with the TRIPS Agreement.

Apart from this the Ordinance stipulated that EMRs could be given if the following criteria are fulfilled. The patent should have been both sealed and marketing approval obtained in any WTO member country and marketing approval obtained in India (the appropriate authority to do this has not been identified in the Ordinance). If these criteria are fulfilled then the patent applicant can apply for 'exclusive marketing rights'. The application has to be made to the Controller General of Patents, Designs and Trademarks (Form 65 of Patent (Amendment) Rules, 1994). After an application for EMRs is filed the Controller will refer the patent application to an examiner who will see whether it comes under Sec. 3 or 4 (exclusions). If it can not be rejected on the basis of Sec. 3 or 4 the Controller General will issue an EMR. These patent applications will be taken up for examination only after 2005. The Ordinance also made applicable the compulsory licensing provision to the EMRs. India notified the Ordinance to the TRIPS Council on 6 March 1995. A subsequent amendment stipulated how to grant EMRs in the case of an Indian applicant. According to reports about 4 applications were received by the Controller for granting EMRs up to September 2001.

The Patents (Amendment) Bill, 1995 was introduced in the Lok Sabha in March 1995. After a cursory discussion, the Lok Sabha passed the Bill. The Government then introduced it in the Rajya Sabha. As the then ruling party did not have a majority in the Rajya Sabha, the opposition was successful in referring the Bill to a select committee of Members of Parliament (Rajya Sabha) on Patents (Amendment) Bill, 1995.

As the parliament did not pass the Patents (Amendment) Bill, the Ordinance lapsed on 27 March 1995 (6 weeks after the beginning of the parliament session). This meant that the Government of India failed to meet its obligations under the TRIPS Agreement. As the tenth Lok Sabha was dissolved in May 1996, the Bill being discussed in the Select Committee lapsed.

The United States formally notified the dispute settlement body (DSB) of the WTO on 2 July, 1996 of its request for consultations with India. The United States held consultations with India under Article 4 of the WTO Understanding on Rules and Procedures Governing the Settlement of Disputes. Sighting the failure of bilateral consultations the United States requested the establishment of a panel on 7 November 1996. Subsequently the DSB established a panel on 20 November 1996. On 28 April 1997 the European Community notified the DSB of its request for consultations with India on the same issue.

The objections of the United States related to there being no legal basis for accepting product patent applications for pharmaceuticals and agricultural chemicals (Article 70.8 of the TRIPS Agreement) and no provision for the grant of EMRs (Article 70.9 of the TRIPS Agreement).



India's defense rested on the grounds that even if there is no legal arrangement it has issued administrative instructions for 'accepting' product patent applications for pharmaceuticals and agricultural chemicals and that the TRIPS Agreement does not stipulate when EMRs come into force.

The Dispute Settlement Panel in its report on 7 September 1997 came to the conclusion that India had violated the TRIPS agreement by not implementing Articles 70.8 and 70.9. India appealed to the Appellate Body on 15 October 1997. In its report dated 19 December 1997 the Appellate Body upheld the ruling of the Panel on substantive issues.

The Government introduced a substantially similar bill, the Patent (Amendment) Bill, 1998 in the Rajya Sabha on 16 December 1998. The Rajya Sabha passed the Bill on 22 December 1998. The Lok Sabha could not pass it in that session. The Government promulgated the Patents (Amendment) Ordinance, 1999 on 8 January 1999. The Lok Sabha passed the Bill with the amendment that an EMR should not include an article or substance based on the system of Indian medicine on 13 March 1999 and Rajya Sabha agreed with this amendment. It came into effect on 26 March 1999 just in time to meet the deadline of 19 April 1999 stipulated by the Appellate Body of the WTO.

### **3. Major changes needed in the patent law**

The TRIPS Agreement requires fundamental changes in the Indian Patents Act, 1970. The major provisions, which are in conflict with TRIPS obligations, are discussed below.

The Act provides only process patents for chemical inventions (including alloys, optical glass, semiconductors and inter-metallic compounds) and inventions relating to food. This has to be changed to provide product patents by 2005. For these technology fields there is a clear transition period of 10 years, unlike pharmaceutical and agricultural chemical inventions.

There is a controversy regarding whether the Act excludes inventions relating to biotechnology. The TRIPS Agreement requires that biotechnology should be included in patenting, except plants and animals *per se*. Process patenting of biotechnology inventions has to be done by 2000 and product patents by 2005. For those biotechnology product inventions which come under pharmaceuticals or agricultural chemicals 'pipeline protection' has to be provided.

The duration provided by the Act is 14 years. For food, pharmaceutical and agricultural chemical patents it is five years from the date of grant or seven years from the date of application, whichever is shorter. The TRIPS Agreement requires a uniform duration of 20 years from the date of application. In the case of food, pharmaceuticals and agricultural chemicals it will mean an increase of 13 years in the life of a patent. The advantage of shorter duration pharmaceutical and agricultural chemicals was more important in the development of Indian pharmaceutical and agricultural chemical industry than any other provision, including licenses of right.

The compulsory licensing and licenses of right provisions of the Act are very comprehensive. To make the Act TRIPS consistent, licenses of rights have to be completely

removed. The compulsory licensing provision has to be narrowed down considerably, especially those pertaining to use of patent monopoly for import, which could lead to compulsory licensing.

Given the importance of the amendments to make the Patent Act, 1970 compatible with the TRIPS Agreement several initiatives have been undertaken by the Department of Industrial Development, Ministry of Industry. Some of these are: (1) an inter-ministerial committee under the chairmanship of the Secretary, Department of Industrial Development, has periodically examined and reviewed issues relating to the legislative aspects on the obligations arising from the TRIPS Agreement. (2) the Department has also circulated an issue-based paper relating to the changes that may be necessary to the Patents Act, 1970. (3) an expert group under the chairmanship of Dr. Raja Ramanna has periodically reviewed intellectual property issues relating to proposed amendments to the Patents Act, 1970. (4) an inter-ministerial working group comprising representatives of Department of Industrial Development of the Ministry of Industry, Ministry of Commerce, Ministry of Chemicals and Petrochemicals, Department of Legal Affairs and Legislative Department in the Ministry of Law, Justice and Company Affairs, has examined in detail all aspects relating to amendments necessary for consistency with the TRIPS Agreement. The objective of this exercise was to strike a balance between the international obligations and safeguarding of public interest.

It has been decided to go ahead with an amendment to the 1970 Act rather than for a new Act to make the patent law TRIPS consistent.

#### **4. The patent (second amendment) bill, 1999**

The Government introduced The Patent (Second Amendment) Bill, 1999 in the Rajya Sabha on 20 December 1999. The Rajya Sabha passed a motion to refer the Bill to a joint select committee on patents (second amendment) bill, 1999 on 22 December 1999 to examine and report. The Lok Sabha concurred with this motion on 22 December 1999. This joint select committee is examining the bill currently.

The main features of the bill, so as to amend the Patents Act, 1970 and make it compatible with the TRIPS Agreement are discussed below. We will discuss the bill that has been tabled in the Lok Sabha.

This amendment also took into consideration the changes that were required in the law after India became a member of the Patent Cooperation Treaty (PCT).

The rights of the patentee have been extended in two ways: one, importation of the patented product or process has been included among the rights. Thus, besides controlling Acts of using, selling or distributing the patented products or processes, the right holders can exercise leverage over importation of such products into India. The second source of strengthening of the rights of the patentees is the longer time period over which the rights can now be enjoyed. Instead of a five to seven years patent term for process inventions involving drugs and 14 years for all other inventions, an uniform period of 20 years from the date of application would be applicable to all patented inventions.

The rights of the patentee have also been strengthened by diluting the provisions pertaining to working of patents in India. Chapter XVI of Patents Act 1970 contained several provisions, which were aimed at ensuring that manufacture of the patented product took place in India to meet the requirements of working of patents. The Agreement on TRIPS, on the other hand, provides that importation of the product into India can be treated as “working of the patent”. Accordingly, the amendments proposed remove the provisions relating to licenses of right and the requirements to manufacture the product in India.

The second amendment of Patents Act 1970 addresses the need to protect the rich biological resources of the country. The revised Act would require that the patent applications include disclosure of the sources and geographical origin of the biological material in the specification, when used in an invention. The grant of the patent can be opposed if such disclosure is not made or is wrongly stated. The same grounds are also provided for revocation of the patent.

## **5. Industrial designs**

The law in force until May 2001 was the Indian Designs Act, 1911. India joined the Paris Convention, which is the international convention dealing with designs, on 7 December 1998. The technical requirements for granting of design protection were that a design of an article might be registered if the feature of shape, configuration, pattern or ornament given to an article by any industrial process or means is new or original. The period of protection was five years, renewable for a further two 5-year periods. There were no working requirements.

The TRIPS Agreement entailed only one major change in the Designs Act, 1911: that of providing an initial life of 10 years.

Instead of amending the Designs Act, 1911 the Government decided to enact a new Act. Designs Bill, 1999 was introduced in the Rajya Sabha on 13 December 1999. The Rajya Sabha passed it on 20 December 1999. The Lok Sabha passed it with some amendments on 26 April 2000. The Rajya Sabha considered and agreed to the amendments of the Lok Sabha and passed the Bill on 15 May 2000. It received the President's consent on 25 May 2000. It came into effect on 11 May 2001.

The main feature of the new Design Act is to provide an initial term of protection of 10 years followed by another 5 years if renewed in time. The design rights extend to sale and import.

## **6. Trademarks**

The law in force until the Trade Marks Act, 1999 was passed by both houses of the Indian Parliament in December 1999 was the Trade and Merchandise Marks Act, 1958. India joined the Paris Convention, the international treaty on trademarks, on 7 December 1998.

The criteria for registration of a trademark was that the mark should be 'inherently adapted to distinguish or capable of distinguishing'. There were two types of trademarks: registered and common law trademarks (use). The length was indefinite, but was to be renewed every seven year.

There were no specific working requirements, but if a trademark was not used continuously for a seven-year period it might have been de-registered, but as far as foreign marks are concerned use within India has been defined quite broadly in court judgements. There was no provision for compulsory licensing.

On the whole the Trade and Merchandise Marks Act, 1958 did not have much conflict with the TRIPS Agreement. The major problems were not providing protection to service marks and 'well known' marks.

The Government decided to enact fresh legislation instead of amending the 1958 Act. The first attempt at enacting a new law was made in 1993. The Government introduced the Trade Marks Bill, 1993 in the Lok Sabha on 19 April 1993. The Department Related Parliamentary Standing Committee on Industry studied the Bill and submitted its report on 21 April 1994. The Lok Sabha passed the Bill on 1 August 1995. After the Lok Sabha passed it, it went to the Rajya Sabha. The Rajya Sabha did not pass the Bill as the then ruling party did not have a majority there; instead it constituted a Select Committee to go into the Bill. While the Select Committee was studying the Bill, the tenth Lok Sabha was dissolved on 16 May 1996 and with it the Bill lapsed.

The second attempt in 1999 was successful. Trade Marks Bill, 1999 was introduced in the Rajya Sabha on 1 December 1999. The Rajya Sabha passed it on 16 December 1999. The Lok Sabha passed it on 22 December 1999. It received the President's consent on 30 December 1999. The main feature of the Trade Marks Act, 1999 are discussed below.

It provides for protection of service marks. It also provides protection for well-known marks. The initial term of protection has been extended to 10 years from the previous 7 years. It also provides for the creation of an intellectual property appellate board for speedy disposal of appeals against the decisions of the Registrar and development of sound procedures and practices in the law of intellectual property rights. It includes enhanced punishment for violation of trademark rights and makes it a cognizable offence. The penalties prescribed are a fine of between Rs 50,000 Indian rupees and Rs 200,000<sup>2</sup> and an imprisonment of not less than 6 months.

## **7. Copyright and neighbouring rights**

The law in force is the Indian Copyright Act, 1957 (as amended in 1983, 1984, 1992, 1994 and 1999), in effect from 1958. India is a member the Berne Convention for the Protection of Literary and Artistic Works (1886) and the Universal Copyright Convention (1952).

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<sup>2</sup> 'Rs' refers to Indian rupees. In the Indian fiscal year 2000, the average exchange rate for Indian rupees versus a US dollar was 46.75.

Under the Copyright Act, registration is optional. The length of protection for literary works; dramatic works; musical works; artistic works and computer programmes is the life of the author plus 60 years; for photographs; cinematography films; and sound recordings it is 60 years. There are provisions for granting compulsory licenses for translation and reproduction of foreign works for educational purposes, as per the Berne Convention and the Universal Copyright Convention

To begin with the Indian copyright law was largely in conformity with the TRIPS Agreement. Whatever marginal changes (broadcasting reproduction right, performers' rights) were necessary were brought in by the amendment in 1994 and further in 1999 (the term of performers rights were extended from 25 to 50 years).

Broadcasting Reproduction Right is protected under Sec. 37 for 25 years. Performers' rights are protected under section 38. As far as rental rights are concerned in the case of computer programmes (Sec 14 (b)); cinematograph films (Sec 14 (d)) and sound recordings (Sec 14 (e)) the copyright holder has the right to prohibit or authorize the hiring of copies of them. The authors' moral rights are protected under Sec. 57.

Infringement of copyright is a criminal offence. The Act prescribes an imprisonment of between 6 months and 3 years and a fine of between Rs 50,000 and Rs 200,000.

## **7. Plant variety protection**

India did not have a *sui generis* law to protect plant varieties. As part of the TRIPS Agreement it had to enact a plant variety protection law. India is not a member of the International Union for the Protection of Plant Varieties (UPOV).

The process of drawing up a new plant variety protection law in India started in 1993. A draft which was prepared that year underwent many revisions. A Protection of Plant Varieties and Farmers' Rights (PPVRF) Bill, 1999 was introduced in the Lok Sabha on 14 December 1999. The Lok Sabha resolved to put the Bill before a Joint Committee of both houses of parliament for study on 21 December 1999. The Rajya Sabha concurred with this motion on 23 December 1999. A Joint Committee of the Parliament, which studied the Bill, submitted its report on 25 August 2000 and made certain changes in the Bill. The Lok Sabha passed the bill on 9 August 2001 and the Rajya Sabha on 28 August 2001. The Act is before the President for his assent.

The main features of the PPVFR Act, 2001 as passed by both houses of Parliament, will be discussed below. We will discuss breeders' rights, farmers' rights, protection to extant varieties and benefit sharing, which the Act covers.

It seems the Government was very innovative in interpreting the TRIPS mandate on plant variety protection. While it grants breeders' rights, it also protects extant varieties, farmers' varieties, farmers' rights and develops a mechanism for benefit sharing. This might have been possible because the TRIPS Agreement does not spell out the norms and standards of plant variety protection and does not refer to UPOV.

## **9. Breeders' rights**

The Government will specify the coverage of the plant variety protection when the Act comes into force. The criteria for protection are novelty, distinctiveness, uniformity and stability. The breeder has to provide information on the source of genetic material used in developing the variety. The rights of the breeder cover production, selling, marketing, distributing, importing and exporting the protected variety. The duration of protection is 15 years for annual crops and 18 for trees and vines.

Two specific provisions have been introduced for protecting their on-farm activities. The first of these provisions provides that the farmer would be “entitled to save, use, sow, re-sow, exchange share or sell his farm produce including seed of a variety protected” under the legislation “in the same manner as he was entitled before the coming into force” of this legislation (Section 39 (1) (iv)). The PPVFR Act, however, imposes a condition on the farmer: the seeds that the farmers are entitled to sell cannot be branded. Although this requirement may not appear to be too demanding on the farmers, it is the definition of “branded seed” provided in the legislation that could impose restrictions on the farmers intending to sell their farm produce without being affected by the breeders’ rights. “Branded seed”, according to the PPVFR Act, “means any seed put in a package or any other container and labeled” in a manner indicating that the seed is that of a protected variety.

The second provision for protecting the on-farm activities of the farmers relates to the full disclosure of the expected performance of the seeds or planting material of varieties protected under the legislation by the plant breeder. In case the seeds or planting material fail to perform in the manner claimed by the breeder, the farmer may claim compensation from the plant breeder. This provision appears to exceed the limits that the plant variety legislation's normally provide and transgresses into the domain of the Seed Act, which is the relevant legislation for verifying the quality of seeds.

An important feature of the PPVFR Act is the priority attached to public interest over the interests of the commercial breeders. In doing so, the legislation authorizes granting of compulsory licenses to ensure availability of seed or reproductive material of the protected variety in a reasonable quantity at a reasonable price.

The grounds for the grant of compulsory licenses provided for under the legislation are the following:

- (a) Three years have elapsed since the date of issue of a certificate of registration,
- (b) Reasonable requirements of the public for seeds or other propagating material of the variety have not been satisfied,
- (c) The seed or other propagating material of the variety is not available to the public at a reasonable price.

If, after giving an opportunity to the breeder of such a variety to file an opposition and after hearing the parties, the Authority may, on the grounds that reasonable requirements of the public with respect to the variety have not been satisfied or that the variety is not available to the public at a reasonable price, order the breeder to license any one interested in undertaking production, distribution and sale of the seed or other propagating material of the variety in question.

The right has to be renewed at the end of six years in the case of annual crops and nine years in the case of trees and vines. There is a provision for review by the authority at the time of renewal. The exclusions of varieties from plant variety protection is possible for those technologies involving genetic use restriction technology and terminator technology. Interestingly the Act provides for an annual fee on the basis of royalty that the breeder gained.

Essentially-derived varieties are protected and have a separate granting requirements and procedure. An essentially-derived variety (EDV) is defined in the Act as having one of the following characteristics: (i) predominantly derived from an initial variety while retaining the expression of the essential characteristics that results from the genotype or combination of the genotype of such initial variety; (ii) any variety that is not clearly distinguishable from a protected variety; or (iii) conforms to such initial variety in the expression of the essential characteristics that result from the genotype or combination of genotype of such initial variety.

Criminal penalties are provided for infringement of protection, imprisonment of between 3 months and 2 years and/or a fine of between Rs 50,000 and Rs 500,000.

Section 18 of the legislation states that any applicant intending to register for protection of plant variety in India would have to make a series of declarations and also provide information about the origin of the genetic material that the variety uses. The imposition of these conditions on the applicant is significant in the context of the ongoing discussions on plant variety protection, particularly in the developing countries.

An applicant has to make a declaration that (i) the variety for which protection is sought does not contain any gene or gene sequence involving the terminator technology and, (ii) the genetic material or parental material acquired for breeding, evolving or developing the variety has been lawfully acquired.

The applicant would also have to provide the complete passport data of the parental lines from which the variety has been derived along with the geographical location in India from where the genetic material has been taken. In addition, the applicant would also have to provide all such information relating to the contribution, if any, of any farmer, village community, institution or organization in breeding, evolution or developing the variety.

#### **10. Farmers' rights, protection to extant varieties and benefit sharing**

The Act provides for the protection of extant varieties. The exact varieties according to the Act are: (i) varieties that have been notified under the Seeds Act, 1966; (ii) farmer varieties;

and (iii) varieties about which there is common knowledge; or (iv) any other variety that is in public domain. Farmers' varieties, on the other hand, have been defined as (i) varieties that have been traditionally cultivated and evolved by farmers in their fields; and (ii) a wild relative or land race of a variety about which the farmers possess common knowledge. The extant varieties need not show novelty. Other requirements such as passport details need not be furnished. The term of protection is 15 years for annual crops and 18 years for trees and vines in all the cases, except those varieties notified under the Seeds Act, 1966. For those varieties notified under the Seeds Act, 1966, it will be from the date of notification. The ownership of those varieties notified under Seeds Act, 1966 rests with the central government for all Indian varieties and the concerned state Government for state varieties.

This Act of providing protection for extant varieties does not have a parallel in history. It does not fit into the theoretical framework governing IPP. The motive behind granting protection to extant varieties seems to be codification of knowledge.

Chapter VI of the Act, "Farmers' Rights", contains specific provisions that seek to safeguard the interests of farmers and other village and local communities engaged in the Acts of plant breeding. The Act proposes to reward the farmer "who is engaged in the conservation and preservation of genetic resources of land races and wild relatives of economic plants and their improvement through selection and preservation". This provision of the legislation is similar to the concept of "farmers' rights" contained in the International Undertaking on Plant Genetic Resources which is currently under negotiation.

The Act evolves a mechanism for benefit sharing. The requirement of disclosing the passport details of the variety and contribution made by traditional knowledge to the variety are the starting points. Individuals, groups of individuals or communities have to register their interest in the variety. The breeder has to make contributions to the National Gene Fund, which will be used for benefit sharing.

## 11. Layout design

There was no *sui generis* law protecting layout design in India. As part of its commitments under the TRIPS Agreement India had to enact a law to protect layout designs. India has signed the Treaty on Intellectual Property in Respect of Integrated Circuits, 1989 (Washington Treaty) but this treaty has not yet come into force.

The Government introduced a "Semi-conductor Integrated Circuits Layout Design Bill, 1999" in the Rajya Sabha on 20 December 1999. The Rajya Sabha passed it on 15 May 2000. The Lok Sabha passed it with some amendments on 16 August 2000. The Rajya Sabha considered and agreed to the amendments made by the Lok Sabha and passed it on 18 August 2000. The President gave his consent on 4 September 2000. This law has not yet come into effect. This is the only law about which India has informed the TRIPS Council under Article 63.2 of the TRIPS Agreement.



The criterion for the granting of a layout design is that it should be original. The duration of protection is 10 years from the date of registration or from the date of commercial exploitation, whichever is earlier. Willful infringement of a registered layout design is a criminal offence. The Act provides for imprisonment of up to 3 years and/or a fine between Rs 50,000 and Rs 1,000,000.

## 12. Geographical indications

There was no *sui generis* law protecting geographical indications in India. As part of its commitments under the TRIPS Agreement India had to enact a law to protect geographical indications. India joined the Paris Convention on 7 December 1998.

‘Geographical indications’ mean any indication which define the goods as originating in the territory of a country or a region or locality in that territory, provided a given quality reputation or other characteristics of the products is essentially attributable to its geographical origin. An application for registration of a geographical indication can be made by an association of persons or producers or any organization or authority representing the interests of the producers of the concerned goods. The second stage in the process of registration is the registration of users of these geographical indications. A producer of the goods in respect of which a geographical indication has been registered may apply to the Registrar for registering him as an authorized user of such geographical indication. The Registrar will determine whether such person is the producer of the goods. The registration of a geographical indication as well as the registered user of the geographical indication is valid for 10 years and can be renewed indefinitely.

Infringement of geographical indications is an offence punishable by imprisonment of between six months and three years and a fine of between Rs 50,000 and Rs 200,000.

## 13. National security issues

The developing countries did not want TRIPS to be a part of GATT/WTO, but the TRIPS Agreement entailed that they give IPP at a very high level and also introduce many new IPRs. Our own interpretation is that the TRIPS Agreement does not give much leeway for developing countries to counteract the monopoly elements in intellectual property rights. For example, the compulsory licensing provisions in Article 31 of the TRIPS Agreement seems to be usable only in case of emergencies. The cases of Brazil and South Africa, which used these provisions in the case of supply of HIV/AIDS drugs at lower prices. Hence, the developing countries necessarily have to look beyond the intellectual property legislation to deal with the negative impact of the TRIPS Agreement. A discussion pertaining to pharmaceuticals, food security and biodiversity is made below.

Pharmaceuticals We can expect a lot of structural changes in the pharmaceutical industry as a result of the introduction of product patents and longer duration, but with India choosing a 10-year transition period the complete effects will be delayed. In the post-TRIPS scenario the impact will depend on the proportion of patented products in the total

pharmaceutical market. We expect a rise in prices. The impact of the rise in prices will depend on whether they are life-saving drugs or not. The impact on technology transfer in this sector is difficult to predict because while a stronger protection should have a positive impact on technology transfer, India's experience in the pre-1970 period is contrary to this experience.

The Government of India does not seem to take any long-term measure to mitigate the negative impact of stronger protection on pharmaceutical industry. While it would have been necessary to have a price control mechanism given the disparities in income in India, the Government is reducing the number of drugs, which are under price control. The strategy of the Government seems to be to give encouragement for R&D in this sector (GOI, 2000), but encouragement of R&D, laudable in itself, is a long-term goal and does not mitigate the short-term problems. The other factor is that the technological and financial capabilities of Indian firms in this sector are not enough to make any impact on new drug discovery. A re-focusing of the drug discovery programme to cater to the health problems of Indians may be an alternative.

The other major problem area seems to be the lack of any important medical biotechnology industry in India. The industry is not taking any initiatives and the projects of the Government do not seem to achieve its objectives. The introduction of biotechnology patents will hinder in the acquisition of technological capability in this area through imitation.

Food security The important intellectual property rights, which will have an impact on food security, are patents and plant variety protection. While these IPRs may result in positive implications of more production as well as productivity gains, one ought to be ready to face any negative implications. The Government has not yet formulated any plans to face such negative implications.

Biodiversity India is a member of the Convention on Biological Diversity. As part of its commitments under the Convention on Biological Diversity it is in the process of enacting biodiversity legislation. This process started in 1993. Currently a Joint Select Committee of the Indian parliament is studying the Biological Diversity Bill, 2000. The conflict between the Convention on Biological Diversity and the TRIPS Agreement (Article 27(3) (b)) is a contentious issue. A way has to be found to resolve this conflict.

The important components of this legislation are: (1) conservation and preservation of biological diversity, (2) traditional knowledge, and (3) benefit sharing. Benefit sharing in this context is a very difficult concept and one has to see if this will work out.

## **B. Institutional aspects**

### **1. Institutional machinery to grant IPRs**

#### Patents

The administrative authority of the Patents Act 1970 is the Controller General of Patents, Designs and Trademarks. The Patent Office is headquartered in Kolkata with branch offices at Chennai, Mumbai and New Delhi. The Patent Information System (PIS), Nagpur was established

in 1980. It is described as a subordinate office under the Department of Industrial Development, Ministry of Industry, Government of India. Hence, all the policy developments as well as moves to modernize the Patent Office come from the Department of Industrial Development.

The functions of the Patent Office are: (i) supervising the work of the Patents Act, 1970; (ii) rendering advice to the Government on matters relating to patents; and (iii) rendering advice to the Government on different aspects of international treaties on patents.

The revenue of the Patent Office in 1999-2000 was Rs 90 million, while the expenditure was Rs 56 million. Staff salaries and allowances account for 57 per cent of the expenditure. The staff strength of the Patent Office in 1999-2000 was 283. Out of this only 53 (19 per cent) are professional, while the rest are support staff (there are 32 examiners forming only 11 per cent of total employees).

The average actual strength of examiners during 1972-2000 was 30 while the sanctioned strength was 48. Due to grossly inadequate infrastructural facilities and quality and quantity of examiners, the average number of patent applications to be examined per examiner was 280 during 1972-1994 while it climbed to 850 in the period 1994-2000, against a norm of 105 per year. However, the actual number of patent applications examined was only 91 in the period 1972-1994 and declined to 89 in the period 1994-2000. The time taken to grant patents was five years from the date of application, and it can be expected to go up. A modernization plan underway regarding the Patent Office contains the provision of 145 patent examiners. This will considerably improve the situation but the number of patent applications to be examined at the 1999-2000 level will still be 260 per examiner.

The present salary structure is failing to attract good talent. The salary structure and poor promotional avenues are demoralizing the staff. The number of management posts being few, the examiners get stagnant. Only three out of 32 examiners have a doctorate degree. The Officers' Association of the Patent Offices in Delhi and Mumbai made representations to the Central Administrative Tribunal (CAT) in 1988 complaining about the working conditions and pay. These complaints are still pending.

During 1994-2001 the average number of applications was 7,600 per year compared to an average of 3,300 per year during 1972-1994. This figure is expected to go up to 10,000 in the next few years. Hence, there is an urgent need for modernization of the Patent Office.

## **2. Modernization of the patent office**

The Department of Science and Technology, Government of India notification of 1987 declared the Patent Office to be a science and technology institution. The three important benefits of this step are: (i) promotions: the implementation of the Flexible Complementing Scheme (FCS) applicable to research and development personnel. This scheme will entail assessment of a person periodically. If found suitable he/she will be promoted to the next grade, even if there is no vacancy. This also implies carrying one's post, which means there will not be any vacancy below; (ii) use of gradation such as Scientist A, B, C rather than formal designations; and (iii) operational and functional autonomy. The implementation of this has been delayed but reports are that it will be implemented shortly. This is the key for modernization of the Patent Office.

The Government is implementing a project for the modernization of the Patent Office. The three aspects involved are: (i) human resources development (recruitment of qualified personnel, Flexible Complimenting Scheme); (ii) computerization (computer hardware, software development, access to internal and external databases for better search of prior art, development of new procedures and training of examiners in the use of computers); and (iii) infrastructural improvements (for example buildings). Comprehensive computerization according to an information technology strategy plan is underway and dedicated application software is being developed. This effort is being supplemented by the World Intellectual Property Organization (WIPO) through its nationally focused action plan for modernization of India's patent office. Expert missions from WIPO visited India during 2000 and 2001 to guide implementation and ensure that international standards are achieved.

A five-year project under the ninth five-year plan (1997-1998 to 2001-2002) to modernize the Patent Office on these lines is expected to cost Rs 750 million. The central government's budget started allocating funds for the modernization of the Patent Office since 1997-1998. Between 1997-1998 and 2000-2001 a sum of Rs 470 million was allocated out of which Rs 35 was utilized. In the 2001-2002 budget, a sum of Rs 200 million was granted for this purpose. Modernization of Chennai and Delhi offices has been completed and those in Kolkata and Mumbai are in progress.

While the sanctioned strength of patent examiners during the period 1999-2000 was 72 the actual strength was only 32. As part of the modernization of the patent office 145 new posts for examiners has been created. If these new examiners are inducted the proportion of examiners to total employees will increase to 30 per cent.

The modernization process has already been completed at PIS. One of the objectives of PIS is to meet the statutory obligation regarding novelty search under the Act. The PIS was basically a paper-based search facility. After WIPO did a survey of the users of PIS in 1989, the modernization project was started in January 1992 and completed in June 1996. WIPO was the executing agency. United Nations Development Programme (UNDP) provided assistance to the tune of Rs 20 million with a matching grant from the Government. Expert missions from WIPO and European Patent Office (EPO) advised on the restructuring of PIS and officials received training. The basic inputs were computers with appropriate retrieval software, on-line access to external and internal databases and skilled and trained manpower. One of the objectives of the modernization project was to 'provide facilities to the branches of the Patent Office to enable them to improve their working procedures'. Hence, the Patent Offices in Kolkata, Chennai, Mumbai and New Delhi have been linked to the PIS by using the National Informatics Center Network (NICNET). Another initiative under the modernization plan is to set up an Intellectual Property Training Institute at the Patent Information System, Nagpur in the year 2001-2002 to train patent examiners, among others.

### **3. Industrial designs**

The administrative authority is the Controller General of Patents, Designs and Trademarks, Kolkata. Applications are accepted and registration of designs are dealt with only at the Patent Office, Kolkata. A modernization programme for the design office is being implemented. The main objective of this programme is to substitute the paper-based search and examination system with an information technology based system. There were 2,874 design applications in 1999-2000, out of which 2,335 were by Indians. The changes in the Design Act because of the TRIPS Agreement is not expected to result in an increase in the number of design applications.

#### **4. Trademarks**

The administrative authority is the Controller General of Patents, Designs and Trademarks, who is the Registrar of Trademarks for the purposes of the Act. The Head Office is in Mumbai. Branches are at Ahmedabad, Chennai, Kolkata and New Delhi. The Head Office alone deals with examination of applications and registration.

The revenue of the Trademarks Office in 1999-2000 was Rs 34.7 million, while the expenditure was Rs 42.4 million, leaving a deficit of Rs 7.7 million. The present strength of the Trademarks Office is 245. Out of this only 26 (10 per cent) are professional while the rest are support staff.

In the post TRIPS scenario the number of applications are expected to go up, especially in the field of service marks. Indications are that there may be a four-fold increase in the number of applications. While in 1990-1991 the total number of trademark applications was 20,778, they were 66,378 in 1999-2000. An additional expenditure of Rs 3 million has been envisaged for the increased workload because of the new Act.

Owing to manual operations in the processing of applications, there was a delay in registering trademarks, which resulted in huge backlogs. The Government in 1993-1994 initiated a three-year project for modernization of the administration of trademarks. The project aimed at enhancing the capability of the Trademarks Registry by modernizing and streamlining the trade marks registration procedures in the country. This took the form of publication of applications through computerization, speedier registration and renewal of trademarks, networking of head and branch offices. M/s Tata Consultancy Services did the systems planning, designing and installation of the computer system. WIPO consultants assisted them. The networking between the main office and the branches is through NICNET. This project was implemented with financial help from UNDP and technical assistance of WIPO. The project, which ended in April 1996, is estimated to have cost Rs 12 million jointly funded by UNDP and the Government

Another project is being implemented to upgrade and modernize the Trademarks Registry during the ninth plan period (1997-1998 to 2001-2002) to build upon the capacities already built up. An allocation of Rs 86 million has been made. The objective of this modernization includes the elimination of the backlog of pending applications, capability to register a trademark within 18 months from the date of filing, and increased application of information technology in the search, examination and administrative functions of the Registry.

An expenditure of Rs 3.5 million is envisaged for the Appellate Board in its first year of operations.

## **5. Copyright and neighboring rights**

The administrative authority is the Registrar of Copyright, Copyright Office, New Delhi. The Copyright Office is responsible for implementation of the Copyright Act, 1957. It is a part of the Department of Education, Ministry of Human Resources Development, Government of India. It does not have a budget of its own. Sec. 9 (2) of the Copyright Act says, "The Copyright Office shall be under the immediate control of the Registrar of Copyrights who shall Act under the superintendence and direction of the Central Government".

The post-TRIPS scenario is not expected to increase the number of copyright registrations. The acceptance of the TRIPS Agreement is not expected to need any strengthening of the Copyright Office.

There is a Copyright Board to hear appeals against decisions of the Registrar.

## **6. Plant variety protection**

Unlike other intellectual property laws the Act creates a Plant Variety and Farmers' Rights (PVFR) Authority to grant protection of plant varieties. Most of the work of granting protection is done by the Registrar General, but some of the activities like protection to essentially derived varieties and grant of compulsory licenses is done by the Authority. The reason for the Authority seems to be the benefit sharing structure in which the Authority plays a crucial role. A provision of Rs 37.7 million has been made for establishing this Authority.

The Act also creates a tribunal to examine appeals from the PVFR Authority and Registrar General of plant variety. Until such a tribunal is established the Intellectual Property Appellate Board will look after cases.

## **7. Layout design**

The Registrar of Integrated Circuit Layout Design is the authority which registers layout designs. A provision of Rs 22.5 million has been made for this Registry. A Layout Design Appellate Board is proposed to be constituted to appeal against the decisions of the registrar. Until this Board is constituted the Intellectual Property Appellate Board will discharge these duties.

## **8. Geographical indications**

The Controller General of Patents, Designs and Trademarks has been designated as the Registrar of Geographical Indications. A provision of Rs 25 million has been made for the

Registry. In the first year of operation, it is expected that about 1,200 applications for registration of geographical indications will be made.

## **9. Enforcement mechanism**

Enforcement can be broadly divided into internal enforcement and border enforcement. Internal enforcement refers to enforcement of IPRs within the country and border enforcement refers to prevention of goods infringing an IPR into entering a country. Internal enforcement can take the form of civil remedy as well as criminal provisions.

IPRs are private rights. Enforcement of these rights is the responsibility of the private owners. In the case of infringement of IPRs the owner of the right has to approach the District Court for remedy. There is no separate judicial machinery for dealing with IPR matters. Appeals against the decisions of the District Court lie in the High Court and then the Supreme Court. All the new IPR laws, except the Designs Act, create appellate bodies to hear cases against the decision of the granting authority. Appeals against the decision of the appellate bodies lie with the High Court.

Traditionally, copyright and trademark infringement was treated as a criminal offence. But the new laws in the case of plant variety protection, layout designs and geographical indications, contain criminal provisions in the case of infringement of these rights. This is a disturbing trend ostensibly done to act as a deterrent to potential infringers. Only patent and design laws do not have criminal provisions in the case of infringement.

In the case of criminal provision for infringement one has to file a first information report to the police, whose responsibility it will be to prosecute the case.

There is no obligation to strengthen internal enforcement machinery in the TRIPS Agreement (Article 41 (5)). The legal framework for enforcement of IPRs in India at present is consistent with TRIPS.

The following developments may increase the work load of the judiciary: (i) reversal of burden of proof in the infringement of process patents; (ii) strengthened IPRs; and (iii) creation of new IPRs such as plant variety protection, layout designs and geographical indications. In regard to border enforcement, only the copyright and trademark laws have explicit provisions for the prohibition of imports of infringing goods. Under the Copyright Act, 1957 Sec. 53 the Registrar of Copyrights on application is authorized to prevent import of infringing copies with the help of the Customs authorities, but it seems this provision has not been used. The Registrar of Copyrights was never approached to prevent infringement of imports of infringing copies at the border.

Under a notification issued under the Customs Act, 1962 the Chief Customs Officer on application is authorized to prevent import of trademark infringing goods. Under Sec. 140 of the Trade Marks Act, 1999 import of infringing goods is prohibited.

In other IPRs, while designs, geographical indications and layout design do not include imports as part of rights conferred, those of patents, copyright, trademarks and plant variety protection include imports as a right. While design, layout designs, trademarks, patents, plant variety protection and copyright laws recognize unauthorized import as infringement, other IPRs laws do not have such a provision.

There are no explicit provisions for the prevention of exports of infringing copies, but as the production of infringing copies is prohibited we can assume that their export will not happen. However, an explicit prohibition may provide double protection for those infringing copies, which have escaped domestic law enforcement.

The present law is consistent with TRIPS. The post-TRIPS scenario may result in more work for border enforcement, but there seems to be no need for the expansion of the existing customs force. It may need retraining of the customs force to be sensitive to intellectual property enforcement.

### **III. USE OF WTO DISPUTE SETTLEMENT MECHANISM AND SPECIAL PROVISIONS OF TRIPS TO SECURE NATIONAL INTEREST**

#### **A. Use of WTO dispute settlement mechanism**

The structure of TRIPS is that while developed countries wanted it the developing countries were reluctant to have TRIPS under GATT/WTO. Hence most of the cases coming before the WTO Dispute Settlement Mechanism (DSM) will be by developed countries which find that some countries are not fulfilling their obligations.

India has not yet used the DSM to try any TRIPS related issue. In fact, the United States took India to DSM on the issue of non-implementation of the mailbox provision of the TRIPS Agreement and won the dispute.

#### **B. Special provisions of TRIPS to secure national interest**

The special provisions, which can secure national interest in the TRIPS Agreement, relate to Article 7 (Objectives) and Article 8 (Principles). These articles refer to 'socio-economic welfare' and 'socio-economic and technological development'. These articles have been termed as 'good intention clauses' which are difficult to operationalize. This is partly true in the sense that these articles have the qualifying term of 'consistent with the provisions of this agreement'. The provisions of this Agreement give a high level of right without any apparent obligations. The challenge before the developing countries is to look for ways to operationalize these provisions. India has not yet operationalized them in its legislation relating to IPRs.



#### **IV. IMPLICATIONS OF TRIPS, PARTICULARLY FOR INDUSTRIAL AND TECHNOLOGICAL DEVELOPMENT**

The TRIPS Agreement changed the face of the intellectual property regime in the world. Many developing countries, which had weaker IPR systems (for example, patents) had to extensively revise their patent laws, or where there were no IPR regimes (the most important examples being plant variety protection, layout designs and geographical indications) had to put in place new IPR systems. During the Uruguay Round discussions the developing countries argued that stronger IPRs will have adverse effect on the technological development of developing countries. The developed countries on the other hand argued that higher IPR protection would not only result in better technology transfer but also stimulate technological development in developing countries. Essentially these assertions, especially by developed countries, were speculative and not based on any country experiences. In fact, developing countries which started off with stronger patent laws experienced difficulties in technology transfer, for example, India with regard to pharmaceuticals in the period prior to enacting new patent legislation in 1970 (Rao, 2001). As most of the IPR laws are blunt instruments, the impact is not felt immediately it will take some time before these effects are felt.

There are a few studies which tried to estimate the effects of stronger patent protection on developing countries. The most notable of this set of studies is Deardorff, 1992. Deardorff (1992) comes to the conclusion that the welfare of non-inventing countries will fall once they introduce a strong patent system. An important reason for the differences in developed and developing countries is the technology gap. One way of preserving this technology gap is the TRIPS Agreement (Dhar and Rao, 1996).

##### **A. Positive implications**

###### **1. Patents**

Positive implications of stronger patent protection can be a general perception that India follows international standards in patent protection. This may be important in encouraging foreign investors to invest in India.

Positive implications of a stronger patent regime for industry could be more investment by domestic and foreign investors. A patent is not a fine tuned instrument; it is a blunt instrument and it takes a lot of time to work itself out and show results. It is expected that while domestic investment may not respond to a stronger patent regime in a big way in either the short or long term, foreign direct investment (FDI) might. It has to be kept in mind, however, that there are many determinants of FDI and the patent regime might not be that important a determinant (in spite of what the surveys of foreign investors say, in the past, that is, pre-1986, the patent regime was not an important determinant of FDI). The fact is that in a post-TRIPS world when all the countries will have a TRIPS-consistent regime patent, that may not play an important role in determining FDI.

Any positive implications of a stronger patent regime will come only if there is an increase in research and development expenditure by the domestic private corporate sector.

There may be positive implications of a stronger patent regime for technological development if technology transfer occurs. There may be two possible outcomes of a stronger patent regime on technology transfer: one is that it will improve technology transfer and the other is that it may discourage it. The possibility of the latter happening is greater, if we go by the past experience of India and other developing countries. The fact that a stronger patent regime will be in place without any mechanism to ensure technology transfer is the other problem.

The other positive implication of a technological nature is the availability of better products which might not have been available with stronger protection. However, the prices of these better and patented products may be within the reach of only a few.

## **2. Designs**

Designs being a weak instrument of protection, we do not foresee them having any impact.

## **3. Trademarks**

Trademarks have always enjoyed strong protection in India. The adjustments made in the legislation were marginal, hence a TRIPS-consistent regime will not have much additional impact.

It adds to the positive atmosphere to encourage foreign investment.

It may help domestic companies to establish a worldwide brand presence, but the problem in doing this is the size of Indian companies rather than the protection afforded to trademarks.

## **4. Copyright**

India had a progressive copyright law even before the TRIPS Agreement. It was a member of both the Berne Convention and the Universal Copyright Convention. The TRIPS Agreement did not add much to that and Indian law is TRIPS consistent. One of the advantages of copyright conventions is that they took the needs of developing countries into account, which the TRIPS Agreement continued to do. India was one of the first countries to afford copyright protection to software in 1984, hence a TRIPS-consistent regime will not have much additional impact.

Copyright has an impact on the software sector, but copyright protection is not that important for this sector in India because the Indian software sector depends on turnkey projects for foreign software companies in which copyright protection is not important. The

Indian software sector does not have the resources to break into mass consumer-based software products in which copyright protection and trademarks are important.

Strengthening and enforcement of copyright protection in other countries will have a positive impact on those industries in India, which produce copyrighted works. The Indian Diaspora is an important market for film and phonograms in India. These industries will benefit from improved protection and enforcement in those countries, which are good markets for these Indian products.

## **5. Plant variety protection (PVP)**

It adds to the positive atmosphere to encourage foreign investment in the seeds sector. When the Indian seeds sector was opened for foreign private investment, after they came in the foreign firms were asking for PVP.

Domestic private sector investment and foreign investment in the seeds sector may rise.

It may encourage domestic private sector and foreign firms to invest in research and development for the development of better seeds. We do not see any benefits of technology transfer in this sector because agriculture is so region-specific. This is borne out by the fact that in the past developments in the seeds sector in temperate developed countries was not transferable to the tropical developing countries. However a PVP may encourage foreign firms in adapting the technology they already have to the local conditions.

## **6. Layout designs**

We do not expect much impact of a *sui generis* protection for integrated circuits because India is not a major producer of integrated circuits.

## **7. Geographical indications**

As geographical indications are a weak instrument of protection, we do not foresee much impact.

Many of the local geographical indications which are of importance for domestic industry will get protection and may encourage investment in these sectors. Some Indian geographical indications which are of importance in foreign markets, such as, Darjeeling Tea and Basmati Rice, may not get any protection because of their non-inclusion of higher protection to them in the TRIPS Agreement.

### **B. Negative implications**

The opposition of developing countries to the inclusion of IPRs under GATT was based on the premise that a higher level of intellectual property protection will have a negative impact on their economies. In this section we will discuss some of the possible negative impact of TRIPS in developing countries.

## 1. Patents

The most immediate impact of a stronger patent system will be on pharmaceutical prices. Patents are very important in this sector because of the ease of imitation of pharmaceutical products. The Indian experience has been that in the pre-1972 period when the Patents Act, 1911 was in force the prices of pharmaceuticals were high and technology transfer in this sector was low. This prompted the Government of India to enact the Patents Act, 1970, which provided only process patents for pharmaceuticals and more important gave a patent term of only seven years from the date of application. This helped the Indian pharmaceutical industry to develop alternative processes and acquire technological capabilities, so much so that they made a niche for themselves in bulk drug exports (see Rao, 2001, and Dhar and Rao, 2001). The prices of pharmaceuticals were also low. The advent of a product patent regime with a 20-year patent term will have a negative impact both on the prices of pharmaceuticals and the growth of the Indian pharmaceutical industry. Subramanian (1994) and Maskus and Eby-Konan (1994) have estimated the likely change in prices after the introduction of product patents in India. The assumptions of the model relate to the market structure before and after the introduction of product patents and the demand elasticity. Subramanian (1994) estimates the price rise to be a maximum of 67 per cent and a minimum of 5 per cent. Maskus and Eby-Konan (1994) estimate the rise in prices to be in the range of 67 per cent and -7 percent.

The industry most affected will be the pharmaceutical industry in India, followed by the biotechnology industry. The industry is already consolidating in anticipation of the impending product patent regime. Currently the industry is long tailed, with a small number of large firms dominating the industry and a large number of small firms. This market structure is likely to change. The patent regime along with foreign investment policies reduced the dominance of foreign firms in this industry during the late 1970s. This is likely to change and the importance of foreign firms in this industry will grow.

The other industry where one can foresee a negative impact will be the biotechnology industry. Developing countries were looking forward to using biotechnology in both industry, especially the pharmaceutical sector, and the agricultural sector, for rapid industrial development. The development of this industry will see a negative impact from the strengthening of the patent system. The development of this industry needs a weak patent system, which helps them in imitating and developing technological capabilities, but with the advent of a strong patent system this may not be possible. Without imitation the industry in developing countries may not develop.

Technological development in developing countries will see the most negative impact of the strengthening of the patent system. The differences in patent protection across countries are caused by the differences in perception of different countries in the role that the patent system plays in technological development. All countries, even developed countries, started with a low level of patent protection and increased patent protection as their technological capacity grew. There is no country in the world which started with low technological development and achieved technological capability through a strong patent system. The impact of the TRIPS Agreement will be to restrict the manoeuvrability of these countries to have a

weak patent system and gain technological capability. We can expect more technological dependence of developing countries on developed countries.

On the one hand while stronger protection may facilitate technology transfer to occur, it may also result in its not occurring. While the patentee will be in a stronger position to determine whether technology transfer occurs by contractual licenses, the developing countries do not have any mechanisms, such as compulsory licensing, to see to it that technology transfer occurs. Even if any technology transfer occurs the outflow of resources on account of technology transfer will be considerable. The World Bank (2001) estimates that technology-related payments on the implementation of TRIPS for developing countries could be \$20 billion. With the TRIPS Agreement strengthening intellectual property protection it would have been necessary to agree upon something similar to a code of conduct on technology transfer (discussed in United Nations Conference on Trade and Development (UNCTAD) in the 1980s) to reduce the negative impact. Technological growth and technology transfer in the case of the pharmaceutical and biotechnology industry will be the most affected.

## **2. Designs**

Since designs are a weak instrument of protection, we do not foresee any negative impact.

## **3. Trademarks**

In the case of trademarks we can expect the use of foreign trademarks to increase in the post-TRIPS scenario. The development of trademarks in both the domestic and international market will suffer.

## **4. Copyright**

We do not foresee any negative impact of a stronger copyright protection.

## **5. Plant variety protection**

Several negative implications of having the PVP in place have been alluded to in the literature. These arise primarily from the control over the market that large firms can bring to bear in the exercise of their rights. This dimension of introducing PVP is particularly significant for developing countries and their small farmers, who dominate the agricultural scene in these countries. The experience of PVP is in developed countries; none of the developing countries have had any experience with PVP.

Some of the negative implications of PVP are: (1) PVP rights issued have shown extreme concentration in a few crops; (2) productivity gains from PVP seem to be very small; (3) PVP is encouraging mergers and acquisitions leading to concentration in the industry; and (4) the seed prices have gone up; in addition to, price movements another indicator was the increase in farm saved seed) (see Dhar (2001) for a detailed discussion).

Apart from negative implications the question to be asked should be whether developing countries need PVP at all. Some of the features of developing country agriculture are: (1) small farmers; (2) dependence of a large section of the population on agriculture; (3) the high share of agriculture in national income and (4) the research and development system of public agriculture is very active and successful (Rao,1997). In these circumstances, the introduction of plant varieties may not be a very good option.

The green revolution occurred with research inputs from international agricultural research institutions and national agricultural research institutions. Investment in public agricultural research is not driven by intellectual property. The motives of this research were diffusion rather than exclusion, hence farmers benefited from public agricultural research. It is a cause for worry that funds for both the international agricultural research centres and national agricultural research systems is declining and the role of private plant breeders, especially private seed firms, is increasing. Technological developments in the future may therefore come from firms rather than public agencies, which will certainly have an effect on technology diffusion.

## **6. Layout designs**

We do not foresee any negative impact of layout design protection.

## **7. Geographical indications**

If the TRIPS Agreement provides for enhanced protection for geographical indications from India, such as Basmati rice and Darjeeling tea, the export of these products will increase and benefit the country.

## **V. EXPERIENCES LEARNED**

The implementation of the TRIPS Agreements in India was a difficult process and hence took a lot of time and in some cases they came into effect after the deadline had passed. India witnessed public debates on the most important IPRs: patents and plant variety protection. While one school of thought says that the TRIPS Agreement leaves space for developing countries to deal with possible monopoly abuses, the other school of thought interprets the TRIPS Agreement as too rigid, leaving no room for manoeuvrability. The experience of implementing the TRIPS Agreement in India shows that except for plant variety protection, India has not been very innovative in exploiting the options in any of the IPRs covered in the TRIPS Agreement.

The conceptual difficulty with this is that while inclusion of TRIPS in WTO and setting high levels of norms and standards for IPRs are based on the premise that a high level of protection will be beneficial in the form of a high level of innovative output, any measures taken to reduce monopoly abuses is seen first as trade distorting, and second as reducing the incentive to invent.

India has just put in place the legislative and institutional framework in order to fulfil its obligations under the TRIPS Agreement. The reason for these extraordinary changes have not come from within but from outside. The negative or positive implications of these changes will take a lot of time to work themselves out.

Other developing countries of the Asian region can learn a few things from the experience of India in implementing TRIPS Agreement. More than others they can look at the benefit-sharing arrangements as developed in plant variety protection and in the Biological Diversity Bill as useful guidelines.

The Competition Bill, 2001 was introduced in the Lok Sabha on 6 August 2001. The Department Related Parliamentary Standing Committee on Home Affairs is currently studying the Bill, which seems to exclude IPRs from its purview. One of the few opportunities provided by TRIPS is its Article 40, which refers to abuses of IPRs, which affect competition and measures to curb them. India should take opportunity of this Article and provide for resort to the competition law in cases of abuse of IPRs instead of only providing such provisions in its IPR laws. India, as do many other countries, uses IPR laws to curb monopoly abuses; it does not use anti-trust laws for this purpose as does the United States. The TRIPS Agreement seems to sanction the use of anti-trust laws for curbing abuses of the IPR monopoly. India should use both IPR laws and anti-trust legislation for this purpose, rather than rely on just one measure.

## **VI. CONCLUSIONS AND RECOMMENDATIONS**

India may be one of the few countries that had a rather difficult time in implementing TRIPS.

India should provide for abuses of IPRs by having them come under its competition law.

There is a need for developing a common position among developing countries on many issues that concern TRIPS. Some of these are discussed below. Now that TRIPS provides for strong IPP, the need for a code of conduct on technology transfer' is more real and urgent than when it was discussed in UNCTAD in the 1980s. The developing countries should revive negotiations on this issue.

Developing countries should strive for an international agreement on traditional knowledge, origin of genetic material and benefit sharing.

Developing countries such as India have been obliged to strengthen their intellectual property laws and in many cases enact new intellectual property legislation as part of an international agreement. Apart from strengthening their laws, these countries have had to strengthen or put in place new IPR-granting institutions, improve their IPR enforcement mechanism, and strengthen their legal infrastructure. This put additional financial burden on these countries. Whether these changes will be beneficial to them or not will take some time to work out.

## ANNEX

### **Implications of the Doha ministerial declaration on TRIPS**

The Ministerial Conference held at Doha, from 11 to 14 November 2001, considers the Agreement on Trade-related aspects of intellectual property rights (TRIPS) in three parts. The first part of the Minister's decisions appears in the Ministerial Declaration, the second in the Declaration on TRIPS Agreement and Public Health and the third part is contained in the Decision on Implementation-Related Issues and Concerns.

The Ministerial Declaration recognizes at the outset the importance of implementing and interpreting the TRIPS Agreement in a manner that is supportive of public health. Reference is made in this context to the Declaration on TRIPS Agreement and Public Health. This Declaration takes on board most of the concerns of the developing countries in a forthright manner. Several points made in this Declaration merit consideration. In the first instance, the Ministers have emphasized that the Agreement on TRIPS needs to address the grave public health concerns afflicting many developing and least developed countries. While indicating that IPP holds the key to the development of new medicines, the Ministers also expressed concerns about its effect on prices. This consensus on the impact on the prices of medicines resulting from IPP should be considered as one of the major achievements of the developing countries in the Ministerial Conference. Above all, however, the Declaration states that the TRIPS Agreement should not prevent WTO members from taking measures to protect public health. The Ministers have gone on to affirm that the Agreement can and should be interpreted in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all. For addressing their public health related concerns, WTO members have been given the right to have recourse to compulsory licensing, an issue that has been the sticking point between the developed and the developing countries for quite sometime now.

Another key issue that this Declaration considers is the exhaustion of IPRs in keeping with the provisions of the TRIPS Agreement. The Declaration states that each member of WTO is free to establish its own regime for such exhaustion, without challenge, subject to the application of the principles of most favoured nation and national treatment.

Two issues relating to the least developed countries (LDCs) also find mention in the Declaration on Public Health. The first is that the period of implementation of the TRIPS Agreement by LDCs in so far as it relates to patents is, increased by another 10 years, up to 2016. The second is the commitment made by the developed country members to provide incentives to their enterprises and institutions to promote and encourage transfer of technology to LDCs.

The Ministerial Declaration has taken into consideration the ongoing work in the council for TRIPS relating to geographical indications. The Ministers have taken two decisions in this regard. The first is to negotiate on the establishment of a multilateral system of notification and registration of geographical indications for wines and spirits by the fifth session of the Ministerial Conference. The second decision is to direct the council for TRIPS to address the issue of extension of the protection of geographical indications provided for in Article 23 to products other than wines and spirits.



The review of the Agreement on TRIPS under Articles 27.3(b) and 71.1 is another issue with which the Ministers have dealt. This review would examine the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by the members. In this work the objectives and principles of the Agreement would be used as the benchmark.

The Decision on Implementation Related Issues and Concerns deals with the application of non-violation complaints provided for under Articles XXIII.1(b) and XXIII.1(c) of GATT 1994. The Ministers have indicated that WTO members will not initiate any complaints under these Articles until a decision is taken in the fifth ministerial conference.

The clarifications on the measures that the countries can adopt to address public health crises provided by the Ministers of the WTO member countries in Doha, notwithstanding their commitments to the Agreement on TRIPS, should be considered as a major step forward for a country such as India. Ever since the issue of intellectual property protection was included in the Uruguay Round negotiations, the key concern that was expressed in India was the impact of the strengthened patent regime on the prices of medicines. It was pointed out that in a country where the vast majority does not have access to modern medicines, even a small increase in the level of prices would result in the exclusion of those at the margin. The recognition by the Ministers that intellectual property protection can also have an impact on the prices of medicines would be seen by many as sanctioning for the continued use of price controls for essential medicines.

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