

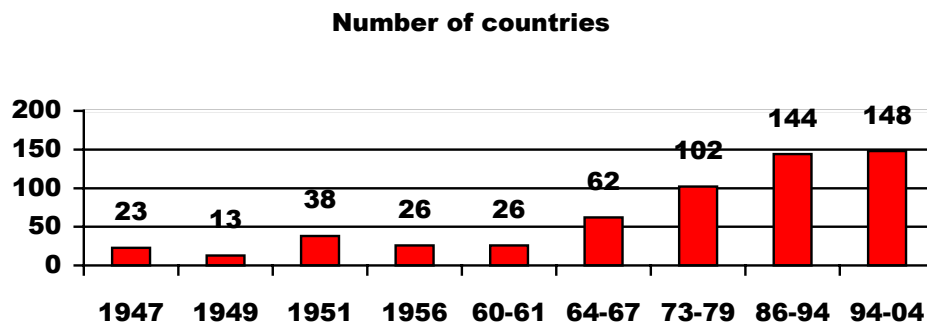
## *Ten years of Intellectual Property Right protection under the WTO*

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### **Background to WTO negotiations**

In the period immediately following World War II, three organizations were set up to monitor international trade and payments. Since these organizations or building blocks emerged as a result of a UN-sponsored conference held in 1944 in a place known as Bretton Woods, the system that emerged was known as the Bretton Woods system. The first two organizations were the International Monetary Fund (IMF) and the International Bank for Reconstruction and Development (IBRD), popularly known as the World Bank. The third organization that was supposed to be set was something known as the International Trade Organization (ITO). ITO was never actually set up. Instead, one had something known as the General Agreement on Tariffs and Trade (GATT). Unlike ITO, had it actually been set up, GATT was only a legal agreement. It was not a proper organization.

GATT's mandate was to liberalize world trade. Barriers to world trade can be of two types - tariffs and non-tariff barriers (NTBs). Tariffs work through prices, that is, they jack up the cost of imports through customs duties. NTBs are not price-based. Examples are import licensing or quotas. They also restrict imports, but not through increasing prices of such imports. As is understandable, unlike tariffs, NTBs are difficult to monitor, police, or even quantify. GATT seeks to address its mandate through a series of negotiations known as multilateral trade negotiations (MTNs). Every once in a while, GATT members come together and decide that a mutually acceptable liberalization package will be implemented. These negotiations are also known as MTN rounds. So far, eight such MTN rounds have taken place - Geneva (1947), Annecy (1949), Torquay (1951), Geneva (1956), Geneva (1960-61, also known as the Dillon Round), Geneva (1964-67, also known as the Kennedy Round), Geneva (1973-79, also known as the Tokyo Round) and Geneva (1984-96, also known as the Uruguay Round).



*Figure 1*

Figure 1 shows the number of countries that participated in these negotiations. At the first round in Geneva in 1947, 23 countries participated and these were founder-members of GATT, India being a founder-member. At the Uruguay Round, the number of participating countries was 123, although the number of WTO (World Trade Organization) members has now gone up to 148. More than 92 percent of world trade now takes place among WTO members. Several countries (such as former socialist countries) are waiting to become members of WTO and the waiting list has more than thirty aspirants. Once these entries take place, perhaps around 98 percent of world trade will take place among WTO members.

Table 1: The GATT Rounds

Year	Place	Name	Negotiations on	Participating countries
1947	Geneva		Tariffs	23
1949	Annecy		Tariffs	13
1951	Torquay		Tariffs	38
1956	Geneva		Tariffs	26
1960-61	Geneva	Dillon Round	Tariffs	26
1964-67	Geneva	Kennedy Round	Tariffs, anti-dumping	62
1973-79	Geneva	Tokyo Round	Tariffs, non-tariff measures, framework agreements	102
1986-94	Geneva, launched in Uruguay	Uruguay Round	Tariffs, non-tariff barriers, agriculture, textiles and garments, natural resource based products, tropical products, GATT articles, Tokyo Round codes, anti-dumping, subsidies, TRIPs, TRIMs, dispute settlement, the GATT system, services	123

When GATT was supposed to liberalize world trade, it was supposed to eliminate both tariffs and NTBs. In fact, GATT has been quite successful in reducing tariffs all around the globe. But because NTBs are much more difficult to pin down, GATT's success in eliminating NTBs has been much more limited. However, once tariffs began to come down, the focus shifted to eliminating NTBs. The Kennedy Round is roughly when this focus shifted and the Tokyo Round had several agreements on NTBs. Perhaps one should also mention that GATT was ostensibly supposed to look at external sector policies. But as international trade and business became much more complicated, it became difficult to differentiate external sector policies from domestic economic policies.<sup>1</sup>

There were three new areas that were discussed for the first time in the course of the Uruguay Round - trade-related investment measures (TRIMs), trade-related intellectual property rights (TRIPs) and services.<sup>2</sup>

*Major Uruguay Round agreements*

- Agreement on Agriculture
- Agreement on Sanitary and Phytosanitary Measures (SPS)
- Agreement on Textiles and Clothing
- Agreement on Technical Barriers to Trade (TBT)
- Agreement on Trade Related Investment Measures (TRIMs)
- Agreement on Article VI of GATT (Anti-Dumping)
- Understanding on the Balance of Payments
- Understanding on the Rules and Procedures Governing the Settlement of Disputes (DSU)
- Agreement on Subsidies and Countervailing Measures
- Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs)
- General Agreement on Trade in Services (GATS)

1 Consequently, GATT increasingly began to discuss domestic economic policies and this trend was also clearly visible in the course of the Uruguay Round. This also made negotiations much more complicated and this was one reason why the Uruguay Round negotiations took eight years to be completed.

2 Strictly speaking, there are of course five new areas, since agriculture and textiles and garments were also exempted from GATT disciplines before the Uruguay Round.

## The Doha Development Agenda (DDA) and subsequent ministerials

The Uruguay Round (1986-94) negotiations led to the inclusion of services and TRIPs in multilateral trade negotiations and also incorporated liberalization of agriculture and textiles and garments within goods agreements. And from 1<sup>st</sup> January 1995, the historical General Agreement on Tariffs and Trade (GATT), which was really a General Agreement on Goods (GATG), was subsumed under the WTO (World Trade Organization). Other than GATG, WTO administers the General Agreement on Trade in Services (GATS) and the TRIPs agreement, the latter through a TRIPs Council. The agreement setting up the WTO requires a Ministerial Conference to be held once every two years.

The first Ministerial Conference was held in Singapore in 1996, which is how the Singapore issues of trade facilitation, transparency in government procurement, competition policy and investment obtain their name. The second Ministerial Conference was held in Geneva in 1998. The third Ministerial Conference in Seattle in 1999 was extremely controversial, because it was expected to announce the launch of a new round of WTO negotiations, known at that time as the Millennium Round. The agenda of the Millennium Round became controversial, with developing countries focusing on market access liberalization and developed countries focusing on newer areas like the Singapore issues. The Seattle Conference failed to launch a new round. And it was left to the fourth Ministerial Conference in Doha in 2001 to launch the DDA (Doha Development Agenda). At that time, it was expected that the DDA would come to a successful conclusion by December 2005, a deadline that is clearly impossible to meet.

The Ministerial Declaration that launched DDA has a section on TRIPs. “We stress the importance we attach to implementation and interpretation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement) in a manner supportive of public health, by promoting both access to existing medicines and research and development into new medicines and, in this connection, are adopting a separate Declaration. With a view to completing the work started in the Council for Trade-Related Aspects of Intellectual Property Rights (Council for TRIPs) on the implementation of Article 23.4, we agree to negotiate the establishment of a multilateral system of notification and registration of geographical indications for wines and spirits by Fifth Session of the Ministerial Conference.

We note that issues related to the extension of the protection of geographical indications provided for in Article 23 to products other than wines and spirits will be addressed in the Council for TRIPs pursuant to paragraph 12 of this Declaration. We instruct the Council for TRIPs, in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPs Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this Declaration, to examine, inter alia, 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 members pursuant to Article 71.1. In undertaking this work, the TRIPs Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPs Agreement and shall take fully into account the development dimension.”<sup>3</sup>

Here is the separate Ministerial Declaration on TRIPs and public health.

“1. We recognise the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics. 2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement) to be part of the wider national and international action to address these problems. 3. We recognise that intellectual property protection is important for the development of new medicines. We also recognise the concerns about its effects on prices.

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<sup>3</sup> There is a reference in this quote to a separate declaration on the TRIPs agreement and public health issues. As was evident from the quotes in Section 5, this had already become an issue by the time the fourth Ministerial Conference was held in Doha in 2001.

4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose. 5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognise that these flexibilities include:

(a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles. (b) Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted. (c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency. (d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4. 6. We recognise that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002." This clarified the provisions on parallel imports (exhaustion) and compulsory licensing and also asked the TRIPS Council to find a solution by December 2002, to the problem confronted by countries that didn't have domestic manufacturing capacities.

The fifth Ministerial Conference was held in Cancun in 2003. By the time the Cancun meeting was held, the deadlock over TRIPs had been resolved. Nevertheless, the Cancun meeting failed because of the impasse over agriculture and the Singapore issues. Subsequently, in July 2004, this deadlock has also been resolved and DDA should move forward. The sixth Ministerial Conference will be held in Hong Kong in December 2005. This doesn't mean the DDA now has a timeframe of December 2006. It is unlikely that the DDA will be completed before 2008.

Here is WTO's view on this aspect of the TRIPs dispute and the August 2003 agreement. "The decision settles the one remaining piece of unfinished business on intellectual property and health that was left over from the WTO Ministerial Conference in Doha in November 2001. The final piece of the jigsaw has fallen into place, allowing poorer countries to make full use of the flexibilities in the WTO's intellectual property rules in order to deal with the diseases that ravage their people.

The decision waives countries' obligations under a provision of the WTO's intellectual property agreement. Article 31(f) of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement says that production under compulsory licensing must be predominantly for the domestic market. This effectively limited the ability of countries that cannot make pharmaceutical products from importing cheaper generics from countries where pharmaceuticals are patented. In the decision, WTO member governments have agreed that the waiver will last until the article is amended. Flexibilities such as "compulsory licensing" are written into the TRIPS Agreement — governments can issue compulsory licenses to allow other companies to make a patented product or use a patented process under licence without the consent of the patent owner, but only under certain conditions aimed at safeguarding the legitimate interests of the patent holder.

But some governments were unsure of how these flexibilities would be interpreted, and how far their right to use them would be respected. The African Group (all the African members of the WTO) was among the members pushing for clarification. A large part of this was settled at

the Doha Ministerial Conference in November 2001. In the main Doha Ministerial Declaration of 14 November 2001, ministers stressed that it is important to implement and interpret the TRIPS Agreement in a way that supports public health — by promoting both access to existing medicines and the creation of new medicines. They therefore adopted a separate declaration on TRIPS and Public Health. They agreed that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health.

They underscored countries' ability to use the flexibilities that are built into the TRIPS Agreement, including compulsory licensing and parallel importing. And they agreed to extend exemptions on pharmaceutical patent protection for least-developed countries until 2016. On one remaining question, they assigned further work to the TRIPS Council — to sort out how to provide extra flexibility, so that countries unable to produce pharmaceuticals domestically can import patented drugs made under compulsory licensing. (This is sometimes called the “Paragraph 6” issue, because it comes under that paragraph in the separate Doha declaration on TRIPS and health.)

One should not of course presume that this solves the public health problem or that it brings developing countries and LDCs closer to the Millennium Development Goals. There are several reasons for this. First, health goals are more a function of preventive health care (sanitation, sewage treatment, clean drinking water, immunization) and these have doubtful efficiency in public sector health care delivery. Second, even in curative health care, drug costs are less than 15% of health care costs. Third, even within drug costs, patented drugs account for less than 10% of drug costs.

## **TRIPs**

Traditionally, IPRs have been divided into two streams. The first stream consists of copyrights and related rights. Copyrights are rights granted to authors of literary and artistic works (like books or other writings, musical compositions, paintings, sculpture, computer programmes or films). There are other rights that are linked to copyrights. These are known as neighbouring rights. Examples are the rights of performers (actors, singers, musicians) or those of broadcasting organizations. Traditionally, the second stream of IPRs is protection granted to industrial property. For instance, distinctive signs that differentiate one particular firm's good or service from that produced by other firms is called trademark.

Alternatively, geographical indications (GIs) can differentiate goods that originate in a geographical area from those that originate in other geographical areas. This kind of IPR protection enables consumers to make informed choices. This kind of protection to the industrial property stream is somewhat more tangible in the sense that a specific object is being granted the protection. A relatively more intangible subset of this industrial property stream is when protection is granted to stimulate innovation. Instances are patents, industrial designs or trade secrets. One must of course remember that protection granted to creators is not without limitations and exceptions. More specifically, the TRIPs agreement covers seven forms of intellectual property – (a) copyrights and related rights; (b) trademarks, including service marks or marks for services; (c) geographical indications; (d) industrial designs; (e) patents; (f) layout designs (topographies) of integrated circuits; and (g) undisclosed information (including trade secrets and test data).<sup>4</sup>

Had there not been a TRIPs agreement, individual countries would have been free to protect IPRs in whatever form they saw fit. The protection, as well as the enforcement, would have varied and there would have been no standardization, not even in the sense of minimum

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<sup>4</sup> Of these, undisclosed information belongs to a slightly different category. Because the other six forms of IPR are about information that is already in the public domain. Unlike that, the property right under undisclosed information is not yet in the public domain.

standards. And in the case of disputes among countries, there wouldn't have been a common forum where these could have been resolved. The idea behind the TRIPs agreement is thus to set minimum standards of protection. These are minimum standards, and individual countries can have higher or stiffer norms, if they so wish. Minimum principles of enforcement are also stipulated. The Uruguay Round agreement entered into force on 1<sup>st</sup> January 1995, which is when the historical GATT was also subsumed under the WTO. But this doesn't mean that the better standards of IPR protection had to be achieved from 1<sup>st</sup> January 1995.

A period of transition is allowed. Hence, the TRIPs agreement also has provisions on transitional arrangements. All disputes go through the WTO's standard dispute resolution mechanism. The entire GATT/WTO system operates on the basis of two building blocks. The first of these is known as national treatment, which simply means that foreign nationals must be treated in exactly the same way that domestic nationals are treated. No discrimination is permissible. The second building block is known as the most-favoured nation (MFN) principle, which means that all WTO members must be treated in exactly the same way. No discrimination between members is permitted. The TRIPs agreement follows these two principles.

### **Why are IPR issues under the WTO**

The WTO (World Trade Organization) is not the only forum for IPR agreements. The World Intellectual Property Organization (WIPO) has been around since 1967, when a convention in Stockholm established it. WIPO became functional in 1970 and has been a specialized agency of the United Nations since 1974. The Paris Convention of 1883 and the Berne Union of 1886 have been mentioned earlier. Both these agreements had their respective secretariats and these were merged in 1893 to form the United International Bureau for the Protection of Intellectual Property (BIRPI, which is the French acronym). BIRPI eventually became WIPO. WIPO, headquartered in Geneva, now administers more than twenty international IPR treaties. Obviously, not every country is signatory to every treaty.

In addition, following the Uruguay Round (1986-94) and the establishment of WTO in January 1995, WTO has an IPR agreement, known as the agreement on trade-related intellectual property rights (TRIPs). When the agenda for the Uruguay Round was being determined in the mid-1980s, there was some resistance to the idea of TRIPs being included. Two main arguments were advanced against such inclusion. First, IPR has nothing to do with trade. At a superficial level, this may seem to be true. But a little reflection will show that this is not the case. If India exports software to the United States, one cannot argue that protection granted to software has nothing to do with trade. If the United States exports pharmaceutical products to India, one cannot argue that protection granted to pharmaceutical products has nothing to do with trade. Trade is driven by investments. So if foreign direct investments (FDI) into India are constrained by lack of IPR protection, one cannot argue that IPR has nothing to do with trade. Besides, the difference between trade issues and non-trade issues is increasingly getting blurred.

The second argument against inclusion of IPR in a trade agenda is slightly different. The WIPO already exists. The WIPO already has agreements on IPR. Why do we then need GATT or the WTO to discuss IPR? Why won't the WIPO do? The WIPO is not good enough for a variety of related reasons. At the last count, the WTO has 148 members. In contrast, very few countries are signatories to various WIPO conventions or treaties. Think of a country that is not a signatory to such a WIPO convention or treaty. That country does not have the law to protect IPR. Or even if it has the law, it does not bother to enforce the law. There is not much that can be done about that country. In contrast, bringing IPR into the WTO fold has several advantages. Not only are more countries members of the WTO, the WTO provides a dispute resolution mechanism and this can be invoked against countries that don't protect IPR. Following a dispute, retaliatory action can be taken against a country that doesn't protect IPR. The WTO's threat system is thus far more credible, which is why IPR was brought into the WTO.

Developing countries have till 2005 for patents. (Many countries only allowed process patents. Product patents will also have to be allowed now.) After WTO's Fourth Ministerial

Meeting in Doha in 2001, LDCs (least developed countries) have till 2016 to implement higher norms. Other than product patents in addition to process patents, the duration of patent protection has to be uniformly twenty years. And compulsory licensing provisions have been tightened up. These provisions are used when a patent is not worked. The government can then instruct that the patent-holder has to compulsorily execute a license in favour of another manufacturer.

TRIPs also has the following additional stipulations. First, national treatment must be observed. The national treatment clause is one of the building blocks of the GATT/WTO system and implies that nationals of other WTO members must be treated in exactly the same way that nationals of the home country are treated. No discrimination is possible. Second, most favoured nation (MFN) treatment must be followed. The MFN clause is another building block of the GATT/WTO system and implies that discrimination among different WTO members is not possible. Each WTO member must be given the treatment that is given to the country that is most favoured. These two guiding principles, national treatment and MFN, must therefore also apply to IPR. Third, norms given in the TRIPs agreement are minimum standards of protection. Countries can have higher standards. Fourth, Articles 7 and 8 of TRIPs need to be mentioned. Article 7 says that TRIPs must ensure technology transfer and among other things, Article 8 says that measures to prevent abuse of IPRs can be introduced.

### **The North and South Perspectives**

In the context of the Uruguay Round, the demand for better intellectual property protection has primarily been a demand articulated by the North, or the developed market economies. The reason for this is simple. Royalty incomes will go up for developed countries, exports will face less competition and grey imports into developed countries will be less likely. Expenditure on detecting and preventing unauthorised use will also go down. Industrial production in the North is now increasingly research and technology intensive and this is also true of many export products. If research and development (R & D) costs are to be recouped, one has to clamp down on piracy.<sup>5</sup>

But the North also makes the case that better intellectual property protection is in the interests of the South, or the developing countries as a group. There are various potential benefits that can be catalogued, not all of which are tangible or easily quantifiable. With better protection, the North may be more motivated to channel R&D expenditure into areas that are of interest to the South.<sup>6</sup> Technology might flow more easily to the South, since the threat of piracy will be less.<sup>7</sup> The price of technology might also come down, since the technology provider no longer charges a markup for misuse. Even within the South, better protection is likely to increase inventive activity and expenditure on R&D. It also follows that the South should be able to benefit from increased royalty inflows as innovative activity is nurtured.

These benefits are however likely to accrue in the long run. In the short run, the concerns of the South are that the costs are more than likely to neutralise the benefits. This is because the South will have to pay increased royalties on technology that was earlier being freely

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5 Perhaps one should mention that technological progress has also made piracy easier and cheap. There are no firm estimates on the extent of piracy. The United States International Trade Commission (1988) study has figures that are often quoted. But the methodology followed in this study is extremely suspect.

6 Thus, R&D does not flow into research on malaria or tropical diseases. See, for example, the arguments advanced by Sherwood (1990).

7 For the pharmaceutical sector, cross-country studies do exhibit a significant positive correlation between foreign direct investment (FDI) inflows and the quality of IPR protection. For other sectors, the results are less robust.

pirated.<sup>8</sup> The costs to the consumer are therefore bound to go up.<sup>9</sup> Stated differently, there is a strand of argument that better intellectual property protection is not per se bad for the South. The improved standards of protection are not being disputed. What is being disputed is the time frame. We are not yet ready for better intellectual property protection.

We do not have a threshold level of technological capability. With inadequate investments in human capital formation, we do not possess the required innovative abilities. Expenditure on research and development is not high enough. And per capita incomes are low. Viewed in this light, the Uruguay Round thrust upon India norms of intellectual property protection that we are not ready for. Hence the opposition to the TRIPs agreement.<sup>10</sup> This should not be interpreted to mean that India has no tradition in the protection of intellectual property. The relevant extant laws are the *Patents Act* (1970), the *Trade and Merchandise Marks Act* (1958), the *Copyright Act* (1957) and the *Designs Act* (1911). The case law in each of these areas is also fairly rich. However, there do not seem to have been any cases on geographical indications, integrated circuits or undisclosed information.

Finally, before one concludes this section, one should mention various international conventions that exist on protecting intellectual property. Most of these are under the auspices of the World Intellectual Property Organisation (WIPO).<sup>11</sup> For example, for patents one has the Paris Convention, the Patent Cooperation Treaty and the Budapest Treaty. For industrial designs, one has the Hague Agreement, the Paris Convention and the Locarno Agreement. For trade marks, one has the Paris Convention, the Madrid Agreement, the Nice Agreement, the Madrid Protocol (not yet in force) and the Trademark Law Treaty (not yet in force). For copyrights and related rights, one has the Berne Convention, the Rome Convention, the Geneva Convention and the Universal Copyright Convention. For geographical indications, one has the Lisbon Agreement and the Madrid Agreement. For integrated circuits, one has the Washington Treaty (not yet in force). And for plant and seed varieties, one has various conventions of the Union for the International Protection of New Plant Varieties (UPOV).<sup>12</sup> Therefore, when it was proposed that intellectual property rights be included in the Uruguay Round of negotiations, several developing countries argued that such issues are better addressed through the WIPO framework.<sup>13</sup>

### **The critical questions on Patents**

There are three kinds of issues in the context of patents. First, there is the question of protecting plant varieties and micro-organisms. Second, there is the question of amending the patent legislation and the resultant impact on the pharmaceutical sector. These changes in legislation have to be incorporated by 1 January 2005. Third, there are transitional arrangements that relate to the period leading up to 2004. We will discuss the second issue in this section and revert to transitional arrangements later.<sup>14</sup>

The TRIPs agreement has an innocuous sounding Article 27 on patentable subject matter and this deserves to be quoted. Article 27.1 states, "Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of

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8 Or if one prefers an euphemism, reverse engineering will no longer be possible.

9 This is in the short run. If increased investments lead to greater competition, there is no a priori reason why costs to the consumer should go up in the long run.

10 However, if this argument is accepted, it becomes impossible to determine what an appropriate threshold is. See, Pujari (1996).

11 See the listing in Commonwealth Secretariat (1996).

12 This is the only one of the conventions that is completely outside the WIPO framework.

13 In the GATT/WTO regime, cross-retaliation across sectors is permitted. Thus, if there are violations in the area of intellectual property rights, action can be taken in the area of services. This would not have been possible under the WIPO framework.

14 This section draws heavily on Debroy (1996).

technology, provided that they are new, involve an inventive step and are capable of industrial application". Thus, three conditions must be satisfied before a patent can be granted. The invention must be new or novel, there must be an inventive step so that the invention is non-obvious, and the invention must be useful in the sense of commercial or industrial application. Provided that these three criteria are met, product and process patents must be available in all fields of technology. It is this clause that requires an amendment to the Indian patent legislation.<sup>15</sup>

In so far as the pharmaceutical sector is concerned, the four major differences between the present Indian legislation and that required by the Uruguay Round agreement are the following:

(1) Coverage - Section 5 of the *Indian Patents Act*, 1970 states, "In the case of inventions - (a) claiming substances intended for use, or capable of being used, as food or as medicine or drug, or (b) relating to substances prepared or produced by chemical processes (including alloys, optical glass, semi-conductors and inter-metallic compounds), no patent shall be granted in respect of claims for the substances themselves, but claims for the methods or processes of manufacture shall be patentable". Thus, as of now, only process patents are available for food, medicines, drugs and chemicals. Once the Uruguay Round agreement comes into force, both product and process patents must be available for all fields of technology.

(2) Duration - Under the existing Indian legislation, when process patents are granted, the duration of the patent is "five years from the date of sealing of the patent, or seven years from the date of the patent, whichever period is shorter". This thus applies to food, medicines and drugs. For every other sector, the present duration of patent protection is fourteen years from the date of obtaining the patent. The Uruguay Round agreement however states that the duration of the patent must uniformly be twenty years.

(3) Working of a patent - A patent is not always worked, it may for instance, not be commercially viable to produce the product at all.<sup>16</sup> In the present Indian legislation, the importation of a product into India is not regarded as equivalent to the working of a patent in India.<sup>17</sup> But Article 27.1 of the Uruguay Round agreement unambiguously states, "Patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced".<sup>18</sup> Therefore, the agreement does not permit any discrimination between an imported product and a domestic product. Importation is tantamount to the working of a patent in India.

(4) Compulsory licensing - The present Indian legislation has several sections on compulsory licensing.<sup>19</sup> This is possible when "the reasonable requirements of the public with respect to the patented invention have not been satisfied" or when "the patented invention is not available to the public at a reasonable price". The Uruguay Round agreement does not rule out compulsory licensing, but the provisions have become much more stringent. It is not going to be that easy to execute compulsory licenses. Nor is there any automaticity about compulsory licensing being possible.<sup>20</sup> These changes in legislation have given rise to various concerns, especially in the context of pharmaceuticals. Broadly speaking, the concerns are the following.

(I) The Indian legislation excludes patent coverage for pharmaceuticals. Once product patents in these areas are granted, indigenous research and development will be adversely affected. This argument tends to suggest that an enormous amount is spent by Indian pharmaceutical companies on R&D. The actual figure is 1-2% of drug sales, as compared to figures of 15% in

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15 The present Indian legislation does not permit product patents in every area.

16 Roughly speaking, not more than 10% of patents are actually worked.

17 The Patents Act states that one must ensure that patents "are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article". See, Section 83.

18 This is in line with the principles of the Paris Convention, which the TRIPs agreement follows.

19 Compulsory licensing is possible after three years after the grant of the patent.

20 It is impossible to be more specific than this without quoting at length from Article 31 of the TRIPs agreement.

Europe and North America and 10% in Japan.<sup>21</sup> Thus, stronger patent protection also tends to encourage R&D, apart from stimulating foreign direct investments into the sector, which also stimulates R&D efforts. The cost of developing a new drug is estimated to be at least 125 million US dollars. Given this kind of figure and given the level of R&D expenditure by most Indian pharmaceutical companies, one cannot help feeling that much of what was being done was plain piracy. Product patents can reverse this trend by encouraging multinational firms and larger Indian groups to invest more in R&D in India. India's advantage of low cost scientific manpower can then translate into the development of new drugs.

(II) Under the present system, domestic pharmaceutical companies can develop new processes for new drugs. New drugs have therefore been introduced in India within three to five years after they arrived on the international market. With the introduction of product patents, these new drugs will not arrive in the Indian market for ten to fifteen years.<sup>22</sup> It is difficult to react to this statement, as it is at best a counterfactual. But it is a fact that foreign companies have been discouraged from marketing their products in India because of fears of piracy. If product patents are introduced, they ought to be encouraged to market their products in India immediately, without even waiting for the four to five years that might be required for the development of alternative processes.<sup>23</sup>

(III) The requirements for ensuring the working of a patent through compulsory licensing have been considerably diluted. It will become virtually impossible to use the provision of compulsory licenses, as the terms and conditions will become too onerous for the exploitation of a sub-licence patent on viable commercial terms. Compulsory licenses can be granted only if efforts have been made to obtain authorization from the right holder on reasonable terms and conditions and such efforts have not been successful. There will be a judicial review of any decision to revoke or forfeit a patent. Since importation is regarded as equivalent to the working of a patent, the failure to import is the only legitimate condition for the issue of a compulsory licence. There is not much to add to this, as it is indeed true that the compulsory licensing provisions will be more difficult to resort to. Discretionary powers vested with the Controller of Patents will henceforth be non-existent.

(IV) There is a transition period of ten years within which the patent legislation has to be changed. But this transition period is misleading as applications for product patents can be filed immediately and exclusive marketing rights have to be granted for a period of five years. We will come back to this point when we discuss transitional arrangements.

(V) The introduction of product patents will confer a monopoly on multinational pharmaceutical companies. The duration of the patent is also simultaneously being increased to twenty years. Consequently, drug prices in India will go up dramatically. Cross-country prices are used to bolster up this argument.<sup>24</sup>

It is indeed true that the system of process patents encouraged a large number of manufacturers to get into the pharmaceutical industry. And it is also true that the resultant competition led to sharp drops in prices, such as for Ibuprofen. Subsumed in these lower costs are also drugs of inferior quality manufactured in garages.<sup>25</sup> Also subsumed in these low costs are expenses saved in not having to spend money on R&D for developing a new drug, including recouping costs of failure and the saving of costs on clinical trials. It is of course indisputable that with the introduction of product patents, drug prices are bound to go up. But there are several

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21 The Japanese example is a good one to use, since Japan did not have product patents for pharmaceuticals before 1976. In 1975, Japanese pharmaceutical companies spent 6% of total sales on R&D. By 1990, the figure had gone up to 10.8%.

22 Keayla (1994) is an example of this kind of argument. With the exception of Rifampicin and Bromhexin, most new drugs have been introduced in India within four years.

23 The price at which these drugs are sold is a separate issue and we will come back to prices later. If a drug is not available in India, its price is technically, infinity.

24 For example, Norfloxacin costs Rs 33.61 in India and the equivalent of Rs 613.77 in the United States, or Ranitidine costs Rs 29.03 in India and the equivalent of Rs 729.93 in the United States.

25 What does one expect with 23,000 manufacturers?

reasons why the fears of an overwhelming price rise are greatly exaggerated. Let us enumerate some of these reasons.

(a) Cross-country comparisons of the prices of any item, be it a drug or some other product, are fraught with problems. Such prices depend on several factors and the absence or presence of product patents is not the only variable that needs to be taken into account. For example, prices of drugs are essentially determined by what the market can bear. The reason drugs are expensive in the United States is because of the existence of a fairly comprehensive medical insurance system. And the reason drugs are cheap in India is because of the Drug Price Control Order (DPCO).<sup>26</sup>

(b) Broadly speaking, there are two categories of drugs - essential drugs and non-essential drugs. If the prices of non-essential drugs go up, that ought not to be cause for much concern. And in so far as essential drugs are concerned, the DPCO keeps these drugs cheap and there is nothing in the Uruguay Round agreement that requires that the DPCO be scrapped.<sup>27</sup>

The Essential Drugs List published by the World Health Organisation (WHO) has a little over 250 entries. Less than 10% of these are covered by patents worldwide. The rest have all become generic and there is no compulsion to grant a fresh round of patent protection to generic drugs. Similarly, if one scans the Indian list of essential drugs, one discovers that less than 10% of them are covered by patents worldwide.<sup>28</sup> Thus, at best, only a few drugs will be affected by the price rise. In the short run, the prices of the others will not be affected at all. In the long run, as patent protection stimulates more R&D and more competition, the prices of all drugs should come down.

(d) There is an impression that granting product patents implies monopolies for twenty years. Even if one accepts this proposition, twenty years is not as long as it sounds. In India, the granting of a patent takes five to seven years from the date of filing the application. Another five to seven years can be added for clinical trials. This leaves six to ten years for a pharmaceutical company to recoup its investments in a new drug. This cannot be regarded as too long as it costs at least 125 million US dollars and around 12 years to develop a new drug. Apart from this, product life cycles have also become shorter and rare indeed is the drug that has a "monopoly" for more than five years.

(e) A product patent does not confer a monopoly on the pharmaceutical company. The pharmaceutical industry has changed a lot since the days of invention of penicillin. Most new drugs are substitutes for existing drugs, with slightly different therapeutic or side effects. Even if a drug is on patent, there will generally be cheaper drugs that are off patent. The question of a monopoly does not therefore arise. Cures for AIDS are often mentioned in this context as possible examples of monopoly. But even in such cases, the granting of product patents encourages competition and leads to substitute drugs being found.

(f) Even if drugs are on patent now, the exclusivity of patent protection does not extend indefinitely. For example, out of the drugs manufactured in India today, almost all are already generic. The price rise will be pertinent not for these drugs, but for the six to eight new drugs that arrive on the international market every year.<sup>29</sup>

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26 This is yet another problem with cross-country comparisons. Countries which have had process patents have simultaneously also had price controls. How does one statistically segregate the importance of these two factors?

27 For completely different reasons, the DPCO became unrealistic and eroded the profitability of pharmaceutical companies. Pharmaceutical companies therefore moved away from producing essential drugs to non-essential drugs and moved away from drugs altogether into other areas. It is because of this that the DPCO was revamped in January 1995 and the number of drugs under price control brought down from 142 to 76. One might argue that there is scope for even further price decontrol, since with a large number of companies and fragmentation of production; competition will ensure that prices do not rise by much.

28 The 10% figure is of course in terms of the number of drugs on the list. There are no reliable figures on sales of drugs on patents as a percentage of total sales of essential drugs. Some fragmentary information suggests that for certain categories, the share could be as high as 45 percent. But this is not an across the board share.

29 If the patent legislation is not changed, these new drugs may not even be marketed in India, except illegally, because of fears of piracy.

## Another sensitive issue - Plant and Seed Varieties

The Uruguay Round agreement has a rather innocuous sounding Article 27 on patentable subject matter. "Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application". This is Article 27.1. Under Articles 27.2 and 27.3, exclusions are permitted. 27.3 is especially relevant. To quote, "Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof."

Both these clauses, particularly (b), have contributed to the controversy. (a) requires that micro-organisms, non-biological and microbiological processes must be patented. The present Indian law does not allow for the patenting of life forms. It is difficult to define micro-organisms precisely. But quite obviously, it not only covers bacteria, but also biological matter like genes, gene sequences, cell lines, cell cultures and viruses (b) requires that plant varieties must be protected through patents or through a *sui generis* system. But the protection must be effective and the protection and the provisions will be reviewed in 1999.

## Copyrights and related rights

Copyright protection extends to literary, scientific and artistic works. To quote from the TRIPs agreement, "Copyright protection shall extend to expressions and not to ideas, procedures, and methods of operation or mathematical concepts as such."<sup>30</sup> Owners of copyrights in protected works have the right to exclude others from using the work without their authorisation. These rights are known as exclusive rights. Among exclusive rights that require authorisation from the copyright holder are the following : (a) reproduction rights - copying and reproducing the work; (b) performing rights - performing the work in public; (c) recording rights - making a sound recording of the work; (d) motion picture rights; (e) broadcasting rights; and (f) translation and adaptation rights. These rights are known as economic rights or market rights.

If one goes back and reads the section on copyrights and related rights in the TRIPs agreement, one discovers that countries have to comply with the provisions of the Berne Convention (1971).<sup>31</sup> However, countries are exempted from following Article 6b is of the Berne Convention. This article concerns non-economic, non-market or moral rights and protects authors, even after they have transferred economic rights, against distortions and acts that are prejudicial to their honour or reputation. Authors can also continue to claim authorship of their work, even after economic rights have been transferred.<sup>32</sup> The Indian copyright legislation did not protect such non-economic rights before 1994. But the *Copyright Act* was amended in December

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<sup>30</sup> Article 9.2. Section 13(1) of the Indian Copyright Act states that copyright protection shall exist for original literary, dramatic, musical and artistic works, cinematographic films and records. Although not explicitly articulated in the statute, the Indian case law makes it clear that originality does not mean that the work in question must necessarily have new ideas. It can also involve a new way of presentation. Moreover, what is protected by the legislation is the form in which ideas are expressed, not the idea itself.

<sup>31</sup> As was mentioned earlier, India is a signatory to the Berne Convention.

<sup>32</sup> It is appropriate to quote Article 6bis and this is the following. "Independently of the author's economic rights, and even after the transfer of the said rights, the author shall have the right to claim authorship of the work and to object to any distortion, mutilation or other modification of, or other derogatory action in relation to, the said work, which would be prejudicial to his honour or reputation. The rights granted to the author in accordance with the preceding paragraph shall, after his death, be maintained, at least until the expiry of the economic rights, and shall be exercisable by the persons or institutions authorised by the legislation of the country where protection is claimed."

1994 and such moral rights are protected.<sup>33</sup> Software is also protected in India through copyright legislation, but before 1994, the Indian legislation was not very clear as to whether the object code, as opposed to the source code, should be accorded protection. International case law was also not unambiguous on this. The TRIPs agreement leaves no scope for ambiguity.<sup>34</sup> And in line with this requirement, the Indian legislation was amended in 1994 so as to ensure that both the source code and the object code are protected.<sup>35</sup>

We have not said anything about the term of protection yet. The TRIPs agreement requires that for copyrighted works other than cinematographic or photographic works, the duration of protection should be fifty years from the date of authorised publication or life of the author plus fifty years. For cinematographic works, the duration of fifty years will be reckoned from after the work has been made available to the public. If the work has not been made available to the public, the fifty years will start from the date of making of the work. For photographic works, the duration of protection should be twenty-five years from the date of making of the work. The duration of protection in India is longer than this. For literary, dramatic, musical or artistic works (other than photographs) published during the life of the author, copyright exists for the life time of the author plus sixty years after his death.<sup>36</sup> The duration of protection for cinematographic films and photographs is also sixty years.

Literary and artistic works are not only disseminated by authors, but also through intermediaries like performing artists, producers of phonograms and broadcasting organisations. Any discussion of copyrights is thus invariably linked with these rights, also referred to as neighbouring rights. The TRIPs agreement states, “The term of protection .... To performers and producers of phonograms shall last until the end of a period of 50 years computed from the end of the calendar year in which the fixation was made or the performance took place. The term of protection granted... shall last for at least 20 years from the end of the calendar year in which the broadcast took place.”<sup>37</sup>

As the above discussion indicates, particularly after the amendments to the Copyright Act in 1994, India has no special problem with the copyright provisions of the TRIPs agreement. In several cases, the Indian legislation is more stringent than what is required under the Uruguay Round. These provisions also imply better copyright protection in all member countries of the WTO. Since India is a major exporter of software, it should be in India’s interests to have such better protection across the globe.

Just as India has no great problem with the copyright segments of the Uruguay Round agreement, there is no great problem with trademarks either. The TRIPs agreement stipulates that trademarks should be registered for a period of not less than seven years and seven years is also what the Indian Trade and Merchandise Marks Act stipulates. Only three simple points need to be made in this section on trademarks. First, the Uruguay Round agreement requires that service marks be allowed.<sup>38</sup> Before 1993, service marks could not be registered in India. For some time, it has been proposed that the Trade and Merchandise Marks Act be amended so as to allow for the registration of service marks and a Bill prepared in 1993 reflected this. That apart, service marks have been protected through actions for passing off.<sup>39</sup>

Second, the agreement rules out insistence on hybrid marks as preconditions for registration. Article 20 of the TRIPs agreement states, “The use of a trademark in the course of trade shall not be unjustifiably encumbered by special requirements, such as use with another

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33 Section 57 was amended.

34 Article 10.

35 Section 2(ffc) was inserted into the Copyright Act.

36 This used to be fifty years, but was increased to sixty years through an amendment in 1992.

37 Article 14. This article is essentially modelled on the Rome Convention of 1961.

38 Article 15 of the TRIPs agreement.

39 See the cases discussed in Mittal (1994). Passing off means the passing off of one’s goods or services as those belonging to another.

trademark, use in a special form or use in a manner detrimental to its capability to distinguish the goods or services of one undertaking from those of undertakings.” This means that one can no longer insist on indigenisation through Lehar-Pepsi and Maruti-Suzuki. However, following economic reforms, this insistence on hybrid trademarks has been given up in India since 1993.

Third, if a trademark is not used, both the Indian legislation and the TRIPs agreement provide for cancellation of registration. To quote from the TRIPs agreement, “If use is required to maintain registration, the registration may be cancelled only after an uninterrupted period of at least three years of non-use, unless valid reasons based on the existence of obstacles to such use are shown by the trademark owner. Circumstances arising independently of the will or the owner of the trademark which constitute an obstacle to the use of the trademark, such as import restrictions on or other government requirements for goods or services protected by the trademark, shall be recognized as valid reasons for non-use.”<sup>40</sup> The point to note is that Indian courts have also taken the view that import restrictions justify the non-use of a trademark in India. The case law shows that prohibitive tariffs have also been considered adequate for the non-use of a trademark.<sup>41</sup>

There is not much to add on designs either. Industrial designs are ornamental features of products and include shapes, lines, motifs and colours. Not every country in the world currently protects industrial designs.<sup>42</sup> By and large, industrial designs are protected in consumer goods sectors like textiles, leather products and automobiles. The TRIPs agreement requires industrial designs that are new or original to be protected.<sup>43</sup> “Members shall provide for the protection of independently created industrial designs that are new or original.”<sup>44</sup> The duration of protection has to be at least ten years.

The *Indian Designs Act*, 1911 provides for protection of industrial designs. Section 47 of this statute states, “When a design is registered, the registered proprietor of the design shall, subject to the provisions of this Act, have copyright in the design during five years from the date of registration. If before the expiration of the said five years application for the extension of the period of copyright is made to the Controller in the prescribed manner, the Controller shall, on payment of the prescribed fee, extend the period of copyright for a second period of five years from the expiration of the original period of five years.” There is thus a minor matter of extending the duration of protection.

### **Geographical indications, integrated circuits and undisclosed information**

So far as norms for protection in individual areas are concerned, this still leaves for consideration geographical indications, integrated circuits and undisclosed information. The first point to note is that there are no specific statutes on protecting these in India.<sup>45</sup> Nor, according to the TRIPs agreement, are such specific statutes necessary.<sup>46</sup> But there is a case for introducing such specific statutes unilaterally.

According to the TRIPs agreement, geographical indications must be protected and some additional and special protection is accorded to wines and spirits.<sup>47</sup> No new and specific statute is

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40 Article 19.1

41 Mittal (1994).

42 See Commonwealth Secretariat (1996).

43 There was some debate during the negotiations about whether the stipulation should be “new and original” or “new or original”.

44 Article 25.1.

45 However, the Ministry of Commerce is in the process of drafting a Bill on protecting geographical indications and another one on protecting integrated circuits. Undisclosed information seems to have been ignored.

46 There might be such requirements in the next round of WTO negotiations, but that is a different matter.

47 Article 23 of the TRIPs agreement. Incidentally, under Article 24.4, if misleading geographical indications have been used for at least ten years before the Uruguay Round agreement came into

required. All that is required is “the legal means” for redressal and this is provided for in India through the Trade and Merchandise Marks Act. The case law also reflects this. For example, in *Mohan Meakin Breweries versus Scotch Whisky Association* (1979), the Delhi High Court affirmed the order of the Registrar of Trademarks by which the Registrar refused to register the words “Highland” and “Highland Chief”. In *Scotch Whisky Association versus Pravara Sahakar Shakar Karkhana* (1992), the Scotch Whisky Association succeeded in restraining the defendants from using a Scottish drummer wearing a kilt or tartan band, or the words “blended with Scotch”. In *Scotch Whisky Association versus Mohan Meakin* (1986), the court restrained Mohan Meakin from using the word “Royal Scot”.

For layout designs of integrated circuits, the requirement is that these be protected in accordance with the Washington Treaty.<sup>48</sup> But no special legislation is required to protect these, although if a country has a specific piece of legislation, that is naturally acceptable. All that is required is that there should be some form of protection and the duration of the protection should be at least ten years.<sup>49</sup> As in the Washington Treaty, to which India is signatory, if special legislation is not enacted, layout designs can be protected through laws on copyright, patents, utility models or industrial designs. In other words, the necessary protection exists in India through these other mechanisms.

Similarly, the TRIPs agreement does not require the enactment of specific legislation on undisclosed information (trade secrets). To qualify for protection, the information must be secret, it must have commercial value and reasonable steps must have been taken to keep the information secret. In fact, there is no explicit requirement that undisclosed information be treated as a form of property. However, such information cannot be disclosed to, acquired by or used by those who have no access to it, without legitimate authorization.<sup>50</sup> The case law on undisclosed information is not very well developed in India. Under criminal law, there are provisions relating to criminal breach of trust, cheating, burglary and extortion, all of which can be relevant when confidential information is misused. Civil law remedies are available through Section 27 of the Indian Contract Act or Section 54 of the Indian Partnership Act. Although the requirements of the TRIPs agreement are satisfied at the moment, one will presumably eventually move towards a statute to protect undisclosed information.

### **Enforcement**

Enforcement of intellectual property rights’ violations has never been particularly strong in India, although it does seem to have improved somewhat in recent years.<sup>51</sup> To the extent that the TRIPs agreement requires better compliance, there is nothing to complain about. Two specific articles in the enforcement section need to be highlighted.

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effect, or used “in good faith” before the Uruguay Round agreement came into effect, they will not be prohibited.

48 This treaty was negotiated in 1989.

49 Ten years from the date of registration, or ten years from the date of first exploitation, when registration is not required. Article 38 of the TRIPs agreement.

50 There is also an additional clause on undisclosed test data and other data whose submission is required by governments “as a condition of approving the marketing of pharmaceutical or of agricultural chemical products”. Member governments must protect such data against unfair commercial use. Article 39 of the TRIPs agreement. Consumer organisations have argued that since they need to independently verify test data on new chemical based products; this puts them at a disadvantage. See, Evans (1996).

51 Enforcement does not improve if the intellectual property rights issue is perceived to be an issue that is thrust down India’s throat as a result of external pressure. It improves when internal pressures for better compliance are generated and this has begun to happen in the case of software and copyrights. In addition, an amendment to the Copyright Act in 1994 removed discretionary powers of courts in terms of deciding on penalties for commercial piracy. That is, the court had the discretion to award a penalty that was outside the stipulated (maximum and minimum) range and this discretion has now been removed. For “non-commercial” piracy, the discretionary power continues.

There are no obligations “to put in place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general”. Nor are there any obligations “with respect to the distribution of resources as between enforcement of intellectual property rights and the enforcement of law in general”.<sup>52</sup> One does not, therefore, have to set up fast-track intellectual property rights tribunals. Had that been the case, one might have violated Article 14 of the Indian Constitution on equality before the law.<sup>53</sup>

In addition, “Members shall provide for criminal procedures and penalties to be applied at least in cases of willful trademark counterfeiting or copyright piracy on a commercial scale.”<sup>54</sup> Intellectual property is usually associated with civil law. But the mention of criminal procedures and penalties in the Uruguay Round agreement does not cause any problems, because the necessary legislation does exist in India.<sup>55</sup> For example, in the Copyright Act, there are provisions to treat all forms of infringement of copyright as offences. The police also have powers to take action. Any person who knowingly infringes or abets the infringement of copyright is treated as an offender and is punishable with a minimum of six months’ imprisonment which may extend to three years, and a fine of between fifty thousand and two lakh rupees.<sup>56</sup> It is a fact that the case law in India does not reveal extended use of penal and criminal law provisions in cases of copyright violations. But the point is that the Uruguay Round provisions do not constitute a legislative problem. The quote from the TRIPs agreement refers to criminal procedures and penalties for copyright piracy and trademark counterfeiting. As in the case of copyrights, the *Trade and Merchandise Marks Act* incorporates penal provisions and there are no substantive legal problems here either.<sup>57</sup> The TRIPs agreement specifically refers to criminal provisions for copyrights and trademarks. At a philosophical level, such principles also ought to extend to other forms of intellectual property protection. But as of now, Indian law has no explicit criminal law provisions for other forms of intellectual property.

### **Transitional Arrangements**

As has been indicated earlier, the changes in the law protecting intellectual property do not have to be brought about overnight. There is a period of transition.<sup>58</sup> For example, all countries have a general exemption of one year from the date of entry into force of the WTO agreement, that is, January 1995. In addition, developing countries have a further period of four years. To extent that product patents do not exist now, but will have to be introduced, there is a further leeway of five years. That is the reason why India has till 1 January 2005 to change the patent legislation.<sup>59</sup>

But although one can wait till the year 2005 to change the patent legislation, there are two changes that have immediate effect. The first concerns the burden of proof, which is relevant when one has process patents. The idea is best illustrated by an extended quote from Article 34 of the TRIPs agreement. It needs however to be clarified that this is only for civil proceedings.

“If the subject matter of a patent is process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process. Therefore, members shall provide, in at least one of the following circumstances, that any identical product when produced without the consent of the patent owner shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process: (a) if the product obtained by the patented process is new; (b) if there is a

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52 Article 41.5.

53 There are an estimated 25 million cases pending in Indian courts and an “average” dispute takes twenty years to be resolved. Since fast track intellectual property rights tribunals are precluded, this also means that such disputes will take a long time to be resolved.

54 Article 61 of the TRIPs agreement.

55 See Gopalakrishnan (1994).

56 Sections 63 and 64.

57 Section 78. If a written complaint is made by the Registrar, a court can take cognizance of an offence. But barring this, offences are non-cognizable and police officers cannot arrest or search and seize goods without warrants.

58 The details are set out in Article 65 of the TRIPs agreement.

59 Least developed countries have a time frame that is even more extended.

substantial likelihood that the identical product was made by the process and the owner of the patent has been unable through reasonable efforts to determine the process actually used. Any member shall be free to provide that the burden of proof indicated in paragraph 1 shall be on the alleged infringer only if the condition referred to in subparagraph (a) is fulfilled or only if the condition referred to in subparagraph (b) is fulfilled.”

Clause (b) is reasonably clear. When a plaintiff holding a patent feels that the patent is being infringed and “reasonable” efforts have unsuccessfully been made to determine the process used by the alleged infringer, the burden of proof will be placed on the defendant. This does not sound unreasonable, since the alleged infringer has claimed that the product is being made by an alternative process and the complainant does not have access to the alleged infringer’s factories or laboratories. While clause (b) is clear enough, clause (a) seems to be confusing. It suggests that even when a new product is produced, the burden of proof will be on the defendant to prove that an alternative process has been used. This does not seem to be very logical. The rationale for (b) is presumably biotechnological processes, where a particular form of gene splicing can theoretically lead to more than one product. However, as was mentioned earlier, a country needs to provide either (a) or (b), and not necessarily both.

There is an impression that the reversal of burden of proof and placing it on the defendant is a violation of existing Indian legal principles. This is not quite true. Take for example, Section 78 of the Trade and Merchandise Marks Act. This states, “Any person who .... makes, disposes of, or has in his possession, any die, bloc, machine, plate or other instrument for the purpose of falsifying, or being used for falsifying, a trade mark..... shall, unless he proves that he acted without intent to defraud, be punishable”.

Apart from burden of proof, in the period leading up to 2005, there is another change that must be introduced. Under Articles 70.8 and 70.9 of the TRIPs agreement, from 1 January 1995, one must begin to accept applications for product patents. These go into a black box and the box is opened up in 2005 to establish right of priority before granting patents. Meanwhile, for each such patent application that has been accepted, exclusive marketing rights (EMRs) have to be granted for a period of five years, subject to three conditions - (1) there must be a valid patent for the product in a WTO member country; (II) marketing approval must have been obtained in a WTO member country; and (III) marketing approval must have been obtained in India.<sup>60</sup> Stated differently, EMRs are like patents granted through the back door, without checks that the normal scrutiny of a patent application would have required. They are granted in lieu of a patent, because although the patent application has not led to the grant of a patent, it has not led to a rejection either.

Stated more accurately, the clauses of exclusive marketing right and acceptance of product patent applications are relevant until the legislation is changed to accommodate product patents, which in the Indian case, may very well be 2005. Thus, had India decided to change the patent legislation in December 1994, without waiting till 1 January 2005, EMRs need not have been granted. Several people have argued that this would have been better than the mess EMRs have led to. Although the transition from process to product patents needs to take place by 1 January 2005, product patent applications must be accepted and exclusive marketing rights granted from 1 January 1995.

### **Disputes at WTO on TRIPs**

There are bound to be disputes at WTO, including those on TRIPs, and these go through WTO’s standard dispute resolution mechanism. No agreement can be so worded as to avoid all disputes and sometimes, there may also be deliberate violation. Incidentally, WTO’s dispute redressal mechanism is far more effective than GATT’s ever was. Here is a list of TRIPs cases that have figured in WTO disputes.

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<sup>60</sup> The government retains the right to intervene if exclusive marketing rights are used against the public interest or in circumstances of extreme emergency. Compulsory licensing provisions also exist despite EMRs.

1. Argentina, patents, test data, compulsory licensing, safeguards, etc  
— Brought by US
2. Argentina, pharmaceutical patents, transition period  
— Brought by US
3. Brazil, “local working” of patents and compulsory licensing  
— Brought by US
4. Canada, pharmaceutical patents  
— Brought by EC
5. Canada, term of patent protection  
— Brought by US
6. Denmark, enforcement, provisional measures, civil proceedings  
— Brought by US
7. EC, patents for pharmaceuticals, agricultural products  
— Brought by Canada
8. EC, trademarks and geographical indications (agricultural products)  
— Brought by Australia
9. EC, trademarks and geographical indications (beer, potatoes, oranges)  
— Brought by US
10. EC/Greece, motion pictures, TV, enforcement  
— Brought by US
11. EC/Ireland, copyright and neighbouring rights  
— Brought by US
12. India, patents, “mailbox”, exclusive marketing  
— Brought by EC
13. India, patents, “mailbox”, exclusive marketing  
— Brought by US
14. Ireland, copyright and neighbouring rights  
— Brought by US
15. Japan, sound recordings intellectual property protection  
— Brought by EC
16. Japan, sound recordings intellectual property protection — Brought by US
17. Pakistan, patents, “mailbox”, exclusive marketing  
— Brought by US
18. Portugal, term of patent protection  
— Brought by US
19. Sweden, enforcement, provisional measures, civil proceedings  
— Brought by US
20. US, discrimination in Patents Code  
— Brought by Brazil
21. US, Section 110(5) — copyright of music in bars  
— Brought by EC
22. US, Section 211 Omnibus Appropriations Act (Rum)  
— Brought by EC
23. US, Section 337 of 1930 Tariff Act  
— Brought by EC
24. Denmark, provisional measures, civil proceedings  
— Brought by US
25. EC/Greece, motion pictures, TV  
— Brought by US
26. Sweden, provisional measures, civil proceedings  
— Brought by US

Understandably, most cases involve developed countries as both defendant and complainant, though this is true of TRIPs and not WTO disputes in general. However, developing countries have often been defendants and in one case, a developing country (Brazil) was also the complainant and the defendant was the United States. India features as defendant in two cases, one brought by

the United States and the second by the EC. The issue was identical in both cases. India was allowed a transition period till 1 January 2005 (Article 70 of TRIPs) to introduce product patents in food, chemicals and drugs. In these sectors, the *Indian Patents Act* of 1970 only allowed process patents. However, during the transition period, India should have received applications for product patents (the mail box or the black box) and granted exclusive marketing rights (EMRs), after scrutiny, for a period of 5 years. This was originally done through an ordinance, which subsequently lapsed and the *Indian Patents Act* couldn't be amended. India argued that EMRs were still being granted executively, even though legislation hadn't been amended. The United States and EC took this dispute to the WTO and India lost the disputes. Once a dispute is lost, changes in legislation or policy have to follow. Otherwise, there can be retaliation.

### **Copyright Vs Patents for Software**

Recent trends in biotechnology and information technology have brought to the forefront a set of issues in the law and economics of intellectual property. These issues have to do with the problem of rewarding multiple inventors in a setting with cumulative innovation.<sup>61</sup> That is, is it possible to provide optimal incentives for innovation simultaneously to the producer of a first generation product and a second-generation product that builds on it? The answer in general is no.<sup>62</sup> The first invention creates an externality for the second inventor and therefore may be worth developing even if the expected cost exceeds its value as a stand-alone product. However, broad patent rights for the first inventor to ensure innovation do not leave enough profit for the second inventor. One solution to this problem is “*internalizing the externality*” via licensing.

Where the first invention is the pure outcome of scientific research, that is, where the value is only the information, it cannot be sold without revealing it, which makes a sale moot, unless strong IP protection or legally enforceable non-disclosure agreements (NDAs) are in place.<sup>63</sup> As discussed earlier, a characteristic of information goods such as software that differentiates them from industrial R&D products is that once the invention exists very little complementary investment is necessary to make it useful, so that without some form of IP protection, conventional economic incentives for their production would essentially not exist. Unlike physical products that merely embody the results of R&D, in the case of information goods, the R&D itself is what is for sale. It is this feature that makes the tension between IP protection, which gives incentives for production but restricts the subsequent use of the information, and measures to promote spillovers from the current generations to those which build on them, particularly acute. The origins of database and software packages in common use are often “lost in the mists of time.”<sup>64</sup> In other cases, they are public and non-protected, but

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61 See Headley (1995) for an interesting discussion of the political/legal history of the idea of extending droit de suite to cover scientific inventions during the earlier part of the twentieth century. This idea essentially foundered on a reluctance to impose compulsory licensing on inventors into the far future and the consequences such a move might have for the publication of the results of scientific research.

62 Scotchmer (1996) shows the following: • Ex post licensing agreements, entered into after the cost of first innovation is sunk can increase the profits available for the two innovators, but cannot achieve the first best, because it is impossible to give the total surplus to each party separately using this (or any other) mechanism, as would be required to invent each of the innovators separately. • Ex ante cooperative R&D investment (RJVs), entered into before the R&D cost is sunk generally will achieve a more efficient outcome (in terms of total welfare), but it is very difficult to identify potential partners ex ante in practice.

63 In the case where such measures (IPR or NDAs) are only partially effective, Anton and Yao (1998) show that a signaling equilibrium exists with partial disclosure of the idea that gives an indication of its quality. This essentially means that the inventor will receive a “lemons” discount for his innovation, because he gives away some of it as a signal. The discount, which can be large, will clearly reduce the provision of ideas unless non-financial motivations come to the fore (such as priority of the open science kind).

64 One widely diffused statistical package for the social sciences was originally developed by a set of graduate students in their spare time in the 1960s. The approximately 50,000 lines of code now contained in the package probably include at most 100 lines of the original code, but the basic design of

have been developed and augmented by private researchers or research firms. Given the recent trends toward stronger IP protection in the commercial world, it is sensible to ask both whether there is an argument for extending these protections in the scientific community and also what the unintended impact of the changes already made might be on that community.<sup>65</sup>

Nichols's assertion that software patents are here to stay, a position intellectual property lawyers also endorse, has been vociferously argued against by Neville where the latter argues whether commercial interests have the political and economic clout to make sure these profitable monopolies persist. Although this implication may well be true, it is improper for computing professionals or patent attorneys to make such political predictions. On the other hand, Nichols's assertion could, despite his disclaimer, be interpreted by a naïve or careless reader as an affirmation of the rightness and goodness of software patents, particularly since the popular press so often publishes similar assertions with jubilation rather than qualification. Several questions must be answered before we can accept this second interpretation. First, what is a software patent? Second, are distinctive software patents justified? Third, should the patent system be extended to provide monopolies<sup>66</sup> for distinctive aspects of digital technology? Patent protection for digital technology lasts 20 years—an eternity in software development. This span virtually ensures that no public benefit of the invention's free use after the patent expires will ever be realized.

In the moral sense at least, digital technology and thus software itself clearly are neither inherently good nor bad—although plenty of technically good and bad software can be found. But software patents are not impersonal technology. The entire intellectual property system is a social artifact. As such, any part of it may be considered good or bad to some degree. Not only is it reasonable that an interested party examine the ethics and morality of any branch of the legal system, but professionals in relevant areas have a social duty to do so. Yet ethical issues are not simple. Nor is the law simple, or even internally consistent.<sup>67</sup>

Patent law and practice is a linguistic nightmare, an important ethical point almost always overlooked in popular articles. The pseudonymous Leonard Lockhard wrote stories on the US patent system that appeared occasionally in *Astounding Science Fiction* magazine during the 1950s. Clearly an insider, in "*That Professional Look*," Lockhard described patent law as "not founded on any known system of logic," but founded instead on "an iron-clad, invariant system of exceptions to a set of ever-changing, quasi-existent rules." These stories delighted patent examiners and attorneys around the world, who knew that ordinary readers would find the everyday occurrences of their professional life ridiculous and incredible. Hobbling software with a

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the syntax has changed little over the years and its origins are clear. Some of the earlier development was financed on research grants, but most of the value added in the past twenty years has been financed by sales of the product. In spite of this, the package retains a strong link to the academic community and is typically sold to them at a substantial discount from the commercial price. This type of situation is very common in the scientific software world, where the primary product being sold back to the academic community from the private sector is service and support rather than programming code. Were the algorithms in the code protected by strong patents, it is likely that these packages would command much higher prices than they do now. See Maurer (1999) for some more examples.

65 In the case of databases, the issues, particularly those raised by the new European Union Database Directive, have been well discussed by David (1999) and Maurer and Scotchmer (1999). Maurer (1999) also discusses a large number of example databases and reviews the policy options available for ensuring their production

66 The monopolies granted are defined only by the several claims of a patent application. The description must support each claim, but that is all. Patent procedures focus on the claims, and patent actions typically focus on the claims' precise wording. Experts in law, not technology, make the legal judgments. These experts must often interpret the meanings of words in claims in bizarre ways because they are required to respect the precedents set by relevant prior judgments, which are often bizarre. Such was the situation half a century ago, and it's worse now. Having laws and legal practices that citizens at large cannot understand is unethical and dangerous.

67 For example, the granting of letters patent confers a monopoly, but most trade practices legislation postulates that monopolies are inherently unethical. Nichols himself writes disparagingly of the "near-monopoly positions of IBM in the 1970s and Microsoft in the 1990s."

medieval artifact like the patent may stifle innovation, benefiting the moneyed few at the expense of everyone else.

The common use of the phrase “software patents” implies that they are a distinctive patent class. Indeed, Nichols claims that software requires separate treatment. But does the US grant distinctive software patents? The relevant literature seems to indicate that the basis for software patents in the US derives not from legislation, but from a new set of guidelines issued in 1996 by the US Patent and Trademark Office. These guidelines “do not have the force and effect of law,” and do not themselves mention software patents as such. Traditional thinking would deny patentability to software, as it has been denied to mere algorithms.

In practice software cannot be distinguished strictly from hardware: What software can do, hardware can do equivalently. Since a software process can be routinely converted to hardware, at least in principle, there is no reason to restrict a process claim to its software implementation. Note that the monopoly of a process claim covers the use of the process. A machine claim grants a monopoly that applies to the use of the machine carrying out a process, not to the process itself, and certainly not to the algorithm. Indeed, under traditional English patent law at least, mere algorithms cannot be patented. There must be a vendible product. If the machine claim merely covers a general-purpose computer performing a particular process embodied in some particular software, the restriction to a general-purpose computer is point-less and not in the inventor’s interests.<sup>68</sup>

No patentable invention could reside in the software itself, just as no patentable invention could reside in any particular pattern of holes punched in the cards used to operate a Jacquard loom. Traditional English patent law explicitly denies patentability to a “mere scheme or plan,” and the US guidelines suggest that a similar principle applies there. In this case the appropriate source of monopoly would be industrial design registration. Digital technology has clearly become important.

Should the patent system therefore be extended to provide monopolies for distinctive aspects of digital technology? We cannot answer this question until these distinctive aspects appear. Digital technology’s main distinctive features may well be those that Nichols<sup>69</sup> lists as practical shortcomings:

- Take-up of digital products or protocols occurs so quickly that if the first to market enjoys patent protection, competing products can easily be excluded.
- The wide distribution and varied uses of digital products make patent infringements extremely difficult to detect, prove, and prosecute for.
- Digital technology’s ubiquity makes it nearly impossible for people using the technology, directly or through the Internet, to determine whether they are infringing a patent or not, even with the best will in the world.<sup>70</sup>

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68 The 1996 US PTO guidelines seem to be silent on article-of-manufacture claims.

69 Nichols claims that “Software is a new kind of entity, with the ability to transform all other technologies, including the creative arts, politics, and economics. It therefore requires separate treatment.” The implied major premise of this syllogism is that new kinds of entities need separate treatment. The arguments against software patents are many and, to a degree, also apply to software copyright. Both Nichols and Barlow advance the most obvious one: Such intellectual property protections are impractical. Digital representations of programs or other text can be copied or otherwise manipulated with trivial ease; their transmission presents an insubstantial pageant which mocks any pretension that we can control it.

70 A more serious argument goes to the heart of the matter. Intellectual property law is founded on securing the public good and software patents or copyright plainly do not secure the public good. The justification for granting a monopoly to an inventor or importer of a technology has long been that the grantee trains others to exploit the invention after the grant expires. Thus, the inventor or importer

## Data exclusivity

Data protection<sup>71</sup> and privacy rights are designed to give individual citizens control over the use of information about them. Freedom of information seeks to give individuals the right of access to information held by governments and corporate bodies. Censorship is the right to be protected from obnoxious information. Finally, we are likely to see the emergence of a right of access to information and advice services. Data exclusivity is generally defined in United States as a period of exclusive marketing rights granted to a new drug application (NDA) upon obtaining marketing approval by the regulatory authority if certain statutory requirements are met.

India has been put on the priority watch list for failing to provide an adequate level of protection or enforcement and market access for persons relying on Intellectual Property protection. The absence of 'data exclusivity' legislation forms the reason for India's inclusion in the list.<sup>72</sup> This becomes important in the context of the provisions of Article 39.3 of the TRIPS agreement for the protection of undisclosed information. Article 39.3 itself has been a debated and the questions that emerge with regard to the issue of data exclusivity are:

- does Article 39.3 of the TRIPS agreement mean 'data exclusivity' or 'data protection'?
- should developing countries India adopt measures other than data exclusivity?
- would data exclusivity be suicidal for the India pharmaceutical industry with a strong generic base?

The Indian government seems to be looking at the option of not enacting data exclusivity for a period beyond four years. As such, once product patents come into force, the protection of a product will be for 20 years. Enforcing data exclusivity would amount to further greening of the patent for a product. However the criticism to this kind of thinking goes is that data needs to be protected to check misuse. And that data protection can be offered under the existing legal provisions. India already has necessary legal provisions to protect data submitted by innovator companies and hence it is felt that there is no need for any further protection. Others feel that it is very important to provide a five-year data protection as is done by all countries. It will also help research in India and increase substantial investments in clinical research. The question is whether the five-year data protection must mandatorily lapse within the 20-year patent life of a product.

### *TRIPs and Agriculture*

The present Indian law does not allow for the patenting of life forms. It is difficult to define micro-organisms precisely. But quite obviously, it not only covers bacteria, but also biological matter like genes, gene sequences, cell lines, cell cultures and viruses. (b) requires that plant varieties must be protected through patents or through a *sui generis* system. But the protection must be effective and the protection and the provisions will be reviewed in 1999.

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gets a short-term benefit from the monopoly, while the public gets a greater long-term benefit from the invention's later, unfettered use. Yet the public gains no more benefit

<sup>71</sup> The concept of Data Protection came out in the late 109602 when the Council of Europe sought to ensure that the European Convention on Human Rights conferred on individuals the right to protect personal information. The concept of data protection has become very well established as an important mechanism regulating the relationship between individuals and the state on one hand and the corporate sector on the other.

<sup>72</sup> Special 301' is a part of the U.S. Trade Law that requires the USTR to identify countries that deny adequate protection for Intellectual Property Rights or that deny fair equitable market access for the U.S. persons who rely on IP protection. PRIORITY WATCH LIST' are the countries or trading partners that have very serious problems in terms of scope and/or impact on U.S. commerce requiring the focus of increased bilateral attention on the problem areas.

The Uruguay Round agreement has a rather innocuous sounding Article 27 on patentable subject matter. "Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application". This is Article 27.1. Under Articles 27.2 and 27.3, exclusions are permitted. 27.3 is especially relevant. To quote, "Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof."

Patenting according to some goes back to the days when in the seventh century BC the Greeks began granting short term exclusive rights to cooks to prepare new recipes in order that the others may be induced to labour at excelling in culinary pursuits. As patenting spread all over the world, the number of things and areas of patentability expanded. But never did the issue of patentability in plants and animals come about. This was considered the common heritage, the God given gift to man. This perception exists even today and is the cause of much of the opposition to plant breeders' and animal varieties rights. Since genetic engineering and DNA treatment have become specialised disciplines, the scope for invention in micro organisms and tissue culture has grown and now this is an established technology which requires enormous amounts of ingenuity and hard work and patience and deserves the same incentives that any invention in any other field does.

An intense debate is being carried out in order to ascertain the extent to which Intellectual Property Rights (IPR) should be protected. And nowhere has this subject been more controversial than for the Indian seed industry. Enforcement of the new regime of protecting intellectual property has met with vociferous opposition from concerned communities ranging from farmers to economists to social workers - together providing diverse sets of reasoning for their resistance. These include concerns with disproportionate accrual of profits to multi-national corporations; destruction of the domestic gene pool; and inadequate productivity gains to farmers.

### **IPR issues for health -The mindset**

At the WHO conference in Geneva in May 1981, Mrs Indira Gandhi, then the Prime Minister of India had said, "My idea of a better ordered world is one in which medical discoveries would be free of patents and there would be no profiteering from life and death." The opposition to drug patents abounds in India. The Trade Related Intellectual Property Rights agreement (TRIPS)<sup>73</sup> under the WTO obligates member countries to grant patents for both products and processes<sup>74</sup> for all inventions in all fields of technology. It extends the patent term to be 20 years from the date of the application, for drugs and chemicals; under the Indian Patents Act of 1970 it was seven years. And makes no distinction between drugs produced locally or imported from another country. Also, the burden of proof now falls on the accused and he now has to prove that he has used a process other than the one used in the patented product.<sup>75</sup> On the other hand is the General Agreement on Trade in Services (GATS).

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73 Prior to the TRIPS agreement, intellectual property rights were governed by the Paris convention of 1883, later revised a number of times, till 1967. This Convention left patents, terms of patent and its duration of protection to be decided by the concerned national government. The pharmaceutical industry witnessed the maximum divergence in practice. Some countries protected the end product. Others protected only the manufacturing process. The rest protected neither.

74 In 1984, the U.S. Trade Act of 1974 was amended (Section 301). The President of the USA now had the power to impose trade sanctions on those countries that gave inadequate intellectual property protection to goods of US origin. This led to seven years of negotiation and the birth of the Uruguay round of TRIPS.

75 Under the Indian Patents Act of 1970 Act the burden of proof is completely on the patent holder.

While other sectors of industry have not been very disturbed, the pharmaceutical industry in India and the health care sector is concerned. The core issue being discussed is the possibility of a huge increase in drug prices and therefore in the access to drugs. India has a transition period for implementation of the changes, which ends in January 2005. In 1999 amendments were made to accept applications for product patents from 1995 and to provide exclusive marketing rights in India for a period of five years or till the grant of product patents of other WTO member countries. However, it must be pointed out right away that TRIPS allows for compulsory licensing, price controls and a competition policy. It is in this context that the issue of a public private partnership becomes relevant and this needs to be discussed. How would the new patent regime help the private sector? In what way would the private health care system benefit? How would the pharmaceutical sector react and adapt to these changes? But by far the most relevant question is - Will the consumer lose out?

### **Health care Infrastructure and the drug market**

India has an enormous public delivery infrastructure and staff, that in the year 1999 included 137,000 sub-centres, 28,000 dispensaries, 23,000 primary health centres (PHCs), 3,500 urban family welfare facilities, 3,000 community health centres (CHCs) and an additional 12,000 secondary and tertiary hospitals (CHCs are 30 bed secondary hospitals). In rural areas, public sector manpower included 29,000 doctors, 18,000 nurse midwives, 134,000 auxiliary nurse midwives (ANMs), 73,000 male multipurpose workers, 21,000 pharmacists, and another 60,000 paramedical staff, in addition to non-technical staff.<sup>76</sup>

Much of the growth in the industry can be traced back to 1970 when the Indian Patent Act was passed and disallowed product patents on drugs and pharmaceuticals. The intention of the act was to encourage the local industry. In the age of self-reliance and indigenisation that India went through in the sixties and the seventies, local brands replaced foreign ones. The effect of the changed law was seen immediately. Foreign applications almost immediately came down.<sup>77</sup> Patent holdings by foreign nationals came down too from 28000 to 15000 in the period 1970 – 80. But like most other noble intentions that were incorporated into law made during the late sixties, this one too went the wrong way. While foreign patent applications came down, Indian applications too did not go up dramatically.<sup>78</sup> What the law could not do in terms of encouraging innovation and research, it did in terms of encouraging production significantly.

Thanks to process patents on drugs, Indian firms could now develop alternative processes for patented drugs<sup>79</sup> and produce these on a cost-effective scale. As a result of these changes, the Indian industry has developed a strong expertise in bulk drugs and formulations. And drug prices are low. Bulk drugs are produced in large quantities and therefore economies of scale come into play. Competition among drug firms also keeps prices low. Most importantly it is Government regulations and the Drug Price Control Order<sup>80</sup> that keeps prices in check. The DPCO was passed in 1962 and has been able to keep prices low. In the 70s, the DPCO covered nearly 70% of all formulations and bulk drug being sold in India. However the reforms package has amended the DPCO too and now only 76 drugs of a total of 143 are controlled by the DPCO.

Indian patent law allows only process patents for pharmaceuticals and food products. Also the duration of the process patent is 7 years from the date of filing or 5 years from the date of

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76 Based on a conference report "A Vision for India's Health System" prepared by World Bank. [http://lnweb18.worldbank.org/sar/sa.nsf/Attachments/one/\\$File/hCh1.pdf](http://lnweb18.worldbank.org/sar/sa.nsf/Attachments/one/$File/hCh1.pdf)

77 From nearly 4000 in 1970 to 1795 in 1980-81.

78 From 1116 in 1970 to 1266 in 1993-94.

79 According to an ORG survey, 30 drugs were being produced in India in January while they were on patents in the US.

80 Even this is not satisfactory for most of the industry. The Government has promised the setting up of an autonomous National Pharmaceutical Pricing Authority, but like other promises, this one too has failed to take off.

sealing, whichever is less. To top this, the Government has wide ranging powers in granting compulsory licenses. These wide-ranging powers also do not provide the patent holder any hearing. The Indian law also does not consider importation to be the same as working of a patent. And in case of process patents, under the Indian Patent law, the onus of proof lies on the patent holder and not on the infringer.

## Drugs and TRIPs

The TRIPs Agreement requires WTO Members to grant and enforce intellectual property rights through enacting or amending necessary legislation at the national level. Although the TRIPs Agreement is only about minimum standards, its provisions relating to pharmaceuticals and seeds are highly contentious. Many poor countries have expressed their serious concern that unqualified patent protection will result in substantially higher prices for products, with adverse consequences for the health and livelihood of their citizens.

On the contrary major developed countries and their Transnational Corporations (TNCs) who own more than ninety percent of drug patents today are of the view that minimum standards prescribed under TRIPs are clearly not strong enough to prevent patent infringement by Third World firms. Unable to further expand the scope of TRIPs Agreement, developed countries, especially USA and EU are now increasingly using bilateral and regional trade and investment treaties to build more extensive protection for intellectual property than set out in TRIPs Agreement. What constitutes a “TRIPs-plus” treaty? GRAIN, an EU based NGO has done an exercise on criteria for “TRIPs-plus” with respect to biodiversity, which is laid out in the table below.<sup>81</sup>

**Criteria for TRIPs-plus**

Subject Matter	TRIPs-plus Provision	Why is this TRIPs-plus
Plants	Extension of standards of protection, such as: reference to UPOV <sup>82</sup> , no possibility of making exclusion from patentability of life forms, reference to “highest international standards” <sup>83</sup>	No reference to UPOV in TRIPs agreement; TRIPs allows countries to exclude plant and animals from patent protection; “highest international standards” is vague and there is no indication that it refers to TRIPs.
Animals	Same as plant	Same as plant
Micro-organisms	Requirement to accede to the Budapest Treaty <sup>84</sup>	No reference to Budapest in TRIPs
Biotech	Requirement to protect “biotechnological inventions”	No reference to “biotechnology” to TRIPs

The draft of the National Health policy 2001 discusses the impact of globalisation on the health sector by sounding warning signals on the adoption of TRIPs. The policy states that “*Pharmaceutical drugs and other health services have always been available in the country at extremely inexpensive*

<sup>81</sup> See GRAIN in cooperation with SANFEC, “TRIPs-plus” through the backdoor: how bilateral treaties impose much stronger rules for IPRs than the WTO, July 2001, available from <http://www.grain.org>

<sup>82A</sup> treaty governing the Union for the Protection of New Plant Varieties, gives patent-like rights to plant-breeders working in the formal seed industry. It rewards a very narrow type of plant breeding, geared toward genetic uniformity and large-scale monocultures.

<sup>83</sup> Numerous EU bilateral treaties bind developing countries to enforce the “highest international standards” of IPR protection. It is unclear which standards these are.

<sup>84</sup> A treaty on the deposit of microorganisms for the purpose of patent protection (1977) creates a union of countries operating common rules on filing samples of patented microorganisms. It is administered by the World Intellectual Property Organisation (WIPO).

*prices. And that India has established a reputation for itself around the globe for innovative development of original process patents for the manufacture of a wide range of drugs and vaccines within the ambit of existing patent laws. With the adoption of TRIPS and the subsequent alignment of domestic patent laws consistent with the commitments under TRIPS, there will be a significant shift in the scope of the parameters regarding the manufacture of new drugs and vaccines. Global experience has shown that the introduction of a TRIPS consistent patent regime for drugs in a developing country would result in an increase in the cost of drugs and medical services. “*

The impact of a new patent law on the pharmaceutical industry has become a much-debated and controversial issue. There is a clear bias against the new patent regime all over the country and there are strong arguments abounding against patenting of drugs. Under the TRIPS agreement, the existing legislation needs to be changed on several counts. Product patents will have to be given to patent holders of drugs, pharmaceuticals and agro chemicals. Nachane<sup>85</sup> points out the fact that most countries have had process patents for drug products and have moved to product patents only recently. UK had process patenting till 1949, Germany moved to product patents in 1968 and Japan, Switzerland, Italy and Sweden have moved to product patents in the late 70s. The patent duration in the new regime will be a uniform 20 years for all products. Compulsory licensing, permitted only for items of public non-commercial use and in national emergencies, can only be resorted to on the merits of each case. Even then the patent holder has the right to be heard and there cannot be any discrimination between domestic produce and imported goods. The burden of proof lies with the infringer and not with the patent holder, unlike what the Patent act of 1970 provides.

### **From Doha to Sydney**

Following the Inter ministerial Conference in Doha, the WTO member states began 2002 to try to resolve the outstanding question of exportation of generic drugs by producing countries to countries which do not manufacture these medicines. The fear is that almost 40 million people affected by AIDS do not have access to life-saving medicines. And the great majority of countries most affected by the epidemic are not in a position to manufacture these drugs for themselves. The WTO must therefore urgently allow generic manufactures to produce, sell and export their products to countries needing these products, and allow the latter the ability to import medicines in necessary quantities and as soon as possible.

Developing country members of the World Trade Organization have given unenthusiastic reviews to two proposals put forward by the European Union aimed at breaking a WTO deadlock over the issues of access to essential medicines and special and differential treatment for poorer members. Developing countries are opposed to the EU's suggestion that discussions on the two issues could drag on for the duration of the Doha Round of trade talks, due to end by January 2005. WTO members originally agreed at their Doha ministerial meeting last year to reach a deal on the access to medicines issue and to formulate recommendations on addressing special and differential (S&D) treatment demands by the end of this year.

The EU proposals were presented to a meeting of senior officials from some two dozen key member countries taking place on the outskirts of Geneva Nov. 5-6. One of the main items at the Sydney meeting is to ensure compliance with the mandate under paragraph 6 of the Doha Declaration on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and Public Health. Paragraph 6 notes the difficulties faced by some developing countries without sufficient domestic manufacturing capacity in utilizing compulsory licensing provisions under TRIPS to override patent rules and secure low-cost generic equivalents from abroad. It calls on WTO members to find an expeditious solution to this problem by the end of 2002. Under current WTO rules, compulsory licensing can only be used for the domestic production of generic equivalents.

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85 In Intellectual Property Rights in the Uruguay Round: Indian Perspective, EPW, February 4, 1995.

Some trade diplomats warned that failure to reach a deal on the medicines issue by the end of 2002 could sour the mood among developing countries and have a negative impact on the WTO's upcoming ministerial conference in Cancun, Mexico in September 2003. Although members generally agree on the need to make TRIPS provisions more flexible to allow for the import of generic medicines produced under compulsory licenses, the debate has become bogged down in technical issues such as which illnesses and medicines should be covered under the exemption, which countries should be allowed to produce generic equivalents of patented medicines for export, which countries should be allowed to benefit from the mechanism, and whether the TRIPS Agreement should be formally amended to accommodate the mechanism.

In addition, major proprietary pharmaceutical producers such as the United States, the EU, and Switzerland are insisting on the adoption of safeguards which would prevent generic medicines produced under compulsory licenses from being diverted to developed country markets and sold for huge profits. The EU compromise proposal states that any exemption to existing TRIPS rules should be limited to the production of medicines "where the gravity of public health problems afflict developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics." Product coverage would include patented pharmaceuticals and diagnostic test kits needed to address the public health problems mentioned above. Countries benefiting from the exemption should include least developed countries and developing countries classified as low income economies by the World Bank.

Other developing countries would be able to benefit if the low-cost medicines are needed to address situations of "national emergency or extreme urgency." Eligible countries would also have to show that they have no or insufficient manufacturing capacity in the drugs sector (i.e. no plants manufacturing active ingredients) and that it would not be able to create such capacities in the short term. All WTO members should qualify as producers of the essential medicines, the EU proposed. Some members of the Quad Group (the United States, EU, Japan and Canada) as well as Switzerland had earlier insisted that production should be curtailed to developing countries in order to minimize the possibility of cheap medicines being sold on rich country markets.

As for safeguards, the EU proposed that producers and importers should take necessary measures to prevent trade diversion, including making the low-cost medicines clearly distinguishable through labelling, marking and packaging. In cases of substantial trade diversion where a producing or importing member is accused of not taking adequate measures to prevent such diversion, the matter shall be discussed in the WTO's TRIPS Council, the EU said. As for the legal mechanism, the EU proposed that members immediately agree to a waiver from WTO rules for the scheme or a moratorium on challenges to the scheme under the WTO's dispute settlement system. Members would then agree on an amendment to the TRIPS Agreement formally recognizing the scheme by the time the Doha Round of trade talks ends.

The EU's proposal on special and differential (S&D) treatment received a decidedly cooler reception from developing countries, who complained it would create further divisions among the WTO membership, according to officials who attended the senior officials meeting. The proposal calls for WTO members to work on a set of S&D principles or guidelines which would provide orientation to a work program on the issue already established within the WTO's Committee on Trade and Development (CTD).

Many of the WTO's existing agreements contain provisions recognizing the need to offer S&D treatment to developing country members, but developing countries complain that these provisions are often ignored by their rich country counterparts. In response, WTO members agreed in Doha that the CTD to examine ways to make S&D provisions more effective and to consider the legal and practical implications of converting S&D treatment measures into mandatory provisions.

### **The current anomaly in TRIPS**

Under TRIPS, the US or UK government can override a patent on a medicine using a ‘compulsory license’ and commission a domestic company to produce a generic equivalent. This ‘last resort’ greatly enhances the government’s ability to negotiate reasonable prices with the patent-holding manufacturer. Developing countries can also issue compulsory licenses but, with few exceptions, don’t have the required domestic manufacturing capacity to produce a generic equivalent, or cannot produce at an economic price. They cannot import generics because TRIPS prevents any producer country where there is patent in force from exporting to them. The 49 least-developed countries, which thanks to a revision of TRIPS at Doha are not required to have pharmaceutical patenting at all before 2016, are also denied access to imported generics for the same reason. Correcting this anomaly is a vital next step to improve access to affordable medicines. It is, however, a measure that limits the damage caused to poor countries by TRIPS - it does not avoid the need for a more substantial review of the agreement from a public health and broader development perspective.

*The rigged rules that industrialised countries and big drug companies seek to impose*

a) The ‘solution’ should only apply to AIDS, TB and malaria, and only to medicines

There is no rationale for restricting scope to these diseases. There are many other diseases that ravage developing countries, for which the treatments are, or will be, patented and expensive. For example, Hepatitis C, which can be fatal, affects 8-10 million people in Egypt alone. Drug-resistant diseases are spreading fast, with enormous human cost: pneumonia kills hundreds of thousands of children every year, while gonorrhoea causes immense suffering for millions of women. Half the victims of the major non-communicable diseases (cardiovascular diseases, cancer, diabetes, chronic respiratory diseases and hereditary disorders) are now from the developing world, often from poorer communities. The solution should not only cover medicines but also vaccines, diagnostic kits and other health products, as these can be patented and expensive.

b) Beneficiary countries should only be the 49 least-developed countries or the low-income developing countries. This condition denies equal rights of access to generic medicines for at least 72 developing countries that cannot, with the probable exception of China, produce this generic version of new drugs for themselves, or do so at a reasonable price. Tens of millions of needy people in countries with limited public health budgets, such as Brazil, Peru, the Dominican Republic, South Africa, Honduras and Namibia would be excluded from benefit.

Developing countries also argue that the mechanism should allow countries in a regional trade agreement to import generics as a group, or that one of the members should be able to supply the regional market with generics, which would permit economies of scale. In addition, Oxfam supports their complementary proposal that North should help to improve capacity in their pharmaceutical sectors by transferring know-how and technologies, since a thriving local industry is the best guarantee of improved access to medicines and overall ‘health security’. In the longer term, prospects for such industries will be greatly enhanced by much more substantial reform of the patent rules.

c) The exporting-country government must issue a ‘compulsory licence’ to permit production and export of the generic version of the patented product, on a case-by-case basis.

It is totally unreasonable to expect the importing country to depend on the political will of another government for access to affordable medicines. Pakistan might need to commission a drug from a manufacturer in India, which is one of the very few developing countries with a sophisticated pharmaceutical industry. It should not have to depend on the Indian government’s willingness to authorise such production. Moreover, the exporting country would be vulnerable to external pressure not to give its consent. Having to seek compulsory licences in both importing and exporting countries also adds to the administrative burden.

d) Developing countries must negotiate with the patent holder prior to using the mechanism, can only resort to it if the price offer is unsatisfactory, and must formally notify the WTO of their intention.

These conditions are unfair because they go beyond existing TRIPS obligations faced by a rich country if it decides to override a patent; they are designed to slow down and complicate the whole process for a developing country.

e) Only developing countries should be able to produce for export under this mechanism.

This condition sounds enlightened but is intended to reduce the number of potential suppliers of generic medicines, to the advantage of the big drug companies. Any country should be allowed to export under the mechanism.

f) Developing countries should undertake measures to prevent the flow of generic medicines back to the markets where the drug is under patent.

The main burden for this should rest with industrialised countries, which already have the means for enforcement (e.g. the recent European proposal to label reduced-price medicines destined for developing countries in order to police illegal re-imports back to Europe). Any measures required of developing countries should be proportionate to the problem, and to their capacity.

Consider para 6, now widely debated in Geneva and elsewhere. “We recognise that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPs agreement. We instruct the Council for TRIPs to find an expeditious solution to this problem and to report to the General Council before the end of 2002.” If, following the second sentence, the TRIPs Council has to find an expeditious solution by the end of 2002; the TRIPs Council (and everyone else) has to understand what the first sentence means. Compulsory licensing and WTO members are concepts that are easy to pin down. But which are the countries that have insufficient or no manufacturing capacities in the pharmaceutical sector?

There are several WTO members that are small countries (and these may also be developed countries). There is no reason for them to have indigenous pharmaceutical manufacturing capacity. It doesn't make commercial sense. Will the TRIPs Council also investigate what these small developed countries are supposed to do? There is no way they can make effective use of compulsory licensing. People will say that developed countries are not the problem, Doha meant developing countries and LDCs. But that's not what Paragraph 6 says. And for developing countries and LDCs, is access to drugs at reasonable prices the issue or is effective use of compulsory licensing the issue?

The two problems are not synonymous. Because of the original vagueness in drafting, Geneva is now busy trying to interpret para 6. Take the three questions posed by Switzerland. “What is the meaning of insufficient or no manufacturing capacity? Which situations justify action? How can solutions be devised that genuinely help countries lacking production capacity rather than helping those with production capacity?” Developing countries think para 6 applies to all WTO members. Developed countries think it should apply to countries with specific eligibility criteria. Exclude small developed countries for example. Pity the ministers aren't around to explain what they meant in Doha. So we still don't know which countries para 6 refers to. The TRIPs Council has a task on its hands.

Other than pinning down countries, one also has to pin down difficulties in effective use of compulsory licensing. Does this imply incentives for technical assistance and technology transfer? What happens if drugs produced under compulsory licences in one country are exported to another country, with the second country, perhaps, having no domestic production capacity? This links up with Article 31(f) of the original TRIPs agreement, which states: “any such use shall be authorised predominantly for the supply of the domestic market of the member authorising such use”. Any such use means use without the authorisation of the right holder and covers compulsory licensing.

The evident problem is with the clause “predominantly for the supply of the domestic market”. Developing countries want this scrapped. The EU wants it amended, with strict criteria for exporting. The US only wants a moratorium on such export-related disputes. But in the case of Article 31(f), one can at least understand what different countries are saying. Unfortunately, this is not what one can say of the other interpretation of para 6 floating around. This interpretation is that Article 30 of the original TRIPs agreement should be amended, so as to allow products made through compulsory licensing to be exported to countries that face public health problems, but have no domestic production capacity. Article 30 is on exceptions to patent rights and in my view, is another classic example of bad drafting.

Here is Article 30. “Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.” This Article has a lot of nice sounding words, but what on earth does it mean? The TRIPs agreement has several articles on rights conferred by a patent. It also has several articles on exceptions to rights. Those articles are specific. But by virtue of being non-specific, Article 30 contributes nothing to general comprehension. The WTO’s dispute resolution mechanism has already had to interpret what Article 30 means. And thanks to para 6 and Doha, the TRIPs Council will now have to interpret what Article 30 means and possibly suggest amendments and explanatory notes. Wouldn’t it have been better had Article 30 been precisely drafted in the first place?

### **Conclusion - Does Intellectual Property Protection benefit India?**

In the Indian context, there is enough empirical evidence to note that free access to foreign technology has led to a great deal of complacency on the part of domestic industry. The industrial policy of import substitution had envisaged a great deal of effort and investments in innovativeness. But free access to foreign technology, in the face of poor IPR implementation, has enabled Indian industry to succumb to the temptation of using foreign technology, tinkering with it and adapting it with minor changes to suit the Indian market. Coupled with licensing and entry barriers, this policy has ensured that most of the manufacturing sector has remained backward, capital intensive and technologically archaic.<sup>86</sup>

There is a popular impression that through the Uruguay Round agreement, India has had to grant an enormous lot in the area of intellectual property rights. There is also an impression that India has no tradition or legislation of protecting intellectual property. As the above sections indicate, both of these propositions are inaccurate. In any process of multilateral trade negotiations, there is an element of *quid pro quo*. There are both costs and benefits and one has to trade off the benefits against the costs. The Uruguay Round discussed fifteen different areas and these can be thematically divided into three different heads – market access<sup>87</sup>, rules of GATT<sup>88</sup> and the new areas<sup>89</sup>.

When India went into the process of negotiations in 1986, the expectation was that India would generally gain in the areas of market access and rules of GATT and lose in the new areas. This perspective has changed somewhat since economic reforms were introduced in India in 1991. Barring the area of intellectual property rights, there is nothing in the Uruguay Round agreement that conflicts with the thrust of India’s unilateral reforms.<sup>90</sup> And even within intellectual property

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86 S. Jacobson, “Government Policy and Performance of the Indian Engineering Industry”, Research Policy, February 1991.

87 Tariffs, non-tariff barriers, textiles and garments, agriculture, tropical products and natural resource based products.

88 Safeguards, anti-dumping, subsidies and countervailing measures, functioning of the GATT system, dispute resolution and MTN (multilateral trade negotiation) agreements and arrangements.

89 TRIPs, TRIMs (trade related investment measures) and services.

90 This is the argument in Debroy (1996) and Ganesan (1994).

rights, the deviation primarily exists for patents and not for other forms of intellectual property. Stated more precisely, the argument is that even if India has lost out on patents, this loss is more than compensated by the gains that have been made in other sectors. However, this debate about the pros and cons of the Uruguay Round agreement is now dysfunctional as the agreement has become *fait accompli*. One needs to look forward and remove systemic problems associated with the administration of an intellectual property rights regime. This is best illustrated in the case of patents.<sup>91</sup>

Compared with the two years in many countries, it takes anything up to six years to obtain a patent in India. This is because of antiquated systems and procedures in the offices of the Controller General of Patents, Designs and Trademarks. For example, in 1992-93, 3467 applications for patents were received in India.<sup>92</sup> Only 2347 applications could be examined. The balance was carried forward and today, the backlog of patent applications that still have to be cleared is more than 11,000. An enormous amount of modernization and computerization is required in the patent offices<sup>93</sup>, apart from speeding up the legal process. One cannot have a global norm for patent protection if the systems are not global. The government has now begun a programme for modernization of patent offices with the use of the Patent Information System (PIS), based in Nagpur.

The modernization and computerization issue is also linked to the question of patent fees. Indian patent fees are among the lowest in the world.<sup>94</sup> It costs Rs. 300 to file a patent application, Rs. 200 for sealing the patent, Rs. 150 for obtaining a certified copy and Rs. 100 as an annual fee for maintaining the patent. If the patent is maintained for fifteen years, this is a total of Rs. 2150, approximately 60 US dollars. Comparable figures are around 4000 dollars for the European Union, 3000 dollars for the United States, 2000-2500 dollars for Japan and South Korea and 1000 dollars for China, for filing the patent application alone. There is thus a case for hiking the fees and using these resources to modernize and install proper databases.

There are many grey areas in intellectual property rights. It is thus also clear that there will be large numbers of cross-border litigation involving intellectual property rights.<sup>95</sup> The turmeric case, which ended in a ruling in India's favour, is only one example of this. Apart from the question of costs, such litigation cannot be handled without systemic improvements. One should therefore move on to undertake such improvements, instead of continually looking backwards and debating the merits and demerits of the Uruguay Round agreement.

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91 There are issues of training personnel which go beyond patents. For example, most police officers do not know if a copyright must be registered or not.

92 On an average, about 90% of patent applications and patents granted, are to foreigners.

93 Search functions are still done manually.

94 There is a large amount of implicit subsidisation, although no one has worked out how much this is.

95 The United States has IPR disputes with Pakistan, Portugal and Japan, apart from India. The European Union has a dispute with Japan. See the WTO's Annual Reports.

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