Lecture 41
Trade-Related Aspects of Intellectual Property Rights

The TRIPS Negotiations and the World Trade Organisation

The origins of the negotiation of an agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) can be traced back to a number of factors, which international policy-making from the 1970s to the mid-1980s. There were attempts, following decolonisation and the establishment of WIPO, to further amend the Paris Convention. Calls for the revision of the Paris Convention increased in the late 1970s when an increase in the unauthorised sale of protected products led the business sector to take the lead in encouraging governments to strengthen protection against what they saw as counterfeiting. Attempts at revising the Paris Convention and the Berne Convention within the context of the WIPO failed because the positions of developed and developing countries were too far apart. On the one hand, governments of developed countries were dismayed at the absence of detailed rules on enforcement at the national level and at the absence of a binding dispute settlement system between states. On the other hand, developing countries were seeking to obtain concessions on the basis of a 1974 UNCTAD report, which was largely critical of the role of the IPR system in the promotion of development in developing countries[1]. The result was a series of inconclusive meetings in the context of WIPO.

The launch of the Uruguay Round of Trade Negotiations in 1994 in the context of the GATT led to new initiatives by countries and actors seeking the strengthening of IPR frameworks. There was significant pressure from corporate lobbies in the US, but the progression of the idea of inserting an IPR agenda in the round of trade negotiations also owed to the fact that there was a broad congruence of interests among big businesses in many countries around the world[2].

Intellectual Property Rights Negotiations in the Uruguay Round

On the basis of the disenchantment with the WIPO process on the part of countries seeking strong IPR protection, the ministerial declaration launching the Uruguay Round of trade negotiations included as one of the subjects for negotiations the elaboration of new rules and disciplines for IPR with a view to reducing impediments to international trade while ensuring adequate protection of IPR[3]. The main issue during the first part of the negotiations was to overcome the strong opposition on the part of some big developing countries, such as Brazil and India to the shift of the negotiating forum for IPR from WIPO to GATT[4].

Overall, the position of opponents like India progressively changed from real opposition to acceptance of the package that was finally proposed in 1993. At first, India argued with other opponents that the protection of IPR had no significant relationship with international trade. The position of the Ministry of Commerce in 1989 was, for instance, that there should be no attempt to extend the patent laws of developed countries to developing countries and those standards, which could be relevant to the former and may be inappropriate to the later, and should not be imposed on them. India, following the financial crisis of 1991 and the new economic

policies of the erstwhile government, progressively softened its opposition to the IPR negotiations.

On the whole, negotiations for the TRIPS Agreement were centered, in a large part, on the search for a consensus among the main negotiating parties whose consent was going to be required for the adoption of the agreement. A large part of the negotiations was the search for consensus positions among the main developed countries while the concessions made to developing countries were largely on the basis of the common positions adopted by the developed countries. This concentric system of consensus starting with an agreement among the most powerful players later extended to less powerful ones has justifiably been described as undemocratic within the paradigm of international negotiations.

The search for consensus led to the compilation of a draft agreement by the Director General of the GATT. This draft was eventually successful, which is still debatable, because it went largely in the direction sought by the US, provided sufficient protection for European geographical indications on wines and spirits and allowed Japan to retain the right of authors to allow the rental of copyright works[5]. Developing countries largely gave up their main demands but got some relatively minor concessions such as the possibility to exclude plant and animals from patentability. The final outcome was, on the one hand, a real success for global business, which obtained most of the concessions it sought. On the other hand, developing countries – apart from the most industrialised among them which did not stand to lose much from the TRIPS Agreement – gave up most of their demands. The reasons for eventually signing up to the TRIPS Agreement were mostly that it was made part of the broader package deal of the Uruguay Round, which included other agreements that were perceived as beneficial to developing countries. In other words, while it may be that some countries did not fully understand the consequences of signing up to the TRIPS Agreement, it was generally understood that it was not a positive outcome for developing countries. Nevertheless, it had to be seen in the broader context of the Uruguay Round, which countries perceived at least at that time, as partly giving in to some of the concerns of developing countries, for instance, concerning the Multifibre Agreement and the Agreement on Agriculture[6].

The World Trade Organisation and its Dispute Settlement Mechanism

The TRIPS Agreement, as mentioned above, was a part of the package adopted as a result of the Uruguay Round. The Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations (hereafter Final Act) included not only a series of trade agreements but also an agreement seeking to transform GATT into a fully-fledged organisation, the World Trade Organisation (WTO). The WTO, having superseded the GATT as of 1995, has taken over the administration of all the substantive and procedural agreements included in the Final Act[7]. This includes firstly the GATT, which generally regulates trade in goods, an Agreement on Agriculture, an Agreement on the Application of Sanitary and Phytosanitary Measures, an Agreement on Textiles and Clothing, and an Agreement on Technical Barriers to Trade. This also includes an Agreement on Trade Related Investment Measures, an Agreement on Import Licensing Procedures as well as new agreements like the TRIPS Agreement

and the General Agreement on Trade in Services[8]. This indicates the breadth of issues covered under WTO-related agreements.

In the field of intellectual property, the role of the WTO remains limited. This is due to the fact that while the TRIPS Agreement is administered by the WTO, it is still WIPO that administers IPR issues on a day-to-day level. Further, the TRIPS Agreement does not establish international IPR standards but minimum standards, which have to be introduced at the national level.

There is, however, at least one major area where the WTO is directly relevant in the field of intellectual property. One of the perceived shortcomings of WIPO, as mentioned earlier, was that it lacked a strong dispute settlement mechanism. This aspect was addressed in the Uruguay Round negotiations not only for the specific case of IPR but also more generally for agreements administered by the WTO. The result is the Understanding on Rules and Procedures Governing the Settlement of Disputes, which is a part of the package deal of the Final Act[9]. The Dispute Settlement Mechanism of the WTO is one of the elements that sets the WTO apart from most other international organisations where dispute settlement tends to be weak or non-binding. In the WTO, the dispute settlement system is compulsory for all member states and compliance with the rulings and recommendations of the Dispute Settlement Body are given special attention[10].

In practice, in the event of a dispute that is taken to the Dispute Settlement Body, three phases can be identified. First, consultations must be held among parties to the dispute. Where negotiations do not resolve the matter, the complaining party can request the establishment of a Panel. This Panel is normally mandated to examine the matter referred in the light of the relevant provisions of the agreements indicated by the parties and to make findings that assist the Dispute Settlement Body in making recommendations and rulings[11]. The Panel drafts a report on the basis of briefs submitted by the parties to the dispute and oral arguments. The report is circulated to the parties before being submitted to the Dispute Settlement Body. The dispute settlement system authorises parties to file an appeal to the Appellate Body, a standing panel of seven senior international trade lawyers, three of whom serve on a given case. Appeals are limited to points of law covered in the report by the Panel[12]. The report of the Appellate Body is submitted to the Dispute Settlement Body and is adopted, unless there is a consensus against the report.

Another feature of the Dispute Settlement Body is that compliance is not left, as is often the case in international law, to the goodwill of member states. The dispute settlement system specifically provides a system through which lack of compliance can lead to compensation and the suspension of concessions[13]. As a result of this strong system making rulings subject to monitoring and effective enforcement, compliance with the Dispute Settlement Body rulings has been high. The dispute settlement mechanism has proved to be an important tool for the major trading nations of the world but has been used relatively infrequently by smaller trading nations and has, for instance, not been used at all by sub-Saharan African countries. The US has, in particular, been involved either as a complainant, defendant or third party in virtually all proceedings that led to the adoption of a report, that is, the Agreement on Trade-Related Aspects of Intellectual Property Rights (Shaffer 2004).

The Agreement on Trade-Related Aspects of Intellectual Property Rights

The TRIPS Agreement is the most important intellectual property treaty for all member states of the WTO though it cannot be treated in isolation of other relevant treaties[14]. It generally provides for the introduction of intellectual property standards already in place in most developed countries to all member states of the WTO. In other words, it constitutes a common minimum programme acceptable to the main developed countries rather than a compromise between the position of developed and developing countries.

The TRIPS Agreement introduces a set of minimum standards of protection that all countries must respect in regulated areas such as trademark, geographical indications, industrial designs, patents, topographies of integrated circuits and undisclosed information[15]. Most developed countries already had standards of protection close to what the TRIPS Agreement requires, and there was, therefore, relatively little they had to do to be in full compliance. For developing countries, however, the situation was and remains quite different. In some cases, certain countries did not have any form of protection in certain fields, such as plants and plant variety, and have, therefore, had to develop entirely new legal frameworks or adopt existing frameworks in place in developed countries. In other cases, countries such as India had specific restrictions on patentability, which had to be removed for TRIPS compliance[16]. In yet other cases, legislation existed but was not being implemented[17]. In general, the TRIPS Agreement has required significant adjustment from developing countries and will require even more from least developed countries.

The TRIPS Agreement reflects its unusual genesis insofar as while it sets its own minimum standards of protection; it also incorporates the substantive standards from existing WIPO-administered conventions such as the Paris Convention. One of its main innovations in the field of intellectual property is that it brings together different categories of IPR, as discussed earlier. Another novelty in the TRIPS Agreement is that it contains detailed provisions on enforcement such as civil procedures allowing action against infringement, border measures to stop the importation of counterfeit trademark and pirated copyright goods and criminal procedures in the cases of willful trademark counterfeiting or copyright piracy on a commercial scale[18]. Further, the TRIPS Agreement is one of the treaties that falls under the dispute settlement system of the WTO, which ensures a much higher degree of compliance than would otherwise be the case.

The central objectives of the TRIPS Agreement outlined in the preamble are the reduction of distortions and impediments to international trade as well as the desire to promote effective and adequate protection of IPR. Besides the emphasis on trade aspects of intellectual property and the emphasis on IPR as private rights, the preamble also recognises the fact that intellectual property seeks to foster public policy goals, including developmental and technological objectives.

The first part of the Agreement provides the general framework that is applicable to the substantive areas covered in the TRIPS. As mentioned above, one of the central characteristics of the TRIPS Agreement is that imposes minimum standards of

protection. In other words, it seeks to harmonise national laws but does not provide for uniformity. Thus, in the specific case of the term of protection of patents, Article 33 makes it clear that a minimum period of twenty years is required, but it does not restrict countries from imposing higher limits, if they wish.

The Agreement also provides for the integration of significant parts of existing intellectual property conventions such as the Paris Convention and the Berne Convention[19]. However, this does not imply similarity, and, in fact, there are significant differences between the TRIPS Agreement and a treaty like the Paris Convention, which did not seek to establish international standards of intellectual property protection but only to harmonise national systems of protection. In other words, the TRIPS Agreement incorporates existing standards and introduces internationally recognised minimum standards that may go beyond incorporated treaties.

Further, the TRIPS Agreement strengthens the principle of national treatment already outlined above in the context of the Paris Convention and introduces the concept of most-favoured-nation treatment to intellectual property. This is one of the direct links with other trade agreements of the WTO since the clause of the most-favoured-nation has been the cornerstone principle of the GATT since 1947[20]. It provides that any advantage granted to a country on a bilateral basis must automatically be extended to all member states of the WTO. This may be of benefit to smaller countries, which benefit from concessions that bigger countries grant each other, but in the context of intellectual property, this is likely to be marginal since smaller and least developed countries are not likely to make much use of such advantages.

Another important issue referred to in the first part of the TRIPS is the exhaustion of IPR. Owing to divergences between negotiating states, no consensus could be found on the question of exhaustion. The issue is whether the first introduction of a patented product in the market by the patent owner or with the patent owner's consent exhausts the rights that can be claimed on the basis of the relevant patent. Let us highlight two main points of interest.

First, there is the question whether the introduction of a patented product in one country exhausts the right in all the countries where the product is patented or only in the country where it is introduced. This has been especially contentious in the case of medical patents because of the links between exhaustion, parallel imports and differential pricing (Cullet 2005). In the case of national exhaustion, there is scope for companies that wish to do so to sell their drugs at different prices in different markets to take into account different levels of economic development and capacity to pay[21]. In the case of drugs for diseases that exist both in developed and developing countries, differential pricing can have positive effects. It allows pharmaceutical companies to sell in developing countries at a level which allows them to maintain their profit levels. At the same time, the segmentation of the market permits the sale to developing countries of the same drug at a price much closer to the marginal cost of production. The limitations of differential pricing include the following two problems: (a) the marginal cost of production may still be much more than what most patents in developing countries can afford. Similarly, though the price of a single dose is "affordable", this may not be the case, if a drug is to be taken for long periods of

time[22]; and (b) differential pricing does not solve the problem of the incentive to the private sector pharmaceutical industry in the case of diseases that occur only in developing countries. The prices that developing countries can afford are not sufficient to entice a company in developed countries to engage in the necessary research and development[23]. Further, there are other problems associated with differential pricing. On the one hand, differential pricing works satisfactorily from the point of view of intellectual property holders, if markets are highly segmented to prevent the leakage of differentially priced drugs to high-income markets[24]. This implies that there can be no parallel importation as provided under Article 6 of the TRIPS, if there is to be differential pricing, as markets must remain separate. On the other hand, Article 6 of the TRIPS constitutes one of the instruments that developing countries can use to take advantage of different prices in different markets either due to different market conditions or due to different IPR regimes. On the whole, Article 6 of the TRIPS provides developing countries with some flexibility within the patent system, while differential pricing with segmented markets provides this flexibility to holders of IPR[25].

Secondly, there is the issue of the actual meaning of exhaustion in specific cases. This is an ongoing issue, in particular in the context of genetically modified seeds. There is still significant uncertainty as to whether patent owners can claim rights only over the actual seeds they sell or also over future generations of seeds created on the basis of the patented seed but without any contribution of the patent owner. Article 6 of the TRIPS Agreement does not provide a general solution to the question of exhaustion. The Doha Declaration on Health goes slightly further in clearly asserting that individual countries can establish their own exhaustion regime and are only bound in doing so by their obligations under Articles 3 and 4 of the TRIPS Agreement[26].

The last articles of the first part of the TRIPS Agreement provide the main basis states implementing their TRIPS obligations can rely on to take into account the socio-economic concerns. Article 7 is the only provision, which evokes the balance between the rights granted to individual IPR holders and the broader interests of the society, at large. In the context of the TRIPS Agreement, the focus is on the use of IPR as incentives for foreign investment and technology transfer. It provides that

> [t]he protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducing to social and economic welfare, and to a balance of rights and obligations (Article 7 of the TRIPS Agreement).

Article 8 of the TRIPS Agreement applies, more specifically, to measures adopted by states to implement their TRIPS obligations. It provides specifically that states can adopt measures to protect public health and nutrition, as well as to promote the public interest in sectors of vital importance to socio-economic and technological development. The scope of the measures that can be adopted is, however, limited by the fact that such measures must be consistent with the operational provisions of the TRIPS Agreement. Member states of the WTO are also entitled to take measures against the abuse by right holders of their rights and against practices that

unreasonably restrain trade or adversely affect the international transfer of technology. In other words, this provides general guidelines for states that want to regulate the scope of intellectual property protection through competition policy. Though there is very little use of these provisions by member states in practice, they have, for instance, been acknowledged by India as being overarching provisions that should qualify other provisions of TRIPS Agreement meant to protect IPR[27].

Patents in the Context of TRIPS Agreement

As mentioned earlier, the TRIPS Agreement incorporates substantive provisions from the Paris Convention. As a result, it adopts the same basic criteria for patentability that were discussed earlier in this chapter, namely novelty, non-obviousness and industrial applicability. A number of innovations can nevertheless be identified. The TRIPS Agreement, for instance, requires patentability of qualifying inventions in all fields of technology[28]. One implication is that countries cannot differentiate between different fields of technology. The TRIPS Agreement also requires patentability in all fields of technology for processes and products. Therefore, no differentiation between product and process patents is allowed.

General principles concerning the scope of patentability establish the widest possible scope. Some optional exceptions have, however, been introduced, allowing member states to take measures at the national level to restrict patentability in certain specific fields. One specific aspect concerns the possibility to exclude diagnostic, therapeutic and surgical methods for the treatment of humans or animals. Broader exceptions include the protection of morality and public order, and, in particular, the protection of human, animal or plant life or health, or avoiding serious prejudice to the environment. These exceptions are qualified by two conditions. First, member states can only apply such restrictions to patentability where it is established that the commercial exploitation of the invention must be prohibited. Secondly, the exclusion from patentability must not be based solely on a general provision prohibiting the exploitation of the product (Gervais 2003). This would, for instance, prohibit a blanket restriction on product patents on micro-organisms or pharmaceuticals. The TRIPS Agreement also addresses separately the question of life patenting at Article 27(3)b. Here, the principle is that life patents such as patents on micro-organisms and non-biological and microbiological processes for the production of plants and animals must be introduced. States remain entitled to exclude the patentability of certain specific categories of products such as plants, animals and especially biological processes for the production of plants and animals. This convoluted arrangement raises significant problems that have already been identified in some jurisdictions. One main question that arises is whether the patentability of a micro-organism extends to a plant into which it is inserted even where the plant is itself not patentable[29].

Article 27(3)b adds one more layer of complexity concerning plant varieties. The question of plant variety protection is only one of many issues related to life patenting but it is of special interest. This is due to the fact that the lack of consensus led to the following statement: ‘Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof’[30]. This implies an obligation to introduce IPR for plant varieties but does not

impose patents as the only form of protection. In fact, the expression *sui generis* indicates that no specific type of IPR is favoured. This is a significant exception in the TRIPS Agreement, which generally includes specific commitments that do not leave much room for differentiation. Plant variety protection is, therefore, one of the few provisions where action is required on the part of all states but where developing countries get a chance to implement the provision in a way that suits their interests in this specific field and related areas. The provision of Article 27(3)b concerning plant variety protection was not specifically drafted with the needs of developing countries in mind, but the lack of specificity allows developing countries significant scope to introduce an alternative plant variety protection system which, for instance, incorporates farmers' rights[31]. This provision is significant because agriculture remains extremely important in many developing countries and a fundamental mainstay of the economies of all least developed countries. It is also important because it could constitute a model towards a revised TRIPS Agreement incorporating more, and more specific, differential treatment in favour of developing countries.

Apart from general exceptions to patentability, some temporary exceptions were also granted. One such exception allowed countries like India to retain specific exclusions to product patentability for ten years after the entry into the TRIPS Agreement. This covered, for instance, the case of product patents in the pharmaceutical sectors, which did not have to be introduced before January 1, 2005[32]. Some conditions were, however, attached to this exclusion. First, the extra time could not be used to change laws in a way that would have taken India further away from compliance, for instance, by introducing further restrictions on patentability during the transition period[33]. Secondly, in the case of restrictions on pharmaceutical and agricultural chemical products, countries could delay the introduction of product patents but had to introduce a means for allowing the filing of applications for patents on such inventions. They also had to apply the criteria for patentability of the TRIPS Agreement and had to provide patent protection for the remainder of the patent term as of 1 January 2005. Further, in the intervening period, patents applicants were to be granted exclusive marketing rights.

Apart from substantive conditions for patentability, states also have to include certain procedural requirements. One important requirement is the necessity to disclose the invention so as to allow a person skilled in the art to carry out the invention, which is one of the basic benefits that society gets in return for granting monopoly rights to the patent holder. Further, states are also allowed to introduce other procedural conditions for the grant of patents as well as for their maintenance[34]. This is important in the context of attempts to protect traditional knowledge through IPR, as this provision may, for instance, provide scope for the introduction of a requirement to disclose the origin of the resources and the knowledge used in a particular patent application[35].

The TRIPS Agreement also includes a number of provisions concerning the rights conferred to patent holders. The principle is that the patent owner has exclusive rights to prevent third parties from making, using, offering for sale, selling, or importing for these purposes the protected product without the owner's consent[36]. Where the patent is for a process, the rights granted extend to the use of the process and also to the use, sale and import of products that are directly obtained through the protected process[37].

These exclusive rights, which amount to a virtual monopoly, are granted for a period of at least twenty years[38].

While the TRIPS Agreement provides extensive rights for patent holders, there remain some possibilities that states can use to restrict the rights conferred. This is first a general clause, which authorises

> 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[39].

The above clause, which only operates at the level of the regulation of the use of a patent already granted, is potentially wide-ranging because there is no definition of the limited exceptions that are allowed. Member states should, thus, be able to use Article 30 to justify a variety of socio-economic measures they may wish to take to control the use made by specific patents. However, there are a number of restrictions to the measures that states can take. Exceptions to monopoly rights can first only be "limited" exceptions and should, therefore, not amount to a patent rights altogether. Secondly, the exceptions must not unreasonably conflict with the exploitation of the patent. And, thirdly, the exceptions should not unreasonably prejudice the legitimate interests of the patent owner. These conditions seem to significantly restrict the scope of the measures that states could take. Similarly, Article 30 includes a section, which recalls that third parties also have legitimate interests. However, the structure of Article 30 seems to imply that the legitimate interests of third parties are sub-ordinate to the interests of patent holders. Though this should be the case, there are situations such as the case of life-saving patented drugs where the legitimate interests of third parties could be deemed to override other interests and allow states to adopt exceptions. In practice, an interpretation of Article 30 favouring third parties may be difficult to sustain. Thus, in a case that dealt with Article 30, the Panel found that while permitting the use of patented substances for experimental purposes was admissible, stockpiling patented pharmaceuticals prior to the expiration of the patent does not fall within the limited exceptions of Article 30, though introduction into the market is prohibited until the expiration date of the patent[40].

There exists another set of measures that can be taken to limit the rights of patent holders. This is what the TRIPS Agreement calls "to use without authorization", otherwise known as compulsory licensing. Compulsory licensing was, first of all, introduced as an instrument allowing governments to sanction a patent holder that does not respect certain conditions of the patent without going to the extreme step of revoking the patent. In the twentieth century, many countries adopted compulsory licensing regimes, some much more stringent than others with the Indian Patents Act 1970 being among the more stringent ones, which will be discussed in detail later in this chapter. The TRIPS Agreement generally maintains the possibility for member states to have a compulsory licensing regime but constrains their ability to determine the specific conditions under which the regime functions. Article 31 provides a number of conditions that states must follow. These include:

(a) Compulsory licensing can only be allowed on a case-to-case basis[41].
(b) States must first try to secure authorisation on commercial terms, unless it is a situation of national emergency or the State wants to make public non-commercial use of the invention.
(c) The term of the licence must be limited in time to the purpose for which it is authorised, must be non-exclusive, and must be mainly to supply the domestic market.
(d) The patent holder is entitled to "adequate" remuneration[42].
(e) The decisions taken are subject to judicial review.

One of the interesting features of the compulsory licensing regime under TRIPS Agreement is that no limitation of the purposes for which compulsory licensing can be granted. This can be treated as a gain for developing countries since the US wanted to restrict the grounds for compulsory licences[43]. Further, states are also free to determine what constitutes a national emergency.

The TRIPS Agreement and Developing Countries

As discussed earlier, it is generally agreed that the TRIPS Agreement constituted a successful outcome for corporate actors and for developed countries. However, this does not necessarily imply that there are no benefits for developing countries to be derived from the implementation of the TRIPS Agreement. The TRIPS Agreement states that there are different economic benefits that can be expected from the introduction of stronger IPR standards. First, the TRIPS Agreement postulates that multi-national corporations, which have intellectual property portfolios, should increase foreign direct investment once they realise that their intellectual property assets are more secure. Secondly, a more secure legal framework should lead to increased levels of transfers of technology, know-how and expertise, thereby contributing to local economic growth. Thirdly, higher levels of protection should stimulate local innovation in relevant fields. And, finally, the TRIPS compliance should reduce the threat of bilateral sanctions, in particular from the US.

Pro tempore, it is difficult to provide an empirical assessment of the impact of the TRIPS Agreement on economic development because developing countries started implementing the rules laid down in the TRIPS Agreement since 2002 only. However, several points can be mentioned. First, there does not seem to have been a correlation between the level of intellectual property protection and flows of foreign direct investment (Matthews 2004). Secondly, intellectual property protection can only lead to useful transfers of technology, if the basic economic infrastructure of developing countries is ready to receive such technology. This may be the case in bigger countries like the US and the European landscape but is not the case in developing countries. Thirdly, the contribution of higher protection for intellectual property assets can only foster local innovation of the type that would benefit from patents, if there is sufficient infrastructure.

On the whole, there is a widespread acknowledgement that there are few, if any, benefits for developing countries like India even in the long-run[44]. Further, there remain significant uncertainties as to the benefits that developing countries can expect

to reap from the existing TRIPS Agreement in the medium and long term. It might, therefore, be expected that the TRIPS Agreement makes significant concessions to developing countries as has been the practice in GATT and as agreed in some other Uruguay Round Agreements[45]. In fact, the TRIPS Agreement gives little flexibility to member states as well as developing countries to implement commitments in a way suited to their socio-economic needs.

However, first, the preamble specifically recognises the special situation of least developed countries and the need to give them sufficient flexibility in implementing their TRIPS commitments. It also recognises that development and technological progress are two of the particularly relevant public policy objectives of IPR system that countries may wish to emphasise. Secondly, there are a few substantive provisions that are directly or indirectly favourable to developing countries. This includes the provision concerning plant variety protection of Article 27(3)b, as mentioned earlier. It also includes Article 66(2), which recognises the need to take specific measures to promote technology transfers to least developed countries. In both these cases, concerned countries have, however, found it difficult to take advantage of the flexibility, which will be discussed later in this chapter. Thirdly, one of the main concessions granted to developing countries has been at the level of implementation deadlines. All countries take similar commitments, but some get a longer period to prepare implementation. Implementation of the common minimum standards of protection was, thus, scaled since the inception of the TRIPS Agreement. Developed countries had one year from the entry into force of the Agreement to put their systems in full compliance with their commitments, developing countries had five years and least developed countries, ten years. A few more specific cases were taken into account both in the original agreement or later on (cited in Cullet 2005), for example, medical patents for least developed countries. In this case, the Doha Ministerial Conference agreed to extend the deadline by another ten years to 1 January 2016[46]. This was confirmed by the Council for TRIPS in 2002[47].

Implementation and Further Negotiations

Negotiating states adopted a package deal in 1994, which paved the way to the establishment of the WTO. There were, however, a number of issues, which had not been resolved in the context of the Uruguay Round. These unresolved issues were sometimes left aside for future negotiations, but there were also several cases where the treaties adopted included provisions calling for further negotiations on specific issues and a number of elements that required to be specified at the level of implementation.

Article 66(2) calls for developed states to take steps to foster technology transfer to least developed countries without specifying how this is to be achieved and how far developed countries must go in helping least developed countries. Implementation of this provision has not been very effective and has not been to the satisfaction of least developed countries[48]. The TRIPS Council – the body charged with monitoring the operation of the TRIPS Agreement – ended up adopting a decision calling on developed countries to provide annual reports on the measures they have taken up and the actual technology transfers involved[49].

There are other cases where the TRIPS Agreement was the result of a compromise that some countries were hoping to see modified. In this case, there is an in-built negotiating agenda within the Agreement, which forces states to go back to the negotiating terms and conditions. This is, for instance, the case of Article 27(3)b of the TRIPS Agreement, which imposed on member states the renegotiation of the provisions allowing the exclusion from patentability of plants and animals as well as the possibility to introduce a *sui generis* regime for the protection of plant varieties. In this specific case, the negotiations, which were due to take place in 1999, have been going on since then, as no consensus on the revision of Article 27(3)b has been found. The re-negotiation of Article 27(3)b has, in fact, become part of a broader agenda in the wake of the launch of new trade negotiations at the Doha Ministerial Conference. This has led to the negotiations on Article 27(3)b being linked to the broader question of the relationship between the Biodiversity Convention and the TRIPS Agreement as well as the question of the protection of traditional knowledge[50].

More broadly, one of the characteristics of WTO treaties is that they are evolving treaties. This is visible at two different levels. First, at the WTO-wide level, the Uruguay Round of Trade Negotiations was only one among a series of such rounds. The establishment of the WTO, as a result of the conclusion of the Uruguay Round, did not imply an end to trade negotiations, and, in fact, the Doha Ministerial Conference proposed substantive negotiations, which have been taking place since 2003. Secondly, at the level of the TRIPS Agreement, Article 71 provides for amendments to the Treaty. While amendments generally require approval of all member states of the WTO, Article 71(2) provides for a simplified procedure where higher levels of intellectual property protection have been accepted in other international treaties to which all members of the WTO are parties. In other words, this could open the door for the adoption of stronger IPR standards in WTO, though they are negotiated under the auspices of the TRIPS Agreement.

The Doha Ministerial Conference and the Declaration on Health

The 2001 Ministerial Conference held at Doha was an important landmark for the WTO. It resulted in the adoption of a framework for further trade negotiations, a declaration on implementation-related issues and a declaration on access to medicines within the context of the TRIPS Agreement (Doha Health Declaration)[51]. The Doha Health Declaration is particularly significant because it constitutes an instance where the Ministerial Conference had to confront issues concerning the implementation of the TRIPS Agreement in developing countries.

The adoption of the Doha Health Declaration was the result of the intense health crises faced, in particular by most sub-Saharan countries affected by HIV/AIDS and the fact that medicines, although available, were highly expensive. It can, to a large extent, be treated as a response to the specific crisis that was most visible at the time rather than as a broader solution to problems of access to drugs in developing countries. In other words, the Declaration is, in large part, a response to the fact that drugs to address the HIV/AIDS condition were available but at completely unaffordable prices for most patients in developing countries.

The significance of the Declaration stems from its recognition that the existence of patent rights in the health sector does not stop states from taking measures to protect public health. More specifically, it affirms that TRIPS 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'[52]. The Declaration is important for developing countries insofar as it strengthens the position of countries that want to take advantage of the flexibility within TRIPS Agreement. It does not open new avenues within TRIPS but confirms the legitimacy of measures seeking to use, to the largest extent possible, the in-built flexibility found in TRIPS. Further, it grants least developed countries a further ten years to implement their patent obligations with regard to medicines. While the Doha Health Declaration has contributed to softening the tone of international debates concerning access to medicines in the context of TRIPS, it stops short of addressing the fundamental question of the relevance and need for patents on drugs in developing countries and in particular in least developed countries. Some of the reservations for developing countries concerning genetic biodiversity are as follows:

(a) The Northern (developed) countries are gene poor while those in the South (developing) are gene rich [see Table 1]. The North is technology rich while the South is technology poor. The Green Revolution and current biotechnology research have widened this gap.
(b) The importation of advanced breeding lines from the North into the South has replaced traditional landraces but contributes to a greater yield in the short-run if supplied with enough inputs that causes unstable and/or lower yield in the long-run (Malik and Zafar 2005).

Table 1 Centre of Origin of Crops

S. No.	Centre of origin	Crops
1	Southwest Asia (Fertile Crescent)	Cereals, legumes (peas, lentils, barley) and diploid cotton
2	Africa	Barley, emmer, flax, chickpea, pea, lentil, lettuce, onion, fig, grape, olive, millets, sorghum, African rice, yams, coffee
3	China and Southeast Asia	Millet, vegetables, soybeans, rice, citrus, tea Bananas, mangoes, coconut, sugar cane
4	America (Mexico, South America)	Maize, potato, sweet potato, bean, tomato, chili pepper, peanut, bottle gourds, cucurbits, sunflower, cotton, pineapple, papaya, avocado, tobacco, cassava (manioc), cacao (source of chocolate),

	vanilla, cashew, pecan, Brazil nut, ornamental flowers (*Zinnia*, marigold, *Fuchsia*, *Canna*, *Nicotiana*, *Salvia*)

Source: World Atlas of Biodiversity, UNEP World Conservation Monitoring Centre, USA, 2002.

Notes and References

[1] See UNCTAD, 'The role of the patents system in the transfer of technology to developing countries, UN Doc TD/B/AC 11/19 (1974).
[2] See, for example, Duncan Matthews 2002.
[3] Ministerial Declaration on the Uruguay Round, 20 September 1986, Multilateral Trade Negotiations, Doc MINDEC.
[4] Concerning the role played by unilateral measures in softening the opposition of opponents to the TRIPS Agreement.
[5] Duncan Matthews 2002.
[6] See General Agreement on Tariffs and Trade: Multilateral Trade Negotiations, Final Act Embodying the Results of the Uruguay Round of Trade Negotiations, Marrakech, 15 April 1994.
[7] Agreement Establishing the World Trade Organisation, Marrakech, 15 April 1994, 33, *International Legal Matters* 1144 (1994) [hereafter WTO Agreement].
[8] See General Agreement on Tariffs and Trade.
[9] Understanding on Rules and Procedures Governing the Settlement of Disputes, 33 *International Legal Matters* 1226 (1994) [hereafter Dispute Settlement Understanding]
[10] Another feature of the dispute settlement system is that it is subject to tight time limits and usually the whole procedure is completed within eighteen months.
[11] Article 7, Dispute Settlement Understanding.
[12] Article 17(6), Dispute Settlement Understanding.
[13] Article 22, Dispute Settlement Understanding.
[14] Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakech, 15 April 1994, 33 *International Legal Matters* 1197 (1994) [hereafter TRIPS Agreement]
[15] Article 1, TRIPS Agreement.
[16] Section 3, Patents Act 1970.
[17] For instance, Seeds and Plant Varieties Act, Laws of Kenya, Chapter 326, adopted in 1972 but only implemented after 1994.
[18] Respectively Articles 42, 51 and 61, TRIPS Agreement.
[19] Article 2, TRIPS Agreement.
[20] Article 1, General Agreement on Tariffs and Trade 1947/1994.
[21] On parallel imports, see generally Frederick M. Abbott, 'First Report (Final) to the Committee on International Trade Law of the International Law Association on the Subject of Parallel Importation', *Journal of International Economics and Law*, 607 (1998).

[22] See, for example, P. Danzon, 'Differential Pricing for Pharmaceuticals: Reconciling Access, R&D, and Intellectual Property' (CMH Working Paper Series Paper No. WG2: 10, 2001).
[23] *Ibid.*
[24] World Health Organisation and World Trade Organisation Secretariats, Report of the Workshop on Differential Pricing and Financing of Essential Drugs, 8-11 April 2001, Hosbjor, Norway. See also Council Regulation (EC) No. 953/2003 of 26 May 2003 to Avoid Trade Diversion into the European Union of Certain Key Medicines, 26 May 2003.
[25] John H. Barton, 'Differentiated Pricing of Patented Products' (CMH Working Paper, Series Paper No. WG4: 2, 2001).
[26] Paragraph 5 (d), Declaration on the TRIPS Agreement and Public Health, Ministerial Conference – Fourth Session, WTO Doc WT/MIN(01)/DEC/2 (2001) [hereafter Doha Health Declaration]
[27] World Trade Organisation, Communication from India, WTO Doc IP/C/W/195 (2000).
[28] Article 27 (1), TRIPS Agreement.
[29] The basic original understanding of patent law was that products of nature could not be patented and that patentability should be reserved to the products of human inventiveness. The first major change to this distinction was the adoption of Plant Patents Act 1930 in the US that provides protection for inventors or discoverers who asexually reproduce distinct and new plant varieties (Plant Patent Act 1930). Between 1930 and 1980, the main developments that occurred in the field of IPR protection were the development of plant breeders' rights in Europe and the US as an alternative form of intellectual property protection for plant varieties. The year 1980 was a landmark in the history of the development of life patents. The US Supreme Court accepted the patentability of artificially created life forms, thereby paving the way for the rapid development of the genetic engineering industry.
[30] Article 27(3)b, TRIPS Agreement.
[31] The concept of farmers' rights was developed partly in reaction to the introduction of IPR in agriculture. Farmers' rights are, therefore, closely linked to patents and plant breeders' rights. However, due to a lack of consensus among states, the concept is still being developed at the international level and the limited recognition at the international level does not include the rights of farmers over their intellectual assets. Historically, the concept of farmers' rights arose as a result of international debates on the asymmetric benefits dervied by donors of plant genetic resources and donors of technology, as well as the lower status ascribed to farmers' activities compared to commercial plant breeding. While commercial plant breeding was increasingly benefiting from the protection offered by plant breeders' rights or other IPR, there was no system of compensation or incentives for farmers (Esquinas-Alcazar 1996). The basic premise for the introduction of farmers' rights was the creation of incentives for the equitable sharing of benefits arising from the use of plant genetic resources and for the sustainable use and conservation of these resources.
[32] Article 65(4), TRIPS Agreement.
[33] Article 65(5), TRIPS Agreement.
[34] Article 62, TRIPS Agreement.

[35] The question of the introduction of a direct or indirect requirement for patent applications to disclose the source of the knowledge or biological resources they have used in the claimed invention has been at the centre of significant debates in international fora. At present, international patent treaties do not include specific requirements to disclose the origin of the resources or knowledge from which the protected invention is derived. This was not the object of much debate before biotechnologists started using biological or genetic resources more frequently in products or processes for much patent protection is sought. The question of a disclosure requirement is important from the point of view of the relationship between the patent system and traditional knowledge. While prior art searches by patent offices may be enhanced by better access to available knowledge, a disclosure requirement would reduce the workload of patent offices by helping them to focus their searches more effectively. Further, disclosing the origin of knowledge or biological resources used in an invention provides an easier yardstick to judge whether an invention has benefited from the existence of traditional knowledge. While the disclosure of the geographical origin is as such novel, patent applications already include significant "disclosure" requirements that include not only the basic disclosure of the invention under all patent laws but also in the case of inventions involving microorganisms, the actual deposit of the microorganism itself (see, for example, Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, Budapest, 28 April 1977).
[36] Article 28, TRIPS Agreement.
[37] Article 28(2), TRIPS Agreement.
[38] Article 33, TRIPS Agreement.
[39] Article 30, TRIPS Agreement.
[40] *Canada: Patent Protection of Pharmaceutical Products*, Report of the Panel, 17 March 2000, WTO Doc WT/DS114/R.
[41] Compulsory licensing for a whole class of products such as all medicines would not be acceptable.
[42] Adequate remuneration is below the cost of a normal licence since there would be no need for compulsion otherwise. See, for example, Jayashree Watal, *Intellectual property rights in the WTO and developing countries* (New Delhi: Oxford University Press, 2001).
[43] *Ibid.*: 320.
[44] Nuno Pires De Carvalho. 2002. *The TRIPS regime of patent rights*. London: Kluwer Law International. Here, Carvalho argues that higher standards of protection for patents are a trade-off that ensures that developing countries are entitled to lower tariffs on their exports to developed country markets.
[45] See, for example, Article 6, Agreement on Agriculture, Marrakech, 15 April 1994, in World Trade Organisation, *The legal texts: the results of the Uruguay Round of Multilateral Trade Negotiations* (Cambridge: Cambridge University Press, 1999).
[46] Paragraph 7, Doha Health Declaration.
[47] Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products, Decision of the Council for TRIPS, 27 June 2002, WTO Doc IP/C/25. See also Least-Developed Country Members: Obligations under Article

70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products, Decision of the General Council, 8 July 2002, WTO Doc WT/L/478.

[48] See, for example, Constantine Michalopoulos, *Special and Differential Treatment of Developing Countries in TRIPS* (Geneva: Quaker United Nations Office, 2003).

[49] Decision of the Council for TRIPS, Implementation of Article 66.2 of the TRIPS Agreement, 19 February 2003, WTO Doc IP/C/28.

[50] See Paragraph 19, Ministerial Declaration, WTO Ministerial Conference, Fourth Session, Doha, 14 November 2001, Doc WT/MIN(01)/DEC/1 [hereafter Doha Ministerial Declaration].

[51] See respectively, Doha Ministerial Declaration, Implementation-Related Issues and Concerns, WTO Ministerial Conference, Fourth Session, Doha, November 2001, Doc WT/MIN(01)/17 and Doha Health Conference.

[52] Paragraph 4, Doha Health Declaration.