
Patents: An Indian perspective

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Introduction

In this chapter, I share my recollections as a representative of India from 1989–90 in the TRIPS negotiations, focusing on India's defensive interests with respect to the patent provisions of the TRIPS Agreement. I also include some relevant background information, as well as some recollections of my interaction with other parties to the TRIPS negotiations.

My role in the TRIPS negotiations began in May 1989, when I was a mid-level official in the Ministry of Industry, Department of Industrial Development. My then supervisor in the government, A.V. Ganesan,² chose to have me specialize in IPRs in order to fill a gap in our knowledge, after India was placed on the United States' Special 301 watch list in April 1989 for the first time, and after the mid-term ministerial review decision in Geneva later that month. My active engagement in the negotiations began in mid-May 1990 when I was sent by the then Secretary of the Department of Industrial Development³ to Geneva on the eve of the presentation of the draft legal text jointly submitted by 14 developing countries.⁴ From then onwards, up until the Brussels ministerial meeting in December 1990, by which time most of the TRIPS text was drafted and only some key political issues remained (see Adrian Otten, chapter 3), it became my task, under the close supervision of my seniors in government⁵ to safeguard India's interests as best I could, particularly with respect to the patent provisions. As it was for many other authors in this volume, participating in the TRIPS negotiations was a particular highlight of my professional life.

Background to India's negotiating position on patents

A.V. Ganesan provides the reader with much of the background to India's negotiating position on TRIPS (see chapter 11), and his account should ideally be read before this one.⁶ He eloquently describes the process of the revision of the

Indian patent law in 1970, the domestic opposition to India even joining the Paris Convention for the Protection of Industrial Property due, in large part, to the interests of the generic drugs industry, and the general public opinion against the grant of product patents for pharmaceuticals for fear of sharply increased prices.

In retrospect, India suffered from several unique drawbacks in the Uruguay Round of multilateral trade negotiations. First, it had few or no offensive trade interests at the time. India's trade-to-GDP ratio – an indicator of integration into the global economy – was low, as it had followed the policy of “self-reliance” in the decades since its independence from colonial rule in 1947.⁷ Even in the textiles sector, where there was hope of increased exports for many Asian countries post-Uruguay Round, India was not seen to be as competitive as others in the region. The joke at the time was that India's bureaucrats were more efficient than its textile exporters, since the large textile quotas they negotiated with major markets such as the European Communities (EC) and the United States were, more often than not, not fully utilized.

Second, India's patent law had undergone revision in 1970 after a long, arduous process through several high-level committees and parliamentary debates. There was a politically powerful group of both left-leaning and right-leaning politicians, academics and even legal luminaries, not to mention India's growing generic drugs industry, who believed that no change should be made to India's patent law and strongly opposed India even joining the Paris Convention. In this regard, the commercial interests of the Indian generic drugs sector coincided with the interests of Indian patients or, more generally, with what was perceived to be national or public interest. This is because in India medicines, including prescription medicines, were and are still paid for out-of-pocket by the patient, making consumers very price-conscious in their choices. While it is common to have as many as 50 to 60 Indian companies producing identical generic versions of a popular medicine, most of the market is held by the top three or four well-known companies, among whom there is intense price competition. Several economic studies have tried to predict price and welfare effects of the introduction of product patents for pharmaceuticals in India. While the numbers vary according to the models used, almost all studies predicted sharp increases in the average price of patented medicines.⁸

However, recent empirical work does not corroborate these fears, showing instead that there is competition even in products where patents have been granted.⁹ While the authors do not explain this result, this may well be the result of Section 11A of the revised Patents Act. This provision allows those who had made

significant investment and were already producing and selling medicines for which patent applications were filed from 1995 onwards in the so-called mailbox (also called the “black box”, since these applications were kept secret) to continue to produce and sell the product at the same scale as before upon payment of reasonable remuneration to the patent owner.¹⁰ In addition, there has been much patent validity litigation in India, with several companies being present even in patented drug markets, particularly in commercially valuable ones. Further, innovator companies have been careful to use differential pricing or voluntary licensing strategies in India, especially after India granted its first compulsory licence. India's first and only compulsory licence was granted in 2012 for a cancer drug on grounds that the price was unaffordable and the patent owner was not supplying the market through imports nor working the patent adequately in India.¹¹ The threat of compulsory licences could be another factor working in favour of lower prices than anticipated. It is hard to predict whether the combination of price sensitivity of demand and such patent strategies will continue to keep the Indian market competitive in future for new generations of medicines.

Be that as it may, during my time in the Uruguay Round negotiations - 1989-90 - no government was willing to risk supporting changes to the patent law, in particular to accept product patents. This was compounded by the fact that, unlike other developing countries, particularly those in Latin America, India had few economically significant demands to make in other areas of the Uruguay Round negotiations in exchange for concessions on TRIPS.

I recall that, given this background, the Indian delegation to the Brussels ministerial meeting in December 1990 was not entirely clear on how to proceed on patentable subject matter. When a breakdown in agriculture negotiations caused a disruption of the Brussels ministerial meeting itself, no delegation was as relieved as the Indian one, as no IP agreement needed to be defended on our return home. That joy was short-lived, as the United States initiated bilateral negotiations to pursue its IP objectives. The counterfactual to the failure of the TRIPS negotiations was always going to be bilateral negotiations, which are generally known to be much more difficult for the weaker of the two parties.

Broader international background to negotiations in the area of patents

It is important to recall the broader international context at the time of the launch of the Uruguay Round. Developing countries had just failed in their attempt to weaken the Paris Convention, particularly with respect to patents. The proverbial

straw that broke the camel's back was the demand of developing countries that compulsory licences be exclusive, meaning thereby that the patent owner be excluded from exploiting the invention in markets where a compulsory licence has been issued.¹² As is well known, this was one of the factors that led to the shifting of forum from WIPO to GATT and to the now-famous prefix "trade-related aspects of" before "intellectual property rights". This proved to be an unexpectedly capacious formula: the only non-trade-related aspect of IPRs that I remember being mentioned during my time in the TRIPS negotiations was moral rights in the context of copyright.

The literature in economics supports the idea that patents are uniquely important for the pharmaceuticals and specialized chemicals sectors. This has been shown through multisectoral industry surveys conducted well before the TRIPS negotiations, focusing on innovation in the United Kingdom and the United States, and repeated over the years in the United States and in other countries.¹³ It is clear that the pharmaceuticals sector disproportionately relies on patents to capture returns to research and development (R&D), unlike other sectors which rely more on lead time, complementary assets, trade secrets and other means to do so.¹⁴

It is therefore no surprise that the pharmaceuticals industry was the main non-state actor influencing the *demandeurs'* position on the patents section of the TRIPS Agreement.¹⁵ The key *demandeurs* were the United States, EC, Japan and Switzerland. The "Quad" that led the Uruguay Round was comprised of Canada, the EC, Japan and the United States. As we will see below, Canada's presence in the Quad was important in moderating the demands of the other three, as in trying to protect its generic drugs industry's interests, it supported those in other countries as well.

Others have noted in this volume and elsewhere that external factors such as the broader global acceptance of market-based policies and the increasingly unipolar nature of world politics formed an important background to the TRIPS negotiations. As the negotiations proceeded and as the United States Trade Representative notched up more and more bilateral successes in persuading the US' trading partners to agree to "effective and adequate" standards on IPRs,¹⁶ especially in the pharmaceuticals sector, the greater or more expansive became the demands of its industry.

It was thus that, from initially demanding the introduction of product patents in all fields of technology, the United States upped the ante in 1991 to demand "pipeline protection" from 1986 onwards, the date of the launch of the Uruguay Round.

This meant that all pharmaceutical inventions for which patent applications were filed and granted in the United States and other jurisdictions from 1986 onwards would be protected for the balance of the patent term in the jurisdictions of all parties to the negotiations. While the United States did ask for transitional protection in its spring 1990 submission,¹⁷ this found no support in any other Quad draft legal text submission in early 1990.

The United States, EC and others argued that the economic impact of the introduction of pharmaceutical product patents was delayed by ten or so years – the average time from the date of patent application to the marketing of patented pharmaceuticals – due to the extensive regulatory requirements of clinical trials, and hence they demanded protection from about ten years earlier than the date of application of the TRIPS Agreement.¹⁸ This pipeline protection demand remained an important one up to the end of the negotiations in 1993 (see Catherine Field, chapter 8). India and other textile-exporting countries were keen on parity between the TRIPS Agreement and the Agreement on Textiles and Clothing, and asked for a ten-year clean transition period without such pipeline protection. The United States and others argued that this would delay the economic impact of the TRIPS Agreement for the pharmaceuticals sector by 20 years, which was unacceptable. Even the Swiss compromise pipeline protection proposal – namely, to grant protection to all pharmaceutical and agricultural chemical products for which patents were filed from 1 January 1995 for the balance of the patent term after the expiry of the transition period, and the interim grant of exclusive marketing rights during the transition period – which was accepted by India and others in December 1991, did not satisfy the United States fully since it reiterated its original demand in 1993, although without success. The 1991 compromise that is reflected in what is now TRIPS Article 70, paragraphs 8 and 9, left India – and other countries that did not yet have product patents for pharmaceuticals – with not even a day of a transition period for the most sensitive sector in the TRIPS negotiations, since patent applications for pharmaceuticals and agricultural chemicals had to be permitted to be filed from 1 January 1995 onwards (see A.V. Ganesan, chapter 11). A similar outcome would have occurred had India accepted pharmaceutical product patents in the TRIPS Agreement without either a transition period or pipeline protection.¹⁹ However, this outcome may, in retrospect, be seen as a compromise, given India's initial demand for a ten-year clean transition period – with its economic effect only kicking in after 20 years – and the United States' demand for pipeline protection for approximately minus ten years – with economic effect kicking in from day one.

Differences among developing country delegations

I have elsewhere contrasted the TRIPS negotiations with the WTO negotiation of the Doha Declaration on the TRIPS Agreement and Public Health, and looked at the reasons for the relative failure of developing countries in TRIPS negotiations and their nearly full victory achieved in the Doha Declaration.²⁰ My main conclusion was that the united front presented by developing countries in the Doha negotiations, as well as external factors such as the moral imperative of providing a reasonable solution to tackle the HIV/AIDS pandemic then ravaging the poorest populations in the world, helped these countries succeed in obtaining their objectives. Clearly, developing countries had differing priorities in the Uruguay Round and did not share common defensive objectives in the TRIPS negotiations.

The text of the document submitted by 14 developing countries in May 1990, was largely prepared by the United Nations Conference on Trade and Development (UNCTAD) Secretariat, although it was cleared in the capitals of the 14 countries.²¹ However, I recall that after its initial presentation by the delegate from Peru on 14 May 1990, it soon became an orphan: in other words, it became a text of which none of the 14 signatories really took ownership.

There were many reasons for this lack of ownership, the most important being that the text itself was not authored by anyone present in the negotiations. It was also, by its collective nature, a compromise text full of contradictions. I recall that on the very day of its presentation, other delegations, notably that of Hong Kong, expressed extreme dissatisfaction, claiming that it provided no guidance whatsoever on what its proponents wanted in the negotiations.

The text was presented in two parts: Part I was titled “Intellectual Property and International Trade”, and only dealt with trade in counterfeit and pirated goods. This part consisted of nine articles and was meant to be the draft TRIPS agreement to be lodged in the GATT from the point of view of these 14 countries. However, Part II on standards of IPRs was also added for safe measure, in order to counter the draft legal texts already submitted by industrialized jurisdictions such as the EC, the United States, Switzerland and Japan. This part was full of further contradictions. For example, Article 4, titled “Patent Protection”, proposed in its first paragraph that patent protection shall be available for inventions in all fields of technology, with five quite reasonable exclusions – most of which find place in the TRIPS Agreement – while adding in its second paragraph further open-ended optional exclusions on grounds of public interest, national security, public health or nutrition. Similarly, provisions on compulsory licences find mention in multiple

provisions, namely Articles 5, 6 and 13, while remedies for anti-competitive practices find mention in Articles 5, 13, 15 and 16.

By about six months after its submission, at the time of the Brussels text,²² the section on patents had evolved a lot from the text of the document submitted by the 14 developing countries and only largely political points remained for ministers to resolve, such as the scope of the subject matter of protection and the term of protection. By this time, India stood largely isolated in its opposition to product patents for pharmaceuticals. India's erstwhile comrade in arms, Brazil, had already, in early 1990, accepted that it would have to concede on this point in order to protect its larger trading interests in agriculture (see Piragibe dos Santos Tarragô, chapter 12). The Brazilian delegation openly conceded this point in the informal TRIPS negotiations in the autumn of 1990, well before the Brussels meeting, leaving no doubt that this issue was not a "make-or-break" one for Brazil. For Argentina, too, provisions in the TRIPS Agreement were mere bargaining chips to obtain its goals in the agriculture negotiations (see Antonio Gustavo Trombetta, chapter 13). However, both delegations continued to battle out the details of the provisions, and their participation proved invaluable to obtaining some concessions in wording in the patents section.

Differences among developed country delegations

Many subsequent commentators and analysts have maintained that the TRIPS negotiations were essentially a North–South negotiation, in which the South was largely ineffective in defending its position or traded off the entire IPRs sector wholesale in pursuit of gains elsewhere. The truth was that on a lot of issues, including in the politically sensitive areas such as patents, trade secrets and test data protection, there were North–North differences that persisted until the end. Developing countries such as India participated in negotiating each provision of the TRIPS Agreement, contrary to certain accounts. They seized opportunities that were offered on account of these intra-North differences, wherever they became aware of such discord. One such case is described in the next section. In many cases, however, the North presented a united front and their differences were either negotiated away bilaterally or aired in informal gatherings such as the Friends of Intellectual Property group to which, to the best of my recollection, perceived hard-core opponents such as Argentina, Brazil and India were never invited (see Thomas Cottier, chapter 4).

In those days, for developing countries with one- or two-person delegations dealing with such a new and complex subject as IPRs, it was not easy to research

and comprehend all the nuances of the laws and practices of even the key developed countries. UNCTAD had hardly any IPR specialists on staff, although there were brilliant international law scholars who had helped prepare the submission of the 14 developing countries.²³ Local expertise in IP policy, as opposed to IP administration, was also rare in developing country capitals. Domestic interests typically wanted the government to resist all demands but offered no realistic compromise solutions. Such expertise was practically absent in the Geneva missions of developing countries, especially in the area of patents. Moreover, during the latter half of 1990, when the negotiations continued with only short breaks, many developing country governments, including that of India, chose, for financial reasons, to keep capital-based delegates in Geneva for months on end, making consultations with local experts difficult.²⁴

Clearly, the core demand for stronger IPR protection worldwide came from private sector entities in certain sectors of the EC, Japan and the United States. The document, *Basic framework of GATT provisions on intellectual property*, jointly produced by the industry associations of these three jurisdictions,²⁵ largely formed the basis for the draft TRIPS legal texts submitted by these parties in early 1990, although earlier submissions to the TRIPS Negotiating Group made by these parties also echoed their essential demands.

A close reading of the different submissions made by the EC, Japan and the United States beginning in 1987 shows nuanced differences in emphasis and wording, particularly with respect to compulsory licensing. It also shows that these Quad members did not originally have such high ambitions. For example, initial submissions made by the United States on inadequacies in existing national IPR systems speak only of exclusive compulsory licences and non-respect of the Paris Convention standards.²⁶ It seems that, for all three, the level of ambition on the working requirements and compulsory licences in 1987-8 was only to get all countries to adhere to the Paris Convention 1967 standard of time limits before issuing a compulsory licence or direct non-revocation of patents on grounds of non-working. Even in later submissions, when the United States wanted to limit the grounds for compulsory licences to declared national emergency and adjudicated violation of antitrust laws, while not accepting such limitations for government use, the only prohibition the United States sought for non-working of patents was against revocation. By implication, the United States might, at this stage – given the views of the other members of the Quad – have reconciled itself to compulsory licences for non-working, provided Paris Convention 1967 rules were respected.²⁷ Later, in 1991, the United States pushed for language on non-discrimination on the enjoyment of patent rights through importation or local

production, which is now in Article 27.1, although this language has been subject to different interpretations by commentators.²⁸

Not surprisingly, Canada, though one of the Quad members, did not submit a draft legal text in the spring of 1990. In its submission of October 1989 on Standards for Trade-related IPRs, Canada argued for strengthening the patent compulsory licensing disciplines in the Paris Convention only insofar as to require transparency, non-exclusivity, adequate compensation and access to judicial review.²⁹ Canada's extensive use of compulsory licences on pharmaceutical patents in the 1980s, with a uniform royalty rate of 4 per cent, is now well-documented.³⁰ Canada was indeed the target of some of the demands of the EC, Japan and the United States in the patents area. Yet, quietly and, in my view, effectively, it played an important role in moderating the demands of other Quad members, particularly in the pharmaceuticals sector, with respect to both patents and test data protection.

Even while the United States was the strongest *demandeur* for higher IPR standards in the TRIPS Agreement, particularly in the patents area, it had laws and policies that could not be easily changed. This provided a useful basis for me to consider how to maintain the compulsory licence provisions in the Indian law.

India's role in the negotiations of compulsory licences

By autumn 1990, the overall dynamics of the negotiations made it inevitable that product patents for pharmaceuticals would have to be conceded at a political level in the forthcoming Brussels ministerial meeting. Given the inevitability of the acceptance of product patents for pharmaceuticals (since leaving the GATT was not really an option for India), my focus was to save India's compulsory licence/licence of right system to the extent possible.

India's 1970 Patents Act had four systems of non-voluntary licences in place:

- Use by or on behalf of government for purposes of government, including public interest
- Compulsory licences on grounds of non-working or that the reasonable requirements of the public have not been met, including making the patented invention available at reasonable terms
- Compulsory licences for dependent patents

- Automatic availability of “licences of right” on patents relating to food or drugs or medicines or chemicals on the expiration of three years from the date of grant of the patents.

Around October 1990, India, led by its Ambassador,³¹ initiated an alliance with other Commonwealth countries that had very similar wording on compulsory licences and use of patents by governments. These laws were based on the United Kingdom patent law, hence the commonality of interest. The idea was to ensure that as much as possible of our respective national provisions be retained in the final agreement. This alliance worked well and, for the first time, “Friends of Intellectual Property”, such as Australia and Hong Kong, spoke in one voice with India, espousing grounds for compulsory licences such as when the “reasonable requirements of the public are not met”. On the government use provision we had less difficulty, as even the United States was on our side and did not want any restriction on grounds for such use. Suddenly India, which had been seen as sitting at one extreme end of the spectrum with little support even from other developing countries, was seen as having credible friends, even if on a limited issue. Alas, this alliance proved very short-lived – no more than a fortnight long – for reasons best known to our Commonwealth allies.

Almost overnight, India became isolated in its opposition to limiting the grounds for compulsory licences to remedy a declared national emergency or adjudicated cases of anti-competitive practices. The government use provision remained broad and had the support of the United States as before. As there was a real danger of the text getting set in this way, I began to contemplate alternatives. Not being the age of the Internet, it was not easy to research the reason why the United States supported the government use provision.

Scouring the draft legal texts, I found the EC approach in its 29 March 1990 submission to be most suitable, as it did not restrict the grounds for compulsory licences but only contained a chapeau stating,

Where the law of a contracting party allows for the grant of compulsory licences, such licences shall not be granted in a manner which distorts trade, and the following provision shall be respected ...³²

I also looked at the United States’ submission of 11 May 1990 and found some similar language.³³ For example, some of the conditions in Article 27 of that document, such as that each case shall be considered on its individual merits, were common with the EC submission.

Before drafting any proposal to the informal TRIPS negotiating group, I had informally checked the ideas I was contemplating with Mogens Peter Carl of the EC and John Gero of Canada.³⁴ Mogens Peter Carl, with whom I had spoken on the telephone from Geneva, said he could consider this approach in principle but would, of course, like to see the proposal in writing and could not commit. John Gero, whom I met in person, also supported the approach in principle. He was the one who drew my attention to the existence of 28 USC Section 1498(a), which, as I later discovered, states:

Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture. (...) For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States.

This wording explained to me why the United States delegation was on the same page as India on government use and I sought to exploit this difference of position with that on compulsory licences. Late one night, with the permission of the head of my delegation, I drafted a provision combining the two separate provisions on compulsory licences and government use under one article titled "Use without authorization of the right holder". The term "right holder" was used in the initial proposal since India wanted this provision to apply to compulsory licences for other types of industrial property, such as industrial designs and lay-out designs for integrated circuits. In order to establish credibility, we conceded that the remuneration should be "reasonable" in all cases – in other words, while the use would be without the authorization of the right holder, he or she would be reasonably remunerated. Another upfront concession was giving up the demand for exclusive compulsory licences, seen as a major concession in the light of the Paris revision process referred to above.

India scored a major negotiating victory when the Indian non-paper or room document, submitted on an ad-referendum basis the next day, was accepted as a basis for further negotiations after it gained the support of the EC and Canada,

as well as - unexpectedly - of Japan. It might have been that the US government use provisions were hurting Japanese industry. This led to the isolation of the US delegation within the Quad on this issue.

As anticipated, in the further course of the TRIPS negotiations, the US delegation could no longer insist on restriction of the grounds for compulsory licences. Instead it began to weaken this common text further to accommodate US laws. It proposed two types of exceptions to the listed conditions in what is now TRIPS Article 31: one, for public non-commercial use and two, for compulsory licences that are granted as a remedy in adjudicated cases of anti-competitive practices.

This explains why there are no restrictions on grounds for use without the authorization of the right holder in the TRIPS Agreement. Without a doubt, this could not have happened without the active support of the delegations of EC, Canada and Japan. The US delegation introduced the text of what is now in TRIPS Article 31(a), that each case of such use would be considered on its "individual merits". This was meant to tighten the provision for other countries, while allowing US government agents and contractors to use patents for public non-commercial purposes within the wording of what is now TRIPS Article 31(b).

Other delegations helped in making the conditions to be followed in what is now TRIPS Article 31 even less restrictive. My recollection is that Australia wanted review to reside with a distinct higher authority and not necessarily with a court of law, a provision that India has used to establish the Indian Intellectual Property Appellate Board. Argentina wanted only the legal validity of the authorization to be subject to higher, independent review.³⁵ Canada weakened the condition on exports by proposing the addition of the word "predominantly" in TRIPS Article 31(f). Without restrictions on the grounds for such use without the right holder's authorization, some of the conditions become far less strict than they seem.³⁶

On the question of whether or not the Indian automatic licence of right system for food and pharmaceuticals could be saved with this proposal, my reasoning was that the provision contemplated only "use" without authorization of the right holder and not the "grant" of a licence. The Indian law did contemplate the Controller General of Patents Designs and Trademarks arbitrating the terms and conditions of the licence of right in the case of disagreement between the patent owner and the potential licensee. Such arbitration necessarily took place before "use" without authorization. However, the ceiling of 4 per cent royalty in the Indian law was unique and untenable – it was something that could be conceded as long as the remuneration was set by and renewed by national authorities, as was already the case.

There were some doubts about what “individual merits” of use could mean when there is no restriction on grounds for compulsory licences. At the time, I was reassured by GATT dispute settlement experts that, if India decided that certain sectors were of vital public interest, such as medical or food technologies, then the individual merits would require the authorities to determine whether the particular patent being considered for the grant of a compulsory licence belongs to these fields of technology or not. With this assurance, I believed at the time that the draft proposal I had submitted could save the broad contours of India’s licence of right system.

Subsequently, in 1991, the text of what is now Article 27.1 introduced the clause of non-discrimination in the grant and enjoyment of patent rights with respect to the field of technology and whether the patented product is imported or locally produced. This was meant to block the automatic licence of right systems such as the Indian one, and the compulsory “working” requirement in patent laws. There may have been creative ways around this provision when drafting legislation in India and, indeed, Canada showed the way with its “early working” or Bolar-type provision under its regulatory review requirements, which was adjudicated at the WTO in 2000, by making its provision technology neutral.³⁷

As for the working requirement, many countries’ laws, including India’s, continue to contain this provision without specifying, as some others have done, that importation would satisfy the working requirement. A WTO dispute case that the United States brought against Brazil in 2000 resulted in a mutually agreed settlement, and so there has been no express finding on whether such provisions are TRIPS-compliant or not.³⁸

At the time of the TRIPS negotiations, I was convinced by the arguments put forward by economists that it was undesirable and inefficient to make technology transfer dependent on compulsory patent-working requirements, when there are more effective policy variables that can be used.³⁹ Indeed, it is difficult to find an example of any country in modern times where such patent-working requirements, with their broad carve-outs for justifiable reasons of technical or economic feasibility, were the main pathway to industrialization or technology transfer. Since Brazil was keen to defend this requirement in the negotiations, given the historical sensitivities on this issue in that country,⁴⁰ India did not strain itself too much on this issue.

All in all, the TRIPS Agreement provision on compulsory licences and use by governments – unlike, for example, that on the term of patent protection – has not

only not led to harmonization of national patent laws but has not increased convergence nor improved coherence. In November 2001, WTO members adopted by consensus the Doha Declaration on the TRIPS Agreement and Public Health, which states in no uncertain terms in its paragraph 5(b) that “Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.” Importantly, this part of the Doha Declaration did not entail any amendment to the text of the TRIPS Agreement, because such freedom to determine the grounds for compulsory licences was already part of the original text (see Mogens Peter Carl, chapter 6). In this context, the Declaration simply served to state expressly what was inherent in the logic of the text.

Factors that came into play for India in negotiating other patent provisions

Subject matter and other exclusions

The subject matter of patents and, more importantly, permitted exclusions of patentable subject matter, was the most sensitive issue for both the *demandeurs* and for India. Even well before December 1990, it became clear to us that the Latin American countries that were supporting the position of the group of developing countries or “approach B” in document W/76⁴¹ – that certain products or processes could be excluded on grounds of public interest, national security, public health or nutrition, including food, chemicals and pharmaceuticals – were ready to give up these exclusions in return for perceived gains in agriculture or other areas in the Uruguay Round.⁴²

African countries were not active in the TRIPS negotiations, except, to some extent, Egypt, Nigeria, Tanzania and the Republic of Zaire⁴³ (at the early stages), where the latter two sought special provisions for least-developed countries (LDCs), almost all of which were conceded in Articles 66.1 and 66.2 of the TRIPS Agreement. Well before the TRIPS Negotiating Group began working on the legal text of the TRIPS Agreement, Bangladesh, on behalf of the group of LDCs, had made clear that LDCs wanted to be exempt from applying TRIPS obligations, and wanted technical assistance to eventually implement them, as well as provisions relating to transfer of technology, all of which they obtained, to a large extent, in the final Agreement.⁴⁴ It was thus that India found itself alone in its opposition to product patents in pharmaceuticals and chemicals – clearly, an unsustainable position in multilateral negotiations. That the term “invention” or the criteria of patentability were left undefined in what is now TRIPS Article 27.1 was not due to

any major foresight in the negotiations, but because they were considered to be sufficiently clear for patent examination purposes. That India could use this “loophole” to insert Section 3(d) in its patent law to prevent incremental, trivial innovation that is allegedly used to extend the patent term of pharmaceutical products was thus not anticipated at the time of the negotiations.

On the optional exclusion of plant and animal inventions, there were considerable intra-North differences, with Canada in particular opposing the patenting of multi-cellular organisms. Canada submitted in October 1989 that it would not be reasonable to oblige all governments to extend patents to multi-cellular life forms, as this area required more technical study to determine the most appropriate form of protection.⁴⁵ At the time, the EC had not yet passed its Biotechnology Directive⁴⁶ and had difficulties in accepting an immediate obligation to provide patents for plant and animal inventions.⁴⁷ The Nordic countries also wanted such exclusions.

The Association of Southeast Asian Nations (ASEAN) countries, and even some Latin American countries, had no problem supporting the patentability of micro-organisms and microbiological and non-biological processes for the production of plants and animals, but could not support the patentability of plant and animal inventions. It was due to these positions that TRIPS Article 27.3(b) is drafted the way it is.

India had difficulties accepting even the patenting of micro-organisms, as its 1970 Patents Act limited patentable inventions to any new and useful:

- Art, process, method or manner of manufacture
- Machine, apparatus or other article
- Substance produced by manufacture and any new or useful improvement thereof.

Not only did India exclude product patents for food, medicine and chemicals, granting only process patents in these fields, it also excluded methods of agriculture and horticulture, so the patenting of microbiological and non-biological processes pertaining to these two sectors was also a problem. Accepting plant variety protection was also controversial in India even post-TRIPS despite assurances by the then GATT Director-General, Peter Sutherland, on permissible exceptions and limitations.⁴⁸

India also wanted patent exclusion for nuclear fissionable material. While Brazil and Japan lent some support for such exclusion, in the end, the general security exception, now found in Article 73 of the TRIPS Agreement, was considered sufficient by all.

India also wanted the exclusion of methods of treatment for humans, animals and plants – it was the only country to seek such exclusion for plants. One view was that such methods, unlike products used for treatment, were not susceptible to industrial application. However, since the TRIPS text held “industrial applicability” to be synonymous with “usefulness”, India and others thought it prudent to retain such an exclusion. Only the United States opposed the optional exclusion of methods of medical treatment, wanting these to be confined only to surgical methods. In the end, the United States’ view did not prevail. In 1996, the US amended its patent law to exclude the availability of some enforcement remedies for patents on medical or surgical procedures used by medical practitioners for the treatment of humans.⁴⁹

For India, conceding product patents for pharmaceuticals was clearly a call that was politically sensitive and had to be taken at the highest levels of government. Civil society groups, notably the National Working Group on Patent Laws which strongly opposed India agreeing to anything in the TRIPS Negotiating Group and even opposed India joining the Paris Convention, continued to campaign against these negotiations. When the so-called Dunkel Draft containing the results of the Uruguay Round became public at the end of 1991, the TRIPS text was pored over by many activists and academics in India and an active campaign was launched to reject the text. “Down with Dunkel” was a slogan painted on many walls around the capital and elsewhere in the country, and this is how Arthur Dunkel unexpectedly came to be a household name in India.

In June 1993, A.V. Ganesan gave an interview to the *Economic Times*, headlined “We don’t have a choice”,⁵⁰ in which he said that India would have to accept the Dunkel Draft and, with it, product patents for pharmaceuticals. This view began to gather public support. He said that the government could devise new mechanisms to minimize the impact of high drug prices, if required, such as price control mechanisms and compulsory licences. He emphasized that India would not accept patents for plants but would only institute a *sui generis* system for the protection of new plant varieties, which did not necessarily have to be based upon the International Convention for the Protection of New Varieties of Plants (1991), and that India would benefit from a ten-year transition period for the introduction of drug patents. It is my view that it was through the detailed explanations coming

from a civil servant widely respected in India that Indians came to accept the inevitability of product patents for pharmaceuticals and plant variety protection as required by the TRIPS Agreement. By then, India had also had two years of successful implementation of economic reforms and was beginning to become rapidly integrated into the global economy.

Despite this, it took many more battles in India's parliament and India's loss of two WTO dispute settlement cases on transitional arrangements⁵¹ before its laws were amended to introduce its TRIPS obligations in these contentious areas.

Rights of process patent owners and reversal of burden of proof

For India, extending the rights of process patent owners to the products directly obtained through the use of the process remained controversial so long as India did not accept product patents for pharmaceuticals and chemicals. India initially hoped that the extension of the rights of owners of process patents to the products directly obtained through the use of the patented processes would serve as a middle ground in lieu of product patents. But clearly this idea was a non-starter, and was not even proposed by India, since conceding product patents or not was clearly to be a binary decision left to the end-game: in my time, it was meant to be left to trade ministers at Brussels.

Indeed, given the sharp sensitivities on this point expressed by the Indian generic drugs industry and the more technical National Working Group on Patent Laws that served to espouse its interest, even such extension was not acceptable in India and remained in square brackets in the draft TRIPS text until well after Brussels.

To me, it was evident that, if product patents were going to be conceded at a political level, little purpose would be served by not extending the rights of process patent owners to the direct product. Indeed, I found the arguments on this particular point made by Michael Kirk, the US negotiator for patents, to be persuasive. How could a process patent owner take infringement action against someone who was simply using the patent elsewhere where the patentee held no process patent and was exporting the product to undercut the patentee's sales in key jurisdictions? Nevertheless, I had no authority to concede this point and so the square brackets remained at Brussels.

On reversal of the burden of proof in litigation involving process patent infringement, the EC and US legal texts of early 1990 contained this provision for the first time. As the text sent to Brussels⁵² shows, the language of this article

was largely negotiated with only one choice left to negotiators, namely, to decide whether the provision should be made optional or obligatory.

There was strong push-back in India to the leaked 1990 draft TRIPS text from the National Working Group on Patent Laws.⁵³ The main fear was that the alleged infringer would be forced to reveal his or her business secrets (despite the proviso to take such a scenario into account) and that the courts would presumptively favour the process patent owner. Even the second option, where the process patentee must first show a “substantial likelihood” that his or her patented process was used, was said to be weak, as hard facts need not be required to be presented. My own assessment was that, since the burden of proof shifts from the plaintiff to the defendant only when the plaintiff has established “substantial likelihood” that his or her patented process is being used, we could accept this provision with all the safeguards built into it with respect to business secrets of the defendant. Section 104A of the amended Indian patent law incorporates both options given in the TRIPS Agreement Article 34 instead of choosing one.

All in all, the criticism of the reversal of burden of proof turned out to be much ado about nothing, once product patents for pharmaceuticals and chemicals were accepted, since this would apply only to cases where process patents alone were taken out.

Limited exceptions

On exceptions to patent rights, the lack of agreement among the *demandeurs* on a positive list approach, which was based on different lists of exceptions proposed originally⁵⁴ and in the course of the negotiations, made the alternative language eventually proposed, in what is now TRIPS Article 30, acceptable to developing countries, including India. The positive list approach was followed in the draft WIPO Patent Law Harmonization Treaty,⁵⁵ which was being negotiated simultaneously with the TRIPS Agreement, but parties eventually failed to reach agreement and this treaty was dropped after a failed Diplomatic Conference in 1991.⁵⁶

The limits of TRIPS Article 30 were tested under the WTO's dispute settlement mechanism (DS114, see endnote 37), where Canada's regulatory review exception was upheld, the result eventually being that the provision that the EC complained about is now part of European Union law. The TRIPS Agreement has ensured that the regulatory review exception has become an explicit part of patent laws around the world, where it was not so earlier because doubt had been cast

on its legitimacy. This is the case in India's Patents Act, 1970, where Section 107A(a) now states:

For the purposes of this Act,—

(a) any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product; ...

Term of protection

It is clear that at the beginning, extremely short patent terms, such as five years, were not acceptable to the *demandeurs*. But the initial idea did not seem to be to oblige all governments to adhere to a 20-year patent term: it seemed to be accepted that the norm was anywhere between 15 and 20 years. While the United States, the EC, Japan, Switzerland, the Republic of Korea, Hong Kong and the Nordic countries supported an obligation of 20 years from the date of filing of the patent application, Australia and New Zealand, at least, preferred a term of 15 or 16 years only.

By taking the position that the term of patents should be left to countries to determine, developing countries might possibly have lost an opportunity to negotiate a shorter length of patent protection. On the other hand, while there may have been some flexibility for some sectors, it was clear that the patent term would have to be at least 20 years from the date of filing for pharmaceuticals. The United States wanted to have patent term extension in this sector to compensate for regulatory delays – a demand that it has successfully achieved in its bilateral and plurilateral agreements. Again, the patent term was a provision that was left to the end-game for a political decision.

Revocation

On revocation of patents, there was an attempt in the negotiations to list the grounds and conditions of revocation. The Paris Convention already allows revocation of the patent on grounds of patent abuse, such as failure to work, but lays down conditions that revocation is permitted only if, after two years of the grant of a compulsory licence to remedy the situation, the abuse continues. Australia, in its submissions, supported this provision. The EC and Japan, in their

earlier submissions, supported the Paris Convention provisions. India, in Section 66 of its 1970 Patents Act, allowed revocation of patents in public interest, which it continues to maintain and use. Brazil, not being party to the 1967 version of the Paris Convention, supported direct revocation of patents on grounds of failure to work. The United States and Switzerland took the position that revocation should be allowed only on grounds of patent invalidity, that is, if the patent was wrongly granted in the first place. In the end, the *demandeurs* considered it prudent to only oblige judicial review in case of patent revocation.

There was an interesting discussion in the TRIPS Council in 1996 on what the single sentence in TRIPS Article 33 means. India took the position that it means that there are no restrictions on the grounds for revocation other than those contained in the Paris Convention, while the United States, and several other delegations that supported the United States, claimed that it meant that patents could only be revoked on grounds of patent invalidity.⁵⁷ Needless to add, no WTO dispute has been brought regarding the implementation of this provision.

Concluding remarks

While developing countries were undoubtedly disadvantaged in terms of their numbers of delegates dedicated to TRIPS negotiations or their level of expertise, I did not experience any bias against us on the part of the GATT Secretariat team, ably led by David Hartridge and Adrian Otten, nor on the part of our genial and effective Chair, Ambassador Lars Anell. Being a part of the WTO Secretariat now, I realize that actions of the Secretariat are motivated by its desire to see that members reach an agreement that all are willing to live with. It is up to members to carefully reflect on their “make-or-break” points and ensure that these are adequately reflected in the text. In general, in the GATT then and in the WTO now, while decision-making still follows the consensus rule, a proposal needs support of at least some of the major players. Today in the WTO arriving at a consensus is becoming more difficult in areas where there are widely divergent interests and no agreement can be reached without accommodating the interests of a number of developing countries, particularly those with growing economic clout owing to their increased integration into the global economy.

The narrative of the TRIPS negotiations illustrates that the package was much more balanced than some TRIPS commentators assume, since they make the mistake of taking the TRIPS text as representing only what its key *demandeurs* had wanted, rather than a genuine product of a multilateral negotiation, with concomitant checks and balances. For my part, I feel proud that, as a

representative of India, I was able to contribute to the balance in the text of the Agreement in a way that improved the armoury of policy measures that WTO members can use to attenuate the adverse effects of patents, where needed. But this could not have happened without the crucial support of some key developed countries as well. Thus, cooperation, coalition-building and compromise are the key words in any successful trade negotiation.

Endnotes

- 1 I gratefully acknowledge helpful comments made on an earlier draft by A.V. Ganesan, John Gero, Catherine Field, Meagan McCann, Adrian Otten, Piragibe dos Santos Tarragô, Antony Taubman, Antonio Gustavo Trombetta, Hannu Wager and Thu-Lang Tran Wasescha.
- 2 A.V. Ganesan, who has a chapter (11) in this volume, was then Additional Secretary in the same department. He later became a member of the Appellate Body of the WTO, for two consecutive terms.
- 3 A.N. Verma, who later became Principal Secretary to the Indian Prime Minister, P.V. Narasimha Rao, spearheaded the economic reform process in India from 1991 onwards.
- 4 GATT document MTN.GNG/NG11.W/71, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods – Communication from Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, India, Nigeria, Peru, Tanzania and Uruguay, 14 May 1990.
- 5 Anwarul Hoda, as Additional Secretary and later Special Secretary, Ministry of Commerce, coordinated India's position in the Uruguay Round of multilateral trade negotiations overall. He later became Deputy Director General of the WTO in 1995.
- 6 I would also refer the interested reader to chapters I and IV of Jayashree Watal, *Intellectual property rights in the WTO and developing countries* (New Delhi: Oxford University Press and London/The Hague/Boston: Kluwer Law International, 2001). Chapter I describes in more detail the TRIPS negotiating process from Punta del Este to Marrakesh and chapter IV covers the negotiations on patents and exclusive marketing rights.
- 7 India's trade-to-GDP (gross domestic product) ratio was only 15 per cent in 1990 and is now over 54 per cent. See the World Bank note on India's foreign trade policy at <http://web.worldbank.org/WBSITE/EXTERNAL/COUNTRIES/SOUTHASIAEXT/EXTSARREGTOPINTECOTRA/0,,contentMDK:20592520~menuPK:1465890~pagePK:34004173~piPK:34003707~theSitePK:579448,00.html> and the WTO country profile of India at <http://stat.wto.org/CountryProfile/WSDBCountryPFView.aspx?Country=IN&Language=F> (both last accessed 7 July 2015).
- 8 I, too, was curious about these price and welfare effects and was among the first to model them. See Jayashree Watal, "Pharmaceutical patents, prices and welfare losses: Policy options for India under the WTO TRIPS Agreement", *World Economy*, 23(5) (2000), 733–52.
- 9 See a recent paper that estimates that price rises may have been of the order of 3–6 per cent only, mostly on newer medicines: see Duggan, et al. "The market impacts of pharmaceutical product patents in developing countries: Evidence from India", NBER Working Paper 20548 (Cambridge, MA: National Bureau of Economic Research, 2014), www.nber.org/papers/w20548.pdf (last accessed 7 July 2015).
- 10 The relevant provision reads: "Provided also that after a patent is granted in respect of applications made under sub-section (2) of section 5, *the patent-holder shall only be entitled to receive reasonable royalty from such enterprises which have made significant investment and were producing and marketing the concerned product prior to the 1st day of January, 2005* and which continue to manufacture the product covered by the patent on the date of grant of the patent and *no infringement proceedings shall be instituted against such enterprises.*" (emphasis added).

- 11 See full text of the speaking order at: www.ipindia.nic.in/iponew/compulsory_license_12032012.pdf (last accessed 7 July 2015).
- 12 See Susan K. Sell, *Power and ideas: North–South politics of intellectual property and anti-trust* (New York: State University of New York Press), 107-140.
- 13 For a survey of the literature, see *The economics of intellectual property: Suggestions for further research in developing countries and countries with economies in transition* (Geneva: World Intellectual Property Organization, 2009), chapter 5.
- 14 Ibid. See chapters 1 and 5.
- 15 An interesting, if one-sided, account of the TRIPS negotiating process is that written by Jacques Gorlin, principal advisor to the R&D-based pharmaceuticals industry, titled *An analysis of the pharmaceutical-related provisions of the WTO TRIPS (intellectual property) Agreement* (London: Intellectual Property Institute, 1999). Ambassador Clayton Yeutter, United States Trade Representative from 1985–8, in a foreword to the book, commends the close industry involvement in TRIPS negotiations.
- 16 The words “effective and adequate protection of intellectual property rights” are part of the Punta del Este Ministerial Declaration, which set the mandate for TRIPS negotiations, and the words “adequate and effective protection of intellectual property rights” are part of the US statute governing Special 301 - see 19 U.S. Code § 2242 - Identification of countries that deny adequate protection, or market access, for intellectual property. rights, available at <https://www.law.cornell.edu/uscode/text/19/2242> (last accessed 9 July 2015).
- 17 See GATT document MTN.GNG/NG11/W/70, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods – Draft Agreement on the Trade-Related Aspects of Intellectual Property Rights – Communication from the United States, 11 May 1990, in which the United States sought transitional protection for the balance of the patent term for subject matter that becomes patentable after the entry into force of the Agreement, if a patent has been obtained in another contracting party and the product has not been marketed in the jurisdiction providing the transitional protection.
- 18 This figure of “ten years” was considered to be authentic at the time and comes from a reputed study: *Pharmaceutical R&D: Costs, risks, and rewards* (US Congress, Office of Technology Assessment, OTA-H-522 (Washington, DC: US Government Printing Office, February 1993) <http://ota.fas.org/reports/9336.pdf> (last accessed 7 July 2015), but is increasingly being questioned by health activists who claim that this period is much shorter and could be as low as 4-5 years or less for priority pharmaceutical products.
- 19 See Jayashree Watal, *Intellectual property rights in the WTO and developing countries* (Oxford: Oxford University Press, 2001), pp. 36-39. See also A.V. Ganesan (chapter 11), on India’s request for a clean transition period of five years.
- 20 See my article “From Punta del Este to Doha and beyond: Lessons from the TRIPS negotiating processes”, in *WIPO Journal*(3)1 (2011): 24-35, www.wipo.int/edocs/pubdocs/en/intproperty/wipo_journal/wipo_journal_3_1.pdf (last accessed 7 July 2015).
- 21 GATT document MTN.GNG11.W/71.

- 22 GATT document MTN.TNC/W/35/Rev.1, Uruguay Round – Trade Negotiations Committee – Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations – Revision, 3 December 1990.
- 23 One key expert, Abdulqawi Yusuf, moved on to other responsibilities in the UN and is now a judge in the International Court of Justice. I am truly grateful to Abdi for the long, illuminating discussions I had with him on IPRs in the period 1989-90.
- 24 I consulted widely on TRIPS enforcement provisions with Pravin Anand, a private IP lawyer in New Delhi who had a great deal of experience with litigation in the trademark and copyright areas. Consulting with Indian industry or academics was more to keep them informed of the negotiating process than to seek advice on negotiating strategy or positions.
- 25 See Intellectual Property Committee (US), Keidanren (Japan), Union of Industrial and Employers' Confederations of Europe (UNICE), (June 1988), *Basic framework of GATT provisions on intellectual property: Statement of views of the European, Japanese and United States business communities*.
- 26 See GATT document MTN.GNG/NG11/W/7, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods – Submissions from Participants on Trade Problems Encountered in Connection with Intellectual Property Rights, 29 May 1987.
- 27 See the section on patents in GATT document MTN.GNG/NG11/W/32, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods – Synoptic Tables Setting Out Existing International Standards and Proposed Standards and Principles – Prepared by the Secretariat, 2 June 1989; this provides a comparison between existing international standards and the submissions of the following: the EC (GATT document MTN.GNG/NG11/W/26, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods – Guidelines and Objectives Proposed by the European Community for the Negotiations on Trade Related Aspects of Substantive Standards of Intellectual Property Rights, 7 July 1988); Japan (GATT document MTN.GNG/NG11/W/17, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods – Suggestion by Japan for Achieving the Negotiating Objective, 23 November 1987); and the United States (GATT document MTN.GNG/NG11/W/14, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods – Suggestion by the United States for Achieving the Negotiating Objective, 20 October 1987).
- 28 Carlos Correa, for example, argues that, since patent rights are negative rights, this language only obliges non-discrimination with respect to the right to protect against infringement, whether it takes place through importation or domestic production. Carlos M. Correa, "Can the TRIPS Agreement foster technology transfer to developing countries?", in Keith E. Maskus and Jerome H. Reichman, eds., *International public goods and transfer of technology under a globalized intellectual property regime* (Cambridge: Cambridge University Press, 2005), 243.
- 29 See GATT document MTN.GNG/NG11/W/47, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods – Standards for Trade-Related Intellectual Property Rights – Submission from Canada, 25 October 1989.

- 30 See, for example, F.M. Scherer and Jayashree Watal, "Post-TRIPS options for access to patented medicines in developing nations", *Journal of International Economic Law*, 1(4) (2002): 913-39.
- 31 Ambassador B.K. Zutshi also wrote an interesting account of TRIPS negotiations: "Bringing TRIPS into the multilateral trading system" in *The Uruguay Round and Beyond, Essays in Honour of Arthur Dunkel*, Jagdish Bhagwati and Mathias Hirsch, eds. (Berlin: Springer, 1998).
- 32 GATT document MTN.GNG/NG11/W/68, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods – Draft Agreement on Trade-Related Aspects of Intellectual Property Rights, 29 March 1990.
- 33 GATT document MTN.GNG/NG11/W/70.
- 34 Mogens Peter Carl and John Gero, who have also contributed to this book, have permitted me to mention them.
- 35 Argentina was ably represented by Antonio Gustavo Trombetta, who also has a thoughtful chapter (13) in this book.
- 36 See chapter 10 of Jayashree Watal, *Intellectual property rights in the WTO and developing countries* (Oxford: Oxford University Press, 2001) for more on how none of the conditions in Article 31 are particularly restrictive, given the lack of restrictions on the grounds for the grant of such use.
- 37 See WTO document WT/DS114/R, Canada – Patent Protection of Pharmaceutical Products – Complaint by the European Communities and their Member States – Report of the Panel, 17 March 2000. See one-page summary at: www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm (last accessed 7 July 2015).
- 38 See the one-page summary of this case at: www.wto.org/english/tratop_e/dispu_e/cases_e/ds199_e.htm (last accessed 7 July 2015).
- 39 Arvind Subramanian, "Compulsory licensing in patent legislation: superfluous and misleading", *Economic and Political Weekly*, 25 August 1990, 1880-1.
- 40 Brazil was ably represented by Piragibe dos Santos Tarragô who has written a brilliant and honest account of his country's position in the TRIPS negotiations in a chapter (12) in this volume.
- 41 MTN.GNG/NG11/W/76, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods – Status of Work in the Negotiating Group – Chairman's Report to the GNG, 23 July 1990.
- 42 For Brazil, it was early 1990 when a new more market-oriented government took office. See Piragibe dos Santos Tarragô (chapter 12).
- 43 Now the Democratic Republic of the Congo.
- 44 See GATT document MTN.GNG/NG11/W/50, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods – Proposals on Behalf of the Least-Developed Countries – Communication from Bangladesh, 16 November 1989. LDCs continue to have a transition period up to July 2021 to implement TRIPS obligations other than national treatment and most-favoured-nation status.

- 45 See GATT document MTN.GNG/NG11/W/47.
- 46 This, Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, came much later. See <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML>.
- 47 See GATT document MTN.GNG/NG11/W/68 in which the EC asked for the exclusion of plant and animal varieties and, essentially, biological processes for their production.
- 48 Peter Sutherland, "Seeds of Doubt - Assurance on 'Farmers' Privilege", *Times of India*, 15 March 1994.
- 49 See 35 U.S. Code § 287(c) for details.
- 50 See "The Tuesday Interview", *Economic Times*, New Delhi, 8 June 1993. In 1994, A.V. Ganesan authored a "Layman's guide to the Dunkel Draft" that was widely circulated by the Rajiv Gandhi Foundation to parliamentarians in India.
- 51 See one-page summaries of DS50 (complainant: the US) and DS79 (complainant: the EC) at www.wto.org/english/tratop_e/dispu_e/cases_e/ds50_e.htm and www.wto.org/english/tratop_e/dispu_e/cases_e/ds79_e.htm (both last accessed 7 July 2015).
- 52 GATT document MTN.TNC/W/35/Rev.1.
- 53 See Rajeev Dhavan, "Making the world fit for prey: GATT and intellectual property rights" (New Delhi: National Working Group on Patent Laws, 1990). Dhavan's opinion piece in *The Hindu*, 10 December 2004, proposed that changes to the third amendment to the Patents Act should be resisted. This gives some idea of the continued opposition to the patent provisions in the TRIPS Agreement. See www.thehindu.com/2004/12/10/stories/2004121002361000.htm (last accessed 7 July 2015).
- 54 For example, the EC proposed in MTN.GNG/NG11/W/68: "Limited exceptions to the exclusive rights conferred by a patent may be made for certain acts, such as rights based on prior use, acts done privately and for non-commercial purposes and acts done for experimental purposes, provided that they take account of the legitimate interests of the proprietor of the patent and of third parties."
- 55 See the basic proposal text at www.wipo.int/edocs/mdocs/scp/en/scp_4/scp_4_3.pdf, Annex, page 35 (last accessed 7 July 2015).
- 56 See www.wipo.int/patent-law/en/patent_law_harmonization.htm (last accessed 7 July 2015).
- 57 See the discussion on the interpretation of TRIPS Article 32 in the TRIPS Council recorded in WTO documents IP/C/M/8, Council for Trade-Related Aspects of Intellectual Property Rights – Minutes of Meeting – Held in the Centre William Rappard from 22 to 25 July 1996, 14 August 1996, and IP/C/M/9, Council for Trade-Related Aspects of Intellectual Property Rights – Minutes of Meeting – Held in the Centre William Rappard on 18 September 1996, 30 October 1996.