11

Negotiating for India

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Background to the TRIPS negotiations, including the mandate

In this chapter, I venture to walk down memory lane and try to recall my experiences with the negotiation of the TRIPS Agreement nearly 25 years ago. I had the honour of representing India at some of the important stages of the negotiations between 1987 and 1993: first, as Additional Secretary, Ministry of Industry, when the administration of patents, trademarks and industrial designs in India was under my charge; then as Special Secretary, Ministry of Commerce and Chief Negotiator of India for the Uruguay Round of multilateral trade negotiations; and finally, as Commerce Secretary of the Government of India, from which position I retired from civil service on 30 June 1993. I hope my memory does not fail me in recalling my experiences with some degree of accuracy at this distance in time.

The focus and thrust of this chapter is on the Indian approach and attitude towards the TRIPS negotiations and the main reasons behind it. To be sure, domestic economic and political compulsions, as well as domestic policies towards foreign trade and investment, lay at the heart of that approach at all stages of the negotiations, more so as divergent pulls and pressures had to be accommodated in the vocal democratic polity of India. These are reflected in this chapter to the extent possible. It is my conviction that domestic economic policies, as well as domestic economic strength and confidence, tend to influence a country's attitude towards the recognition and rewarding of IPRs. This is well exemplified by India, and therefore, the chapter does not stop at merely looking at the past but also touches upon how India looks at IP protection now and how it could leverage this to achieve its economic and technological goals. Now that the TRIPS Agreement is firmly in place, the chapter also points to the way forward, to gain wider acceptance of the Agreement and of IP protection in general.

The Uruguay Round marked a defining moment in international economic and trade relationships. It is said with modesty that the WTO of 1995 had "evolved"

from the GATT of 1947, but if the ambit and authority of the WTO is recognized, it is perhaps no exaggeration to say that the WTO is as different from the GATT as homo sapiens is from a Neanderthal. With the establishment of the WTO, multilateral trade no longer means trade in goods only, and multilateral trade rules no longer means only rules that stop at national borders and that do not intrude into the domestic policy space of members. Three factors, in particular, changed the complexion of the multilateral trade rules and they all had an impact on the negotiation of the TRIPS Agreement: first, the extension of the trade rules to the areas of services, investment and IPRs (besides subjecting agriculture and textiles also to multilateral trade disciplines); second, the adoption of the concept of "a single undertaking", which, *inter alia*, paved the way for exchange of concessions and commitments across sectors and induced countries to look at the Uruguay Round package as a whole; and third, the dispute settlement undertaking that made it obligatory for members to resolve trade disputes only through the dispute settlement mechanism of the WTO and to seek multilateral authorization before any retaliation or cross-retaliation across sectors was undertaken. It is therefore important that the negotiation of the TRIPS Agreement is viewed not in isolation but as part of a larger package of agreements under the Uruguay Round.

When the idea was mooted in the early 1980s to launch a new round of multilateral trade negotiations, it lay in the logic of things that the industrialized countries, led by the United States, would insist upon the inclusion of services, investment and IPRs in the purview of multilateral trade rules. The industrialized world was fast losing its competitive edge in world trade in the manufacturing sector, especially in respect of standard technology goods. But its strength and supremacy in capital- and technology-intensive services, in various high-technology fields, and in areas where protection of IPRs was crucial for market dominance, was intact and needed to be preserved and promoted. Market access, market protection and market penetration for such goods and services across the world were critical for industrialized countries, to advance the interests of their big transnational companies. Such interests were represented by a formidable array of companies whose operations ranged from banking, insurance and telecommunications in the services sector to pharmaceuticals and chemicals, films and music, computers and software, and seeds and biotechnology in manufacturing and other fields.

At the commencement of the Uruguay Round, Japan and the United States were in the forefront for the inclusion of IPRs in the mandate of the negotiations. The other industrialized countries, including Australia, Canada, New Zealand, the Nordic countries and Switzerland, joined the fray later. As for the European Communities (EC), it had an ambivalent stand at the beginning of the negotiations

about the extension of GATT rules to IPRs, probably because it was unsure of its impact upon the legislation of its member states. But, as the negotiations proceeded, the EC became an equally staunch advocate for the protection of IPRs under multilateral trade rules. Its approach has sparked the perceptive comment that the EC could have lived without a TRIPS Agreement at the beginning of the negotiations, but could not have done so at the end of it.[1] I should hasten to point out, however, that, although the industrialized countries were united on the issue that substantive norms and standards for the protection of IPRs should form an integral part of the multilateral trade rules, there were a number of differences among them, at least on two counts: first, they had their differences on the scope or form of protection of some of the IPRs, such as computer software, broadcasting and television rights, geographical indications (GIs), life forms and so on; and second, they had differing views on how developing countries with special problems needed to be accommodated, especially with respect to transition periods, "pipeline protection" and compulsory licensing in the pharmaceuticals and food sectors. But these differences among them were of a different class and character.

On their part, the developing countries, including India, were least enthusiastic on the extension of the authority of the GATT to new areas such as services, investment and IPRs. They had both philosophical and practical reasons to oppose the enlargement of GATT's jurisdiction: first, their long-held conviction that the role and reach of the GATT ought to be limited to the goods sector and that the GATT was best equipped to deal only with "border measures"; second, their apprehension that such an extension would seriously intrude into their domestic policy space and constrain their freedom to pursue economic and social policies best suited to their individual needs; and third, from a purely practical point of view, they had nothing to gain but much to lose from undertaking obligations and commitments in these new areas. In short, they saw themselves not as *demandeurs,* but as hapless defenders in these new areas, with no *quid pro quo* for them from any agreements on these subjects.

With respect to IPRs in particular, they had the additional reservations that the protection and enforcement of IPRs was not trade-related, that WIPO was the appropriate forum in which to deal with IP issues, and that, as the industrialized countries were the owners of nearly 99 per cent of global patents and other forms of IP, any agreement for their protection would only favour them at the cost of developing countries. In particular, they were concerned that stringent patent protection would emaciate their capacity to provide affordable health care to their poor. They were also apprehensive that, as they were not familiar with all the

technical issues involved in the protection of IPRs, especially in the case of newer technologies, they might be negotiating from a lack of both strength and knowledge on the subject.

It was against this contentious backdrop that the mandate for the inclusion of IPRs in the agenda of the Uruguay Round was negotiated and formulated in Punta del Este in September 1986. The text of the mandate read in part:

> In order to reduce the distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade, the negotiations shall aim to clarify GATT provisions and elaborate as appropriate new rules and disciplines.
>
> Negotiations shall aim to develop a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods, taking into account work already undertaken in the GATT.
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> These negotiations shall be without prejudice to other complementary initiatives that may be taken in the World Intellectual Property Organization and elsewhere to deal with these matters.[2]

The mandate is certainly not an epitome of clarity, coherence or consistency. Given the divergent positions of the industrialized and developing countries on the mandate, it was not surprising that it took another two and a half years for the content of the mandate to be settled. The industrialized countries laid emphasis on the two phrases "taking into account the need to promote adequate and effective protection of intellectual property rights" and "elaborate as appropriate new rules and disciplines". According to them, it was the lack of adequate protection of IPRs that led to "distortions and impediments to international trade". On the contrary, developing countries placed their faith in the three phrases "In order to reduce the distortions and impediments to international trade", "to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade" and "the negotiations shall aim to clarify GATT provisions", as well as in the clear-cut provisions of the second subparagraph, and the reference to WIPO in the final subparagraph. Both sides insisted that the texts that they relied on warranted the inclusion of substantive norms and standards for protection of IPRs within the mandate, or, oppositely,

their complete exclusion. When the scope of the mandate was finally settled in April 1989 in favour of the inclusion, it was not so much because the developing countries came to see clarity or conviction in the mandate as because of other factors, including, in particular, the pressures exerted on them by the United States through unilateral action under its Trade Acts, changes in the internal policies and negotiating approach of some developing countries, the trade-off perceived by some developing countries from the inclusion of agriculture in the negotiations, and the hope that sufficient flexibilities could be negotiated to balance protection with their own policy objectives.

India's approach to the TRIPS negotiations

Let me now turn to India's approach to, and attitude towards, the TRIPS negotiations, which, as I stated earlier, is the focus of this chapter. There were three distinct phases in India's approach, each guided by the dominant economic policies followed by the country at the relevant time. The first phase was from the Punta del Este mandate of September 1986 until the meeting of the Trade Negotiations Committee (TNC) of the WTO in Geneva in April 1989. The second phase was from April 1989 until the issue of the so-called Dunkel Draft in December 1991, when the specific provisions for substantive norms and standards for the protection of IPRs were discussed in the TRIPS Negotiating Group. The third phase was after the issue of the Dunkel Draft, when efforts were made by India to seek improvements in the provisions relating to transition period and pipeline protection for pharmaceutical patents. In each of these phases, there were shifts in India's stand based on its own examination of what changes it would have to make in its laws, what would be their impact on domestic policies, how those changes could be made politically acceptable and how much time would be needed to gain such acceptance.

The first phase, from the Punta del Este mandate until the TNC meeting of April 1989

From the beginning of the negotiations until the TNC meeting of April 1989, India was firmly opposed to the inclusion of substantive norms and standards for the protection of IPRs within the negotiating mandate. It must be admitted that, in the wide-ranging and gruelling negotiations that took place in Punta del Este in September 1986 on various issues, India spent more of its energy and resources on the negotiating mandate for services and on advocating a "twin-track approach" to the implementation of the results of the negotiations, than on the formulation of the negotiating mandate for IPRs. The extension of the jurisdiction of the GATT

to the services sector was then considered by India to be more inimical to its interests than anything else on the agenda. (Oh, how times have changed! The services sector now accounts for nearly 55 per cent of the country's gross domestic product (GDP) and India is riding on the back of a vibrant computer software industry to manage its external balance of trade. No one seems to be worried now in India over the General Agreement on Trade in Services (GATS) and its inclusion in the WTO). That India's participation in the Negotiating Group on IPRs was not as robust and active as it might have been was revealed, to some extent, by the fact that, at the concluding session of the Punta del Este negotiations on 20 September 1986, India made a weak statement: that its understanding of the scope of the mandate on IPRs was that it was limited to trade in counterfeit goods and anti-competitive practices of the right holders, and that the mandate did not extend to substantive norms and standards for the protection of IPRs.[3]

Be this as it may, India stuck to the position until April 1989 that substantive norms and standards for the protection and enforcement of IPRs went beyond the scope of the negotiating mandate and could not therefore be considered by the TRIPS Negotiating Group. Apart from the philosophical and practical grounds that I have referred to earlier, there were two India-specific factors that prompted it to adopt this stand.

First was the inward-looking and non-market-oriented economic policies that India was pursuing at the time. Excessive government control over the economy and the "Licence Permit Raj" were still in their heyday. Foreign investment and foreign trade were shunned as either unnecessary or anti-self-reliance. Far from inviting foreign investment, in the late 1970s, India implemented an aggressive policy directing foreign companies operating in India to divest or dilute their foreign shareholdings. Although the philosophy of leaning to the left of centre on economic and social issues is always endemic in India, at the time, there was considerable opposition to globalization and India's integration into the global economy among academics and activists, as well as from the political classes. India's foreign trade (exports and imports) was less than 10 per cent of its GDP and it was considered to be good for India to stand on its own feet. In this milieu, the extension of the GATT's jurisdiction to new areas such as services, investment and IPRs was anathema to India. For India, the GATT had been established solely to deal with tariffs and trade remedy measures in the goods sector and its jurisdiction must remain such. Its extension to the new areas was seen as an attempt on the part of the industrialized world to impose its hegemony on developing countries to further the interests of its multinational companies. It may

sound strange that such views flourished in a country with a vibrant and vocal democracy that allowed for every kind of freedom except economic freedom. That the economy was consequently operating far below its true potential was, unfortunately, missed.

But the more important factor behind India's opposition to TRIPS was the character of the Indian Patents Act 1970 and the Indian pharmaceuticals industry that it had spawned. Under British rule, India had the Patents and Designs Act 1911, which granted product and process patents in every sector and prohibited compulsory licences without the involvement of the patent holder. Local pharmaceutical production by Indian companies was therefore at a standstill and imported medicines held sway in the marketplace, albeit at unaffordable prices. This situation led to the formation of the Indian Drug Manufacturers Association in 1961 and it lobbied strongly for the enactment of a new patent law that would encourage local production of pharmaceuticals and thereby make them available to people at low prices. Following the recommendations of a committee appointed under the chairmanship of a High Court judge, a new law, namely, the Indian Patents Act 1970, was enacted, which repealed the 1911 Act insofar as it related to patents. The new Patents Act 1970 came into force on 20 April 1972.

The new law was truly a turning point for the domestic pharmaceuticals industry. Five features of the new law are worth noting here to show how far apart it was from the TRIPS Agreement. First, the Act provided for only process patents, and prohibited product patents, in the food, pharmaceutical and chemicals sectors. Second, the Act provided for a term of only seven years for process patents in the food and pharmaceuticals sectors, while for process patents in the chemicals sector, and for product or process patents in all other sectors, the term was 14 years from the date of filing. Third, compulsory licences could be granted liberally under the Act, including for non-working of the patents. Fourth, the Act allowed for automatic "licences of right" in the food, pharmaceuticals and chemicals sectors, under which anyone could produce and sell such products on payment of a royalty not exceeding 4 per cent. Fifth, in the case of process patents also, the owner of the patent had to prove the alleged infringement of his or her patent in a court of law. In a nutshell, the Indian Patents Act 1970 did not allow a patent worth its salt in the food, pharmaceuticals and chemicals sectors.

The Act was a shot in the arm for the domestic pharmaceuticals manufacturers. Thanks to the abundant skilled manpower available in India in chemical technology, especially in the synthesis of chemical molecules, the domestic pharmaceuticals industry started producing new patented chemical entities through reverse

engineering, choosing pharmaceuticals that had proved their safety and efficacy in the industrialized world and that had also become commercial blockbusters there. In addition, governmental regulations that compelled the manufacture of medicines from the basic stage, prohibiting simply the transformation of intermediate products into bulk pharmaceuticals or formulations, as well as the setting up of public sector undertakings in the pharmaceuticals sector, also helped India acquire the necessary skills in the manufacturing of pharmaceuticals. Within three to five years of new drugs being introduced into the world market, they were introduced in India at a fraction of their world prices. Although this did not lead to new drugs being discovered in India for diseases relevant to India (a point to which I will return), it is not an exaggeration to say that, if India today is a major supplier of generic drugs to the world market, the seeds of it were sown by the Indian Patents Act 1970.

It was the combination of these two factors, the insular and inward-looking economic policies of the country and the growth and achievement of the domestic pharmaceuticals industry under the Patents Act 1970, that lay at the bottom of India's strident opposition to the inclusion of protection of IPRs within GATT disciplines. For India, such an extension of the GATT's jurisdiction would have required not marginal or incremental amendments but a complete and radical overhaul of its Patents Act 1970, which was an extremely difficult political proposition for the country. It must be noted here that the same advocates against the extension of the GATT's jurisdiction to IPRs were also dead against India joining the Paris Convention for the Protection of Industrial Property. Although India was arguing that WIPO was the appropriate forum for dealing with IP, India is one of the perhaps few countries that joined the Paris Convention after it had subscribed to the TRIPS Agreement.[4] Even though the Paris Convention allowed considerable discretion to parties in framing their patent laws and had no worthwhile enforcement mechanism against transgression, India was then opposed to joining it. The reason was that it would have entailed the acceptance of international obligations on patent protection that would diminish India's freedom to formulate and implement its patent law the way it wanted.

The second phase, from April 1989 until the Dunkel Draft of December 1991

The question then arises as to what caused India to change its stand and agree to the inclusion of substantive norms and standards for the protection and enforcement of IPRs within the scope of the TRIPS mandate in the TNC meeting of April 1989. I was a member of the Indian delegation that participated in the

mid-term review meeting in Montreal in December 1988 and the TNC meeting in Geneva in April 1989. From my recollections of the pulls and counter-pulls that operated at the policy-making level at the time, and which made policy choices difficult and controversial, both politically and otherwise, I venture to say that three factors were prominent behind the change in India's stand.

The first of these, it must be admitted candidly, was the pressure exerted by the United States through its unilateral actions under Section 301 of the US Trade Act 1974 and the Special 301 provisions of the US Omnibus Trade and Competitiveness Act 1988. India had the distinction of being on the priority watch list of the United States from 1989 onwards, with the exception of the years 1991 to 1994, when its status was even worse, that of a Priority Foreign Country. This designation arose primarily due to the lack of pharmaceutical patent protection in India. Retaliatory action against Indian garment and other exports to the United States was looming large over India like a Damocles' sword, especially in the last few years of the Uruguay Round. Avoidance of trade friction with the United States was a necessity in order to safeguard the interests of the Indian exporters whose complaint was, why should they be penalized for no fault of their own? In this context, it is also worth noting that India had a number of scientific and technical cooperation relationships with the United States at both the academic level (e.g. between universities) and the level of government science departments. The need for adequate protection of IPRs in India was raised by the American side as well, if those relationships were to be sustained.

The second factor was the incipient beginning of a change in India's economic policies. Although a significant outward orientation in the policies was not yet on the cards, there was a clear move in the direction that India must attempt to integrate its economy into the global economy and that this must be an objective of India in the Uruguay Round negotiations as well. When I was appointed Special Secretary and Chief Negotiator for India for the Uruguay Round in July 1989, an instruction given to me was that I should make this objective of India clear in my bilateral meetings with other countries.[5] In the Summit Conference of Heads of State or Government of the Non-aligned Movement held in Belgrade in September 1989, which I attended, the Indian Prime Minister specifically stated that India wanted to integrate its economy into the global economy and that he hoped the Uruguay Round negotiations would help developing countries to do so on favourable terms. This shift in approach meant that India did not want to be seen in the negotiations as always being in a denial mode and that it tabled its own specific proposals of its demands on other countries or in defence of its position.

The third factor was a perceived shift in the approach of other developing countries to the inclusion of substantive norms and standards for protection of IPRs in the agenda. Some of them felt the pressure from the United States under Section 301 of its Trade Act 1974 in the same way as India did. Some in the Cairns Group thought that their interest in the agriculture sector should not be harmed by their intransigence on the TRIPS negotiating mandate. Some others thought that, rather than fight a losing battle, a better strategy would be to bargain that, while norms and standards might be included in the agenda, it should be on the basis that they would stop with those enshrined in the Paris Convention and the Berne Convention for the Protection of Literary and Artistic Works, but not go beyond them. I recall such a view being articulated in a subtle manner by an Association of Southeast Asian Nations (ASEAN) member state in the Montreal mid-term review group on TRIPS, in order to avoid deeper inroads being made by industrialized countries in patent and copyright protection. Whatever was the true state of play in this respect, there was reason for India to believe at the time that it was only a question of time before developing countries gave up their position that the Punta del Este mandate did not go beyond the issues of trade in counterfeit goods and anti-competitive practices of right holders.

India also thought that, once the substantive norms and standards for protection of IPRs was brought into the mandate, efforts could be made to balance protection of IPRs with the developmental, technological and policy objectives of the host countries, to carve out exceptions for the special needs of developing countries, and to obtain sufficiently long transition periods for switching over to the new regime. There were indications, at least from some developed countries, that differential treatment for developing countries in this manner could be worked out during the course of negotiations.

It is possible that, to an outsider, and to many in India as well, these reasons for a sudden shift in India's stand might appear to be specious or unconvincing, apart from the reason that India simply surrendered to the pressure exerted by the United States and gave up its principled position. That the pressure exerted by the United States, not only on India but also on some other developing countries was the prime reason is not disputed, but the shift in stand needs to be seen in the context of the entire gamut of the Uruguay Round negotiations, including the TRIPS mandate (which could not convincingly be interpreted to be limited only to trade in counterfeit goods) as well as the shift in India's internal policies.

Needless to say, there was sharp and extensive criticism in India, in both the press and the academic and political arena, over India's tamely agreeing to the protection

of IPRs under pressure from the United States and thereby sacrificing the interests of both the domestic pharmaceuticals industry and the health care of the Indian poor. The Indian Government's explanation that efforts would be made in the further negotiations to have provisions that would balance protection of patents with public policy objectives, including the health care needs of the poor, carried little conviction. I still recall an article in a leading Indian newspaper, written by Inder Malhotra, a highly respected and widely read journalist in India, in which he called 5 April 1989, the date of the TNC meeting, a "Black Wednesday for India", excoriated the government for its abject surrender of vital national interests and called for the immediate sacking of the leader of the Indian delegation to the negotiations, the then Commerce Secretary of India (not me, fortunately, who was only a lesser fry in the delegation!).

After the finalization of the negotiating mandate in the TNC meeting of April 1989, India tabled, for the first time, a comprehensive document setting out its views on norms and standards for protection of various types of IPRs.[6] It did not suggest their formulation in legal terms but was about the principles that must inform them, from a developing country's perspective. With respect to patents, the document argued for freedom and flexibility for developing countries in the matter of grant of patent protection in sectors such as food and pharmaceuticals. For India, the value of the document lay not so much in its capacity to persuade the industrialized world to an opposite point of view, but in its conveying the message that India was interested in substantive engagement on the issues and that its chief concern was that protection of patents must be balanced by the host country's needs and public policy objectives. The document, widely reported in the Indian press, also helped allay the earlier criticism over India's having changed its stand on the negotiating mandate, as it showed that the government was committed to the issue of negotiating a balance between protection of patents and protection of the public interest.

The next important document from the standpoint of the developing countries was that tabled collectively by 14 developing countries, including India.[7] This document submitted specific proposals on all aspects of the negotiating mandate in legal language, dividing the subject into two parts: Part I dealing with "Intellectual property and international trade", including trade in counterfeit and pirated goods; and Part II dealing with the "Standards and principles concerning the availability, scope and use of intellectual property rights". As the first statement of the negotiating position of the countries concerned, it naturally took an extreme position on a number of issues, especially with respect to the obligations of the right holders and the scope of the protection granted. A few of the proposals in

the document would illustrate this fact: it stated that, while patent protection will be available in all fields technology, a licence of right will also be automatically available to any person wanting to work the patent in the case of food and medicines; it is for each national legislature to determine the duration of patent protection it wants to grant; a patent owner has the obligation to work the patented invention in the territory of grant, failing which a compulsory licence is liable to be granted; a compulsory licence may also be granted, where necessary, in the public interest to secure free competition; and the agreement shall be implemented in the relevant international organization.

On their part, the industrialized countries had already tabled their proposals in early 1990, taking equally strident positions that focused only on watertight protection and enforcement of IPRs. According to them, a compulsory licence could be granted only in narrowly defined circumstances and certainly not for the non-working of patents. The negotiations therefore lingered on in this phase without any tangible meeting ground until the text was reached at the Brussels ministerial meeting in December 1990. That text merely put in brackets the contentious proposals of each side on issues such as duration of patents, obligation to work patents, exclusion from patentability of food, chemical and pharmaceutical products, and forum of implementation of the agreement. With the breakdown of the Brussels ministerial meeting for other reasons, this phase of the negotiations went into limbo.

There were, however, several silver linings in the Brussels text that proved useful at the later stage of the Dunkel Draft, as they gave policy options to developing countries to attenuate the adverse effects of protection of IPRs. One, in particular, stands out – it relates to compulsory licences (Article 34 of the Brussels text and Article 31 in the TRIPS Agreement). Of note, first, is the inclusion of the proposition that a compulsory licence could be granted on the individual merits of each case. This meant that the reasons for the grant of a compulsory licence were not circumscribed or conditioned, so long as the "merits" of the case at hand justified the grant of the compulsory licence. Second, in the case not only of public non-commercial use by the government but also of a national emergency or other circumstance of extreme urgency, a compulsory licence could be granted without prior negotiation with the right holder (Article 34(b) and (o) of the Brussels text and Article 31(b) of the TRIPS Agreement). Along with the support of some developed and developing countries, the Indian negotiators were able to get these important provisions included in the article on compulsory licences, while, at the same time, accommodating the viewpoint of the other side in the subsequent

provisions of that article pertaining to the conditions that will be applicable once a compulsory licence is granted.[8]

The third phase, spanning the Dunkel Draft and thereafter

The famous Dunkel Draft came out in December 1991 but it had been a work in progress for quite some time beforehand. It was a child of the fatigue of the negotiators who, having gone around in circles over a long period and having reached an impasse on critical issues of the negotiations, entrusted the conundrum to Arthur Dunkel, the Director-General of GATT and a suave Swiss diplomat, for him to come out with a package that, in his personal view, reflected the agreements reached by the negotiators and possible compromises on the contentious issues still to be resolved. Arthur Dunkel produced such a package on the basis of the suggestions he received from the Secretariat and the chairs of the various negotiating groups, including the TRIPS Negotiating Group. With the benefit of hindsight, I venture to say that he did a fair and impressive job, with every country finding good and bad parts in his package, like the curate's egg. This was reflected by the fact that many countries, particularly from the developing world, wanted that the delicate package that he had so carefully worked out should not be unravelled lest the whole negotiations fell apart and the Uruguay Round sank into oblivion.

I was appointed as Commerce Secretary of the Government of India in November 1991 and my immediate responsibility was to deal with the Dunkel Draft, *inter alia*, in close consultation with developed and developing countries. A striking new development on the Indian scene was that the new government that had come into power in June 1991 had embarked on major economic reforms, necessitated as much by the dire economic straits the country had reached as by the conviction that the country needed a reversal of its economic policies. While everyone recognized that the country was operating far below its economic potential, the new government had the courage to decide that the solution lay in adopting outward-looking and market-oriented economic policies that were congenial to foreign investment and foreign trade. It is now an accepted fact that the seeds of economic reforms and of the reversal of inward-looking economic policies were sown in India in mid-1991. As the new policies yielded tangible gains to the economy, the pursuit of outward and market-reliant policies has gathered momentum in the subsequent years and such policies have not only come to stay but have become an integral and staple part of the economic landscape of the country.[9]

The Dunkel Draft was, naturally, considered by India in the light of its changing economic policies. Underlying that consideration was also the pragmatic approach that a multilaterally agreed set of rules, even if they were not in favour of India in every respect, was preferable to bilateral or other arrangements that might exact a higher price from India. It was therefore felt that the right course of action for India was to stay within the multilateral trading system, take a constructive and effective part in it, and try to seek improvements in the rules with the support of like-minded developing and developed countries. A system of compulsory multilateral resolution of disputes, according to an agreed set of rules, was also considered to be of advantage to India to withstand unilateral punitive actions on the part of other countries.

The Dunkel Draft on the TRIPS Agreement was also examined by India within this scenario. As that text and the final TRIPS Agreement did not differ much as far as India was concerned, I will refer now only to those aspects where India attempted to secure changes in the Agreement and failed. When it became clear to India that patent protection would be extended to all fields of technology and that the pharmaceuticals sector would neither be excluded from product patent protection nor would automatic licences of right be allowed for it, India chose to focus on the following five issues as the next best options: compulsory licensing provisions, transition period, flexibilities in the agreement, recognition of underlying public policy objectives and multilateral dispute resolution. Of these, India was largely satisfied with the kinds of provisions that came out in the Dunkel Draft, except for the transition period and the concomitant pipeline protection.

With respect to the contentious issue of compulsory licences, India was satisfied with the final provision that a country was free to grant a compulsory licence on the individual merits of each case. This implied that, while automatic or across-the-board grant of compulsory licences would violate Article 31(a), selective and judicious grant of compulsory licences would not fall foul of it. The grounds for the grant of a compulsory licence were not conditioned or circumscribed by that Article and were left to the judgment of the authority granting the licence, who had only to show that it was justified by the merits of the case at hand. The other conditions enumerated in Article 31 came into play only after a compulsory licence was granted. India had no serious problems with those conditions. Even without the provisions of Article 31, the legality of the grant of a compulsory licence or payment of adequate remuneration to the patent holder would have been subject to judicial review in India.

While on the subject of compulsory licences, I must also refer to the other contentious issue of "working of patents", as both an obligation of the patent holder and a ground for grant of a compulsory licence. A corollary issue is whether importation constitutes working of a patent or not. My own view has always been that this issue gets blown up out of context. If the manufacture of a product is economically, technically or commercially unviable or difficult in a country, because of the small volume of demand, regulatory approvals or any other reason, it is unfair to argue that it must still be produced in the country by the patent holder because there is a patent granted to it. If the country needs the product and the patent holder or his or her licensee imports it into the country, it is as good as working the patent. Conversely, even if an automatic licence of right is available, no one else is likely to produce it for the same reasons. They might, at best, try to import it from sources other than the patent holder. On the other hand, if a product is technically and commercially viable to be produced in a country, first, there is no a priori reason why the patent holder would not see that opportunity. Second, even if he or she does not do so, recourse to a compulsory licence is open to the country on the grounds that the product is widely needed to tackle a particular situation, that the market is not being served adequately or is being served by imports at very high prices and that a competitive source of production is considered necessary in the public interest. In other words, a compulsory licence could be thought of not because the patent is not worked in the country but because of the particular facts of the situation at hand. Given the open-ended nature of the compulsory licensing provision in Article 31(a), India felt that the working or non-working of patents was not an issue of serious concern to it. In any event, India had reason to believe that, given the size of its domestic market and its abundant technical skills in the manufacture of pharmaceuticals, it was unlikely that a patent holder would forego the opportunity of producing the product in India for the Indian market, if they found that it makes economic and commercial sense to manufacture the product in India.

I should also refer to another dimension of compulsory licences based on the Indian experience. It is the extent to which compulsory licences are actually used when they are freely available. As noted earlier, the Indian Patents Act 1970, which came into force in April 1972, did not grant product patents for pharmaceutical products and, furthermore, it allowed automatic licences of right for them. It was therefore a free-for-all situation for the domestic pharmaceuticals industry. Even in this era of freedom, during the 15-year period 1983–97, when 653 new drugs (new chemical entities) were introduced into the world market, India saw only 72 of them in its market. Typically, they were introduced into the Indian market by the

domestic manufacturers within three to five years of their introduction into the world market, after their efficacy, safety and commercial success had been established elsewhere. Even of the 72 new drugs so introduced, only about ten to 15 could be considered to be top-selling drugs in the Indian market. The Indian experience, even in the halcyon days of the Patents Act 1970, was that only about 10 to 15 per cent of the patented drugs introduced into the world market were introduced into the Indian market by the domestic firms because they found only so few of them to be worth introduction for commercial reasons. This belies the lay perception that every patented drug that comes into the world market will automatically be introduced into the market of a developing country as well, if only licences of right for them were freely available. On this issue, there is thus much exaggeration by the protagonists on both sides of the fence – those who allege that compulsory licences will kill patent protection and those who claim that free compulsory licences is the panacea to ward off the injurious effects of the patent system. It will help informed debate if global data were collected on a country basis on the number of compulsory licences granted, the reasons for their grant and the commercial performance of those licences.

Turning to the other issues noted earlier, India was reasonably satisfied with the Dunkel Draft on the recognition of the underlying public policy objectives, as set out in the Preamble and Articles 7 and 8, and the flexibilities (i.e. the nature and extent of discretion allowed) embodied in some of the important provisions of the Agreement. India was conscious of the fact that the objectives and principles were too broadly worded, hortatory in nature and subject to compliance with the provisions of the Agreement. It is always a matter of debate in WTO law as to what weight and effect would be given to them by panels and the Appellate Body in the event of a dispute over a particular measure. Even so, their articulation under specific articles would be of value to the defence of a contested measure as they reflect what the negotiators had in mind to balance protection with other objectives, especially when the measure in question is not in breach of the basic structure of the Agreement.[10]

As regards the flexibilities embodied in the Agreement, the one with respect to "inventive step" is worth mentioning here in the Indian context. Under Section 3(d) of the amended Indian patent law, the tweaking of existing molecules or the dressing-up of a combination of existing molecules, with a view to the "evergreening" of patents, is not to be considered as an inventive step. The decision of the patent examiner is, of course, subject to judicial review, as all administrative and executive acts are under the Indian legal system. The existence of similar flexibilities in various other provisions of the Agreement is a matter of

considerable importance, not only to India but to all developing countries as well. As long as a measure is consistent with the basic provisions of the Agreement, the flexibilities provide an important tool to the developing countries to balance the protection of rights with their needs and objectives.

As regards dispute resolution, by the time the Dunkel Draft came out, the basic architecture of the dispute settlement mechanism of the WTO had taken shape and came to be reflected in it. This was a subject of considerable importance, for not only the TRIPS Agreement but all the multilateral agreements covered by the WTO. In fact, the single undertaking concept of the Uruguay Round was underpinned, crucially, by the common dispute settlement mechanism for all the agreements, as embodied in the Dispute Settlement Understanding (DSU). Developing, and a number of developed, countries had demanded an outright prohibition of all unilateral measures and punitive actions, to shield themselves from actions such as those they consistently faced under Section 301 provisions of the US trade laws. They did not succeed beyond getting an anaemic text in Article XVI.4 of the Agreement Establishing the World Trade Organization (WTO Agreement) that "each Member shall ensure the conformity of its laws, regulations and administrative procedures with its obligations" under the covered agreements. However, in the DSU they substantially got what they wanted: first, all disputes arising out of the covered agreements shall be compulsorily and exclusively settled through the multilateral dispute settlement mechanism of the WTO; and second, no retaliatory or cross-retaliatory action shall be taken without the multilateral authorization of the Dispute Settlement Body. As the TRIPS Agreement was also covered by the DSU, and as this prevented cross-retaliation without following the multi-layered process incorporated in the DSU, India was reasonably satisfied with the outcome in this matter.

It was with regard to the transition period and pipeline protection that India was disappointed with the Dunkel Draft and the TRIPS Agreement. As India had to completely overhaul its Patents Act 1970 and had to cope with considerable political, academic, scientific and industry opposition to the new regime envisaged by the TRIPS Agreement, India lobbied for a clean transition period of at least ten years. No pipeline protection to patents in the transition period was acceptable to India. India gave a proposal to Arthur Dunkel, with the support of the EC, to the effect that "low-income economies", as defined by the World Bank, be allowed an additional transition period of five years (over the normal period of five years for all developing countries) to introduce product patents in the food, pharmaceuticals and agrochemicals sectors.

The Dunkel Draft did allow an additional transition period of five years to developing countries for all fields of technology in respect of which a developing country did not provide product patents as at the date of application of the agreement (Article 65.4 of the TRIPS Agreement). But it was qualified by the requirement to provide pipeline protection, namely, that such a country should provide a mechanism for receiving product patent applications as at the date of application of the WTO Agreement (1 January 1995) and keep them pending for examination until the expiry of the ten-year transition period. It must also grant exclusive marketing rights for the products covered by such pending applications, provided a product patent and a market approval had been granted to them in some other member in that ten-year period. This requirement of pipeline protection was applicable only to product patent applications filed on or after 1 January 1995 in respect of pharmaceutical and agrochemical products, not for foodstuffs, chemicals in general or any other product (Articles 70.8 and 70.9 of the TRIPS Agreement).

This form of pipeline protection was called the "Swiss pipeline protection" as it was proposed by Switzerland. There is no doubt it was less virulent than the form of pipeline protection advocated by the United States, which originally wanted such exclusive marketing rights to be given for all pharmaceutical and chemical products that were covered by product patents from 1986 onwards (from the launch of the Uruguay Round) and which later toned down its proposal to at least such product patents that were in force on the date of entry into force of the WTO Agreement (1 January 1995). India argued that neither form of pipeline protection was acceptable to it as it virtually eliminated any transition period for introduction of product patents for pharmaceutical and agrochemical products. The developed countries were under pressure from the United States, which would not accept any agreement without a pipeline protection. The thrust of the argument of the United States was that, if the TRIPS Agreement were to apply only to product patent applications filed after expiry of the ten-year transition period in the developing country concerned (i.e. on or after 1 January 2005), patent protection would be available only to new drugs that would come into the world market after 2002 or 2003, since it took at least seven to eight years for a drug to come into the market after patent grant and regulatory approvals. Such a prolonged waiting period for deriving benefit from the TRIPS Agreement was unacceptable to India. Switzerland was also interested in pipeline protection because of its own strong pharmaceuticals industry, but was willing to accept it being restricted to product patent applications filed on or after the entry into force of the WTO Agreement.

On behalf of India, I pointed out that there must be a tenable nexus for the grant of exclusive marketing right for a product and that such a nexus could not be that

the product enjoyed patent protection elsewhere in the world, as patents have only national jurisdictions. Therefore, any grant of exclusive marketing rights for a product without a product patent application having been filed in India was most likely liable to be rejected by the judiciary in India. The EC appreciated both the arguments of India – that pipeline protection virtually eliminated any transition period for grant of product patents to these products, and that the American form of pipeline protection was liable to be struck down in India on judicial review – and therefore supported the Swiss form of pipeline protection as a compromise.[11]

I was not happy with even the Swiss form of pipeline protection. I tried to persuade my government that it would be better for India to go in for a clean transition period of only five years, like other developing countries and thereby restrict the applicability of the TRIPS Agreement to product patent applications filed in India on or after 1 January 2000. That would have enabled the Indian pharmaceuticals industry to continue to manufacture drugs that were patented elsewhere on applications filed there up to 31 December 1999, that is to say, the Indian pharmaceuticals industry would have had an extra period of five years and that would have meant freedom for it to choose from another 200 new drugs for domestic manufacture. But a shorter transition period of five years did not find favour with the political leadership as it was considered to be too short a period to bring about the necessary legislative changes. A longer transition period was considered necessary by the government to allay the apprehensions over the TRIPS Agreement and to explain the Uruguay Round package as a whole to the public and the parliament. As a consequence of the pipeline protection provisions in the TRIPS Agreement, the grant of product patents for pharmaceutical and agrochemical products is perhaps the only example of a WTO obligation for the acceptance of which a concerned developing country did not get a single day of transition period! The inequity of this extreme measure has escaped attention in the discussions on the TRIPS Agreement.

Other categories of intellectual property

Thus far, this chapter has been overly concentrated on patents because patent protection, especially in the pharmaceuticals sector, was the issue that caused much concern and controversy in the negotiations, not only for India but also for developing countries generally. Within the patents area, there was also concern over the patenting of micro-organisms and *sui generis* protection for plant varieties, but it was to a lesser degree because of the newness of the subjects and the flexibilities incorporated in the Agreement. Some of these concerns were outside the purview of the TRIPS Agreement, such as the ethical and moral

aspects of patenting life forms and genes, harmony with the Rio Convention on Biological Diversity, prevention of biopiracy, recognition and rewarding of traditional knowledge of indigenous communities, compensation for the use of the biological resources of developing countries, farmers' and researchers' rights in plant variety protection and the like. But a general lack of understanding of all the issues involved and the broad wording of the provisions helped limit contentious negotiations in these areas.

As regards the other six categories of IP covered by the TRIPS Agreement, namely copyright, trademarks, GIs, industrial designs, layout-designs of integrated circuits and trade secrets, India did not have much of a problem because the Indian policies, laws, regulations, administrative procedures and judicial framework were either in conformity with the proposed obligations or the changes that might be required in them were minimal in nature. For example, in the area of copyright, computer programs and compilations of data were being protected under the Indian copyright law from 1984 onwards. The Indian film industry was as vociferous as Hollywood on the prevention of piracy of cinematographic works. Regarding trademarks, under both common law tradition and statutory law, trademarks, including service marks, were adequately protected under the Indian law to safeguard the interests of both the consumer and the owner of the trademark. India had a stake in the protection of GIs as it wanted such protection to be extended to products of Indian origin such as Darjeeling tea. The Indian Designs Act 1911 provided adequate protection to industrial designs and India was also interested in strengthening its indigenous design capabilities. With respect to layout-designs of integrated circuits, India was already a signatory to the Treaty on Intellectual Property with Respect to Integrated Circuits (IPIC or Washington Treaty) of May 1989 and was taking steps to enact the necessary legislation to implement it. Regarding trade secrets, subject to the owner of the trade secret or the know-how exercising due diligence and care in protecting its secrecy, theft of a trade secret was punishable under Indian criminal law as theft of any other property.

On the question of exhaustion of IPRs (parallel imports), India was in favour of international exhaustion of such rights and was therefore satisfied with the freedom allowed by Article 6 of the Agreement in this matter. With respect to the important issue of enforcement of IPRs, India had little difficulty in agreeing to the measures proposed because these were largely in conformity with its own laws, regulations, administrative procedures and judicial system. Judicial review is guaranteed in the Indian legal system against all executive or legislative acts and would have applied regardless of the WTO agreements. Also, on the question of

reversal of the burden of proof, under the Indian Evidence Act, the philosophy is that the party which is in exclusive possession of a piece of relevant evidence is obligated to produce that evidence in a court of law to substantiate or defend its assertion.

The other six categories of IP did not, therefore, evoke much ire or attention in India. I have often felt (and sometimes written) that it is ironic and unfortunate that, despite protecting most IPRs in line with international standards, except for patents for pharmaceuticals, and despite adhering to the rule of law in such protection, India has unwittingly created an impression around the world that it does not respect or recognize IPRs. This is even more ironic because India has innate scientific and technological capabilities and is keen to build a knowledge- and technology-based society.

Reflections on India's approach to the negotiations

To conclude this negotiating history from the Indian perspective, the TRIPS Agreement was unusually contentious right from the beginning of the Uruguay Round negotiations and until their conclusion on the basis of the Dunkel Draft, especially with respect to the area of patents. Although the developed countries had internal differences in their positions on certain issues, there was a sharp cleavage on the fundamental issues of protection between developed and developing countries, more than under any other agreement of the negotiations, including the Agreement on Agriculture, the GATS and the Agreement on Trade-Related Investment Measures (TRIMS). It is undeniable that developing countries as a whole yielded more ground under the TRIPS Agreement than under any other agreement of the WTO, given the fact that such stringent protection of IP favoured only the industrialized world. The developing countries can only draw some consolation from the fact that the TRIPS Agreement formed part of a larger package from which they could derive benefits and advantages in other areas of interest to them. At times, there was more heat than light in the negotiation of the TRIPS Agreement, reminding one of the words of Winston Churchill that "the worst quarrels only arise when both sides are equally in the right and in the wrong". The TRIPS Agreement is now firmly in place, but it must not be overlooked that it addresses the concerns of the past. The technological changes that are taking place so swiftly and so sweepingly in almost every field may soon render these concerns obsolete and may throw up new concerns requiring a paradigm shift in the approach to deal with IPRs.

India's present approach to intellectual property rights

The TRIPS Agreement is no longer as emotive and explosive an issue in India as it was at the time of its negotiation. The main reason behind this change is the increasing outward orientation of India's economic policies and the growing strength and confidence of its economy. At present, economic reforms are being given a further hard push in India in order to raise steeply the levels of investment and economic growth. Foreign investment and foreign technology are being actively and openly courted under flagship programmes with titles such as "Make in India", "Skilled India", "Digital India", "Smart Cities", "Clean Energy Development" and the like. Pursuant to these programmes, foreign investors are being assured not only of stability and predictability in policies and of the "ease of doing business" in India but also of protection of their IPRs according to international standards. For the first time, foreign investment, foreign trade and foreign technology, as well as related economic policies, are being viewed in a holistic manner so that they complement and reinforce each other to realize these programmes. To signal a new approach towards IPRs, a think tank has recently been appointed by the government to make recommendations for the formulation of a national policy on IPRs. It has published its recommendations, suggesting a wide range of measures for adoption under the logo "Creative India; Innovative India". One of its recommendations is the setting up of a National Institute of Excellence on IPRs for enhancing the awareness of IPRs among all stakeholders, including, in particular, domestic innovators and creators of IP. The think tank has also stated that Indian laws are TRIPS compliant and that India would do well to join more international conventions on IP (e.g. the Madrid Protocol).

In this changed scenario, the TRIPS Agreement has almost become a blessing in disguise for India. Having become a signatory to it, and having a good track record of abiding by international agreements it has entered into, India can now confidently assure foreign investors and technology suppliers that their IPRs will be protected in accordance with internationally accepted standards as embodied in the TRIPS Agreement. The TRIPS Agreement can also help India avoid unnecessary trade frictions with other countries by suggesting that a grievance over protection of IP can be resolved through the dispute settlement mechanism of the WTO. Given the size of the Indian domestic market, and its projected growth rates, such an assurance of protection of IPRs (in addition to other supportive policies) may well encourage foreign investors to establish manufacturing facilities in India through subsidiaries and joint ventures or to license their technologies to domestic manufacturers.[12]

With respect to the pharmaceuticals sector in particular, according to a recent study by global consultants McKinsey & Company, the Indian pharmaceuticals market will more than double from the 2013 level of US$ 18 billion to more than US$ 45 billion by 2020, making India the sixth-largest pharmaceuticals market in the world.[13] The study says that it is not the lack of protection of IPRs but deficiency in infrastructure and the restrictive policy towards clinical trials that constrain global research and development (R&D) engagement with India. The study also points to new chemical entities beginning to come out of Indian R&D. Thus, with the rapidly growing size of the Indian pharmaceuticals market, and assurance of protection of IPRs according to the TRIPS Agreement, patent-owning companies are more likely to establish their own manufacturing (and even some part of their R&D) facilities in India to penetrate and protect the Indian market. Should this happen, the need for using compulsory licensing provisions is likely to diminish in the coming years. However, if the circumstances warrant it, India could use them selectively and judiciously to meet genuine public interest needs. As noted earlier, the grant of compulsory licences on the individual merits of each case is permissible under the TRIPS Agreement and is as much an integral part of the Agreement as the protection of patent owners' rights.

There are, however, two aspects relating to the pharmaceuticals sector that need India's close consideration. The first is that the Indian pharmaceuticals companies must be encouraged, through fiscal, financial or other incentives, to spend on R&D that would lead to discovery of new drugs for diseases specific to India. The pharmaceutical companies of the industrialized world concentrate their R&D on discovering drugs of significance to those countries because that market is lucrative to them. They have no incentive to focus on diseases afflicting the poor societies. As has been aptly remarked, the industrialized world suffers from "old age" diseases, whereas developing countries, such as India, still suffer from "age-old" diseases.[14] It is therefore argued that, while the West needs "lifestyle changes", the East needs "life-saving changes". This dichotomy cannot be solved by compulsory licences because they only lead to the production of drugs that have been discovered for the Western market. The Indian pharmaceuticals companies are not inclined to spend on R&D for diseases relevant to India, both because they do not have the financial muscle to spend large amounts of money on R&D and because they do not find the market for such drugs to be commercially attractive. Now that product patent protection would be available for drugs, they could be induced to change their strategy and make efforts to discover drugs for diseases afflicting the poor in India. The Indian Government must find ways and means to raise and allocate sufficient resources for the development of drugs,

vaccines and diagnostic kits for diseases that are endemic to India, putting to use the scientific and technical talent available in the country for this purpose.[15] There is no easy alternative to self-reliance and self-determination for finding drugs to cure "diseases of poverty".

The second aspect is the attention to be paid to the introduction of generic drugs into at least the Indian market immediately on the expiry of their Indian patents. The application of Section 3(d) of the Indian patent law to prevent evergreening of patents is only a partial solution to this problem. For drugs that will be on patent protection in India for 20 years under the TRIPS Agreement, mechanisms must be put in place to ensure that generic versions of those drugs are placed in the Indian market (and also in the markets where patent expiry takes place simultaneously) immediately on the expiry of the patents in India. The limited exceptions provisions of Article 30 of the TRIPS Agreement could be prudently used to enable companies to prepare for, produce and stock such drugs for commercial introduction into the Indian market immediately on the expiry of the Indian patents.

The way ahead for the TRIPS Agreement

Now that the TRIPS Agreement is in place, after all the controversies that surrounded it when it was conceived, the way ahead lies in adopting measures that will enhance its acceptability not only among developing countries but also among academics and activists who are concerned over its impact on health care for the poor and the public interest in general.

The heart of the issue in this regard is the balancing of protection of IPRs with the protection of public health needs, especially in poorer societies. As Ambassador Lars Anell, Swedish diplomat and Chair of the TRIPS Negotiating Group put it recently, the question with respect to protection is "how much is too much",[16] or, put differently, "how much" is not "enough" or "adequate" protection. It is difficult to answer this question, but it highlights the imperative need for balancing protection with other public policy objectives and for regarding the balancing act not as a limited exception to protection but as an equally important and inseparable part of protection itself. Looked at this way, every act of compulsory licensing or parallel imports would not be viewed as an egregious erosion of the rights of the holder of the IP.

Second, the way the TRIPS Agreement is interpreted and implemented so as to respect this balance is critical to secure and enhance its fairness and credibility.

The preamble to the TRIPS Agreement emphasizes the need for "recognizing the underlying public policy objectives ... including developmental and technological objectives" of the host countries, and this is elaborated in more specific terms in Article 8.1 of the Agreement to indicate the kinds of measures that the host countries may adopt to realize these objectives. The TRIPS Agreement also consciously embodies certain flexibilities to enable countries to adopt measures that they may consider to be best suited to their individual needs. To secure a balance between protection and public interest, it is important that all these features of the Agreement are given full weight and meaning in the actual interpretation and implementation of the Agreement.

A third element that can help promote greater acceptability of the TRIPS Agreement is to avoid unilateral actions, either to pressure developing countries to refrain from using the flexibilities allowed under the Agreement, including the grant of compulsory licences, or to adopt levels of protection greater than those envisaged by it. The TRIPS Agreement itself goes far beyond the ambit of the Paris and Berne Conventions, and it is therefore unfair to put pressure on the developing countries to go farther than the TRIPS Agreement for protection of IPRs. In the same vein, if a dispute were to arise concerning compliance with any obligation under the TRIPS Agreement, the dispute must be resolved in good faith through the dispute resolution mechanism of the WTO and not through unilateral coercion or threat.

In addition, there must be increasing and purposeful efforts, based on global consensus, to make generic drugs available easily, to mitigate the possible abuses arising from patent protection. There are two facets to this problem. First, when the patents are still in force, the use of compulsory licences and parallel imports must be supported to create cheaper sources of generic drugs, especially to deal with epidemics and diseases that require global cooperation and action. The second aspect is to ensure that cheaper generic drugs come into the world market immediately on the expiry of patents and that this is not impeded by either the enhancing of the patent term or legal or regulatory hurdles. This is of significance even to the developed countries where consumers suffer from price gouging even more than in the developing world. To my mind, the credibility and sustainability of an agreement such as the TRIPS Agreement depends on how well it adapts itself to bringing generic drugs into the market, subject, of course, to protecting the legitimate rights of the patent owners and their receiving adequate remuneration for their patents. In this regard, it is also important that the 2001 Doha Declaration on the TRIPS Agreement and Public Health is not allowed to remain as a mere expression of noble intentions on paper, but is implemented in practice with

purpose and sensitivity, whenever acute problems of public health arise and availability of drugs at affordable prices becomes a critical factor in dealing with them.

Lastly, there are academics and activists who argue that protection of IP is unnecessary because, even without such protection, inventions and investments in R&D would have taken place to the same extent for purely commercial reasons. It is difficult to say whether the evidence relied upon for this assertion is valid for all cases. Rather than base policy-making on such a risky assumption, a more prudent approach would be to accept the need for protection as a necessary incentive, but balance it with larger societal needs. The balancing act requires application of restraints, such as compulsory licences, parallel imports, avoiding extension of the term of protection, supporting generic drug production, curbing anti-competitive and abusive practices, and other measures that would prevent stifling of competition in the market place.

Conclusion

Let me return to the Indian story and conclude this chapter on a lighter note. I attended the ministerial review meeting held in Tokyo in November 1989. On its concluding day, the Japanese minister in charge of the meeting told the gathering that Japan was not bad at making pencils and that therefore he would like the audience not to disregard the pencils kept on their tables. The participants who until then had paid little attention to the pencils started looking at them more closely, and there was immediately a mad rush to collect them as souvenirs. This was because the pencils carried the logo “IN GATT WE TRUST”. I have preserved a couple of them until today. Having come a long way from opposing the TRIPS Agreement, but looking now to leverage it for its own benefit, India could well adopt the motto “IN TRIPS WE TRUST” in its quest to attract foreign investment and technology and to ward off Section 301-type coercions!

Endnotes

1 See Appendix 1.

2 GATT document MIN.DEC, Multilateral Trade Negotiations – The Uruguay Round – Ministerial Declaration on the Uruguay Round, 20 September 1986.

3 It is my understanding that a few other developing countries, namely, Brazil, Cuba, Peru and Nicaragua, also made similar statements at the concluding session at Punta del Este.

4 India joined the Paris Convention in 1998.

5 Between July 1989 and September 1989, I had bilateral meetings with the EC in Brussels, Sweden in Stockholm, Norway in Oslo, Brazil in Sao Paolo and Thailand in Bangkok, when I indicated to those countries that a key overall objective of India in the Uruguay Round negotiations was to integrate the Indian economy into the world economy on beneficial terms and that India would put forward specific proposals of its demands from this standpoint.

6 GATT document MTN.GNG.11/W/37, Uruguay Round – Group of Negotiations on Goods (GATT) – Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods – Standards and Principles concerning the Availability Scope and Use of Trade-Related Intellectual Property Rights – Communication from India, 10 July 1989. This document was presented by me in the TRIPS Negotiating Group immediately after my taking over as the Chief Negotiator of India for the Uruguay Round. In an interview with the Indian newspaper *The Hindu*, Julio Lacarte Muró, an acclaimed GATT warhorse and the then Uruguayan Ambassador to the GATT in Geneva, described the document as the most comprehensive and lucid articulation thus far of the viewpoint of the developing countries on IPRs. The *Financial Times* reported that India had submitted a comprehensive paper on the norms for IP protection from the perspective of the developing world.

7 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.

8 I must record here that Jayashree Watal, then a negotiator on behalf of India and now a Counsellor in the Intellectual Property Division of the WTO, played an important role in this negotiation. She referred to the consistent practice of the United States itself of its government agencies using patented inventions for a public purpose without the involvement of the patent holder. The reader is directed to her account (chapter 16) for more details on this subject.

9 An idea of the distance that India has travelled on the economic front can be had from the fact that, in 1991, when the changes in economic policies were ushered in, India's exports and imports were of the order of US$ 15 billion and US$ 17 billion respectively, and its foreign exchange reserves were only about US$ 2 billion. In 2014, exports were of the order of US$ 350 billion and imports US$ 480 billion. The foreign exchange reserves are now (March 2015) of the order of US$ 330 billion. The size of the Indian economy is now close to US$ 2 trillion and it is poised to exceed US$ 5 trillion within the next five years. India is now a major destination for foreign direct and portfolio investments.

10 The Doha Declaration on the TRIPS Agreement and Public Health, 14 November 2001, which sets out principles and objectives in the area of public health, must also be viewed in this light.

11 Even today, I have my doubts whether Articles 70.8 and 70.9 of the TRIPS Agreement would have survived judicial scrutiny in India had they been challenged. But the situation did not arise; as I understand it, there was only one case of exclusive marketing right application in India in the transition period of ten years.

12 The Indian economy is now close to US$ 2 trillion in size and is projected to grow at 8 per cent or more per annum from the next couple of years. The economy is therefore likely to reach US$ 5 trillion in size within a short period of time, perhaps five years. Given a favourable investment climate, including protection of IPRs according to international standards, such a market is bound to attract manufacturing facilities, including those with advanced technologies.

13 Narayanan Suresh, "McKinsey: Indian pharma to touch $45 bn in 2020", *BioSpectrum*, 28 June 2013.

14 Typically, these are infectious tropical diseases transmitted by mosquitoes, flies and parasites, and their prevalence and persistence in poor societies is mainly due to lack of sanitation infrastructure and hygiene. The World Health Organization has been urging national governments to increase their investments to prevent, control and treat such diseases, including certain neglected tropical diseases.

15 In this context, it is worth recalling that Médecins Sans Frontières has been advocating that the developed countries should support the formulation of an international "Neglected Diseases Drugs Act" for the development of drugs for diseases that are endemic to poor countries, and that they should provide publicly mandated resources for the discovery and development of such drugs.

16 See Appendix 1.