

Chapter 9

WTO and the Pharmaceutical Industry in India

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This chapter analysis, what we in the introductory part has called “rule making” under global political regulation. The TRIPs-agreement is chosen as an example to illustrate how international organisations, such as the WTO, set up frames for global juridical infrastructures. The TRIPs-agreement can be looked upon as an external demand for compliances with international standards for patent protection, which in many cases also has been part of national industrial policies in developing countries. This raises (at least) two research issues. First, how does the TRIPs-agreement, as an example of global rule making, de facto impact upon industries, and secondly, how does global rulemaking constrain the political manoeuvre room for national policy makers or the relative autonomy of the state.

One of the countries where the new demand for better protection of Intellectual Property Rights has had a large impact, both economically and politically, is India. When the TRIPs-agreement is fully implemented, it can be assumed to have a profound influence upon the pharmaceutical industry in the country - which earlier had mushroomed under the absence of product patents. This chapter will therefore look into 1) how the TRIPs-agreement is expected to impact upon the pharmaceutical industry in India, and 2) how the political process, leading to the adoption of the TRIPs-agreement in India, has developed. Because it is too early to draw a picture of the post-TRIPs situation in India⁵⁶, this study will be carried out as an analysis of the industrial structures in the pharmaceutical industry, in order to see how the old patent regime has influenced the industry, and for which companies the pre-TRIPs patent legislation constitute a barrier for further growth, and for what kind of companies is it essential for their survival.

⁵⁶ There is a ten years respite on parts of the TRIPs-agreement for India, because the country only recognised process patents on pharmaceutical products before the TRIPs-agreement entered into force in 1995.

The second research issue, concerning constraints on state autonomy, is difficult to tackle in a few pages, and a number of different analytical perspectives can be applied. One way to tackle the issue, however, is to analyse how much influence the Indian government got during the Uruguay Round negotiations on TRIPs, and how the contemporary political debates materialised during the political process in India before the establishment of the WTO in 1995. This perspective offers an opportunity to look on state “autonomy from” external political and economically forces, but also to see the Indian states “autonomy to” formulate policies which complied with the country’s international obligations, despite internal political pressure.

Historical background for the pharmaceutical industry in India

The Indian government introduced a new Patent Act in 1970, which only recognised process patents (instead of product patents) for products with chemical substance (including pharmaceuticals, agro-chemicals and food products). This was especially important for the pharmaceutical industry, because a large part of the cost normally lies in the research and development phase. The 1970 Patent Act gave the pharmaceutical industry in India decisive competitive advantages by allowing companies to copy the chemical substance (the so-called bulk drug) from patented products by only changing the method by which the patented molecule was produced. This had changed the pattern of competition in the pharmaceutical industry in India - away from competition on the development of new medical treatments, toward volume/price led competition.

The R&D in the pharmaceutical industry in India is strongly oriented towards this mode of production. Production companies, state research institutions and technology centres has been involved far more in process innovations than in product innovations in order to develop new ways to produce a known medical compound’s molecule, or to reduce the production costs. The 1970 patent act have also been a decisive explanation why Indian companies, since the beginning of the 70’s, has become more and more dominant on the Indian market for pharmaceutical products. Today national companies’ accounts for between 60-70% of the Indian market, compared to only 10% in 1970. The shift in market share has been due to the new competitiveness and thereby increases in the number of Indian companies. But also due to the circumstance that some multinational companies pulled

out from the Indian market as a reaction to the new patent act and the introduction of stronger price control. Another reason was that the MNC's who remained in India in some cases did not introduce their newest products on the Indian market, because domestic companies in many cases were able to introduce a copy version, and dump the price a few weeks after the product was introduced. The larger MNC's product portfolio in India is for this reason, often different from other countries.

The development of the national pharmaceutical industry in India

The structure of the pharmaceutical industry in India is for various reasons atypical, when compared with the rest of the world. There exist a large number of small and medium scale companies in India, which is contrary to the structure normally seen in the pharmaceutical industry in other countries. The 1970 patent act has made it possible for many companies to enter into the production of the same therapeutically drug, which has increased the numbers of producers. But this also resulted in a low unit margin, making increases in sales volume one of the few options for many companies if they should increase their earnings.

The production of pharmaceutical products in India is also characterised by a disintegrated production, where the companies focus on particularly parts of the value chain. There are different reasons for this; one being that it is relatively easy to enter into the market of pharmaceutical products, due to the fact that it has been allowed to copy existing products, low capital costs in some formulation segments and government subsidies for setting up small scale units (ICRA, 1999:60). Often, smaller companies did not have the financial strength necessary to invest in production of both bulk drugs and formulations, and many companies have therefore either chosen to become suppliers to other companies or outsource parts of the production. Finally there exist a large number of trading companies who is not engaged in production at all.

Another explanation of the difference between the Indian pharmaceutical industry and the industry in other countries is that in the pharmaceutical industry in general, production costs only amount to a smaller part of the total expenditure. Estimates show that 40% of the cost structure in an R&D-based MNC stems from Sales and Marketing, 20% from R&D, while only the remaining 40% are production costs. In India, where the market is characterised by many companies competing in the same medical

treatments, and where limited amounts are spent on R&D, most of the expenses stems from production. For a high-growth Indian company, production costs are around 83% (material costs alone are 50%) and marketing is 12% (ICRA, 1999:107). Because for the largest share of total costs are production costs, manufacturers will to a higher extent use external suppliers, which have chosen to specialise in bulk drugs or other chemical compounds which they sell at competitive prices in comparison with the opportunity costs of the purchaser since they can produce under economic of scale. Outside purchase of intermediary products thus reduces the total production costs.

The companies in the industry are often categorised into three groups:

- 1) The organised sector, which consists of larger companies registered by the Director General of Technical Development (at federal level),
- 2) The small-scale sector, with companies registered by the state authorities, and
- 3) The informal sector, without formal registration by the authorities.

The organised sector - the larger pharmaceutical companies - consists of relatively few large companies, some of which are in joint venture with, or controlled by, foreign pharmaceutical companies, and 200 larger independent Indian companies. Beyond this it is estimated that there are nearly 20 thousands small-scale companies, or companies in the informal sector, (OPPI, 1999) which in different ways are involved in production of formulations, bulk drugs or related items for the industry. Even though the small and medium scale companies exceed the organised sector in numbers by a factor close to 1:100, they only account for 12% of the market. The small-scale companies producing formulations often sell their product unbranded and instead they use the generic name of the active molecule to describe the content (ICRA, 1999:56). The smallest producers often produce simple formulations, which is sold through local medical practitioners. The development in numbers of pharmaceutical companies is shown in figure 9.1.

It appears from the chart in figure 1 that the increase in the number of companies has mainly taken place after 1970, when the new patent legislation was introduced - and especially since the beginning of the 1980s. The increase in numbers is due to the smaller companies, while the number of large scale-companies has remained relative fixed around 200-300.

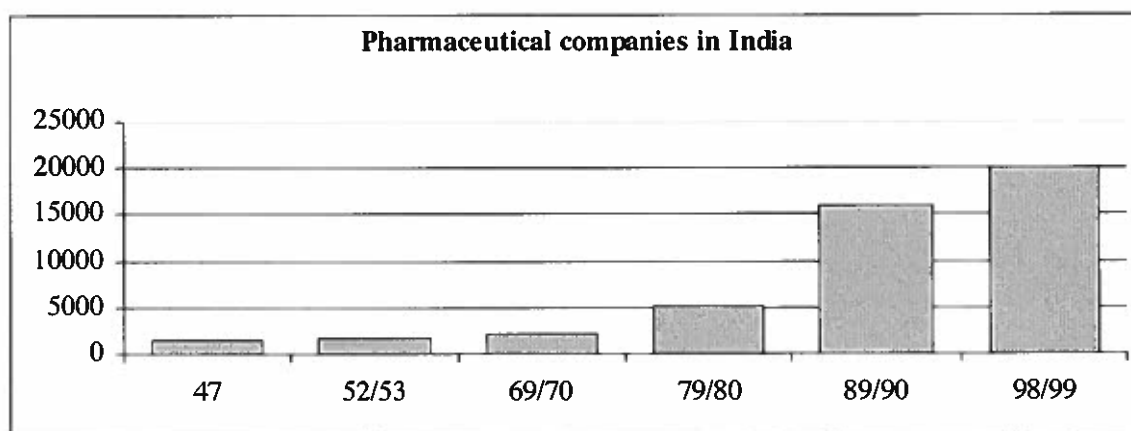


Figure 9.1. The development in numbers of pharmaceutical companies in India from 1947-1998. Source: Chaudhuri, 1999 & OPPI Annual Report 1982 & 1998-99.

An estimate of the employment in the pharmaceutical industry is 460.000 people (290.000 in the organised sector and 170.000 in small-scale units). In addition there are about 750.000 persons employed in supplying industries in India, making the total numbers of employed in the pharmaceutical industry more than 1.2 million people (OPPI, 1999).

Import and export of pharmaceutical products

Since the late 80's India has moved from being a net importer of pharmaceutical products to becoming a net exporter, and in the financial year 1998-99, India's net exports of pharmaceutical products were 22,3 billion Rs or more than 30% of the value of the total production of pharmaceutical products. The import export statistics also demonstrates the success for the Indian pharmaceutical industry, which couldn't compete on the world market in the 1960's and early -70's. In the late 1960's, exports only amounted to 50 million Rs. or 2,5% of the value of pharmaceutical

products produced in India in 1968-69. More than half of the exports were finished formulations, and nearly 20% came from herbal medicine and products. Two important disadvantages for the industry then was lack of economies of scale in the production due to a relative low domestic demand and a weak infrastructure in the pharmaceutical industry (Development Council, 1969:42). Throughout the 1970's and -80's this picture has changed. The general increase in production has made it possible to produce under scale and the development has also improved the industry infrastructure regarding suppliers, traders and middlemen.

Exports are divided into formulations and bulk drugs. Formulations are typically exported to Russia, Eastern Europe and third world countries in Africa and Southeast Asia, while bulk drugs also are exported in larger quantitative to countries in Europe and the United States. There is a big difference in the strategies the companies have to adapt, and the profits there can be made, by exporting the two different kinds of products to western countries.

The export quota in the pharmaceutical industry remained relatively low until the late 80's and the beginning of the 90's (see chart in figure 9.2), after which a significant upwards shift in exports compared with the total production took place. From the beginning of the 90's and until the middle of the decade the export quota increased by nearly 70%.

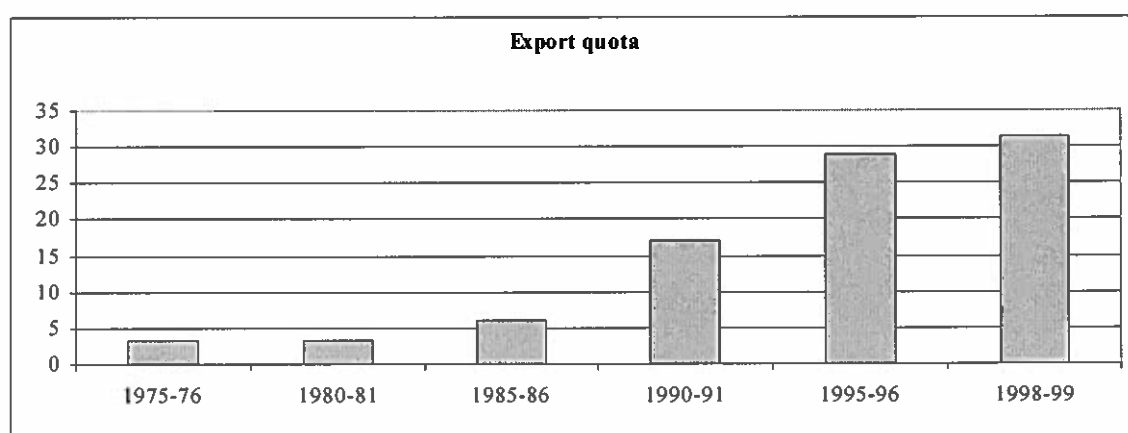


Figure 9.2. Export of pharmaceutical products in India as a percentage of the total production from 1975-98. Own calculation. Source. OPPI, 1982 & 1998-99.

New export opportunities

For Indian companies there are able to enter the North American or European markets for formulations there are large profits to be earned due to the high price level in these countries. But before the companies can reach this far, two difficult steps has to be overcome; the production facilities has to be approved by the authorities in the concerned countries, and a strong marketing division has to be built-up in order to sell the formulations to the consumers. In reality it is very difficult for the Indian companies to overcome these two obstacles. The approval process itself is time consuming and expensive, and will furthermore often require investments in new plant facilities and advanced quality control. It is only in the last years that it has been a realistic option for the largest Indian companies to start export to the US and EU- countries. The Indian companies which has entered these markets, has often done this by way of strategic alliances with companies who already have build up marketing divisions in the countries concerned.

In the next couples of years, some of the best selling pharmaceuticals world-wide will go out of patent, creating an enormous market for generics in the US and Europe. Some of the leading Indian pharmaceutical companies are planning to inter the generic markets in the US for some of these drugs (Businessworld, 2000:20), and the company strategies are geared toward these new ways of production and marketing. In the recent years large amounts have been, or are above to be, invested in new plant facilities, which can conform to the requirements of the American Food and Drug Authorities (FDA) regarding quality and production methods.

R&D in the concerned companies has also been considerably upgraded in order to secure ways to produce the drugs without being at odds with patents protecting other components than the bulk drug itself, e.g. patented methods to improve depot effects and absorption in the body. These companies (and other R&D based companies in India) already have - or will - in the coming years reach a level where they them self need protection of their scientific discoveries, and a stronger protection of Intellectual Property Rights (IPR) will in some cases be an advantage to these companies.

For companies which plan to enter the market for formulations in the US or Europe, strategic alliances with companies that are already represented on the European or American market can be another important part of the

company strategy. The ability to build confidence and offer exclusive access to the Indian market for the associated company is key elements in this context. The prospects of a strong IPR in India can therefore be important for some of the fast growing Indian pharmaceutical companies, planning to enter markets in the OECD countries, because it can secure exclusive marketing rights in India and thereby make it more attractive for the associated companies.

The importance of the IPR for pharmaceutical companies in India

While it is too early to come up with final conclusions about how the TRIPs-agreement will impact upon the pharmaceutical industry in India, it can be concluded that the absence of strong protection of intellectual property rights in India since 1970 resulted in the development of a strong, and price competitive, pharmaceutical industry in the country. It can furthermore be argued that stronger IPR of post-1995 innovations will prevent Indian pharmaceutical companies from entering new markets, making market expansion even more difficult, and over time reduce the Indian companies market shares. And with the low unit margin on pre-1995 medicine this will result in close downs of Indian controlled companies, and increased costs on medicine. However, a stronger IPR protection can also create new business opportunities for a small number of the large Indian pharmaceutical companies, who can use the better IPR protection to create strategic alliances with foreign companies based in OECD countries. Hence, the TRIPs-agreement can create both globalisation “winners” and “losers”.

Putting IPR on the political agenda in India

Due to the negative effects mentioned above, stronger protection of IPR in India has not been a requirement from the national industry, instead it was not put on the political agenda under the Uruguay Round by the US and other developed countries. This did, however, not happen without striking a blow. IPR never was a subject to any of the agreements made under GATT before WTO came into force in 1995⁵⁷. But in the Ministerial Declaration on the Uruguay Round of Negotiations from 1986, trade related aspects of intellectual property rights were introduced for the first time as a subject for negotiations under the GATT system, in order to reduce “the distortions and impediments to international trade, and taking into account the need to

⁵⁷ Instead the World Intellectual Property Organisation (WIPO), which is a specialised agency under the United Nations, dealt with international matters on IPR.

promote effective and adequate protection of intellectual property rights” and furthermore that the negotiations should “aim to develop a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods” (Ministerial Declaration on the Uruguay Round), but without mentioning national patent legislation or the enforcement hereof.

It was decided to set up a special Negotiating Group on Trade Related Aspects of Intellectual Property Rights including Trade in Counterfeit Goods. But already at the Group’s first meeting April 1987 it was clear that there were very different opinions of the Group’s task and the mandate given to it in the Ministerial Declaration. Several developing countries stressed that the Negotiation Group should abide strictly to the mandate given to it by the Ministerial Declaration, and that the Negotiating Group “should keep in mind the developmental function of intellectual property protection in developing countries” (GATT Document, MTN.GNG/NG11/2).

Due to the reluctance in the negotiations it took more than 2 years before the negotiating parties reached some kind of compromise at the meeting of the Trade Negotiations Committee in Geneva in April 1989, when India as the last country agreed to include a broader agenda in the negotiations (Banerjee, 1994:242). Despite the compromise, which made a broader agenda for the negotiations about IPR possible, there were still decisive disagreements between the North and South on how to secure public interests and transfer of technology between the developed and the developing countries. The compromise was the result of a wider package deal, which included progress in negotiations on the fading out of the existing Multi-Fiber Agreement (MFA) (Shukla, 2000:20).

After the April meeting in the Trade Negotiations Committee the focus was on the whole changed from: if an agreement on IPR under the GATT system should include standards for national protection of IPR, to: to what degree public interests and development issues should be considered in the agreement. India did though, in papers submitted to the Negotiating Group in September, return to its pre-April ’89 stand (GATT documents NG11/W/39 to NG/W/41), however at that time the negotiations had moved on to the new agenda decided in April. Hence the Developing Countries changed tactics in the negotiation on IPR and started to voice concerns about securing social and developmental issues, as well as transfer of technology from the developed countries in the agreement (GATT Documents, MTN.GNG/NG11/12) in order to contain the negative impact on their

economies. The new conflict then where on the formulation of the de-facto wording of the TRIPs-agreement.

Special 301

It was, however, not only due to the compromise between the textile exporting developing countries and the more R&D based economies in the OECD countries that the developing countries agreed to include a broader agenda in the TRIPs-negotiations. Pressure, especially from the United States, on the countries who opposed a strong protection of intellectual property rights played a decisive role. The former US president, Ronald Reagan, signed an amendment to the American Omnibus Trade and Competitiveness Act in August 1988, the so-called Special 301, which gave the US Trade Representative power to take action against countries, which according to the United States, had “unfair trade practices”, which included inadequate protection of IPR. And during the Uruguay Round negotiations Trade Representatives from the United States used the new amendment to held bilateral talks with a number of countries, which originally had refused to include national protection of IPR threatening with economic sanctions.

The developing countries’ continued reluctance to adopt, what the United States and the other industrialised countries saw as adequate protection of intellectual property, resulted in increased bilateral pressure on a number of developing countries by the United States Trade Representatives (USTR). In May 1989, several developing countries, including India, Brazil, Mexico and Thailand, were placed on a “priority watch list” under the “Special 301” provision (Iyer, et.al., 1996:8), for eventual further trade-sanctions against these countries. Some of the countries included in the list used the next meeting in the Negotiating Group on TRIPs to state “their deep concern about certain decisions taken by the United States under Section 301” and accusing it for “jeopardising the work of the Negotiating Group and threatening to wreck the Uruguay Round” (GATT Document, MTN.GNG/NG11/13).

But the United States hard-line negotiating policy continued in the years after. Countries in which intellectual property practices were seen as inadequate, or a threat to United States commercial interests, were moved between a “priority watch list” and a “regular watch list” according to their stand on IPR. In April 1992 India, which consistently refused to change its stand on the matter due to strong domestic resistance from NGOs (see later), and a large pharmaceutical industry which was dependent on copy

production, was targeted by the USTR, who suspended duty free treatment of Indian imports of a value of 60 million US\$ under the Generalised System of Preferences under GATT.

The Dunkel Draft

The discussions continued in the different Negotiating Groups under the Uruguay Round, including the one on TRIPs, and progress was made in some areas on Intellectual Property Rights. There was, however, still fundamental disagreements on the question if trade in counterfeit goods and protection of trade secrets should be accepted as a category of intellectual property, to be dealt with under the GATT-system. Hence two different proposals for an agreement on TRIPs were drafted, one which distinguished between trade in counterfeit goods and other areas of IPR, prepared by India and other developing countries, and another proposal, which did not make the distinction. (GATT Document, MTN.GNG/NG/W/76). At the Ministerial Meeting in Brussels in December 1990, which was supposed to conclude the Uruguay Round, the disagreements wasn't solved and as a result of this the negotiations on TRIPs couldn't be concluded.

The Chairman of the Trade Negotiating Committee and former Director General for GATT, Mr. Dunkel, was authorised to finalise a compromise draft, summing up the discussions in the different Negotiating Groups under the Uruguay Round. The draft, known as the "Draft for Final Act", or "The Dunkel Draft", was finalised in December 1991 and – while much of its content was agreements already arrived at the Montreal and Brussels Ministerial Meetings in 1988 and 1990 – it also contained suggestions on most of the disputed areas. Based on this, the negotiations between the European Communities and the United States went on for another two years before the Uruguay Round officially could be concluded in December 1993.

In the draft for the TRIPs-agreement, the Draft Text had used the proposals from the Developed Countries, which didn't make the distinction between trade in counterfeit goods and other questions of IRP, as suggested by a group of Developing Countries. The draft furthermore only mentioned development issues, or the safeguarding of public interests, such as public health, in very general terms, in effect giving it an inferior position when confronted with the protection of commercial rights (see paragraph 8 in the TRIPs-agreement). But in the negotiating process, the Draft for Final Act got

status as a paper of “consensus” meaning that if changes were to be made in the text, it would require unanimity among the negotiating parties. When the Draft for Final Act at the same time stated that “No Single element of the Draft Final Act can be considered as agreed till the total package is agreed” (GATT Document, MTN.TNC/W/FA) it was a choice of “take it or leave it”, and leaving GATT/WTO wasn’t an option for many of the developing countries. Most of the developing countries had neither a position in the world market, nor the bureaucratic and administrative capacity to engage in bilateral trade negotiations with a large number of countries, and hence it would mean economic ruin to stay outside the new World Trade Organisation. Even though the agreement on TRIPs, along with other new areas, was inconsistent with developmental and public interests of many of the developing countries, they still only had poor alternatives to joining the WTO and accept the agreement reached on TRIPs as it stood.

To sum up the TRIPs negotiation process, the agreement were more or less forced upon the country, and clearly didn’t reflect India’s economically and politically interest. Instead, The negotiating history of TRIPs during the Uruguay Round shows that the different Indian Governments first resisted introducing IPR in a GATT/WTO context, and later on, when it had made concessions on the matter, tried to build in more comprehensive safeguards into the TRIPs-agreement, in order to secure public interests and developmental issues, but with poor results. The Government therefore found itself in a situation in 1994, where it had to adopt and implement new laws related to Intellectual Property Rights that it didn’t support itself and – furthermore - were an obvious political target for the different domestic political forces opposing the agreement.

The political process in India

The political process in India has not only been characterised by the external influence from GATT/WTO, but also – and especially - by a endogenous cocktail consisting of domestic political conflicts, commercial interests, NGOs and an anti-imperialistic/Swadeshi⁵⁸ ideology, which is imbedded in India in both the civil society, the trades and industries, in the bureaucracy, and in the political life. This was reinforced by the circumstance that the

⁵⁸ Swadeshi stems from Mahatma Gandhi, and stresses the importance of endogenously managed development in order to achieve economic freedom and has been an important ideology and political cornerstone in India since independence.

patent issue was considered to be the most important part of the Dunkel Draft in India (Debroy, 1996:155), which made it difficult to gain broad political and public support for the required changes in the different TRIPs-related laws in the Indian Parliament.

The pre 1994-process

If one looks at the process before and after the Draft Final Act was finalised in December 1991, one will find a clear shift in the official Indian position on the matter and the rhetoric used in the debate. But already before the Draft Final Act was finalised, there was harsh domestic criticism of the way the Indian Government was handling the situation. The April 1989-compromise in GATT had already resulted in extensive criticism, both in the Parliament and in the public debate. Not least because it was made without consulting the Parliament, where the Government in earlier debates had stated that it had no intentions of changing the patent laws (Iyer, et. Al., 1996:32). However, the official Indian policy in the area hadn't changed much. In a several pages long Press Statement in July 1989, the Government stated that "*India is of the view that it is only the restrictive and anti-competitive practices of the owners of intellectual property rights that can be considered to be trade-related, because they alone distort or impede international trade*" and furthermore "*that there is a close correlation between the level of the economic, industrial and technological development of a country on the one hand, and the nature and extent of patent protection granted by it on the other*" (Press Information Bureau, Government of India, 28 July 1989, quoted in Iyer, et. al., 1996). It was this stand there was pursued by the government in the papers submitted to the Negotiating Group in September 1989 (GATT documents NG11/W/39 to NG/W/41), but without success (see earlier).

In December 1989 a new minority Government, the National Front, assumed office after the ruling party, Congress (I), conceded defeat in the general election held in November '89. The former Finance minister and member of the Congress (I), V.P. Singh from the Janata Dal party headed the new government. However, the National Front Government had to gain support from both the Hindu-nationalist party, the BJP and different Communist and left wing parties in Parliament in order to establish a working majority (EIU 1993/94:5). The ruling coalition, and the parties supporting it, could unite on pursuing a policy with more emphasis on self-reliance ideologies and the new government sharpened the criticism of the April '89 compromise in

Geneva. During debates in Parliament in March-August 1990 it stated that India would not participate in any negotiation under threat of retaliation (whereby it meant the USTR Special 301 investigation against India) (Iyer, et. Al., 1996:35). The more critical rhetoric from New Delhi did, however, not materialise into a comparable hardened stance during the Negotiation Group's meeting in Geneva in order to bring the negotiations back to a pre-April '89 situation. But at the same time, it neither made efforts to comply with the US demands for better IP-protection in the country.

The National Front Government resigned in November 1990 because it lost a vote of confidence after the BJP withdrew its support to the government. A breakaway faction from the Janata Dal Party formed a new, very slim and unstable, minority government supported by the Congress (I), but after only 6 months it had to call for a new general election. The election was held in May 1991, and the Congress (I) resumed power in June '91 under Mr. Rao, who formed a new minority government, which remained in power until May 1996.

A condensed version of the political situation in India during the period from 1989 to '91 is that "globalisation sceptic" parties held parliamentary key positions, but the political situation remained very unstable, not at least due to violent communal and cast conflicts, which weakened India during the GATT negotiations. The unstable political situation was furthermore steeped up by economic and foreign exchange problems, especially on the capital account, as an in-direct result of the Gulf War (Joshi & Little, 1999: 66). However, there continued to be broad political support behind the GATT- and TRIPs-sceptic line in Parliament. In September 1991 more than 150 members of the two houses, representing all major parties, signed a public statement, together with around 100 "eminent citizens", warning against the results of the GATT negotiations on IPR and protesting against the USTR threat of trade sanction under the Special 301.

Other Political Players

There were other important actors involved in the political debate in India on TRIPs and the Dunkel draft during this period. One of the most active organisations campaigning against changes in the Indian 1970 patent legislation was "The National Working Group on Patent Laws" (NWG). The NWG had originally been launched after discussions in the Indian pharmaceutical industry, but went further as it was agreed to work closely together with NGOs on the patent issue, inasmuch as it also was of concern

to the general public, because changes in the patent legislation inevitably would lead to higher prices on medicine. The NGW involved itself in the public debate, and supplied politicians and journalist with information and estimates of the effects on medicine prices if India changed the patent legislation.

As a response to the public debate in India at the end of the 1980's, some of the multinational pharmaceutical companies with subsidiaries in India decided to set up a branch of the pro-patent organisation InterPat⁵⁹ in the summer 1990. The media strategy of InterPat was different from the one of NWG, as it couldn't count on public support. Instead InterPat was targeting politicians, leading managing directors and professional opinion leaders by issuing a newsletter debating the patent issue and arguing for the benefits from having strong patent protection for the Indian Industry. The organisation also hosted several international conferences in India, together with other pro-patents organisations, where foreign experts were invited to present papers.

The involvement from the NWG, InterPat and other NGO's, who were engaged in the patent issue, had a significant impact upon the public debate in India. On the one hand the organisations contributed to create awareness about respectively advantages or disadvantages of amendments to the patent legislation and to create a debate covering a large and complex issue, which was negotiated outside India and outside the Indian medias' normal searchlight. However the emergence of the lobby organisations/NGO's (especially those campaigning against the TRIPs-agreement) should also be viewed as a national/local response to global economic change processes where the actors were forced to make there influence bear, because the bargaining situation had changed in favour of those supporting strong protection of intellectual property rights. The TRIPs-agreement put the patent issue back on the political agenda in India, which the TNCs operating in the country and their industry association hadn't been able to do since the 1970 Patent Act came into force.

The Debate on the Dunkel Draft in the Indian Parliament

After the Dunkel Draft was finalised in December 1991, the new Indian Government changed its position on the matter, and de facto accepted that India would have to conform its IPR-related legislation to the TRIPs-

⁵⁹ InterPat is an international organisation working for a uniform and strong protection of IPR in all countries.

agreement if the country wanted to become a member of the new global trade organisation. Though the Government avoided confrontation on the issue during debates in Parliament and were cautious about tabling its views on the matter, which must be seen in the light of the broad public resistance to the Dunkel Draft. The strategy of the opposition, as well as the NGO's supporting them, were to avoid that the Government sneaked TRIPs-related laws through Parliament without a large public and parliamentary debate on the issue. And during debates in Parliament, in December 1992 and again in August 1993, members of the Lok Sabha protested of the lack of information from the Government. Besides throwing more light on the consequences and effects of the law this strategy had two advantages. One was that large public interest could force the Government to assume a more "national" policy on the matter, and secondly it would gain time by consequently postponing the decision making on the area. The NWG as well as several politicians requested that the Government did not sign the Dunkel Draft before it was debated both in Parliament, and in organs such as the National Development Council, and that a Joint Parliamentary Committee had analysed the effects of the Dunkel Draft on the Indian economy (NWG, 1992; Minutes from the debate in Lok Sabha 23rd December 1992).

In the December '92 debate in Parliament, the Government refused to form a Joint Parliamentary Committee, as suggested by the opposition which should take a closer look on the Dunkel Draft's impact upon Indian economy with the argument that *"if a parliamentary committee as such is formed, then naturally I do not know what time they can finalise ... So, I am not able to commit at this point of time"* (Minister of Industry, P.J. Kurien, 23rd December 1992 in the Lok Sabha, col. 175). The Government had clearly taken a pragmatic stand on the Dunkel Draft, stating that India could not be outside a multilateral trade system and that the Dunkel Draft furthermore would phase out the MFA of the GATT system, which was of enormous importance to India, as it would influence around 30% of the country's export. It also stated that India had tried hard to keep IPR (along with other issues) out of the GATT-negotiations, but without succeeding because other developing countries like Brazil, Yugoslavia and Egypt had agreed to implement it in the GATT negotiations. (P.J. Kurien, 23rd December 1992 in the Lok Sabha, col. 224).

In December 1993, the Dunkel Draft was once more debated in Parliament. The Government repeated its stand on the results of the GATT negotiations; that the Dunkel Draft did have negative effects upon Indian economy, but

the country could not stand outside the a multilateral agreement on trade. The Opposition - both the left-wing parties and the nationalist BJP - criticised the Government for not forming a front, together with other developing countries, against the results of the GATT negotiations, and argued that the federal States should be heard on the issue. This didn't happened. India signed the Final Act and the Agreement Establishing the WTO in Marrakesh, Morocco in April 1994, and by doing so, India at the same time committed itself to change a number of laws and regulations.

The post-Marrakesh situation

The Parliamentary problems, however, were not over for the Indian Government after they had signed the agreements in Marrakesh. Before India could become a member of the WTO, it had to comply with new standards for protection of IPR.

The TRIPs-agreement allows countries, which before 1995 only recognised process patents, a ten years transition period before they would have to comply with the TRIPs-standards. But if a country chose to use the transition period, they had to secure that patents registered after 1995 would still be effective after 2005, when the transition period had elapsed. For this purpose two things had to be in place. One was the granting of Exclusive Marketing Rights (EMR) for new products, and the other a "Mailbox" facility, where new patents could be kept until 2005, at which time they would be examined by the patent offices. India did not have legislation in place to meet the WTO-obligation and therefore had to make amendments to the 1970 patent act, before they could join the WTO.

However, amending the patent legislation was not without problems. The Government had the necessary support in the Lok Sabha, but did not have a majority in the Upper house, the Rajha Sabha, and the amendment-bill had to pass both houses before it could be adopted. Therefore the Government used another strategy. After the Parliament was adjourned in December 1994, the Government issued the Patents (Amendment) Ordinance, securing EMR and a Mailbox facility in order to meet the preconditions for entering the WTO on 1st January 1995. The ordinance, though, had to be approved by Parliament within 6 weeks after the next parliamentary session had commenced - or else it would lapse. The Rao-Government therefore

introduced the Patent (amendment) Bill, 1995 in February 1995 to the Lok Sabha, where the bill passed. But in the Rajya Sabha the attempt failed, and due to this the Patents (Amendment) Ordinance, 1994 lapsed. India then was in a situation that it had joined the WTO but did not fulfil its legal requirements. In May 1996 the Lok Sabha was dissolved due to general elections, with the result that the Patent (amendment) Bill, 1995 also lapsed, because it still hadn't passed in the Rajya Sabha.

The 1996 elections led to BJP becoming the single largest party in the new Lok Sabha, but the party failed to secure the necessary support from other parties to be able to form a stable government. Instead a new Centrum-Left minority government, the United Front, was formed. In July 1996 the UF Government proposed to introduce the Patent Amendment Bill, 1996, which should incorporate some of the modifications sought by members from UF and BJP to the 1995 Amendment bill (The Economic Times, 30th July, 1996), but the proposal never materialised.

Case against India in WTO's Dispute Settlement System

Meanwhile, the industrialised countries intervened in the political process. In November 1995 the WTO set up a panel which should handle a complaint filed by the US, stating that India had failed to meet its obligation of providing a legal framework for its Mailbox facility and securing EMR for post-95 products. The US won the case against India in September 1997. India then brought the ruling from the dispute panel to WTO's Appeal Body, arguing that the TRIPs-agreement gives the countries the freedom to determine the appropriate method of implementing the provisions of the TRIPs-agreement (Article 1 in the TRIPs-agreement). As a response to this, the EU filed a new complain to WTO's Dispute Settlement Body, repeating that India had failed to meet its obligation of providing a legal framework for its Mailbox facility and EMR. In January 1998, the Appeal Body under the WTO came to the same conclusion as the Dispute Panel, and recommend that India change its patent legislation before April 1999, in order to provide legal authority for its mail box facility and to secure EMR (The Hindustan Times, 29th April, 1999). India also lost the similar case, brought by the EU, in the Dispute Panel in September 1998, and India was once again committed to change its Patent legislation before April the 19th 1999 (Business Standard, October 1998).

Split in the anti-WTO coalition

While the complaint against India was dealt with in the WTO system, politicians and NGOs in India, who had been working to maintain the 1970-patent legislation as it stood, mobilised their forces. The NWG, The Indian Drug Manufacturers Association and a parliamentarians group called "The Forum of Parliamentarians on Intellectual Property" along with other NGOs started to involve themselves in the campaign against the TRIPs-agreement. The campaign against the TRIPs-agreement carried political punch due to an alliance between the Hindu-nationalist party, the BJP, and the left-wing parties, which together had a clear majority in both Houses of Parliament, as well as large public support.

The UF-Government chose to call for general elections before time in February-March 1998. As a result, a new BJP-lead coalition government, headed by Mr. Vajpayee, assumed office. This also meant an end to the alliance between the left-wing parties and the BJP. During negotiations in the fall of 1998, the BJP-lead government affirmed that India would meet its international obligations, and declared that an amendment bill to the 1970 Patent act would be introduced during the winter session of Parliament. Finally, in March 1999, the Patent (Amendment) Bill, 1998 was passed - more than 4 years too late and only weeks before the WTO's Dispute Panel's dead line. India passed the last TRIPs-related amendments in 2002.

Concluding remarks

The concluding observations there can be made from the political process in India shows that national actors have succeeded in postponing the TRIPs required amendments to the patent legislation for several years. But international pressure from USA and the EU, through the WTO's Dispute Settlement Mechanism, has forced India to comply with the TRIPs-agreement. The political manouvre room for the Indian state has been constrained from both below (ngo's, industry and national political institutions), and from above (WTO, OECD countries and TNCs). While "global rulemaking" impact upon nation states "autonomy from" extranal political forces, it can, when the global rules are inconsistent with local economic and social interests, also prove to limit the states "autonomy to" comply with the country's international obligations.

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