Chapter Nine

THE AGREEMENT ON TRIPs AND LIMITS ON STATE ACTION
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I. Introduction

The basic principle which formulates the nature and scope of obligations under the Agreement on TRIPS mandatorily confers an obligation on the Members to give effect to its provisions.1 Further, it specifies that "...Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement".2 However, it allows its members to determine the appropriate method of implementing the provisions of the Agreement within their own legal system and practice. At first glance, it looks as if these provisions accord states a primacy in the process of application of the Agreement. The preamble to the Agreement on TRIPS refers to such ideas as "...taking into account differences in national legal systems"; "...recognizing the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives"; "...recognizing also the special needs of the least-developed country members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base".3 In the following

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1Article 1, The Agreement on TRIPS in Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations (Marrakesh, 1994), p.321.

2Ibid.

3Preamble to the Agreement on TRIPS, n.1, p.320.
analysis, however, an attempt has been made to highlight the serious limits placed on States action. The analysis also attempts to identify the space left for States to defend national interest.

II. Scope of State Action: Limits Identified

The preamble recognises IPRs as "private rights". The implications of such a reference are manifold. Firstly, it transforms the overall policy approach towards the rights conferred in the Agreement. Secondly, it shifts the emphasis from existing mode of protection which attempts to harmonize public interest and private gains. Lastly, it influences the interpretative matrix of the principal provision of the Agreement. The Agreement clearly outlines the extent and scope of measures which need to be reflected in the legal systems. In sum, it places limits on State action. In the ensuing analysis we shall consider these aspects in greater detail.

A. Substantive Issues

The Agreement on TRIPS provides, as we have seen, for a totally new regime of IPRs. The standards and principles, embodied in it are to be properly reflected in the internal legislations of Member States. Even then, it is worthwhile to identify areas wherein some space is available for developing countries to take into account their own needs in the larger interest of their population. Our focus, in this analysis is of course limited to patents.
Patentability defines the extent and scope of patentable subject-matter. States, in their internal legislations, have not followed a uniform definition of patentability. The divide existing between the perceptions of developed countries on the one hand, and developing countries on the other has already been dealt with both historically and conceptually. The Agreement on TRIPS provides detail criteria of patentability in Article 27, which states: "... patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application". This provision provides for two exceptions by making a reference to paragraph 4 of Article 65 and paragraph 8 of Article 70. Article 65 deals with "Transitional Arrangements". It provides for certain concessions to developing and least-developed countries. There is also a reference to paragraph 3 of Article 27 which provides for the exclusion of some subject-matters from patentability. This aspect is examined later. To begin with, it is essential to examine the "Transitional Arrangements" and other related areas to find out the freedom a State has in enacting an enabling legislation, keeping in view its own requirements.

(a) Transitional Arrangements

The concessions provided in Article 65 relate to the periodicity of the application of some of the features of patentability criteria. It, for example, provides for developing

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4 See Chapter Six.

5 For these aspects see Chapter Three and Four, which deal with the evolution of such differences.
country members "a delay for a further period of four years" as regards the date of application of the provisions of the Agreement on TRIPS. Apart from this general provision, it also provides for a specific concession as regards the product patent protection in a developing country. It says:

To the extent that a developing country member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that members...it may delay the application of the provisions on product patents...to such areas of technology for an additional period of five years".\(^6\)

This transitional arrangement at the first blush looks equitable. However, it is provided that during the transitional period Member States should ensure that any changes in its laws, regulations and practice must not result in a lesser degree of consistency with the provision of the TRIPs Agreement.\(^7\) From this, the following implications follow. In the period of transition Member States cannot change the substantive provisions of their intellectual property laws resulting in the lesser degree of consistency with the provisions of the Agreement. The applicability of this status quo requirement not only covers laws and regulations but, more importantly, practices undertaken within the State.

(b) **Pipeline Protection**

The delay of five years provided for the inclusion of product patent protection in the national patent laws is taken away in a different form altogether. For this purpose one

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\(^6\)Article 65 (4), The Agreement on TRIPS in *Final Act*, n.1, p.348.

\(^7\)Ibid.
will have to consider the implications of Article 70. As mentioned already, Article 27 while outlining the scope of "patentable subject matter" makes a reference to Article 70(8) which *inter alia* provides for situations where a Member does not make available patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27. Such situations are brought in conformity with the standards and principles of the Agreement by a unique mechanism. This mechanism has three aspects, namely, (a) from the date of entry into force of the Final Act a means by which applications for patents for such inventions could be filed; (b) apply to these applications, the criteria of patentability as laid down in this Agreement; and (c) provide patent protection for the reminder of the patent term in conformity with the standards prescribed in the Agreement.\(^8\)

The implications flowing from Article 70(8) seem to be of no consequence at the first instance. Because it only seeks provisions for the filing of mere applications for patents for pharmaceutical and chemical products. However, it specifies further that it should be "commensurate with its obligations under Article 27". So, the implications, it should be noted, are quite significant. The substantive aspects of Article 27 are applicable to these applications while their examination is undertaken. Priority will also run from the date of application. So, there exists an application for patent with all the attendant rights of the patent. If anybody invents in the intervening period any new product or process he will have to retrace his steps to acquire a fresh patent as there already exists a ‘patent’. This is quite far-reaching in another sense also. Priority date is accorded to

\(^8\)Article 70 (8), The Agreement on TRIPs.
the patent application without first examining whether it fulfils the patentability criteria. In other words, it negates the very principles embodied in Article 27. More deeper consequences, however, follow from clause (9) of the Article 70 which seeks to confer on these patent applications what is termed as "exclusive marketing rights".

(c) Exclusive Marketing Rights

The Agreement on TRIPS does not define anywhere the exact nature of "exclusive marketing rights" (EMRs). Article 70(9) merely provides that:

where a product is the subject of a patent application in a Member in accordance with paragraph 8(a), exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another member and marketing approval obtained in such other Members.9

Its reference to "obtaining marketing approval" is intriguing for it differs from country to country. The idea of introducing "exclusive marketing rights" is to facilitate prospective patent holders to acquire and retain their control over the market which otherwise may be lost to them. It does call for a change in the internal legal framework. For instance, the President of India, promulgated an Ordinance, namely, The Patents (Amendment) Ordinance, 1994 on 31 December 1994 to give effect, inter alia to the

9Part VI of the Agreement on TRIPs deals with "Transitional Arrangements".
"exclusive marketing rights" by introducing a new Chapter IVA to the Patents Act 1970. This facilitated India implementing the WTO Agreement. 11

This Ordinance, however, lapsed on 26 March 1995 on account of the failure of the Government to muster enough support for the passage of the Bill in the Rajya Sabha. 12 This Bill had been passed in the Lok Sabha earlier with a very slender margin. Subsequently, a decision was taken by the Government to refer the Bill to the Parliamentary Standing Committee on Industries. 13 Even in the recently concluded 1995 monsoon session of the Parliament, the Government failed to get the Bill passed. There had been some debate in India as regards the implications of non-fulfilment of the obligations as required under the Final Act of the WTO Agreement. According to one unsubstantiated view "severe conditionalities, like India being forced to implement the complete changes under the GATT agreement within five years instead of available 10 years of transition period are possible". 14 However, the Indian Government maintained that no serious repercussions are expected. 15

The Commerce Minister P. Chidambaram, without actually addressing the defects in the substantive aspects of the Bill, stated in a meeting organised jointly by WTO and

11 "For the detailed treatment of the Patents (Amendment) Ordinance, 1994 see Chapter Five.


15 "Ibid."
Asian Development Bank that "it was important to have the bill passed to fall in line with WTO commitments".¹⁶ In contrast, Argentine Congress voted on a patents Bill before approving it on 30 March 1995 to fulfil its obligations under WTO. Unlike the Indian Ordinance the Argentine Bill excluded five-year EMRs during the transition period till 2003, when the new Argentine law comes into force.¹⁷

(ii) Non-Voluntary Licensing

A careful scrutiny of Article 31 shows us two immediate implications. Firstly, by using the phrase "other use of the subject matter of a patent without the authorization of the right holder", Article 31 seems to widen the scope of the protection and the consequent applicability of conditionalities.¹⁸ Reference in this phrase is not to the "patent" per se, but to the "subject matter of a patent". In other words, the requirements of this provision will apply automatically to the patents which seek to protect "identical" or "similar" subject matter.¹⁹ Although the words "identical" or "similar" do not appear in Article 31 the effect contemplated or the probable interpretation mooted for the word "subject matter" in future may not be altogether different.

¹⁶The Economic Times (New Delhi), 28 March 1995.


¹⁸For discussion on "Non-voluntary Licensing", see Chapter Eight. It also discusses its features and also TRIPs formulation in this regard in Article 31.

¹⁹Article 34, refers to "identical" product while outlining the "Burden of Proof" requirements. Final Act. n.1, p.335.
Secondly, Article 31 requires the Member States to "respect" its provisions wherever other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government is allowed in its laws. This, in our view, is very important. Because, it allows a State certain amount of freedom while formulating its patent law taking into account its own needs. The word "respect" denotes some amount of "recognition" or "reflection". It does not say how exactly a State should go about doing this. But, it is mandatory. Whether a State has accorded adequate "respect:" or not, once again, is a matter of interpretation.

One crucial question which needs consideration is whether this formulation allows the incorporation of the traditional features of non-voluntary licensing. These traditional features could be briefly listed as (a) a fixed time frame for its commencement of operation; (b) the satisfaction of the state authority in deciding the fulfilment of "public interest", including the reasons for non-working or failure to work; (c) compensating the patentee on the basis of determination made by the State; and (d) allowing the patentee to show legitimate reasons for non-working or his failure to work.²⁰

It may be noted that Article 31 more or less fulfils all these requirements with a totally different focus. Firstly, it chooses to determine the authorization of any such use on its individual merits. In this regard, a State is not given any supremacy to decide on its own in general terms the grounds for issuance of non-voluntary licences. Secondly, it requires the proposed user to make efforts on reasonable commercial terms and

²⁰These features are generally found in Article 5A of the Paris Convention. For the evolution of these features refer to Chapter Three.
conditions to obtain the authorizations and such efforts should have been unsuccessful within a reasonable time. There is no definiteness about the two terminologies, namely, "reasonable commercial terms" and "within a reasonable time". It may become nearly impossible for proposed user to conclusively determine these two factors. In other words, a State cannot determine or define in its normative structure the extent of these terminologies so as to expect a predictable situation. A strict legal interpretation of these terminologies is also not possible as it involves factors which are not essentially legal.

Commercial value of an authorization, for instance, will have to be considered on the basis of existing market conditions and the overall viability of the authorization itself. If these factors are not favourable the "right holder" can very well disagree to authorize. This interpretation which will most likely dominate the future negotiations of authorizations simply overlooks the aspects of working and its spin-off benefits to society. The basic objective of patent system as a tool to encourage invention in return for a 'working' within a specified time is disregarded. This requirement of an authorization however, could be waived in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It only requires the State in these cases to promptly notify the "right holder".

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21 For the brief interpretation of these terminologies see Chapter Eight.

22 There is nothing to bind the "right holder" so that within a reasonable period he would be mandated to compulsorily 'work' the patented invention. Whether such a provision could be introduced on the basis of Article 8 will be examined later.
(a) National Emergency and Circumstances of Extreme Urgency

Article 31 while providing for "Other Use Without Authorization of the Right Holder" refers in Clause (b) to two situations in which the requirement of obtaining authorization from the right holder could be waived. These situations are -- the case of a national emergency or other circumstances of extreme urgency. Both these situations, it should be noted, are not definable in definite terms. Accordingly, these two situations are not mentioned in any national legislation as a ground for authorising the 'other use'. Majority of the countries seek to provide in their national legislation for the non-voluntary licences on the grounds of non-working. There are also other grounds on which it is issued, such as -- for interdependence of patents; in the public interest; abuse of monopoly; in the interest of public health, or in case of inventions relating to food or to medicines. The nearest ground which could be attributed to 'national emergency' is the issuance of non-voluntary licence on the ground of 'national defense'. It has been provided in the national legislations of Czechoslovakia, Hungary, Nigeria, Philippines, Republic of Korea, Rumania, Sudan and Yugoslavia.

The reference to 'national emergency' and 'circumstances of extreme urgency' was made in the proposals of the developed countries which were submitted to the Uruguay Round negotiations. The United States' proposal particularly referred to the

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23 Article 31(b), Final Act, n.1, p.333; see Chapter Eight for the interpretation of these terms.


25 Ibid.
"declared national emergency." The Japanese proposal, on the other hand, referred to the public interest concerning national security or critical peril to life of the general public.

(b) Measures to Protect Public Health, Nutrition and Promote Public Interest

In the above discussion so far we have dealt with the issues concerning limits placed on the State in such areas as patentability, and authorization for other use. There is, however, one provision in Article 8 which provides a general exclusionary mechanism which could be taken into account while framing or amending laws and regulations. Article 8 provides that:

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

Considering the freedom granted in Article 8 to the States to formulate laws taking into account certain factors, it is necessary to examine its scope. First of all, it

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26MTN. GNG/NG 11/W/14-Rev.1, 17 October 1988, Suggestion by the United States for Achieving the Negotiating Objective.

requires that measures which it allows are to be consistent with the provisions of the Agreement. Secondly, measures protecting public health and nutrition could be formulated. Even measures to promote public interest in sectors of vital importance which are important for the concerned State's socio-economic and technological development could also be adopted. However, the adoption of measures to prevent abuse of IPRs by right holders or practices which unreasonably restrain trade or adversely affect the international transfer of technology 'may be needed'.

On the basis of the principles enunciated in Article 8 some exceptions could be contemplated to the exclusive rights conferred by a patent. However, this is restricted by Article 30 of the Agreement which provides that

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

So, while providing exception to patent rights members are obligated to not to "unreasonably conflict with a normal exploitation of the patent". Again, it depends on what is actually presumed by an "unreasonable conflict" as used in Article 30. What standards will decide these factors? National laws, justify these factors, could include certain measures protecting public health or public interest. For developing countries, in general, the sectors of vital importance are health care and pharmaceutical. This is

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2A reference should also be made to Article 1 of the Agreement which, inter alia, provides that "Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement".
evident from the fact that majority of the developing countries, including some developed
countries excluded from patentability, till recently, the drugs and pharmaceutical
products.29

(c) TRIPs and Impact on Drug Prices

The Agreement on TRIPs in Article 27 envisages availability of patents "for any
inventions whether products or processes, in all fields of technology." Within the
stipulated transitional period countries whose patent regime provides only for process
patents in certain sectors, particularly pharmaceutical and drugs, will have to grant
product patents also. India, being a signatory to the Final Act, will also have to
undertake necessary changes in its patent laws. With these changes the prices of drugs,
according to some, is sure to go up.30 In India, it is argued, the introduction of Patents
Act, 1970 had brought about tremendous changes in the growth of drug industry. Drug
prices, for instance, were among the highest in India before the introduction of the
Patents Act, 1970.31 In the last two decades, due to a provision excluding
pharmaceutical from product patenting, the indigenous formulations of new drugs through

29Existence, Scope, n.24, p.96; Nearly 49 countries excluded pharmaceutical products from patenting;
About 35 countries excluded food products from patenting; pharmaceutical and food processes were
excluded in 19 countries, which also included countries such as, New Zealand, Denmark, Canada, Finland,
Greece, Portugal, Norway and China.

Journal of Scientific and Industrial Research, vol.52, (1993), p.271; Also see submissions made to the
Department-Related Parliamentary Standing Committee on Commerce, Parliament of India (Rajya Sabha,
1993). p.43.

31Ibid., This was also the comment made by Senator Kefauver who headed an American Senate Committee
in 1959.
new processes brought down not only the prices, but also facilitated the introduction of new variations.

According to some others there is no correlation between drug prices and the introduction of product patenting. In their view drug prices were maintained at a particular level by employing the mechanism of Drug Prices Control Order (DPCO). They point out that "the DPCO has been a major influence on prices, while many people have been (knowingly or unknowingly) highlighting the prices of drugs patented, which form a very small percentage of the total consumption in India". Further, it is concluded that "In the pharmaceutical sectors, India is quite competitive and the prices will be affected mainly due to decontrol of prices rather than introducing product patents".

The facts enumerated in various other studies, on the other hand, show that there is a direct correlation between product patenting and the drug prices. First of all, it is necessary to examine whether with the introduction of product patenting a large percentage of essential drugs will be affected or not. According to one statement the percentage of such patented drugs would not exceed more than 10 to 15 per cent of the

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\(^3\)The Drug Prices Control Order was first promulgated in 1970. In 1979 a revised Drug Price Control order was issued and it became controversial due to its pricing policies; see, Dinesh Abrol and Amitava Guha, "Production and Price Controls : The Achilles Heel of National Drug Policy" in Amit Sen Gupta, (ed.), *Drug Industry and the Indian People* (New Delhi, Delhi Science Forum: 1986), p.126.

\(^4\)Prasad and Bhat, n.32, p.1043.

\(^5\)Ibid.
total drugs in the market. A study conducted by the Operations Research Group (ORG) did not support this view. The study has pointed out that for fourteen major therapeutic groups, antibiotics, anti-bacterial and anti-leprosy etc., taken together the share of the patented drugs in the domestic production was about 46 per cent. Following table shows the share of patented drugs in India:

Table 9.1: Share of Patented Drugs in India

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Therapeutic Groups</th>
<th>Percentage under Patents</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Antibiotics</td>
<td>40.23</td>
</tr>
<tr>
<td>2.</td>
<td>Antibacterial</td>
<td>98.80</td>
</tr>
<tr>
<td>3.</td>
<td>Systemic Antifungal</td>
<td>25.66</td>
</tr>
<tr>
<td>4.</td>
<td>Anti-Leprotic</td>
<td>69.96</td>
</tr>
<tr>
<td>5.</td>
<td>Cardiovascular</td>
<td>40.18</td>
</tr>
<tr>
<td>6.</td>
<td>NSAIDS</td>
<td>22.16</td>
</tr>
<tr>
<td>7.</td>
<td>Tranquilizers</td>
<td>74.42</td>
</tr>
<tr>
<td>8.</td>
<td>Anti-Convulsants</td>
<td>65.93</td>
</tr>
<tr>
<td>9.</td>
<td>Anti-Convulsants</td>
<td>65.92</td>
</tr>
<tr>
<td>10.</td>
<td>Antipeptic Ulcer Drugs</td>
<td>55.30</td>
</tr>
<tr>
<td>11.</td>
<td>Oral Anti-Diabetics</td>
<td>47.53</td>
</tr>
<tr>
<td>12.</td>
<td>Anti-Asthmatics</td>
<td>21.34</td>
</tr>
<tr>
<td>13.</td>
<td>Anti-histamines</td>
<td>32.41</td>
</tr>
<tr>
<td>14.</td>
<td>Cytostatic and Anti-Leukemics</td>
<td>88.79</td>
</tr>
</tbody>
</table>

The problem becomes more complex when the latest drugs are prescribed and put to extensive use. As pointed out in the Parliamentary Report, the payment of royalty to the original product and its technology is one factor which will result in the increase in prices. It is clear from the above table that the argument that large member of patented drugs in India would be off patents in the next few years is not true. In other words, patents will be issued to new therapeutic drugs and with product patenting in place the prices of drugs will remain high. According to one critic two factors continue to determine the behaviour of drug markets: "One, that the latest therapeutic equivalents with high shares of patented drugs dominate the market. Two, product patent expiry has minimal downward effect on drug prices and market shares".

With the beginning of Uruguay Round negotiations and the trade liberalization efforts undertaken in most of the developing countries, it is stated that important changes have been made in the principles of patent protection. The Trade and Development Report, 1994 seeks to point out that:

At the start of the negotiations in 1986, approximately 50 countries did not confer full patent protection on pharmaceutical. This was also the case, in some instances, of food and beverages. Since then, however, important legislative changes have taken place in many developing countries within the framework of the economic and trade liberalization process which these countries are undergoing. For instance, changes in patent legislation with respect to pharmaceutical have been introduced in Bolivia, China, Chile, Colombia, Ecuador, Indonesia, Mexico, Peru, the


Republic of Korea and Venezuela. Other countries are likely to follow the same path even before the entry into force of the Agreement.\textsuperscript{37}

Although Article 8 provides the basic principles to formulate or amend national laws, the State's willingness to undertake such exercises are restricted. It is only in Article 27(2) and Article 31(b), as examined already, that there is some space left for introducing certain changes with a view to promote public interest in sectors of vital importance. However, the second part of Article 8 needs closer scrutiny as well. It refers to measures which could be adopted to prevent abuse of IPRs or the resort to such practices which unreasonably restrain trade or adversely affect the international transfer of technology. The aspects concerning the "restraint of trade and the international transfer of technology" need to be examined in the light of provisions relating to anti-competitive practices and the efforts made so far, particularly by the developing countries to evolve a suitable Code of Conduct for the Transfer of Technology.

The provision in Article 8 that "appropriate measures...may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade", has far-reaching implications. According to Trade and Development Report, 1994 (Supplement), "the adoption of the exclusive "competition

test" in the Agreement has put an end to a long-standing international debate as to how to treat restrictive practices in transactions pertaining to transfer of technology.\footnote{Ibid., p. 193.}

A report by the Secretary-General of UNCTAD on the consultations carried out till 1992 concerning International Code of Conduct on the Transfer of Technology had, however, pointed out that "divergences remain on conceptual questions in Chapter 4, regarding the manner in which restrictive practices in transfer of technology transactions should be treated in an international code. Likewise in respect to chapter 9, different approaches have been advocated by those countries favouring a clearer recognition of the freedom to choose the law applicable to their contractual relations and those wishing to stress the observance by the parties of the laws of their individual countries from which a contract must not derogate".\footnote{"Negotiations on an International Code of Conduct on the Transfer of Technology : Consultations Carried out in 1992", Report by the Secretary-General of UNCTAD, TD/CODE TOT/58, 22 October 1992.} So, the Secretary-General of UNCTAD had asked the Governments to provide views on the following issues which were outstanding in the draft Code of Conduct, in particular on the acceptability of:\footnote{Ibid: Following countries had sent their views on these issues: Canada, People’s Republic of China, Czech and Slovak Federal Republic, Iraq, Netherlands, Niger, Philippines, Saint Lucia, Switzerland and United States of America. It is interesting to note that excluding Philippines and the United States all the other countries more or less supported the continuation of negotiations.}

* Exclusive application of competition law principles to the evaluation of restrictive practices;

* Adherence to freedom of contract and freedom of choice in respect to applicable law and forum for dispute settlement.
In the light of these developments in the next section we shall examine Article 40 of the Agreement which particularly deals with the "Control of Anti-Competitive Practices in Contractual Licences".

iii. Anti-Competitive Practices

An area in which a State could exercise its freedom to frame suitable law is anti-competitive practices. It is stated that the members may take remedial measures to contain practices determined after judicial or administrative process to be anti-competitive.43 In such circumstances a State does not have to wait for the authorization from the right holder on reasonable commercial terms. Even the condition concerning the authorization for the predominant supply for the domestic market of the member could be waived. The calculation of adequate remuneration as compensation for such use will also be dependent on the extent of anti-competitive practices. The discretion of terminating the authorization will also lie with the State. This is, however, subject to the conclusive determination of anti-competitive practices.

The definition and regulation of anti-competitive practices, particularly in contractual licences could be found in Article 40 of the Agreement on TRIPs.44 This provision notes that some licensing practices or conditions pertaining to IPRs which restrain competition may have adverse effects on trade and may impede the transfer and

43 Article 31(k) in the Agreement on TRIPS. See Final Act, n.1, p.334.

44 Article 40, Final Act, n.1, p.337.
dissemination of technology. Accordingly, it does not prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of IPRs having an adverse effect on competition in the relevant market. It allows Members to adopt appropriate measures to prevent or control such practices. By way of an example Article 40 describes two such practices, namely, exclusive grant back conditions and conditions preventing challenges to validity and coercive package licensing. The Paris Convention which has a reference in the Agreement outlines the extent and scope of unfair competition. It seeks to assure nationals of the Union an effective protection against unfair competition. It defines an act of unfair competition as "any act of competition contrary to honest practices in industrial or commercial matters". The increasing trend of anti-competitiveness or restrictive trade practices has created special problems for the developing countries. It is not easy, particularly for the developing countries to detect and regulate such practices. Such practices often lack transparency. For example, it is difficult to detect conspiracies between firms to eliminate competition by reaching agreement among competitors to fix prices and allocate markets in cartel agreements. These practices may have different forms also, namely, activities aimed at eliminating competitors through refusal to deal, resale price maintenance, tied selling and predatory pricing. Reference should also be made to takeovers, mergers and acquisitions. Lately, control over technology through various


4 "Ibid.

techniques should also be considered in the light of draft Code of Conduct on the Transfer of Technology.

With a view to establish international voluntary standards in regard to such restrictive practices a major initiative was undertaken within the framework of negotiations for a Code of Conduct on the Transfer of Technology under UNCTAD's auspices. It identifies a series of measures including grant-back provisions, exclusive dealing, restrictions of research, restrictions on use of personnel, price fixing, restrictions on adaptations, exclusive sales or representation agreements, tying arrangements, export restrictions, patent pool or cross-licensing agreements, restrictions on publicity etc.

At the close of the Sixth Session of the UNCTAD, a draft was circulated on the International Code of Conduct for the Transfer of Technology. It, inter alia had contained 9 chapters outlining the various aspects of methods to facilitate smooth and equitable international transfer of technology. Chapter 3 provided for the 'national

*Ibid. Work undertaken at UNCTAD in the early seventies led to an agreement at UNCTAD IV in Nairobi that RBPs can adversely affect international trade, particularly that of developing countries as well as economic development of these countries and that action should be taken at the international level, including negotiations with the objective of formulating a set of principles and rules for the control of RBPs; also see Report by the Secretary-General, n.41.

*These RBPs have been considered in greater detail in Chapter 8.


*Ibid. There was, however, no unanimity in accepting the last two clauses of the Preamble which inter alia concerned the scope of applicability of the Draft Code. Chapter 2, on the other hand, provided a set of 10 objectives which sought to "establish general and equitable standards on which to base the relationships among parties to transfer of technology transactions and governments concerned, taking into consideration their legitimate interests, and giving due recognition to special needs of developing countries for the fulfilment of their economic and social development objectives."
regulation of transfer of technology transactions' on the following basis: (i) To recognize that a close relationship exists between technology flows and the conditions under which such flows are admitted and treated; (ii) To promote a favourable and beneficial climate for the international transfer of technology; (iii) To take into consideration in an equitable manner the legitimate interests of all parties; (iv) To encourage and facilitate transfers of technology to take place under mutually agreed, fair and reasonable terms and conditions; (v) To take into account the differing factors characterizing the transactions such as local conditions, the nature of technology and the scope of undertaking; and finally (vi) to be consistent with their international obligations.²

The Draft Code provides reasonable standards which could be adopted in the national regulations. Furthermore, there are specific measures which need elaboration in the national legislations. Chapter 3 of the Draft Code provides for such measures.³ Chapter 4, as noted already, deals with the regulation of restrictive business practices.⁴

In the light of the provisions of Article 40, we should, however, examine the possibilities of envisaging a legislation at the national level for RBPs. It should be noted that Article 40 allows a Member to specify in its legislation licensing practices or

²Ibid., p.6.

³Ibid., This covers such areas as currency regulations, financing facilities, tax and pricing policies, technical and organizational aspects of transfer of technology.

⁴Ibid., p.8; These practices have already been discussed in greater detail in Chapter 8. So here only reference is made to these practices.
conditions that may in particular cases constitute an abuse of IPRs. Such practices may also have an adverse effect on competition in the relevant market. In such instances, Article 40 authorizes a Member to adopt appropriate measures to prevent or control such practices. It, on the other hand, does not specify what actually should constitute these "appropriate measures". It is, however, provided that these measures should be adopted consistently with the other provisions of this Agreement. So, in the absence of specific list of RBPs mentioned in the Agreement it should be concluded that it is appropriate for the national laws to adopt provisions envisaged in the Draft Code so long as they are consistent with the provisions of the Agreement.

v. **Burden of Proof: Need for Some Guidelines**

The reversal of burden of proof as envisaged in Article 34 of the TRIPs text will necessitate changes in the laws of many countries. According to a WIPO study, the reversal of the "burden of proof" is provided for in the laws of most countries where the "extension of process patent protection to products exists, e.g., Canada, France, Germany, Italy, Japan, Malaysia, Republic of Korea, Spain, Switzerland and United Kingdom. On the other hand, it is not provided for in the laws of the countries where he said "extension" does not exist e.g., Argentina, Australia, India and the US. If the formulation of the TRIPs Agreement is to be incorporated in the national laws, such a

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8Ibid.
reversal is viewed as a derogation from general *onus probandi* principles that unjustifiably increases the power of the title-holder at the expense of small and medium-sized enterprises. In order to mitigate the effects of such a reversal few broad guidelines may have to be necessarily outlined in the national laws, particularly in the case of developing countries.

The foremost feature of such a guideline should incorporate a flexible approach. In other words, it should recognise the fact that the onus of providing a proof essentially depends on the circumstances of the case. For instance, there is also a basic assumption that a plaintiff who first takes recourse to law should convince the Court about the *prima facie* existence of a certain factual situation. Pending that, the Court may seek greater clarification, by way of proof if need arises, from the defendant.

**B. Procedural Measures**

The Agreement on TRIPS provides for an elaborate network of requirements concerning enforcement and administrative measures in Part III and Part IV. Enforcement measures are crucial in any intellectual property protection regime. The necessity and effectiveness of having substantive provisions to define and outline various aspects of intellectual property legislation depends largely on these measures. Infringement proceedings form an integral part of the remedial measures. However, these measures

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are basically limited to territorial application in concurrence with existing domestic law. There may be differences in the operative style of the judicial bodies taking into account the ground realities. It is not easy to identify the factors which actually constitute fair and equitable procedures. In view of this, it is provided in Article 41(5) that the enforcement measures as enunciated in Part III do not create any obligation to put in place a judicial system for the enforcement of IPRs distinct from that for the enforcement of law in general and that it does not affect the capacity of Members to enforce their law in general.

For developing countries it particularly creates the difficulty of diverting adequate resources to enhance the effectiveness of enforcement measures and machinery. To put at rest this probable difficulty it is provided in Article 41 (5) itself that "Nothing in this Part creates any obligation with respect to the distribution of resources as between enforcement of IPRs and the enforcement of law in general." However, difficulties persist. The UNCTAD's Trade and Development Report, 1991, notes:

...The stricter enforcement of agreed procedural standards sought by developed countries would certainly increase the costs of administering intellectual property systems, costs that many developing countries already find extremely burdensome. Enforcement provisions, including border control measures, would also imply changing various aspects of national legislation (including rules of jurisdiction) that might be difficult to implement in view of the differences in administrative and judicial systems."

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(i) Civil and Administrative Procedures and Remedies

For the first time, procedures relating to civil and administrative remedies have been given due importance while outlining enforcement measures. This requirement, however, has to be considered from the point of view of domestic law. As mentioned earlier, without adequate provisions for the enforcement measures, the effectiveness of the substantive provisions may be nil. Even accepting this, the provisions concerning civil and administrative remedies should have been limited to general guidelines. Instead, the existing structure in the Agreement makes it mandatory on the members to make available to right holders civil judicial procedures concerning the enforcement of any IPR covered by the Agreement.40

In order to effectively check infringement the Agreement places in the judicial authorities the authority to order a party to desist from an infringement.41 Even it provides for payment of damages which should be adequate to compensate for the injury the right holder had suffered because of an infringement.42 There are also a few remedies to create an effective deterrent to infringement, such as the disposal of infringing goods outside the channels of commerce or if legally permitted, to destroy such infringing goods. However, it is also provided that while considering such disposal methods, the need for proportionality between the seriousness of the infringement and

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40 Article 42, The Agreement on Trips in Final Act, n.1, p.339.
41 Article 45, The Agreement on TRIPS, in Final Act, n.1, p.339.
42 Ibid.
the remedies ordered as well as the interests of third parties should be taken into account. The Agreement on TRIPS also provides for the effective provisional measures to prevent possible infringement and to preserve relevant evidence in regard to the alleged infringement.

While considering these procedural measures care should be taken to examine aspects which may require a State to put in place its limited financial resources to their effective operation. It is also not easy to decide in a given situation whether measures applied are adequate or not. Moreover, there may be other extraneous factors which need consideration. As regards the provisional measures, for example, common law approach has always been formulated by taking into account varied factors. The House of Lords in American Cyanamid Vs. Ethicon for instance, did not accept the approach hitherto held by the Courts with regard to the granting of interlocutory injunction. The long held view was that an applicant for an interlocutory injunction had to establish a *prima facie* case that he would succeed at the trial before the court and was required to look at the balance of convenience.

In the American Cyanamid case the claim was for an interlocutory injunction restraining infringement of a patent the validity of which was contested by the defendants and the House of Lords was unwilling to contemplate a lengthy investigation of the

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*Ibid., Article 46.*

*Ibid. Article 50. There are elaborate provisions concerning special requirements related to border measures.*
merits at the interlocutory stage. The House of Lords therefore laid down a new approach for interlocutory injunctions generally, not just those sought for patent infringement. Under the new approach, the applicant need only show that there was a serious question to be tried (rather than clearing the higher hurdle of a *prima facie* case) after which the Court should then go straightaway to the balance of convenience.

The above mentioned case shows the discretionary powers vested in the Courts to resolve the dispute. The strict provisions as enunciated in the Agreement may not be effectively adhered to. In that case what could be the implication? It appears that an affected Member is entitled to acquire all the information and can approach the Dispute Settlement Body of the WTO. The Dispute Settlement Body will ultimately decide the feasibility of not only the domestic legislation concerning enforcement, but may also seek to comment on the customs and practices of the Member. This leaves very little option to a Member. In the long-run a Member will have no alternative but to harmonize the policies and the legal set up to fulfil the requirements embodied in the Agreement.

In sum, the elaboration of these norms in the Agreement entail on its Members financial burdens in the form of creation and maintenance of infrastructure for the

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"Ibid."
enforcement of the remedial measures. The flexibility of laws and procedures, as mentioned earlier, depend largely on the interpretations given to them by the appropriate judicial authorities. These interpretations are not necessarily final as it could be adjudicated through Dispute Settlement Body as envisaged in the Final Act. This is, however, preceded by the provisions concerning institutional arrangements which primarily include a Council for the Trade-Related Aspects of IPRs.

C. Dispute Settlement Body: Provisions for Surveillance and Retaliations

In the Final Act, the procedures relating to settlement of disputes appear as Annex 2. The title of this Annex says: "Understanding on Rules and Procedures Governing the Settlement of Disputes". In order to administer these Rules and Procedures a Dispute Settlement Body (DSB) is envisaged. The DSB is authorized to establish panels, adopt panel and Appellate Body Report, maintain surveillance of implementation of rulings and recommendations. There is also a general obligation on the DSB to inform the

"Reference should be made to Article 67 of the Agreement on TRIPS. In order to facilitate the implementation of the TRIPS Agreement, it requires the developed country members to provide "on request and on mutually agreed terms and conditions technical and financial cooperation in favour of developing and least-developed country members". Such assistance not only includes preparations of laws and regulations, also includes "support regarding the establishment or reinforcement of domestic offices and agencies relevant to these matters, including the training of personnel."

"Article 68, Final Act, n.1, p.349.


"Ibid."
relevant WTO Councils and Committees of any developments in disputes related to provisions of the respective covered agreements.  

The primary purpose of the dispute settlement system is to provide "security and predictability to the multilateral trading system". The finality of the decisions adopted by the DSB is limited in the sense that its recommendations and rulings "cannot add to or diminish the rights and obligations provided in the covered agreements". In other words, the decisions or interpretations given out by the DSB do not create any precedents. Furthermore, a Member, before bringing a case has been asked to "exercise its judgement as to whether action under these procedures would be fruitful". The general approach required for the assessment of the dispute settlement procedure seeks to look at these procedures as non-contentious and wants its members to engage in these procedures in good faith in an effort to resolve the dispute.

Having considered briefly the objectives of the DSB, in the following discussion we shall briefly outline the various stages in the dispute settlement mechanism. These various stages leave little or no option for the States. The first step begins with the

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1"Ibid; Article 2(2).

2"Ibid., Article 2(3).

3"Ibid. It is, however, provided in Article 2(7) that "The aim of the dispute settlement mechanism is to secure a positive solution to a dispute". Further, even the preference for the kind of solution contemplated is also mentioned. It is stated that "...A solution mutually acceptable to the parties to a dispute and consistent with the covered agreements is clearly to be preferred. In the absence of a mutually agreed solution, the first objective of the dispute settlement mechanism is usually to secure the withdrawal of the measures concerned if these are found to be inconsistent with the provisions of any of the covered agreements".
consultation procedures. There is a time limit provided for these consultations (Table 9.1 shows the time limits and the procedures to be adopted). If consultations do not take off within the stipulated period, the concerned members could request the establishment of a Panel. As regards developing countries, it is merely stated that during consultations their particular problems and interests should be given special attention. The mechanism also provides for the informal procedures such as good offices, conciliation or mediation at any time by any party to a dispute. (See Table 9.1).

If all these fail to settle the dispute a procedure to establish a Panel will be taken up. One crucial aspect of the constitution of the Panel is that no consultations need be held with the parties to the dispute. It is, in fact, the prerogative of the WTO Secretariat to propose the nominations for the Panel. So, the WTO Secretariat is mandated to maintain an indicative list of governmental or non-governmental individuals possessing the required qualifications. Further, it is clearly provided that the parties to the dispute should not oppose nominations except for compelling reasons.

"Article 4 of the Understanding, n.69.

"Ibid.

"Article 4(10) of the Understanding, n.69.

"Article 5 of the Understanding, n.69.

"The procedures relating to the establishment of a Panel is provided for in detail in the Understanding. Article 6 deals with the "Establishment of Panels; Article 7 - "Terms of Reference of Panels; Article 8 - "Composition of Panels"; Articles 11 and 12 deal particularly with the functions and procedures to be adopted by the Panels.
There is a provision which seeks to consider the interests of developing countries. It provides that "when a dispute is between a developing country member and a developed country member, the Panel shall, if the developing country member so requests, include at least one panelist from a developing country member." For the least developed country members, it is provided that "At all stages of the determination of the causes of a dispute and of dispute settlement procedures involving a least-developed country members, particular consideration shall be given to the special situation of least-developed country members. In this regard, members shall exercise due restraint in raising matters under these procedures involving a least-developed country member".

After finalizing the terms of reference within a stipulated period, the issuance of the report by the Panel normally should not take more than six months. It is also provided that the period from the establishment of the Panel until the report's circulation should not exceed nine months. (See Table 9.1). The adoption of the panel report is followed by a surveillance mechanism", which, inter alia calls for the "prompt compliance with recommendations or rulings of the DSB in order to ensure effective resolution of dispute". As noted already, the working schedule of the panel or Appellate

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7Article 8 (10) of the Understanding, n.69, p.359.

8Article 24 deals with the "Special Procedures Involving Least-Developed Country Members. It has been, however, observed that developing countries have rarely used the GATT dispute settlement mechanism in the past and will not do so in the future: see. Frederick S. Ringo, "The Trade-Related Aspects of Intellectual Property Rights Agreement in the GATT and Legal Implications for Sub-Saharan Africa: Prospective Policy Issues for the World Trade Organization", Journal of World Trade, vol.28 (December 1994), no.6, p.121; P.B. Kohona, "Dispute Resolution under the World Trade Organization", Journal of World Trade, vol.28, (1994), n.2, p.23.
Body is strictly bound to a time frame. Even if it requires to exceed the permitted limit of time as provided in the *Understanding* it will have to adduce reasons in writing together with an estimate of the period within which it will submit its report. Following table synoptically outlines these time-frames.
Table 9.2: Procedures and Time-frames in Dispute Settlement Mechanism under DSB

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Time-frame</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initiation of Consultation</td>
<td>Members must reply to request within ten days, and enter into consultations within thirty days unless mutually agreed otherwise.</td>
</tr>
<tr>
<td>Good offices, conciliation and mediation</td>
<td>If the parties agree</td>
</tr>
<tr>
<td>No response from members</td>
<td>If no response from members or no consultations within thirty days, complainant may request a panel.</td>
</tr>
<tr>
<td>Negotiations</td>
<td>Sixty days (unless parties agree that consultations failed). If no settlement, the complainant may request a panel.</td>
</tr>
<tr>
<td>Within twenty days of establishment of the panel</td>
<td>Terms of reference are determined. If there is no agreement on the panelists, the WTO Secretariat to determine the panelists in consultation with DSB Chairman and the Council/Committee Chairman.</td>
</tr>
<tr>
<td>Period</td>
<td>From the date the composition/terms of reference have been decided until the issuance of the report should normally not take longer than six months. The period from the establishment of the panel until the report’s circulation should not exceed nine months.</td>
</tr>
</tbody>
</table>
A party to the dispute notifies the DSB to appeal within sixty days after the report’s circulation (or the DSB decides by consensus not to adopt the report)

From the date the appeal is formally notified, the appellate proceedings shall, in principle, not last more than sixty days, and, in any case, not more than ninety days.

The DSB will not consider reports until twenty days after their circulation to Members. Objecting Members will have at least ten days to explain their objections prior to the DSB meeting. The report shall be adopted by the DSB within sixty days (for appellate reports: thirty days) after the circulation (unless the DSB decides negatively).

Within thirty days, the party concerned informs the DSB of its intentions. If the party does not comply with the recommendation it will have to negotiate with the complainant. Twenty days after the reasonable period expires, retaliations may be authorized.

Source: Yermulst and Driessen, n.69, p.160.

According to one view, the dispute settlement mechanism could be presented as a three-segment process. The first phase concerning consultation and negotiation is essentially considered as ‘political’. In this phase states parties to the dispute have some freedom to formulate their arguments. Once the panel is constituted and the terms of reference is finalized, the second phase begins. This phase is genuinely judicial phase with the preparation of the panel report with complete independence. With the adoption and

approval of the panel report by the Council, the third phase which is again essentially
political, begins. Once the panel reports are adopted, the DSB is given the general power
to keep under surveillance the implementation of the adopted recommendations or
rulings. Any member can raise the issue of implementation of the recommendations or
rulings at the DSB at any time following its adoption. Even any Member who may not
be directly connected with dispute could now take up the issue of implementation.82
In other words, the options before the States, for implementing the decisions of the DSB
are limited and are well defined.

The retaliation clause which appears in Article 22 is worded differently.83 It says:
"Compensation and the suspension of concessions or other obligations and temporary
measures available in the event that the recommendations and rulings are not
implemented within a reasonable period of time". Further, it is made clear that
'compensation is voluntary and, if granted, shall be consistent with covered
agreements".84

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82 Article 21 of the Understanding deals with the "Surveillance of Implementation of Recommendations and Rulings".

83 It is pointed out that "whatever the choice of words which are used to conceal the dire fact. In the new
documents they speak of "compensation" or "countermeasures". "but these euphemisms are not innocent.
Retaliation is really what is meant", See Pescatore. n.81, p.15.

84 Article 22 of the Understanding provides for these measures. It is provided, for example, that the
suspension of concessions should be at the first instance relate to the same sectors in which the Panel or
Appellate Body has found a violation or other nullification or impairment. If it is not practical the
suspension could be extended to other sectors. If it is ineffective in other sectors, the procedure allows
suspension under another covered agreement. Further, Article 22 also provides for the arbitration
proceedings in such cases where a Member raises objections to the level of suspension proposed.
The procedures for the implementation of the decisions of the DSB leave no space for any option to the States. If States decide not to undertake the implementation of the decisions, Article 22 strictly provides for the "cross-sector retaliations". More significantly, the decisions adopted by the DSB become a part of the covered agreements. The last phase of surveillance and implementation is for this reason is not entirely in the interest of developing countries.

D. World Trade Organization (WTO): Dilution of State Authority

The scope of the state action is severely restricted by the structure and power of the WTO. One of the major objectives of the WTO is to outline the broad economic policy framework at the global level. States have very limited space to operate within this framework of the WTO. In the following analysis such limitations vis-à-vis the objectives of the WTO will be examined.

The scope of the common institutional framework of the WTO extends to the conducting of trade relations among its Members in matters related to the agreements and associated legal instruments included in the Final Act. This could be stated as the immediate objective of WTO. It, on the other hand, proposes to have a larger role in the overall global economic policy-making. With a view to achieve this objective, the WTO is mandated to cooperate, as appropriate, with the IMF and with the IBRD and its

*The Preamble to the Agreement Establishing the WTO, *inter alia*, states, "Recognizing further that there is need for positive efforts designed to ensure that developing countries, and especially the least developed among them, secure a share in the growth in international trade commensurate with the needs of their economic development"; Article II (a) the "Agreement Establishing the World Trade Organization".*
affiliated agencies. The structure of the WTO to accomplish these objectives consists of a three tier institutional mechanism. At the first level there is a Ministerial Conference composed of representatives of all the Members. It is the principal decision-making body and will meet at least once every two years. The General Council composed of representatives of all the Members constitute the second level. It will conduct the affairs of the WTO during the intervals between meetings of the Ministerial Conference. At the third level is the system of Committees, such as, a Committee on Trade and Development, a Committee on Balance-of-Payments Restrictions and a Committee on Budget.

The relations of the WTO in the form of Cooperation or other appropriate arrangements are not limited only to its Members and other intergovernmental organizations. There is a provision for the consultation and cooperation with non-governmental organizations concerned with matters related to those of the WTO. While dealing with these bodies the WTO deals with them in an independent capacity with its own legal personality. Involvement of non-governmental organizations (NGOs) is notable for various reasons. Firstly, in matters of trade it is very difficult to find precedents wherein NGOs have been so directly involved in an international trade organizations. Secondly, the involvement of an NGO does not merely end at

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*Ibid., Article III (5).*

*There are Councils as per Article IV in the specialized areas such as Council for Trade in goods, a Council for Trade in Services and a Council for TRIPs. These bodies are entitled to establish necessary subsidiary bodies as required. The work of the DSB also comes under the General Council.*

*Article V, Agreement Establishing the World Trade Organization.*
"consultation". It even extends to cooperative endeavour. Thirdly, although States acquiesce the participation of NGOs in the areas like human rights and environment, their response to such participation in matters concerning trade and investment is not clear.

The process of decision-making at the WTO is through consensus. If there is no consensus, it is provided that the WTO will decide the matter by voting in which each Member of the WTO will have one vote. It could be seen that utmost importance is attached to the matters of interpretations of the Agreement and of the Multilateral Trade Agreements. Only the Ministerial Conference and the General Council have the exclusive authority to adopt interpretations. The decision to adopt an interpretation is to be taken by a three-fourths majority of the Members.

There are certain general provisions which need careful consideration. The supremacy of this Agreement is confirmed in the following provision which, *inter alia*, says "In the event of a conflict between a provision of this Agreement and a provision of any of the Multilateral Trade Agreements, the provisions of this Agreement shall prevail to the extent of the conflict". Furthermore, it is upon each Member to ensure the conformity of its laws, regulations and administrative procedures with its obligations as provided in the annexed Agreements. The conformity standard envisaged in the above provision covers not only laws and regulations, but also administrative procedures. In

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*Article IX, n.86, p.13.

*Ibid.

*Article XVI, n.86, p.18.
other words, it is envisaged that the change should not only touch the mere substantive aspects, but also peripheral procedural aspects within the Member States.

III. Summation

The primary objective of this Chapter had been to examine the provisions of the TRIPs Agreement vis-a-vis the serious limits placed on the state action. The Agreement on TRIPs, mandatorily confers an obligation on the Members to give effect to its provisions. It also allows its Members to determine the appropriate method of implementing the provisions of the Agreement within their own legal system and practice. Accordingly, the main focus of this chapter was also to identify the space left for States to defend their national interest. These aspects had been considered in two parts. First part of the study dealt with the substantive issues and the second part essentially looked into the procedural issues. At the end, the implications flowing from the two important institutional mechanisms, namely, Dispute Settlement Body and the World Trade Organization, were dealt with a specific approach of limits placed on the State authority.

The determination of the criteria of patentability and the issuance of non-voluntary licensing constituted the discussion on substantive aspects. The limitations on the States to enact the enabling legislations taking into account their priorities and national interest begin at the stage of implementing the provisions of "transitional arrangements" itself. As shown in this chapter, the concessions envisaged in the "transitional arrangements"
were taken away by the provisions relating to "pipeline protection" and "exclusive marketing rights". One of the serious implications flowing from this related to the granting of product patents indirectly by approving the provisions relating to "exclusive marketing rights". This was specifically applicable in the field of pharmaceutical and agricultural chemicals. In this regard, a reference had also been made to the Ordinance promulgated by India to give effect to these provisions. Although the Indian Patents (Amendment) Ordinance, 1994 lapsed on 26 March 1995, the implications arising out of its enactment could have seriously affected the India’s interest in the field of drugs and medicines.

This chapter also examined the implications of Article 31 of the TRIPs Agreement relating to what had been termed as "Other Use without the Authorization of the Right Holder". The foremost difficulty would arise, as argued in this chapter, in providing an effective mechanism to adapt this provision to the existing compulsory licensing requirements. Furthermore, a State might also find it difficult to determine or define in its normative structure the extent of terminologies employed in Article 31 of the TRIPs Agreement. However, Article 8 provided a general exclusionary mechanism which could be taken into account while framing or amending laws and regulations. This provision sought to allow a member to adopt measures necessary to protect public health and nutrition, and to promote the public interest in the sectors of vital importance to the socio-economic and technological development. The measures adopted, however, had to be consistent with the provisions of the Agreement. One of the major implications of this exclusionary mechanism related to the prices of drugs. In view of this, the chapter also
examined, albeit briefly, the impact of uniform criteria of patentability on the drug prices. The primary focus of this examination had, however, been India and its policy towards maintaining drug prices.

The definition and regulation of anti-competitive practices as provided in Article 40 of the Agreement on TRIPs also formed a major part of the discussion in this chapter. The incorporation of measures relating to anti-competitive practices, particularly concerning licensing practices or other conditions, would be essential to restrict the abuses of IPRs and its adverse effect on competition in the market. While arguing this, the chapter also made a reference to the existing international voluntary standards to regulate restrictive practices such as the Code of Conduct for the Transfer of Technology and its incorporation in the national laws.

Although the issues relating to the "reversal of burden of proof" essentially concern the procedural aspects, the implications, as considered in this chapter, were substantial. In order to mitigate its effect, particularly on the developing countries, a guideline would be necessary to assist the national courts. The second part of the chapter outlined the implications of certain procedural issues, particularly concerning enforcement measures. The chapter also noted the problems in adopting the civil and administrative procedures and remedies as envisaged in the TRIPs text.

The concluding part of the chapter outlined the provisions relating to DSB and WTO. These two institutional mechanisms to implement the provisions of the Agreement left very little space for state action. The DSB, for instance, was authorized to establish
panels, adopt panel and Appellate Body Report, maintain surveillance of implementation of rulings and recommendations. The WTO, on the other hand, sought to conduct trade relations among its Members in matters related to the agreements and associated legal instruments included in the Final Act.