CHAPTER 8
8. ACTION TO BE TAKEN BY INDIA TO MAXIMISE THE BENEFITS FROM TRIPS PROVISIONS IN WTO

Looking into the present day world of global need is, close cooperation among the developed and developing countries and avoidance of trade frictions and disputes amongst themselves in the interests of the mankind. The provisions of all International Agreements, Conventions, Treaties etc will have advantages and disadvantages to the member countries. Such Agreement, Conventions, Treaties are a bundle of provisions containing the rights and obligation which have to be accepted in toto or without it by all the member countries. The advantages and disadvantages of the provisions will vary from country to country based on various factors such as economical, technological and industrial development of the country concerned.

It is a well recognised fact that the bilateral agreements between countries, especially between the developed and developing countries, have proved to be unsuccessful as these are not realistic or rational because it is mostly the will of the giver rather than on any commercial and long commitment. Therefore, it would be advantageous to support and strengthen a multilateral system involving more countries than the mere isolated individual transaction.

The WTO Agreement is a multilateral International Agreement, which has come into force after very long and difficult negotiations between developed and developing nations. This Agreement is the result of great and difficult efforts of the member countries even though at the
initiatives of developed countries who create a common code of trade and IPRS among world trading nations and therefore it would be advantageous in the longer period to support and strengthen the system.

The WTO became a fait accompli almost from the year 1995. The overwhelming majority of developing countries have acceded to it and are busy cutting their losses and maximizing their gains. They are trying to take advantage of the opportunity provided by the WTO for expanding their trade and enhancing their competitiveness. An attempt has, therefore, been made in this part to look ahead to the future and suggest how the developing countries like INDIA can best cope with the challenge of the new world trading order and to use it to their advantage the flexibility provided in the texts of the agreements included in the Final Act.

In the Final Act, the developing countries were by and large denied the differential and more favorable treatment promised to them before the Punta del Este Declaration. This kind of treatment has now been reserved for the least developed among developing countries, largely because this group of developing countries, on account of their extreme vulnerability, pose no competitive threat to developed countries. The developing countries in general including the least developed countries will have no separate regime, and no exception or waiver from the general rules other than those permitted to developed countries. They have been given some relief by way of longer transitional period and lower level of liberalization commitment in agriculture, but in general, they have to
assume all the obligations and join all the regimes provided for in the different agreements of the Final Act on par with developed countries.

It is true that the Agreement has its shortcomings. Taking it as a multilateral agreement it would be beneficial if the Agreement is considered as the foundation and slowly and gradually build upon a system incorporating rules which are unbiased, transparent, stable and balanced for both the developing and developed countries and enforced sincerely by all the member countries irrespective of their economical, technological or societal status. If such a system is guaranteed it would help the member countries particularly the developing and least developed countries to remove their problems relating to poverty, health, education thereby raising the living standards of the people living in those countries.

No country which is a member of the WTO Agreement, however powerful or weak can boast itself that its own policies, laws or regulations could remain unaffected by the provisions of the Agreement. It should be the endeavor of each member country to narrow down the gap between its own laws and the obligations it assumes by virtue of its membership of the Agreement. In short, every member country has to have a “give and take” attitude and will be required to change, in varying degrees, its laws, regulations and practices to conform to its international obligations.

Another way of looking at the issues relating to TRIPS in the WTO Agreement is that if there is huge variation between the national law, regulation or practices of a member country and the obligation the
country is called upon under the WTO Agreement. It may be more of a reflection of the extent to which the country is required modification in relation to international trends than of its Municipal law, regulation and practices.

Due to the development of efficient communication system the world has become very small. Many unique developments are taking place in Science and Technology and that too in quick time. No country in the world, including the developed countries can boast itself that it can survive without the help, cooperation and assistance of other country or countries however small it may be. In the world of tomorrow national geographical boundaries will not have any meaning with regard to the flow of information, knowledge, Goods and services.

In this context the TRIPS provisions in the WTO Agreement can be considered as a success, as a foundation, which was possible after a long seven years of hard negotiations amongst its members. It is a fact that there are difficulties experienced by the developing countries in the implementation of various provisions of TRIPS. Still the TRIPS provisions may be regarded as the beginning of the unification of the global IPR law like patent law. Keeping TRIPS as the basis, it may be possible in the future for modifying the provisions incorporating therein-appropriate provisions to safeguard the interests of both the developing and developed countries.

Therefore the developing countries should make sincere efforts, without further delay, to review the TRIPS provisions and identify the areas in the TRIPS which they find it difficult to implement. It is very
essential that the practice of repeatedly arguing that the provisions of TRIPS are difficult to implement without proper identification and analysis as well as proposing alternate provisions should be stopped. In other words the developing countries should give a well-focused attention to the various provisions of TRIPS. Then identify, analyse, justify and propose alternate provisions. For this purpose they may form a Group / Block of developing countries. Such an approach would not only be powerful but also would certainly receive adequate attention when put up before the WTO. The Group/ Block so formed can also take up the issue of the currently going proposal of starting a new round of negotiations involving the subjects of environment and child labor, which will be at this juncture detrimental to the developing countries.

The developing countries as a whole may not have, a large share in to-day's world trade But they make up for this deficiency by way of having a majority (for the purpose of consensus,) in WTO which is an important asset in enforcing at a decision in WTO. Therefore the developing countries can join together and form a Group / Block and present their views in a focused, balanced, clear and in a way to express their solidarity. The consensus driven in WTO against any developed member/s cannot afford to ignore such an approach. The result will be a success for the developing countries. This may prima facie sound philosophical but if pursued with sincerity it would be practicable because “if there is a will there will be a way”. This can be achieved by our nation as a leader who was looked by many developing countries as savor developed country among developing countries.
In this contest, it may be appropriate to refer to the Article 7 of the TRIPS provisions of the WTO Agreement which states as follows: - "Parties may, in formulating or amending their national laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interests in sectors of vital importance to their socio economic and technological development provided that such measures are consistent with the provisions of this Agreement". Accordingly, the Group / Block so formed can formulate appropriate provisions based on the Article 7 and get the approval of WTO. Thereafter the Governments of the member countries can use such provisions in their legislations.

Another way of looking at the TRIPS provisions may be that they may act as a catalyst to kindle and enhance the ability to develop new products. Many industrialized countries may like to take advantage of the available resources natural or otherwise, and the market potential available in the developing countries to tie up with domestic enterprises for undertaking joint R & D programs. Such a scenario has already started emerging in India particularly in the Pharmaceutical area, consequent on India opening up her economy and became a signatory to the WTO Agreement. The situation has changed even before India has complied with all the commitments under the Agreement. Therefore, one can very well visualize the situation when India complies with all the requirements by the expiry of the interim period allowed under the Agreement. A similar position may develop in other developing countries also.

In respect of traditional knowledge and geographical indicators
encourage NGO's private body, industrialist and professional to develop data base and proved further on new invention and or to obtain IPR rights.

For example in the case of Patent Law there are three basic reasons for the grant of compulsory license. These are (1) insufficient working of the patented invention (2) for the working of the dependent patent (granted later) without infringing the patent earlier granted and (3) in the public interest especially in the areas of health, food & nutrition & Security.

An acceptable approach for the grant of compulsory license for the manufacture of products particularly pharmaceutical products may be to grant such license on the ground that the products in question are required in the country concerned in substantial quantities and also at reasonable prices for which competitive sources are very essential. The judicial combination of public interests requirements and the provision of grant of compulsory license on the ground of failure to work or insufficient working without legitimate reason may be helpful. This approach may also help keeping the options open to grant compulsory license regardless of whether the patentee works the patent in the country of grant or not.

If a patented drug is a major breakthrough and is widely needed, as for example a drug for AIDS or cancer, the price impact could be phenomenal. The strategy which may be adopted by the country to combat such a price increase appears to be in selectively and judiciously invoking the compulsory licensing provisions. Where a drug is clearly an
essential one that is required by the common man very regularly at a reasonable price, the compulsory license provisions should be brought into play without inhibiting the rights of the patentee or his licensee to manufacture the product in the country which has granted the patent or to import into the said country. Making multiple sources of production and availability with a view to create competition in the market, appears to be a good and justifiable approach to meet the country's national requirements.

The provisions of TRIPS in the WTO Agreement permits grant of compulsory license on the "individual merits" of each case. A compulsory license can be granted under the provisions of TRIPS only after the compulsory license seeker has approached the patent owner to obtain compulsory license on reasonable, commercial terms and conditions and his efforts have not proved successful within a reasonable period of time. A compulsory license cannot also be given without the patent owner being heard by the competent authority. A compulsory license is also subject to judicial review.

In this context the Article 8 (Principles) and 40 (Control of anti-competitive Practices) of the TRIPS provisions of the WTO agreement should be taken advantages of.

Article 8 says "that the countries may adopt measures to protect public interests in sectors of vital importance to their socio economic and technological development ". It also says that appropriate measures may be needed to prevent the abuse of intellectual property rights by the holders of such rights or resort to practices which
unreasonably restrain trade or adversely affect the international transfer of technology.

Article 27 provides member nations to exclude from patentability of such inventions which are not conducive to public order, morality including protecting human, animal and plant life on health or avoiding serious prejudice to the environment.

Article 40 says that "countries can specify in their legislation's the licensing practices or conditions that may constitute abuse of intellectual property rights".

The TRIPS Agreement contains no explicit provision for compulsory licensing. A measure of involuntary licensing is implicit in Article 31 of the text under the title "Other Use Without Authorization of the Right Holder". But there are fundamental differences between the provision of 'compulsory licensing' in the patent Act 1970 and those in Article 31. The most fundamental difference is that whereas the former is intended to serve the public interest, the whole purpose behind the latter is to protect the interest of the right holder even while allowing for 'use without authorization' of the patent under exceptional circumstances. The scope of authorization under Article 31 is for a limited purpose of non-commercial use only and for the limited duration. This will not serve the purpose of meeting the requirement of the general public. A number of conditions must be fulfilled before 'use without authorization' is made.

The provision in the TRIPS text of 'use without authorization' is virtually pre-empted by another provision in the text (Article 27(1) which states:' patents shall be available and patent rights enjoyable without
discrimination as to whether products are imported or locally produced.' In other words, the import of the product will be as good as producing it by locally working the patent. This gives carte blanche to the right holder not to work the patent locally and go on supplying the market by imports. It will no longer be possible to use prolonged non-working as a ground for giving a compulsory license.

Taking advantage of these inherent provisions of TRIPs the developing countries can jointly argue and put up a strong case establishing that time is not only ripe but also not appropriate to represent the debacle the product patents regime brought in the area of pharmaceuticals in their countries and demand the expand the use of compulsory license and the alteration of the definition of importation of patent as working of patent.

It can also be emphasized that the member countries which currently insist on bringing into force the product patent regime were themselves also in the same position at one point of time earlier as the developing countries are placed now. Having reached the status of developed ones they cannot now impose stricter conditions on those countries which are in the developing stage completely forgetting their own earlier situation.

The TRIPS provisions relating to Biotechnology is that the member countries should provide patent protection to microorganisms. As regards protection for new plant varieties, member's countries have the option of including it under their patent law or can have a separate
system which should be effective. What is meant by the term "effective" has not been defined. For any other inventions relating to biotechnology the member countries have been given the power to decide rules as per their requirements.

No international Convention provides any definition for the term "microorganisms" or lays down any criteria regarding the nature and scope of protection to be provided. It may be appropriate to consider whether a suitable definition for the term "microorganism" should be framed and that definition incorporated in the patent legislation.

The main strength of the developing countries like INDIA in respect of IPR is their possession of valuable traditional knowledge in the areas such as health care, medicinal plants, art, culture and the like. Currently there is no safe system of protecting this knowledge. But the developed countries especially USA, are adopting ways and means to protect such knowledge which is in public domain for many years, in some pretext or other. Measures have to be taken on a priority basis to stop this practice.

The developing countries can consider establishing a separate IPR system like *sui generis* system for protecting the knowledge developed by them and by their use traditionally. They should also take advantage of the provisions contained in the Biodiversity Convention by providing mandatory provisions in the Patent law / Sui Generis system that in the case of inventions relating to or based on a traditional knowledge of a developing country, the application should specify the country of origin of the resources employed and the traditional
knowledge used in developing the invention desired to be protected (process or product). A letter incorporating the consent of the owner of the traditional knowledge and indicating how the benefits financial or otherwise arising out of the IPR protected would be shared with the owner of the traditional knowledge used should also accompany the application. Currently the developing countries seem to have no idea of the implications of the provisions of TRIPs and are in varying degrees of confusion and understanding. The suggestion made above may help to create proper understanding and appreciation of the provisions as well as an uniform implementation of the provisions amongst the member countries. In this regard INDIA passed its own act.

The problem with giving EMRs under the conditions laid down in the TRIPS Agreement will be that its effect will be the same as of granting patent rights and yet it will not be necessary to follow such rigorous scrutiny of the application as will be done if patents were to be granted. Exclusive marketing rights will have to be given if a patent or marketing approval has been taken in any other member country. That country may not have an adequately developed chemical industry or a testing facility. This will mean that new drugs will be introduced in India without any proper chemical trial. This will be injurious to public health. Besides, giving exclusive marketing rights means that the patent will not be made public and no objection will be invited. And yet local invention in the product will be pre-empted.

The best thing for the government of India to do will be not to allow an application to lie in the black box, but to examine it as though a
patent has to be given without much delay. The Government should go through the whole drill of examining the application, notifying it and inviting public objections, even though what is involved is the granting of EMRs and not a patent. Otherwise amend the patent law providing product patents to all inventions.

In order to safeguard their development and other interests, the developing countries should take full advantage of the flexibility provided in the TRIPS Agreement in drafting or revising their national legislations. In particular, full advantage should be taken of the provisions in the Agreement regarding exclusions from patentability. The exclusions should include life forms, plants and plant varieties on the ground that their patenting can have the effect of patenting plants, and genes, cells and other biological materials on the plea that they are in the nature of discoveries and not inventions. There could also be exclusions on the ground of human health and environment and for protecting public order and morality. It has been further suggested that national legislations should provide for compulsory licensing on the grounds covered not only in Article 31 on Use Without Authorization but also in Article 7(Objectives) and Article 8(Principles). Article 31 provides that a patent can be used without the authorization of the patent holder, by reason of national emergency. In circumstances of extreme urgency, in cases of public non-commercial use, for dealing with anti-competitive practices or for the exploitation of a dependent patent. According to Article 8, member states can adopt measures necessary to protect public health and nutrition, to promote public interest in sectors of vital importance to their
socio-economic and technological development, to prevent the abuse of IPRs by right holders and prevent resort to practices, which unreasonably restrain trade or adversely affect the international transfer of technology. These provisions, it is suggested, would justify compulsory licensing in the sensitive sectors for ensuring adequate supply at reasonable prices of essential goods like food and medicines to the public and for facilitating transfer of technology.

The following other suggestions have been put forward for inclusion in national legislations:

(a) Preserve the 'breeders exception' and 'farmers privilege''

(b) Provide for compensation by the title holder to traditional farmers who have supplied genes or knowledge for the development of the protected variety.

(c) Provide for protection of traditional knowledge and innovation of the local and indigenous people.

(d) Specify, in accordance with article 40(1) 'licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market.

(e) Use Article 6 on exhaustion to provide for parallel imports of patented goods.

(f) Take steps to amend the law provide more products for protection under geographical indications.