WTO, Pharmaceuticals and Health:
Impacts and Strategies

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1. Executive Summary

WTO: a new trade arena

The establishment of WTO in 1995 ended almost half a century of GATT and ushered world trade in a new arena. Uruguay Round (final GATT round) first time included areas like intellectual property, trade in services, agriculture etc. in international trade negotiations and concluded groundbreaking agreements. "Marrakesh Agreement Establishing the World Trade Organisation", collectively called "Multilateral Trade Agreements" include agreements on: trade in goods and services; TRIPs; and legal instruments related with settlement of disputes in international trade and trade policy review mechanisms. As a membership organisation the WTO's power is centred on the biannual conference of trade ministers.

General trading Principles under WTO include acceptance by members of all the trade agreements as a package deal, non-discrimination between trading partner countries and between national and foreign companies, progressive liberalisation and harmonisation of national trade policies and making these transparent and facilitating free competitions. WTO has special provisions for developing countries.

Pharmaceuticals

Drugs are an integral part of the modern health care system. They are important for saving human lives and their regular supply is thus crucial. Today one-third of the world's population lacks access to essential drugs. WHO's essential drug concept provides the basis for achieving this goal, especially in developing countries. The discrepancies between industrialised and developing countries are marked in per capita annual drug expenditure (Japan spends $411 whereas Bangladesh spends $1), drug consumption (75% of the world’s population, living in developing countries, consume only 11% of the globally available drugs) and drug manufacturing (in 1980, more than 90% of global drug production took place in seven industrialised countries).

WTO agreements relevant to pharmaceuticals

TRIPs and TBT agreements are most relevant to drugs. According to TRIPs agreement a minimal patent protection is must for members to provide through national legislation i.e. both product and process patents at least for 20 years. TRIPs co-exist with Paris and Berne Conventions. Member countries have to provide "national treatment" and "most-favoured-nation treatment". According to TRIPs, IPRs should contribute to the promotion of technological innovation and to the transfer and dissemination of technology. It also calls for measures necessary to protect public health and nutrition, and to promote the public interest while members make amendments in their patent laws. Applicant for patent has to disclose the necessary information to the authorities and there are exceptions provided to the exclusive rights. The agreement allows the use of the patent by the third party without authorisation of the right holder and also allows members to adopt measures to overcome any anti-competitive practices. Also transitional periods are designed to allow developing countries sufficient time to bring their administrative and regulatory systems in line with a multilateral trade agreement.

The main objective of TBT is to ensure that the technical rules and regulations imposed by member states to protect consumers do not constitute unnecessary barriers to international trade, or disguised measures for discrimination.

Impacts on pharmaceuticals

The TRIPs Agreement has definite impacts on the availability of and access to drugs, especially in developing countries. There is need to understand optimistic as well as cautious views about the implications. There is a general dearth of impact studies however, researchers have come up with mixed evidence about different impacts.

Drug prices: twenty years of monopoly over a pharmaceutical product would enable the patent holder company to keep the price of the drug high for at least two decades. During this period patients would have no choice for cheaper alternatives.

Availability of drugs: there would be no retrograde impact on the availability of those drugs in developing countries that were in the market before and during the transitional period.

Local pharmaceutical industry: there is going to be a negative effect on the national pharmaceutical companies in majority of the developing countries.

Transfer of technology and foreign direct investment: there is no evidence to date about any positive impact of the TRIPs agreement on transfer of technology and foreign direct investment in developing countries with reference to pharmaceutical business.

Research & Development: because of the dominance of the TNCs on pharmaceutical business and because above 80% of the market lying in the industrialised countries the research oriented companies are more interested in new drugs for problems prevalent in these countries. The review of the drug development between 1975-97 confirms this view.

Impacts on public health

The negative impacts on the availability of drugs can further worsen the existing health conditions in developing countries. At present 40 million people die every year in developing countries out of which more than 13 million deaths occur among children under five years of age. Most of these deaths are preventable and can be effectively treated if essential drugs are made available. The challenges of old diseases (malaria, tuberculosis, STDs etc.) becoming drug resistant and emergence of at least 30 new diseases require improvements in the existing treatments and developments of new drugs. With existing drug development trend towards the diseases prevalent in industrialised countries, public health situation is likely to further worsen in developing countries.

Strategies for adapting to the new trade environment

Two sets of strategies exist for governments in developing countries to deal with the new trade environment with reference to pharmaceuticals: better appreciation of the concessions/exceptions provided in the TRIPs agreement and by adopting non-trade measures that governments should take anyway to promote the availability and affordability of drugs.

Cautious approach: there is no need for developing countries to go beyond the minimal protection criterion set-out in the TRIPs agreement.

Exceptions to the exclusive rights: careful and intelligent use of limited exceptions (allowed in Article 30) members can insulate their national interests against likely negative implications of the TRIPs agreement. Since "limitations" are not defined in the legal text, members may interpret the concept of exceptions to achieve their defined national objectives.

Technological innovation and transfer of technology: by virtue of Article 7 countries can consider: scientific research and experiments involving patented inventions; tests carried out before the expiry of the patent to establish the bio-equivalence of a generic drug.

Article 8.1: provides leeway to members to adopt measures necessary to protect public health and nutrition. It also promotes the public interest in sectors of importance to their socio-economic and technological development by keeping with the spirit of the provisions of this agreement.

Compulsory licensing: there are twelve provisions to be considered by members for grant of compulsory licenses in Article 31. Compulsory licensing is crucial to be incorporated in the national patent laws by the developing countries in order to ensure access to needed medicines.

Control of anti-competitive practices in contractual licensing: according to Article 40 governments are permitted to incorporate measures to control anti-competitive practices in contractual licenses, which can help them to bring drug prices down in the country.

Parallel imports: parallel import is allowed in the TRIPs agreement. Having this measure in the repertoire developing countries can make medicines available to the people in case the prices of patent holders in the country are too high or supply is too low.

TBT: it recognises that no country should be prevented from taking measures necessary to ensure the quality of its exports, or for the protection of human, animal and plant life or health, of the environment, or for the prevention of deceptive practices, at the levels it considers appropriate.

Non-trade agreement measures: national drug policy (NDP) based on essential drug concept is a recipe for universal availability of needed, effective, safe and affordable drugs especially in developing countries. Specific measures in the context of NDP includes licensing of drug manufacture and import, drug registration, limiting promotional costs, licensing of wholesalers, retailers, essential drug lists, various strategies for cost containment, drug price control, drug information and education, improvements in drug prescribing and promotion of rational use of drugs.

Conclusion

TRIPs agreement requires member countries to amend their patent laws to ensure the incorporation of minimal patent protection provided in the TRIPs. According to their status and their use of transitional periods, developing countries have been engaged in making the amendments in their laws. Very crucial at this point is that how intelligently they make use of the concessions and exceptions provided within the agreement. Experts agree that there is a lot of space within the text of the agreement which if exploited fully but responsibly can help countries

to safeguard their public good objectives with reference to availability of essential drugs e.g. provisions of compulsory licensing, parallel imports etc.

2. Introduction

From 1st January 1995, the day the World Trade Organisation (WTO) came into being, discussion about the possible effects of WTO agreements on pharmaceuticals has intensified. More specifically, concerns have been raised about the impact of "Agreement on Trade-Related Aspects of Intellectual Property Rights" (TRIPs) on supply of and access to medicines in developing countries.

Clearly, there are two points of view about the likely impacts. Proponents of strong and prolonged pharmaceutical patent protection believe that it will encourage the pharmaceutical industry to dedicate more resources for research and development of new treatment breakthroughs. Advocates of public health in developing countries on the other hand raise concerns about likely future prospects after full implementation of relevant WTO agreements i.e. high drug prices, low access, weakening of national pharmaceutical industry, etc. Dissatisfied with the existing drug situation in these countries, where almost half of the population does not have reliable access to medicines, public health experts foresee further problems in the wake of TRIPs implementation.

As a result of these debates the 49th World Health Assembly (WHA) in 1996 through a resolution[1] requested the Director-General "to report on the impact of the work of the World Trade Organisation (WTO) with respect to national drug policies and essential drugs."

In 1998 the WHA discussions on Revised Drug Strategy were also hinged on the issues related with impacts of WTO agreements on pharmaceuticals. The portions of the resolution[2] related with "negative impacts on local manufacturing capacity and access to and prices of pharmaceuticals in developing countries…" and "public health rather than commercial interests have primacy in pharmaceutical policies" became points of intense debates. Even after long deliberations of the drafting committee (13 hours) a consensus could not be reached.[3] Eventually the WHA could not adopt the resolution and it was referred back to the Executive Board for examining all over again.

This paper is written as a contribution to the ongoing discussions. The paper in the first part introduces the new trade order and existing inequitable global pharmaceutical situation. Cognisant of the conflicting views on the issues under discussion, the second part analytically reviews the relevant WTO agreements and explains the important sections. The third part discusses the impacts of the agreements, primarily with reference to supply of and access to drugs in developing countries. While explaining each impact both optimistic and cautious interpretations are presented.

The fourth part presents a picture of emerging health problems, especially in developing countries, and a scenario about constrained availability of medicines as a result of prolonged protection of Intellectual Property Rights (IPRs) of patented drugs under the TRIPs agreement.

The fifth and last part first discusses possible strategies for adapting to the new trade environment with regard to exploitation of the concessions and exemptions provided within the agreements. Both conservative and permissive understanding about exceptions is presented. The second section of this part dwells on drug policy measures that countries should take to offset the negative impacts and make drug supply and management systems more efficient.

Part 1

3. WTO and new trade regime

The establishment of the World Trade Organisation was agreed upon in April 1994 at the Marrakesh Ministerial Meeting. In the same meeting the Final Act of the Uruguay Round was also signed by the trade ministers from around 125 countries. Adoption of the resulting agreements from the Uruguay Round and creation of the WTO ended almost half a century of the General Agreement on Tariffs and Trade (GATT).

3.1 GATT

The GATT was born after the Second World War in 1948 after a series of negotiations in Havana and Geneva. In 1944 it was first envisaged as an International Trade Organisation (ITO) along with the World Bank and the International Monetary Fund but ITO could never materialise. The GATT secretariat was actually the Interim Committee of the International Trade Organisation, which was established to administer the trade agreement until such time as the ITO came into being, which never happened. The establishment of ITO was blocked by the US and a few other countries.

The GATT moved forward through many rounds of talks, racking up seven including the Uruguay Round: Geneva, Annecy, Torquay, Dillon, Kennedy, Tokyo, Uruguay. The aim of these rounds was to lower high tariff levels between countries after the Second World War through a process of bid and counter-bid in order to ease the flow of international trade. Gradually, as the rounds proceeded the scope of negotiations widened from strictly being tariff-related to non-tariff issues.

3.2 Uruguay Round

The last round of talks under the GATT was the Uruguay Round. The round began in 1986 and ended in December 1993. It was the largest trade negotiation ever; most probably the largest negotiation of any kind in human history. Originally there were 15 subjects to be covered in the Uruguay Round, and it was the largest agenda to be covered by any previous rounds. It covered almost all trade, from toothbrushes to pleasure boats, from banking to telecommunications, from the genes of wild rice to AIDS treatments. Alongside the usual tariff talks were discussions on the opening up to trade of areas such as agriculture and textiles. The Round also included, for the first time in trade negotiations, issues such as services, trade and investment, intellectual property, and concluded groundbreaking agreements on these.

3.3 WTO and the agreements

The WTO started functioning from 1st January 1995. Its establishment marked a new era in international trade. It has not only institutionalised the GATT but also embraces many other wider trade-related issues. Membership is limited to countries and by October 1997 it had 132 members. Thirty-six countries have an observer status, although all of these, except the Holy See (Vatican), and, for the time being, Ethiopia, Cape Verde and Bhutan have applied for membership. China is still an observer and talks for its accession are underway.

The following agreements and legal instruments are an integral part of the "Marrakesh Agreement Establishing the World Trade Organisation", collectively called "Multilateral Trade Agreements":

1. Multilateral Agreements on Trade in Goods
2. General Agreement on Trade in Services and Annexes
3. Agreement on Trade-Related Aspects of Intellectual Property Rights
4. Understanding on Rules and Procedures Governing Settlement of Disputes
5. Trade Policy Review Mechanism

Multilateral Agreements on Trade in Goods is a set of thirteen specialised agreements including agreements on agriculture; application of sanitary and phytosanitary measures; textiles and clothing; technical barriers to trade; trade-related investment measures; pre-shipment inspection; rules of origin; import licensing procedures; subsidies and countervailing measures; and safeguards.

The WTO's power is centred on the biannual conference of trade ministers. The first one took place in Singapore in December 1996, the second in Geneva in May 1998. This conference makes major decisions about what the WTO does, what the agreements mean and where the negotiations go next. Three important arms of the Ministerial Conference are: General Council; Trade Policy Review Body; and Dispute Settlement Body. The Secretariat acts as an advisory and research service for its Ministerial Conference and other bodies.

3.4 General trading Principles under WTO

The WTO has introduced the rule of law in international trade. It facilitates the settlement of trade-related disputes among member countries through its rules and procedures. The following are the general trading principles under the WTO.

3.4a A package deal

Membership entails acceptance and adherence to all the multilateral trade agreements that were part of the Marrakesh Agreement. This is unlike the GATT, which toward its end became a mutually negotiated treaty between countries.

3.4b No discrimination

This principle calls for a uniform trading policy toward all the trading partner countries. No special favours can be extended or denied to other countries under the "most-favoured-nation" clause. Likewise, national companies cannot be protected against foreign companies - they have to be given "national treatment".

3.4c Progressive trade liberalisation

Removal of tariff and non-tariff barriers to ease the flow of international trade is the ultimate aim. Industrialised countries have already minimised such barriers. Most of the developing countries have already liberalised their trade, while others are quickly following suit.

3.4d Predictable policies and transparency

National trade policies should be predictable and transparent. Changes in this sphere should be notified to the WTO, and should be in line with the provisions of the multilateral trade agreements. The trade policy review mechanism ensures this.

3.4e Competition

The WTO promotes free competition between trading countries and between companies operative within a member state. It sets out rules for countries to impose countervailing measures against anti-competition tactics like dumping and subsidies.

3.4f Special provisions for developing countries

Keeping in view the likely problems faced by developing countries in liberalising trade, special provisions have been made for them in certain areas with certain time limits. The ultimate aim remains the integration of all member states into a harmonised international trading system.

3.5 Pharmaceuticals

Equitable and appropriate health care is universally considered a basic human right. Pharmaceuticals are an integral part of the modern health care system. They are important for saving human lives and reducing pain and suffering. Regular supply and universal access to medically needed drugs is thus crucial.

Drugs are different from other consumer goods. When they are required, their non-availability can be detrimental to human life. Governments make special arrangements to ensure the availability of relevant, effective, safe and affordable medicines to the people. National drug policies and laws are made to regulate the pharmaceutical sector with the aim to ensure provision of quality medicines to all according to their needs. WHO's essential drug concept provides the basis for achieving this goal, especially in developing countries.

For the purpose of this paper it is useful to review briefly the present global drug situation. It would be helpful later on to contextualize the implications of the WTO agreements on this sector.

3.5a Access to medicines

According to WHO estimates one-third of the world's population lacks access to essential drugs.[4] Up to 90% of medicines are purchased through private retail shops in developing countries[5], and up to 90% of the household health budget is spent on buying medicines[6]. The burden falls heaviest on the poor.

3.5b Expenditure on medicines

Public sector spending on medicines takes up to 40% of the annual health budget in many countries.[7] In real terms, industrialised countries spend far more on medicines than developing countries. In 1990, the annual drug expenditure per capita in the top three industrialised countries was: Japan $411, Germany $111 and the US $191. This expenditure in the least three developing countries was: Mozambique $1, Bangladesh $1, and India $3.[8]

3.5c The global market

The estimated value of the world pharmaceutical market in 1990 was approximately $174 billion to $186 billion, and projection for the year 2000 as high as $330 billion. The major market areas in 1990 were: USA 33%, Western Europe 31.9%, Asia 15.4%, Latin America 3.9%, Eastern Europe 3.1%, Africa 1.8%, and Australia 1.0%.[9] In 1985 the WHO estimated that 75% of the world's population, living in developing countries, consumed only 11% of the globally available drugs.[10]

3.5d The business share

The global production of pharmaceuticals is predominantly concentrated in a few transnational companies (TNCs). A survey in 1991-93 revealed that the top 10 pharmaceutical TNCs take in more than half the global sales.[11] In 1980, more than 90% of global drug production took place in seven industrialised countries. And out of all the drugs produced in developing countries in the same year, two-third were produced in only six countries: Argentina, Brazil, Egypt, India, Mexico and the Republic of Korea.[12]

Part 2

4. Relevant WTO Agreements

Two WTO agreements are of great relevance and importance to the pharmaceuticals, especially in developing countries:

1. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs)
2. The Agreement of Technical Barriers to Trade (TBT)

4.1 The TRIPs Agreement

The Agreement on TRIPs is most relevant to pharmaceuticals. Intellectual property rights are considered extremely important for the pharmaceutical industry. One of the main industrial demanders for incorporating intellectual property issues into the GATT framework was the pharmaceutical industry. Developing countries opposed this inclusion.[13] . The TRIPs agreement is the most controversial of all the trade agreement.

Before the TRIPs agreement, World Intellectual Property Organisation (WIPO) was supervising the administration of various international conventions; the most important of which is the Paris Convention. This came into force in 1883. Under its provisions countries were free to determine the areas of non-patentability, duration and the set of exclusive rights conferred on patent holders. Countries had been deciding about introducing / strengthening national patent laws according to the level of their technological advancement. According to a historical review of national patent law development, France introduced patent protection in 1960, Germany in 1966, Japan in 1976, South Korea in 1987 and Italy as early as in 1988.[14] TRIPs, by requiring harmonised system of patent protection from all the member states of the WTO, has taken away this choice from the countries.

For the purposes of the TRIPs agreement "intellectual property" refers to copyrights and related rights (applicable in musical, literary, artistic, audio-visual areas, computer programs and compilation of data), trademarks, geographical indications, industrial designs, patents, lay-out designs (topographies) of integrated circuits and, protection of undisclosed information.

In the following section important articles of TRIPs are examined with reference to patent protection, which is a form of industrial property and is most relevant to pharmaceuticals:

4.1a Minimal must

At the very outset Article 1.1 determines the nature and scope of the TRIPs. It makes clear that the agreement has to be implemented by the member states in its entirety through national legislation. In the case of TRIPs there is no bar, however, on members to have more extensive protection than is required by the agreement although they are not obliged to do so. TRIPs do not replace the Paris and Berne conventions on intellectual property rights, which are administered through WIPO; rather it co-exist with these conventions.

4.1b National Treatment

Article 1 deals with the uniform application of the Agreement to the nationals of other member states operative in the territory of a particular member country. Foreign companies holding legal patents under the national patent laws would be treated as if they are the national companies of that country. Any discrimination in this regard would be considered as a breech to the agreement.

4.1c Most-Favoured-Nation Treatment

Article 4: *"With regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members."*

4.1d Transfer and dissemination of technology

Article 7: *"The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of the producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."*

4.1e Protection of public health and promotion of public interest

Article 8.1: *"Members may, in formulating or amending their laws and regulation, 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."*

Article 8.2 emphasises the need for appropriate measures to prevent the abuse of intellectual property rights by right holders and to prevent resorting to practices that unreasonably restrain trade or adversely effect the international transfer of technology.

4.1f Patentable subject matter

Article 27 of Section 5 (Patents) deals with what is patentable under the agreement. According to 27.1: *"…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."*

With reference to pharmaceuticals this is very important. According to this minimal criteria countries would be obliged to provide both process and product patents i.e. the method of making

a drug and the drug itself. Before the WTO it was up to governments to decide that if they wanted to provide product patents for pharmaceuticals.

Article 27.2 and 3 are very important:

Article 27.2*: "Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect* ordre public *or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law."*

Article 27.3*: "Members may also exclude from patentability:*

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis *system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years[a] after the date of entry into force of the WTO Agreement. "*

4.1g Rights conferred

Article 28 has assumed special importance with reference to parallel imports. Article 28.1 reads:

"A patent shall confer on its owner the following exclusive rights:

(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing (See footnote 6) for these purposes that product;

(b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process."

4.1h Disclosure of information

Article 29 conditions the acceptance of patent application to the disclosure of information to the national patent office by the applicant. The article reads:

"1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.

2. Members may require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants."

4.1i Exceptions to Rights conferred

Article 30: *"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."*

[a] Review process is due in 1999.

4.1j Other use without authorisation of the right holder

Article 31 is important to understand the notion of compulsory licensing. It sets out twelve provisions to be respected by the governments whose laws allow the other use of the subject matter of a patent without the authorisation of the right holder. For complete text of the article see Annex 1.

4.1k Term of Protection

Article 33 reads: *"The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date." See footnote 8*

Through this article a harmonised term of twenty years of patent protection has become mandatory for all member states. Prior to the WTO arena, countries had been deciding about the patent term according to their own conditions.

4.1l Burden of Proof

Article 34.1 refers to the scenario in which the process patent may have been infringed. For the purposes of civil proceedings the *"judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process."* According to this article, in case of suspected infringement of a process patent the accused would be considered guilty in the eyes of the law unless proven innocent.

4.1m Control of anti-competitive practices

Article 40 deals with the control of anti-competitive practices in contractual licenses. The article recognises the fact that some commercial licensing practice may have adverse effects on trade and may impede the transfer and dissemination of technology. 40.1 enables members to *"adopt, consistently with the other provisions of this Agreement, appropriate measures to prevent or control such practices, which may include for example exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member."*

4.1n Enforcement through national laws

Part III of TRIPs is about enforcement of intellectual property rights. Article 41.1 in Section 1 (General Obligations) reads: *"Members shall ensure that enforcement procedures as specified in this Part are available under their law so as to permit effective action against any act of infringement of intellectual property rights covered by this Agreement, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements. These procedures shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse."*

4.1o Transitional arrangement

Transitional periods are designed to allow developing countries sufficient time to bring their administrative and regulatory systems in line with a multilateral trade agreement.

Articles 65 and 66 deal with transitional arrangements. This time period varies according to the level of development of the country. For developed countries it is one year (1996), and for least developed countries it is extendable ten years (2006).

Generally it is five years for developing countries and countries in transition (2005) but those developing countries which did not provide patent protection before joining the WTO or which at that time provided protection only to process patents they are granted extra five years grace period to amend their patent laws.

4.1p Protection of existing subject matter

Article 70 is about patent protection in member countries during the transitional period. One the one hand these countries have ratified the WTO multilateral trade agreements by becoming its members, and on the other hand they are in transition with reference to the TRIPs. What about the protection of existing subject matter in these countries during the transitional period? Article 70.8 lays out a system for this with regard to pharmaceuticals and agricultural chemical products. The article reads:

"Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 17, that Member shall:

(a) notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;

(b) apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application; and

(c) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with Article 33 of this Agreement, for those of these applications that meet the criteria for protection referred to in subparagraph (b)."

This means that member developing countries who were not providing patent protection to pharmaceuticals by 1st January 1995, by virtue of becoming WTO members it became obligatory for them to make adequate arrangements to at least receive patent applications during this period. This is called "letter box" facility. At the end of the grace period - when according to Articles 65 and 66 (Transitional Arrangements) and Article 41 (Enforcement Through National Law) - these countries are obliged to implement TRIPs agreement in their entirety. Then these applications will be examined and, where applicable, patents will be provided from the date of filing of applications. In other words, the applications received in the "letter box" during the transitional period will be protected for the rest of the period. If patents are provided at the end of the patent protection then the term of 10 years protection will be counted from the day the application was filed.

4.2 The Agreement of Technical Barriers to Trade (TBT)

TBT is one of the thirteen agreements under Multilateral Agreements on Trade in Goods. Like other WTO agreements it is binding on the members.

The main objective of TBT is to ensure that the technical rules and regulations imposed by member states to protect consumers do not constitute unnecessary barriers to international trade, or disguised measure for discrimination. However, it is important to appreciate that the agreement in its introduction recognises that:

" …no country should be prevented from taking measures necessary to ensure the quality of its exports, or for the protection of human, animal and plant life or health, of the environment, or for the prevention of deceptive practices, at the levels it considers appropriate, subject to the requirement that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade, and are otherwise in accordance with the provisions of this Agreement;"

The agreement encourages the development of international systems of standardisation, conscious of the fact that too many different standards do not make liberalisation of international trade.

Five basic principles of the agreement are[a] :

1. Non-discrimination
2. Measures appropriate to risk
3. Harmonisation and mutual recognition
4. Transparency
5. Preferential treatment for developing countries

[a] For details of these principles see *The Results of the Uruguay Round of Multilateral Trade Negotiations*: *The Legal Texts*, published by GATT Secretariat, Geneva, June 1994.

Part 3

5. Impacts on pharmaceuticals

The TRIPs Agreement, through setting up minimal standards for patent protection and obligating members to legally enforce these, would influence the availability of and access to pharmaceuticals, especially in developing countries.

5.1 Impact studies

At present due to methodological difficulties there is a dearth of empirical evidence. Generally, there are two opposing points of view about the potential impacts.

Some experts argue that universal harmonisation of patent protection would benefit developing countries. This would mean development of new drugs by local pharmaceutical companies, increased flow of technology and foreign direct investment, and better health of the population due to availability of wider range of quality products.[15], [16], [17]

Many others, mostly from developing countries but also a few academics from industrialised countries[18], raise concerns about the unfairness of harmonisation of patent protection and its attendant negative impacts: high drug prices and further decline in access of the people to medicines, weakening of local pharmaceutical companies, increased dependence on Transnational Companies (TNCs), and decreased transfer of technology and foreign direct investment.[19], [20], [21], [22], [23], [24], [25], [26], [a]. Estimates about likely impacts of the TRIPs agreement during pre-TRIPs period (1993) found that introduction of pharmaceutical patents would entail significant welfare losses and income gains to patent holders.[27]

5.2 High drug prices and lack of choice

It is logical to understand that twenty years of monopoly (Article 33) over a pharmaceutical product would enable the patent holder company to keep the price of the drug high during this period. This means that generic equivalents would come to markets only after the expiry of the patent term. During this period patients would have no choice for cheaper alternatives.

Optimistic view

Few experts think that there would be no or very little impact on the prices of medicines. Redwood for example in 1994 found that in the case of India taking into account the transitional period of the TRIPs Agreement, there will be absolutely no impact on prices of new patented drugs on the Indian market during the 1990s and only minimal effects during the period 2003-2005. Not more than 15% of the drugs by value of the Indian market will be covered by patents some time after 2005 and the remaining 85% of the market will continue to be exposed to the full

[b] For selected annotated bibliography see: WHO. *Globalization and Access to Drugs: Implications of the WTO/TRIPs Agreement*, Health Economics and Drugs, DAP Series No. 7, World Health Organization; 1997. WHO/DAP/98.9

impact of generic competition, to which patented drugs themselves ultimately contribute when their patent expires. No significant effect can be anticipated until after 2005, because the weight of the patented drugs will be too small for economic impact and price control can stop a "price explosion" at any time.[a]

Same author in 1995 in another study carried out in Brazil found that "cost-to-Brazil" of lost differentials between pioneer brands and copies is unlikely to exceed an estimated 5% of the value of the market segment that would eventually be patent protected. [28]

Cautious view

A Multi-country study (India, Indonesia, Pakistan, the Philippines and Thailand) in 1995 found welfare and price effects of the new IPR regime to be negative. Price increases estimated for patented drugs ranged for from 5 to 67%.[29] Another study concluded, after an analysis of detailed market data on patentable drugs in the pre-product patents stage in India, an average increase in price of about 51%. Like wise for Argentina, in 1995, a significant drug price increase of 71% was calculated.[30]

Prior to the WTO Agreements many countries (India, China, Brazil, Malaysia, Thailand, Mexico, Argentina, Egypt, Canada) had either excluded pharmaceuticals from their patent systems or provided only process patents. In the absence of product patents the local companies can develop the drugs through different processes than those patented and can make locally developed cheaper versions available to the people. The following table explains the time lag in introduction of some very important drugs in the Indian market after they were introduced in the international market:[31]

Time lag between introduction of a new drug in the world market and its availability in India

Drugs	Year drug was introduced in		Time lag (years)
	World market by the inventor	Indian market by domestic companies	
1. Salbutamol	1973	1977	4
1. Mebendazole	1974	1978	4
3. Rifampacin	1974	1980	6
4. Naproxen	1978	1981	4
5. Bromhexin	1976	1981	6
6. Ranitidine	1981	1985	4
7. Captopril	1981	1985	4
8. Norfloxacin	1984	1988	4

Source: Keayla B. K. (1994), Uruguay round-final act 1994 - TRIPs agreement: impact of new patent regime on pharmaceuticals, pesticides and seeds, National working group on patent laws New Delhi.

Table 1

[a] Quoted in UNCTAD (1996), The TRIPs Agreement and Developing Countries, Geneva.

Under WTO regime all these important drugs from the public health point of view, would have remained unavailable at low prices for about another fifteen years. In 1994 it was estimated that approximately 50 percent of branded drugs that were marketed by the ten Indian-owned drug firms owed their early launch to the Indian Patents Act 1970 which did not cover the product patents.[32]

5.3 Impact on availability of drugs

Optimistic view

According to Article 70.1 (Protection of Existing Subject Matter):
"This Agreement does not give rise to obligations in respect of acts which occurred before the date of application of the Agreement for the Members in question."

This means that there would be no retrograde impact on the availability of those drugs in developing countries that were in the market before and during the transitional period.

Cautious view

The application of the agreement at the end of the transitional period would affect the availability of those new drugs for which either applications were filed during the transitional period through the "letter box" facility, or all those drugs which would be patented after the transitional period. The availability of new drugs would be controlled by the new TRIPs regulations after 2000 or 2005 in developing countries, and generally after 2006 in least developed countries (Article 65).

5.4 Impact on local pharmaceutical industry

Optimistic view

There can be hardly any optimistic view about the impact of prolonged patent protection on the local pharmaceutical industry in developing countries. No reference could be found in favour of any positive impact of the TRIPs agreement on the local drug companies.

Cautious view

Under Article 1 the members have to extend "national treatment" to the pharmaceutical TNCs. In other words, the national governments would be unable to provide protection of any kind to their domestic companies. Majority of the developing countries have a relatively weak pharmaceutical industrial base.

In 1994 a study in Republic of Korea found that changes in IPR policy "created a market loss for most (pharmaceutical) firms but a gain for those with more technological capability".[33] Similarly in a multi-country study in 1995[34] it was estimated that in India annual profit transfer to foreign firms was estimated to between $ 101 million and $ 839 million.

Although the WTO aims to promote free competition, but how fair can it be with such a huge difference between pharmaceutical TNCs and local pharmaceutical companies in developing countries?

The history of patents tells that today's industrialised countries introduced strong patent protection only after obtaining an appropriate level of technological advancement. For example, in 1876 when the German industry was in its infancy and the patent law was yet to be evolved, Bismarck appointed a committee to study the likely impact of the patent system on the industry. Committee members also included founders of Siemens and Hoechst. Their observations made interesting reading[35]:

"Today industry is developing rapidly..... monopolisation and abuse of patent rights will inevitably expose large segments of the industry to serious injury. The government must protect industry against these dangers..."

5.5 Impact on transfer of technology and foreign direct investment

Optimistic view
Article 7 and 8.1 assume that the enforcement of intellectual property rights would promote the international transfer and dissemination of technology. There is no evidence, however to date about any positive impact of the TRIPs agreement on transfer of technology and foreign direct investment in developing countries with reference to pharmaceutical business.

Cautious view
Although prior to WTO arena many developing countries had conditioned the grant of patent protection to the "working of the patents" in a country e.g. India. By conditioning the manufacture of drugs inside a country the aim was to ensure the transfer of technology and FDIs. The TRIPs Agreement has taken away that condition. Now it is not mandatory for the patent holders to actually manufacture the drugs in the country where they have patent protection. It would now be the TNCs' decision to transfer technology or to just import medicines. Going by this argument, the poor developing countries, already with a weak industrial base, would be less likely to receive technology and their chances to improve the local industry would be less bright than before. There is evidence that the transfer of technology and foreign direct investment may be stimulated in the absence of patent protection.[36]

5.6 Impact on Research & Development

Research and development of new drugs is mainly undertaken by pharmaceutical TNCs. They invest in research activities and want returns on their products. Governments recognise this and provide them monopoly rights for a specified period of time as an encouragement for their contribution and incentive for future research in developing new drugs. The TRIPs Agreement has taken away from governments the prerogative to decide on these issues according to their individual country situations and are introducing internationally harmonised international patent protection system.

Optimistic view

In 1995 a study on the impacts of patents in Italy since 1978 on R & D expenditures and new product introductions found that drug product patenting exhibited a strong upward trend well before the change in the patent regime and that after 1977 there was a statistically significant rise in the number of Italian patents received per US $ of R & D outlays. Although the researchers could not find an impact on the introduction of new chemical entities. [37]

Cautious view

Studies are available which have assessed the impact of introducing pharmaceutical product patent on both domestic and global expenditures on R & D. In the case of Argentina Nogués in 1990[38] found no reason to expect an increase in domestic R & D in pharmaceuticals due to the recognition of the product patent, because the development of the new chemical entities would be outside the reach of the local companies.

To understand the prospects of increased research activity in developing countries under the TRIPs, the pharmaceutical industry world-wide needs to be appreciated. At present more than 80% of the drug production takes place in industrialised countries. Seventy-five per cent of the world population living in developing countries consumes only 14% of the world's drug supply, while 15% of the population residing in industrialised countries uses rest of the 86%[39]. So it is logical that the more attractive market for TNCs is in industrialised countries, research activity would also be geared toward developing new drugs for health problems prevalent in those countries and less towards diseases in the developing countries.

An overview of the new drug development over a period of 22 years i.e. between 1975 to 1997 supports this assumption. Among the 1223 new chemical entities marketed during this period, 379 (30.9%) are considered therapeutic innovations but only 13 (1%) are specifically for tropical diseases. Two of these are improved versions of the existing products (new formulations of Pentamidine and Amphotericin B), two are the result of the military research (Halofantrine Hydrochloride and Mefloquine), 5 come from veterinary research (Albandazole, Benznidazole, Ivermectin, Oxamniquine and Praziquantel) and only 4 (0.3%) may be considered direct results of R&D activities of the TNCs (Artemether, Aovaquone, Eflornithine and Nifurtixom).[40]

As far as local pharmaceutical companies in developing countries are concerned, very little research is done on developing actual new drugs. Most of the research by these companies focuses on developing process technologies which after TRIPs (Article 27) would be negatively affected as members of WTO are bound to provide product as well as process patents.

Part 4

6. Public health implications

"Globalisation of trade and services also poses global threats to health. The health of the world's citizens is inextricably linked, and is less determined by events within geographical limits… Despite the progress that can be achieved in a world without frontiers, there is a danger that insistence on cross-border uniformity, or even on unwarranted minimum levels, could reduce the scope of mutually beneficial trade."[41]

Those concerned about the existing health conditions in developing countries worry about the negative impact on availability of drugs under TRIPs and the attendant public health implications. People in these countries are already suffering for want of medicines for preventable and treatable health problems. Old diseases like tuberculosis and malaria present new problems of drug resistance and there is also emergence of new and serious diseases for which no treatments are available. The world today stands on the "brink of a global crisis in infectious diseases".[42]

6.1 Preventable deaths

At present 40 million people die every year in developing countries out of which more than 13 million deaths occur among children under five years of age. About ten million of these deaths are due to acute respiratory infections, diarrheal diseases, tuberculosis and malaria alone. These deaths can be prevented to a large extent if essential drugs are made available. At present about one-third of the world's population lacks access to these inexpensive medicines a great majority of whom live in developing countries.[43]

6.2 Drug resistance in old diseases

Old communicable diseases like tuberculosis, malaria and sexually transmitted diseases (other than HIV/AIDS) have posed problems of drug resistance. Plague, kalazar and malaria, which were once thought of at the verge of eradication, have re-emerged as great public health threats. In 1993 WHO declared tuberculosis as a global emergency. A major part of these problems lie in developing countries e.g. 95% of tuberculosis cases and 98% tuberculosis deaths are in developing countries.[44] The situation calls for research and development of effective drugs to overcome this problem and better treatment regimens are expected to be developed in future.

Diseases	Drug resistance
• Tuberculosis	‣ Cure rates of up to 95% (which can be achieved for drug susceptible tuberculosis) fall to 56% or less with isoniazid and rifampicin resistance.
• Gonococcal infection	‣ One of the most common sexually transmitted diseases. Nisseria gonorrhoeae, the causative bacterium has acquired high resistance to penicillin and tetracyclines in most countries. It now requires the use of much more expensive drugs which are often unavailable.
• Malaria	‣ Plasmodium, causative agent of malaria has developed resistance to anti-malarial drugs. Resistance to Chloroquine, the most commonly used drug, has been found in all most all endemic countries.
• Dysentery	‣ The epidemic strain has acquired increasing resistance to standard antibiotics. The epidemic dysentery caused by this strain results in the death of up to 15% of those infected.
• Typhoid	‣ The bacterium has developed resistance to antibiotics commonly used in the past for treatment. Without effective antibiotic treatment, typhoid treatment 10% of those infected.

Information Source: WHO (1996), The world health report 1996: fighting disease, fostering development, World Health Organisation, Geneva.

Table 2

6.3 Emergence of new diseases

At least 30 new diseases have been scientifically recognised around the world in the last 20 years including HIV/AIDS, Hepatitis due to A, B, C, E viruses, a completely new strain of cholera called Vibrio cholerae 0139, Ebola virus causing Ebola haemorrhagic fever, Hantavirus infections etc.[a]

Most of these new diseases have no effective treatments available at present.

Following table explains the toll these diseases are taking at present:

Diseases	Toll
• HIV/AIDS	‣ Today more than 20 million adults are estimated to be infected. The cumulative total could reach 40 million in the next 5 years.
• Hepatitis B	‣ Hepatitis B has infected 2 billion people alive today, of whom 350 million are chronically infected and therefore at risk of death from liver disease.
• Hepatitis C	‣ About 100 million are chronically and incurably infected with hepatitis C and are at risk.
• Hepatitis E	‣ Hepatitis E can cause major epidemics in countries with hot climates.
• Vibrio cholerae 0139	‣ A completely new strain of cholera, called Vibrio cholerae 0139, appeared in south-eastern India in 1992.
• Ebola virus	‣ The Ebola virus was unknown 20 years ago. The Ebola haemorrhagic fever outbreak in Zaire in 1995 was fatal in about 80% of cases.
• Hantavirus infections	‣ Since Hantavirus infections were first recognised in the US in 1993, they have been detected in more than 20 American states. They can cause a pulmonary syndrome with a fatality rate of over 50%. Cases have also occurred in Canada and in Argentina, Brazil and Paraguay.

Information Source: WHO web site: <http://www.who/ch>

Table 3

[a] For examples of etiological agents and infectious diseases in humans and/or animals recognized since 1973 see Annex 1 in: WHO (1996), The world health report 1996: fighting disease, fostering development, World Health Organization, Geneva, page 112.

6.4 Future scenario

Old diseases are retaliating with new strength and new diseases are emerging with fatal potential. Both of these pose daunting challenges in terms of their prevention and cures. Medical researchers require better understanding about their origin and natural histories of these diseases so that effective treatment approaches can be developed. In future even if new drugs and vaccines are developed against these scourges would it be possible to make these available to the patients in developing countries? This is a question bothering many around the world. Under the new regime of IPR protection, at least one can safely say that new drugs and vaccines would not be as easily available to the people in developing countries as they are now (before the ending of the transitional periods).

Following is an excerpt from the editorial of a recent issue of *La Prescrire*, an independent drug bulletin from Paris:

Fourteen new or modified vaccines have been released since 1980. Other more effective, better tolerated or more usable vaccines are in the pipeline for a growing number of diseases, but they may well benefit only the rich minority. Unicef and WHO are now warning that funding EPI is becoming increasingly difficult.
And the recent GATT agreements will block low-cost production of these new vaccines in developing countries, at least in the short term.
Will children in poor countries have to wait 10 or 20 years until they can be protected against these diseases, as was the case with hepatitis vaccine?[45]

Part 5

7. Strategies for adapting to the new trade environment

Two sets of strategies exist for governments in developing countries to deal with the new trade environment with reference to pharmaceuticals. One, by understanding the concessions/exceptions provided within the TRIPs agreement and exploiting these to their full advantage. And two, non-trade agreement measures that governments should take anyway to promote the availability and affordability of drugs, including policy steps to control the expenditures on non-priority medicines.

7.1 Understanding exceptions in the TRIPs Agreement

Various articles in the TRIPs agreement provide certain exceptions to members which they can consider while introducing / modifying their patent laws. Also, some articles are open to members' interpretation. They need to be fully understood in order to be benefited. Experts have analysed these sections with a view to presenting options to developing countries.[46] In the following section each such area is discussed in two ways: conservative understanding and permissive understanding. Conservative understanding means in general, how the industry / industrialised countries would implement it and permissive understanding means how developing countries / public health people might like to implement the agreements to uphold the public good.

7.1a Cautious approach

Article 65.5 has been interpreted as a "freezing clause", which means that if members in the transitional period introduce patent protection more than what the TRIPs require as a minimal then after the transitional period they may not be allowed to revert back. So it is better to be cautious while introducing / modifying national patent laws and to use minimal approach.

Conservative understanding

TNCs would like to see that governments use the TRIPs agreement as a minimum criterion for enhancing IPR protection beyond what is required by it.

Permissive understanding

Governments, especially in developing countries, may like to stick to the essential minimal requirements and even look for concessions in these.

7.1b Exceptions to the exclusive rights

Article 30 allows limited exceptions to the exclusive rights conferred by a patent provided they are limited, could be justified and do not negatively affect the patent-holder's rights.

Conservative understanding

Limited exceptions should only be used sparingly. They should not be used in any way, which undermine the exclusive rights conferred by a patent.

Permissive understanding

Through careful and intelligent use of limited exceptions members can insulate their national interests against likely negative implications of the TRIPs agreement. Since "limitations" are not defined in the legal text, members may interpret the concept of exceptions to achieve their defined national objectives of equitable access to needed drugs.

7.1c Technological innovation and transfer of technology

Article 7 says that patent protection should contribute to the promotion of technological innovation and transfer and dissemination of technology to the mutual advantage of the producers and users of technological knowledge, and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Conservative understanding

Ensured strong patent protection would automatically lead to technological innovation and transfer and dissemination of technology

Permissive understanding

By virtue of this article, countries can consider the following possibilities[47]:

- scientific research and experiments involving patented inventions;
- tests carried out before the expiry of the patent to establish the bio-equivalence of a generic drug.

7.1d Public health, nutrition and promotion of public interest

Linked with the notion of exceptions is Article 8.1, which clearly provides leeway to members to adopt measures necessary to protect public health and nutrition. It also promotes the public interest in sectors of vital importance to their socio-economic and technological development by keeping with the spirit of the provisions of this agreement while formulating or amending their patent laws and regulations.

Article 8.2, however tries to strike balance between "the need for appropriate measures for preventing the abuse of intellectual property rights by right holders and for preventing resorting to practices which unreasonably restrain trade or adversely effect the international transfer of technology."

Conservative understanding

Article 8.2 is vital for IPR protection. Adoption of measures to protect public health and nutrition and public interest in sectors of vital importance to their socio-economic and technological development may be misused by the countries and it may unreasonably restrain trade or adversely effect the international transfer of technology.[48]

Permissive understanding

- parallel importation of the protected product;
- acts carried out on a private basis and for non-commercial purposes;
- preparation of drugs by unit and on medical prescription in pharmacy dispensaries;

7.1e Compulsory licensing

Article 31 (Annex 1) deals with "Other Use Without Authorisation of the Right Holder". There are twelve provisions to be considered by members for grant of compulsory licenses. Compulsory licensing is a legal method through which the relevant administrative authority is allowed to grant a license, without the permission of the patent holder, on various grounds of public interest. Government itself can use the license or it can authorise a third party to use it. However, there are a few ambiguous areas in compulsory licensing which would be clarified in the years to come in the judgements of relevant dispute settlements.

Conservative understanding

TRIPs aims to prevent the issuance of compulsory licenses. It did this by attaching certain conditions with it:

- authorisation of such use will be considered on its individual merits;
- authorisation will be granted only if the proposed user has made efforts to obtain the license on reasonable commercial terms;
- the scope and duration of the authorisation must be limited;
- authorisation is non-exclusive;
- authorisation is non-assignable;
- the predominant objective of the authorisation must be supply to the domestic market;
- the authorisation will be suspended if the circumstances which led to it cease to exist;
- the patent holder will be given adequate remuneration, taking into account the economic value of the authorisation.

These minimal conditions need to be respected by the countries.

Permissive understanding

Compulsory licensing is crucial to be incorporated in the national patent laws by the developing countries in order to ensure access to needed medicines.

Many countries have provision of compulsory licensing in their patent laws purely to safeguard the public health interest of the people. French patent law, for example, categorically provides that "if required in the interest of public health, patents issued for drugs may be subject to the regime of compulsory licenses." This is in order to overcome the issues of insufficient quantity, quality and high prices of drugs". Likewise Canadian government introduced compulsory licensing in its patent laws in 1969 in response to high drug prices although through Bill C-11 in 1987 the drugs were provided protection from compulsory licensing for 7-10 years. As a result of this protection the drug prices started rising again in Canada.[49]

Five types of licenses are allowed by the TRIPS although there is no expressed bar on countries to introduce other types:

- licenses for use by government;
- licenses granted to third parties authorised by government;
- licenses granted in conditions of emergency or extreme urgency or for non-commercial public use;
- licenses granted after an administrative or judicial process revealing anti-competitive practice;

- licenses arising from a dependent patent[a].

Remaining within the scope of the TRIPs, compulsory licensing can be "appropriate measures" to protect and promote the following:

- technological innovation *(*Article 7*)*;
- transfer and dissemination of technology *(*Article 7*)*;
- social and economic welfare *(*Article 7*)*;
- public health and nutrition *(*Article 8*)*;
- public interest in social sectors of vital importance *(*Article 8*)*;
- socio-economic and technological development *(*Article 8*)*;
- *ordre public* or morality
- national emergency or circumstances of other extreme urgency (Article 30)
- public non-commercial use (Article 30);
- competition (Article 30);
- local working of patents (Article 1)[b]

7.1f Control of anti-competitive practices in contractual licensing

Article 40 deals with the control of anti-competitive practices in contractual licenses. The article recognises the fact that some commercial licensing practice may have adverse effects on trade and may impede the transfer and dissemination of technology.

Conservative understanding

Governments may try to unnecessarily control anti-competitive practices in contractual licenses, which may in turn have adverse effects on trade and may impede the transfer and dissemination of technology. To overcome this governments should, in line with 40.2 specify in their national legislation, practices that would constitute an abuse of intellectual property rights and can be considered anti-competitive.

Permissive understanding

Governments are permitted to incorporate measures to control anti-competitive practices in contractual licenses, which can help them to bring drug prices down in the country.

7.1g Parallel imports

The concept of parallel imports is about international exhaustion of a patent. Parallel import means importing the same product in a country by the state or any third party where it is already patented By virtue of exhaustion of this exclusive right, parties other than patent holder can import the patent product without being accused as infringers of the patent. Prerequisites for this kind of importation are: availability of the same product in some other country; legality of such importation provided through the national patent law of the importing country and comparative low price.

[a] A patent that cannot be exploited without infringing on another patent.

[b] TRIPs is ambiguous about local working issues. Article 1 of the agreement states that certain provisions of the Paris Convention, including the possibility of the of compulsory licenses for absence of local working whereas Article 17.1 appears to recognize the legality of import monopolies.

Conservative understanding
A parallel import is against the spirit of the IPR protection. It is a breach of Article 18. In the presence of parallel import the companies cannot get returns on their investments in research and development of new drugs. An important case is being fought by pharmaceutical TNCs in South Africa against Section 15C of Medicines Control Bill which enables South African government to do parallel import of medicines.

Permissive understanding
Parallel import of pharmaceutical products should enhance market competition, bring prices down and as a result increase financial access of the people to treatment. Having this measure in the repertoire developing countries can make medicines available to the people in case the prices of patent holders in the country are too high or supply is too low.

Parallel import is allowed in the TRIPs Agreement. Although Article 18 confers exclusive rights to the owner of the product patent to prevent third parties not having the owner's consent from the acts of making, using, offering for sale, selling, or importing for these purposes that product but the footnote to this article is very important. It reads:

"This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provision of Article 6"

According to Article 6 no issue related with exhaustion of rights can be taken to WTO for dispute settlement except those related with Article 3 (National Treatment) and Article 4 (Most-Favoured-Nation Treatment). This means that international exhaustion is not an offence if a member country incorporates it in its statute because even an "aggrieved" party cannot request the constitution of a dispute settlement panel in accordance with the "Understanding on Rules and Procedures Governing Settlement of Disputes".[50] This way parallel import is justified under the TRIPs agreement.

This is a very important measure that developing countries can take to make drugs available at relatively cheaper prices. The 1996 National Drug Policy of South Africa mentioned parallel import as one of the cost cutting strategies and in 1997 the health minister Dr Zuma made a Medicines Control Bill in which she included a section 15C which basically enabled parallel import of drugs. New Zealand and Ecuador also recently legalised parallel import, in addition to the EU countries, Norway, Iceland etc. Japan and US also allow parallel import for ordinary commodities but not for pharmaceuticals.

7.1h The Agreement of Technical Barriers to Trade (TBT)

The main objective of TBT is to ensure that the technical rules and regulations imposed by member states to protect consumers do not constitute unnecessary barriers to international trade, or disguised measure for discrimination.

Conservative understanding
The spirit of the agreement is to overcome the disguised use of unnecessary technical rules, regulations and standards in the way of trade flow.

Permissive understanding
TBT recognises that no country should be prevented from taking measures necessary to ensure the quality of its exports, or for the protection of human, animal and plant life or health, of the environment, or for the prevention of deceptive practices, at the levels it considers appropriate.

By using TBT countries can ensure the quality of medicines imported. Also the principle of "Preferential treatment for developing countries" recognises the special needs of the developing countries in development, finance and trade; the need for special standards and regulations for indigenous production procedures, and the special problems that may justify exceptions to the obligations under the agreement, in particular the institutional and infrastructure problems which they face.

7.2 Non-trade agreement measures

Although there is an independent need for efficient drug supply system to achieve the objectives of universal availability of and equitable access to essential drugs in the country this need becomes more important and urgent under the new trade environment. To insulate national public health interests from the possible negative influences of the WTO agreements, the strive for making drug supply systems more equitable and efficient should become more serious.

The trade policy of a developing country may override the health sector and does not take into account its essential needs. It is up to the policy makers in the health departments to take appropriate and timely measures to offset such negative effects from drug supply systems. On the one hand, there is a need for closer collaboration between trade and health ministries to jointly draw up strategies to exploit the exceptions in the TRIPs agreement and on the other hand there are a number of measures which should be taken by the health ministries to make the drug supply systems more efficient. In the context of this paper, such measures can be called non-trade agreement measures.

WHO promotes the idea of national drug policy based on essential drug concept. It is a recipe for universal availability of needed, effective, safe and affordable drugs especially in developing countries.

Private sector plays a dominant role in supply of drugs in majority of the developing countries. National drug policy should cover both public and private sectors. A well thought of drug policy, based on essential drug concept and implemented sincerely can ensure the availability of medicines to all according to their needs.

Following table lists more specifically the measures that should be taken to achieve the ultimate objective of a good national drug policy i.e. equitable access, with comments about the usefulness about the each:

Measures	Comments
♦Drug Manufacture & import ‣ Licensing	• Improves availability and quality of drugs
♦Drug registration	• Helps in ensuring efficacy, safety and quality of drugs
♦Drug Marketing & promotion ‣ Limiting promotional costs	• Up to 15-25% of ex-factory drug cost is spent on advertisements and is intended to influence consumption patterns. Limitations are intended to reduce price and rationalise consumption
♦Drug Supply ▾ In Private Sector ‣ Licensing of wholesalers ‣ Licensing of retailers ‣ Incentives to whole sellers/retailers ‣ Accreditation schemes ▾ In Public Sector ‣ Drug selection ‣ Bulk Purchasing	• Improves availability and quality of drugs • Improves availability, quality and use of drugs • Improves availability of drugs • Lead to rational use of drugs • Essential drugs lists are developed based on public health needs, therapeutic value, safety and cost • Lead to efficient use of resources and improves availability • Substantially lowers cost
♦Drug Price Control ‣ Use of generic products ‣ Regulation of producer and distribution prices ‣ Regulation of retail margins	• Up to 90% of expenditures on drugs in developing countries is out-of-pocket. Up to 40% of health budget is spent on drugs in public sector. Price control enhances affordability • Introduces greater price competition and lowers prices • Improves availability, affordability and rational use of drugs • Improves affordability and rational use of drugs
♦Drug Financing ‣ User fees and co-payments ‣ Community drug schemes ‣ Health insurance schemes	• May discourage excessive consumption but may have negative consequences on affordability and equity • Keep drugs affordable to the people • Keep drugs affordable to the people
♦Drug Information & Education ‣ Setting standards for undergraduate training ‣ Professional's continued education ‣ Training of drug sellers ‣ Standard treatment guidelines ‣ Public and patient education ‣ Regulation of drug information ‣ Drug price information	• Makes education relevant, promotes rational drug use • Contribute to rational use of drugs • Contribute to rational use of drugs • Contribute to rational use of drugs • Promotes rational drug use and knowledge about cost-effective treatment • Promotes rational drug use • Promotes cost-effectiveness in treatment
♦Drug Prescribing ‣ Prescribing controls or incentives ‣ Prescribing generic ‣ Dispensing clinicians	• Reduces consumption and/or shift prescriptions towards cheaper or generic drugs • Lowers prescription cost and confusion about trade names • Effects availability and rational use of drugs
♦Drug Use ‣ Promotion of rational use	• Optimise the usefulness of drugs.

Table 4

Conclusions

Multilateral Trade Agreements, enshrined by WTO claim to have brought rule of law in international trade. These agreements, which also include the establishment of WTO, are negotiated covenants between countries according to their trade interests. The aim of the agreements is to harmonise the national trade policies to facilitate the international trade by global melding of the markets.

Although there is now enough information available about how these agreements were finalised, what went behind the scenes and how industrialised countries (backed up by the corporations) pushed their agendas and how developing countries had to agree to the terms.[51] Whatever the process was it is now a history. The reality is that WTO is there and has 132 countries as its members. Except China all the important countries are members, which means that all of them accept the Multilateral Trade Agreements as they exist. In case where members feel that their national interest is compromised, they have to make efforts to change the system by operating from within the system.

TRIPs agreement has definite implications on pharmaceutical situations in developing countries. In most of the cases and at least in the short term these implications can further deteriorate the existing inequitable situation with regard to access to drugs which in turn can worsen the public health profile in developing countries.

TRIPs agreement requires member countries to amend their patent laws to ensure the incorporation of minimal patent protection provided in the TRIPs. According to their status and their use of transitional periods, developing countries have been engaged in making the amendments in their laws. Very crucial at this point is that how intelligently they make use of the concessions and exceptions provided within the agreement. Experts agree that there is a lot of space within the text of the agreement which if exploited fully but responsibly can help countries to safeguard their public good objectives with reference to availability of essential drugs e.g. provisions of compulsory licensing, parallel imports etc.

But who stopped developing countries to take non-trade measures to ensure reliable supplies of essential drugs e.g. national drug policies, essential drug lists etc. If many countries have these policies, how many have actually implemented these to improve their national drug situations? More than ever before these measures are required to ensure equity in health.

Annex 1

Article 31 of TRIPs

Other Use Without Authorisation of the Right Holder

Where the law of a Member allows for other useSee footnote 7 of the subject matter of a patent without the authorisation of the right holder, including use by the government or third parties authorised by the government, the following provisions shall be respected:

(a) authorisation of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorisation from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorised, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be authorised predominantly for the supply of the domestic market of the Member authorising such use;

(g) authorisation for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorised, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorisation;

(i) the legal validity of any decision relating to the authorisation of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;)

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorisation if and when the conditions which led to such authorisation are likely to recur;

(l) where such use is authorised to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and

(iii the use authorised in respect of the first patent shall be non-assignable except with the assignment of the second patent.

Reference Notes

[1] WHO (1996), World Health Assembly Resolution - WHA 49.14, Geneva.
[2] WHO (1998), Resolution on Revised Drug Strategy - EB 101.14, Geneva.
[3] Balasubramaniam K (1998), The revised drug strategy, *HAI News*, No. 101, June 1998
[4] WHO (1998), Action Program on Essential Drugs: Report of the biennium, World Health Organization, Geneva.
[5] Lee D, Balasubramaniam K. & Ali H.M. (1993), Drug Utilization Studies: their transferability between industrialized and developing countries *in* Drug Utilization Studies: methods and uses, *edited by* Dukes M.N.G., WHO, Regional Publications European Series No. 45, WHO, Copenhagen.
[6] World Bank (1993), World development report 1993: Investing in health, World Bank (Oxford University Press), Washington D.C.
[7] WHO (1998), The world health report: life in the 11st century, a vision for all, World Health Organization, Geneva.
[8] Ibid.
[9] Ibid.
[10] Ibid.
[11] Thorpe, Tracey (1994), "Leading Companies 1991/1993", *Scrip Magazine*, January, 1994.
[12] WHO (1988), The World Drug Situation, World Health Organization, Geneva, 1988.
[13] Raghavan Chakravarthi (1990), Recolonization: GATT, the Uruguay Round & the Third World, Zed Books and Third World Network, Penang, Malaysia.
[14] HAI (1997), Power, patent and pills, Health Action International, Amsterdam.
[15] Bale HE. *Uruguay Round negotiations on intellectual property: a step forward?* 3rd Presentation at the Annual Conference on International Trade, Washington College of Law of the American University; 3 October 1991.
[16] FIIM/IFPMA. *GATT/TRIPS and the pharmaceutical industry: a review*. Geneva: 1995
[17] Otten A. The implications of the TRIPs agreement for the protection of pharmaceutical inventions. Presentation at the International Conference of Drug Regulatory Authorities. Bahrain: 10-13 November 1996. WHO Drug Information. 1997. (11):1.
[18] Wiessman R. A long, strange TRIPs. University of Pennsylvania Journal of International Economic Law. 1996; (17): 4.
[19] Balasubramaniam K. *GATT and the Third World.* A presentation at International Convention on People's Approach to GATT Negotiations organized by National Working Group on Patent Laws, February 18-10, New Delhi.
[20] Balasubramaniam K.Heads - TNCs Win: Tails - South Loses or the GATT/WTO/TRIPs Agreement. A presentation at HAI seminar on GATT/WTO and Essential Drug Polices. 4 October 1996. Available in: Power, patent and pills; a seminar report, Health Action International, Amsterdam.
[21] Challu PM. The consequences of pharmaceutical product patenting. World Competition. 1991; (15)1.
[22] Correa CM. The Uruguay Round and drugs. WHO Task Force on Health Economics. Geneva: World Health Organization; 1997. WHO/TFHE/97.1
[23] Nogues J. patents and pharmaceutical drugs: understanding the pressures on developing countries. *Journal of World Trade*, 1990; (14)6: 81-104
[24] Redwood H. *Brazil - the future impact of pharmaceutical patents.* Oldwicks Press Ltd.; 1995.
[25] Abouuelenein A A.Trade related Aspects of Intellectual Property Rights (TRIPs) and the pharmaceutical industry in Egypt. Federation of Egyptian Industry; Cairo, June 1996.
[26] Ahuja SD. GATT and TRIPs - The Impact on the Indian pharmaceutical industry. Patent World. September 1994, 18-34
[27] Nogues J. Social costs and benefits of introducing patent protection for pharmaceutical drugs in developing countries. *The Developing Economics*. March 1993; (31-1): 14-53.
[28] Redwood, Heinz (1995), *Brazil - The Future Impact of pharmaceutical Patents*, Oldwicks Press, Suffolk.
[29] Subramaniam, A. (1995), "Putting some numbers on the TRIPs pharmaceutical debate" *International Journal of Technology Management*, Vol. 10, No. 1/3, pp. 151-168
[30] Chambouleyron, Andrés (1995), "la nueva ley de patentes y su efecto sobre los precios de los medicamentos. Análisis y propuestas", Estudios, Afio XVIII, No. 75 (Octubre/Diciembre), pp. 156-168.
[31] Keayla B. K. (1994), Uruguay round-final act 1994 - TRIPs agreement: impact of new patent regime on pharmaceuticals, pesticides and seeds, National working group on patent laws (center for study of GATT issues), New Delhi.
[32] Redwood, Heinz (1994), *New Horizons in India: The Consequences of Pharmaceutical patent protection*, Oldwicks Press, Suffolk.

[33] Kim, Sang-Gon, Kong-Kyun Ro & Pyung-II Yu (1994), "Intellectual property protection policy and technology capability", Science and Publi Policy, Vol. 11, No. 1 (April) pp.111-130
[34] Ibid.
[35] Keayla B. K. New patent regime: implications for domestic industry, research and development and consumers. National Working Group on patent laws (center for study of GATT issues),
[36] Arman K. Reconsidering patents and economic development: a case study of the Turkish pharmaceutical industry. *World Development*, No. 13, February 1995.
[37] Scherer, F. M. and S. Weisburst (1995), "Economic effects of strengthening pharmaceutical patent protection in Italy", *IIC-International Review of Industrial Property and Copyright Law,* Vol. 26, pp. 1020-1022
[38] Ibid.
[39] Ibid.
[40] Pecoul, Chirac, et al, Access to Essential Drugs in Poor Countries; A lost Battle?, *JAMA*, Vol. 281, No. 4, 361-367.
[41] Ibid.
[42] WHO (1996), The world health report 1996: fighting disease, fostering development, World Health Organization, Geneva.
[43] Ibid.
[44] Ibid.
[45] Prescrire International *(October 1997, Vol 6, No 31, p156*
[46] Correa C. Options for implementing the TRIPs Agreement in developing countries: draft report of an expert group on TRIPs and developing countries convened by the Third World Network, TWN, 1997, Geneva.
[47] (*op. cit.* **)
[48] IFPMA (1995), GATT TRIPs and Pharmaceutical Industry: a Review, International Federation of Pharmaceutical Manufacturers Associations, Geneva.
[49] Lexchin. J. Pharmaceuticals, patents and politics: Canada and Bill C-11, *The International Journal of Health Services*, Vol. 13, No. 1, 1993
[50] For details see The Results of the Uruguay Round of Multilateral Trade Negotiations: The Legal Texts, published by GATT Secretariat, Geneva, June 1994.
[51] Ibid.