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Pharmaceutical Patent Protection
and the Right to Medicine –
TRIPs Agreement in Focus

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Preface

To the people who have helped me in the past one year either in my life or in my study!

Abbreviations

API	International Active Pharmaceutical Ingredient
GATT	General Agreement on Tariff and Trade
IGO	Inter-government Organization
IFPMA	The International Federation of Pharmaceutical Manufacturers Association
IPRs	Intellectual Property Rights
LDCs	Least Developed countries
NGO	Non-government Organization
PhRMA	Pharmaceutical Research and Manufacturers of America
R&D	Research and Development
SPAC	State Pharmaceutical Administration of China
TAC	Treatment Access Campaign
TNCs	Trans-national corporations
TRIPs	Agreement on Trade Related Aspects of Intellectual Property
UDHR	Universal Declaration on Human Rights
USTR	US Trade Representative
WHO	World Health Organization
WTO	World Trade Organization

1 Introduction

Equitable and appropriate health care is universally considered as a basic human right, and pharmaceuticals are an integral part of the modern health care system. Essential medicines save human lives and reduce suffering. Access to essential drugs is, therefore, a critical part of this fundamental human right.

The issue as to pharmaceuticals protection within the scope of patent has been debated under the occasion of various international forums for more than two decades. Patent protection is a crucial instrument in the development of the pharmaceutical industry, which depends to a large extent on costly research and development programs, the results of which being relatively easy to copy and thus making protection of the inventions more necessary than in other areas of industry. Patent systems, however, though enhancing innovation and development of new drugs, do restrict access to life-saving drugs, by raising the price of medicines, and thus, all else being equal, generally adversely affects on the health of the population of poorer states. Essential drugs are, however, not ordinary commodities. Every effort should be aimed at improving access to essential medicines for those who need them.

With the current globalization of trade, access to drugs becomes a critical issue, which needs particular attention. Looking back, under the Paris Convention for the Protection of Industrial Property, Member Countries were left free to determine the scope of protection as regards patent. Accordingly, Member Countries could design their laws in accordance with their needs, priorities and interests without according protection to pharmaceuticals, or they could choose to grant protection to pharmaceutical processes only.

TRIPs largely consolidates and strengthens previous international Agreements on IPRs. In this respect, TRIPs is not substantially new. However, the most important implications for globalization and the full observation of human rights of the Agreement lie in the universalisation, harmonization and minimum-standards application of IPR protection and the method of enforceability through WTO dispute settlement mechanisms.¹ Specifically, questions arise as to whether, TRIPs adequately balances the intellectual property right and the public health concern. Under the TRIPs Agreement of the WTO, Member Countries are

¹ “Globalization and its impact on the full enjoyment of human rights”, by Special Rapporteurs J. Oloka-Onyango and Deepika Udagama on a session of UN Sub-Commission on Human Rights, from South Bulletin 19, <http://www.southcentre.org/info/southbulletin/bulletin19/toc.htm>

obliged to provide protection with respect to both pharmaceutical processes and products under the ambit of patent. Member Countries are required to meet TRIPs recommendations without regard to the level of development, needs and priorities. Undoubtedly, due to this uniform rule, the great impact on the pharmaceutical products can be imagined, especially in developing and least developed countries. Until recently, in most developing countries, pharmaceuticals in general and pharmaceutical products in particular were not protected.

Although under the TRIPs Agreement, Member States are granted some flexibilities in implementing those strict standards, the vague expression in the provisions and the difficulties in the practice all become the obstruction for Member States especially for developing and least developed countries to fully make use of those provisions. Therefore, there is a need to further interpret TRIPs Agreement in terms of the public health concerns.

Under the pressures from all sides, a Ministerial Declaration on the TRIPs Agreement and Public Health was adopted on 14 November 2001, in Doha. (The Doha Declaration) This Declaration enables the people on the globe to see the aurora of reform in the intellectual property regimes regarding public health. Clarifying the flexibility in the TRIPs Agreement, the Declaration entitles developing country Members autonomy to make and implement domestic public health policies with respect to intellectual property protection. Nevertheless, this Declaration does not fully dismantle obstacles created by the TRIPs Agreement, which significantly constrain the autonomy of national legislatures to shape intellectual property laws in the public health perspective.² And also this Declaration leaves some unresolved issues for the future negotiation. Among them the “paragraph 6” issue and the “paragraph 7” issue may influence the implementation of the whole Declaration.

In the application of the Agreement, each country is finding its way to take the maximum advantage from the allowed flexibilities. But some may confront trouble, among them three cases need to be referred to, namely, “Canada — Patent Protection for Pharmaceutical Products” Case; case between United States and Brazil concerning “local working”; and the dispute between United States and South Africa. Among them, Brazil and South Africa have established domestic system to solve the matter of public health.

China is a new member of WTO and the biggest developing country in the world. How to deal with the link between pharmaceutical patent protection and the access to medicine is a big challenge to the Chinese government.

² “Reshaping the TRIPs Agreement Concerning Public Health: Two Critical Issues”, by Haochen SUN, *Journal of World Trade* 37(1): 163–197, 2003. Kluwer Law International.

This article seeks to clarify these complicated relations and put more attention on the developing countries as regards the implementation of the TRIPs Agreement. By analyzing the cases and the provisions of both the Agreement and the Declaration, the last part attempts to provide recommendations to all sides regarding the issue of pharmaceutical protection and the right of access to medicine.

2 The Relationship between the Right to Medicine and IPR Protection

2.1 The Right to Health and Access to Medicine in International Instruments

Health gives motive power to one's life, while medicine is the artificial instrument to restore a healthy body. Health in general has been recognized as one important human right codified in many international instruments. Among these instruments, one document needs to be stressed when connecting to this right, namely, the International Covenant on Economic, Social and Cultural Rights.

In Article 12:1 of the ICESCR, the "States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health". Moreover, in its General Comment No. 14 (2000), the UN Committee on Economic, Social and Cultural Rights has emphasized that the human right to health is recognized in numerous worldwide, regional and national human rights instruments and "includes certain components which are legally enforceable".³

Article 12:2 adds, "The steps to be taken by the State Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:

- (a) ...
- (b) ...
- (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases.
- (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness."(See article 12.2 ICESCR)

Under article 12 (2) (c), the control of diseases refers to States' individual and joint efforts to make available relevant technologies and the promotion of strategies of infectious disease control.⁴ Furthermore, under the next article, states are obliged to provide equal and timely access to basic preventive, curative and rehabilitative health services and appropriate

³ For instance the Article 25 of the UDHR also provides for the right to health. General Comment No. 14 (E/C.12/2000/4)

⁴ General Comment No. 14 (2000), para.16

treatment of prevalent diseases, illnesses, injuries and disabilities, preferably at the community level. The right to facilities, goods and services also includes the provision of essential drugs.⁵

Similarly, the General Comment provides that: “States parties to the Covenant also have international obligations to “provide essential drugs, as from time to time defined under the WHO Action Program on Essential Drugs” and to “take measures to prevent, treat and control epidemic and endemic diseases”.”⁶

From the above, it can be concluded that access to medicine is an essential method to implement the right to health, but more than the function as an instrument, the availability of medicines itself is one aspect of access to health. Without access to essential medicine, there is no cure at all. As the World Health Organization once observed that: “Access to health is a human right, Access to essential drugs is part of the human right to health.”⁷ Therefore, to ensure the person who needs it can gain the medicine is of significance for everyone in the same planet. Regarding this common recognition, access to medicine is also stipulated in several international document and international organizations. By virtue of this, as one part of the right to health, the access to medicine itself has evolved into a legal right, which needs to be implemented and realized.

The concept of accessibility is very important. It means that policies pursued must aim to make drugs available for all who wish to have them, and at affordable prices.⁸ If the objective is accessibility, then the best possible supply must be ensured. Access to basic medicines depends on numerals factors, according to WHO, these include “ (1) affordable prices (2) sustainable adequate financing (3) rational selection and use of medicines and (4) reliable health and supply systems. ”⁹ Although the latter three points are equally important in order to place the problem of access to drugs in the right perspective, in health and trade discussions, the focus is usually on drug prices.¹⁰

⁵ Ibid. Para. 17

⁶ General Comment No. 14 (2000), para.43 and 44.

⁷ WHO. “WHO Medicines Strategy 2000-2003.” *Policy Perspectives on Medicine*. Dec 2000.

⁸ “Globalization and Access to Drugs Implication of the WTO/TRIPs Agreement.” World health organization 1999.P.17.

⁹ “A New Era in Global Trade”, WHO Policy Perspective on Medicines, No.3 March 2001. http://www.who.int/medicines/library/edm_general/6pagers/PPM03ENG.pdf

¹⁰ “WTO Agreements and public health, A Joint Study by the WHO and the WTO Secretariat.” WHO ISBN 92 4 156214 5,WTO ISBN 92-870-1223-7,Printed by the WTO Secretariat, VII-2002-6,000,_ World Trade Organization / World Health Organization, 2002. P88

Regarding the price, it is generally accepted that pharmaceutical products cannot be regarded as ordinary goods or products.¹¹ In the first place this is because consumers are not in a position to judge, for example, the quality of drugs, hence the need for a monitoring and surveillance system ensured by the State.¹² Secondly, this is because drugs play a significant social role in that they are an integral part of the realization of a fundamental human right - the right to health.¹³ This is why they are classified as essential goods, to emphasize that they have to be accessible for all people.¹⁴ Even that, however, in fact, many people who suffer from serious diseases cannot obtain enough medicine only because of the high price.

Since most poor people in developing countries currently pay for health care, including drugs, out of their own pockets, access to medicine is particularly sensitive to cost. In the context of HIV/AIDS, the Secretary-General of the UN recently stated that, “we must put care and treatment within everyone’s reach. Even a year ago few people thought that effective treatment could be brought within reach of poor people in developing countries. ... People no longer accept that the sick and dying, simply because they are poor, should be denied drugs which have transformed the lives of others who are better off”.¹⁵

The cause for the high price of drugs certainly depends on many factors; however, one factor has great relation with the intellectual property protection. Therefore this brings us to the next issue we are going to discuss.

2.2 The Polarity Function of Intellectual Property Protection on the Access to Medicine

Like the right to health, intellectual property right is also a human right, as enunciated in the same documents.

Article 27.2 of the UDHR and Article 15.1(c) of the ICESCR recognize the right to intellectual property protection, which establishes everyone’s “right to the protection of the

¹¹ “Pharmaceuticals in the Trade Related Aspects of Intellectual Property Rights (TRIPs) Agreement of the World Trade Organization (WTO) A Briefing on Trips”, World Health Organization Regional Office for the Western Pacific Manila August 2000. P1.

¹² Ibid.P.10

¹³ Ibid.P 10

¹⁴ “Globalization and Access to Drugs Implication of the WTO/TRIPs Agreement.”, op.cit.p.18.

¹⁵ “Secretary-General proposes global fund for the fight against HIV/AIDS and other infectious diseases at African leaders summit”, SG/SM/7779/Rev.1-AFR/313/Rev.1-AIDS/7/Rev.1, 26 April 2001, <http://www.un.org/News/Press/docs/2001/SGSM7779R1.doc.htm>

moral and material interests resulting from any scientific, literary or artistic production of which he is the author” as a human right.¹⁶ Like all human rights, this is couched in terms of the human right of the individual to be accorded such protection. At the same time Article 15.1(a) and (b) of the ICESCR recognizes the right of everyone to “take part in cultural life” and to “enjoy the benefit of scientific progress and its applications”.¹⁷ Here, it is clear that there is a need to balance the human right to intellectual property protection in Article 15.1(c) with Article 15.1(a) and (b) which recognize the right of everyone to take part in cultural life and to enjoy the benefits of scientific progress and its applications.

When we try to find a linkage between the intellectual property right and the access to medicine, the subject of the patent protection of pharmaceutical compositions seems vitally important and controversial. First it is a subject with strong social connotations: it touches on areas as sensitive as health and man’s quality of life, even his survival. Secondly, the chemical and pharmaceutical industry depends to a large extent on costly research and development programs for the production of new inventions, which means that it is more necessary than in other areas of industry to be able to protect them with patents. This is compounded by the fact that chemical and pharmaceutical products are more often than not relatively easy to copy. Thus, the challenge we face is how to reach an appropriate balance between sharing the high costs associated with research and development activities and, at the same time, sharing the results of these activities, in terms of access to new drugs to treat the diseases prevalent in different countries.¹⁸ The following paragraphs will discuss the subtle relationship and try to find this balance.

¹⁶ See article 27 in UDHR“1. Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its beneficial.2.Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.”

¹⁷ See Article 15.1 in ICESCR“1. The States Parties to the present Covenant recognize the right of everyone:

- (a) To take part in cultural life;
- (b) To enjoy the benefits of scientific progress and its application;
- (c) To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.”

¹⁸ "IPRs, WTO and R&D Funding For Public Health”, Jayashree Watal£–in the international meeting on ‘a global framework for supporting health research and development in areas of market and public policy failure’, Geneva on 29 April 2003.

2.21 The Effect of Patent Protection in Promoting the Invention, Development and Marketing of New Drugs, By Providing Incentives for Research And Development.

“Stronger IPRs are seen as a vehicle to promote economic development and developing countries alike, by improving both the stock of technological knowledge and the flow of that knowledge between countries. In this respect economic analysis has suggested a direct link between tighter IP protection and increased innovative activity.¹⁹

In respect to patent protection and price, no one would object this statements: A higher cost of a new product is not properly linked to the “manufacturing cost” but rather to its previous development process, whereas the development of “copy”, i.e. generic version of the new drug, requires foremost the identification of the original product ingredients. Therefore without a patent regime the innovator would obviously be at a disadvantage with regard to competition.²⁰

Similarly, proper protection for pharmaceuticals could bring more innovation and intentions on drugs for rare diseases. For instance, recent experiences show that, in Mexico, patent legislation enacted in 1991, quadrupled investment in three years. In Canada, after the improvements made on its patent law in 1987 and 1992, investment in research and development has grown steadily reaching more than 10% of sales.²¹ More recently, in Brazil, after the approval of patent legislation in May 1996, the research based pharmaceutical industry has confirmed investments of \$ US 1.4 Billion, estimating a total of \$ 2.3 Billion by the year 2000. From these so far, \$ 200 million will go into research and development and \$100 million into education and training.²²

Besides the above—the transnational pharmaceutical corporations (TNCs) seem to have more excuses to support the high price theory.

TNCs argue that a high price is a result of a need to recover the money invested in R&D, as well as the fact that the production, is found in countries where costs are relatively high. They try to indicate that being granted proper protection, they would be more eager to

¹⁹ UN – *Transnational Corporations and Management Division*, Department of Economic and Social Development – Intellectual Property Rights and Foreign Direct Investment, NY 1993, p. 23

²⁰ The right to health and right to intellectual property in the EU. Analysis of the internal and external policies. Master thesis By Beata Faracik.

²¹ “Patent Protection For Pharmaceuticals”,

http://www.sice.oas.org/ftaa/belo/forum/workshops/papers/wks7/prma_e.asp

²² *ibid.*

either move their production to 'lower production cost' countries or license their patents to developing countries.

Other grounds such as "The level of patent protection is closely correlated to the level of economic development." or "a strong domestic patent system helps to provide a rapid flow of new products to the market place." and "The generic pharmaceutical industry thrives in a country with strong patent protection." are always be referred to justify the patent protection for pharmaceuticals.²³

But what is behind these advocates? It is not difficult to find the wire puller - transnational pharmaceutical companies. We all know since a pharmaceutical corporation is not a charity rather than that, it is a profit-pursuing entity, and may be one of the most profitable industry in the world. They are essentially driven towards economic reward; the objective of promoting respect for human rights would at best appear to be a secondary consideration.²⁴ With the huge money behind, they can provide many grounds for the protecting of pharmaceuticals. Promoting R&D may be the strongest one. We all admit that to grant patent protection to pharmaceutical is a way to recover the money invested in R&D, further to promote the whole pharmaceutical industrial's developing capability, but this is not the point for this issue. As we all know that the striking feature of the patent protection is the exclusion. This kind of exclusion leads to the monopoly either in marketing or in the R & D field. So, what really matter is that could the exclusive right coming from the patent protection, be justified at any time as to stimulate the innovation?

In general, from a strictly economic point of view, a patent monopoly is a very inferior means of financing research.²⁵ Because we all know that stringent patent protection sometimes based on the waste of the social resource. A basic principle of standard microeconomics is that the price of a good should be equal to the cost of producing an additional unit. Monopoly pricing, especially at 15 or 20 times the cost of production, is enormously wasteful and inefficient. In the case of essential medicines, this consequence of patent protection is inseparably linked to the exclusivity of it, which allows companies to impose extremely high prices on their products, which aim not only at cost-coverage but also at unreasonably high income, thereby, pharmaceuticals became the second largest by

²³ Ibid.

²⁴ "The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights", Report of the High Commissioner, Commission On Human Rights Sub-Commission on the Promotion and Protection of Human Rights Fifty-second session Item 4 of the provisional agenda, E/CN.4/Sub.2/2001/13 27 June 2001

²⁵ "Free Trade For Life-Saving Medicines", Mark Weisbrot, South Bulletin 09 http://www.southcentre.org/info/southbulletin/bulletin09/bulletin09-04.htm#P151_30458

market value industry sector in the world.²⁶ And the toll of this inefficiency is measured in human lives.

What is more, the fact that pharmaceutical corporations typically spend more than twice as much on marketing as they do on R&D raises questions about how much of the revenue from patents actually finds its way into socially beneficial research.²⁷ According to the industry's own tax records,²⁸ Merck this year spent 13% of its revenue on marketing and only 5% on R&D, Pfizer spent 35% on marketing and only 15% on R&D, and the industry overall spent 27% on marketing and 11% on R&D. Meanwhile, all of sub-Saharan Africa constitutes only 1.3% of the pharmaceutical market and the industry spends 0.2% of its R&D funds on African diseases, meaning that the R&D problem on "neglected diseases" (neglected by those not suffering from them, that is) will perpetuate until the market-based ideology is broken²⁹

Industry also tends to gloss over the existence of public funding for the development of products patented by industry. The emphasis on R & D investment conveniently omits mention of the fact that some of the financing for this research comes from public sources; how then can it be justifiably argued that the benefits that derive from such investment should accrue primarily to private interests?³⁰ Taxpayers and publicly funded institutions often play a key role in discovering new inventions, with the pharmaceutical industry obtaining the patent - and reaping the financial rewards - after the basic discovery. These institutions are now becoming more reluctant to unconditionally hand over their research. In December 2000, a dispute between the US National Institute of Health (NIH) and Bristol Meyers Squibb became public. NIH is demanding \$9.1 million in royalties from overseas sales of didanosine, used in the treatment of HIV/AIDS.³¹

Moreover, patents are increasingly becoming corporate assets, part of the stock of a company that reflects its competitiveness on the market.³² This can lead research into an innovation race. Consequently, while patenting activity is particularly high in the

²⁶ "Overtaking telecommunications and IT hardware and thus rising from fourth place last year according to 2002 FT 500 survey." Financial Times, 10.05.2002, <http://specials.ft.com/ft500/may2002/index.html>

²⁷ "Patents, TRIPs & Public Health", from Oxfam paper "Patent Injustice: How World Trade Rules Threaten the Health of Poor People.", South Bulletin 09, http://www.southcentre.org/info/southbulletin/bulletin09/bulletin09-03.htm#P82_12402

²⁸ obtained from the Securities and Exchange Commission.

²⁹ Pharmaceutical Research and Manufacturers of America, PhRMA Annual Membership Survey, 2002. <http://lists.essential.org/pipermail/ip-health/2003-January/004053.html>

³⁰ "Globalization and its impact on the full enjoyment of human rights", op.cit.

³¹ "Patents, TRIPs & Public Health", op.cit.

³² "The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights", op.cit.

pharmaceutical industry, many patents cover “me-too” drugs - drugs that are just different enough to be considered novel for the purposes of patent protection, but in fact have similar effects as prior patented drugs.³³ With “me-too” drugs, the economic gain for the patent holders is likely to be significant, but the question arises as to how the economic incentive of IPR simultaneously promotes the right to health in this situation. On the one hand, the presence of “me-too” drugs, even if patented, might lower the costs of drugs for consumers due to increased competition. On the other hand, it could result in the clogging of future research by the presence of too many patents, as well as a significant concentration of control over the dissemination of drugs in the hands of certain corporations.³⁴

Similarly, WHO has identified this situation where standards for the grant of patents can contribute to “ever-greening” - a process where minor innovations to patented innovations are themselves patented which can effectively extend the life of the patent beyond the original 20-year grant. Extending the active patent life beyond the limited period of protection could hold up other research efforts.³⁵ The reason is relevant where research into a final product or process - for example, a drug - relies on several levels of innovation all of which are susceptible to IP protection. In such cases, patents on innovations from the early stages of research can be used to control and possibly block life-saving innovations that depend on the use of the first innovation.³⁶

The problem that pharmaceutical companies creatively use the patent system to extend monopolies and boost profits always causes constant source of complaint from the generic-drugs industry.³⁷ For instance, in 1999 SmithKline Beecham (SB) secured a new patent on its 20-year-old best-selling drug, Augmentin, by modifying the pediatric version. Although the old forms will be available off-patent, extensive marketing is likely to induce doctors to prescribe the new drug when it comes on the market.³⁸ Other high-profile cases have included Eli Lilly seeking extensions of its patent on Prozac (an anti-depressant with sales in excess of US\$2bn annually), and the US Federal Trade Commission prosecuting Aventis for paying generic manufacturers not to produce low-cost rivals to its brand-name drugs.³⁹

³³ *ibid.*

³⁴ *Ibid.*

³⁵ “Globalization, TRIPS and access to pharmaceuticals”, WHO Policy Perspectives on Medicines: WHO Medicines Strategy: 2000-2003, No. 3, March 2001 (WHO/EDM/2001.2), p2

³⁶ M.A. Heller and R.S. Eisenberg, “Can Patents Defer Innovation? The Anticommons in Biomedical Research”, *Science*, 1 May 1998, vol. 280, pp. 698-701, www.sciencemag.org

³⁷ “Patents, TRIPs & Public Health”, *op.cit.*

³⁸ *ibid.*

³⁹ *Ibid.*

A large number of the drugs that have qualified for an extension in patent protection have not been subjected to major innovations with regard to their active ingredients. It is not difficult to see why pharmaceutical corporations seek to extend the period of patent protection. When a US court decided in August 2000 to grant Eli Lilly two years less extension to its patent on Prozac that the company had been requesting, its share value fell by almost one-third, wiping US\$38bn from its market capitalization.⁴⁰ Patent expiry, and the prospect of competition from generic versions of drugs marketed at a fraction of the brand-name price, pose obvious problems for corporations precisely because share price valuation is increasingly determined by the patent life of key drugs.⁴¹

The story may be more serious regarding developing countries. As WHO has noted, the commercial motivation of IPRs means that research is directed, first and foremost, towards “profitable” disease. We could see the profit orientation function by TNCs on the poor people. Diseases that predominantly affect people in poorer countries - in particular tuberculosis and malaria - still remain relatively under-researched.⁴²

In fact, R&D into medicines for some diseases is a good example of exactly the opposite. For neglected diseases such as sleeping sickness, Chagas disease or leishmaniasis, which only affect poor people, a patent holder will never be able to make a profit by charging high prices, so little R&D is conducted on these diseases.⁴³ According to WHO, “questions remain as to whether the patent system will ensure investment for medicines needed by the poor. Of the 1,223 new chemical entities developed between 1975 and 1996, only 11 were for the treatment of tropical disease”.⁴⁴ The market fails when it comes to ensuring adequate pharmaceutical research and development (R&D) for neglected diseases such as malaria, a range of other tropical diseases and tuberculosis.⁴⁵ The argument for a patent system encouraging R&D for medical needs in their countries falls far short.

Furthermore, a good number of the tests and clinical trials for life-saving drugs are carried out on people who come from developing countries and LCD's, or from among the less-privileged in developed countries. Such input in the R & D process is seldom recognized.

⁴⁰ Ibid.

⁴¹ *ibid*

⁴² P. Drahos, Human Rights, “Globalisation and intellectual property rights”, paper presented at the Workshop on international trade, finance and investment and economic, social and cultural rights: the role of the Committee on Economic, Social and Cultural Rights in a Globalizing Economy, Geneva, 6 May 2000, p. 7.

⁴³ “Drug patents under the spotlight.” *by the Medicines Sans Frontieres*, South Bulletin 59, http://www.southcentre.org/info/southbulletin/bulletin59/bulletin59-06.htm#P509_84186

⁴⁴ WHO/EDM/2001.2, *op. cit.*, p. 5.

⁴⁵ “A New Era in Global Trade”, WHO Policy Perspective on Medicines, No.3 March 2001.*op.cit.*

Ironically, it is the very same sort of people who offered themselves for the testing trials who are then eliminated from benefiting from the final drug on account of prohibitive costs and an iniquitous patents system.⁴⁶

Given all the above, it is a conclusive opinion of the Special Rapporteurs that the argument for stringent patent protection as essential to the promotion of innovation and invention is one that over-privileges the owners of capital.⁴⁷ As we have already pointed out, these invariably happen to be multinationals. Furthermore, there is the wider issue of the misuse of patent protection, as exemplified by the me-too drugs and the evergreen patent, which obviously become the obstacle on the way of R&D. The fact that in some countries, which have strong generic industry, many of the pharmaceutical companies that were extremely resistant to reducing their prices are now scrambling to match (and undersell) the prices of competing generics is a telling demonstration of the fact that the argument about R&D costs might not be as weighty as previously asserted.⁴⁸

2.2.2 The Effect of Patent Protection in Limiting Access to Existing Drugs and Vaccines.

Let's see the other side of the coin, which is the point I want to draw your attention to the issue. Since the above has discussed the positive influence of the pharmaceutical patent protection, (although this effect should be considered under many circumstances and also may be not such definitely for recognition, but we cannot totally deny it.) the following is about to go deep into its negative effect on the access to medicine.

As we have mentioned above, the most widely discussed effect is the higher prices charged for patented products. It is for these reasons that the patent protection of innovations concerned with chemical, pharmaceutical and food products has been one of the most controversial subjects in industrial property. The exclusion of chemicals from patentability occurred for the first time in history in a German law of 1877.⁴⁹ The reasons given at the time were that it was necessary to reinvigorate an industry that was lagging behind its counterparts in other countries. Even before that, a French law of 1844 had expressly excluded pharmaceutical chemicals from patentability.⁵⁰

⁴⁶ “Globalization and its impact on the full enjoyment of human rights”.op.cit.

⁴⁷ *ibid.*

⁴⁸ *Ibid.*

⁴⁹ “Intellectual Property And The Right To Health” By Silvia Salazar, “intellectual property and human rights”, a panel discussion to the commemorate the 50th anniversary of the universal Declaration of human rights Geneva, November 9, 1998.

⁵⁰ *Ibid.*

The presence of IP protection over drugs can play a role in determining the affordability of drugs. However, in market reality companies often abuse this semi monopoly status by pricing drugs at excessive level. Even though access to medicines is dependent not only on affordable prices, but also upon rational selection and use of medicines, sustainable adequate financing, reliable health and supply systems, it is still the price that constitute the crucial part of the treatment process⁵¹ There is evidence to suggest that the effect of patents on affordability is significant with drug prices falling sharply when generic substitutes enter a market to compete with drugs upon patent expiry.⁵² In 2001 the average brand name drug cost more than \$72 per prescription, while the average price for generic drugs, just as safe and effective as the brand name drugs, were just \$17 per prescription.”⁵³ Not everyone can afford the \$10 000 –15 000 person/year treatment with brand named drugs for a lengthy period. It is particularly true in case of countries where the expenditure on health per person a year may be as low as \$10.⁵⁴

According to UNAIDS, the high prices of HIV treatments are due, in part, to patent protection which allows control over their manufacture and sale.⁵⁵ The UNDP Human Development Report 2000 notes that generic production of the HIV treatment fluconazole in India has kept the price at \$55 for 150 milligrammes compared with \$697 in Malaysia, \$703 in Indonesia and \$817 in the Philippines.⁵⁶ Similarly, a report to the CESCRC has noted that the AZT treatment is produced at a supply cost of \$48 a month in India as compared with \$239 in the United States.⁵⁷

The price patent holders charge for an AIDS drug cocktail remains at around US\$10,000 in rich markets.⁵⁸ Antiretroviral drugs are expensive not because of the cost of manufacture, but because of the patent monopolies that enable drug companies to set whatever price they

⁵¹ Avert, HIV & AIDS drugs in Africa, <<http://www.avert.org/aidsdrugsafrika.htm>>, 13/02/2002

⁵² Watal, Jayashree, “Workshop on differential pricing and financing of essential drugs”, background note prepared by Jayashree Watal, consultant to the WTO secretariat, p. 14.

⁵³ News Flash, White House hopes to make generic drugs available more quickly by blocking patent suits, <www.nj.com/printer/printer.ssf?/newsflash/get_story.ssf?/cgifree/getstory_ssf.cgi>, 2002-10-21

⁵⁴ Avert, HIV & AIDS drugs in Africa.op.cit.

⁵⁵ UNAIDS, Statement of the Joint United Nations Programme on HIV/AIDS (UNAIDS) at the Third WTO Ministerial Conference, Seattle, 30 November-3 December 1999
<http://www.unaids.org>

⁵⁶ UNDP, Human Development Report 2000, Oxford University Press, New York, 2000, p. 84.

⁵⁷ A. Chapman, “Approaching intellectual property as a human right: obligations related to article 15 (1) (c)” (E/C.12/2000/12), para. 63.

⁵⁸ Medicines Sans Frontieres, “Drug patents under the spotlight.” op.cit.

choose. Indian generic companies can now provide three-drug antiretroviral cocktails for less than \$300 a year per person.⁵⁹

In the face of growing political pressure and moral outrage, the drug companies have begun to offer some of these drugs at increasingly steep discounts. But even Merck's latest offer, ostensibly at cost for two of the commonly used drugs that make up the AIDS "triple cocktail", would still leave the price at 3-4 times what generic competition would bring.⁶⁰

In sum, what patent brings to us, is the incentive for the innovation of new drugs, and more importantly, is the high unaffordable price. When it comes to this, it is not a rational way to do away with the patent protection from the drugs industry; instead we still need the intellectual property as the protection. But since it is aware that medicine is not the common goods as the other commodity. It has its own special feature, which is so significant to our health that we must distinguish medicine from other patent products. In the scale of the protection, the line should be drawn to the side of access to medicine, especially when it comes to developing countries, only the tilt can make the equality.

⁵⁹ How Fast Track May Interfere With Poor Countries' Access To Essential Medicines www.Essentialaction.Org

⁶⁰ "Free Trade For Life-Saving Medicines", Mark Weisbrot.op.cit.

3 The Battle Between Developing Countries and Developed Countries

While developed countries represent nearly 90 per cent of global drug sales, 90 per cent of the 14 million deaths due to infectious diseases are in developing nations.⁶¹ Business interests in the developed world claimed large losses from the imitation and use of their innovations in developing countries and LDCs. They also asserted that IPRs would benefit the developing countries by encouraging foreign investment, by enabling transfer of technology and greater domestic research and development (R&D). On the other side, developing countries and LDC governments were worried about the higher prices that stronger IPRs would entail and about the harm that their introduction might cause to infant high tech industries. Therefore, to gain the medicine and to gain the profit through patent protection is the battle between the TNCs and the poor people or in other words the battle between the developed countries and the developing countries.

3.1 The Striking Comparison Between Developing And Developed Countries In Respect Of Medical Treatment

WHO estimates that currently one third of the world's population lacks access to essential drugs, with this figure rising to over 50% in the poorest parts of Africa and Asia.⁶² UNAIDS has stated that 95 per cent of HIV sufferers are in developing countries.⁶³ Over 22 million Africans, 6.7 million South and Southeast Asians, and 1.4 million Latin Americans are infected with HIV. Over ninety percent of the world's HIV-infected people live in these regions of the world. Millions of people are dying because of the lack of access to affordable medicines.⁶⁴

⁶¹ Sanjay Basu, Patents and Pharmaceutical Access, South Bulletin 59. http://www.southcentre.org/info/southbulletin/bulletin59/bulletin59-08.htm#P626_110535

⁶² WHO Medicines Strategy: Framework for Action in Essential Drugs and Medicines Policy 2000-2003. Geneva: World Health Organization, 2000 (WHO/EDM/2000.1).

⁶³ UNICEF/UNAIDS/WHO/EDM/MSF project, "Selected drugs used in the care of people living with HIV: sources and prices", October 2000, p. 1.

⁶⁴ http://www.ilga.org/Current%20activities/urgent%20actions/iglhrc/aids_drugs_now_wto.htm

Costs of drug treatments exceed \$10,000 a year per person in the United States, and were at similar levels in Africa just a few years ago -- a level which populations with per capita income marked in the hundreds of dollars obviously cannot afford.⁶⁵

In the context of HIV/AIDS treatments, high prices have had a substantial impact on impeding access for sufferers. HIV/AIDS medicines are not affordable to developing country governments or to most people with AIDS in these countries. In the United States, people who are infected with the HIV virus can now have their lives extended indefinitely through a combination of drugs known as AIDS cocktails. The cost of these drugs is \$10,000 to \$15,000 a year - placing them far out of the reach of the 33 million people in low-income countries, including 25 million in sub-Saharan Africa, who need them.⁶⁶

The problem becomes particularly acute as developing countries have a high dependence on private expenditure for the purchase of medicines compared to developed countries, in spite of their higher levels of poverty.⁶⁷ In developing countries, 25 to 65 per cent of total health expenditures is spent on pharmaceuticals, but government health budgets are too low to purchase enough medicines and poor people often cannot afford to buy them on their own.⁶⁸

WHO Director-General, Dr Gro Harlem Brundtland once made a speech that: At present, one-third of the world's population still has no guaranteed access to essential drugs – and most of these people have little or no access to primary health services either. As we have seen, the inequities are striking. In developed countries, there may be one pharmacist for every 2000 to 3000 people. A course of antibiotics to cure pneumonia can be bought for the equivalent of two or three hours' wages. One-year treatment for HIV infection costs the equivalent of four to six months' salary. And the majority of drug costs are reimbursed. In developing countries, there may be only one pharmacist for one million people. A full course of antibiotics to cure a common pneumonia may cost one month's wages. In many countries, one year of HIV treatment - if it were purchased - would consume the equivalent of 30 years' income. And the majority of households must buy their medicines with money from their own pockets.⁶⁹

⁶⁵ How Fast Track May Interfere With Poor Countries' Access To Essential Medicines
http://www.globaltreatmentaccess.org/content/press_releases/02/022102_A_FS_FAS_TRA CK.pdf

⁶⁶ “Free Trade For Life-Saving Medicines”, Mark Weisbrot.op.cit.

⁶⁷ Watal, Jayashree, “Workshop on differential pricing and financing of essential drugs”, background note prepared by Jayashree Watal, consultant to the WTO secretariat, p. 9.

⁶⁸ Wto Agreements and public health. Op.cit.P 88

⁶⁹ Speech of the WHO Director-General, Dr Gro Harlem Brundtland, Geneva 2 July 2001 24th Session, Codex Alimentarius Commission

3.2 Health and Development

In a UN report, it is claimed that: “Poverty is an important reason that the babies are not vaccinated, clean water and sanitation are not provided, drugs and other treatments are unavailable, and mothers die in childbirth.”⁷⁰ Health has become a more central concern in development, both as a contributor to, and an indicator of, sustainable development. While health is a value in its own right, it is also a key to productivity.⁷¹

The right to health as well as the access to medicine is not merely a matter relating to individuals, it carries also economy related aspects associated with it. Economic development itself is considerably dependent upon the health level of the population, as people's productivity depends on their level of nutrition and general well being. If the society is to function properly and enjoy economic well being, a healthy population is needed as the proper functioning of the economy suffers from illness-related absenteeism.⁷²

HIV/AIDS is a typical example to address this issue. Not only does it concern the enjoyment of the right to health, it is also a significant obstacle to the realization of the right to development. Looking at the health dimension: in 1999, 5.4 million people were newly infected with HIV, 34.3 million people were living with HIV/AIDS throughout the world and 2.8 million people had died from the virus.⁷³ A recent report of UNAIDS illustrates the developmental dimensions of HIV/AIDS. For example, surveys note that households caring for a family member with AIDS suffer dramatic decreases of income. In education, HIV is taking its toll, first by eroding the supply of teachers who fall ill as a result of the virus, second, by health treatment eating into family education budgets, third, by adding to the pool of children who are growing up without parental support which may affect their ability to stay at school. In the agricultural sector, sickness of farm workers has resulted in a fall in agricultural output and might threaten food security. HIV is hurting business through absenteeism, lower productivity, and higher overtime costs for workers

⁷⁰ United Nations reported in an April 4 Inter Press Service study

⁷¹ UN report “Health and Sustainable Development”, 4 April 2001.

⁷² van Krieken, Peter - Health gaps and Migratory Movements, RWI Report No. 31, Lund 2000, p. 9; See also: Eze C. Osita - “Right to Health as a Human Right in Africa”, The Right to Health as a Human Right. Workshop – The Hague, Dupuy, Rene-Jean (Ed.), 27-29 July 1978, Sijthoff and Noordhoff 1979, p. 83

⁷³ The AIDS Pandemic Current Worldwide Statistics.

<http://www.rotaryaidsproject.org/facts.html>

obliged to work longer hours to replace sick colleagues.⁷⁴ Indeed, the effects of HIV on the enjoyment of the right to development are so strong that the Secretary-General of the UN in his address to the African Summit described HIV/AIDS as “our biggest development challenge”.⁷⁵

These alarming cases show that, high price has become an obstacle for the poor people to gain the health and also an obstacle for the whole country’s development process. Therefore, for low-income countries and poor people in particular, bringing down the cost of medicines is key to gaining access to drugs. What makes this disaster? Not the only one, but the dominant one, is the patent protection.

In Europe, where the patent system originated, the relevant provisions went on from being a vehicle for promoting the development of local industry.⁷⁶ Countries have been designing the provisions of their patent laws according to their particular levels of development and specific needs. It is said that, once they had achieved a certain level of development of their pharmaceutical industries, the developed countries amended their legislation to extend patent protection to pharmaceutical products.⁷⁷ What is certain is that it was not until 1960 that France introduced protection, with Germany following in 1968, Italy in 1978, and Japan and Switzerland in 1976 and 1977 respectively.⁷⁸ Meanwhile, ironically at the same time, the majority of the developing countries, acting in response to economic policies of import substitution and to a general feeling that intellectual property protection systems were not conducive to scientific and technological development, indeed actually hampered it, took steps to exclude chemical, pharmaceutical and food products from patentability.⁷⁹ It was argued at the time that the scientific and technological gap separating developed from developing countries was too wide, and that patent systems were quite simply liable to widen it further. From that point of view, therefore, there were indications of a serious threat to any prospects of the right to health being guaranteed.⁸⁰

⁷⁴ UNAIDS, Report on the Global HIV/AIDS Epidemic, Geneva, June 2000, (UNAIDS/00.13E), p. 26 ff.

⁷⁵ “Secretary-General proposes global fund for the fight against HIV/AIDS and other infectious diseases at African leaders summit”, SG/SM/7779/Rev.1-AFR/313/Rev.1-AIDS/7/Rev.1, 26 April 2001, <http://www.un.org/News/Press/docs/2001/SGSM7779R1.doc.htm>

⁷⁶ WHO Medicines Strategy: Framework for Action in Essential Drugs and Medicines Policy 2000-2003.op.cit.

⁷⁷ Silvia Salazar, “Intellectual Property And The Right To Health” op.cit.

⁷⁸ *ibid.*

⁷⁹ *Ibid.*

⁸⁰ WHO Medicines Strategy: Framework for Action in Essential Drugs and Medicines Policy 2000-2003.op.cit.

When the time patent system is only an domestic matter, this issue may not be too serious, however the creation of a new universal standard bring this conflict to a more complicated situation, when that both the patent protection for pharmaceuticals, and the problem of access to drugs because of high price monopolies, are intimately tied to the current "free trade" agenda.⁸¹

⁸¹ Sanjay Basu, *Patents and Pharmaceutical Access*, op.cit.

4. TRIPs Agreement: A New Balance or A New Disaster

4.1 The Background of the Agreement

The previous rounds of GATT negotiations had been confined to discussion of ways to eliminate trade barriers at national frontiers to bring about an optimal expansion in international trade and better use of the world's resources of wealth. In contrast to this, the negotiations over TRIPs were not about freeing trade. Rather, they were about more protection and tighter control.⁸²

Intellectual property rights were included in the agenda of the Uruguay Round on the initiative of industrialized countries, following pressure from a variety of economic groups.⁸³ The general trend in industrialized countries has been that the “boundaries of the patent system are re-drawn (almost always by widening) as industries which are used to working with patents extend their ambit of operation.”⁸⁴ According to the World Development Report for 1997, “Poor countries often lose out because the rules of the game are biased against them – particularly those relating to international trade. The Uruguay Round hardly changed the picture.”⁸⁵ Given the fact that TNCs are the holders of the largest percentage of IPRs, it is quite clear that the main thrust of the negotiations favored the enhancement of monopoly corporate power.⁸⁶

It is thus very clear that the Uruguay Round negotiations were largely dominated by industrialized countries and that developing countries were constrained to accept commitments sometimes running counter to their economic and social development.⁸⁷ The result is the birth of a universal standard TRIPs Agreement. TRIPs largely consolidates and strengthens previous international Agreements on IPRs. In this respect, TRIPs is not substantially new. However, the most important implications for globalization and the full observation of human rights of the Agreement lie in the universalisation, harmonization and minimum-standards application of IPR protection and the method of enforceability through WTO dispute settlement mechanisms. This fact marks a radical break with the

⁸² “Globalization and its impact on the full enjoyment of human rights”.op.cit.

⁸³ “Globalization and Access to Drugs Implication of the WTO/TRIPs Agreement.”op.cit.

⁸⁴ Medicines Sans Frontieres, “Drug patents under the spotlight.” op.cit.

⁸⁵ UNDP. Human Development Report 1997. New York & Oxford: Oxford University Press; 1997

⁸⁶ “Globalization and its impact on the full enjoyment of human rights”.op.cit.

⁸⁷ “Globalization and Access to Drugs Implication of the WTO/TRIPs Agreement.”op.cit.

earlier GATT strategy of differential and more favourable treatment for developing countries adopted at the Tokyo Round.⁸⁸

Because the geographical distribution of know-how is concentrated in industrialized countries, this harmonization is likely to strengthen their existing economic superiority, in particular by prohibiting developing countries from copying a new product by reverse engineering, and thereby developing their own technology.⁸⁹

4.2 Implications of the TRIPs Agreement on Patents for Pharmaceutical Products

In general, the TRIPs Agreement requires WTO Member States to grant patent protection to all inventions in any branch of technology.⁹⁰ This provision was expressly aimed at pharmaceutical products, for which certain developing countries, as well as developed countries, had refused to grant patents. Because of the high prices of patented drugs and the large amount of expenditure required for research and development (R&D) in the pharmaceutical field, some countries had chosen to imitate products patented in industrialized countries in order to meet their national requirements for drugs at a lower cost and to develop their local industry. Other countries with no pharmaceutical industry could also buy these copies of patented drugs at competitive prices. If national regulations on patents do not provide for the protection of pharmaceuticals, or if they are not respected, the Member State in question may, pursuant to the disputes settlement process, incur commercial sanctions imposed by the WTO Dispute Settlement Body.⁹¹ Even though some countries choose to risk the complaint by the other Member States, because the compliance may cost much more, compared with the sanction. So let us draw our attention on this controversial Agreement and try to find its characteristic then to discuss the impact of this Agreement respectively in detail.

⁸⁸ *ibid.*

⁸⁹ *Ibid.*

⁹⁰ See Article 27.

⁹¹ “Pharmaceuticals in the Trade Related Aspects of Intellectual Property Rights (TRIPs) Agreement of the World Trade Organization (WTO) A Briefing on Trips”. *Op.cit.*

4.2.1. The differentia provisions in TRIPs

4.2.1.1 Protection for Both Pharmaceutical Products and the Process

The subject under the protection by the new rules not only confines the pharmaceutical product itself but extends to the whole process as well.

Article 28.1(b) provides that: "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"

This extension of the protection of the manufacturing process to the resulting product increases the protection conferred upon the holders of know-how. The issue has been raised as to whether, in practice, the inventor of a new manufacturing process for a product already known and not protected by a patent could be granted exclusive rights to that product under the Agreement. This would only happen if the patented process used to manufacture the product was totally or partially unique and irreplaceable. The fundamental question that then arises is whether or not it would be possible, based on this reasoning, to obtain an exclusive right to exploitation for a drug not covered by a patent,⁹² you can obtain a patent for a process – this would prohibit other from using that process to obtain the same result through a new process for the manufacture of that drug. The answer would appear to be negative, since only the product directly obtained by the new process enjoys the protection attaching to the new process. This implies that a manufacturer using the old manufacturing process could not be accused of infringement of the process patent. However, the extension of process protection to a product may lead to an increase in lawsuits, which may be a deterrent to small local companies.⁹³

The TRIPs Agreement protects not only the process through which the product is produced but also the product itself. Therefore it is not possible to manufacture and sell a patented drug made through a new process. Some countries (India, China, Brazil, Malaysia, Thailand, Mexico, Argentina, Egypt and Canada), prior to the TRIPs Agreement, had either excluded pharmaceuticals from their patent system or provided only process patent. In the absence of product patents, the local companies could develop the drugs through different

⁹² For example, a drug included in the WHO Model List of Essential Drugs

⁹³ "Globalization and Access to Drugs Implication of the WTO/TRIPs Agreement." op.cit.

processes than those patented and could make locally developed medicines cheaper versions of the product.⁹⁴

4.2.1.2 The Long Protection Period

Pursuant to Article 33, the duration of patent protection will not cease until a period of at least 20 years from the date on which the patent application was filed has passed. This means that, under the TRIPs Agreement, Member States have to grant patents, for a minimum of 20 years, to any inventions of a pharmaceutical product or process that fulfils the established criteria of novelty, inventiveness and usefulness.⁹⁵

International conventions before TRIPs did not specify most of the minimum standards for patents. Indeed, when the Uruguay Round of WTO trade negotiations was launched in 1986, more than 50 countries were not granting patents on pharmaceuticals⁹⁶ and some 20 WTO Members still did not do so by the time of the conclusion of the TRIPs negotiations. A few of these countries did not provide process protection in this area as well. The duration of patents was less than 20 years in many countries.⁹⁷

This provision may result in an increase in the duration of the patent owner's monopoly in many Member States where there is no therapeutic competition. In the pharmaceutical field, the logical consequence of this provision is that drugs will be sold at high prices, as is the case for all monopoly products, for a longer period of time, and manufacturers of generic products will have to wait longer before they can produce the drug in question and sell it at a more accessible price. It is thus in regard to the length of protection that the Agreement will have one of its most important harmonizing effects. Unlike other provisions, which leave Member States a certain amount of room for manoeuvre, the Agreement is particularly strict and specific concerning the duration of patents.⁹⁸

4.2.2 The General Impact Of Trips Agreement

4.2.2.1 Impact on price

⁹⁴ "Pharmaceuticals in the Trade Related Aspects of Intellectual Property Rights (TRIPs) Agreement of the World Trade Organization (WTO) A Briefing on Trips". Op.cit.

⁹⁵ *ibid.*

⁹⁶ Medicines Sans Frontieres, "Drug patents under the spotlight." op.cit.

⁹⁷ Wto Agreements and public health. Op.cit.

⁹⁸ "Globalization and Access to Drugs Implication of the WTO/TRIPs Agreement."op.cit.

The possible effects of the changes in pharmaceutical patent protection in the health sector may be seen from different perspectives. The likely impact of the new rules on the prices of medicines has been addressed by a number of studies, undertaken before and after the adoption of the TRIPs Agreement. From those studies it is recognized that twenty years of monopoly on a pharmaceutical product will enable the patent holder to keep the price of the patented drugs high – because:

- Copies of the drugs under patent either produced locally or imported should be banned from the market.
- The generic equivalents would come onto the market only after the expiry of the patent of a patented drug. During this period of patent protection, there will be no cheaper alternatives.⁹⁹

For example as the India National Working Group on Patent Laws has pointed out in 1996 drug Zantac retailed in India for 18.53 rupees, in UK at the equivalent of 481.42 and in the USA at the equivalent of 1050.70 rupees. Under TRIPs India is obliged to introduce product patents for medicines. In Pakistan, where such protection already exists, Zantac now retails at the equivalent of 260.40 rupees (11.27 times its price in India).¹⁰⁰

More instance, in the pre-TRIPs period, Nogués (a World Bank economist) estimated consumer misallocation in developing countries and found that the introduction of pharmaceutical patents would entail significant welfare losses for consumers and income gains to patent owners.¹⁰¹ After the adoption of the TRIPs Agreement, Subramanian (an IMF economist) examined the likely impact of introducing pharmaceutical product patents in small and large countries, in cases where either a perfectly competitive market or a Nash-Cournot duopolistic market becomes a monopoly under patents.¹⁰² The same author later applied this model to the particular case of Asian countries (India, Indonesia, Pakistan, Philippines and Thailand). He investigated annual price, welfare and profit effects for these countries consequent upon the TRIPs Agreement.¹⁰³ Welfare and price effects were found to be negative for these countries, though given the transitional periods provided for by the Agreement and the extensive time required for the approval of new medicines, the effects would not be felt immediately. The same methodology, when applied to Argentina, also indicated a significant price increase (71%) and a fall in consumption (50%) when

⁹⁹ “Pharmaceuticals in the Trade Related Aspects of Intellectual Property Rights (TRIPs) Agreement of the World Trade Organization (WTO) A Briefing on Trips”. Op.cit.

¹⁰⁰ Drahos, Peter – op.cit., p. 27

¹⁰¹ General Policy Issues, WHO Drug Information Vol. 12, No. 4, 1998, p216.

¹⁰² “Globalization and Access to Drugs Implication of the WTO/TRIPs Agreement.” World health organization 1999. op.cit.p87

¹⁰³ *ibid.*

monopoly follows a competitive situation, and 16% and 25%, respectively, in the duopolistic-monopoly scenario.¹⁰⁴

Though the results of the various studies undertaken on possible price increases for medicines vary significantly, there is no doubt that patents lead to prices higher than those prevailing without protection. The generation of monopolistic rents is, in fact, the very purpose and essence of the patent system. Hence, while introducing or strengthening patent protection, in conformity with the TRIPs Agreement, its possible social effects, particularly on the low-income population, should be explicitly and carefully considered.¹⁰⁵

4.2.2.2 The TRIPs Agreement of Patent Protection and the Incentive for R&D for New Drugs

In the previous part, the general impact by patent on the incentive for R&D has been introduced, in this part, the attention will be concentrated on TRIPs Agreement in connecting with the R&D. Relating to this issue, two questions should be raised as the thread for discussion.

The First, to what extent does a world-wide requirement to protect pharmaceutical inventions at the level of TRIPs standards enhance the overall level of incentives for R&D into diseases in general and,

Secondly, to what extent will such a requirement affect incentives in the case of diseases, which predominantly afflict people in developing countries.

Just a day before the TRIPs Council meeting, the International Federation of Pharmaceutical Manufacturers Association (IFPMA) said at a press briefing in Geneva that if there is a rush to take the TRIPs apart, it would be the overall R&D efforts that would suffer. An argument often repeated by the industrialized country governments as well and seldom disputed even by developing country governments in the TRIPs Council meeting.¹⁰⁶

This is also supported by the Pharmaceutical Research and Manufacturers of America (PhRMA) in its paper on “The Importance of TRIPs Implementation” addressed to the

¹⁰⁴ Ibid.

¹⁰⁵ Ibid.

¹⁰⁶ Someshwar Singh—“Testing The Balance Of Rights In TRIPs”—South Bulletin 15, http://www.southcentre.org/info/southbulletin/bulletin15/southbulletin15-02.htm#P120_24308.

U.S. Trade Representative for Services, Investment & Intellectual Property. It argues that “minimum international standards for intellectual property protection are part of the rule of law fabric essential to attract the foreign direct investment and technology transfer needed for sustainable economic growth”¹⁰⁷

However, NGOs argue that the big pharmaceutical companies recoup their investments from their main markets in the industrialised nations and not from markets in developing countries!¹⁰⁸ The fact is that, any tendency to decentralize R&D activities will occur primarily among the industrialized countries themselves. Of course, there are also many examples of FDI in developing countries. However, in many of these cases the reason behind such, was not as altruistic as it may seem at first glance: R&D investment in such countries often aims at identifying and obtaining access to specific natural resources not available at home.¹⁰⁹

While there have been some studies of the effect of the introduction of pharmaceutical patent protection on the level of local R&D in the countries that have introduced it.¹¹⁰ The results vary from study to study and no general picture seems to emerge.¹¹¹ There does not appear to have been a study which has specifically addressed the obvious promotion in the R&D by TRIPs. However, one expert in this area has observed that extension of product patent protection as a result of TRIPs could result in a rise in demand of as much as 25 per cent of global spending on patented drugs, even without taking into account the case of China.¹¹² And, widespread concern has also been expressed that, left to itself, the patent system, even after TRIPs implementation, will not lead to sufficient incentives for R&D into the diseases prevalent amongst the poor in developing countries, such as malaria.

And the fact indicates that even new drugs are developed under the incentive by patent protection, they cannot fully function based on the costly price. As the 1990s - decade of HIV/Aids pandemic - proved, only a margin of sick people took advantage of newly

¹⁰⁷ <http://www.phrma.org/intnatl/news/2002-02-22.46.pdf>, p. 8

¹⁰⁸ Someshwar Singh – “Testing The Balance Of Rights In TRIPs” – op.cit.

¹⁰⁹ For more see: UN – Transnational Corporations and Management Division, Department of Economic and Social Development – Intellectual Property Rights and Foreign Direct Investment, NY 1993, p. 6

¹¹⁰ These studies include: Nogues, 1990 (Argentina); Kawaura and LaCroix, 1995 (Korea); Scherer and Weisburst, 1995 (Italy); LaCroix and Kawaura, 1996 (Japan); Lanjouw, 1997 (India); Maskus, 1997 (Lebanon); Korenko, 1999 (Italy); Lanjouw and Cockburn, 2000 (India).

¹¹¹ Lanjouw, J.O. The Introduction of Product Patents in India: "Heartless Exploitation of the Poor and Suffering"?, Growth Center Discussion Paper, Yale University, and NBER Working Paper no. 6366, 1997.

¹¹² Ibid.

developed medicines – others simply cannot afford them. One of the reasons for this is because of the TRIPs Agreement patent protection of new pharmaceuticals.

From the above we can see that the introduction and strengthening of patents for pharmaceutical products and process will certainly not lead to an increase in R&D investment by enterprises in developing countries, which have to contend with a lack of technical infrastructure, and financial and human resources. Likewise, the non-patentability of pharmaceutical products existing prior to the TRIPs Agreement gave developing countries the opportunity to progress and to acquire basic technology through reverse engineering before being able to invest in R&D.¹¹³

4.2.3 The Special Impact on Developing Countries

The same rules ought to generate different impact on different observers, and sometimes may be with a totally opposite effect. In seventeenth-century Europe, they were used by absolutist monarchs to reward royal favourites and create private monopolies at great cost to the public. There is no doubt that patents are highly profitable, and that they have an important bearing on the share prices of pharmaceutical corporations. But the arguments for extending patent protection and providing stricter enforcement through the WTO, particularly in developing countries, are at best weak, and at worst specious.¹¹⁴

Industrialized countries compel developing countries to obey the same rules as them. Patent laws in many developing countries are now set through a combination of World Trade Organization (WTO) directives, World Intellectual Property Organization (WIPO) advice, and U.S. bilateral trade pressure.¹¹⁵

But some differences are neglected. 75 percent of the world's population in developing countries consume only 14 percent of the world's drug supply. Fifteen percent of the population in industrialized countries consume 86 percent.¹¹⁶ Free trade policies and trade Agreements are not addressing the obvious market failure to develop and market affordable drugs for diseases most prevalent in poorer regions, such as TB, malaria and HIV/AIDS.¹¹⁷

¹¹³ “Globalization and Access to Drugs Implication of the WTO/TRIPs Agreement.” World health organization 1999.op.cit.p20

¹¹⁴ Oxfam paper "Patent Injustice: How World Trade Rules Threaten the Health of Poor People." op.cit.

¹¹⁵ Drahos, P. Bilateralism in Intellectual Property. Oxfam Briefing Paper: <http://www.oxfam.org.uk/policy/papers/bilateral/bilateral.rtf>

¹¹⁶ Global Ecology Handbook, Edited by Walter Corson, Beacon Press 1990

¹¹⁷ Health Action International (HAI) Speaker: Zafar Mirza, “Globalization and Access to Drugs Implication of the WTO/TRIPs Agreement.” World health organization 1999.op.cit.p.89.

Because the TRIPs Agreement requires developing countries to pass national legislation guaranteeing patent terms of two decades for pharmaceuticals. Under the new rules, governments will no longer be permitted to allow local companies to produce, market, and export low-cost copies of patented drugs. This has major implications at two levels.

First, in countries, which have developed strong generic-drugs industries (which specialize in copying), there may be reduced self-reliance in pharmaceuticals, coupled with higher prices. Secondly, poor countries which lack strong generic industries will be prevented from importing from these sources. The prices of new drugs for both common and rare conditions is expected to double soon after January 2005 (2).¹¹⁸

Let's look into the specific cases to further clarify this issue.

4.2.3.1 India

One of the strongest generic-drugs industries in the world is in India. Before 1970, the country was almost entirely dependent on imported drugs. Today, over 70 per cent of pharmaceuticals consumed in the country are locally produced. India has some 250 large pharmaceutical firms and 16,000 small producers.¹¹⁹

Local market prices are far lower than international prices for equivalent products. Moreover, India has one of the lowest inflation rates for drugs prices. Leading Indian companies such as Cipla and Ranbaxy are also important exporters. This transition has been achieved partly as a result of a 1970 patent law; under which local companies were allowed to copy patented drugs, provided that they found a new process.¹²⁰

At that time, under the Indian Patents Act, 1970, there is no Product Patent protection for pharmaceuticals. There is only Process Patent protection. The duration of process patent protection in India is seven years from the date of filing or five years from the date of sealing of the patent, whichever is shorter, for pharmaceuticals, food products and agrochemicals as against fourteen years for all other items. This gave a boost to the Indian pharmaceutical industry. Therefore, India was very actively involved in opposing the TRIPs component of the GATT Agreement, especially the proposal for product patents on pharmaceutical innovations.

¹¹⁸ Drahos, P. Bilateralism in Intellectual Property. Oxfam Briefing Paper: <http://www.oxfam.org.uk/policy/papers/bilateral/bilateral.rtf>

¹¹⁹ Oxfam paper "Patent Injustice: How World Trade Rules Threaten the Health of Poor People.". op.cit.

¹²⁰ *ibid.*

However, now that India has signed the treaty, though most unwillingly, WTO rules commit India to full implementation of the new IP regime by 2005, and its patent law has already been reformed to give interim exclusive marketing rights for patents.

4.2.3.2

Egypt

Egypt has also progressed rapidly towards self-reliance in pharmaceuticals.

Today, over 90 per cent of drugs consumed are locally produced. Exports have also grown rapidly. As in India, local drug prices are far cheaper than those for imported equivalents, partly as a result of strict price controls.¹²¹

Local prices are on average one-fifth of those for imported Equivalents. Like India, Egypt achieved these outcomes under a flexible IP law, according to which patents expired after ten years - half of the period envisaged under the WTO regime. That law is now being reformed to ensure its compliance with WTO rules.

4.2.3.3 Others

Other countries such as Brazil, Argentina, and Thailand have also developed strong local drugs industries under patent regimes which have placed a premium on improving access to essential drugs, rather than on the protection of monopoly rights.

In each case, major legislative reforms have now been undertaken to bring domestic legislation into line with WTO rules, often under extreme duress. The US in particular has consistently used the threat of trade sanctions to ensure compliance with the TRIPs regime.

In January 2001, the US government asked for a WTO dispute settlement panel to rule on aspects of Brazil's new patent legislation. (This case will be further developed later) This is the first time a formal complaint has been made about a developing country's alleged non-compliance with TRIPs, and is a clear Declaration by Washington that the gloves are coming off at the WTO.¹²²

¹²¹ Ibid.

¹²² Oxfam paper "Patent Injustice: How World Trade Rules Threaten the Health of Poor People.". op.cit

The strengthening of IP rights through the WTO has raised far wider development issues. The problem is that IP provisions have moved beyond their proper function of providing reasonable rewards to inventors, to create long-term, tighter monopolies in developing countries.¹²³

The Government of Kenya has publicly criticized pharmaceutical companies for donating drugs with one hand, and then preventing the country from producing lower-cost variants with the other. In Zambia, the cost of donated AZT, financed by UN agencies and donors, is higher than the cost of generic products available from India and Thailand. This suggests that the benefits of publicly financed spending, including the numbers of patients treated, are being restricted.¹²⁴ In other words, the public-health gains associated with public-private partnerships are being eroded by what amounts to corporate misuse of monopoly power.¹²⁵

In reality, many of the new anti-bacterial drugs now being developed could bring enormous benefits to poorer countries, provided that they are delivered on affordable terms. This is especially true with respect to the treatment of drug-resistant strains. Drug-resistance poses an enormous threat to poor communities across the developing world.¹²⁶ It means that illness is less susceptible to treatment, and that the costs of treatment increase - in some cases dramatically. The danger is that, in the absence of competition from generic-drugs producers, new patented drugs will be placed far beyond the means of the poor. Examples of drug resistance abound in cases of Pneumonia (3.5 million deaths annually), Diarrhoea (2.2 million deaths annually), Malaria (1.1 million deaths annually), and Gonorrhoea (62 million new cases annually).¹²⁷

A 'Political Report' by Max van den Berg, Vice-President for Foreign Affairs and International Trade, PES Group, comprising Socialist members of the European Parliament, has found that TRIPs has imposed substantial costs on developing countries with little evidence of benefits.¹²⁸ The following report, released on 23 September 2002, proposes a number of conclusions, based on written and oral evidence presented to a PES

¹²³ *ibid.*

¹²⁴ *Ibid.*

¹²⁵ *Ibid.*

¹²⁶ Oxfam paper "Patent Injustice: How World Trade Rules Threaten the Health of Poor People." *op.cit*

¹²⁷ *ibid.*

¹²⁸ "European Union Urged To Reform TRIPs" by Max van den Berg, Vice-President for Foreign Affairs and International Trade, PES Group, South Bulletin 43 http://www.southcentre.org/info/southbulletin/bulletin43/bulletin43-02.htm#P71_23813

Group Seminar "Intellectual Property: A New North-South Divide?" held on 6th June 2002.¹²⁹

The 6th June seminar heard evidence from several participants of the heavy costs which the TRIPs Agreement will impose on developing countries, as its provisions take effect:

Creating the administrative and legal structures necessary to implement TRIPs will cost developing countries on average around \$100 million.

International patents - more than 90 per cent of which are Northern owned - generate billions of dollars each year in net income flows from South to North.

Subsistence agriculture, dependent on the traditional saving, use and exchange of seeds, is threatened by the patenting by Northern corporations of plant and seed varieties; seed patents could also promote the spread of environmentally damaging monocultures.

In the health sector, TRIPs restricts access to technology, raising drug prices and distorting markets.

Participants also questioned whether developing countries benefited from the incentive effect which was the rationale for TRIPs. Evidence presented to the seminar suggested:

TRIPs had not led to the hoped-for investment and technology transfer to developing countries. The R&D spending of pharmaceutical companies has largely neglected the diseases most prevalent in developing countries.¹³⁰ IP protection cannot stimulate development of drugs for which there is no economic market because of lack of purchasing power in the South. At least up to now, undoubtedly, developing countries haven't gained much beneficial as the developed countries have.¹³¹ In stead if they try to change the present situation with compliance to TRIPs Agreement, they may pay a huge cost not only money but also life. Anyway, since the strict provision has been accepted by developing countries, they may not have time to regret or want to deny it. Thanks to the efforts made by some developing countries and NGOs, there is something left in the TRIPs Agreement, which can be taken advantage of the poor countries. This is the most valuable part for developing counties and also the most controversial part in this Agreement.

¹²⁹ *ibid.*

¹³⁰ *Ibid.*

¹³¹ *Ibid.*

4.3 TRIPs Flexibility

From the health sector's perspective, intellectual property standards, including those specified in TRIPs, should take protection of public health into account. However, current standards historically derived from those of developed countries are not necessarily appropriate for countries struggling to meet health and development needs. Developing countries can therefore use the flexibility of TRIPs provisions and its safeguards to protect public health. This means as soon as the Agreement comes into force in a Member State, unauthorized copies of patented drugs can only be produced and commercialized with the authorization of the patent holders. However, among other measures, a system of compulsory licensing and parallel imports may be applied in order to protect public health through access to affordable essential drugs.

4.3.1 Compulsory licensing

Compulsory licensing means that the law allows the granting of a license without permission from the patent holder. In practical terms, this means that a Member State may allow the national authority to grant a third party the permission to manufacture or commercialize a drug, which is still under patent. The patent-holder, however, retains intellectual property rights and "shall be paid adequate remuneration" according to the circumstances of the case (Article 31).

In the pharmaceutical sector compulsory licenses have been used to stimulate price-lowering competition and to ensure availability of needed medicines.¹³² Most developed countries and many developing countries now provide for compulsory licensing through national legislation. A comprehensive patent regime should include adequate provision for the granting of compulsory licenses. Grounds for compulsory licensing may include public interest, problems linked with national emergencies such as epidemics, public non-commercial use, or anti-competitive practices (Article 31). Whether or not compulsory licenses are issued, national legislation, which provides for compulsory licensing allows governments to provide the medicine in the case of abuse of rights by the patent-holder, or commercial non-availability. Any such use should be authorized predominantly for the supply of the domestic market of the Member authorizing such use (Article 31f).¹³³

The above kinds of use without authorization of the right holder are expressly envisaged by the Agreement. However, Member States are not limited in regard to the grounds on which they may decide to grant a licence without the authorization of the patent holder. They are

¹³² "A New Era in Global Trade", WHO Policy Perspective on Medicines.op.cit.

¹³³ *ibid.*

in practice only limited in regard to the procedure and conditions to be followed.¹³⁴ French law, for example, explicitly allows for compulsory licences 'if required in the interests of public health', notably when drugs are made available to the public in insufficient quantity or quality or at abnormally high prices'.¹³⁵

Achievement of the objective of accessibility requires adequate exploitation of such possibilities for use without the permission of the patent holder in order to guarantee satisfactory conditions of supply. Compulsory licences are the easiest and most effective way to increase the supply of products, by acting directly on marketing conditions or by deterring patent holders from taking measures that would arbitrarily reduce supply or artificially or excessively increase prices.¹³⁶ In this sense, the operation of this license enable the competent government to take consideration of the public health needs when necessary.

While compulsory licenses are not geared towards establishing technology partnerships between patent holders and users, they can be useful in providing a local producer the means of supplying needed drugs at cut rates. Further, the provision for the award of compulsory licensees in local legislation can be an effective negotiating tool. Hesitant patent holders might be encouraged to enter voluntary license Agreements or produce needed drugs locally in order to avoid the possibility of an award of a compulsory license.¹³⁷

4.3.2 Parallel Importation

In relation to the issue of parallel import of pharmaceuticals, Article 6 of the TRIPs Agreement provides that for the purpose of dispute settlement under this Agreement nothing in this Agreement shall be used to address the issue of exhaustion of intellectual property rights. Nevertheless, the rights conferred by a patent (Article 28 of the TRIPs Agreement) may not be contravened; these rights include the right to prevent importation of patented products. This means under trips Agreement parallel importation is allowed.

¹³⁴ Globalization and access to drugs implication of the wto/TRIPs Agreement. World health organization 1999.op.cit.P35

¹³⁵ Oxfam paper "Patent Injustice: How World Trade Rules Threaten the Health of Poor People.". op.cit

¹³⁶ Globalization and access to drugs implication of the wto/TRIPs Agreement. World health organization 1999.op.cit.P36

¹³⁷ For a more detailed discussion on compulsory licensing provisions in the TRIPs Agreement, see World Trade Organization, "Environment and TRIPs", Committee on Trade and Environment, 8 June 1995 (WT/CTE/W/8).

The same effect is reflected in Article 28 on the title-holder's exclusive rights where the footnote to this Article confirms the same kind of flexibility.¹³⁸

Parallel importation is importation, without the consent of the patent-holder, of a product legally marketed in another country by the patent-holder or by another authorized party.

The aim of parallel importing is to promote and assure price competition for patented products by allowing importation of equivalent patented products marketed at a lower price in another country by or with the consent of the patent-holder.¹³⁹ In TRIPs terminology, the patent-holder's rights to control the international movement of a pharmaceutical have been "exhausted" when the product has been placed on a market by, or with the consent of the patent-holder.¹⁴⁰ The TRIPs Agreement does not prohibit Members from applying the principle of international exhaustion - that is, allowing parallel importation of patented pharmaceuticals once they have been placed on the market in any country. Article 6 explicitly states that disputes relating to exhaustion are not subject to the WTO dispute settlement process.¹⁴¹ The TRIPs Agreement leaves Member States free to decide whether or not to apply parallel imports. If applied, the relevant legislation will have to provide for this possibility.

Parallel importing can be used to circumvent differential pricing by companies, and is widely used. In the UK, parallel imports from within the European Union account for about 12 per cent of all prescriptions, reflecting the high prices charged by drugs companies in Britain compared with other European countries. Parallel imports account for almost one-fifth of sales of Glaxo Wellcome (GW) products in the UK.¹⁴²

4.3.3 Bolar Provision

The United States, Canada and some EU countries provide "early working" exceptions for patent rights, permitting the testing of medicines prior to the expiration of patents in order to obtain regulatory approval to market a product. The US early working exception is sometimes referred to as a "Bolar" provision -- a reference to a US Supreme Court decision that prohibited this practice and was later overturned by legislation, as part of the US

¹³⁸ See the footnote of Article 28: 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 provisions of Article 6.

¹³⁹ "A New Era in Global Trade", WHO Policy Perspective on Medicines.op.cit.

¹⁴⁰ *ibid.*

¹⁴¹ *Ibid.*

¹⁴² Max van den Berg, Vice-President for Foreign Affairs and International Trade.op.cit.

Hatch/Waxman Act.¹⁴³ Some EU governments have early working exceptions as part of more general exceptions for experimental use. Trips article 30 also provides exceptions to patent rights, which says: 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.

This provision also provides for early submission of application for registration of patented drugs by generic manufacturers. Bolar provision allows interested (generic) manufacturers to start producing test-batches of a product before patent expires, in order to collect necessary data for submission to regulatory authorities.¹⁴⁴ Manufacturers of generic drugs can submit an application for the registration of a drug, which is still under patent. When the patent expires, the manufacturer may immediately start marketing the product if already approved for registration. This will reduce the delay for generic products to enter the market after the patent has expired, and thereby enhance competition.¹⁴⁵

The purpose of this exception is to help generic drug producers to place their products on the market as soon as the respective patent expires. The US Drug Price Competition and Patent Term Restoration Act (1984), for instance, has permitted testing to obtain approval of generic products before the expiration of the relevant patent. Similar provisions were established in other countries, such as Canada, Israel and Argentina.¹⁴⁶ and in relating to this provision, there is also a dispute between EU and Canada, which will be discussed later.

Moreover, TRIPs provides transitional periods during which countries are required to bring their national legislation and practices into conformity with its provisions. The latest dates for WTO Members were/are: 1996 for developed countries; 2000 for developing countries (as a general rule); 2005 for developing countries who had not introduced patents before joining the WTO; and 2006 for least-developed countries.¹⁴⁷ TRIPs specifically recognizes the economic, financial, administrative and technological constraints of the least-developed

¹⁴³ James Love, “[Ip-health] Draft statement on early working of pharmaceutical patents” Tue, 18 Jan 2000 02:00:10 -0500 (EST) <http://lists.essential.org/pipermail/ip-health/2000q1/000049.html>

¹⁴⁴ Pharmaceuticals In The Trade Related Aspects Of Intellectual Property Rights (TRIPs) Agreement Of The World Trade Organization (WTO).op.cit.

¹⁴⁵ *ibid.*

¹⁴⁶ Carlos M. CORREA*, “Implementing National Public Health Policies in the Framework of WTO Agreements ” *Journal of World Trade* 34(5): 89–121, 2000. _ 2000 Kluwer Law International. Printed in The Netherlands.

¹⁴⁷ See Article 65 in TRIPs Agreement.

countries. It therefore provides the possibility for further extension of the transitional period.

4.4 The Limitation of TRIPs' Flexibility

The flexibility parts of TRIPs Agreement certainly provide a chance for the member states to deal with the conflict between pharmaceutical patent protection and the public health. Especially for developing countries, these flexibility really desire positive affirmation, however, in some cases, these provisions may have limitations.

4.4.1 Limitation on Compulsory Licensing

Relating to this flexibility, the TRIPs Agreement imposes specific conditions on Member States to admit compulsory licenses:

- authorization of such use will be considered on its individual merits;
- authorization will be granted in some cases only if the proposed user has made efforts to obtain the license on reasonable commercial terms;
- the scope and duration of the authorization must be limited;
- authorization is non-exclusive;
- the predominant objective of the authorization must be to supply the domestic market;
- the authorization may be suspended if the circumstances that led to it cease to exist, while protecting the interests of the authorized party; and
- the patent holder will be given adequate remuneration, taking into account the economic value of the authorization.¹⁴⁸

These are the minimum conditions stipulated by the Agreement, and Member States must fulfill them when they grant compulsory licenses. The conditions must, therefore, be included in the new national patent legislation.¹⁴⁹

Besides those expressly mentioned minimum standards, the main limitation of a compulsory license, in practice, is that a country needs to have a reasonably sophisticated pharmaceutical industry in order to produce the medicine concerned, and must be able to achieve economies of scale to bring the price down to affordable levels.¹⁵⁰ The great majority of developing countries fail on both counts. The solution might be to import from a generic manufacturer in a larger country but this is unlikely to be economically viable

¹⁴⁸ See Article 31 in TRIPs Agreement.

¹⁴⁹ Pharmaceuticals In The Trade Related Aspects Of Intellectual Property Rights (TRIPs) Agreement Of The World Trade Organization (WTO).op.cit.

¹⁵⁰ Oxfam paper "Patent Injustice: How World Trade Rules Threaten the Health of Poor People.". op.cit

unless a compulsory license has also been issued in the exporting country. Even if it has, TRIPs allows compulsory licensing only if it is 'predominantly' for domestic needs, so the exporting country may find itself accused of breaking the rules.¹⁵¹ This defect is fatal which makes that the countries lacking manufacture capacity find it difficult to use the compulsory licensing for public health needs.

In addition, in theory the TRIPs Agreement provides scope for combating monopoly pricing through national legislation, in practice this is likely to be easier in countries such as the USA, which has strong anti-trust laws and administrative capacity, than in developing countries.¹⁵² In each of these areas there is considerable potential for legal challenges from pharmaceutical companies, which are likely to prove most effective in countries, which lack the capacity to meet them. The use or threat of trade sanctions in support of corporate claims will further weaken the position of developing-country governments.¹⁵³

4.4.2 Limitation on Parallel Importation

Where a patented product is marketed at a lower cost in another country, governments can allow 'parallel imports' from that country in order to take advantage of the price differential - but only if this option is built into their national legislation. The pharmaceutical TNCs are lobbying hard for developing countries to prohibit parallel importing. For instance, in 1998 and 1999 the United States considered threatening South Africa with trade sanctions if it invoked this provision of TRIPs in the case of AIDS drugs (a position urged by domestic pharmaceutical manufacturing interests.)¹⁵⁴ In addition, dispute between the two countries also involved with this problem. (This case will be discussed later) Paradoxically for a WTO Agreement, TRIPs allows this prohibition, which is a barrier to international trade, thereby revealing a clear bias towards TNCs interests.

And from a public-health perspective there are serious limitations with parallel importing as a safeguard mechanism. One is the absence of information on market prices for pharmaceutical products.¹⁵⁵ Another is that pharmaceutical companies may seek to establish uniform global prices at the highest possible level. Unless governments retain the

¹⁵¹ *ibid.*

¹⁵² *Ibid.*

¹⁵³ *Ibid.*

¹⁵⁴ Bond, Patrick. 1999. Globalization, Pharmaceutical Pricing, and South African Health Policy: Managing Confrontation with U.S. Firms and Politicians. *International Journal of Health*

¹⁵⁵. Oxfam paper "Patent Injustice: How World Trade Rules Threaten the Health of Poor People.". *op.cit*

right to import generic-equivalent products, the protection against monopoly pricing is likely to prove weak.¹⁵⁶

4.4.3 Limitation on Bolar Exception

In order to ensure that low-cost generic supplies can come on-stream immediately after patent expiry, TRIPs allows governments to include in national legislation the right of generic companies to develop, test, and register (though not stockpile) products prior to patent expiry. Nevertheless, developing countries have been under pressure from the USA not to allow early working in their patent laws.¹⁵⁷ The US government and TNCs are also demanding protection for company data submitted to regulatory authorities on the testing and effectiveness of new drugs - a measure which will lead to further restriction of legitimate generic competition. The pharmaceutical TNCs claim that the data protection they seek is mandated by TRIPs, though this interpretation is contested by generic manufacturers.¹⁵⁸

4.4.4 Limitation on Price Control

Governments retain the right to establish price controls, provided that they do not discriminate between foreign and local suppliers. However, price-control legislation is being fiercely resisted by drugs companies in both the developed and the developing world.¹⁵⁹ Regrettably, TRIPs weakens the bargaining position of developing-country governments when dealing with companies, by making compulsory licensing a difficult last resort. Without the threat of compulsory licensing, a company is less likely to agree lower prices.¹⁶⁰

4.4.5 Limitation on the Transitional Period – Mailbox Provision

According to Article 65, some developing countries are delaying patent protection for pharmaceutical products (and agricultural chemicals) until 1 January 2005.

This is allowed under provisions that say a developing country that did not provide product patent protection in a particular area of technology when the TRIPS Agreement came into force (on 1 January 95), has up to 10 years to introduce the protection.¹⁶¹

¹⁵⁶ *ibid.*

¹⁵⁷ *Ibid.*

¹⁵⁸ *Ibid.*

¹⁵⁹ *Ibid.*

¹⁶⁰ *Ibid.*

¹⁶¹ See Article 65: 4. To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in

However, for pharmaceuticals and agricultural chemicals, countries eligible to use this provision (i.e. countries that did not provide protection on 1 January 1995) have two obligations.

They must allow inventors to file patent applications from 1 January 1995, even though the decision on whether or not to grant any patent itself need not be taken until the end of this period — Article 70.8. This is sometimes called the “mailbox” provision (a metaphorical “mailbox” is created to receive and store the applications). The date of filing is significant, which is why the mailbox provisions were set up. It is used for assessing whether the application meets the criteria for patenting, including novelty (“newness”).

And if the government allows the relevant pharmaceutical or agricultural chemical product to be marketed during the transition period, it must — subject to certain conditions — provide the patent applicant an exclusive marketing right for the product for five years, or until a decision on a product patent is taken, whichever is shorter.¹⁶²

4.5 TRIPs Principle Relating to the Right to Public Health

Besides the flexibility provisions in TRIPs Agreement, which may be used to resist the negative position of TRIPs, there are other provisions which should be considered as the general guidance for dealing with the patent protection and the public health.

In the Vienna Declaration of 1993, States recognized that “human rights are the first responsibility of Governments”.¹⁶³ Out of the 141 members of WTO that have undertaken to implement the minimum standards of IP protection in the TRIPs Agreement, 111 have ratified ICESCR.¹⁶⁴

its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years.

¹⁶² See Article 70 (9): Where a product is the subject of a patent application in a Member in accordance with paragraph 8(a), exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member.

¹⁶³ Vienna Declaration and Programme of Action adopted by consensus by the World Conference on Human Rights on 25 June 1993, UN Doc. A/CONF.157/23, 12 July 1993, article 1.

¹⁶⁴ “The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights”, op.cit.

As mentioned in previous parts, the right to health and the access to medicine is a universal human rights, more than that, to implement and realize it has become the obligation of all member states. Therefore, the general comments provides that: States parties should ensure that the right to health is given due attention in international Agreements and States parties should take steps to ensure that these instruments do not adversely impact upon the right to health.¹⁶⁵ Similarly, States parties have an obligation to ensure that their actions as members of international organizations take due account of the right to health.¹⁶⁶

Although it is clarified that the tensions really exists in the TRIPs Agreement between rights of individuals to intellectual property protection and the public interest. Leave aside these restrictions; there are some provisions, which take the human rights, especially the right to health into consideration.

4.5.1 The Preamble in the Agreement

The general part in the TRIPs Agreement (preamble and general provisions) stresses the need to promote adequate and effective protection of intellectual property rights, but to do so as part of a series of broader economic objectives. The protection of intellectual property rights is not an absolute and exclusive obligation.¹⁶⁷ Several general provisions were included in the Agreement to provide a balance between the rights of patent holders and their obligations vis – vis to the society.

The preamble to the Agreement states that:

"Recognizing the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives..."

This means that the protection of intellectual property rights is not an end in itself but has a functional role to play in relation to the priority objectives of public policy for which these rights were created. It should be harnessed to the service of development.¹⁶⁸

4.5.2 Article 1

At this point, Article 1 - Nature and Scope of Obligations - is of critical importance, for it establishes that Member States are not obliged to grant greater protection than that set out

¹⁶⁵ General Comment No. 14 (2000), para. 39.

¹⁶⁶ Ibid.

¹⁶⁷ Globalization and access to drugs implication of the wto/TRIPs Agreement. World health organization 1999.op.cit

¹⁶⁸ ibid.

in the Agreement. It also recognizes that Member States are entirely free within the framework of their own legal systems and practices as to how they implement the obligations to which they have subscribed. The Article states that:

"Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice."

Member States may, therefore, base the provisions of their national regulations on these principles. They can also bring their regulations into line with the obligations of the Agreement in such a way that their national objectives for the protection of intellectual property also accord with those established for other sectors of State activity which the latter deems to be necessary, provided such regulations do not contravene the Agreement.¹⁶⁹

And the overall objective and principle of TRIPs Agreement are embodied in the TRIPs crucial articles: article 7 and article 8. Therefore each provision of the TRIPs Agreement should be read in light of the objectives and principles set forth in Articles 7 and 8. Such an interpretation finds support in the Vienna Convention on the Law of Treaties (concluded in Vienna in 23, May 1969), which establishes, in Article 31, that "a treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose".¹⁷⁰ In particular, the provisions in Article 7 and Article 8 of the Agreement may be considered by Member States as a framework to define limitations to exclusive rights, as well as the enactment of legislative provisions concerning compulsory licensing, for instance, in order to keep prices at a reasonable level or to ensure access to particular medicines by the population.¹⁷¹

¹⁶⁹ Pharmaceuticals In The Trade Related Aspects Of Intellectual Property Rights (TRIPs) Agreement Of The World Trade Organization (WTO).op.cit.

¹⁷⁰ "Developing country group's paper", submitted by a group of developing countries to the TRIPs Council, for the special discussion on intellectual property and access to medicines, 20 June 2001 IP/C/W/296

¹⁷¹ Pharmaceuticals In The Trade Related Aspects Of Intellectual Property Rights (TRIPs) Agreement Of The World Trade Organization (WTO).op.cit.

4.5.3 Article 7

Article 7, clearly indicates the subordination of the protection of intellectual property rights to public policy objectives in other areas of the State's activity, especially social and economic welfare, which depends in part on national health and social policies. This Article also stresses that the interests of all sectors involved must be taken into account. It states:

“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 producers and users of technological knowledge and in manner conducive to social and economic welfare, and to a balance of rights and obligation”.

Article 7 is a key provision that defines the objectives of the TRIPs Agreement. It clearly establishes that the protection and enforcement of intellectual property rights do not exist in a vacuum.¹⁷² They are supposed to benefit society as a whole and do not aim at the mere protection of private rights. Some of the elements in Article 7 are particularly relevant, in order to ensure that the provisions of TRIPs do not conflict with health policies: the promotion of technological innovation and the transfer and dissemination of technology; the mutual advantage of producers and users of technological knowledge; social and economic welfare; and the balance of rights and obligations.

Article 7 states that the protection and enforcement of intellectual property rights “should” contribute to the aforementioned objectives. Such language stems from a recognition by Members that the mere existence and the exercise of IPRs, such as patents, do not necessarily result in the fulfillment of the objectives of the Agreement. In the context of health policies, for instance, patent rights should be exercised coherently with the objectives of mutual advantage of patent holders and the users of patented medicines, in a manner conducive to social and economic welfare and to a balance of rights and obligations.¹⁷³ When confronted with specific situations where the patent rights over medicines are not exercised in a way that meets the objectives of Article 7, Members may take measures to ensure that they will be achieved - such as the granting of compulsory licenses.

The objective of the promotion of technological innovation and the transfer and dissemination of technology places the protection and enforcement of IPRs in the context

¹⁷² Ibid.

¹⁷³ Ibid.

of the interests of society. Such an objective is essential for the promotion of health policies, as it encourages the development of domestic production of pharmaceutical products. Whenever economically feasible, local production of pharmaceutical products is extremely important to ensure that medications are more readily available in the market, and at more affordable prices. Local manufacturing of pharmaceutical products also encourages sustainable access to medications by insulating the price of patented medicines against currency devaluations, as well as supporting the development of local expertise, which is vital in addressing local needs.¹⁷⁴ As mentioned above, these objectives can be obtained by the normal exercise of patent rights. Where the patent holder fails to meet the objectives of the TRIPs Agreement and of public health policies, however, Members may take measures to ensure transfer and dissemination of technology to provide better access to pharmaceuticals.

Also regarding patent protection of pharmaceutical products, the concept of “balance of rights and obligations” and of “mutual advantage of producers and users of technological knowledge” are relevant to ensure that the exercise of the exclusive rights provided by patent rights is subject to limitations, which are expressed in different provisions of TRIPs, such as those relating to compulsory licenses and parallel imports.

4.5.4 Article 8

Article 8, in paragraph (1) allows national regulations to be adapted to the fundamental objectives of public policy set by governments in certain domains, provided these regulations are not contrary to the provisions of the Agreement. Public health and nutrition receive a special mention among these objectives, which amounts to express recognition of measures that might be adopted to guarantee accessibility. By virtue of this Article:

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

However, this principle is then qualified with the remarkable requirement that measures be ‘consistent with’ the Agreement. Oxfam believes that TRIPs should be amended to include a clear statement that ‘nothing in the Agreement shall prevent the adoption of measures to protect public health’.¹⁷⁵

¹⁷⁴ Ibid.

¹⁷⁵ Oxfam paper "Patent Injustice: How World Trade Rules Threaten the Health of Poor People.". op.cit

Paragraph (2) of this fundamental Article should also be mentioned, in so far as it once again expresses the need for a well-balanced interpretation of measures to protect intellectual property rights. These should be protected in such a way that they do not give rise to abuses detrimental to the necessary balance between national objectives and sectoral interests for which the State is the guarantor. Thus, in accordance with Article 8.2:

“Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by rights holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology”. “Appropriate measures” could be, for instance, compulsory licensing and parallel imports.

The reading of those provisions should confirm that nothing in the TRIPs Agreement would prevent Members from adopting measures to protect public health, as well as from pursuing the overarching policies defined in article 8.¹⁷⁶ With regards to these articles, members should therefore implement the minimum standards of the TRIPs Agreement bearing in mind both their human rights obligations as well as the flexibility inherent in the TRIPs Agreement, and recognizing that “human rights are the first responsibility of Governments”.¹⁷⁷

4.6 Cases under TRIPs Agreement relating to access to medicine

In spite of the entry into force of the TRIPs Agreement, the state of protection of pharmaceutical products is still not uniform throughout the world. Some countries had already amended their legislation, even before signing the Agreement. Some were compelled to do so by the risk of economic reprisals from their main trading partners, while still others acted in expectation of possible access to better and wider markets. The majority of the small, less developed countries, however, are making use of the transitional periods that the Agreement has allowed them, and have not amended their legislation.¹⁷⁸

Due to the complicated situation and the vague language in the provisions, it is difficult for some countries to make use of the flexibility for the reason that what they act may be

¹⁷⁶ “Developing country group’s paper”, op.cit.

¹⁷⁷ Economic, Social And Cultural Rights, The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights Report of the High Commissioner E/CN.4/Sub.2/2001/13 27 June 2001

¹⁷⁸ Silvia Salazar, op.cit.

regards as non-compatible with their obligation under TRIPs Agreement by other countries. The following cases are crucial in relating to patent protection of pharmaceuticals and the public health. Two of them relevant to the use of the flexibility in the TRIPs Agreement that have arisen in the WTO are often referred to. The last is concerned with the critical issue- the battle between the right to medicine in South Africa and pharmaceutical TNCs. From these cases we may see the attitude from the different sides in relating to the implementation of TRIPs Agreement.

4.6.1 “Canada — Patent Protection for Pharmaceutical Products” Case

This dispute was between Canada and the European Communities in which the WTO panel endorsed the compatibility of the "regulatory" or so-called "Bolar" exception with the TRIPs Agreement, but found against the stock-piling provision in the Canadian law.¹⁷⁹

In late 1997, the European Community contended that Canada's laws did not provide adequate protection of patented pharmaceutical inventions by allowing domestic generic pharmaceutical makers to conduct tests and carry out other preparations for producing a drug before a patent expired, without the patent holders approval, and to stockpile generic drugs six months before a drug's patent expires - alleged violations of TRIPs Article 27.1, 28.1 and 33.

Canada countered that its laws were valid exceptions under Article 30, which allows "limited exceptions to the exclusive rights conferred by a patent."

In March 2000, the dispute panel validated the Canadian law allowing generic drug makers to test patented drugs or undertake other actions necessary for the purposes of seeking marketing approval for their generic versions or file for licenses prior to the patent's expiration. But it found that stockpiling of generic products was not permitted under TRIPs Article 28. According to the Panel ruling, the key issue was whether stockpiling with no restrictions on amount could constitute a "limited" exception to patent owner's rights. "With no limitations at all upon the quantity of production, the stockpiling exception removes that protection entirely during the last six months of the patent term, without regard to what other, subsequent, consequences it might have. By this effect alone, the stockpiling exception can be said to abrogate such rights entirely during the time it is in effect."¹⁸⁰ Thus, manufacturers must wait until patent expiry before starting commercial production. According to an article at the time, "Generic drug manufacturers note that the ruling would

¹⁷⁹ WT/DS114/1

¹⁸⁰ WT/DS114/R, para. 7.33.

result in only modest production delays for generic drugs, but goes a long way to protect consumer interests by cutting time-to-market for generic drugs by as much as two to three years"¹⁸¹

The panel's decision in the EU-Canada case on the early working exception—which, as mentioned, upheld the legality of such exception. It stated that such legislation is compatible with obligations under the TRIPs Agreement. This decision illustrates, that there is some room under the Agreement to adopt measures aimed at the protection of public health.¹⁸²

4.6.2 Case between United States and Brazil concerning “local working”

4.6.2.1 The Background of the Case

According to the Brazilian Ministry of Health, there are currently 536,000 people with HIV in Brazil; there have been 196,000 notified cases of AIDS and 95,000 deaths; 85,000 people are currently receiving approved combination therapies for HIV under the Brazilian Free Distribution of AIDS Drugs for All program.¹⁸³ Hailed around the world as having one of the most successful AIDS-control programs - treating patients for free - Brazil's fight to sustain its success has not been easy. The bulwark of this fight has been the country's ability to produce drugs locally and negotiations to reduce prices of imported drugs. On both these fronts, Brazil is under pressure. The United States therefore, challenged the Brazilian Intellectual Property Law which calls for 'local working' of patents.¹⁸⁴

4.6.2.2 The Merits of the Case

This case was a complaint brought under the WTO dispute settlement system in May 2000 by the United States against a provision of the Brazilian industrial property law of 1996. The provision in question had not been used and therefore the dispute was about the consistency of the Brazilian legal framework for the grant of compulsory licenses with the provisions of the TRIPs Agreement. In its request for establishment of a panel, the United

¹⁸¹ "DSB Rules On Generic Drugs", Bridges, 8 February 2000, International Centre for Trade and Sustainable Development, Geneva.

¹⁸² Carlos M. CORREA Implementing National Public Health Policies in the Framework of WTO Agreements, *Journal of World Trade* 34(5): 89–121, 2000. _ 2000 Kluwer Law International.

¹⁸³ "Brazil To Abrogate Patent To Cut Cost Of Aids Fight" £-by Mary Robinson, the UN High Commissioner for Human Rights South Bulletin 19 http://www.southcentre.org/info/southbulletin/bulletin19/bulletin19-03.htm#P136_38970

¹⁸⁴ *ibid.*

States alleged that Article 68 of Brazil's 1996 industrial property law, imposes a "local working" requirement (i.e. the product has to be produced locally) as a condition for granting a patent in Brazil. If this condition is not met within three years, the Law allows the government to grant a compulsory license (i.e. without the consent of the patent holder). The United States challenged the provision whereby it claimed that a compulsory license shall be granted on a patent if the patented product is not manufactured in Brazil or if the patented process is not used in Brazil. In addition, according to the United States, if a patent owner chooses to exploit the patent through importation rather than "local working," then Article 68 would allow others to import either the patented product or the product obtained from the patented process. The United States argued that Article 68 of Brazil's 1996 industrial property law discriminates against US owners of Brazilian patents whose products are imported into, but not locally produced in, Brazil. Article 68 was also said to curtail the exclusive rights conferred on these owners by their patents. For the United States such legislation was part of an industrial policy.

Brazil contested the industrial policy nature of its challenged provision. It argued on the contrary that its legislation was compatible with TRIPs and referred to the US requirements as being contrary to and above the TRIPs standards. For Brazil, its legislation was not discriminatory and in fact it contained provisions parallel to those of Sections 204 and 209 of the US Patent Code, in particular with regard to the local working requirements. According to Brazil, under Section 204 "Preference for the United States Industry", the US Patent Code required that small business firms and universities that receive federal funding "manufacture substantially" their inventions in the United States. For Brazil, Section 209 of the same Code also established a local working requirement for federally owned patents. Brazil indeed requested consultations regarding the TRIPs compatibility of the said US legislation.¹⁸⁵

Since the dispute was settled before parties exchanged any formal written submission,¹⁸⁶ it is difficult to know with accuracy all the arguments that were put forward during the bilateral consultations or that could have been raised by the parties. In June 2001, Brazil and the United States settled their WTO dispute.¹⁸⁷ The United States withdrew its WTO complaint against Brazil, while Brazil agreed that if it deemed it necessary to apply Article

¹⁸⁵ See document WT/DS 224/1.

¹⁸⁶ The United States requested the establishment of a Panel (Brazil - Measures Affecting Patent Protection, complaint by the United States (WT/DS199/3)) in January 2001. A panel was established in February 2001 and Cuba, the Dominican Republic, Honduras, India and Japan reserved their third party rights.

¹⁸⁷ On 5 July 2001, the parties to the dispute notified to the DSB a mutually satisfactory solution on the matter (WT/DS199/4).

68 to issue a compulsory license on patents held by US companies, it would hold prior bilateral talks with the US. The US indicated that it expected that Brazil would not proceed with its challenge of US legislation on the ground that it requires local working. The parties explicitly considered the Agreement, "an important step towards greater cooperation between the two countries regarding our shared goals of fighting AIDS and protecting intellectual property rights."

It would be wrong to see the US-Brazil trade dispute as a narrow technical challenge to a non-health-related concern. Such an approach is not only inaccurate, but also misleading and dangerous. The US action is aptly described by the Brazilian trade representative at the WTO:

"[T]he TRIPS Agreement reflects a delicate balance that took developing countries to the limits of acceptability. This delicate balance was reflected, in the case of Brazil, in internal legislation which is fully consistent with the letter and the spirit of the Agreement. The United States is now seeking an interpretation of TRIPS that threatens to upset such balance."¹⁸⁸

It should also be noted that Brazil has successfully used, on at least two occasions, the threat of compulsory licensing to secure more favorable terms in its negotiations for the supply of HIV/AIDS drugs with major pharmaceutical companies.¹⁸⁹

4.6.2.3 The practice of Brazil to Use the Flexibility

Despite the result of the above case is not decided by the WTO DSB, and we do not know the attitude from WTO authority to the disputes, however, at least Brazil successfully used the flexibility provided that under TRIPS Agreement to gain its public interest. Hence, the specific measures taken by Brazil government need to be mentioned.

Currently, the Ministry of Health is providing 12 different pharmaceuticals as the basis of the combination therapy, 7 of which are produced in Brazil - the other 5 are imported. The advantages of local production are significant.¹⁹⁰ Today, the Government spends US\$ 319 million on purchasing local and imported drugs to supply its HIV program. The Ministry of Health estimates that if all those drugs had been imported, the cost to the Government

¹⁸⁸TAC Statement on US Complaint Against Brazil at WTO, <http://www.tac.org.za/Documents/Statements/usvsbrzl.html>)

¹⁸⁹ "WTO Agreements and public health, A Joint Study by the WHO and the WTO Secretariat."op.cit.

¹⁹⁰ "The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights".op.cit.

would be in the range of US\$ 530 million which, according to the Ministry, would make the program unviable. It should be noted that Brazil already spends 56 per cent of the US\$ 305 million spent annually on its HIV program on the 5 imported drugs included in the 12 drugs comprising the “cocktail”.¹⁹¹

Of the 12 therapies, 2 are protected by patents in Brazil (Efivirenz and Nelfinavir, held by Merck Sharp & Kohme and Roche, respectively).¹⁹² While some of the seven drugs produced locally are protected by off-shore patents, production began before 1997 (the year in which the Brazilian patents law entered into force) so the local production does not infringe the rights of overseas patent holders. However, significant expenditures are incurred in relation to the purchase of the two patented drugs. The Ministry of Health indicates that purchase of the two patented drugs through importation has alone consumed 36 per cent of the resources of the HIV treatment budget.¹⁹³ With the appearance of new and more effective drugs for combating AIDS, the Ministry of Health estimates that more expensive drugs protected by patent will slowly begin to comprise the combination therapy. This development, according to the Ministry of Health, could place their HIV treatment program at risk.

For this reason, the Brazilian Government has sought ways to encourage the international pharmaceutical industry to enter negotiations for the sale of drugs, taking into account the purchasing power of particular markets. In this regard, Brazil makes specific reference to the UNDP Human Development Index as an indication of relevant purchasing strength.¹⁹⁴ To do this, the Government notes that it will employ all available resources in Brazilian legislation - while observing the international undertakings entered into by Brazil - to make drugs accessible to their citizens. Part of this strategy has involved the Brazilian Intellectual Property Law which came into force in 1997.

The Brazilian IP law allows a government authority to issue a compulsory license where a patent holder exercises patent rights in an abusive manner, or by means of an abuse of economic power proven by an administrative or court decision. There are certain other instances where compulsory licences may be issued, including under article 71, in cases of national emergency or public interest. The terms "national emergency" and "public interest" are defined in the Presidential Decree on Compulsory Licensing (1999). According to the decree, "(a) national emergency is understood to be a condition of impending danger to the

¹⁹¹ *ibid.*

¹⁹² Mary Robinson.op.cit.

¹⁹³ *ibid.*

¹⁹⁴ *Ibid.*

public, even if existing only in a part of the national territory". Further, "(t)here are considered to be within the public interest those facts, among others, related to the public health, nutrition, protection of the environment, as well as those of primordial importance to the technological or social and economic development of this country". This links closely with provisions of the TRIPs Agreement which allow for use of a patent without the authorisation of the right holder in certain circumstances, including "in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use".

The existence of these safeguard provisions has been helpful in improving the implementation of the Brazilian HIV treatment program. While no compulsory license has been issued under the Brazilian IP law (up to now), the provisions have been useful in negotiations with patent holders. The use of rights over the two patent drugs Efavirenz and Nelfinavir are cases in point.¹⁹⁵ In the case of Efavirenz, the Government had begun research into the drug with the aim of achieving full capability to manufacture it locally. With local manufacture in mind, a request to issue a compulsory license for the drug had also been submitted. Since the Agreement with the patent holder (to lower prices), the request for a compulsory license has been put on hold, but research is continuing in case the Government finds it necessary to issue a compulsory license in the future. In the case of Nelfinavir, while negotiations for a decrease in prices were continuing, the Government continued research into the production of the drug and the Ministry of Health had indicated that, if negotiations did not lead to a significant decrease in price, it would consider requesting a compulsory license so that Nelfinavir can be produced by national laboratories.

The results of the Brazilian strategy have been significant. In terms of the enjoyment of Brazilians' right to health, there has been a reduction in deaths due to AIDS by 50 per cent over the last four years. Further, there has been a reduction of 80 per cent in cases of hospitalisation due to opportunistic diseases with a reduction in the appearance of the most serious opportunistic diseases tuberculosis (by 60 per cent), citomegalovirus (by 54 per cent) and Kaposi sarcoma (by 38 per cent). The programme has also made economic sense. The reduction in hospitalisations has saved the Ministry of Health \$422 million. Moreover, costs of funding the programme are coming down. In 1999, the Ministry of Health spent \$ 336 million on drugs to reach 73,000 patients. In 2000, the Ministry spent the lower amount of \$319 to meet the needs of 85,000 patients. Local production of generic drugs has led to production cost cuts of, on average, 70 per cent (the reduction in the price

¹⁹⁵ Ibid.

of Zalcitabina (ddC) has been 95 per cent) and the Government has even achieved a reduction in the price of imported drugs of an average of 10 per cent. In the longer term, the programme has improved local technological and research capacity, which could enable it in the future to assist developing countries struggling with the HIV/AIDS pandemic, in particular countries in Africa.

4.6.3 The Dispute between United States and South Africa

This case was the dispute between the United States and South Africa in relation to South African legislation aimed at allowing parallel imports and compulsory licenses for medicines. Despite the legality of such measures under the TRIPs Agreement, the US government and pharmaceutical industry put enormous pressure on the South African government to eliminate such measures.¹⁹⁶ Supported by a number of active NGOs (particularly those concerned with the dramatic rise of HIV-related infection in South Africa), the South African government resisted such pressures and eventually obtained the suspension of the judicial case brought by US companies as well as the withdrawal of South Africa—in December 1999—from the “Super 301” list.¹⁹⁷

4.6.3.1 Background

The background of this domestic dispute is the following. When South Africa emerged from apartheid, the government was confronted with a problematic pharmaceutical pricing structure: drug companies had set their prices to target the country-within-a-country of the rich, white upper class, essentially ignoring the vast number of (black) people who could not afford these prices. Concerned with matters of equity, the government passed the Medicines and Related Substances Control Amendment Act in 1997 to assist in implementation of its 1996 National Drug Policy. That Policy was designed "to ensure an adequate and reliable supply of safe, cost-effective drugs of acceptable quality to all citizens of South Africa and rational use of drugs by prescribers, dispensers and consumers"¹⁹⁸

Due to the gravity situation, one might have thought that South Africa was trying to introduce radical legislation, abolishing all patent rights. In reality, nothing is further from the truth: the law is consistent with the TRIPs Agreement, and all of the most important

¹⁹⁶ See the US Trade Representative Press Release, April 30, 1999, listing the countries that may be subject to trade sanctions under Section 301 of the US Trade Act.

¹⁹⁷ Carlos M. CORREA.op.cit.

¹⁹⁸ “WTO Agreements and public health, A Joint Study by the WHO and the WTO Secretariat.”op.cit.

provisions are already enshrined elsewhere around the world, typically in developed countries. The Act provides that the minister of Health may protect public health in certain conditions by allowing the importation into South Africa of generic, low cost medicines, to substitute for higher cost proprietary medicines already in use.¹⁹⁹ The mechanisms that the South African government would have at its disposal to give practical effect to this provision are referred to "parallel importing" and "compulsory licensing."

The aim was to reduce the cost of treating HIV/AIDS by between 50-90 per cent. With over four million AIDS sufferers, and national life-expectancy projected to fall by 20 years by 2010, it is difficult to argue that the government's action was not justified on public-health grounds. Yet it was subject to a legal challenge by a number of pharmaceutical companies producing anti-retrovirals.

4.6.3.2 The Development of the Case

The Pharmaceutical Manufacturers Association of South Africa (PMA), joined by 39 international pharmaceutical corporations, filed suit on 18 February 1998, in South Africa's High Court (In the High Court of South Africa, Case Number 4138/98). The case was to be heard at the Constitutional Court in Pretoria in March 2001 (the case was delayed again, reportedly on account of technical objections by the drug companies and was to resume on 18 April, 2001). The same pattern of events has unfolded elsewhere. Whatever the letter of the WTO law, pharmaceutical companies had pressed for very restrictive policies on the use of compulsory licensing - and their demands had usually been supported by the USTR²⁰⁰.

The PMA charged that the South African government, in Section 15 of its Medicines and Related Substances Control Act, was in violation of its obligations to TRIPS Agreement. Adherence to the TRIPS Agreement is a condition of membership in the World Trade Organization. Among other things, TRIPS assures uniform and exclusive patent protection for intellectual property (including drugs), for a minimum patent life of 20 years. During the protected period the patent holder maintains the exclusive rights to make, use, sell, or import the patented product in a given country. According to the PMA, both parallel importing and compulsory licensing of patented AIDS drugs are prohibited under TRIPS and therefore are inconsistent with South Africa's WTO membership.

¹⁹⁹ Bond 1999. op.cit.

²⁰⁰ "Patents, TRIPs & Public Health", from Oxfam paper.op.cit

In fact, the PMA's position is not supported, or at best only weakly supported, by a close reading of the TRIPS Agreement.²⁰¹ In the case of parallel importing, the TRIPS Agreement explicitly states (in Article 6) that nothing in the Agreement should be taken to apply to the issue. In the case of compulsory licensing, Article 31 of TRIPS specifies procedures by which a WTO member country may apply to a patent holder for permission to manufacture generic versions of a protected product, a procedure that may be waived "in the case of a national emergency or other circumstances of extreme urgency." Ironically, the United States itself considered very similar actions in order to bring down the price of Ciprofloxacin at the height of the anthrax scare in the fall of 2001.²⁰²

From the time the PMA lawsuit was filed, a global coalition formed in support of the South African government's position and buried the pharmaceutical industry under a relentless avalanche of negative publicity. The Treatment Access Campaign (TAC), a South African activist group formed initially by three people living with AIDS, and Doctors Without Borders took the lead in a multimedia, global campaign on behalf of millions of powerless poor across the developing world whose access to life-saving medications was, in the campaign's portrayal, being held hostage to the greed of multinational corporations. One by one, some of the largest pharmaceutical corporations began offering new discounts to South Africa and other poor countries. Still the negative publicity directed toward pharmaceutical companies continued. In the United States, the Clinton administration announced that it was reversing its opposition to South Africa's action in passing Section 15 of the Medicines Act, a decision that was upheld early in the new Bush administration. On 17 April 2001, the pharmaceutical manufacturers withdrew their lawsuit.²⁰³

4.6.3.3 The Significance of the Case

The public relations disaster that the court case had turned into was clearly a key factor in forcing the companies to withdraw the case. It takes a potent combination of factors to compel one of the world's most powerful industries to completely change course and abandon a cause that it has pursued relentlessly for more than three years. In this case, a

²⁰¹ Correa, Carlos M. 2001. The TRIPS Agreement: How Much Room to Maneuver? *Journal of Human Development* 2: 79–107

²⁰² Bradsher, Keith, and Andrews, Edmund. 2001. U.S. Says Bayer Will Cut Cost of Its Anthrax Drug. *New York Times* (23 October)..

²⁰³ Wall Street Journal, 18 April 2001.

powerful alliance of public pressure (both within South Africa and internationally), solid legal argumentation and steely resolve on the part of the government, and some timely international intervention, all contributed.

Activist pressure in the North had driven American and European governments to back away from their earlier pro-industry positions, and the European Parliament and a number of Ministers of various European nations even called on the companies to abandon their lawsuit. In a mere six weeks, 300,000 people from over 130 countries signed an international petition drive launched by Medicines Sans Frontières (MSF) calling on the companies to drop the case.²⁰⁴

Within South Africa, the TCA, had been accepted as an *amicus curiae* (friend of the court) in the case, which would have ensured that embarrassing details about the pharmaceutical industry's pricing policies and the heavy government sponsorship of the research and development of HIV medicines would have been heard in open court.

While the public pressure clearly brought the companies to the table, it was the government's commitment to the legislation and its strong negotiators that guaranteed that the companies were unable to extract compromises in exchange for dropping the case. It is also clear that Kofi Annan, - Secretary General of the UN, played an important role in resolving the case, from reports describing his contacts with both major multinational pharmaceutical companies and South African President Thabo Mbeki.

Aids activists cheered when the announcement was made, in a case that was seen as a landmark battle in the effort to secure medication for Africa's 26 million HIV carriers. Now, the South African authorities are expected to enact the law, which they have argued is desperately needed to tackle the country's Aids crisis. Kevin Watkins, of the British aid group Oxfam, described it as a "comprehensive climb down" by the drugs companies. "We have lost three years in the fight against Aids, but it is a great victory for the people of South Africa and for the global campaign to make drugs more affordable."²⁰⁵

The following is the statement made by South Africa's Minister for Health, Tshabalala-Msimang, on 19 April 2001:

²⁰⁴ 'DROP THE CASE' PETITION BY MSF, South Bulletin 09
http://www.southcentre.org/info/southbulletin/bulletin09/bulletin09-01.htm#P55_9441
²⁰⁵ BBC, Thursday, 19 April, 2001, 15:32 GMT 16:32 UK

“The settlement that we have announced today is the product of a large number of people in many countries. It is the work of countless South Africans who stood up in an expression of national unity and clearly supported the approach of government. It is the achievement of organizations, activists and governments elsewhere in Africa and on other continents who recognized our particular battle as part of a broader movement for justice in health care. While the South African Government's drug policy was driven mainly by domestic factors, we never lost sight of the international dimension and we hope our experience has contributed in some way to the larger debate on access to affordable health care for developing countries and for the poor in wealthier nations.”²⁰⁶

This court case was never contained to the borders of South Africa, and its resolution has ramifications throughout the African continent and beyond.

First, the importance of the case that was followed closely from Alaska to Zanzibar cannot be overstated. In many ways, the case was less about the narrow technical provisions to reduce the price of medicines than it was about the rights of a government to place the health of its people over vested corporate interests. As such, it sets an important precedent, signaling to other developing countries that they need not capitulate to the pressure tactics of the pharmaceutical industry or Northern governments acting at their behest.

This case also demonstrates the extent to which the intellectual property rights have become one of the key battlegrounds between developing countries and the interests of multinational firms. When intellectual property rights were included in the WTO during the Uruguay Round of trade negotiations, there was much less awareness of the potential for patent protection to lead to adverse public health consequences than there is today. The HIV/AIDS epidemic, in particular, has made the link between patent protection, high drug prices, and access to medicine painfully clear, as millions die in developing countries, unable to afford the drugs that have turned HIV from a death sentence to a chronic condition in the North.

This catastrophe has sparked calls to reexamine the TRIPs Agreement, and in June, 2001 the Council for TRIPs held a special session on the public health impact of the Agreement, a meeting called for by Zimbabwe on behalf of the African Group of WTO members.²⁰⁷

²⁰⁶ South African Health Minister's Statement, South Bulletin 11
<http://www.southcentre.org/info/southbulletin/bulletin11/bulletin11web-01.htm>

²⁰⁷ Developing Countries Must Stand Firm On People Over Patents—Toby Kasper—SOUTH BULLETIN 11,
<http://www.southcentre.org/info/southbulletin/bulletin11/bulletin11web-02.htm>

One of the other lessons of the court case is that although the multinational pharmaceutical industry finally did the right thing, its resources are such that it can hold up the implementation of legitimate, WTO-consistent legislation almost indefinitely. Thus this court case, while a victory, can only be seen as one piece of the much larger puzzle that providing treatment to people with HIV/AIDS represents.

Nevertheless, the final victory must be tempered by its high costs: during these three years, more than 400,000 South Africans have died of HIV/AIDS. Additionally, it is important to recognize that the legal victory alone will not automatically translate into improved care for people with HIV/AIDS; further steps are necessary before the hopes raised by this case - particularly for access to life-saving anti-retroviral medications - can be realized

4.7 The Assessment on TRIPs in Terms of the Access to Medicine

20 years protection on pharmaceutical products and process; compulsory licensing, parallel importation and other flexibility; transitional period for developing and LDCs; general principle to respect public health; and the powerful DSB sanction system. These are what TRIPs Agreement brings to us. Someone says that: (TRIPs) is a dream come true for trade lawyers, and a nightmare for the general public.²⁰⁸ Because TRIPs does not spare pharmaceutical products or processes. Life-saving drugs are treated at par with Barbie dolls, motor cars or famous wines: because TRIPs confers the same rights to patent holders and makes absolutely no distinction between products and processes.²⁰⁹

The critics always point out those typical comments to TRIPs Agreement. In fact, we have to admit that unification of the strict provisions are the result of the great pressure from the powerful countries, standing at their own point without consideration of the poor sufferers in the other countries. The consequences will be significant. Human rights and thousands upon thousands lives are overlooked. It is impossible to count that how many people will be affected by these strict provisions. What we can imagine is that the impact of these articles is out of imagination. Since this Agreement has entered into force and be implemented by most member states now, it is impossible to overturn the whole Agreement. Fortunately, if the flexibility and the principle in the Agreement can exert a huge function to overcome the negative side, this Agreement may be not as such bad as

²⁰⁸ Oxfam's paper Patents, TRIPs & Public Health.op.cit.

²⁰⁹ Someshwar Singh, op.cit.

somebody's description. To assess this Agreement, we need an overall view; take all the provisions into consideration. And the key is whether the flexibility and the objective provisions could work for the developing and LDCs' interesting.

For instance, the Fifty-Second World Health Assembly recognized that "the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) provides scope for the protection of public health".²¹⁰ The TRIPs Agreement has partially addressed public health concerns. For example the vague expression in Article 8.2 statements. ("Members may, in formulating or amending their national laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.") This provision incorporates the "necessity" test mentioned above, but seems to subject it to an additional "compatibility" test (not present in Article XX of the GATT) that, if broadly interpreted, may nullify a possible exception based on public health or other grounds. However, the "consistency" requirement may refer to ordinary or everyday public health measures, which could not undermine TRIPs obligations in a permanent way, as distinct from public health emergencies, which could trigger different criteria of "inconsistency" under Article 8.1 and allow for temporal derogations of obligations under the Agreement.

The World Health Assembly's annual meeting in May 2001 devoted substantial attention to lack of access to essential drugs, which has become acute in light of the devastating human and economic impact of HIV/AIDS in many countries. WHA, as WHO's governing body, adopted a resolution (WHO Medicines Strategy, 54.11) which noted that "the impact of international trade Agreements on access to, or local manufacturing of, essential drugs and on the development of new drugs needs to be further evaluated."²¹¹

Connected to this issue, on international trade Agreements and pharmaceuticals, WHO has five key public health messages.²¹²

First, patent protection is a necessary and effective incentive for research and development for needed new drugs. Essential drugs are not just another ordinary commodity. Patents must therefore be managed in an impartial way to benefit both the patent holders and the public. Protectionism has never benefited public health. WHO supports governments to enact national legislation which can draw advantage from more open trade and a better

²¹⁰ Scherer, F.M., and Ross, D. (1990), *Industrial Market Structure and Economic Performance*, Houghton Mifflin Company, Boston.

²¹¹ WTO Agreement and public health. Op.cit.

²¹² *Pharmaceuticals In The Trade Related Aspects Of Intellectual Property Rights (Trips) Agreement Of The World Trade Organization (Wto)*, op.cit.

regulated international system. WHO also supports governments in incorporating the safeguards that have been built into the WTO/TRIPs Agreement to protect the rights of the public.

Second, priority-setting for research and development in the pharmaceutical market is imperfect. There are also striking market failures when there is a desperate demand for products that are available – but not within the reach of those in need. WHO has initiated with other partners innovative mechanisms to stimulate research and development in areas of high public health need such as malaria and tuberculosis. WHO is actively encouraging public sector financing for critical public health problems and neglected tropical diseases.

Third, WHO strongly supports the development of mechanisms for preferential low prices for essential drugs in lower-income countries. Lower-income countries simply cannot be expected to pay the same price for essential drugs as the wealthier countries. For governments, industry, and other stakeholders, there is a range of measures which might be used to achieve preferential pricing. But where there is an abuse of patent rights, where patented essential drugs are not on the market, or where a national emergency exists, recourse to compulsory licensing is a legitimate measure consistent with the TRIPs Agreement.

Fourth, WHO supports the implementation of the TRIPs Agreement to ensure prompt availability of generic drugs upon patent expiration. WHO has long promoted the use of generic drugs of assured quality. Experience from countries with “generic-friendly” policies clearly demonstrates that the market competition created by these policies increases affordability of medicines, stimulates true innovation within the research-based industry, and encourages increased production efficiency by the generic industry.

Fifth, trade Agreements should not create barriers to trade. An important WTO principle is that technical regulations, standards and assessment procedures should be based on international standards, guides and recommendations. In the area of pharmaceuticals, WHO norms, standards and guidelines represent such international consensus. WHO will actively promote these guidelines.

But since TRIPs Agreement put the stress on the TNCs side, many organizations then focus to call on the human rights sides and try to avoid the negative sides TRIPs brings about.

For examples, at its April 2001 session, the UN Commission on Human Rights adopted a resolution (2001/33) calling upon States to refrain from taking measures which would deny

or limit equal access to pharmaceuticals used to treat pandemics such as HIV/AIDS. In addition, the Commission called upon States to ensure that, as members of international organizations, they apply international Agreements in support of public health policies that promote access to affordable pharmaceuticals and medical technologies.²¹³

The World Health Assembly's annual meeting in May 2001 requested the Director General of WHO to "enhance efforts to study and report on existing and future health implications of international trade Agreements in close cooperation with relevant intergovernmental organizations." In cooperation with other intergovernmental organizations, WHO will continue to provide its Member States with information about options within TRIPs for protecting public health, pursuant to previous resolutions adopted by WHO's governing body.²¹⁴

²¹³ Wto Agreement and public health

²¹⁴ World Health Assembly Resolutions 52.19 and 53.14

5. Trips-Plus Protection and USA's special 301

Before go to the next step-Doha Declaration, there are two points relevant to the TRIPs Agreement need to be mentioned.

5.1 TRIPs-Plus Protection

Besides the obligation under trips, many developing countries are being required not only to comply with TRIPs Agreement standards but in some cases, as also illustrated by the case of South Africa, some Industrialized countries have requested more than that. They have pushed for TRIPs-plus protection.

TRIPs-plus is described by WHO as attempts to enact national legislation that extends the life of a patent beyond the TRIPs minimum of 20 years, limiting compulsory licensing in manners not necessarily mandated under TRIPs and preventing exceptions that may facilitate the prompt introduction of generics, such measures may result in an intensification of the overall struggle to promote and protect human rights.²¹⁵

This always happens when some developed countries, especially the United States of America, find that the provisions of the TRIPs Agreement still do not provide sufficient protection for the pharmaceutical industry. They therefore advocate a bilateral arrangement with the introduction of a retroactive system whereby, in countries where there has hitherto been no protection for pharmaceutical products and the law changes.²¹⁶ For example, within the context of AGOA (African Growth and Opportunity Act) where, lured by the possibility of market access to the United States economy, African States may be forced to make concessions on the recognition and protection of IPRs that are higher than those stipulated in TRIPs.²¹⁷ Usually, a period of grace is allowed during which it is possible to patent products that have already been patented in other countries, but have not yet been actually marketed in those countries. This system is known as the pipeline system, and has been introduced in the legislation of a number of countries including Mexico and Brazil²¹⁸.

²¹⁵ “Globalization and its impact on the full enjoyment of human rights”, by Special Rapporteurs J. Oloka-Onyango and Deepika Udagama.op.cit.

²¹⁶ Silvia Salazar.op.cit.

²¹⁷ “Globalization and its impact on the full enjoyment of human rights”, by Special Rapporteurs J. Oloka-Onyango and Deepika Udagama.op.cit.

²¹⁸ Silvia Salazar.op.cit.

“Given the challenges presented above, many Latin American and Asian countries, acting under bilateral pressures from industrialized countries, have already made concessions by adopting the TRIPS-plus framework” said by Argentine expert Carlos Correa,²¹⁹ and have designed legislation that may be considered more restrictive than the TRIPs Agreement permits. For example, many developing countries and LDC's are using mechanisms such as compulsory licensing and parallel (or "gray") market importation. Although not prohibited under the TRIPs Agreement, such measures have nevertheless resulted in contention between developing country Governments and multinational pharmaceutical companies. Most contention has focused on the new lifesaving drugs intended for the treatment of HIV/AIDS. The most prominent of these pharma-battles have involved Kenya, India, Brazil, Ghana and South Africa, but they are not the only ones.²²⁰

Based on available experience, WHO does not recommend applying TRIPs-plus requirements or extending TRIPs requirements to non-WTO Members before the public health impacts of so doing have been fully assessed.²²¹

Since the public health impact of TRIPs requirements have yet to be fully assessed, WHO recommends that developing countries be cautious about enacting legislation that is more stringent than the TRIPs requirements.

5.2 USA's "Special 301"

Even before the trade Agreement had been signed, the US Trade Representative (USTR) was using the threat of trade sanctions to demand stricter protection of US corporate interests in developing countries. In 1988, the 'Special 301' provision was adopted, granting the USTR the right to impose sanctions on countries with weak patent laws. It was promptly used against Brazil. 'Special 301' continues to serve as a corporate battering ram.²²² Described by the ex-USTR, Charlene Barshefsky, as 'one of the most powerful weapons in our trade arsenal', it has been used to enforce compliance with WTO rules, and in some cases to go beyond them.²²³

²¹⁹ TRADE-AMERICAS: US Takes Hardline on Drug Patents By Gustavo Capdevila, <http://lists.essential.org/pipermail/ip-health/2001-April/001203.html>

²²⁰ "Globalization and its impact on the full enjoyment of human rights", by Special Rapporteurs J. Oloka-Onyango and Deepika Udagama.op.cit.

²²¹ A New Era in Global Trade, op.cit.

²²² *ibid.*

²²³ Oxfam paper "Patent Injustice: How World Trade Rules Threaten the Health of Poor People." op.cit.

The driving force behind the use of 'Special 301' for the enforcement of IP protection in drugs is the Pharmaceutical Research and Manufacturers of America (PhRMA). Its board includes representatives of corporate giants: Pfizer, GW, Novartis, Johnson and Johnson, Aventis, Merck, and Bayer. Its President, Alan Holmer, is himself a former USTR. Members of PhRMA played a central role in persuading the Clinton Administration to threaten trade sanctions against South Africa when its government authorized the parallel import of cheap generic anti-HIV/AIDS drugs. It was also instrumental in persuading the US to protect the exclusive rights of Pfizer to market fluconazole in Thailand, where the government was planning to introduce a compulsory licensing arrangement.

More generally, PhRMA has maintained a sophisticated lobbying campaign directed against countries that it regards as a special threat, notably India, Egypt, Argentina, and Brazil. One of the common features of these countries is that they have strong generic industries which not only provide low-cost competition in domestic markets, but also export low-cost generic drugs to third countries.

In January 2000 PhRMA filed petitions to the USTR claiming widespread and systematic non-compliance with world patent rules in these four countries. The use of price controls and compulsory licenses to allow generic production of brand-name drugs was identified as a major problem, especially in India. Four months later, the USTR placed Brazil and Argentina on the 'Special 301' Priority Watch List - in effect, a short-list of candidates for unilateral trade sanctions. The annual 'Special 301' review also warned that future actions would be brought against other countries, including Israel, Egypt, and the Dominican Republic.

The number of countries threatened by 'Special 301' trade sanctions is cause enough for concern. Countries have been selected on the grounds that they pose a strategic threat, either because of the size of their domestic market (as in Brazil), or because a particular generic industry has developed a major export capacity to supply third-country markets with low-cost drugs (e.g. India), or because it is a small country which has remained unresponsive to protracted threats (such as the Dominican Republic).²²⁴

India has been a consistently high-profile target for PhRMA, which regards the country's generic-drugs industry as a major threat to its members' interests. It claims market losses in excess of US\$100m in the Indian market and further losses caused by generic companies

²²⁴ *ibid.*

which 'aggressively export their products to third countries.' India is one of the main sources of cheap drugs for Africa and other low-income countries.²²⁵

The Government of India has been warned that it faces trade sanctions if it continues to allow the generic copying of patented drugs and refuses to accept more restrictive criteria for issuing compulsory licences. Among the specific drugs targeted by PhRMA for more stringent patent protection is ciprofloxacin, one of the most widely used anti-infective drugs in the country. This action is taking place despite the fact that India is availing itself of the full transition period allowed for under WTO rules (i.e. until 2005), and that there are currently no serious grounds for initiating dispute settlements under WTO auspices. Despite this, an assessment by PhRMA in January 2001 concluded that 'PhRMA urges the USTR to initiate a dispute settlement in the WTO against the Government of India'.

In the Dominican Republic, the USTR has threatened to withdraw trade preferences following complaints from PhRMA. These include Generalised System of Preferences (GSP) arrangements for textiles and tobacco. The issue is a national industrial property bill which authorises compulsory licensing and parallel importing of cheap drugs. The wording of the PhRMA complaint against the Dominican Republic is instructive, in that it gives an insight into the broader strategy of attacking what are seen as strategic targets. 'The situation in the Dominican Republic poses a threat to regimes in neighbouring states, (and) is being used by activist organisations as a potential precedent to weaken the fabric of the TRIPs Agreement.'²²⁶

Argentina has long been one of the prime targets of PhRMA, which describes the country as 'the worst expropriator of US pharmaceuticals in the hemisphere', and a leader by bad example. Following a petition from PhRMA, a WTO dispute process was initiated against Argentina in May 2000. The aim of the action is to restrict recourse to compulsory licensing, to restrict the definition of national health emergencies, and to restrict the access of local generic producers to clinical test data on patented products (thereby delaying the introduction of generic competition). The PhRMA claims losses of over US\$50m annually in Argentina.²²⁷

In Vietnam, PhRMA has requested 'Special 301' action to counter what it describes as 'a pronounced trend towards protectionism in favour of locally-manufactured pharmaceutical

²²⁵ Ibid.

²²⁶ Ibid.

²²⁷ Ibid.

products'. It has targeted key provisions in the new Vietnamese Civil Code which allow a compulsory licence to be issued if the government deems it necessary for the treatment or prevention of disease. PhRMA wants this provision withdrawn - and the USTR has threatened trade sanctions if action is not taken.²²⁸

In Thailand, the USTR has threatened trade sanctions unless the government dilutes laws allowing compulsory licensing and parallel importing, and withdraws drugs procurement policies which favor the local industry. These sanctions follow a PhRMA petition noting that Thailand is 'currently under severe pressure from non-government organizations' to issue compulsory licenses for pharmaceutical products. PhRMA has also attacked the use of parallel importing to gain access to low-cost copies of drugs categorized as 'essential' by the World Health Organization (WHO). It claims that its members are losing sales in the order of US\$30m per annum as a result of patent violation. It is not unreasonable for corporate interests to attempt to influence trade policies on IP. What is worrying in this case is the extent of that influence, and the absence of countervailing power. PhRMA is systematically targeting the very safeguard provisions which were negotiated to protect public health. The fact that they are able to do so reflects their formidable financial power and the close ties between government and industry. Between 1997 and 1999, PhRMA's members spent US\$236m lobbying Congress and the executive branch of government. Another US\$14m was provided to political parties in 1999 alone.

Approximately two-thirds of corporate investment in political lobbying in the USA is directed towards the Republican Party. The political pay-off to lobbying investments has been considerable. Many representations and appeals for trade sanctions from the pharmaceuticals industry have met with a sympathetic response from the USTR, resulting in extreme pressures on developing-country governments.²²⁹

²²⁸ Ibid.

²²⁹ Ibid.

6.Doha Declaration - the Landmark for Hope

6.1 Background

After the adoption of TRIPs Agreement, many different human rights NGOs as well as IGOs all express their deeply concerns about the implementation of this trade Agreement and its impact on the right to health. Under such occasion, WTO could not keep silent any longer. This resulted in a new Declaration.

At the request of the African Members of the WTO (the African Group), the TRIPs Council held a special discussion on intellectual property and access to medicines as part of its week-long regular meeting in June 2001. This was the first time that this matter had been put on the agenda of on WTO body. The work that subsequently took place in the Council for TRIPs fed into the preparatory work for the WTO Ministerial Conference held in Doha, Qatar in November 2001 and into the Declaration on the TRIPs Agreement and Public Health that was adopted by consensus by the WTO Ministers at that Conference.²³⁰

In the WTO Ministerial Declaration on “The TRIPs Agreement and Public Health” of November 2001, all WTO Members “affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all”. Rather than granting a general waiver from WTO law in favour of the human right to health, WTO Members preferred to specify those TRIPs provisions which they understand to grant sufficient flexibility for promoting public health and access to medicines for all.²³¹ “reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPs Agreement, which provide flexibility for this purpose”.²³²

6.2 Further Analysis

The Declaration aims to respond to the concerns expressed about the possible implications of the TRIPs Agreement for access to drugs. It does so in a number of ways.

²³⁰ WTO Agreements and public health.op.cit.

²³¹ Ernst-Ulrich PETERSMANN, Human Rights and the Law of the World Trade Organization *Journal of World Trade 37(2): 241–281, 2003. _ 2003 Kluwer Law International.

²³² See WTO document WT/MIN (01)/DEC/W/2 of 14 November 2001, para. 4.

First, it emphasizes that the TRIPs Agreement does not and should not prevent Members from taking measures to protect public health and reaffirms the right of Members to use, to the full, the provisions of the TRIPs Agreement which provide flexibility for this purpose. These important Declarations signal an acceptance by all WTO Members that they will not seek to prevent other Members from using these provisions.²³³

Second, the Declaration makes it clear that the TRIPs Agreement should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all. Further, it highlights the importance of the objectives and principles of the TRIPs Agreement for the interpretation of its provisions. Although the Declaration does not refer specifically to Articles 7 and 8 of the TRIPs Agreement, entitled, respectively, "Objectives" and "Principles", it should be noted that developing country Members attach particular importance to these provisions. These statements thus provide important guidance to both individual Members and, in the event of disputes, WTO dispute settlement bodies.

Third, the Declaration contains a number of important clarifications of some of the flexibilities contained in the TRIPs Agreement, while maintaining Members' commitments in the TRIPs Agreement.

With regard to the least-developed country Members of the WTO, the Declaration accords them an extension of their transition period until the beginning of 2016 for the protection and enforcement of patents and rights in undisclosed information with respect to pharmaceutical products. Until then, these countries are exempt from these TRIPs obligations.

And also, the TRIPs Council was mandated to find an expeditious solution to the problem of WTO Members with limited manufacturing capacities in making effective use of compulsory licencing and to report to the General Council before the end of 2002.

It should also be noted that, while emphasizing the scope in the TRIPs Agreement for measures to promote access to medicines, the Declaration also recognizes the importance of intellectual property protection for the development of new medicines and reaffirms the commitments of WTO Members in the TRIPs Agreement.

²³³ WTO Agreements and public health.op.cit.

This landmark Declaration, which affirms that the TRIPs should be interpreted and implemented so as to protect public health and promote access to medicines for all, demonstrates that a rules-based trading system is compatible with public health interests. The careful and systematic attention which WTO Members afforded to fine tuning the balance that needs to be found in the intellectual property system is indicative of the prominence accorded to public health on the international trade agenda. The Declaration enshrines the principle that WHO has publicly advocated and advanced over the last four years, namely, the re-affirmation of the right of WTO Members to make full use of the safeguard provisions of the TRIPs Agreement in order to protect public health and promote access to medicines.

7 The Implementation Of Doha Declaration

The Ministerial Declaration on TRIPs and Public Health was one of the most significant decisions of the Doha Ministerial Conference.²³⁴ However, as Ambassador B.G. Chidyausiku observes, “The question is now, how do we make it effective? How do we make it deliver the medicines to the people? How do we avoid this Declaration ending up as a dead letter?”²³⁵

Especially, if a WTO Member has insufficient or no manufacturing capacities in the pharmaceutical sector, it would face difficulties in making effective use of compulsory licensing under the TRIPs Agreement. And how to solve this problem is of great significance to actually make the Declaration effective.²³⁶

7.1 “Paragraph 6” Issue

The Declaration acknowledges the specific problems of developing countries and least developed countries that are faced with serious public health problems but cannot provide essential drugs under patents for their people. Paragraph 6 of the Declaration states “We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPs Agreement. We instruct the Council for TRIPs to find an expeditious solution to this problem and to report to the General Council before the end of 2002”.

Then a three-day meeting of the WTO's TRIPs Council (5-7 March, 2002) marked the beginning of a new phase of ‘official’ debate on the subject of TRIPs and public health. It therefore called post-Doha talks. In the 5 March session, initial proposals or suggestions for dealing with the domestic production capacity question were submitted from members.

²³⁴ <http://www.southcentre.org/info/southbulletin/index2.htm>.

²³⁵ Ambassador B.G. Chidyausiku, Zimbabwe, on the Doha Declaration. Quoted from *Implementation of the Doha Declaration on the TRIPs Agreement and Public Health: Technical Assistance—How to Get It Right*, conference report, 28 March 2002, International Conference Centre of Geneva (CICG).

²³⁶ Haochen SUN, Reshaping the TRIPs Agreement Concerning Public Health: Two Critical Issues, *Journal of World Trade* 37(1): 163–197, 2003. © 2003 Kluwer Law International.

With regards to the implementation of Doha Declaration, the proposal by the EC contains two options. First, it needs to look at the interpretation of the TRIPs Agreement with regard to Art. 30 - in terms of an exception to facilitate a solution for governments, which do not have the manufacturing ability. The other one is to look at article 31 (f), where if you issue a Compulsory License, a substantial amount must be for the domestic market. So either we ignore that or amend the TRIPs Agreement - art. 31(f) - so that governments can issue a compulsory license and receive those drugs without impinging on the provisions of the TRIPs Agreement. So the proposal of the EC is to have an effective interpretation of the TRIPs Agreement using art. 30 and/or go for an amendment to the article 31 (f).²³⁷

The US came out with a position paper that talked about going into effective interpretation of the issuance of compulsory licenses (art. 30) and suggested a moratorium for those countries that are in need from being taken to the Dispute Settlement Body. This is argued as being faster and less cumbersome.

Then, the developing countries and the Africa Group came up with a statement, where they said: It does not really matter how we are going to bell the cat. The main purpose is to help those states, which do not have the manufacturing capacity to meet their public health concerns - whether we issue it under article 30 or 31 (f) or through issue of a CL - or a combination of the three, is not really material. What we want is to be able to take concrete action on what our Ministers tasked us to do before the end of 2002.

The offer from the US on 'moratoriums' are usually time-bound and could be a short-term solution to a problem. Whereas what people are looking for is the long term and durable solution. Also, the offer from the US and EC and its members states have certain pre-conditions. For them to be able to meet these amendments and interpretations, there must be an understanding that mechanisms would be put into place whereby there would be no re-exporting the drugs manufactured under such arrangements to developed country markets. So some kind of guarantee is one of their main concerns.

The Africa group and developing countries are saying they do not want a situation where we come up with a solution to this problem but that solution is so cumbersome - with pre-conditions and conditions - that it might make it even more difficult to implement it than

²³⁷ Chairperson Of The Trips Council, Ambassador Boniface Chidyausiku Of Zimbabwe - Operationalising Doha Declaration On Trips And Public Health - South Bulletin 31. http://www.southcentre.org/info/southbulletin/bulletin31/bulletin31-04.htm#P192_41150

the current provisions in the TRIPs Agreement. So they want something that is workable, that does not have to impinge on their flexibility and ability to make use of what is available under the TRIPs Agreement. Thus, it is an area that people need to look into. The EC says it is a 'conceptual' paper they have submitted and are willing to discuss and come up with further elaboration or dialogue on these issues so as to put into concrete results what the Ministers have directed us to do.

After almost a year of discussion and negotiation, the TRIPs Council considered a draft decision at the end of December 2002. The draft received very wide support. But there was no consensus and at the time of writing the issue remains unresolved.

The 16 December 2002 draft takes the form of a waiver. It would allow countries that can make drugs to export drugs made under compulsory licence to countries that cannot manufacture them. The waiver would last until the TRIPs Agreement is amended. It would include provisions on transparency (which would give a patent owner some opportunity to react by offering a lower price), and special packaging and other methods to avoid the medicines being diverted to rich-country markets. An annex would describe what a country needs to do in order to declare itself unable to make the pharmaceuticals domestically. And over 20 developed countries would announce that they would not import under this decision.

The draft decision refers to drugs needed to address the public health problems recognized in Paragraph 1 of the original Declaration that ministers issued in Doha. This says: "We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics."

Almost all members said that in the spirit of compromise they could join a consensus supporting the 16 December 2002 draft, even though most of them felt the text was far from ideal.

Developing countries had various concerns, mainly about what they considered to be burdensome conditions, such as on transparency and preventing the medicines being diverted to the wrong markets. Developed countries were concerned that the decision did not go far enough in preventing the medicines being diverted to the wrong markets. Some said they would have preferred a different legal route.

During the drafting of its implementing text, the U.S. Trade Representative (USTR) Mr. Robert Zoellick became the only member of the WTO (reportedly under direct White

House pressure) to prevent the execution of the deal in its stated form.²³⁸ Although he had already signed his name to the Doha Declaration, the USTR would only agree to allow the implementation if most developing countries with manufacturing capacity were excluded from exporting and if complex legal mechanisms were constructed that would effectively prevent any least developed country from actually being able to import generic medicines; it would also limit any sort of importation to a short list of diseases for which there are currently no drugs or only old medicines off patent.²³⁹ The revised deal would effectively secure the continuing global drug price monopoly for the U.S. industry. (this will be deliberate in the next chapter) The industry ties were not covert--at the World Economic Forum in Davos, the Pfizer Corporation announced to the business press that it had taken over the negotiating seat from the USTR and was directly negotiating with the WTO council.²⁴⁰¹⁰ The talks on implementation were deadlocked as Pfizer and other companies intervened.

Further attempts to break the deadlock took place in January and February 2003, but they failed. Since then, discussions have taken place outside the WTO.

The issue remained on the TRIPs Council's agenda, and at the 4–5 June 2003 meeting, the chairperson concluded that he intended to remain in close contact with delegations, with a view to resuming consultations as soon as developments show that this would be useful. He urged delegations to continue to dialogue with each other, and to look for ways of resolving the final problems in the text of 16 December 2002. He stressed the desirability of finding a multilateral solution before the Cancun Ministerial Conference, preferably in time for the 24 July General Council meeting, when the TRIPs Council, like other subsidiary bodies, was expected to report, before the Ministerial Conference.²⁴¹

7.2 “Paragraph 7” Issue

Paragraph 7 of the Doha Declaration says: “We agree that the least-developed country members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPs Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed

²³⁸ Elliott, L. & C. Denny. US wrecks cheap drugs deal. Guardian UK, 21 December 2002. <http://www.guardian.co.uk/international/story/0,3604,864071,00.html>

²³⁹ Doctors Without Borders. Reneging on Doha. Briefing Paper: <http://www.accessmed-msf.org/documents/renegingondoha.pdf>

²⁴⁰ Forbes. Pfizer's McKinnell says drug patent talks progress. 28 January 2003.

²⁴¹ Trips and public health: the situation before Cancun Trips: Doha Declaration Paragraph 6 http://www.wto.org/english/tratop_e/TRIPs_e/health_background_e.htm

country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPs Agreement. We instruct the Council for TRIPs to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPs Agreement”.

However, originally, the LDCs were given transition period of 1995-2006 for providing patent protection. To extend that period from 2006 to 2016, a decision by the Council is needed to operationalise the Declaration. The LDCs asked for a clarification of the para 7 of the Ministerial Declaration in terms of what it means in reality. For instance, countries, which have not yet made any commitments with respect to Exclusive Marketing Rights (EMRs) and mail-box provisions, would they continue to be free from such restrictions after 2006? There is need for further consultations on this, as it is not explicitly spelt out in the Doha Ministerial Declaration.

The WTO council responsible for intellectual property, on 27 June 2002, approved a decision extending until 2016 the transition period during which least-developed countries (LDCs) do not have to provide patent protection for pharmaceuticals. The Council for TRIPs also approved a waiver that would exempt least-developed countries from having to provide exclusive marketing rights for any new drugs in the period when they do not provide patent protection. The TRIPs Agreement allows developing countries extra periods to delay providing patent protection for pharmaceuticals. But countries making use of the extra period still have to allow inventors to submit patent applications during the period (Article 70.8, sometimes called the “mailbox” provision). If a country’s health authority then approves a new drug for sale, the patent applicant has to be given exclusive marketing rights for five years even though there is no patent (Art.70.9). The waiver exempts least developed countries from having to give these exclusive marketing rights.

“I am pleased that WTO members have acted promptly to implement this important part of the Doha Declaration on TRIPs and public health, and have seen fit to go beyond the strict reading of that Declaration by also approving a draft waiver on exclusive marketing rights,” said WTO Director-General Mike Moore.²⁴²

²⁴² WTO NEWS: 2002 PRESS RELEASES, Press/301,28 June 2002,INTELLECTUAL PROPERTY: TRIPs AND PUBLIC HEALTH, http://www.wto.org/english/news_e/pres02_e/pr301_e.htm

8. Subsequent development of Doha

After Doha Declaration, the situations seems developing to the side favoring developing countries, however, since the paragraph 6 issue remains unresolved, the big countries takes every chance to safeguard and enlarge their superiority by seeking further restrictions on developing countries.

At the 55th WHO Assembly held 13-18 May 2002, developing countries wanted to address the issue and allow the world's top health institution to discuss the health implications of the USTR's "revised" proposal. With regards to resolve "paragraph 6" issue, in a small group of five negotiating countries, the US has been seeking further provisions on a deal nearly agreed to in 2002, known as the "December 16" or "Motta text."

On top of the Motta text, US demands apparently include:

Restricting the solution to "humanitarian use," a vague clause that may disqualify normal generic production;

An "opt-out" clause, that will further hinder the economic viability of the solution;

Heavier burdens on suppliers to change the packaging of products made under this system; and

A "review mechanism," to monitor usage of the system and diversion of generics back into wealthy markets; this is a redundant layer of bureaucracy that can easily be manipulated to pressure countries out of the system.

At the top of a long list of ironies is the fact that the USTR's list of diseases for which generic drugs can be produced excludes the severe acute respiratory syndrome (SARS)--which, of course, didn't exist publicly until after the USTR had produced his list. This highlights the importance of keeping the Doha Declaration in its original form--whereby country health ministries can tackle an epidemic as it occurs rather than waiting for their populations to die and spread the disease to wealthier nations which have the generic manufacturing capacity to actually control it (and this is particularly important in the case of SARS, for which genome components and potential therapeutic agents are already being patented,²⁴³). The USTR's revised proposal would also produce mechanisms that would prevent countries like Korea and the Philippines from producing drugs (let alone Canada

²⁴³ McGee, B. Hong Kong, Canada, US scientists file SARS patents. Bloomberg News, 5 May 2003.

and China, hit by SARS)--effectively preventing their industries from being able to build themselves to a level that would offer competition to the U.S. industry--because they supposedly have some form of manufacturing capacity. The problem is that public health authorities need the ability to produce drugs cheaply and quickly; neither Korean nor Pilipino production facilities are adequate to produce drugs for many syndromes, and as a result the hundreds of chronic myeloid leukemia patients in South Korea protesting for access to the drug Glivec (produced by Novartis and sold at OECD prices in that country) are simply being told to go home and die.²⁴⁴ Meanwhile, the USTR is circumventing the WTO altogether by proposing bilateral trade Agreements with a number of countries who are bullied into producing strong patent laws in excess of those agreed to under the TRIPs Agreement, in exchange for bribing the wealthier sectors of those countries with tariff and export deals.²⁴⁵

Taken together, the effects of these provisions would be to discourage countries from using the system at all, and to heavily restrict generic production. The Motta text is already extremely cumbersome and does not provide an economic incentive to export generics. It seems that the US is pushing for additional limitations to the Motta text, which would be included in an accompanying "Chairman's Text".²⁴⁶

On the contrary, both the WHO and intellectual property experts have recommended a much simpler, workable, and economically viable solution: allowing generic production for export as a limited exception to a patent right. This is the solution the NGOs also favor.

"We recommend the WTO start with a clean slate," said Michael Bailey of Oxfam. "WTO Members should take the time to find a real solution. Surely it is more important to get medicines to the most vulnerable populations, than simply to have a deal cut by Cancun."²⁴⁷

One year later, the Regional Consultation on the WTO/TRIPs Agreement and Access to Medicines: Appropriate Policy Responses was held in Colombo on 17-19 April 2003. It was organized jointly by the Health Action International - Asia Pacific, the Third World Network, the Sri Lanka Ministry of Health, and the World Health Organization (South East Asia Regional Office).²⁴⁸ Among the 70 participants were senior health and trade officials and representatives of health-related NGOs and social movements from 18 Asian and

²⁴⁴ <http://www.cptech.org/ip/health/gleevec/>

²⁴⁵ Sanjay Basu.op.cit.

²⁴⁶ US seeks further restrictions on generic medicines for developing countries http://www.oxfam.org/eng/pr030825_TRIPs_health.htm, 25 August 2003,

²⁴⁷ *ibid.*

²⁴⁸ Post Doha Debate on TRIPs and Public Health.op.cit.

Pacific countries, as well as international experts and resource persons. Participants at the Regional Consultation (or workshop) gathered together to analyze the effects of the TRIPs Agreement on access to medicines, and to discuss appropriate policy and legal responses at national, regional and international levels. Taking the reports of the discussion groups into account, the workshop has come up with the following recommendations:

Each country in the region should give the highest priority to formulating appropriate policies, regarding patents and access to medicines, In so doing, each country should maximize the use of the rights to protect and promote the health of its citizens and to provide affordable medicines for all;

In particular, policy makers in each country should take the a number of steps:

Such as: limit the scope of approval of patent applications to patents, examine existing legislation and administrative process regarding patents and prices of medicine laws and introduce provisions that maximize the rights of the country in order to effect importation or production of medicines. And establishing institutions and institutional arrangements for coordination between different government departments and also establishing consultative mechanisms with NGOs, social movements and private sector so that a coordinated national response can be effectively made;

NGOs and social movements should take steps to monitor the developments in TRIPs the national status and situation regarding patents and medicines, and to communicate to the policy makers. A strengthened system of information sharing, communications and research should be established and also encouraged generic drug producers to strengthen their activities.²⁴⁹

²⁴⁹ Regional Consultation on the WTO/Trips Agreement and Access to Medicines: Appropriate Policy Responses, Third World Network, April 17-19, 2003

9. Case of China

9.1 Drug Bill in China

China is also a country, which suffers gravity epidemic situation of aids. The number of infectious cases is increasing fast. According to the estimate from experts, since 1985 the year in which the first case was found in China, until the end of 2002, the number of infectious people is amount to one million. It can be imagined that the number will reach 10 million in 2010, if no effective measures are adopted. In addition, in China, the aids sufferer has to bear 75.5% of the medical treatment at his own expenses, 10.3% at public expenses and 7.9% from insurance.

At present, among the infectious and sufferers, 70% are under the poverty line, who cannot bear the costly medical fee and test fee. According to a staff in Beijing You'an hospital, the outpatient's fee for aids is charged 40 RMB, the blood test fee is 50 RMB. The costly imported drugs for medical treatment however, is charged 10 thousand US dollars per year before the depreciation. The internal drugs for common treatment costs 3000 RMB per month; only treatment for virus will need 1680 RMB, not to say various other treatments. The prevailing treatment for aids- cocktail treatment -costs 15 thousand dollars per year in developed countries, 10 thousand dollars in developing countries. After the hard negotiation between the government and the abroad pharmaceutical companies, the price for cocktail treatment went down to 3000-4000 dollars per year. However even under this condition, those infected who come from countryside can't burden that much. In China how many people are able to receive cocktail treatment on earth? Only around 100 people can afford this treatment consistently in China, said one official of sanitation department, in a press conference in September 2002.

Ye lei, the high program official of UN Children Fund once said when he was interviewed by a reporter, "WTO sets rules for the "emergency", according to this specific rule, if China has the developing level of 800-1000 GDP per person, the cocktail treatment is supposed to cut down 90% accordingly. Even in this price, the majority of Chinese sufferers cannot afford it yet."²⁵⁰

²⁵⁰ All the data from the journal "WTO Economy Guidance", China.2002-2003.

9.2 Pharmaceutical Industry in China

The above striking facts are not unfamiliar to us. In chapter 2, we noted that many developing countries are in a similar situation as China, - a large number of the patients and shortage of medicine. The high price of the medicine prevents people from obtaining sufficient treatment. Unlike some countries, China has big potential capabilities for manufacturing of pharmaceuticals.

China's modern pharmaceutical industry was built, following the establishment of PRC in 1949,²⁵¹ on the basis of imitating new drugs developed in the west. The government, from the very beginning, stressed the importance of providing low-cost medicines to people, therefore invested heavily in chemistry research. This has put China in an advantageous position half a century later as a major supplier of API (international active pharmaceutical ingredient) with a large pool of pharmaceutical chemistry experience and talents.

China began a massive transformation of its state-owned enterprises and financial systems in the past decade in preparation for WTO entry. Many of the former state-owned enterprises as well as private enterprises became public companies in recent years and therefore these companies significantly improved their financial strength. As a result of this development, many major Chinese API manufacturers are now relatively well funded to take on major facility upgrade, R&D and international market development projects.

In the past two decades, China has emerged as a major player in the API market amid a growing trend of multinational pharmaceutical companies in API outsourcing. The growth of international generic companies, which traditionally rely on outsourcing for their raw materials and on cost efficiency, further elevates the importance of China as a low cost and long-term API supply source. According to China Association of Pharmaceutical Chemicals Industry, China's export volume and value of APIs in 2000 reached 106,500 tons and RMB 12,350 million (US\$1,490 million), up by 0.45% and 10.0% respectively compared with 1999. The export accounted for 48.4% of the total API output in 2000 by the country.²⁵²

While many domestic Chinese industries are expected to face tough challenges and competition from foreign companies following the anticipated WTO entry by China, experts predict that the API manufacturers in China will stand to gain international market shares in the post-WTO era.

²⁵¹ SOURCING FROM CHINA, <http://www.pharmlinkChina.com/Sourcing3.htm>

²⁵² Ibid.

What this report tells us? Certainly China has the ability to imitate drugs and to supply international active pharmaceutical ingredient. But this is only limited to the ingredient. This can't solve the medicine short disaster. Most New and efficient medicine are all under the patent protection regulated by international treaties and domestic legislation. And unlike the other developing countries, China has a relatively good reputation in the legislation for the protection of medicine.

9.3 Pharmaceutical Protection in China

Under the current regime in China, pharmaceutical makers can protect their products with a varied arsenal of laws and regulations, including intellectual property laws, and pharmaceutical protection laws and regulations. Among these are the 1995 Trade Secrets Law, the 2000 Patent Law, and the 1993 Pharmaceutical Protection Act. The Act specifically targets foreign pharmaceuticals and related technology. In addition to taking advantage of protective measures, pharmaceutical companies must abide by specific pharmaceutical industry regulations.²⁵³

9.3.1 Patent Law

In general, under the frequently pressure for USA, from the early 1993, China's new patent law has given the patent protection for pharmaceutical products for 20 years. And the administrative regulation for protecting foreign pharmaceutical products has also came out at that time. It had to be noted that China became a WTO member in 2001 and the TRIPs shall come into force for China at the end of 2002. However China was forced by the US to amend its patent legislations as early as in 1992 and establish the mailbox system to retrospectively protect foreign patents obtained during 1984 and 1993.

China's original Patent Law took effect in 1985 and was first amended in 1992. The 1992 law treats pharmaceuticals like any other patentable item. Nevertheless, the categories "methods of treatment of diseases" and "scientific discoveries" are still prohibited from patent protection. (1992 Patent Law, Article 25.) These exceptions have not been invoked against pharmaceutical product patents, and they are interpreted as prohibiting a monopoly on techniques of surgery or other patient treatment, or scientific experiments, not on the

²⁵³ "Protection of Pharmaceuticals in China", Published in National Law Journal, September 1999, by Laura W. Young <http://www.wangandwang.com/pharmic.htm>

manufacture of pharmaceuticals that result from scientific discovery or that may be used as part of a patient treatment protocol.

The Patent Law has been revised so that it is generally in conformity with TRIPs, granting a twenty year term for patent of inventions, allowing review of patent rejections, and other administrative provisions (Patent Law, 1992 Articles 45, and 43). However, contrary to the requirements of TRIPs there is no judicial level of review for Patent appellate decisions. The final level of appeal is the Patent Reexamination Board. (Patent Law, 1992 Article 43.)

One aspect of China's 1992 patent law, which may cause concern, is the compulsory license provision. These allow any "qualified" entity to apply for a non-exclusive, non-transferable, compulsory license to a patented drug or medicine, in the event of a national emergency, or upon showing that the entity has tried, but been unable to obtain a license on "reasonable terms" within a "reasonable time period". (Patent Law, 1992 Article 51, 56.) Since then compulsory license provisions already meet with the requirements of TRIPs, they are not to be changed in 2000 law. The Patent Office has yet to actually grant a compulsory license and the system remains untested. It appears that enough foreign pharmaceuticals have entered the Chinese market so that no distributors have felt the need to make such an application.

Confronted by the TRIPs agreement, the Standing Committee of the 9th People's Congress amended the 1984 Patent Law for the second time on 25th August 2000. (Patent Law of the People's Republic of China, amended by the Decision of Decision Regarding the Revision of the Patent Law of the People's Republic of China, adopted at the 17th Session of the Standing Committee of the ninth National People's Congress on August 25th, 2000. In accordance with TRIPs' requirements, the amended law stipulates that for example, "offering for sale" has been included in the exclusive rights of a patent holder. A third party is prohibited from offering the patented products for sale without the authorization of the patent holder. (Id, Article 11) The 2000 Amendment also explicitly provides that although the invention belongs to the Unit (danwei) when it is invented during the work of the inventor, the inventor must be remunerated. (Id, Article 6) The 2000 Amendment also provides detailed methods of calculating compensation. Id, Article 60 Furthermore, it admits that the decisions of the SPB may be subjected to judicial review. Id, Article 41

When patent holders find patents are being or to be infringed, they can ask the courts to stop the infringement and help safeguard their rights before bringing up a suit. (Id, Article

61) Before the amendment, China had no such practice. The amended law removes those restrictive provisions that patent rights be classified as holding or owning rights according to the ownerships of firms and institutions. It stipulates that State-owned and non-state enterprises or institutions enjoy the same treatment in obtaining patent ownership rights. This aims to spur state-owned firms to get well prepared for fierce international competitions before China enters into WTO. Previously, State-owned entities only had patent holding rights.

To help curb the increasing numbers of cases of gang infringement and repeated infringements, the new Patent Law authorizes patent administrations to crack down on patent counterfeit activities, confiscate illegal income and fine patent violators. (Id,Article 58) The move aims to authorize judicial departments to better fight patent infringement. The amended law has greatly simplified the procedures of patent application, check-up and transfer. It also cuts the red-tapes for domestic units or individuals to apply for patent protection in foreign countries.

All these amendments are aimed at being compatible with the trips Agreement and creating legal environments for entering WTO.

9.3.2 Pharmaceutical Administrative Protection Act

The Pharmaceuticals Administrative Protection Act was enacted in 1993 to address the needs of foreign pharmaceutical companies whose medicines had been released before China's Patent Law was first revised, and that were thus ineligible to apply for patent protection under Chinese law, or who wanted monopoly status immediately before the probably lengthy patent review process could be concluded. The Act thus grants a type of substitute patent protection for medicines that are not, or are not yet, patented in China. A foreign pharmaceutical company must register with the State Pharmaceutical Administration of China ("SPAC"). The applicant, according to the law, must hire as its agent the Hua Ke Medical and Pharmaceutical Intellectual Property Consulting Center to submit the application to the SPAC for protection. (The Act, Articles 6 and 7.) Protection is granted upon issuance of a Certificate of Administrative Protection, which will then also be published. The certificate grants a monopoly status for seven and one half years. (The Act, Article 13.)

In order to qualify for the certificate, the pharmaceutical product must satisfy several conditions:

They must not have been patented in China prior to January 1, 1993. They must have monopoly status in their nation of origin from the period of January 1, 1986 to January 1, 1993. This time period is the seven years immediately preceding the revision of China's patent law. They cannot have been introduced into the market before the approval of their Certificate. (The Act, Article 5.) In addition, the applicant must be a national of a nation which has in force a treaty granting reciprocity on such pharmaceutical protection. (The Act, Article 3.)

The certificate can be opposed by a third party with evidence that the pharmaceutical product does not qualify for certification. (The Act, Article 16.) If a certificate holder's monopoly is infringed, the certificate holder can bring an action with the SPAC, and enjoin the third party from manufacturing and selling the infringing medicines. Since all manufacture and sales of drugs must be pursuant to a permit issued by SPAC, and the SPAC has the authority to revoke all permits, it is relatively simple in theory to stop an infringer. (The Act, Article 19.) The holder of a certificate can also file a civil action in court against the infringer of the certificate. According to the SPAC, there have been fewer than 100 certificates issued under the Rules. There have been more than 100 applications, some of which are still pending.

9.3. 3 Rules on Imported Medicines

Before any pharmaceutical product can be distributed in China, it must obtain a distribution permit pursuant to China's Pharmaceutical Administration Law. (The Act, Article 9.) In effect since 1984, this law governs all activities related to manufacture or distribution of medicines and drugs. The Law provides administrative penalties, including monetary fines of RMB20,000 for importing medicines without prior inspection, or trial of new medicines without prior approval, etc., or RMB 30,000 for other failures such as failing to mark the expiration date or otherwise properly label a medicine, etc. The Law also provides for a variety of levels of penalties such as confiscation of profits or revocation of permits for producing or selling fraudulent medicine, poor quality medicine or medicines that have not been approved for a permit.

9.4 Trips obligation on China

While Chinese pharmaceutical companies have very strong may be the strongest copy capability for drugs among developing countries. But since China has entered the gate of WTO since 2002, China is under the obligation of TRIPs Agreement. The TRIPs

Agreement will affect Chinese pharmaceutical industry in several ways, but among them, the most impact concerns pharmaceutical patent protection.

During the negotiation of TRIPs council relating the TRIPs Agreement and public health, China stood at the developing countries' side all the time. The paragraph 6 in Doha Declaration is directed to those who have insufficient or no pharmaceutical capability to use the compulsory license for public health need. Although China does not belong to them, the outcome of negotiation regarding to this article will have great influence on China.

9.5 Conclusion on China

Actually, the 1992 Amendment of Patent Law, has already reached the protection level of TRIPs. In addition, the pharmaceutical administrative protection regime protects foreign pharmaceutical patents granted between 1984 and 1993. So what China needs to consider now therefore is not how to comply with the TRIPs, but how to make use of the flexibility of the TRIPs to meet the public health concern is the big challenge to Chinese government. China has not made full use of the flexibility provisions in the TRIPs. Because Chinese scholars are eager to seek advanced standards of patent protection advocated by developed countries. And neglect the current specific situation in their own country. In the case of ADIS, until now, China has lagged behind developing-world nations -- among them India, South Africa and Brazil -- in challenging the world's pharmaceutical giants to cut prices for medicines to treat HIV, the virus that causes AIDS.²⁵⁴ This is the main point that why in China a Chinese patient with Aids is amount to be sentenced execution. But this situation is going to be changed. The majority of Chinese AIDS patients may soon be able to use a domestic version of a drug cocktail to treat their illness as domestic pharmaceutical firms begin to produce cheap, generic anti-HIV medicines.

Last year, a little-known private company, Shanghai Desano Biopharmaceutical Co., applied to the country's State Drug Administration to generically produce two anti-HIV drugs known as ddI and d4T and plans to apply to make AZT, the first medicine approved to treat the HIV infection. And the state-owned Northeast General Pharmaceutical Factory says it has also applied to the government to make HIV drugs for domestic sale.²⁵⁵ But the result

²⁵⁴ Leslie Chang, Staff Reporter of The Wall Street Journal, *Wall Street Journal* - November 15, 2001, <http://www.aegis.com/news/wsj/2001/WJ011103.html>.

²⁵⁵ The result has not come out.

Unlike another AIDS drug, AZT, which was approved for domestic production by a different company last month, ddI is still under patent protection in China. Through changing the way a medicine is combined or other details of preparation, the applications don't violate the protections the medicines enjoy in China, explains Shanghai Desano's Mr. Li. "We are using a different formulation," said Amy Guo, general manager for the Beijing subsidiary of Shanghai Desano, which already manufactures the raw materials for AIDS drugs for export. "They use tablets, we use powder."²⁵⁶

And Chinese authorities have approved domestic production of this drug. The approval for ddI came "earlier than we expected," said Ms. Guo, adding the company hopes that applications to produce two other AIDS drugs would soon be approved. Together, that would allow patients in China to obtain a year's supply of the cocktail therapy for between \$400 and \$600, said Ms. Guo. The big pharmaceutical companies, after responding to pressure within and outside China to lower prices, currently offer the cocktail combination in China for about \$3,500 a year.²⁵⁷ We expect that moves could dramatically change the way China treats what has become one of its biggest health epidemics.

This case shows that China is looking for a way to balance the trips obligation and public health concern from legislation and in practice.

²⁵⁶ China Approves Production Of Generic AIDS Drug, Wall Street Journal - September 16, 2002, Leslie Chang, Staff Reporter of The Wall Street Journal

²⁵⁷ China Approves Production Of Generic AIDS Drug, Wall Street Journal - September 16, 2002, Leslie Chang, Staff Reporter of The Wall Street Journal

10 Conclusion and Recommendations

Despite under a long time debate, the issue of the pharmaceutical patent and the access to medicine is far from termination. In the battle of various conflicting interested group, each compromise may save thousands of lives, and may also sacrifice much more lives. In any case, however, we must bear in mind the following conclusions.

On the one hand, health is not only a matter concerning ones life. Health is also at the center of the development challenge, not only because health is the outcome we want from economic development but because health is one of the essential inputs into economic development.²⁵⁸ When poor countries are besieged by diseases, they also cannot achieve economic progress. So health has to be at the very core of a global strategy to fight poverty. But the fact is, we find that millions of people die every year because of preventable or treatable diseases because they are simply too poor to gain access to the life-saving health interventions. And one of the main factors contributing to this tragedy is the patent protection for pharmaceuticals, which undoubtedly results in the high price for medicine.

On the other hand, intellectual property rights are legal mechanisms whose ultimate goal is to provide incentives to private industry to make products or processes available to the public. But, as Health Action International (HAI) Speaker: Zafar Mirza holds that: "A patent is not an absolute right nor an end in itself; public health is an end in itself. Public health goals and commercial interests of companies sometimes coincide and sometimes diverge. They are not identical. When they conflict, governments should always have the ability to choose public health as a legitimate reason for limiting or conditioning commercial interests and rights."²⁵⁹

Consequently, pharmaceutical products cannot be regarded as commodities in the same sense as cars, television sets, or electrical components. Vital public-health interests are at stake. This is why ring-fenced safeguards for public health should be seen as an integral part of the TRIPs Agreement. Developing countries themselves need to ensure that national legislation makes full use of the space, albeit limited, provided by existing safeguards. This means establishing, in national legislation, clear criteria for granting compulsory licences on public-health grounds. More generally, developing countries have to ensure that they

²⁵⁸ Report by Harvard economist Professor Jeffrey D. Sachs, the recent World Health Assembly meeting in Geneva.

²⁵⁹ WTO Agreement and Public Health. op.cit.

develop the expertise and institutions needed to defend the public health of their citizens when disputes arise at the WTO. This means investing more resources in developing such capacity and, especially for the poorest countries, supporting national efforts through international assistance.²⁶⁰

10.1 Recommendations at the Developing Countries' Level

In the battle to resist all kinds of diseases, the developing countries and LDCs are always in the most difficult position, which make those countries have to take more careful policies to obtain their interesting and be compliance with the obligation under international treaties. The general advises are as follows.²⁶¹

- Public health concerns should be considered when implementing the TRIPs Agreement. Member States should provide limited exceptions to the patent holder's exclusive rights in their domestic laws. The issue of compulsory licenses and parallel imports should be allowed.
- Member countries should make the fullest use of the periods of transition for incorporating the necessary provisions into their domestic laws.
- Member countries should undertake necessary measures to monitor the impact of the Agreement on access to essential drugs.²⁶²

In this perspective, South Africa can be referred to as a good case in terms of effective domestic measures.²⁶³

1 Enact a Medicines and Related Substances Control Amendment Act

2 Set up the Pricing Committee whose job will include the gathering of pharmaceutical intelligence and advising the Minister on a transparent pricing system for medicines

3 Activate the system of generic substitution, which will have major benefits for consumers in the private health care sector -- and especially medical schemes.

²⁶⁰ Patents, TRIPs & Public Health.op.cit.

²⁶¹ Pharmaceuticals In The Trade Related Aspects Of Intellectual Property Rights (Trips) Agreement Of The World Trade Organization (WTO).op.cit.

²⁶² BS/lvvg/TE/17/04/2000/WTO-TRIPs Agreement Rev. 25 July 2000

²⁶³ Toby Kasper£¬DEVELOPING COUNTRIES MUST STAND FIRM ON PEOPLE OVER PATENTS£¬SOUTH BULLETIN 11, <http://www.southcentre.org/info/southbulletin/bulletin11/bulletin11web-02.htm>

Beside, the developing countries also should:

4. Develop effective national drug policies and promote the adoption of essential drug lists

Health Action International (HAI) Speaker: Zafar Mirza globalisation and access to drugs

A noteworthy study of international drug pricing done in the 1980s showed that the presence of successful national drug policies was a major factor in lowering drug prices. Furthermore, countries that adopt essential drug lists will have a mechanism for determining what drugs are needed according to the disease patterns in their own countries and can base approvals and/or government procurement based on need, efficacy and price.

5. Use compulsory licenses to achieve public health goals

Under TRIPs, member countries have the right to issue compulsory licenses on patents based on various public interest grounds (e.g., making essential drugs available at lower cost), subject to several safeguards and limitations.

6. Permit parallel imports of pharmaceuticals

Global free trade should include the right to shop globally for the best prices. Parallel imports are particularly important for smaller economies that suffer from inadequate competition. Where allowed, parallel imports have shown to be effective in lowering drug prices. A study of the price of HIV drugs in the United Kingdom shows that parallel imports offer an average saving of 41percent from the list price and a 30 percent saving from the best contract price.

7.Promote the production and use of generic drugs

Bioequivalence testing, allowed close to the expiration of a patented drug (e.g. six months), does not violate a patent. Preventing testing until the end of the patent has the same effect as granting an extension on that patent by forcing a delay in introducing a generic, which means extended higher prices for consumers.

8.Promote access to drug information

IPP in national legislation or through international trade Agreements should not be used to unjustifiably maintain corporate control over drug information. Specifically, access to clinical trial data is necessary for the public and health care professionals to make rational decisions about drugs.

9. Use the differential pricing

Differential pricing has been defined as the adaptation, in some measure, of prices to the purchasing power of consumers in different countries.²⁶⁴ This could mean, for example, pricing HIV drugs at lower rates for developing countries but maintaining prices in developed country markets. The logic behind differential pricing is that higher prices can be shared in wealthy markets that can afford them, while letting poorer countries enjoy lower prices. Consequently, effective strategies to maintain higher prices in wealthy markets so that developing countries can benefit from cheaper drugs will have to be considered as part of any differential pricing strategy - possibly through some form of market segmentation. There are many ways in which market segmentation might be achieved. Where treatments are protected by IPRs, drug licensing Agreements with geographical restrictions could be used so that cheaper drugs do not leak back to wealthier markets.²⁶⁵

10.2 Recommendations at the Developed Countries' Level

Developed countries, especially United States, should cease its bi-lateral attempts to discourage developing countries from using compulsory licensing and parallel importing to address vital public health concerns. Furthermore to cut down the price of essential drugs and assist developing countries to establish a international system for the drugs supply.

10.3 Recommendations At the International Level

Since developing countries need an appropriate system of intellectual property protection but the TRIPs Agreement does not seem to have been designed as a serious attempt to meet their needs.²⁶⁶

The TRIPs Council should consider recommending significant changes to the TRIPs Agreement:

To ease the obligations imposed on developing countries - including lengthening of transitional periods and the introduction of additional special and differential provisions.

²⁶⁴ Watal, Jayashree, "Workshop on differential pricing and financing of essential drugs", background note prepared by Jayashree Watal, consultant to the WTO secretariat, p. 11

²⁶⁵ Ibid.p18.

²⁶⁶ Max van den Berg, Vice-President for Foreign Affairs and International Trade, PES Group.op.cit.

To strengthen those provisions designed to promote the transfer and dissemination of knowledge and to achieve a balance between the rights of patent holders and the wider public interest.

The solution to the problems of countries with little or no pharmaceutical manufacturing capacity must fully respect the spirit of the Doha Declaration, by ensuring that the decisions needed to tackle public health problems should as far as possible be in the hands of the public authorities of the country concerned. The solution must also minimise the risk of bureaucratic delays which could put at risk a timely response to public health crises. The solution which best meets these criteria is an authoritative interpretation of Article 30 of TRIPs, making clear that production for export in response to public health problems such as are covered by the Doha Declaration is permitted as an exception to patent holders' rights. While there are differing views among international patent lawyers on the legal arguments involved, there would seem to be no fundamental legal obstacles to an Article 30 solution. While the European Commission, on a number of grounds, favours Article 31, it should be prepared to respond helpfully to arguments from developing countries for Article 30.

Furthermore, the WTO is only eight years old. Countries are still in the process of joining, including many developing countries. Countries should have impartial technical advice about coming into WTO compliance with TRIPs. The number of disputes involving public health issues is still limited. In such cases, the WTO needs to have impartial advice from public health experts.²⁶⁷

Note: just learned from website http://www.wto.org/english/news_e/pres03_e/pr350_e.htm

WTO member governments broke their deadlock over intellectual property protection and public health today (30 August 2003). They agreed on legal changes that will make it easier for poorer countries to import cheaper generics made under compulsory licensing if they are unable to manufacture the medicines themselves.

This 30 August 2003 Agreement allows any member country to export pharmaceutical products made under compulsory licences within the terms set out in the decision (text below). All WTO member countries are eligible to import under this decision, but 23

²⁶⁷ Health Action International (HAI) Speaker: Zafar Mirza globalisation and access to drugs.op.cit.

developed countries are listed in the decision as announcing voluntarily that they will not use the system to import.

A separate statement by General Council chairperson Carlos Pérez del Castillo, Uruguay's ambassador, is designed to provide comfort to those who feared that the decision might be abused and undermine patent protection. The statement (see below) describes members' "shared understanding" on how the decision is interpreted and implemented. It says the decision will be used in good faith in order to deal with public health problems and not for industrial or commercial policy objectives, and that issues such as preventing the medicines getting into the wrong hands are important.

A number of other countries announced separately that if they use the system it would only be for emergencies or extremely urgent situations. They are: Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey and United Arab Emirates

The decision covers patented products or products made using patented processes in the pharmaceutical sector, including active ingredients and diagnostic kits.

It is designed to address the public health problems recognized in Paragraph 1 of the Doha Declaration on TRIPS and Public Health, which says that WTO ministers "recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics."

The decision takes the form of an interim waiver, which allows countries producing generic copies of patented products under compulsory licences to export the products to eligible importing countries. The waiver would last until the WTO's intellectual property Agreement is amended.

The negotiations on the decision were conducted by the chairpersons of the TRIPS Council: Ambassador Eduardo Pérez Motta of Mexico (2002) and Ambassador Vanu Gopala Menon of Singapore (2003).

Supplement A

DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Adopted on 14 November 2001

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.
2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.
3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.
4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

(a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

(b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

(c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

(d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

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