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Title

THE EU AND WTO TRADE NEGOTIATIONS ON ACCESS
TO PHARMACEUTICALS TO DEVELOPING COUNTRIES:
FOCUS ON AFRICA

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Summary

Since the turn of the century, there has been increasingly desperate efforts by developing countries to improve access to affordable drugs to treat the major communicable diseases, notably HIV/AIDS, Malaria and Tuberculosis which are routinely and efficiently killing millions of people in Africa, Aids alone causing more than three million deaths a year. Aids in America and Western Europe hasn't been conquered, but it has been controlled. Why, then are we seeing the epidemic spin out of control in Africa? Why are the drugs capable of inhibiting HIV having no impact in the countries where the virus is now rampant? Put simply, the people that need the latest anti-retroviral drugs in Africa cannot afford them and the people that make them are driven by a hard-headed pursuit for profit.

The best available drugs are usually available only under patent, and therefore tend to be very expensive, particularly for poor countries. Hence the debate about how provisions in the WTO Agreement on intellectual property (TRIPS) can be used by developing countries to ensure access to affordable drugs. In Doha, the EU was playing an important role to broker an agreement, Governments agreed on a declaration which recognised the gravity of the public health problems in developing countries, especially those resulting from HIV/AIDS, Malaria, Tuberculosis and other epidemics. The Declaration recognises the right of each WTO Member to grant compulsory licensing. But what about those countries without manufacturing capacities?

I have equally looked at how the system of tiered pricing, would allow manufactures to offer the lowest possible prices to the poorest countries without jeopardising their profits in developed countries, sign voluntary licensing agreements to facilitate local production of medicines and ensure that developing countries benefit from technology transfer; increase capacities for local production of generic medicines through the development of laboratories, research centres and pharmaceutical industries, leading to effective competition on the national markets; exploiting the flexibility provided by TRIPS Agreement to obtain compulsory licensing, exhaustion regimes and other types of exceptions for resolving public health problems.

I have equally endeavoured to explore how the cautious optimism for a public policy-oriented perspective of TRIPS is having a place alongside the United States who support exclusivity of patent protection. I have analysed how Brazil, South Africa and Thailand have sorted out issues with the US with regard to parallel imports and compulsory licensing laws. My intention has been to investigate how the EU and WTO can find a durable and lasting solution to facilitate access to pharmaceuticals to the major communicable diseases which have made Africans to become endangered species.

Abbreviations

<abbreviation>	<explanation>
ACP	Africa Caribbean Pacific
EC	European Communities
EU	European Union
GATT	General Agreement on Tariffs and Trade
GSK	GlaxoSmithKline
IPRs	Intellectual Property Rights
NGO	Non Governmental Organisation
R&D	Research and Development
TRIPS	Trade Related-Aspects of Intellectual Property Rights
US FDA	United States Federal Act
WHO	World Health Organisation
WTO	World Trade Organisation

1 Introduction

The question of ensuring that developing countries have access to pharmaceuticals is quite simply a matter of life and death for many of their citizens. But how can they do so when those medicines are often under patent? For the World Trade Organisation (WTO) and indeed for the International system as a whole, this question has become a test of our ability, the ability of the multilateral system, to respond to proven need. From all points of view, they had better not fail this test. They have to reach an agreement on how to tackle this problem. That is why the European Union (EU) has taken the initiative to try to find a way through.

Since the turn of the century, with increasingly desperate efforts by developing countries to improve their access to affordable drugs to treat infectious diseases, notably HIV/AIDS, Tuberculosis and Malaria, which are routinely, efficiently, killing millions of people, AIDS alone causing more than three million deaths a year. In Southern African Countries, the infectious rate is as high as 20% of the population. In 2001, for example, Botswana had an infectious rate of 38.80%, Swaziland 33.40%, Zimbabwe 33.70%, Lesotho 31.00% and South Africa 20.10%.¹ By 2001, at least fifteen million Africans had died of AIDS and another 28.5 million in Sub Saharan Africa were living with the disease.² In the Central African Sub Region, Cameroon 11.80 % of the population is estimated to be living with HIV/AIDS as of 2001. AIDS, in America and Western Europe hasn't been conquered, but it has been controlled. Why, then are we seeing the epidemic spin out of control in the developing world? Why are the drugs capable of inhibiting HIV having no impact in the countries where the virus is now rampant? Put simply, the people that need the latest anti-retroviral drugs in Africa cannot afford them - and the people that make them are driven by a hard-headed pursuit for profit. In the United States, for example, drug treatment has quadrupled the median survival time for Americans diagnosed with AIDS from one to four years.³ In 2002, Tuberculosis accounted for 15% of the deaths and Malaria 22% in Africa. It would cost Sub-Saharan Countries between 9% and 67% of GDP to provide a cocktail of three anti-Aids drugs (triple combination therapy) to all people with HIV.⁴

The best available drugs are usually available only under patent, and therefore tend to be very expensive, particularly for poor countries. Hence the debate about how provisions in the WTO agreement on intellectual

¹ Joint United Nations Programme on HIV/AIDS, Report on Global HIV/AIDS Epidemic 124(2000) hereinafter UNAIDS Report.

² Press Release , World Bank, World Bank Steps Up Fight Against AIDS in Africa (Sept. 2000)

³ US Study Finds AIDS Patients Surviving Longer (Mar. 14, 2001), at <http://www.cnn.com/2001/Health/conditions/03/14/aids.survival.reut/index.html>

⁴ UNAIDS, 1997 FIGURES.

property (TRIPS) can be used by developing countries to ensure access to affordable drugs. In Doha⁵, the EU was playing an important role to broker an agreement, governments agreed on a declaration which recognised the gravity of the public health problems in developing countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics. The declaration recognises the right, in this context for each WTO member to grant compulsory licences. But what about those countries without manufacturing capacities? This provision⁶, however, helps only those countries that have the capacity to produce the required pharmaceuticals; it is practically worthless to those who don't-usually the poorest countries with the most severe public health problems. The WTO members therefore committed themselves to finding a solution for these countries before the end of 2002. Unfortunately, after long and intense negotiations, they failed. Because of the concerns about the disease to be covered, the U.S blocked a deal allowing some developing countries to bypass patents on certain drugs so they could import cheaper generic versions. This proposal had the support of nearly all the other WTO members, including the EU, Japan and Canada. Failure to meet the deadline has now made it much more harder to successfully tackle the other complex issues in the Doha Development Agenda.

In developing countries, little or no infrastructure is available for the population at large, particularly concerning healthcare services. In addition, cultural differences may also exist regarding traditions, family or community structures and moral values. Many poor and highly aid-dependent countries are redefining their policies and systems and moving towards a sector-wide approach, setting broad policy frameworks and establishing long-term partnerships with donors. However, this is a long-term process, and there is an urgent need to address the increasing spread and impact of major communicable diseases in the developing world.

The problems multiplied, and all the while, the concerns of the global pharmaceutical companies that this had the potential to weaken their research into new medicines became even more strident. In the EU view, and most other players, 'these concerns, if not unfounded in some cases, were exaggerated. And if the poor countries are unable in any case to buy the medicines, where are the lost profits for the industry, what is needed is a multilateral, binding solution: one which provides the necessary legal certainty for both industry and developing countries'.⁷

In the view of European Commissioner for Trade, 'the elusive solution is staring us in the face'⁸ There is no better demonstration of how much the trade policy world has changed than to watch the agonised and complex

⁵ WTO, The Doha Declaration Explained, at http://www.wto.org/english/tratop_e/dohaexplained_e.htm

⁶ http://www.eu.int/comm./development/sector/social/communicable_en.htm

⁷ Access to Medicines: Time for a Multilateral Conclusion, Article by Pascal Lamy, European Commissioner for Trade, Published in the Herald Tribune (11-12 January 2003)

⁸ Ibid

debate about access to medicines which has transfixed the World Trade Organisation for the last year or so. But while trade policy historians will no doubt find it fascinating, trade ministers should remember that we are talking about life and death. Using the expertise of the WHO in tandem with the updated rules of the WTO might just be the way to do that.

In view of the urgent need to fight communicable diseases, the EC and their member states have already taken a number of initiatives in the area of access to affordable medicines for developing countries. On 14 May 2001, the Council of Ministers endorsed the Commission's comprehensive Programme for Action targeted at major communicable diseases. The Council Resolution focuses on three main goals: maximising the impact of existing interventions, increasing the affordability of key pharmaceuticals, and increasing investment in research and development of specific global goods.⁹

The purpose of my thesis then is to find out how the EU and WTO can find a durable and lasting solution to facilitate access to pharmaceuticals to the major communicable diseases like HIV/AIDS, Malaria and Tuberculosis which are routinely and efficiently killing millions of people in the developing world. I will be analysing how best to use the legal options available to countries and communities who face the monopolization of their supply of medicines, not only for the health and safety of their people in general but specifically for low-end consumers facing major communicable diseases. I will equally show that the place of social policy, such as in the provision of drugs to low-end consumers faces a built-in problem of international economic governance. This built-in problem is a public/private protection that is biased against the inclusion of public policy goals that are inconsistent with free trade/IPR protection in the GATT/WTO framework. I will explore the tension between commodity and public policy-oriented perspectives of TRIPS. This tension is part of the ambiguous legacy of social policy in international economic governance that can be exploited in favour of facilitating access to drugs for low-end consumers. The WTO recently endorsed this view of balancing between the interests of producers and consumers of intellectual property rights in its background paper to the African Trade Ministers conference in Libreville, Gabon.¹⁰

If developing countries could implement the TRIPS as it is, some of the concerns could be minimized. However, this is not so: increasingly they are facing political pressure and threats particularly from the US government, preventing them from implementing what is legally allowed. In the last two years, South Africa passed legislation to permit generic substitution and

⁹ The programme for Action (COM(2001)96) was adopted by the commission on 21 Feb. 2001 see web site:

http://www.cc.cec.8082/comm./development/sector/social/social/health_en.htm

¹⁰ Libreville 2000-Meeting of African Trade Ministers, WTO Doc. NoM/LIB/SYN15 (Oct.23,2000), available at <http://www.itd.org/Libreville/docs/MMLIBSYN15.doc>.

parallel imports in pharmaceuticals, a practice common in Europe and allowed under TRIPS. The US government, at the request of the pharmaceutical industry, using trade threats, has asked South Africa to repeal its legislation. Similarly Thailand which had a statute allowing compulsory licensing, has been threatened by the US government and has repealed its own regulation. And the pharmaceutical industry is lobbying the US government to put pressure and possible economic punishment on countries for implementing TRIPS as it is. Eighty percent of the pharmaceutical industry is based in the US and the US government appears to be lobbying for pharmaceutical company commercial interests.¹¹

I will equally look at the role of the United States on the ongoing debate between the EU and WTO to facilitate access on pharmaceuticals to developing countries. Here, I will look at how the cautious optimism for a public policy-oriented perspective of TRIPS is having a place alongside the United States who supports exclusivity of patent protection. I will explore how South Africa, Brazil and Thailand have benefited from such an understanding by the United States with regard to compulsory licensing laws. Another reason for hope is the Executive order signed by president Clinton in 2000 ordering the USTR not to impose trade sanctions against a Sub-Saharan African country pursuing a policy or law aimed at addressing the AIDS epidemic¹².

Considering my research methodology, I intend to design a ‘road-map’ which will allow concurrently use for some theory testing and theory building. The reason for this choice is such that my thesis would be based on few previous findings while remaining open to new information and understanding of the problems that are likely to emerge in the course of my research. In this light, I intend to make a good use of theory which will help delimit my thesis to its most effective design, to investigate the nature of the problem and to develop relevant knowledge and practical understanding that enables new ways of working to break the current impasse in the ongoing negotiations.

¹¹ Trade Related Aspects of Intellectual Property Rights(TRIPS) and Pharmaceuticals by Eva Ombaka and Published at <http://www.wcc.org/wwc/what/jpc/trade.html>

¹² Exec. Order No. 13.255,65 Fed. Reg. 30,521, 30, 522 (2000). This executive order also required sub-Saharan African countries to provide adequate and effective intellectual property protection as a precondition for increasing access to AIDS drugs. Id at 30, 521.

2 The EU and Public Health Policy to Developing Countries

2.1 The Impact of Existing Interventions:

The European Community policy aims to respond to what is now generally acknowledged as a global emergency to developing countries: the death of five million people from three major communicable diseases: HIV/AIDS, malaria and tuberculosis. Each disease kills more than one million people per year, mainly in developing countries, posing a serious threat to health. The main objective of the European Community Development Policy¹³ is to foster sustainable development designed to eradicate poverty in developing countries and to integrate them into the world economy. As stated in the policy paper, few investments are wiser than those in good health. Investments in health can make a major contribution to poverty reduction welfare and economic growth: countries with higher levels of health grow faster. In the poorest developing countries¹⁴, communicable diseases, particularly HIV/AIDS, malaria, and tuberculosis continue to limit development.

The Commission intends to prioritise within the total development co-operation budget, health, AIDS and population interventions over the next five years (2002-2006). The proportion allocated stood at 8% in 2000 (approximately Euro 800 million) and will be steadily increased as delivery capacity improves. Within those interventions, increased support will target HIV/AIDS, malaria and tuberculosis, and the actions identified in the programme for action, in accordance with the needs of each country. The Commission intends to invite developing countries to identify opportunities to direct unspent committed resources within country programmes to address the communicable disease burden.

The Commission will equally consider the use of 'all ACP' and other regional funds¹⁵ for rapid resources transfer to partners to increase access and utilisation of existing approaches and scale up innovation practices such as social marketing of bed nets, condoms, prevention and care of mothers

¹³ COMM(2000) 212 of 26.4.2000

¹⁴ In the context of this programme for Action, the poorest developing countries include the least developing (currently 48 countries(UNCTAD:2000) and the other low- income countries with a GNP per capita of less than USD 765(Currently 24 countries DAC:2000).

¹⁵ The legal bases for contributions may include co-operation (articles 177 et seq. of EC Treaty) including co-operation with international organisations (article 181), public health (article 152) and research policy (163 et seq.). Special instruments applicable in the field include Council Regulation No 550/97, 24 march 1997, on HIV/AIDS in developing countries, and Council Regulation on population policies and programmes in developing countries No 14847/97, 22 July. Commitments are subject to the eligibility conditions specified in the applicable instruments.

with HIV, etc. such to the conditions contained in applicable instruments, funds may include the possibility for transfer to UN agencies NGOs and non traditional partners at the request of developing Countries.

Through national and regional co-operation, capacity building, and financial and technical assistance the Commission intends to support the strengthening of pharmaceutical policy and practice. Particular efforts will be directed to improving budgeting and financial management, planning. Quality assurance, purchasing tendering, distribution and optimal use of pharmaceuticals. The Commission will support the development of regional/sub-regional quality control laboratory networks to ensure appropriate quality control of pharmaceuticals. This is particularly important in the context of local production and use of generics in accordance with WHO approved standards. Further more, developing countries will equally be assisted at a regional or national level, to develop high-quality, local production of key pharmaceuticals, many of which are off-patent and could be produced immediately.¹⁶

The European Community equally intends to encourage EU and non-EU generic and research-based industries to enter into licensing agreements and joint ventures with suitable developing country partners. This will require adequate incentives, such as securing a high standard of protection for intellectual property rights, obtaining access to developing country markets by mutual recognition of marketing approvals, and ensuring that products destined for developing country markets are not exported to the community or other developed country markets.

2.2 Increasing Affordability of Key Pharmaceuticals

The European Community is at the forefront of international efforts to establish a global tiered pricing¹⁷ system for key pharmaceuticals for the poorest developing countries. A successful tiered pricing system targeted at the poorest developing countries must also be able to prevent production diversion to other markets, thus undermining prices. Its is essential, in order to preserve confidence in such a system, that effective safeguards are in place to ensure that all low-priced pharmaceuticals destined for specific markets are delivered to, and remain in, those markets. Such safeguards include technical measures, such as differential labelling, packaging and trademarks to identify preferentially priced products, special enforcement procedures to be applied in the importing and/or exporting country, and

¹⁶ Communication From The Commission To the Council and The European Parliament: Programme for Action: Accelerated action on HIV/AIDS, malaria and tuberculosis in the context of poverty reduction.

¹⁷ Tiered pricing describes a system whereby different prices are charged in different markets. It refers to the pricing system by which producers of key pharmaceuticals, including both patented and non-patented medicines, make those products available to the poorest countries at significantly discounted prices.

contractual arrangements between the exporter, importer and distributor of the medicines.¹⁸

Adequate access to medications at affordable prices is recognised as one of the most effective elements of public health policies to reduce mortality rate and infectious rates. In the case of the HIV/AIDS, for instance, some of the most successful policies have been possible through the provision of increased access to generic and patented medicines to those in need. Access can be limited by a number of factors, such as financial hurdles, physical and infrastructure barriers, and information gaps, among others.¹⁹ When intellectual property rights are properly granted and exercised, they may meet their objectives of contributing to the development of new medicines. However, there should be a common understanding that confirms the right of governments to ensure access to medications at affordable prices and to make use of the provisions in the Agreement whenever the scope or exercise of IPRs result in barriers to access to medicines.

International Concertation (eg under the auspices of the UN or the WTO) will be needed to contain the risk of product diversion, but it will also require the full participation and cooperation of governments in developed and developing countries, the public and private sector, and of NGOs. Pharmaceutical companies are investigating ways of repackaging medicines for AIDS patients after a scandal in which cut-price drugs destined for Africa were illegally exported to Europe in October 2002. At least 15 million dollars worth of drugs for HIV positive patients – destined for sale at big discount in West Africa were diverted in the European Market in Holland and Germany.²⁰ Drug companies say that if the profitability of their AIDS drugs in wealthy markets is damaged by cheap AIDS drugs flowing back from Africa, they may reduce research into new therapies. A GlaxoSmithKline (GSK) spokesman said the company was ‘extremely saddened’. ‘The victims of this illegal trade are the HIV/AIDS patients of Africa,’²¹ he said.

For developing countries and poor people in particular, bringing down the cost of medicines is key to gaining access to drugs.²² In developing countries, 25 to 65 percent of the total health expenditures is spent on pharmaceuticals, but government health budgets are too low to purchase

¹⁸ Measures foreseen in this regard should not affect the free movement of goods within the Community.

¹⁹ TRIPS: Council Discussion on Access to Medicines, Developing Country Group’s Paper. IP/C/W/296, Advanced Copy Received June 2001. See http://www.wto.org/English/tratop_e/trips_e/paper_develop_w296_e.htm

²⁰ Industry Tackles Aids Drug Scandal: Available online, <http://www.bbc.co.uk/1/hi/world/Europe/2296157.stm>

²¹ Ibid

²² WTO Agreements and Public Health

enough medicines and poor people often cannot afford to buy them on their own. Several measures exist for making drug prices more affordable.²³

In Cote d'Ivoire for example, one of West Africa's wealthiest Countries, only about five hundred (500) of the estimated one million (1.000.000) people infected with AIDS are receiving treatment. According to a New York Times editorial, cost is the main obstacle. Even though the Ivorian and French governments subsidize over half of the price, the drug regime is still 1-10 Dollar a month while the average monthly wage is only about 50 Dollars.²⁴ Though most who work in international health believe that the problem of access to drugs is the result of several contributing factors, cost is certainly one of them. And much of the blame for high cost is laid at the feet of the pharmaceutical industry and their leveraging of prices, particularly through the use of patents and effective monopolies.²⁵

The pharmaceutical industry counters with two arguments: 1) without the high-profit margin on patented drugs they wouldn't be able to afford the research costs necessary to develop the next generation of drugs;²⁶ 2) access to drugs is not just about drug prices, so undercutting drug companies ability to set prices without also addressing issues like overall access to quality care will not solve anything.²⁷ Critics respond that the pharmaceutical industry is one of the most lucrative in the world and even without the profits on monopolized 'critical drugs' they would still be able to find their current level of research and development many times over. And, they say, reducing drug cost even if there are other contributing factors, would be a major step which would have an effect in and of itself.

In response to these criticisms, the Anglo-American pharmaceutical giant, GlaxoSmithKline announced on the 28th of April 2003 that it has further reduced the not-for-profit prices of its HIV/AIDS medicines for the world's

²³ a) Price controls to restrict manufacturers' prices; b) price negotiation for high volume or pooled purchasing; c) reduced import duties and national or local sales taxes; d) distribution of price information on drug ingredients and finished doses; e) reduced distribution, dispensing and market costs; f) promoting competition through generic products and prompt manufacture of generic drugs upon expiration of patent terms; g) promoting conditions that would be conducive to differential pricing of pharmaceuticals; h) voluntary licensing under certain conditions for newer life-saving drugs still on patent; I) use of TRIPS safeguards, such as parallel imports and compulsory licensing, for patented drugs and use of exclusive rights which permit early testing and approval of generics ('Bolar' Provision). For a more detailed discussion see www.wto.org on WTO Agreements and Public Health.

²⁴ Pompey, Fabien. (September 9, 1999). Aids-CoteIvoire: Ivorians derive little benefit from low-cost AIDS programme. Agence France-Press. Available: <http://www2.aegis.com/news/afp/1999/AF990929.html>. (September 10, 1999)

²⁵ Helfrich, Christian: University of Washington: The WTO and Health. Available online: <http://www.Washington.edu/wto/issues/health.html>

²⁶ Pratt, E. J. Intellectual Property (online). Available: <http://www.Pfizer.com/pfizerine/policy/intellectualpropfrm.html>. (1999, Sept. 15)

²⁷ Kuesters, G. (1999, Sept.7). Problem of Access to Pharmaceuticals. Position Paper provided in response to email request for information from Hoechst Marion Roussel AG. Available: <http://www.Washington.edu/wto/issues/pharmaceuticals.html>.

poorest countries by up to 47%. The latest reduction lowers the not-for-profit price of combivir – the backbone of WHO-recommended HIV/AIDS treatment regimes – to 90 cents per day. GSK’s single, not-for-profit prices are available to a wide range of customers in the Least Developed Countries and all of Sub-Saharan Africa – a total of 63 countries. Eligible customer groups include governments, Non-governmental organisations (NGOs), aid agencies, UN agencies, and International purchase funds like the Global Fund to Fight AIDS, TB and Malaria.²⁸ The announcement was made prior to a roundtable meeting on access to medicines hosted by European Commissioners Pascal Lamy and Philip Busquin. GSK is the leading supplier of HIV/AIDS medicines, providing almost twice as many anti-retrovirals as the second largest supplier. GSK is also an industry leader in research and development of medicines and vaccines for diseases of the developing world, including HIV/AIDS vaccine. At present, GSK has secured 131 arrangements to supply preferentially priced HIV/AIDS to 55 countries, of which 25 are outside the 63 core countries. As a result, GSK has increased shipments of combivir to the developing world from 2.2 million tablets in 2001 to nearly six million in 2002- the equivalent of about 3 million daily doses²⁹

Another way of addressing this problem is the donation of drugs by pharmaceutical companies, as an important contribution to making essential drugs affordable to the poorest countries. Even so, donations are not considered to be a long-term solution to the affordability problem because of their time-limited nature. According to the WHO background paper for the WHO-WTO meeting on differential pricing, donation programmes, ‘can make major contributions to better global public health, particularly when directed at the time-limited needs such as disease eradication. At the same time, for many of the most common problems responsible for high disease burdens, donated drugs are unlikely to be a sustainable solution to meeting long-term country needs.’ The prospects of such contributions providing a sustainable solution may be enhanced where they are accompanied by measures by developed country governments, such as tax incentives. What is clear, however, is that low prices and even donations cannot substitute for the need for the international community to provide greater financial support for healthcare in the poorest countries, both for the reinforcement of the local healthcare system and for the purchase of drugs, vaccines and goods necessary for other forms of treatment or preventive care.

²⁸ GlaxoSmithKline again reduces its not-for-profit price of HIV/AIDS medicines for the developing world: combivir down to 90 cents per day from 1.70 dollars. Available online: http://www.gsk.com/press_archive/press2003/press_04282003.htm

²⁹ GlaxoSmithkline, see note 25

2.3 Increasing Investment in Research and Development:

There is very little empirical evidence of the impact of stronger intellectual property protection on domestic R & D in developing countries. In part, this reflects the fact that major reforms introduced during the 1980s have not been in effect long enough to be firmly evaluated. The evidence presented by those who support intellectual property reform tends to be based on questionnaires treating the hypothetical reaction of companies to stronger protection.³⁰

Analysis of the elasticity of R & D investments to changes in the protection of intellectual property in developing countries generated considerable scepticism for many years. For example, in 1970 Grundmann asserted 'that by far the most efficient way for developing countries (and also industrialised countries) of encouraging the production of new technology is an increase in education in the technical and science field and not a law on the protection of inventions.'³¹ Frischtak, in his analysis of the Brazilian intellectual property rights system, points out that strengthening intellectual property rights 'could contribute to firms making R & D a more systematic activity with an overall stronger commitment to innovation,' although he cautions against overstating its role 'in explaining the technological performance of Brazilian industrial firms.'³²

The EU intends to study and develop an incentive package to encourage more private investment by Research and Development based (R & D) industries in new products to confront the major communicable diseases in developing countries. The Commission will equally encourage and support initiatives for an early dialogue on regulatory aspects in relation to new products for the three major communicable diseases. The Commission is already involved with the World Bank in research on public demand and willingness to pay for an AIDS vaccine. This includes support for studies to improve market understanding and to assess the potential health impact and affordability of an HIV vaccine. The result of this research will yield much-needed information for policy makers in developing countries as well as for donors. Although these efforts demonstrate some positive engagement, recommendations focus primarily on market-oriented strategies. This is demonstrated by the European Commission's statement that it plans to offer 'appropriate incentives to encourage private investment into research and development.'

³⁰ Paul Goldstein: *International Intellectual Property Law; Cases and Materials*: University Case Book Series. New York Foundation Series 2001

³¹ Grundmann, H.E. 1970. 'The Economic Arguments for Patents and Their Validity for Developing Countries,' *Indian Economic Journal* 19,2:198.

³² Frischtak, C.R. 1989. 'The protection of Intellectual Property Rights and Industrial Technology Development in Brazil.'

It is important for developing countries to be involved at all stages of the research and development process for new public goods. Lasting impact is expected both from basic professional as well as advanced research training on science and technology capacity and health services performance. Increased support to research activities should include support for collaborative molecular and clinical, epidemiological, operational and social studies, strengthening the base for health-related research. Emphasis should also be put on gender balance and poverty focus. Moreover, support should also be given to ensure appropriate ethical standards and review systems.

Building capacity in developing countries is a very important strategy for stimulating R & D. Public health institutions in some developing countries are playing an increasingly important role in drug development. For example, the Thai government's support for malaria research has led to the development of an effective modern pharmaceutical version of artemisinin, a traditional Chinese medicine. In clinical trials drugs, using Thai artemisinin cured 90% of malaria cases,³³ and elsewhere cut infection among children by 90% in camps for displaced people on the Thai/Burmese border.³⁴ However, while this new formulation is saving lives in Thailand, it is not recognised as a legitimate treatment by international regulatory agencies because the research reporting methods used in Thailand do not match international agencies' reporting requirements. In this case, 'harmonisation' regulations on drug R & D, which were created to meet the needs of wealthy markets, are hampering access to new treatments created in developing countries.

Drug research, development and production is increasing in, developing countries that had not been considered in the past to have innovative R & D capacity. Some initiatives to build capacity in developing countries involve stimulating collaboration between the public and private sectors in those countries. For example, the International AIDS Vaccine Initiative (IAVI) is working directly with university scientists, governments and companies in South Africa, Kenya, Uganda, India and China. The IAVI has in particular identified India as an ideal location for 'fast-tracking' vaccine development, given the country's thriving pharmaceutical industry, experience in clinical trials and government commitment to research.³⁵

It is equally important to mention GlaxoSmithKline (GSK), which has equally been involved in research into diseases and vaccines of the developing world for many years, primarily the WHO's priority diseases: malaria, HIV and tuberculosis. GSK is the only pharmaceutical company

³³ Dr. Krisana Kraisintu and Dr. Chada Phisalaphong, et al, 'Domestic Production of Dihydroartemisinin in Thailand,' paper, Research and Development Institute, Government Pharmaceutical Organization, Thailand (June 2001).

³⁴ 'One Perfect Combination: Malaria Therapies Double up to Beat Resistance,' Wellcome News. Wellcome Trust. (Online). Available: <http://www.wellcome.ac.uk/en/biosfginttrpinfcom.html> (2001, September 4).

³⁵ International AIDS Vaccine Initiative. (Online). Available: www.iavi.org (2001, August 13).

conducting research and development into all three of the WHO's top priority. GSK is currently working on anti-malarial therapy known as LAPDAP. LAPDAP is an affordable malaria treatment for use where current therapies are failing because of increased resistance. Many of their clinical trials are conducted in developing countries, because that is where the patients and local healthcare professionals with relevant clinical expertise reside. LAPDAP will be launched in 2003.³⁶

³⁶ GlaxoSmithKline: Diseases of the Developing World. (Online). <http://science.gsk.com/about/disease.htm>.

3 WTO and TRIPs

3.1 WTO and Public Health

As the world becomes increasingly integrated, it becomes less and less possible for different policy areas to be handled independently of each other. The linkage between trade and health has been the focus of much debate: real concerns should be dealt with and any misunderstandings should be clarified based on sound evidence and rigorous analysis. Another important issue is that health and trade policy makers can benefit from closer cooperation to ensure coherence between their different areas of responsibilities. The endorsement by the international community of the Doha Declaration on TRIPS Agreement and Public Health (Nov. 2001) is a very visible expression of governments' commitments to ensuring that the rules-based trading system is compatible with public health interests. The multilateral trading system has a lot to contribute to increase global welfare. In addition, the expertise and work of other organizations are needed to find effective solutions to the health pandemic in the third world. In their common pursuit of sustainable development, the WTO and EU are important partners.

Clearly, WTO has no mandate to establish public health policies, which should remain within the mandate of international bodies, such as the World Health Organisation (WHO). The Special discussion on TRIPS and public health at the TRIPS Council is not a one-off event. It should be part of a process to ensure that the TRIPS Agreement does not in any way undermine the legitimate right of WTO Members to formulate their own public health policies and implement them by adopting measures to protect public health.

3.2 TRIPS and the two visions in conflict each other (maximum profit possible and public policy-oriented perspectives)

Patent protection for pharmaceutical products is an area where the problem of finding a proper balance is particularly acute – namely, between the goal of providing incentives for future inventions of new drugs and the goal of affordable access to existing drugs. It is especially important from a social and public health point of view that new drugs and vaccines to treat and prevent diseases are generated, and that incentives provided by patent system effectively promote this. This is an area where it is very important to find a proper balance between two complementary public health goals.³⁷ The TRIPS Agreement was seriously debated against a background of at least two visions in conflict with each other on the role of private property

³⁷ The Doha Declaration Explained, see note 4

in international society. Under the commodity conception of private property, TRIPS embodies a form of IPR protection aimed at realizing the maximum profit possible in the market place. Under the alternative view, TRIPS can be conceptualised as embodying a vision that balances the returns producers seek for their research and development and the benefits that IPRs extend to society. Here, the focus is much broader than giving producers of IPRs the right to realize the maximum profit possible.³⁸

The 'maximum profit possible' view of the commodity conception of IPRs is justified on the basis that it is only reasonable and fair to compensate owners of intellectual property for their investment in research and development. Under this view, those who put their effort, labour, and capital into the market should get a return or reward for their input, without the risk of piracy. According to this commodity logic of private property, producers have an incentive to produce only when these returns are guaranteed. This view proceeds from a very strong view in favour of sanctity of property. This view further justifies intellectual property protection as a necessary precondition for promoting transfer of technology to developing countries.

The foregoing view however, understates the invariable tensions that this commodity logic of private property generates in the context of public policy. Hence, for example, earlier in the negotiations during the Uruguay Rounds, the United States was greatly opposed to reading flexibility (or limitations) into TRIPS. However, there has seemed to be a recognition of the need to be flexible in implementing TRIPS in the last two years. Hence, in May 2000, President Clinton signed an Executive Order ordering the United States Trade Representative (USTR) not to impose sanctions under section 301 of the Trade Act of 1974 or revoke any intellectual property laws or policies of Sub-Saharan African countries related to promoting access to HIV/AIDS pharmaceuticals or medical technologies to affected populations.³⁹ Similarly, in the United States constitutional jurisprudence, the Supreme Court has stopped short of treating rate regulations as

29In *Munn v. Illinois*, 94 US. 113, 135-36 (1876), the Supreme Court held that the Illinois state government has the investment power to regulate owners' returns on their businesses, which trumps private agreement regarding price and limits investment returns to private property. This power the Supreme Court held, arose where there was a public interest that justified such regulation of private property. *Id.* At 126-27. In other words, where an industry is inter-wined with a public interest, State governments have the power to limit profit. The Law in question was similar to many laws passed in Midwest at the time to regulate the warehousing and transportation of grain. In *Bluefield Water Works & Improvement Co v. Public Service Commission*, 262 US. 679. 692-93 (1923), the court held that there is 'no constitutional right to profits such as are realized or anticipated in highly profitable industries .' Hence on the issue of protection of private property rights, the Court seems to suggest that only a minimum rate of returns is constitutionally required; protection of property rights has to be reasonable and fair. There is an implicit protection of the consumer, to the extent that a profit also entails fair price to the consumer. However, note that following the Supreme Court decision in *Chicago, Milwaukee & St. Paul Ry. v. Minnesota*, 134 US. 418 (1890), a doctrine shift from *Munn* occurred.

³⁹ Executive Order No. 13,255, 65 Fed. Reg. 30,521, 522(2000). This executive order also required Sub-Saharan African countries to provide adequate and effective intellectual property protection for increasing access to HIV/AIDS drugs, *Id.* At 30,521.

deprivation of property without due process.⁴⁰ My claim is that the commodity logic of IPR protection simultaneously and dialectically co-exists with an alternative logic of IPR protection that recognises as legitimate the accommodation of public policy concerns as falling within the purview of the TRIPS agreement. In essence, the TRIPS agreement is predicated on an implicit balance between the interests of producers and consumers of IPRs.⁴¹

Hence, while TRIPS evidences the success of those committed only to the commodity private property, this vision has been in severe contention and tension with an alternative vision of IPRs. The alternative vision is characterised by the assertion that public policy issues such as human rights, and public health issues like AIDS, Tuberculosis and Malaria have a legitimate place in TRIPS. This tension is partly a reflection of seeing the significance of TRIPS regime within the context of prevailing social, political and economic circumstances. These circumstances in turn influence the construction and interpretation of the legal norms of TRIPS regime and, as such, produce a tension with the prevalent commodity conception of IPRs.⁴² Seeing TRIPS this way demonstrates the nature of its built-in public/private dichotomy, which is most evident when we start considering policy options and choices it provides for or forecloses.

My intention is in developing policy-oriented perspective of private property rights guided by the principle that private property rights have a social as well as political character, apart from their economic character in seeking the highest returns for owners of private property. Private property is valued not only as an end and right in and of itself, but also in terms of its social utility, which comes from political demands such as those related to accessibility and affordability of IPR protected products that will help to meet public health needs of low-income individuals.⁴³

Each provision of the TRIPS Agreement should be read in light of the objectives and principles set forth in Article 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

⁴⁰ In *Munn*, 94 US. At 125 Chief Justice Waite noted that under certain circumstances, price regulation may constitute a deprivation of property without due process. However, in the context of pharmaceuticals under the TRIPS agreement, there is no parallel to price deregulation, especially following the wave of deregulation that has accompanied the wave of globalisation since the late 1980s.

⁴¹ See James Thuo Ghaii, *Re-Characterising the Social in the Constitutionalisation of the WTO: A Preliminary Analysis*, Widener L. Symp. J.

⁴² This does not in any way suggest that international legal regimes like TRIPS do not have an autonomy of their own, independent of prevailing circumstances.

⁴³ Joseph William Singer, *The Edges of the Field: Lessons on the obligations of Ownership* 20 (2001), notes that property law ‘ is highly protective of the prerogatives of owners, but also recognizes that ownership may impose vulnerabilities on others and limits the rights of owners when their actions impinge on the legitimate interests of other.’

be given to the terms of the treaty in their context and in the light of its object and purpose.

Article 7 is the 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 vacuum. They are supposed to benefit society as a whole and do not aim at mere protection of private rights. Some of the elements of 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 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.⁴⁴

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 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 pharmaceuticals. 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 exercise of IPRs, such as patents, do not necessarily result in the fulfilment of the objectives of the Agreement. In the context of health policies, 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.⁴⁵

⁴⁴ TRIPS: Council Discussion on Access to Medicines: Developing Country Group's Paper. Paper Submitted by a group of Developing countries to the TRIPS Council, for special discussion on intellectual and access to medicines, 20 June 2001: Available online: http://www.wto.org/English/tratop_e/trips_e/paper_develp_w296_e.htm

⁴⁵ Ibid

4 Legal Options Available to Developing Countries

4.1 Parallel Imports (Grey-Market)

Parallel imports or grey-market imports are not imports of counterfeit products or illegal copies. These are products made and marketed by the patent owner (or trademark- or copyright-owner, etc.) in one country and imported into another country without the approval of the patent owner.⁴⁶ Almost all countries engage in parallel trade⁴⁷ For example, suppose company 'A' has patented a drug, which it makes under patent in India and South Africa, but sells at a lower price in South Africa. If a second company buys the drug in South Africa and imports it into the Republic of Cameroon at a price that is lower than company A's price, that would be a parallel or grey import.

The legal principle here is 'exhaustion', the idea that once company 'A' has sold its product (in this case in South Africa), its patent is exhausted and it no longer has any rights over what happens to that product. The TRIPS Agreement simply says that none of its provisions, except those dealing with non-discrimination ('national treatment' and 'most-favoured-nation treatment'), can be used to address the issue of exhaustion of intellectual property rights in a WTO dispute. In other words, even if a country allows parallel imports in a way that might violate the TRIPS Agreement, this cannot be raised as a dispute in the WTO unless fundamental principles of non-discrimination are involved as stipulated in Article 6⁴⁸.

There are various reasons for the existence of price differences among national markets: the different status of a product's intellectual property rights standing in different countries; differences in inflation rates or exchange rates changes; differences in price attributable to national price regulations which control prices of a given product at different levels; differences in per capita income and tastes as reflected in demand and price differences across borders; different marketing and sales strategies of patent-holders and sales volume variations across markets and differences in regulatory systems, product liability laws and tax levels. It is often difficult

⁴⁶ Maskus K. E .Chen Y. (2000, Oct. 1). Vertical Price Control and Parallel Imports: Theory and Evidence (Online). World Bank Research. Abstract from: World Bank Working Paper Number 2461.

⁴⁷ Home page of Consumer Project on Technology. Health Care and Parallel Imports. (1998 Sept. 10). Available: <http://www.cptech/ip/health/pi> (2001, March 24)

⁴⁸ Pharm-Policy: WTO on Bolar, Compulsory Licensing and Parallel Imports: Available online: <http://lists.essential.org/pipermail/pharm-policy/2001-June/001172.html>

to disentangle these factors and all may be present when trying to analyse price differences between the two or more countries.⁴⁹

Article 6 of the TRIPS Agreement is extremely relevant for Members, especially developing countries, and particularly the least developed and smaller economies among them. Article 6 provides that Members are free to incorporate the principle of international exhaustion of rights in national legislation. Consequently any Member can determine the extent to which the principle of exhaustion of rights is applied in its own jurisdiction, without breaching any obligation under the TRIPS Agreement.⁵⁰

Whenever Governments deem it appropriate, adoption of the principle of international exhaustion of rights, can be a useful tool for health policies. Where the prices of pharmaceuticals are lower in a foreign market, a Government may decide to allow, importation of such products into the national market, so as to allow offer of drugs at a more affordable prices. Such measures may be beneficial to prevent anti-competitive practices on behalf of patent owners who offer their patented products at unreasonable high prices in the domestic market. In this case, patent owners would compete with other legitimate products: given that their exclusive rights would be exhausted, the interests of the patent owner would not be damaged.

For developing countries, in particular, least developed countries, and smaller economies, ‘parallel importation’ can be a significant way of increasing access to medication, where the prices charged by patent holders for their products are unaffordable. Moreover, in situations where the local manufacture of the product is not feasible, and therefore compulsory licenses may be ineffective, parallel importation may be relevant tool to ensure access to medication, where prices charged by patent holders for their products are unaffordable⁵¹. While developing countries say parallel imports are clearly allowed under Article 6 and that it is essential to ensure prices are as low as possible, the EU, US and Switzerland warned that this could undermine ‘differential pricing’ if cheaper products flow into developed countries’ markets.⁵²

At this juncture it is worth mentioning the case which attracted much attention, the challenge in South African Courts by 39 Pharmaceutical companies⁵³ contending that that South Africa Medicines and Related Substances Control Amendment Act of 1997 was inconsistent with the

⁴⁹ Bale, Harvey, E. (1998) The conflict between parallel Trade and Product Access and Innovation: The case of Pharmaceuticals . Journal of International Economic Law (1998) 637-653. Oxford University Press.

⁵⁰ TRIPS: Council Discussion on Access to Medicine, see note 18 supra

⁵¹ TRIPS: Council Discussion on Access to Medicines supra, note

⁵² WTO News: 2001 News Items. Governments Share Interpretations on TRIPS and Public Health. Available

online:http://www.wto.org/English/news_e/news01_e/trips_drugs_010620_e.htm

⁵³ WTO Agreements and Public Health: www.wto.org

South African constitution. The background of this domestic dispute is the following. In 1997, the Parliament of South Africa adopted the Medicines Related Substances control Amendment Act (the 'Medicines Amendment Act') to assist in the 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'. The Medicines Amendment Act, included several key components, among them provisions on generic substitution of prescription drugs, rationalization of pricing and reform of the Medicines Control Council. The Medicines Amendment Act empowered the Minister of Health to authorise and prescribe conditions for the parallel importation of drugs under patent in South Africa.

Prior to the provisions of the Medicines Amendment Act taking effect, 39 pharmaceutical companies sued the South African Government in order to block its implementation. The companies alleged that the Act was inconsistent with the newly adopted Constitution of South Africa in that it authorised the Minister to abrogate the rights of the patent holders and violate the terms of the TRIPS Agreement. The Government argued that its legislation was entirely consistent with TRIPS Agreement that allows WTO Members to authorise parallel importation, that the legislation did not address compulsory licensing, that the Minister was not granted broad powers to abrogate patent holders interests, and that, therefore, the legislation was entirely consistent with the South African constitution. No case was brought to the WTO claiming that South Africa had breached the TRIPS Agreement.

In April 2001, the pharmaceutical companies in the High Court of Pretoria withdrew their suit against the Government, and agreed to pay the government's legal costs in defending this case. Various other substances have referred to where countries have considered they have been under pressure from industry and or/ foreign governments not to avail themselves fully of the flexibility provided in the TRIPS Agreement. These matters have not been brought to the WTO. However, it should be noted in this connection that Article 1.1 of the TRIPS Agreement explicitly states that Members may 'but shall not be obliged to' implement in their law more extensive protection than is required by the Agreement. One of the preambular provisions of the TRIPS Agreement emphasises 'the importance of reducing tensions by reaching strengthened commitments to resolve disputes on trade-related intellectual property issues through multilateral procedures'.

To keep drug prices affordable, many countries promote the production or importation of generic versions of essential medicines. Until a recent WTO Dispute panel ruling, WT/DS114/1: Canada – Patent Protection of

Pharmaceutical Products, complaint by the European Communities (EC),⁵⁴ however, it was unclear whether the TRIPS Agreement allowed governments to permit generic drug manufacturers to undertake and complete the task of obtaining regulatory approval from the public health authorities for their generic versions before the expiry of the patent term. The Dispute Panel ruled that TRIPS allows generic manufacturers, without the permission of the patent holder, to produce and/or import and use quantities necessary to conduct bio-equivalency and other tests and to submit samples needed to obtain regulatory approval before the expiry of the patent. This allows generic drugs to be placed in the market more quickly than if this work had to wait until the patent actually expired. This policy is sometimes referred to as the ‘Bolar Exception’ which under the US law is known as the ‘Regulatory Exception’. The Dispute Panel however clarified that, TRIPS Agreement does not permit ‘stock-piling’ or large-scale commercial production of generic drug before the patent expires.

The European Union has a policy of regional exhaustion within its territory.⁵⁵ It permits producers to segregate to primary markets on the basis of patent licenses. However, the vertical market is ‘policed’ by the first sale doctrine: First sales in any EU country ‘exhaust’ the patent holder’s right to control the movement of goods to anywhere else in the Union but not from outside the EU region. The Commission has made clear in several instances that even an agreement that primarily has its effect in the export market could potentially lead to re-importation of products and thereby trade between Member States.⁵⁶ The ECJ held in *Silhouette*⁵⁷, that national rules providing for the exhaustion of trade-mark rights in respect of products put on the national market outside the EEA under that mark by the proprietor or with his consent are contrary to Article 7(1) of the first Directive 89/104 on trade marks. An interpretation of the directive to the effect that it leaves Member States free to provide in their national law for exhaustion, not only in respect of products put on the market in the European Economic Area but also of those put on the market in the non-member countries, is contrary to the wording of Article 7 and to the scheme and purpose of the rules of the directive concerning the rights which a trade mark confers on its proprietor.

Parallel imports exist in all EU Member States. It is estimated that up to fifteen percent of all pharmaceutical products sold in the EU may be parallel imports. Currently, the sources of parallel imports are countries such as Greece, Spain, and Portugal but, when the EU expands, new entrants such

⁵⁴ ‘DBS Rules on Genetic Drugs’, Bridges, 8 February 2000, International Centre for Trade and Sustainable Development, Geneva.

⁵⁵ Maskus K. E & Chen Y. *Supra*, note 41

⁵⁶ Decision 72/238/EEC. *Raymond & Nagoya Rubber Co.*, footnote 4, Commission decision 76/159/EEC, SABA, 15 December 1975: OJ 1976 L28/19, (1976), 1CMLR D61. Cited by Lidgard, H. H. Lund University: IPR, BIOTECH & Technology Transfer, Reading Material, Spring 2003

⁵⁷ C-355/96 *Silhouette International Schmied GmbH & Co. KG v. Hartlauer Handelsgesellschaft mbH*: ECR 1998 Page 1-04799

as Hungary, Poland and Czech Republic are likely to prove even more popular markets for parallel importers to obtain their stocks.⁵⁸

Under US patent law, parallel imports are legal. In the special case of pharmaceuticals, parallel imports are restricted under the system of regulation of health and safety of pharmaceuticals, as in the case in several other countries, but not others. The US restrictions on parallel imports of pharmaceuticals have a basis in the US FDA statutes, but not in the US patent law.⁵⁹

Substantial research findings suggest that parallel trade issues are complicated, requiring extensive knowledge and comprehension. While, the welfare effect of parallel trade is ambiguous, that depends on circumstances, conflict of interests between manufacturers on innovation and consumers in decreasing price discrimination continues. For the pharmaceutical industry, there are fierce arguments that involve natural conflicts between an intellectual property system which is based upon the right to exclude use, and ethical and public health goals which seek to make healthcare universally available.

4.2 Compulsory Licensing

Compulsory licensing is when a government allows someone else to produce the patented product or process without the consent of the patent owner. The TRIPS Agreement allows compulsory licensing as part of the agreement's overall attempt to strike a balance between promoting access to existing drugs and promoting research and development into new drugs. But the term 'compulsory licensing' does not appear in the TRIPS Agreement. Instead, the phrase 'other use without the authorization of the right holder' appears in the title of Article 31. Compulsory license is only part of this since 'other use' includes use by governments for their own purposes.⁶⁰

Compulsory licensing and government use of a patent without authorization of its owner can only be done under a number of conditions aimed at protecting the legitimate interests of the patent holder. For example: Normally the person or company applying for a licence must have first attempted, unsuccessfully, to obtain a voluntary licence from the right holder on reasonable commercial terms-Article 31b. If a compulsory licence is issued, adequate remuneration must still be paid to the patent holder-Article 31h.

⁵⁸ Taylor J. Garrett (2001), Parallel Imports and Pharmaceutical Products (2,3 paragraphs). Topical Issues. Intellectual Property (Online). Available: [http://www.tjg.co.uk/topical/intellectual property/ip parallel imports 0899. html](http://www.tjg.co.uk/topical/intellectual%20property/ip%20parallel%20imports%200899.html) (2001, Mar.24)

⁵⁹ Ki-huen Kwok, Parallel Trade: the case on pharmaceuticals. May 2001.

⁶⁰ (Pharm-Policy) WTO on Bolar, Compulsory Licencing and Parallel Imports, supra note

However, for ‘national emergencies’, ‘other circumstances of extreme urgency’ or ‘public non communicable use’ (or ‘government use’) or anti-competitive practices, there is no need to try for a voluntary licence – Article 31b.⁶¹ Compulsory licensing must meet certain additional requirements. In particular, it cannot be given exclusively to a single licensee, and usually it must be granted mainly to supply the domestic market. Compulsory licensing cannot be arbitrary.

The question then is: What are the grounds for using compulsory licensing? The TRIPS Agreement does not specifically list the reasons that might be used to justify compulsory licensing. In Article 31, it does mention national emergencies, other circumstances of extreme urgency and anti-competitive practices-but only as grounds when some of the normal requirements for compulsory licensing do not apply, such as need to try for a voluntary licence first. In effect, Article 31 allows compulsory licensing, although it is qualified by at least eight preconditions.⁶²

The Doha Declaration on TRIPS Agreement and Public Health clarifies some of these provisions, while maintaining Members’ commitment in the TRIPS Agreement. It makes it clear that each Member is free to determine the grounds upon which compulsory licences may be granted. This, for example is a useful corrective to the views often expressed in some quarters implying that some form of emergency is a pre-condition for compulsory licensing. The Declaration makes it clear that each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency and public health crisis, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent such circumstances.

In the work on the Declaration, the issue arose of the ability of countries with limited manufacturing capacities to make effective use of compulsory licensing. It is not in dispute that Members can issue compulsory licences for importation as well as for domestic use. However, concern has been

⁶¹ Ibid

⁶² See generally Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex IC, Legal Instruments-Results of the Uruguay Round vol. 31.33.I.L.M. 81 (1994), Article 31. These conditions are: 1) that authorization of the use without the consent of the patent owner must be considered on its individual merits; 2) that efforts to obtain a voluntary licence on reasonable terms and conditions must first be made (except for government use, which only requires notification); 3) that the scope and duration of the use must be limited to the purpose for which it was authorized; 4) that the use must be non-exclusive; 5) that the authorization must be predominantly for the supply of the domestic market of the Member authorizing the use; 6) that the authorization of the use can be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur; 7) that the patent owner must be paid adequate remuneration, taking into account the economic value of the authorization and the decisions relating to the authorization; and 8) that remuneration must be subject to judicial review or other independent review by a distinct higher authority within that member. Id.

expressed as to whether sources of supply from generic producers in other countries to meet such demand will be available, particularly in the light of the provisions of Article 31(f) of the TRIPS Agreement which states that any compulsory licences granted to generic producers in those other countries shall be ‘predominantly for the supply of the domestic market of the Member’ granting the compulsory licence. This concern may become greater as countries with important generic industries, such as India, come under an obligation to provide patent protection for pharmaceutical products as from 2005. In this regard, the Declaration recognizes the problem and instructs the Council for TRIPS to find an expeditious solution and to submit a report before the end of 2002.⁶³ At the time of writing this paper, the Council has not yet arrived at a solution.

What can be said is that a WTO Member is free to grant a compulsory licence for the importation of goods which are under patent in its own territory, as long as the imported goods have been produced in a country where they are not patented, or where the term of protection has expired. However, the European Community (EC) and their Member states also point to another possible interpretation of the Agreement⁶⁴ which would allow a Member to issue a compulsory licence to a manufacturer in another country, provided the government of that country recognised the licence (which it would not be obliged to do under the Agreement), and provided that all the goods manufactured under the licence were exported to the country granting the licence. It should be noted, however, that it is far from certain whether such a ‘permissive’ reading of the Agreement would stand scrutiny by a panel or the Appellate body. The EC⁶⁵ and their Member States are ready to discuss this matter in order to reach consensus on this issue among all WTO Members.

The best public policies about compulsory licensing of essential medical technologies are those that will best serve public health goals, and which explicitly address the obvious ethical dilemmas. Patents are used to restrict access to inventions. This is considered a necessary practice in order to create economic incentives to fund R & D. But we cannot be blind to the impact of these mechanisms, if left unchecked, particularly when the consequences of exclusion are illness or death. The restrictions on access must be reasonable, and they not create situations where the entire populations are denied to known therapies.

Part of this concern has resulted from the fact that, at the end of the Uruguay Round, at least one WTO Member, the United States, did not accept that standards of protection of intellectual property provided for in the TRIPS Agreement were necessarily adequate and decided that it would continue to

⁶³ For a detail analysis see: WTO Agreements and Public Health. Available at: www.wto.org.

⁶⁴ WTO: TRIPS: Council Discussion on Access to Medicines, EU’s Paper. Available online: http://www.cc.cec:8082/comm./trade/pdf/med_lic.pdf

⁶⁵ Ibid

seek higher standards of protection through other means, including its procedures under the Special Section 301 of its Trade Act. However, in May 2000, the US Government issued an executive order⁶⁶ stating its commitment to refrain from actions intended to seek the revocation or revision of intellectual property laws applying to HIV/AIDS-related drugs or technologies, provided that they were TRIPS-consistent. The executive order extended to measures being introduced in Sub-Saharan African countries to address the HIV/AIDS pandemic. In February 2001, the Bush Administration reaffirmed the commitment of the United States to a flexible approach on health and intellectual property and the United States has since informed WTO Members that, as the United States takes steps to address the major health crisis, such as the HIV/AIDS crisis in Sub-Saharan Africa and elsewhere, it would raise no objection if Members avail themselves of the flexibility afforded by the TRIPS Agreement⁶⁷.

Two cases relevant to the use of the flexibility in the TRIPS Agreement that have arisen in the WTO are often referred to. One is the dispute between Canada and European Communities⁶⁸ 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.

The other 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 the consistency of the Brazilian legal framework for the grant of compulsory licences with the provisions of the TRIPS Agreement. In its request for the establishment of a panel, the US alleged that Article 68 of Brazil's 1996 industrial property law, imposes a 'local working' requirement which stipulates that a patent shall be subject to compulsory licensing if the subject matter of the patent is not 'worked' in the territory of Brazil. Specifically, the US challenged the provision whereby it claimed that compulsory licence shall be granted on a patent if the patent product is not manufactured in Brazil or if the patent 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 US argued that Article 68 of Brazil's 1996 industrial property law discriminates against US owners in, Brazil. Article 68 was also said to curtail the exclusive rights conferred on these owners by their patents. For the US, such legislation was part of an industrial policy.

⁶⁶ US White House Executive Order 13155, May 20, 2000 – Access To HIV/AIDS Pharmaceuticals and Medical Technologies.

⁶⁷ US statement on intellectual property and access to medicines at the 20 June 2001 TRIPS Council Meeting, available at <http://www.ustr.gov/sectors/speech01.pdf>.

⁶⁸ WT/DS114/1 *supra*.

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’, 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 to the US legislation⁶⁹. Since the dispute was settled before the parties exchanged any formal written submissions,⁷⁰ it is difficult to know with accuracy all the arguments that were put forward during the consultations or that could have been raised by the parties.

In June 2001, Brazil and the United States settled their WTO dispute.⁷¹ The US withdrew its WTO complaint against Brazil, while Brazil agreed that if it deemed it necessary to apply Article 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 should also be noted that Brazil has successfully used, on at least two occasions, the threat of compulsory licensing to secure more favourable terms in its negotiations for the supply of HIV/AIDS drugs with major pharmaceutical companies.

This demonstrates that flexible handling of intellectual property protection under the TRIPS Agreement is very important. The political settlement of the dispute between major pharmaceutical drug companies and South Africa on the terms of supply of critical medicines against HIV/AIDS, and the dispute between the US administration and the German based pharmaceutical giant Bayer on the price of anthrax medicine CIPRO in 2001 revealed that under extreme circumstances, e.g. a major threat to public health, it can be necessary to bend intellectual property rights.

Various other instances have been referred to where countries have considered that they have been under pressure from industry and/or foreign

⁶⁹ See document WT/DS224/1

⁷⁰ 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 party rights.

⁷¹ On 5 July 2001, the parties to the dispute notified to the DSB a mutually satisfactory solution on the matter (WT/DS199/4).

governments not to avail themselves fully of the flexibility provided in the TRIPS Agreement. These matters have not been brought to the WTO. However, it should be noted in this connection that Article 1.1 of the TRIPS Agreement explicitly states that Members may ‘but shall not be obliged to’ implement in their law more extensive protection than is required by the agreement. One of the preambular provisions of the TRIPS Agreement emphasizes ‘the importance of reducing tensions by reaching strengthened commitments to resolve disputes on trade-related intellectual property issues through multilateral procedures’. Moreover, Article 23 of the WTO Dispute Settlement Understanding commits Members who believe that other Members are not living up to their TRIPS (and other WTO) obligations to seek recourse in accordance with the Dispute Settlement Understanding and not to make determination or take action except in accordance with it.

Furthermore, in Asia, after the Asian financial crisis, Thailand was in no position to afford AIDS drugs sold at US prices. Local health groups accordingly lobbied the Thai and US governments to licence local companies to manufacture anti-HIV drugs and drugs to treat opportunistic AIDS infections. They pointed out that many lives would be saved and that the patent holder, instead of receiving virtually nothing from the Thai market, would benefit from a steady if not unspectacular stream of compensatory payments. In response the US government persuaded the Thai government not only to drop its plans for compulsory licensing of didanosine (DDL), but also to change its patent and trade laws to outlaw compulsory licensing altogether. It threatened to reduce Thailand’s access to the US market for its jewellery exports, one of Thailand’s major sources of foreign exchange, while at the same time offering to cut tariffs on Thai jewellery and wood products entering the US market. This was in spite of the fact that the US government does not even have patent rights on didanosine (DDL) in Thailand.⁷²

Where a country does need medicines to fight major communicable disease and cannot afford their market price, the real question to be considered is how to finance that country’s access to these drugs. It is clear that many factors other than patented drugs play a major role in a successful health strategy – including living conditions, medical facilities, nutrition, and means for the distribution and administration of medicines. It is also clear that many pharmaceuticals which are effective in combating diseases in the developing world are not subject to patent rights (see table below). It has been pointed out that the availability of health services adapted to local needs, efficient distribution systems, tariff and tax free treatment for drugs equally play an important role in ensuring access to medicines⁷³

⁷² Third World Network: Compulsory licensing good for US public, not others: Article by Someshaw Singh: Available online: <http://www.twinside.org.sg/title/public-cn.htm>

⁷³ Workshop on differential pricing and financing of Essential Drugs organised by WHO and WTO, in Norway

DISCUSSION ON ACCESS TO MEDICINES AND CROSS BORDER COMPULSORY LICENSING: BACKGROUND FACTS

A/ Prevalence of TB, malaria, HIV/AIDS and existence of drug patents

Table I provides information concerning the prevalence, in the developing world, of the diseases specifically mentioned in the Doha Declaration on TRIPS and Public Health. **Table II** provides general information concerning the existence of patents on drugs for treating these diseases, and details of patent coverage in Africa for antiretroviral drugs. The combination of these facts suggests that the existence of patents alone is not responsible for the lack of access to such drugs.

Table I Prevalence of TB, malaria and HIV/AIDS in developing countries

Disease	Deaths w-wide	New Cases	Prevalence in Developing World
TB ⁷⁴	2 million per year	>8 million per year	2 million in sub-Saharan Africa; 3 million in South East Asia, 0.25 million in Eastern Europe (per year)
Malaria ⁷⁵	1 million per year	300 million per year	90% of deaths w-wide in Sub-Saharan Africa
HIV/AIDS	3 million ⁷⁶ in 2001	5 million ⁷⁷ in 2001	95% in developing world ⁷⁸ ; 40 million HIV cases w-wide; 28.5 million (71%) in Sub-Saharan Africa ⁷⁹

⁷⁴ WHO fact sheet on tuberculosis no 104, revised August 2002, see website. <http://www.who.int/mediacentre/factsheets/who104/en>.

⁷⁵ Roll Back Malaria, see WHO website fact sheet on malaria no 94, <http://www.who.int/inf-fs/en/InformationSheet01.pdf>.

⁷⁶ UNAIDS Report on the Global HIV/AIDS Epidemic 2002, page 8.

⁷⁷ UNAIDS Report on the Global HIV/AIDS Epidemic 2002, page 8.

⁷⁸ "Patent Protection and Access to HIV/AIDS Pharmaceutical in Sub-Saharan Africa", A Report Prepared for the World Intellectual Property Organization (WIPO), International Intellectual Property Institute, 2000.

⁷⁹ UNAIDS Report on the Global HIV/AIDS Epidemic 2002, page 8.

Table II Patents on drugs for TB, malaria and HIV/AIDS

Disease	Patents on relevant drugs
TB and malaria	Some 95 % of the pharmaceutical products on the World Health Organization's Essential Drugs List are now "off patent", that is, no longer protected by patents ⁸⁰ . This list includes 9 anti-tuberculosis drugs and 8 drugs against malaria ⁸¹ .
HIV/AIDS	<p>Most anti-retroviral drugs not protected by patents in majority of developing countries.⁸²</p> <p>Some 95 % of the pharmaceutical products on the World Health Organization's Essential Drug List - which includes many drugs used to treat various aspects and side effects of HIV/AIDS - are now "off patent", that is, no longer protected by patents⁸³. This list includes 12 antiretrovirals.⁸⁴</p>

4.3 Technology Transfer

The development, acquisition and use of various technologies is a key factor in the competitive position of national economies. The transfer of technology to developing countries is attracting increasing attention in the WTO with the establishment in Doha, of a Working Group on Trade and Technology Transfer. A number of provisions in the WTO agreements mention the need for a transfer of Technology to take place between developed and developing Countries. Many developing and least developed countries have indicated dissatisfaction with the way in which existing WTO provisions have been operationalized, and sought the establishment of a working group in Doha.

The Working Group on Trade and Transfer of Technology (WG3T) is a new WTO group established largely in response to developing country concerns. It was established pursuant to paragraph 37 of the Doha Declaration which

⁸⁰ WIPO *Emerging issues in IP: Patents & access to drugs and health care*. "Striking a Balance: Patents and Access to Drugs and Health Care". http://www.wipo.org/about-ip/en/studies/publications/health_care.htm

⁸¹ WHO Essential Medicines Model List (Revised April 2002) Core List. <http://www.who.int/medicines/organization/par/ed/eml.shtml>

⁸² "Patent Protection and Access to HIV/AIDS Pharmaceutical in Sub-Saharan Africa", page 36, Report Prepared for The World Intellectual Property Organization (WIPO), International Intellectual Property Institute, 1996, 2000.

⁸³ WIPO *Emerging issues in IP: Patents & access to drugs and health care*. "Striking a Balance: Patents and Access to Drugs and Health Care". http://www.wipo.org/about-ip/en/studies/publications/health_care.htm

⁸⁴ WHO Essential Medicines Model List (Revised April 2002) Core List. <http://www.who.int/medicines/organization/par/ed/eml.shtml>

reads as follows: ‘Trade and Transfer of Technology: We agree to an examination, in a working Group under the auspices of the General Council, of the relationship between trade and technology transfer, and of any possible recommendations on steps that might be taken within the mandate of the WTO to increase flows of technology to developing countries. The General Council shall report to the Fifth Session of the Ministerial Conference on progress in the examination.’⁸⁵

The TRIPS Agreement contains standards that affect transfer of technology and a number of provisions related to directly transfer technology. The stated objectives of the Agreement include that the ‘...protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology ...’. Similarly, the Article on Principles states that Members may adopt measures to promote technological development provided these measures are consistent with the provisions of the TRIPS Agreement. The TRIPS Agreement also stipulates that ‘developed-country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base’⁸⁶. This is very important for developing countries instead of asking them to be perpetual recipients of pharmaceuticals and products produced in the developed world – that is not how we look at things. TRIPS is suppose to benefit everybody. When we look at TRIPS, we should take decisions in cognisance of the provisions of Article 7 and 8, and in fact those provisions are not being met.

And as Jeffrey Sachs, an eminent economist, said in 2002 ‘...there is an opportunity to re-think the intellectual property rights regime of the world trading system vis-à-vis the world’s poorest countries. In the Uruguay Round negotiations, the international Pharmaceutical industry pushed very hard for a universal coverage of patent protection without considering the implications for the poorest countries. There is little doubt that the new IPR arrangements can make it more difficult for consumers in the poorest countries to access key technologies, as we’ve seen vividly in the case of essential medicines. The countries negotiating the new Doha Round have already committed to re-examining the IPR issue in light of public health priorities, and they are wise to do so. It also might be the case that tightening of IPRs may slow the diffusion of technology to the world’s poorest countries that has traditionally come through copying and reverse engineering. Those hallowed pathways of technological diffusion are increasingly being slowed, and the effects on poorest countries may be

⁸⁵ Industry Canada: Trade and Technology Transfer. Available online: <http://strategis.ic.gc.ca/epic/internet/inibi-iai.nsf/vwGeneratedInterE/bi18684e.html>

⁸⁶ World Trade Organisation. Preparation for the Fourth Session of the Ministerial Conference. Proposal for the Establishment of a Working Group for the Study of Inter-relationship between Trade and Transfer of Technology. (WT/GC/W/443-18 Sept. 2001)

unduly hindered. This is an area for close observation, policy attention, and continuing research.’⁸⁷

For developing countries, like the developed countries before them, the development of indigenous technological capacity has proved to be a key determinant of economic growth and poverty reduction. This capacity determines the extent to which these countries can assimilate and apply foreign technology. Many studies have concluded the most distinctive single factor determining the success of technology transfer is the early emergence of an indigenous technological capacity.⁸⁸

But developing countries vary widely in the quality and capacity of their scientific and technical infrastructures. A commonly used indicator of technological capability is the extent of patenting activity in the US and through international applications through the Patent Cooperation Treaty (PCT). In 2001, less than 1% of US patents were granted to applicants from developing countries, nearly 60% of which were from seven of the more technologically advanced developing countries.⁸⁹ In the PCT, developing countries accounted for under 2% of applications in 1999-2000, with over 95% of these applications coming from just five countries: China, India, South Africa, Brazil and Mexico. As we have seen R & D expenditure is heavily concentrated in developed countries, and in a few of the more technological advanced developing countries. Few developing countries have been able to develop a strong indigenous technological capability. This means that it is difficult either for them to develop their own technology, or to assimilate technology from developed countries.

But the determinants of effective technology transfer are many and various. The ability of countries to absorb knowledge elsewhere and then make use for their own purposes is also of crucial importance. This is a characteristic that depends on the development of local capacity through education, through R & D, and the development of appropriate institutions without which even technology transfer on the most advantageous terms is unlikely to succeed. The effective transfer of technology also requires the transfer of ‘tacit’ knowledge, which cannot be easily codified (for example, as in patent

⁸⁷ Sachs J. Global Innovation Divide’, In Jaffe, A., Lerner, J. and Stern, S. eds. (forthcoming) ‘Innovation and the Economy: Volume 3’, MIT Press, Cambridge MA. Source: <http://eol.law.harvard.edu/openlaw/eldredvashcroft/supct/opening-brief.pdf>

⁸⁸ Radovesic, S. (1999) ‘International Technology Transfer and Catch-up in Economic Development’, Elgar, Cheltenham, p. 242. Also Saggi, K. (2000) ‘Trade, Foreign Direct Investment and International Technology Transfer: A survey’, World Bank, Washington DC. Source: http://www1.worldbank.org/wbiiep/trade/papers_2000/saggiTT-fin.pdf, and Rosenberg, N(1982) ‘Inside the Black Box; Technology and Economics’, Cambridge University Press, Cambridge.

⁸⁹ Those developing countries which were granted over 50 US patents in 2001 included: China 266, India 179, South Africa 137, Brazil 125, Mexico 87, Argentina 58, Malaysia 56. China (Taiwan) received 6545 and Korea 3763 but these are not developing countries on the World Bank classification. Our count is that 1560 US patents were granted to developing countries on the World Bank list, out of total grants of 184057 in 2001. source: http://www.uspto.gov/web/offices/ac/ido/oeip/taf/cst_all.pdf

disclosures or instruction manuals). This is why even the best designed programmes to foster national capacity for research which are funded by donors have not always been successful. Since many technologies of interest to developing countries are produced by organizations from developed countries, the acquisition of technology requires the ability to negotiate effectively based on an understanding of the particular area of technology. This process requires a determined approach on the part of the recipient of technology to acquire the necessary human capital and the appropriate institutions. Countries such as Korea started at a low level of technological expertise forty years ago, comparable to many low income countries today, but have now become innovators in their own right.

This aspect of the process of technology transfer is largely in the hands of developing countries themselves. But this does not mean that developed countries, or international policies more generally, cannot facilitate or hinder the process. The TRIPS agreement recognises in Article 7 that IPRs should contribute to the 'transfer and dissemination of technology' but also, in Article 8, that measures needed to be taken to prevent abuse of IPRs including practices that 'adversely affect international transfer of technology.' Article 40 includes provisions to prevent anti-competitive practices in contractual licences. And Article 66.2 obliges developed countries to provide incentives to their enterprises and institutions to promote technology transfer to the least developed countries in order to 'enable them to create a sound and viable economic base'. These provisions in TRIPS reflect some of the provisions in the draft international Code of Conduct on Technology Transfer, on which negotiations between developed and developing countries failed in the 1980s.⁹⁰

As regards TRIPS, the evidence suggests that the provisions in Article 66.2 have been ineffective. Developed countries do not appear to have taken additional measures to encourage technology transfer by their firms and institutions. Moreover, the fact that the article applies only to LDCs seems unduly restrictive. As noted above, these are likely to be countries for the most part with the least absorptive capacity. In effect, I do not think Article 66.2 is the most appropriate way to address the entire issue of technology transfer to developing countries. Moreover some of the IPR provisions used historically to facilitate technology transfer, such as the use of compulsory working, have been significantly diluted under TRIPS. Since technology is mostly in private hands and TRIPS is principally concerned with the protection of IPRs, rather than technology transfer, it is uncertain as to whether TRIPS, rather than the WTO more generally, is the right focus for a discussion on technology transfer and that is why the establishment of the Working Group on Trade and Technology Transfer is a welcome initiative.

⁹⁰ The history and current implications are reviewed in Patel, S., Roffe, P. & Yusuf, A. (2001) 'International Technology Transfer: The origins and Aftermath of the United Nations Negotiations on a Draft Code of Conduct', Kluwer Law International, The Hague.

Although most applied technology is privately owned, it is important to remember the extent to which public spending on basic and applied research supports the process of technological development. Developed country public research spending now often has the explicit objective of enhancing international competitiveness and increasingly, the results of such research may be patented. Not only is research funding often tied to nationals, perhaps understandably, but also the benefits of such research may be restricted to nationals. For instance the law in the US restricts for the most part the licensing of publicly financed technologies to nationals, a policy for which the scientific and economic logic is less clear.⁹¹

⁹¹ The National Institute of Health (NIH) in the US has recently proposed a policy to vest the Worldwide IP rights derived from foreign research collaborators in the US Government, except in the collaborator's own country. Source: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-039.html>

5 The US Health Policy to Developing Countries

Many least-developed countries, for example in Africa, and some developing countries, lack sufficient manufacturing capacity in the pharmaceutical sector to make effective use of compulsory licensing as currently provided by the TRIPS Agreement. The US government has historically used its economic might to bully poor countries to adopt patent laws far stricter than WTO rules. With the protection offered by the Clinton Executive order on intellectual property and medications for poor countries, the glimmer of hope springs. The US has decided to take a more active approach to health crises in the developing world with an announcement on December 20, 2002 of an interim plan⁹² to help poor countries import generic medicines to combat HIV/AIDS, tuberculosis, malaria and other diseases that pose a national crisis. In the interim plan, the US pledged to permit these countries to override patents on drugs produced outside their countries in order to fight HIV/AIDS, malaria, tuberculosis, and other types of infectious epidemics, including those that may arise in the future.

There is growing evidence that the US Government does, at last, regard the global AIDS epidemic as a policy priority – officials even describe it as a ‘national security threat’. But even if cheaper anti-retroviral drugs can be channelled into the areas where they are most needed, that will do little to alleviate the crisis. Because pills alone are of little use in countries without the most basic healthcare – in cultures untouched by AIDS education, and in economies collapsing under the weight of mass poverty. America’s challenge now is to move from the argument over drug availability and forge a new, far-reaching partnership with countries at the centre of the AIDS epidemic.

In the November 2001 Doha trade negotiations, Ministers affirmed that global trade rules permit compulsory licensing of drugs for such domestic health emergencies. One issue left remaining was how to enable poor countries without domestic production capacity to import under compulsory license from third countries drugs needed for HIV/AIDS, malaria, tuberculosis, and other infectious epidemics. The US has indicated its commitment in finding a workable, transparent, sustainable and legally binding solution that will fulfil the Doha Declaration directive as soon as possible and to encourage other countries to reflect on the original purpose of the Doha Declaration and to work for a solution that is consistent with it. The Department of Commerce is working with the office of the US Trade

⁹² US Announces Interim HIV/AIDS Plan for Poor Countries: Measures taken in absence of WTO consensus on intellectual property. (20 December 2002) Available online: <http://usinfo.state.gov/topical/econ/wto/02122002.htm>

Representative and other federal agencies to develop an acceptable solution.⁹³

The pharmaceutical industry is unique among US industry sectors. The industry is consistently ranked one of the top performing industries. Fortune ranked the pharmaceutical industry as best performer in 2001. Large, diversified and global, the US pharmaceutical industry plays a crucial role in the US economy. On a global scale, the United States, is expected to be the engine for growth in the World Pharmaceutical market between 2002 and 2005. Due to innovation, the US will increase its dominance of the global pharmaceutical market to 60.5% by 2005 according to IMS health reports.⁹⁴ The International market for pharmaceuticals offers a wealth of potentials for US companies and is expected to grow at 7.8 percent annually to 406 billion dollars in 2002.⁹⁵ From the above analysis there is every reason for the developing world and the international community to expect the US to play a leading role on access to pharmaceuticals to the developing world. More than 50% of all new medicines are invented in the US. Therefore, we recognise that the solution both to today's – tomorrow's health problems will likely come from US companies.

The United States remains the largest bilateral donor of HIV/AIDS assistance, providing 45% of all international spending on AIDS. In fiscal year 2003, President George Bush has requested 1.3 billion dollars to combat HIV/AIDS internationally. This is an 82% increase over the 2001 appropriations. The President has pledged 500 million dollars to the Global Fund to combat the international scourge of HIV/AIDS, malaria and tuberculosis and the President announced a new 500 million International Mother and Child HIV Prevention Initiative that seeks prevent the transmission from mothers to infants and improve health care delivery in Africa and the Caribbean.⁹⁶ However, there are fears within some quarters that the US will use the offer as a foreign policy instrument. As one critic⁹⁷ put it if you are a 'bad guy', even if your people are dying, it is immaterial and that the US should give the money to UNAIDS, the WHO and the Global Fund. These institutions know which countries need the maximum assistance in terms of prevalence rates of HIV/AIDS. But it is argued that when such aid is dispensed bilaterally, certain countries that are desperately in need of assistance would be left out.

⁹³ ExportAmerica.

⁹⁴ ExportAmerica: Pharmaceuticals by Hurt W. and Marnie M., Chemicals, Pharmaceuticals, and Biotechnology, Trade Development: Available online: http://www.trade.gov/exportamerica/NewOpportunities/no_pharmaceuticals.html

⁹⁵ Ibid

⁹⁶ US Dept. Of State: US announces interim HIV/AIDS Plan for Poor Countries. Measures taken in the absence of WTO consensus on intellectual property, 20 Dec. 2002. Available online: <http://usinfo.gov/topical/econ/wto/02122002.htm>

⁹⁷ Ambassador Chidyausiku, a former chairman of the WTO's TRIPS Council and long time coordinator of Africa Group, in an interview, captioned WTO Procrastination on Public Health. Available online: <http://www.southcentre.org/info/southbulletin52-08.htm>

While the US pharmaceutical has done an outstanding job marketing its products, it has done a poor job marketing itself. The US pharmaceutical industry does more philanthropic work than any other domestic industry sector. From 1996 to 2000, America's pharmaceutical companies gave more than 1 billion dollars in health and infrastructure donations to the developing world. For example: Merck donated funding and medicines to Botswana comprehensive HIV/AIDS Partnership to improve HIV/AIDS education; Bristol-Myers Squibb contributed 115 million dollars through its Secure the Future Programme, which supports orphans, women and children with HIV/AIDS in Sub-Saharan Africa; and Pfizer funded the Academic and prevention centres in Uganda. Bristol Myers Squibb (BMS)- pledged R600- million Rand until 2004 for HIV/AIDS research and community outreach programmes in South Africa, Botswana, Namibia, Lesotho and Swaziland. In all, the pharmaceutical industry has a positive impact on humanitarian efforts in more than 100 developing countries around the world.⁹⁸ While the effort of the pharmaceutical industry is laudable, making drugs available to the developing world at affordable prices and at medically effective manner would go a long way to provide a long and lasting solution to the health pandemic in the developing world.

The US and EU have equally made a joint commitment to help stem and roll back the spread of HIV/AIDS, malaria, and tuberculosis in Africa, and to address their severe economic, social and personal consequences. According to a joint a statement issued on the 18th of Dec. 2000⁹⁹, they agreed that the scope of the problem requires a multi-faceted approach and the mobilization of significant resources aiming at the overall objective of alleviating poverty and to secure a lasting impact of any specific action to combat HIV/AIDS, malaria and tuberculosis. They both call upon countries to address and incorporate fully the health and development implications of the communicable diseases in the elaboration of their poverty reduction strategies and programmes. During the EU-US summit in Göteborg in June 2001, the establishment of a global fund to fight communicable diseases was agreed. It was also agreed that the EU and US should work with the pharmaceutical industry and with affected countries to facilitate the broadest possible provision of drugs in an affordable and medically effective manner.¹⁰⁰

⁹⁸ ExportAmerica, see note 90

⁹⁹ Text: US; EU Issue Joint Statement on Diseases in Africa: Issued at US-EU Summit in Washington December 18, 2000. Available online.
<http://www.aegis.com/news/usis/2000/US001213.html>

¹⁰⁰ The European Commission: Available online .
http://europa.eu.int/comm./development/sector/social/communicable_en.htm

6 The role of Governments and International Community

State Obligation to Respect, Protect and Fulfill the Right to Health

One normative initiative that complements the proposal for conceptualising and implementing strategies that facilitate low-end consumers access to affordable drugs to communicable diseases is the emerging international right to health. Although there has not been much attention paid to norm creation in this area¹⁰¹, there have been significant developments that have already laid a rights framework to facilitate access to essential medicines to consumers alongside other health-related needs.¹⁰²

States have at least three obligations here: to respect, protect, and fulfil the right to health. The duty to respect obligates not to discriminate in the provision of health care, as well as to remove the obstacles and barriers to access.¹⁰³ The duty to protect requires the maintenance of policies 'conducive to health protection'. Finally, the duty to fulfil obliges governments to have a national health plan with specific targets aimed at progressively realizing a right to basic health care.¹⁰⁴

However, social rights such as the right to health have not received as high a premium as civil and political rights, especially in the present international context of development, where social goodies are thought to flow from the inexorable forward march of the market.¹⁰⁵ Indeed, economic reform programmes under the aegis of the Bretton Woods Institutions¹⁰⁶ and bilateral donors have only led to lower budgetary allocations for social spending in areas such as health care. It is in this context that initiatives by national governments to address the communicable disease crisis and the handouts of drugs by pharmaceutical companies must be understood.

In addition, delivery of drugs is also an issue of international trade following the adoption of the TRIPS agreement after the Uruguay Round in 1994. Given that communicable diseases, like Human rights and

¹⁰¹ Leary, V. , The Right to Health in International Human Rights Law, 1 Health & Hum. Rts. 24, 26 (1994)

¹⁰² For an excellent review, see Paul Hunt, Reclaiming Social Rights: International and Comparative Perspectives 107-51 (1996)

¹⁰³ Chapman, A. R. Exploring a Human Rights Approach to Health Care Reform 28 (1993)

¹⁰⁴ Ibid.

¹⁰⁵ Susteiu C. Against Positive Rights: Why Social and Economic Rights Don't Belong in the New Constitution, 2 E. Eur. Const. Rev. 35, 35-38 (1993)

¹⁰⁶ The Bretton Woods Institutions are the World Bank and the International Monetary Fund (IMF). They are named for the Bretton Woods conference of July 1944, at which they were conceived.

environmental issues, is a social claim within the context of the WTO. Governments have the power to influence drug development, both through direct research funding and policies to influence the activities of the private sector. Not only can governments make a difference, they have a responsibility to do so. They should increase both their funding of and direct involvement in drug development for communicable diseases. But for the past twenty years, despite clear evidence of the decline in the private sector, government leaders have only stood by silently.¹⁰⁷

Leaders in disease-endemic countries have done little to improve the R&D situation of communicable diseases. In 1990, the Commission on Health Research for Development proposed that all governments allocate 2% of health expenditure to research. According to the Global Forum for Health Research and its Partners, none¹⁰⁸ of the low and middle-income countries studied were making this level of contribution in 1998.

A number of recent events have illustrated the effects of TRIPS Agreement on public health policies. In this respect, one landmark case was the law suit brought by a pharmaceutical industry Association and 39 of its affiliate pharmaceutical companies against the government of South Africa regarding the provisions of medicines and related substance control amendment Act. The South African government's resolve on the correctness of its policy, serious weaknesses in the technical arguments of the plaintiffs together with the strong pressure from domestic and international public opinion resulted in the withdrawal of the case. The case also signalled that public opinion is seriously concerned that intellectual property rights may be interpreted and implemented in a manner that runs counter to the promotion of public health policies by governments.

Further, in April 2001, the 5th Session of the United Nations Commission on Human Rights adopted Resolution 2001/33¹⁰⁹, on 'Access to Medication in the Context of Pandemics such as HIV/AIDS', which was approved by overwhelming majority of its members. The Resolution recognizes access to medicines in the context of pandemics as an essential human right. The Commission 'calls upon States, at the national level, on a non discriminatory basis for all to: 1) refrain from taking measures which would deny or limit equal access for all persons to preventive, curative or palliative pharmaceuticals or medical technologies used to treat pandemics such as HIV/AIDS or the most common opportunistic infections that accompany them; 2) adopt legislation or other measures, in accordance with applicable international law, including international agreements acceded to, to safeguard access to such preventive, curative or palliative pharmaceuticals or medical technologies from any limitations by third parties ; adopt all

¹⁰⁷ MSF: A Matter of Public Responsibility. Available online.

<http://www.msf.org/content/page.cfm?articleid=a8293378-5af5-4afe-a9ca1d673...>

¹⁰⁸ Commission on Health Research for Development, Health Research: Essential Link to Equity in development. (New York, N.Y: Oxford University Press, 1990) Global Forum for Health Research , 2001 publication.

¹⁰⁹ WTO: TRIPS Council Discussion on Access to Medicines. See note

appropriate positive measures to maximum of the resources allocated for this purpose so as to promote effective access to such preventive, curative or palliative pharmaceuticals or medical technologies.’

7 Conclusion

It is well known that improved health has been a determining factor in the rapid economic growth of many parts of the world during the 20th century. Communicable diseases, notably HIV/AIDS, Malaria, Tuberculosis continue to slow down human development. It is possible to improve the health of the poorest people by targeting investment on these communicable diseases.

The price of essential medications and basic proprietary medicinal products needed to prevent and treat the main communicable diseases is one of the major obstacles to improved health and access to health care for the poorest people in developing countries. Most medicines are produced and patented in industrialised countries and thus remain unaffordable for the poor. A comprehensive synergistic approach to this problem will be for the EU and the US to increase current aid in order to consolidate national policies and practices regarding pharmaceutical products, with the ultimate aim of improving quality assurance, distribution etc; review the prices of essential medication for these three principal communicable diseases, as well as the impact in terms of import duties and taxes.

It will equally be important to apply a system of tiered pricing, allowing manufacturers to offer the lowest possible prices to the poorest countries without jeopardising their profits in developed countries; sign voluntary licensing agreements to facilitate local production of medicines and ensure that developing countries benefit from technology transfer; increase capacities for local production of generic medicines through the development of laboratories, research centres and pharmaceutical industry, leading to effective competition on national markets; exploiting the flexibility provided for under the TRIPS Agreement to obtain compulsory licencing for resolving public health problems or coping with the crisis.

The TRIPS Agreement provides some flexibility for governments to fine-tune the basic balance provided for in the Agreement in the light of national social, developmental and other public policy objectives. While its rule require that national legislation embody certain minimum standards of protection, they afford considerable discretion in how these are implemented in practice. In each area of intellectual property, it allows governments to provide for exceptions, exclusions and limitations to rights, such as in the case of national emergencies, public non-commercial use, or remedying anti-competitive practices. This can be done, for example, in the form of compulsory licensing, exhaustion regimes and other types of exceptions, provided certain conditions are fulfilled.

Investing in research and development of global public goods used in the fight against the three diseases is a long term solution aimed at overcoming obstacles to investment and research in development. Three complementary

strategies can be envisaged here: boosting the amounts and the effectiveness of public investment, particularly by increasing support for research in developing countries; development of an incentive package for private investment (e.g. venture capital encouragement, purchasing funds etc.); participation in a global partnership to ensure that better account is taken of the needs of developing countries. To achieve success, a global international approach is required. Poverty reduction through improved health will likewise require cooperation between all international players i.e. institutions such as the EU, WTO, UN, WHO as well as NGOs and the private sector.

In launching the Doha Development Agenda, Trade Ministers placed development issues and the concerns of developing countries at the heart of the negotiations; they made commitments on technical assistance and capacity building to help developing countries participate effectively in the negotiations; they also established timeframes and a final deadline for concluding the negotiations. It is crucial that all these commitments be fully realized. At the same time, the two factors that are vital to success in the Doha negotiations – political commitment to the overall endeavour, and willingness to compromise – have been too little in evidence to date, including in areas of particular interest and concern to developing countries. It is of special concern that WTO Members were unable to meet the 2002 deadlines relating to special and differential treatment, access to essential medicines for countries lacking capacity to manufacture such drugs themselves, and concerns of some developing countries about difficulties they were experiencing in implementing existing WTO Agreements and Decisions.

The present disappointments must be converted into renewed political commitment and determination to negotiate in earnest. It will be worthwhile for the negotiators to address the immediate obstacles so that progress can be achieved in all areas of the Doha Development Agenda, as required by a single undertaking commitment. Progress is urgent because the World has to respond to the devastating and global impact of HIV/AIDS, malaria, tuberculosis and support particularly to the almost thirty million Africans now living with HIV/AIDS.

In September 2003, Trade Ministers will assemble in Cancun, Mexico, to review progress in negotiations and guide the Round towards its timely conclusion. I use this opportunity to urge the negotiators to address the difficult decisions now so that solutions can be identified, gaps narrowed and forward momentum injected into the process well before September 2003, so that a lasting and durable solution can be found on the current impasse on access to pharmaceuticals to developing countries to treat the major communicable diseases.

TRIPS: TEXT OF THE AGREEMENT (SELECTED ARTICLES)

Agreement on Trade-Related Aspects of Intellectual Property Rights

Article 1
Nature and Scope of Obligations

1. 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.
2. For the purposes of this Agreement, the term “intellectual property” refers to all categories of intellectual property that are the subject of Sections 1 through 7 of Part II.
3. Members shall accord the treatment provided for in this Agreement to the nationals of other Members. (1) In respect of the relevant intellectual property right, the nationals of other Members shall be understood as those natural or legal persons that would meet the criteria for eligibility for protection provided for in the Paris Convention (1967), the Berne Convention (1971), the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits, were all Members of the WTO members of those conventions. (2) Any Member availing itself of the possibilities provided in paragraph 3 of Article 5 or paragraph 2 of Article 6 of the Rome Convention shall make a notification as foreseen in those provisions to the Council for Trade-Related Aspects of Intellectual Property Rights (the “Council for TRIPS”).

Article 2
Intellectual Property Conventions

1. In respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention (1967).
2. Nothing in Parts I to IV of this Agreement shall derogate from existing obligations that Members may have to each other under the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits.

Article 3
National Treatment

1. Each Member shall accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection (3) of intellectual property, subject to the exceptions already provided in, respectively, the Paris Convention (1967), the Berne Convention (1971), the Rome Convention or the Treaty on Intellectual Property in Respect of Integrated Circuits. In respect of performers, producers of phonograms and broadcasting organizations, this obligation only applies in respect of the rights provided under this Agreement. Any Member availing itself of the possibilities provided in Article 6 of the Berne Convention (1971) or paragraph 1(b) of Article 16 of the Rome Convention shall make a notification as foreseen in those provisions to the Council for TRIPS.
2. Members may avail themselves of the exceptions permitted under paragraph 1 in relation to judicial and administrative procedures, including the designation of

an address for service or the appointment of an agent within the jurisdiction of a Member, only where such exceptions are necessary to secure compliance with laws and regulations which are not inconsistent with the provisions of this Agreement and where such practices are not applied in a manner which would constitute a disguised restriction on trade.

Article 4
Most-Favoured-Nation Treatment

With regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members. Exempted from this obligation are any advantage, favour, privilege or immunity accorded by a Member:

(a) deriving from international agreements on judicial assistance or law enforcement of a general nature and not particularly confined to the protection of intellectual property;

(b) granted in accordance with the provisions of the Berne Convention (1971) or the Rome Convention authorizing that the treatment accorded be a function not of national treatment but of the treatment accorded in another country;

(c) in respect of the rights of performers, producers of phonograms and broadcasting organizations not provided under this Agreement;

(d) deriving from international agreements related to the protection of intellectual property which entered into force prior to the entry into force of the WTO Agreement, provided that such agreements are notified to the Council for TRIPS and do not constitute an arbitrary or unjustifiable discrimination against nationals of other Members.

Article 5
Multilateral Agreements on Acquisition or Maintenance of Protection

The obligations under Articles 3 and 4 do not apply to procedures provided in multilateral agreements concluded under the auspices of WIPO relating to the acquisition or maintenance of intellectual property rights.

Article 6
Exhaustion

For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

Article 7
Objectives

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 a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Article 8
Principles

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

Article 30
Exceptions to Rights Conferred

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.

Article 31
Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use (7) of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

- (a) authorization of such use shall be considered on its individual merits;
- (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;
- (c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

- (d) such use shall be non-exclusive;
- (e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
- (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;
- (g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;
- (h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;
- (i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
- (j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
- (k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;
- (l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:
- (i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
- (ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and
- (iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

SECTION 8: CONTROL OF ANTI-COMPETITIVE PRACTICES IN CONTRACTUAL LICENCES [Back to top](#)

Article 40

1. Members agree that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology.
2. Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases

constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. As provided above, a Member may adopt, consistently with the other provisions of this Agreement, appropriate measures to prevent or control such practices, which may include for example exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member.

3. Each Member shall enter, upon request, into consultations with any other Member which has cause to believe that an intellectual property right owner that is a national or domiciliary of the Member to which the request for consultations has been addressed is undertaking practices in violation of the requesting Member's laws and regulations on the subject matter of this Section, and which wishes to secure compliance with such legislation, without prejudice to any action under the law and to the full freedom of an ultimate decision of either Member. The Member addressed shall accord full and sympathetic consideration to, and shall afford adequate opportunity for, consultations with the requesting Member, and shall cooperate through supply of publicly available non-confidential information of relevance to the matter in question and of other information available to the Member, subject to domestic law and to the conclusion of mutually satisfactory agreements concerning the safeguarding of its confidentiality by the requesting Member.

4. A Member whose nationals or domiciliaries are subject to proceedings in another Member concerning alleged violation of that other Member's laws and regulations on the subject matter of this Section shall, upon request, be granted an opportunity for consultations by the other Member under the same conditions as those foreseen in paragraph 3.

Article 66

Least-Developed Country Members

1. In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period.

2. Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base.

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