

# TRIPS, Drugs and Public Health: Issues and Proposals

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Third World Network

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**Issues and Proposals**

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## SUMMARY

A global health crisis is at hand. Millions of people die each year from infectious diseases that are treatable and preventable in many cases. The death toll is unacceptably high in developing countries, where many die because they do not have access to effective and affordable medicines. The public outrage over the high prices of HIV / AIDS medicines has also raised public awareness of the problem of access to medicines and the role of patents in increasing the prices of medicines.

Patents on pharmaceutical products and processes provide drug companies with monopolies over the production and marketing of medicines, allowing them to fix prices at high rates to maximise profits. The World Trade Organisation's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) has come under criticism for facilitating the extension of these patent rights around the world. The obligation under the TRIPS Agreement to implement high standards of intellectual property protection, including a minimum 20-year protection term for patent rights and the obligation to recognise product and process patents, effectively eliminates competition from generic pharmaceutical producers and allows for increased prices of medicines that will now be beyond the reach of even more patients in the developing countries.

Public criticism is mounting, as are questions about the legitimacy of patents on life-saving medicines. This has led to calls for changes or amendments to the TRIPS Agreement, which many feel is too heavily in favour of private rights and commercial interests, and against public interests.

The process in the WTO's TRIPS Council (which monitors the operation

of the TRIPS Agreement) to have special discussions on the issue of TRIPS and public health (as a result of requests from developing-country WTO Members) provides an opportunity for WTO Members to consider the means of addressing the negative impacts of the Agreement on public health and access to medicines.

This paper discusses some issues relevant to the discussion on the TRIPS Agreement, patents and access to affordable medicines. It is organised into five main parts.

Chapter 1 provides an introduction and background to the public concerns over the worldwide health crisis, the TRIPS Agreement and patents on drugs, and the process of the special discussion on patents and medicines in the TRIPS Council.

Chapter 2 on patents and prices examines the effect of patents and monopolies on the prices of medicines. The discussion here provides evidence of the impact of patents on the pricing of medicines, as well as examples of anti-competitive behaviour of the multinational pharmaceutical corporations.

Chapter 3 on the TRIPS Agreement and access to medicines looks at some of the limitations on the exclusive property rights of patent holders which are specifically provided for within the TRIPS Agreement. These include compulsory licensing and parallel imports, which can be used to curb anti-competitive practices and abuses of intellectual property rights. Compulsory licences and parallel imports are important tools in the context of protection of public health and promoting access to affordable medicines.

However, narrow interpretations of the TRIPS provisions relating to compulsory licences and parallel imports put forward by some developed-country Members have led many developing-country Members to feel restricted in their ability to employ these measures at the national

level. There have also been cases of pressures applied on developing countries in relation to their use of compulsory licences and parallel imports. The cases of the Brazil-US dispute in the WTO and the pharmaceutical companies' legal challenge against the South African government were just two obvious examples of such pressures.

In light of these developments, there have been calls for clarification and revision of the TRIPS Agreement in order to ensure developing countries' ability to effectively exercise their rights within the Agreement. What are the changes needed to the TRIPS Agreement and to the WTO process that can improve the situation? Chapter 5 puts forward recommendations for possible actions and makes some proposals for clarification and amendment of the TRIPS Agreement, in the context of the process of the special discussions in the TRIPS Council as well as other WTO processes.

This paper also assesses the role of differential or tiered pricing within the current debate on patents and medicines. Chapter 4 examines the proposal for a global tiered-pricing or differential-pricing system, first mooted by the European Union and currently under discussion in the World Health Organisation (WHO) and the WTO.



# **1 INTRODUCTION AND BACKGROUND**

## **Health Crisis in Developing Countries**

About 14 million people die each year from infectious diseases, many of which are preventable or treatable, such as acute respiratory infections, diarrhoeal diseases, malaria and tuberculosis. Up to 45% of deaths in Africa and Southeast Asia are thought to be due to an infectious disease (World Health Organisation, 2000). The death toll is unacceptably high in developing countries, even as health indicators show improvements in many countries of the world. This health crisis is caused by several interlinked factors – poverty, and the lack of access to health services, water and sanitation being just some of them. However, a vital factor in the promotion of public health – and very often a matter of life and death – is the supply of effective and affordable medicines and people's access to such medicines and treatments.

In the case of HIV / AIDS, a human tragedy of mind-boggling dimensions is now at hand. Of the 36 million people with HIV / AIDS in the world, 25 million are in sub-Saharan Africa. In certain African countries, more than a quarter of the adult population are infected with HIV, and life expectancy is projected to decline dramatically in the next 10 years. For example, life expectancy in South Africa is projected to fall by 20 years by the year 2010 due to the spread of HIV / AIDS. The HIV / AIDS epidemic has put the spotlight on the issue of affordability of essential medicines. In industrialised countries, AIDS deaths have been dramatically reduced partly because of the availability of life-saving medicines. However, the cost of a year's worth of the standard treatment, a combination of three antiretroviral drugs, may come up to US\$10,000-15,000 (the *Guardian*, 12 February 2001). This price level puts such treatment out of reach of most



people in the developing world, where 95% of the people with HIV are from.

Public interest worldwide has been aroused by the health crisis in the developing countries, caused by the exorbitant prices of drug treatments. HIV/AIDS medicines are a high-profile example, but there are also many cases of medicines for other life-threatening diseases being made unaffordable, simply because companies owning or controlling patents on the medicines have been able to block competition from other firms and other products. Prices of patented medicines are very much linked to the monopolies enjoyed by pharmaceutical companies, protected and maintained by patent rights.

### **The TRIPS Agreement and Patents on Drugs**

Patent rights are being extended around the world through the provisions of the World Trade Organisation (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Proponents of the TRIPS Agreement argue that patents and other intellectual property rights (IPRs) are essential for promoting research and development (R&D) as well as stimulating innovation. Yet, there has been scant evidence that the introduction of TRIPS-compliant standards of IPRs protection has promoted transfer of technology, R&D or innovation in developing countries.

The intensive use of the patent system by corporations is intended to protect their competitive edge and markets by keeping out competitors. This strategic use of the patent system has the effect of stifling R&D, preventing innovation and restricting information flows in the developing countries. Patent protection is sought to be justified on grounds that the negative effect of monopoly rights will be outweighed by the incentive for creative activity, innovation and R&D. The value of this trade-off is being questioned because the price and competition costs of strict

patent protection have been very high. In the health and pharmaceuticals sector, this trade-off often comes with life-or-death consequences.

The implementation of the TRIPS Agreement gives rise to factors that can put access to medicines out of reach for millions of people in the developing world. The TRIPS Agreement obliges WTO Member countries to adopt and enforce high standards of IPRs protection, which were derived from the standards used in developed countries. Prior to the Uruguay Round of multilateral trade negotiations that spawned the WTO, some 50 countries did not grant patent protection for pharmaceutical products (United Nations Conference on Trade and Development, 1996). This number included certain developed countries such as Portugal and Spain, and many developing countries such as Brazil, India, Mexico and Egypt. Many developing countries regarded the absence of protection as necessary to promote access to drugs at competitive prices. Conforming to TRIPS – by recognising and strengthening protection of IPRs over pharmaceutical products and processes – will cause problems for developing countries. Implementation of the TRIPS Agreement may lead to high drug prices, low access to medicines and a weakening of pharmaceutical industries in the developing countries.

It is feared that patent protection for pharmaceutical products and processes will have the effect of reducing or eliminating competition from generic production of medicines. There are about 10 industrialised countries with the pharmaceutical industry and research base capable of developing new chemical entities or new medicines. The multinational drug companies in these countries own most of the pharmaceutical technologies and products through patents (Balasubramaniam, 2001). The minimum 20-year patent protection period required by TRIPS effectively grants a pharmaceutical company a monopoly over the production, marketing and pricing of patent-protected medicines. During this protection period, the price of the patented medicine could be kept high in the absence of competition. By virtue of TRIPS protection, no generic equivalent can come into the market until expiry of the 20 years, thus

denying patients cheaper alternatives.

Domestic manufacturing of pharmaceutical products in developing countries will come to a standstill. Developing countries are able to produce new medicines by a process of reverse engineering; that is, researchers in developing countries may develop a new process different from the process invented (and protected by patent) to manufacture the new medicine or chemical entity. Reverse engineering is thus possible in countries where the patent law protects processes but not products. However, the TRIPS Agreement extends the scope of patent protection to both products and processes. Implementation of TRIPS therefore means that generic production of medicines will no longer be possible.

It is also a concern that the requirement for both product and process patents may be abused. For example, it would be possible to apply for patent rights over a product for 20 years, and thereafter, further periods of 20 years each could be applied for products produced by the patented process. Some experts caution that the 20-year protection can also be abused to extend the monopoly through process patents as well as patents on usage form, dosage form and combination form. In the US, for example, patents have been taken out on new combinations of drugs even when the product patent on the basic drug – the active ingredient – has long expired. Monopoly protection would be extended through minor changes to the existing medicines where the product patents have expired.

Developing-country pharmaceutical producers will find themselves pushed out of the market, not being able to compete with the large multinational corporations (MNCs). For the smaller producers in the developing world that specialise in and depend on manufacturing cheaper generic alternatives, this would no longer be possible – at least not until the expiry of the 20-year period. In some developing countries, domestic production capacity may never be developed.



The TRIPS Agreement further requires patents to be granted regardless of whether the product is imported or locally produced. This means that patent holders can merely import their product, without having to "work" the patent in the country granting patent protection. This will mean that an MNC can supply global markets under its patent monopoly by exporting the finished product instead of transferring technology or making foreign direct investment. This does not support the argument of TRIPS proponents that strict patent regimes will increase the flow of technology and investment into developing countries.

TRIPS proponents and the pharmaceutical industry further argue that patent protection is essential to ensure R&D for new drugs, but there has been little evidence to demonstrate that the patent system will ensure investment in R&D for diseases that afflict mainly the poor. Of the 1,223 new chemical entities developed in the 21-year period between 1975-1996, only 11 were for the treatment of tropical diseases (World Health Organisation, 2001). The last major new tuberculosis drug was developed 30 years ago, although tuberculosis remains a major cause of death in many developing countries. There is concern that R&D in the pharmaceutical sector is concentrated on products intended for the lucrative developed-country markets, given the increased investments for R&D on drugs for impotence, obesity and baldness, instead of R&D on new and more effective drugs for life-threatening or poverty-related "Third World diseases", including malaria and tuberculosis. The diseases of the poor attract very little R&D by the large pharmaceutical companies because they are not promising income generators. Only 0.2% of health-related R&D worldwide goes into pneumonia, diarrhoeal diseases and tuberculosis – diseases which account for 18% of the global disease burden (United Nations Development Programme, 1999).

Civil society groups and non-governmental organisations (NGOs) have called for revision of the TRIPS Agreement so as to ensure a proper balance between the protection of private rights and corporate interests, and the promotion of public interests in the socioeconomic and techno-

logical development of Member countries, including public health. Public criticism of the TRIPS regime is mounting, as are questions about the legitimacy of patents on life-saving drugs and the global monopolies provided to pharmaceutical companies by such patents. There is increasing public concern that the present model for IPRs protection advocated by TRIPS is too heavily tilted in favour of private right holders and against the public interest.

All this is leading to a crisis of legitimacy for TRIPS. In the six years since its coming into force, there has been increasing evidence of many social and economic problems caused by the introduction of stricter IPRs as a result of the implementation of the TRIPS obligations. The public outrage over HIV / AIDS medicines has added fuel to the negative public perception about the IPRs system and about the role of TRIPS.

### **Special Discussion on TRIPS and Public Health**

Against this backdrop of public criticism, WTO Members commenced a process of special meetings of the TRIPS Council to discuss issues related to patents and access to medicines. The Africa Group of countries in the WTO had proposed a special session of the TRIPS Council to address the controversy surrounding patents and access to medicines, describing the areas for action as follows:

“Our challenge is to address the question of affordable drugs in a manner that is fair and equitable to all stakeholders; in a way that seeks to avoid the abuse of patent protection through recourse to uncompetitive practices; a way that seeks to provide legal clarity in the interpretation and application of the relevant TRIPS provisions which allow the adoption of certain measures to enable the protection of health; indeed, a way that seeks to realise the objectives and principles of the TRIPS Agreement, and to restore confidence in a rules-based multilateral trading system.”

After initial opposition from certain developed countries, WTO Members agreed on a Special Discussion of the TRIPS Council in June 2001. During the Special Discussion, 50 developing countries (including the Africa Group, and countries from Asia, the Caribbean and Latin America) put forward a joint statement to the TRIPS Council, calling on the WTO membership 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".

The developing countries wanted affirmation of this common understanding, in order to clarify the differing (and restrictive) interpretations of TRIPS being advanced by some developed countries. They expressed concern that such restrictive interpretations would unduly limit their rights to undertake the full range of public health policy measures, for fear of legal challenge either in domestic courts or before the WTO dispute settlement mechanism. The Special Discussion in June ended with most WTO Members, including a number of developed-country Members, expressing support for the developing-country proposal for action at the WTO's Ministerial Conference in Doha, Qatar in November 2001. They also agreed to hold another Special Discussion in September 2001. The US, however, struck a discordant note, when it refused to acknowledge that there were problems related to TRIPS and access to medicines. It asserted that the TRIPS Agreement strikes a proper balance between offering incentives for innovation and ensuring access to medicines, and that there were inherent flexibilities in the Agreement, such as the transition period for developing countries.

During an informal meeting of the TRIPS Council in July 2001, developing countries reiterated their intent to secure a tangible outcome to the Special Discussion process. They have called for the initiation of a process to identify elements to be included in the Doha Ministerial Declaration which would give practical effect to the affirmation of the primacy of public health over TRIPS.



The process of identifying these elements and the issues related to them is expected to come under much discussion and debate within the TRIPS Council and the WTO, especially in light of the upcoming Ministerial Conference. This paper highlights some of the issues pertinent to the debate:

- How do patents on drugs affect access to medicines? The following chapter examines the effect of patents and monopolies on the prices of medicines.
- The TRIPS Agreement places certain limitations on the exclusive property rights of patent holders. These include compulsory licensing and parallel importation, measures which can be used in the context of protection of public health and promoting access to affordable medicines. However, pressures have been applied on developing countries to eschew the use of such measures. Chapter 3 discusses these measures, and the obstacles faced by developing countries in the use of such measures.
- What is the role of differential or tiered pricing in the debate on patents and medicines? Chapter 4 explores the proposal for a global tiered-pricing or differential-pricing system, first mooted by the European Union and currently under discussion in the World Health Organisation (WHO) and the WTO.
- What are the changes needed to the TRIPS Agreement and to the WTO process in order to improve the situation? Chapter 5 considers some of the possible actions and makes some proposals for clarification and amendment of the TRIPS Agreement, in the context of the Special Discussion and the WTO processes beyond it.

# 2

## PATENTS AND PRICES

### Effects of Patents and Monopolies on Prices

Product patents enable medicines to be sold at prices that are artificially high due to the curbing of competition. Product patents provide for absolute protection of the product. Process patents, on the other hand, provide protection in respect of the technology and methods of manufacture. With process patents, generic versions of medicines may be produced through alternative processes, allowing for competition from other producers. Product patents, however, prevent generic production.

The TRIPS Agreement, in requiring patent protection for both products and processes, will allow the patent holder an effective monopoly on the production and sale of the patented product for the duration of the patent (which, under TRIPS, is a minimum of 20 years). The patent holder is therefore able to exercise a monopoly in the pricing of the product. This relationship between patents and drug prices must be viewed in light of the WHO estimate that one-third of the world population currently lack access to essential medicines, and this number is likely to increase.

The effect of patents and monopolies on prices is demonstrated by data which compare prices of patented or branded products and those of generic products; prices of the same product sold in different countries; and the prices of raw materials used in the production of medicines, in the open competitive market and in transfer-pricing practices of MNCs. Some key points can be inferred from the available data:

- (1) Prices of branded or patented products are often far higher than

**the prices of similar medicines produced by alternative or generic sources.**

A comparison of prices for HIV / AIDS medicines illustrates the fact that the drug MNCs sell their medicines at much higher prices than those charged by generic producers. For example, the US price of 3TC (Lamivudine) marketed by Glaxo is US\$3,271 (per patient per year) whilst Indian generic manufacturers, Cipla Ltd. and Hetero Drugs Limited, offer their generic versions for \$190 and \$98 respectively. In the case of Zerit (Stavudine), the US price offered by Bristol-Myers Squibb is \$3,589 (per patient per year) as compared to \$70 and \$47 for the generic versions by Cipla and Hetero respectively. As for Viramune (Nevirapine) marketed by Boehringer Ingelheim, the US price is \$3,508, compared to the Cipla and Hetero prices of \$340 and \$202 (Kavaljit, 2001). This point is further illustrated by Cipla's offer of \$350-600 for a year's supply of a combination of these three anti-AIDS medicines, as compared to the price of \$10,000-15,000 for the branded medicines. In August 2001, Cipla launched a three-in-one AIDS tablet, which combines the three drugs, Lamivudine, Stavudine and Nevirapine. The new tablet, called Triomune, is said to cost patients around \$38 for a month's supply (Reuters, 6 August 2001).

**(2) When generic competition is introduced, prices of the patented product will fall.**

Competition from generic producers will result in the lowering and levelling of prices of medicines. For example, the drug fluconazole is marketed by generic companies in Thailand at \$0.29 and in India at \$0.64. This compares with market prices for brand-name drugs at \$10.50 in Kenya, \$27 in Guatemala and (until recently) \$8.25 in South Africa (Oxfam, 2001).

The case of Brazil offers another good example. When the Brazilian



government began producing AIDS drugs generically, the prices of equivalent branded products dropped by 79%. The domestic production of AIDS drugs has enabled the Brazilian government to offer universal free treatment, making its AIDS programme one of the most successful, having halved the AIDS death rate and saved \$472 million from averted hospitalisations (Medecins Sans Frontieres, 2001).

- (3) When a drug company sells the same product in different countries, it adopts a policy of price differentiation, setting price levels "according to what the market can bear".**

In a country where alternative or generic medicines are available, a branded product is usually priced lower due to the competition it faces from the cheaper alternatives. The same brand may be sold at higher prices in other countries where there is no competition from generic producers.

A 1998 Health Action International survey on Zantac, an anti-ulcer drug manufactured by Glaxo, indicated that the company lowered the price of the drug in India (marketed as Zinetac) because of competition. Several generic manufacturers in India produce ranitidine, the generic name for the active substance contained in Zantac. The survey showed that 100 tablets (150mg) of Zantac were sold for \$2 in India, \$3 in Nepal, \$9 in Bangladesh, \$30 in Vietnam, \$37 in Thailand, \$41 in Indonesia, \$55 in Malaysia, \$61 in Sri Lanka, \$63 in Philippines and \$183 in Mongolia. It was also sold at \$23 in Australia, \$77 in Canada, \$196 in Chile, \$132 in El Salvador, \$150 in South Africa and \$97 in Tanzania (Health Action International, 1998).

- (4) Multinational drug companies practise transfer pricing in the trade of raw materials used in the drugs, and this raises the cost of medicines in developing countries.**

A study by Dr Zafar Mirza (The Network Association for Rational Use of

Medication in Pakistan) compared prices of pharmaceutical raw materials imported into Pakistan for local manufacture by drug MNCs. The study found that several MNCs exported the raw materials to their subsidiaries in Pakistan at much higher prices than the prices of the same raw materials if purchased from the open international market at competitive rates (Health Action International, 1994). In the case of one drug produced by a German-based company, the price for the raw materials charged to the company's subsidiary in Pakistan was \$11,092 per kg whereas the competitive international price was \$320 – a price difference of 3,360%. For an Italian-based drug MNC, the price of the raw material transferred from the MNC to its Pakistani subsidiary was 7,044% more than the price in the international market.

- (5) There is a belief that drug companies sell their branded products more cheaply in developing countries. This is often not the case. Prices of some branded products are higher in many developing countries. This makes medicines even less affordable, as countries with much lower per capita incomes have to pay much higher prices for the same medicine as compared to prices in developed countries.

Another study by Health Action International shows that retail prices of 10 out of 13 commonly used drugs for which comparable data are available are higher in Tanzania (annual per capita Gross National Product of \$120) than in Canada (per capita GNP of \$19,380). The average retail prices of 20 commonly used drugs in 10 developing countries of Central and South America are all higher than the average retail prices of the same drugs in 12 countries of the Organisation for Economic Cooperation and Development (OECD, the "rich countries" club). The average prices of drugs surveyed in South Africa are higher than in any of the eight Western European countries for which data are presented (Health Action International, 1998).

## *Conclusions*

The above discussion suggests that the pharmaceutical industry fixes the prices for medicines by setting the limits according to what the market can bear (Balasubramaniam, 2001). Profit maximisation, through elimination of competition and maintenance of market monopoly, is the main objective. Patent protection is the most effective tool for drug MNCs to keep out competition from generic producers and thus maintain monopoly control over the production, marketing and pricing of medicines.

The pharmaceutical industry and its government supporters justify patents on medicines and high prices on the ground that R&D for pharmaceutical drugs is extremely expensive. Thus far, there is little convincing evidence to support this claim. Research indicates that industry estimates for R&D on each new drug range from \$350-500 million, while independent estimates range from \$30-160 million. Whichever estimate is used, revenues from many life-saving drugs are found to very easily exceed their R&D costs. For example, in 1999, the sales of Bayer's ciproflaxin totalled \$1.63 billion and Pfizer's sales of fluconazole totalled \$1 billion (Medecins Sans Frontieres, 2001).

The drug MNCs' claim that their huge investments in R&D warrant the high prices for their products is debatable in another respect. A number of the patented drugs were not in fact discovered by the MNCs. Rather, public-funded institutions and universities were largely responsible for the initial R&D of several medicines. For instance, the National Institutes of Health (NIH) in the US was instrumental in the discovery of a number of AIDS medicines. In fact, the NIH estimated that in 1995, its contribution to the overall US health R&D accounted for 30% of the total, whilst that of private industry amounted to 52% (Oxfam, 2001). The United Nations Development Programme's (UNDP) *Human Development Report*



1999 states that some 70% of drugs with therapeutic gains were produced with government involvement (United Nations Development Programme, 1999). And yet, it is the pharmaceutical industry that reaps most of the profits from the production and sale of medicines.

In addition, available data suggest that pharmaceutical companies spend more on marketing and administration than on R&D. As percentages of sales, R&D expenses account for 10-20%, while marketing and administration add up to 30-40% (Medecins Sans Frontieres, 2001).

It is not sufficient reason for pharmaceutical companies to justify high drug prices in developing countries as an incentive for R&D on new drugs. Eighty percent of the projected worldwide drug market is in North America, Europe, Japan and Australasia. All of Africa accounts for only 1.3% of the world market in pharmaceuticals. In fact, Africa and Asia, with 67% of the world's population, account only for 8% of the world market (Balasubramaniam, 2001). The small markets in developing countries will not significantly affect the R&D costs. The profits of the pharmaceutical industry will also be little affected by weaker patent protection in developing countries which would enable the latter to manufacture and market medicines at lower prices.

The Africa Group in the WTO has stated: "[A]ll this has further aroused public interest and led to the conclusion, in some quarters, that patents have enabled drug companies to raise prices of their products far above the levels that can be afforded by a great number of people. Further it is argued that contrary to the principles and objectives of the TRIPS Agreement, the present model of intellectual property rights protection is too heavily tilted in favour of rights holders and against public interest. ... In the same manner, patent protection is seen, whether rightly or wrongly, as shielding drug firms from competition from other firms and other products" (Zimbabwe, 2001).

An important conclusion made by K. Balasubramaniam, Pharmaceutical Advisor of Consumers International, is as follows:

“Consumers in developing countries can have regular access to affordable drugs when chemical intermediates, raw materials and finished products are available at competitive prices in the world market. This will not be possible when new life-saving drugs are given protection for 20 years and patent holders have the exclusive monopoly for manufacture, distribution and sales. The only way to ensure that chemical intermediates, raw materials and finished products are available at competitive prices in the world market and countries can freely import them is to have appropriate legislation, which will provide for compulsory licensing and parallel importing. Developing countries need assistance to enact such laws. They should not be in a rush to initiate the complex process of reform of the national legislation on IPR” (Balasubramaniam, 2000).

Despite the clear need for developing countries to exercise their rights to compulsory licensing and parallel imports to enable their people to have access to affordable medicines, a major and perhaps **the most disturbing aspect of the crisis of patents and drugs is that obstacles have been and are being put in the way of developing countries seeking to make use of TRIPS provisions on compulsory licensing or parallel imports in order to buy or produce drugs at more affordable prices.**

**The case of access to affordable medicines has illustrated a disturbing aspect of TRIPS: that this Agreement has facilitated, and is continuing to facilitate, anti-competitive behaviour and the flow of trade in products at prices that are influenced or determined by monopolistic elements, which hinder trade at free-market prices. This runs counter to the trade-liberalisation principle of the WTO.**

# 3

## THE TRIPS AGREEMENT AND ACCESS TO MEDICINES

For many developing countries, the interpretation and implementation of the TRIPS Agreement requires resources and capacity in excess of those existing. Implementation of the Agreement entails a very significant extension in the scope and duration of patent protection for developing countries, many of which had not hitherto provided patent protection for pharmaceutical products. Experts from developing and developed countries alike fear substantial increases in drug prices in the countries that had not granted such patents in the past.

However, the TRIPS Agreement, in its present form, does contain certain provisions that can be used to limit patent rights. These limitations or exceptions are to be effected through national legislation in order to curb abuses of IPRs and anti-competitive practices, and, generally, to offset the negative impact of patent monopolies.

Two of the most important measures in this regard are the right of governments to grant compulsory licences and the application of the principle of exhaustion of IPRs, which allows for parallel importation of patented products. These measures are perhaps the most crucial in enabling access to affordable medicines, particularly in developing countries that do not yet have local production capacity in the pharmaceutical sector. There are also other important exceptions to patent rights allowed by the TRIPS Agreement, including exceptions for experimental use and the "Bolar" exception, which are relevant in the discussion on pharmaceutical products. This paper will focus on the use of compulsory licensing and parallel importation measures.



## Compulsory Licensing

Compulsory licensing enables a government to issue a licence to a third party, whether a private company or government agency, to use or exploit a patent without the patent holder's consent. Compulsory licensees generally compensate the patent holder through payment of remuneration.

Many developed countries make available some forms of compulsory licences, either in their patent laws or under the specific sector legislation. Such licences are regarded as a crucial element in their patent laws and are mechanisms used to promote competition and prevent abuse of patent rights and monopolies. The mere existence of a legal provision for compulsory licensing may be enough to persuade patent holders of the need to act reasonably in cases of requests for voluntary licences, whilst strengthening the bargaining position of potential licensees (Third World Network, 1998).

In the context of pharmaceutical patents, such licences constitute an important tool to promote competition and increase the affordability of drugs, without depriving the patent holder of reasonable compensation.

### *Grounds for Grant of Compulsory Licences*

Provisions relating to compulsory licences or "non-voluntary licences" are contained in Article 31 of the TRIPS Agreement. Article 31 makes specific mention of five possible grounds for the granting of compulsory licences, that is, in cases of refusal to deal, in situations of national emergency and extreme urgency, to remedy anti-competitive practices, in cases of public non-commercial use and to facilitate the use of dependent patents. Since Article 31 does not lay down an exhaustive list of grounds for the issuance of compulsory licences, WTO Members should be free to determine further grounds for such issuance. Therefore, the TRIPS Agreement should not be interpreted to limit the right of countries

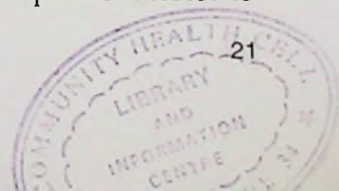
to establish compulsory licences on other grounds not explicitly mentioned.

Questions have indeed arisen as to whether WTO Members may issue compulsory licences on other grounds not specified within the TRIPS Agreement. On this point, reference should be made to the provisions of the Paris Convention for the Protection of Industrial Property related to compulsory licences, which have been incorporated into the TRIPS Agreement (by virtue of the latter's Article 2.1). The Paris Convention allows countries wide discretion to issue compulsory licences "to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent". During the Uruguay Round negotiations, efforts were made by a number of developed countries to limit the freedom available to countries under the Paris Convention in the grant of compulsory licences. However, these efforts failed due to strong resistance from developing countries. The compromise reached was to leave open the grounds on which such licences could be granted.

The Paris Convention recognises the right to grant compulsory licences on the ground of failure to work (i.e., where the patent is not exploited locally) or insufficient working (Article 5A). This provision of the Paris Convention has been incorporated into the TRIPS Agreement. On this basis, failure to work, or insufficient working of, a patent should be a legitimate ground for the issuance of compulsory licences. From a developing-country perspective, the local working of a patent is desirable, apart from its being necessary for making products available and affordable, for the technology-transfer opportunities it offers and for the reduced foreign-exchange expenditure that would otherwise have gone towards purchasing imports. However, some developed countries, in particular the EU and the US, have tried to press for a very narrow interpretation of the TRIPS Agreement, one which seeks to prohibit the grant of compulsory licences on the ground of non-working of a patent.

Where a developing country finds that it is in the public interest to

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encourage domestic production of patented medicines, for the purposes of controlling and preventing diseases and in the interests of availability and affordability, compulsory licensing will be a vital policy tool.

However, this alone may not be sufficient. At present, only a few developing countries – Argentina, China, Egypt and India (Korea and Mexico, now classified as OECD members, are two other such countries) – have strong enough national pharmaceutical sectors to be able to develop and manufacture medicines through the process of reverse engineering (Balasubramaniam, 2001). Therefore, these are the developing countries that are in a position to use compulsory licences to enable domestic firms to manufacture patented drugs.

Such a measure would, however, be meaningless for the rest of the developing-country Members of the WTO, which do not have the domestic manufacturing capacity. This raises the question of whether these countries would be able to grant a compulsory licence for the importation of the patented medicine product. This may in fact be the only viable means to use a compulsory licence in cases where domestic manufacturing capacity does not exist, where the size of the local market does not justify local manufacture, or where there is a need to promptly address an emergency situation. In these cases, a compulsory licence could be granted to enable a compulsory licensee to import from a compulsory licensee, or from other sources, in another country.

There is a further question of whether a compulsory licensee producing a patented drug would be allowed to export the patented product. The TRIPS Agreement stipulates that a compulsory licence must be “predominantly” for the supply of the domestic market. Therefore, exports are possible, although they should not constitute the main activity of the licensee with regard to the licensed product. In cases when a compulsory licence has been granted to remedy anti-competitive conduct, this limitation need not apply. This is the practice in the US in cases of compulsory licences granted under anti-trust legislation.



Developed countries have largely relied on compulsory licences as a tool to limit exclusive rights and prevent or remedy abusive practices. Recent legislative changes in these countries prove that the compulsory-licensing system is still much in use (Correa, 2000a). The grounds and conditions on which compulsory licences have been regulated and granted in developed countries illustrate the flexibility and potential of the compulsory-licensing system to address a multiplicity of public interests and concerns.

Such evidence indicates that arguments voiced by developed countries' governments and industry against compulsory licences as a deviation from acceptable IPRs standards are not reflected in the policies actually applied in these countries (Correa, 2000a). They are practising double standards by denying developing countries the use of effective policy mechanisms that they themselves have applied and continue to apply.

## **Parallel Imports**

Parallel imports involve the import and resale in a country, without the consent of the patent holder, of a patented product that was put on the market of the exporting country by the patent holder (Correa, 2000a). The underlying concept behind parallel imports is based on the principle of exhaustion of rights. This principle is premised on the fact that where the patent holder has been rewarded through the first sale or distribution of the product, he/she no longer has the right to control the use or resale of the product (Correa, 2000b). This would also be in line with the WTO's trade-liberalisation objective that from the moment a product is marketed, the patent holder can no longer control its subsequent circulation.

Nothing in the TRIPS Agreement prohibits parallel importation. Indeed, Article 6 specifically allows each Member country the freedom to incorporate the principle of international exhaustion of rights – the underlying justification for parallel imports – in its national legislation. It further

states that Members are not subject to the WTO dispute settlement system for disputes relating to exhaustion of rights.

Parallel imports are of particular importance in meeting public-health interests, since, as we have seen, the pharmaceutical industry generally sets prices differently throughout the world for the same medicines. Parallel imports would prevent market segmentation and price discrimination by patent holders on a regional or international scale. Parallel importation of a patented medicine from a country where it is sold at a lower price will enable more patients in the importing country to gain access to the medicine. Such measure would also not prevent the patent owner from receiving remuneration for the patented invention in the country where the product is first sold. In this regard, parallel importation must be regarded as a legitimate measure which WTO Members are permitted to adopt to protect public health and nutrition as provided for in Article 8 of the TRIPS Agreement.

In order to avoid a possible discrimination complaint under Article 27.1 (which touches on non-discrimination in the enjoyment of patent rights) and benefit all sectors of the economy, it is recommended that parallel importing should be permitted within national legislation for patented goods in all fields of technology and not only for health-related inventions (Correa, 2000a).

Developed countries and their corporations discourage parallel imports on the grounds that companies would then charge a single price worldwide – thus leading to an increase in the price that may be charged in low-income countries – were parallel importation to be implemented. This argument is a weak one, for, as shown above, available evidence provides proof that in many developing countries, the prices of the same medicines are in fact much higher than in developed countries.

## **Obstacles to the Use of Compulsory Licences and Parallel Importation**

It is vital that the right of governments to use compulsory licences and parallel importation measures is upheld and respected. Such measures must also be capable of effective implementation.

The TRIPS provisions governing these measures are, however, coupled with numerous conditions, making them difficult to operationalise effectively and speedily. More significantly, although the TRIPS Agreement allows for these measures to be undertaken for the protection of public health, some developed countries have sought to give a narrow interpretation of the provisions relating to compulsory licences and parallel imports, with the purpose of restricting the scope of such measures. This situation has led to the perception that there is a lack of legal clarity or common understanding of the TRIPS provisions. As the Africa Group has stated, "recent legal challenges by the pharmaceutical industry and some members in national law and the WTO/DSU [Dispute Settlement Understanding] have highlighted the lack of legal clarity on the interpretation and/or application of the relevant provisions of the TRIPS Agreement" (Zimbabwe, 2001).

This was a reference to recent legal challenges faced by South Africa and Brazil. In South Africa, the government was challenged in court by 39 pharmaceutical companies which sought a court declaration that the country's legislation on compulsory licensing was illegal. The companies eventually dropped the challenge under intense public pressure. In the WTO, Brazil was hauled up by the US before the dispute settlement system for enacting legislation (which has yet to be enforced) allowing for compulsory licensing in cases of non-local working. In June 2001, the US withdrew its complaint against Brazil on the apparent condition that Brazil would, prior to issuing a compulsory licence under the disputed legal provision, hold "talks" on the matter with the US.



Although these challenges have been withdrawn, the threat of similar challenges still exists. This situation has led to some unease and uncertainty on the part of developing-country Members, which are now hesitant or feel circumscribed in their ability to undertake such measures in their national legislation.

Equally disturbing is the fact that some developed countries, in conjunction with their corporations and industry lobbies, have been exerting political pressure on developing countries to prevent them from exercising their rights under TRIPS, and from enacting policies and laws on compulsory licensing and parallel imports for HIV/AIDS drugs and other drugs. Articulating the same concerns in the TRIPS Council, the Africa Group has reported on "attempts ... by some developed countries through bilateral and regional arrangements to get developing countries to apply TRIPS-plus measures, or to forego their rights" (Zimbabwe, 2001).

Examples of such pressures include the bilateral pressure applied on the South African government by the US administration against measures which would allow for compulsory licensing and parallel importing. The pressure was subsequently eased when AIDS activists caused significant embarrassment and damage to then US Vice-President Al Gore's 2000 presidential campaign. Thailand has also suffered a similar experience. US pressure was brought to bear on the Thai government to ban parallel imports and to restrict the use of compulsory licences, under threat of high tariffs on Thai exports (Medecins Sans Frontieres, 1999).

**It is therefore necessary for the WTO Members to clarify and come to a common and agreed understanding of the TRIPS provisions. Compulsory licensing and parallel imports are clearly permitted within the TRIPS framework. Therefore, developing countries should be allowed the maximum flexibility in interpreting and implementing the TRIPS Agreement provisions, and should be allowed to do so without fear of**

litigation or other pressures. It is vital that interpretations allow full flexibility for developing countries to exercise their rights to provide affordable medicines to their people, rather than restrict the scope and ability of developing-country Members to adopt measures to ensure access to medicines.

Proposals for clarification or interpretation of the TRIPS Agreement along these lines are made in Chapter 5.

# 4

## TIERED- OR DIFFERENTIAL-PRICING SYSTEM

In response to the growing controversy over the issue of access to medicines, the European Commission (the executive branch of the European Union) has proposed a "tiered-pricing" system that would work to offer lower drug prices to developing countries whilst maintaining prices in the developed countries. The concept of differential pricing has also been taken up by the WHO and WTO Secretariats.

Whilst these initiatives signal an effort to respond to public demands that the issue be tackled, the differential-or tiered-pricing approach must also be viewed with caution. Lessons should be drawn from the UNAIDS Accelerating Access Initiative which involves industry discounts on AIDS drugs. The process has been described as "slow, grudging and piecemeal". After almost a year since the announcement of the initiative, the medicines are still too expensive for the majority of the AIDS patients.

The country-by-country, company-by-company approach has contributed to the delay and has also resulted in different prices for different countries. There are also concerns that the individual deals differ in terms of the duration and quantity. It was recently reported that only Senegal, Uganda and Rwanda have negotiated deals for discounts on triple combination drugs, with the prices falling from \$1,821 to \$1,008 in Senegal, and from \$3,971 to \$1,974 in Uganda, per patient a year for a triple-therapy regimen (Medecins Sans Frontieres, 2001).

The announcement and offer by Indian generic producer, Cipla, demonstrates that much more is possible. Cipla has offered much lower prices on triple combination HIV/AIDS treatment (\$600 to governments and \$350 to the medical relief organisation Medecins Sans Frontieres) without



restrictions on time, geography or quantity. This means that pharmaceutical companies are capable of much bigger price cuts. Since Cipla's offer, there have in fact been offers of further discounts from the pharmaceutical companies.

The fact that the pharmaceutical industry favours the differential-pricing concept has also raised questions about a hidden agenda – to offer the differential-pricing scheme in exchange for restrictions on countries' rights to adopt compulsory licensing or parallel importation measures. The EU, in proposing the differential-pricing system, has also raised the issue of the need for safeguards against the "leakage" of low-priced medicines destined for specific markets into the markets of developed countries.

**It will be crucial for discussions or negotiations for such a system to be carried out in an equitable, fair and transparent process, given the circumstances. Most importantly, a differential-pricing scheme must not be offered as a substitute for WTO Members' rights to adopt compulsory licensing or parallel importation laws and measures. The tiered-pricing system must not result in conditions that restrict such rights being imposed on participating countries.**

If an initiative on differential pricing is to be considered, it must be approached on a multilateral basis and not on a country-by-country basis. It should not be limited either by place (the countries involved) or by time (limited to only a number of years). Negotiations and outcomes thereon must be transparent, involving all countries (and certainly all WTO Members) in a fully participatory way, and must also involve transparent prices, rules and regulations. The beneficiaries must include all developing countries and not be limited to only the poorest countries. Some life-saving medicines are priced beyond the reach of most of the world's population. Middle-income countries should be included in such a system, as they are more likely to have the capacity and infrastructure to treat large numbers of people immediately. In addition, Medecins

Sans Frontieres has called for tiered pricing to be based on the equity principle. This requires dramatically reducing medicine prices to a level that is reasonably affordable to the patient so that the medicines will not simply cost less but will truly be affordable to the patients who need them.

# 5

## CONCLUSIONS AND PROPOSALS

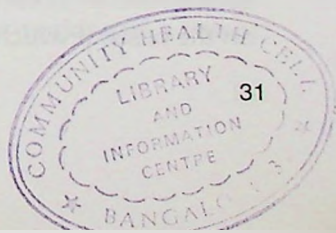
The TRIPS Council Special Discussions on TRIPS and Public Health represent an important opportunity to address growing concerns that implementation of the TRIPS Agreement will hinder access to affordable medicines. As the developing countries have made clear, they regard the Special Discussions as a process which will culminate in a tangible and implementable outcome, hence their proposal for the Doha Ministerial Declaration to specifically address the issue. The developing countries have identified several elements which they consider vital to be included in the Ministerial Declaration, including the use of Articles 7 and 8 in the interpretation of all provisions in the TRIPS Agreement; the right of Members to determine the grounds on which compulsory licences may be issued; recognition of compulsory licences issued to a foreign manufacturer; the right to parallel import; a moratorium on all dispute actions aimed at preventing or limiting access to medicines, or protection of public health; and the extension of transition periods for developing and least developed countries.

In this context, this paper makes some recommendations for action by WTO Members, including proposals for clarification and interpretation and, where required, revision of the TRIPS Agreement. It is suggested that these proposals could be realised as part of the decisions agreed to at the forthcoming WTO Ministerial Conference in Doha in November 2001.

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## **WTO Members' Rights to Adopt Effective Compulsory Licensing and Parallel Importation Measures**

Compulsory licensing and parallel imports are policy options which are clearly allowed under the TRIPS Agreement, and they must remain so. The problem of differing or divergent opinions on the provisions thereon in the TRIPS Agreement must be addressed in a manner that allows developing countries the maximum flexibility in interpreting and implementing the provisions. In the context of access to medicines, it is vital that interpretations be adopted that allow full flexibility for developing countries to exercise their rights.

It is also critical that developing-country Members be able to make national policies with a sufficient degree of comfort and not find themselves in situations of uncertainty, including being at risk of being taken before the dispute settlement system of the WTO, when exercising their rights within TRIPS. In this regard, Members must have clear and agreed guarantees that the TRIPS Agreement does not prevent or limit their obligation to protect public health and to respond effectively to outbreaks of diseases or pandemics and other health priorities. WTO Members should also support the implementation of policies and rules that encourage generic competition and local production of life-saving drugs. It is in this light that some of the provisions of the TRIPS Agreement should be interpreted and clarified.

### *Compulsory Licensing*

The TRIPS Agreement refers to a number of grounds for the grant of compulsory licences but does not limit the right of countries to establish such licences on other grounds not explicitly mentioned (Correa, 2000b). Article 31 of the TRIPS Agreement, which refers to the issuance of compulsory licences, does not lay down an exhaustive list of grounds for such issuance. Therefore, WTO Members can determine other grounds on the basis of which compulsory licences can be issued.

The usefulness of Article 31 as a provision to balance against broad patent rights that hinder access to affordable medicines will be unnecessarily limited if other grounds (besides the five possible ones specifically referred to therein) cannot be accommodated.

**In order to effectively protect public health and promote access to affordable drugs, developing countries must be able to grant compulsory licences on a range of grounds, including the following:**

- (a) in cases of failure to work or insufficient working;**
- (b) for importation of a patented product;**
- (c) for export of a patented product.**

Sub-sections (a), (b) and (c) below explain the rationale and set out more detailed proposals for the three grounds listed above.

Another problem confronting developing countries is the difficulties they face or may face in having to follow several procedural requirements or conditions prior to or in the process of granting compulsory licences. Article 31 specifies several such conditions, including procedures for obtaining the authorisation of the right holder on reasonable commercial terms, and payment of "adequate remuneration". These procedural conditions should not become a hindrance to the issuing of compulsory licences. Sub-section (d) below provides a proposal to address this matter.

**(a) Compulsory licence for non-working or insufficient working**

As mentioned earlier, the Paris Convention for the Protection of Industrial Property recognises the right to grant compulsory licences on the ground of failure to work or insufficient working, in order to prevent abuses arising from the exclusive rights conferred by patents. This provision of the Paris Convention is incorporated into the TRIPS Agreement. Therefore, the failure to work, or insufficient working of, a patent

is a legitimate ground for the issuance of compulsory licences. From a developing-country perspective, the local working of a patent is desirable as it presents opportunities for technology transfer to promote domestic manufacturing capacity. The ability to produce domestically will also help in reducing the outflow of foreign exchange for the purchase of imports, an important factor for many developing countries.

However, there have been cases of some countries advocating a very restrictive interpretation of the TRIPS Agreement that seeks to prohibit compulsory licensing on the ground of non-working of a patent. There is no justification for such an interpretation; thus, there should be a clarification to the effect that the non-working or insufficient working of a patent shall be a ground for the grant of compulsory licences.

### Proposal

The following clarification shall be made:

*Members may issue compulsory licences for the exploitation of a patent where the patent fails to be worked or is insufficiently worked in the country.*

#### (b) Compulsory licence for importation of patented product

A compulsory licence for exploitation of a patent on the grounds of non-working or insufficient working is appropriate where a country already has a reasonably advanced pharmaceutical industry for pharmaceutical production. At present, however, very few developing countries have this capacity. Where domestic manufacturing capacity is limited or non-existent, other measures are needed.

The TRIPS Agreement should not prohibit the option of using compulsory licences for the importation of a patented product. This may often



be the only viable means to use a compulsory licence in countries where domestic manufacturing capacity does not exist, where the size of the local market does not justify local production, or where there is a need to promptly address an emergency situation.

The compulsory licensee may import from a compulsory licensee who has been granted a licence to produce a patented medicine in another country. In addition, for compulsory licensing to be effective and to respond speedily to a national health need, WTO Members should also have the right to issue a compulsory licence to obtain medicines from a generic manufacturer in another country that has the necessary production capacity.

## Proposal

The following clarification shall be made:

*Members may issue compulsory licences for:*

- (1) *importation of a patented product or a product directly made with a patented process; and*
- (2) *importation of a patented product or a product directly made with a patented process from a compulsory licensee in another country or a producer in another country where the product is not protected.*
- (c) The ability of a compulsory licensee to export

A further question arises as to whether and to what extent a compulsory licensee could be allowed to export the product which he/she is licensed to produce. The TRIPS Agreement stipulates that a compulsory licence must be "predominantly" for the supply of the domestic market (Article 31(f)). Therefore, exports are allowed, although there appears to be a

limitation on the amount or proportion that can be exported. However, in cases when a compulsory licence has been granted to remedy anti-competitive conduct, this limitation is waived.

It should be clarified that the TRIPS Agreement allows the export of medicines produced under a compulsory licence, and a flexible interpretation should be given regarding the amount of export. In many countries with small populations, it may not be economically worthwhile for a local manufacturer to produce only for the local market, and thus the producer should be enabled to export should it apply for and obtain a compulsory licence. If a restrictive interpretation is applied (i.e., that exports are not allowed under compulsory licences or are allowed only under narrow conditions), there is a danger that compulsory licences may only be of use to countries with large enough markets to justify domestic production. In this case, countries with smaller populations would be penalised in that they would not be able to have a viable industry due to the restriction on exports. Smaller local markets in developing countries often deter potential compulsory licensees from accepting licences, since the domestic demand may not be sufficient for production to be cost-effective. The ability to export will provide an incentive for compulsory licensees in such countries. Therefore, a domestically-based manufacturer that has been granted a compulsory licence to produce a patented product primarily to satisfy domestic demand, can have the licence extended to cover export of the product so as to enable the manufacturer to enjoy economies of scale and thus be cost-effective.

Another major benefit of a flexible interpretation that allows for export is that there will be a greater volume of medicine supply, and at more affordable prices, to other countries that may wish to import from the compulsory licensees. It is unrealistic to expect every WTO Member to be able to develop the technologies and investments required for domestic production capacity. Therefore, these countries should be free to import from compulsory licensees (by virtue of the principle of exhaustion) to address public-health needs. There will be global welfare gains and more

affordable medicines especially for consumers in developing countries.

## Proposal

The following clarification shall be made:

*Members may issue compulsory licences that authorise the licensee to produce for the domestic market and to also export a portion of its production, and this portion can be significant and should not be unduly restricted (by Article 31(f)).*

### (d) Simplification of procedural conditions

As explained above, the right of developing-country Members to grant compulsory licences is constrained by the procedural conditions (specified in Article 31) they have to meet prior to or in the process of granting the licences. These conditions can limit the ability of governments to respond speedily and effectively to public-health needs. Thus, a decision should be taken to ease the conditions on grounds of public health. Eventually a revision of Article 31 may be required.

## Proposal

A decision shall be taken at the WTO Ministerial Conference as follows:

*Members shall review the procedural conditions for the granting of compulsory licences with a view to simplifying and limiting the conditions to enable Members to better respond to public-health needs and situations.*

### Parallel Imports

Parallel imports are of particular importance in the health sector since the



pharmaceutical industry generally charges different prices in different countries for the same medicines. Parallel importation can prevent market segmentation and price discrimination by patent holders on a regional or international scale. Parallel importation of a patented medicine from a country where it is sold more cheaply will enhance access of more patients in the importing country to the medicine.

Parallel importation is implemented in many countries, both developed and developing. It is a useful policy tool by which developing countries will be able to provide quick access to life-saving drugs, and to respond speedily to a health crisis or need. In this regard, parallel importation must be considered a legitimate measure which WTO Members are permitted to adopt to protect public health and nutrition as is provided for in Article 8 of the TRIPS Agreement.

No provision in the TRIPS Agreement prohibits parallel importation. As stated above, Article 6 allows each Member country the freedom to incorporate the principle of international exhaustion of rights in its national legislation. It should therefore be properly clarified that parallel importing is allowed under the TRIPS Agreement. Parallel importation can be undertaken where:

- (a) the patented product has been marketed in another country by the patent holder; or
- (b) the product is sold under a compulsory licence; or
- (c) the product is marketed in another country through legitimate means without the authorisation of the patent holder, such as where the product is not protected in the exporting country (i.e., in the case of a generic producer of medicines such as Cipla in India).

In order to avoid a possible discrimination complaint under Article 27.1 and benefit all sectors of the economy, parallel importing should be permitted for patented goods in all fields of technology and not only for health-related inventions (Correa, 2000a).

## Proposal

The following clarification shall be made:

*Members shall be allowed to implement parallel importation policies and regulations in the following manner:*

- (1) importation of a patented product originating in any country, where the product was marketed in such a country by the patent owner or his licensee, or where it was sold under a compulsory licence; or*
- (2) importation of a product marketed in a foreign country in a legitimate manner, including in the case of non-authorisation by the patent holder, such as where the product was not protected in the exporting country.*

## Bilateral and Regional Pressures

Serious and grave concerns have been expressed over attempts to discourage or deny Member countries from invoking the options and flexibility provided for in the TRIPS Agreement, through pressures applied in bilateral and regional arrangements. There have also been attempts to exert pressure on developing countries to implement in their national IPRs laws unnecessarily strict standards of IPRs protection that go beyond what is required by the TRIPS Agreement ("TRIPS-plus" measures).

There should be a commitment by all WTO Members that they will not pursue strategies of pressure or intimidation against countries that take measures to protect public health and promote access to drugs. Any attempt to coerce developing countries into foregoing their rights under the TRIPS Agreement would deal a serious blow to the credibility and

legitimacy of the Agreement and the WTO.

### **Proposal**

**The following decision shall be incorporated in the Doha Ministerial Declaration:**

*Members shall affirm their commitment not to exert bilateral or regional pressures on developing-country Members to forego their rights to adopt effective compulsory licensing and parallel importation measures and other measures to promote public health permitted under the TRIPS Agreement, or to pressurise or compel them to adopt measures and standards beyond their obligations in the TRIPS Agreement.*

### **A Moratorium on Dispute Settlement Cases**

The threat of being brought before the WTO dispute settlement system can cause uncertainty, anxiety and unease. Such a situation prevents developing-country Members from having the level of comfort and confidence to exercise their rights adequately or fully within the flexibility of the TRIPS Agreement. There should thus be a moratorium on WTO dispute actions that are aimed at preventing or limiting Member countries' capacity to address access to medicines and public-health issues. Specifically, Members should agree that there shall be no cases brought against developing-country Members in relation to the exercise of their rights to adopt compulsory licensing and parallel import measures, until a satisfactory resolution is achieved on the question of patents and access to medicines.

### **Proposal**

**There shall be a decision incorporated in the Ministerial Declaration as follows:**



*Members shall agree to abide by a moratorium on all dispute actions that are aimed at preventing or limiting developing-country Members' capacity to promote access to medicines and protect public health, particularly with regard to the exercise of their rights to adopt compulsory licensing and parallel importation measures. The moratorium shall be with immediate effect, and shall be in force until a satisfactory resolution is achieved on the question of patents and access to medicines.*

## **Excluding the Patenting of Medicines**

In respect of more effective measures to protect public health and promote access to medicines, a discussion should commence on the means by which countries can be given the flexibility of an option to exclude medicines (or certain categories of medicines) from patenting. Where the patenting of drugs has resulted in problems of access and high costs that prevent or hinder the treatment of diseases and the saving of lives, an option should be available for developing countries to exempt or exclude medicines from patenting on public-health grounds. Such exemptions or exclusions can be accommodated within the provisions of certain Articles of the TRIPS Agreement (with revisions where needed).

Both Articles 27.2 and 27.3 specify the exclusions from patentability that a country may provide for at the national level. Proposals for exclusion of medicines from patentability under these provisions are provided below.

### *Article 27.2*

Article 27.2 states that:

“Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or

plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law”.

## Proposal

The following clarification shall be made:

*Article 27.2 enables Members to exclude from patentability medicines or certain categories of medicines, including medicines that are essential, life-saving, vitally needed or used for treatment of poverty-related diseases.*

### *Article 27.3*

Article 27.3 states that:

“Members may also exclude from patentability:

- (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
- (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes ...”

This Article provides a list of subject matter that can be excluded from patentability. Article 27.3 should be amended by including medicines or categories of medicines in the list.

## Proposal

A decision shall be made at the Ministerial Conference that Article 27.3 be amended by adding a new sub-paragraph (c), which shall read as follows:

*Members may also exclude from patentability:*

*...*

*(c) life-saving, vitally needed medicines and medicines for the treatment of poverty-related diseases.*

## **Overall Balancing of Rights in TRIPS Agreement**

The question of overall balancing of rights is not specific to the issue of access to drugs alone, but is rather a problem that arises from the implementation of the TRIPS Agreement generally. The imbalances and problems in the Agreement need to be addressed. Many of the proposals to redress these problems in TRIPS are contained in the "implementation" proposals in paragraphs 21 and 22 of the Draft Ministerial Text of the Seattle Ministerial Conference, and several of these proposals relate to the objectives and principles of the Agreement set out in Articles 7 and 8. The credibility of TRIPS would be enhanced if these proposals are adopted by Members, and if Articles 7 and 8 are effectively operationalised or improved upon. The following is a proposal on improving Article 8.1.

### *Article 8.1 ("Principles")*

Article 8.1 states that "Members ... may adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socioeconomic and technological development, provided that such measures are consistent with the provisions of this Agreement".

Article 8.1 offers some scope for WTO Members to take necessary measures in the context of public health and access to medicines. However, the extent of its usefulness is limited by the phrase "provided that such measures are consistent with the provisions of this Agreement" as the latter to a large degree negates the underlying premise of Article 8, which is to allow WTO Members the flexibility to adopt policy measures



for the public good. It should therefore be clarified that the public-interest intention of Article 8 should not be frustrated, and a revision of the provision should be undertaken for this purpose. In line with a suitably amended Article 8.1, Members will have certainty when they adopt measures to protect public health. Such measures would include compulsory licensing, parallel imports and exclusion from patentability of medicines (or some categories of medicines).

## **Proposal**

**A decision shall be made at the Ministerial Conference that Article 8 shall be amended as follows:**

*No provision in this Agreement shall have the effect of preventing or limiting the right of any Member to adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socioeconomic and technological development.*

## **Tiered or Differential Pricing**

A tiered- or differential-pricing system may make a limited contribution to addressing the problem of access to medicines. To be effective and equitable, initiatives on tiered or differential pricing must be approached on a multilateral basis, with the participation of patent holders and generic producers in fair and transparent negotiations.

However, it is crucial that any differential-pricing initiative must not be used to extract promises of IPRs protection that could make medicines more expensive in the long term. As such, discussions on these initiatives should be undertaken outside of the WTO and the TRIPS Council. The discussions or negotiations shall not prejudice the rights of countries to adopt policy options permitted under TRIPS, namely the right to imple-

ment compulsory licensing and parallel import measures, nor should such initiatives be seen as an alternative to generic competition.

## **Proposal**

*Discussions or negotiations on initiatives on tiered or differential pricing shall not prejudice the rights of countries to adopt policy options in TRIPS, namely, the right to implement compulsory licensing and parallel import measures, nor should such initiatives be seen as an alternative to competition from generic drugs.*

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## TRIPS, DRUGS AND PUBLIC HEALTH: ISSUES AND PROPOSALS

Millions of people die each year of diseases which are preventable or treatable, and this health problem has assumed crisis proportions in the developing world. For most patients in the poor countries, the medicines to treat these lethal ailments are simply priced out of reach by producers who enjoy monopoly control over the manufacture and distribution of the drugs – control granted by rigorous intellectual property standards mandated under the World Trade Organisation (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

While the TRIPS regime is seen to be heavily tilted in favour of private intellectual property rights holders and against the public interest, there are provisions in the Agreement which allow Member countries to limit patent rights to address public-health needs. This report by Third World Network discusses the policy options permitted under these safeguards – two of the most important of which are compulsory licensing and parallel importation – to secure access to affordable medicines. Proposals are forwarded for clarifying these provisions to affirm developing countries' right to invoke them with full flexibility. As well, the report suggests amending TRIPS rules where required in order to ensure that the Agreement will not stand in the way of measures taken by developing countries to protect public health and to save human lives.

### TWN INTELLECTUAL PROPERTY RIGHTS SERIES

is a series of papers published by **Third World Network** to provide a critical analysis of intellectual property rights protection from a Third World perspective. A particular focus is given to the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and its implications for developing countries.