

One Small Step or One Giant Leap Towards Access to Medicines For All

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ABSTRACT

In December 2005, the World Trade Organisation members amended the Trade Related Aspects of Intellectual Property Rights agreement to find a solution to the problem of access to medicine. However, intellectual property provisions, as delineated in bilateral and regional free trade agreements, have the potential to undermine their purpose and success.

INTRODUCTION

A land mark in the fight for availability of generic medicines in developing countries was arrived at in November 2007. The European Union (EU), announced it had formally accepted the World Trade Organization (WTO) approved protocol of 2005, amending the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement. The amendment makes permanent a temporary waiver of the Doha Agreement of 2001, allowing for drugs produced under compulsory licence to be predominantly for the supply of the domestic market. However, in order for the decision to have legal effect, two-thirds of the 151 WTO members are required to ratify the agreement. EU acceptance only brings the number to 41^a. With so many obstacles one must wonder if universal access to medicines a realistic goal?

The rules of TRIP govern the proprietary interests in ideas, processes and products, and how the protective measures encompassed in these rights may be penetrated in the event of a "national emergency". The Doha Declaration of 2001 reaffirmed the flexibilities available within TRIPS, and asserted that the agreement should be interpreted in a manner that protects and promotes access to medicines and public health. Doha later led to the agreements of 2003 and 2005, which represented other stepping stones in the fight for availability of generic medicines in developing countries. This article considers the applicability of the 2005 agreement and how recent US free trade agreements (FTAs) are now compromising its potential.

GENERIC MEDICINES

Currently 33.2 million people worldwide are living with Human Immunodeficiency Virus (HIV)/ Acquired Immune Deficiency Syndrome (AIDS). Of these, over 31.3 million live in developing countries, with two-thirds in sub-Saharan Africa (2). A number of academic commentators attribute the problem to the apathy of most Western countries (3). While HIV/AIDS crosses national and class boundaries, it is not an epidemic here in Europe as it is in Africa. The public may well be aware of this problem, but few are affected by it on a daily basis. Therefore, the issue becomes sidelined and the lacklustre response from the developed world means that developing countries must address their needs themselves but they often encounter difficulties with patenting laws and subsequent threat of litigation. The availability of generic drugs is the only

manner in which developing countries can begin to tackle this growing problem.

Pharmaceutical Research and Manufacturers of America (PhRMA) argues that adequate patent protection should be afforded to encourage investment in Research & Development (R&D) and that a failure to give adequate patent protection results in a disincentive to invest in this important area. While the author agrees that inventiveness should be rewarded, the author submits many policy arguments advocating the development of the generic pharmaceutical industry. One such argument is that R&D may take many years and this is reflected in the price of on-patent drugs. A number of fundamental issues arise in justifying on-patent drugs for immediate crises as long-term R&D is redundant when people are dying (4). For those diseases which are not immediately threatening, few in developing countries can afford to pay for the on-patent drug. The crude reality is that for many illnesses affecting developing countries, there is no R&D by pharmaceutical companies. Companies will not invest in such drugs when patients cannot pay for them. The flexibilities developed and interpreted in TRIPS therefore represent an effective solution in promoting access to essential medicines.

PATENTS AND LICENCING

The Doha Declaration in 2001 catalysed a number of subsequent agreements on the provisions of TRIPS and their potential to fulfil the agenda of access to medicines for all. Essentially a number of "flexibilities" are contained within the agreement. For example, member states are protected against anti-competitive practices and patents may be used without permission in limited circumstances.

The Doha Declaration arose as an interpretative tool in the analysis of TRIPS, which states that compulsory licensing shall be "predominantly for the supply of the domestic market". Basically, the majority of developing countries do not have the available resources to develop on-patent pharmaceuticals locally. The reinterpretation thus represents a means of ensuring access to essential medicines in developing countries. In 2003, a temporary waiver was issued allowing for the issuance of compulsory licences. Countries without the requisite manufacturing capability were permitted to import drugs from countries with local manufacturing capacity. This was based on the caveat that exporting countries would not use the

^a Delineated in Paragraph 4 of Doha Declaration.

Declaration "...to pursue industrial or commercial policy objectives." Poorly developed countries or those countries capable of proving an absence of manufacturing capability could avail of the provision.

The implementation of the Doha Declaration represents a means for developing countries to address their public health problems as it provides flexibility by granting number of other options: compulsory licensing, the use of parallel importation, and the development of generic medicines to combat HIV/AIDS, malaria, and tuberculosis. In July 2007, Rwanda informed the WTO that it was availing of the Declaration to import cheaper generics made under compulsory licensing elsewhere and thereby became the first country to avail of this provision.

POTENTIAL PROBLEMS

A number of potential problems arise in attempts to implement the Doha Declaration. In addition to economic and political challenges, there are also substantial administrative burdens, which Professor Brook Baker regarded as "cumbersome" and a "procedural labyrinth." First, in the case of compulsory licences, both importing and exporting countries must issue licences. The compulsory licence issued by the exporting country is based on a "single-supply basis," hence this process must be repeated for each request. Secondly, a developing country must prove insufficient or no local manufacturing capacity in order to qualify. Finally, notice must be given to the WTO of the intention to use particular products, the quantities of such products, and the particular country's lack of adequate manufacturing capacity. Although the administrative requirements on drug-by-drug, country-by-country basis are not insurmountable, they do represent a further obstacle to acquiring good quality generic pharmaceuticals.

Parallel importation can give rise to defective and second-rate products arriving on the market. The agreement lays down requirements for those countries importing the goods to take "reasonable steps" in preventing the re-exportation of the goods, in particular labelling and marking of the product. This incurs an additional expense inevitably borne by the importing country. Countries exporting drugs under this provision will also need to satisfy strict administrative requirements. Correa has argued that administrative requirements specifying that low-priced medicines cannot be produced because "...meaningful economies of scale have not been reached..." results in a failure "to promote access to medicines for all" (5).

Amir Attaran and Lee Gillespie-White argue that patents themselves are not a barrier in the access to antiretroviral drugs in Africa (3). They state that poverty, lack of international funding, and limited donor spending represent more significant barriers. Essentially, they concluded that few patents existed in South Africa at the time and that

"geographic patent coverage [did] not appear to correlate with antiretroviral treatment access." Attaran and Gillespie-White blame the lack of international aid for maintaining the status quo. Non-Governmental Organisations disagree with the contentions of Attaran and Gillespie-White and argue that the most fundamental patents have been strategically patented by pharmaceuticals, and those which are unpatented remain so as they would not aid in community development^b. The fact that other antiretroviral drugs may exist off-patent is of little practical value if the majority of patients are using a particular "in use" antiretroviral drug.

The developing world makes up 80% of the world's population yet accounts for only 20% of its uptake of pharmaceutical goods. Helena Vines Fiestas, author of a recent Oxfam report, confirms, "High levels of intellectual property protection have not resulted in new cures for diseases that affect poor people," and further cites a United Nations estimate that nearly 2 million people in developing countries are denied access to essential medicines (6).

Patents invariably pose a great obstacle for those seeking treatment, as patented drugs are outside their price bracket. Attaran (7) explains that in 65 low and middle income countries the level of patenting for products is very low averaging only 1.4 patents per country. However, the drugs that are on patent are the most practical and effective regarding income and infrastructure in these countries. In comparison, the off-patent drugs are more expensive and difficult to administer and are thus not desirable to suffering patients. These results highlight the policy arguments regarding the corporate structure and access to essential medicines

Cohen et al. (8) in a recent paper examined the current state of affairs in Ghana. Through his compilation of information, we learn that in real terms the treatment of HIV/AIDS would require someone working on a minimum wage 5 days to cover the cost of treatment. Yet to add to this, many patients are unemployed and thus are unable to afford this treatment. The availability of generic drugs is thus a viable solution.

A further question arises as to why so few countries have aligned themselves with the waiver on licensing. While protective measures for developing countries are present in the TRIPS agreement, a fear exists that governments may be wary of using such measures for fear of political ramifications. In April 2007, the Thai government announced it would issue compulsory licences to manufacture low-cost versions of the non-nucleoside reverse transcriptase inhibitor efavirenz, the second-line combination anti retro viral drug lopinavir/ritonavir, and the antiplatelet clopidogrel. Abbott, who produces but lopinavir/ritonavir and clopidogrel has now withdrawn all its future products from the Thai market. Following the Thai example, Brazil in July 2007 issued a compulsory licence and will now import a cheaper, generic Indian-made version

^b On analysis certain flaws become evident in their study – it fails to take into account income levels, the rates of infection and the usage of the drug in question. A fundamental issue arises in that if the majority of on patent pharmaceuticals exist in countries with the highest levels of HIV/AIDS then these patents represent a barrier to the treatment of victims.

of the patented efavirenz drug. In the face of threats from drug companies, such moves are an exemplary beacon if universal access is to be obtained.

DATA EXCLUSIVITY & FREE TRADE AGREEMENTS

The EU position on data exclusivity is compliant with TRIPS^c. Essentially the first person to manufacture a product must submit evidence as to its safety and effectiveness. A subsequent generic manufacturer who wishes to bring the same drug to the market does not need to repeat the experiments once they show that the drug is of the same quality as the original drug. This allows the drug to come on the market quickly and at low cost due to the absence of an accumulation of clinical trials data.

While TRIPS allows for the protection of undisclosed clinical test data from “unfair commercial use”^c, no period of data exclusivity is specified, and the act does not specify that the original applicant have a period of data exclusivity. However, recent US bilateral and multilateral agreements are resulting in onerous TRIPS-plus requirements. The US free-trade agreements (FTA) effectively prevent generic manufacturers from using the original data to establish the safety and effectiveness of the drug. The FTAs refer to “HIV/AIDS, tuberculosis, malaria and other epidemics” and reflects the wording in Doha (9). Generic manufacturers must either wait a further five years, allowing technically five additional monopoly years for the patent holder, or engage in tests of their own which are crippling expensive. This represents a formidable obstacle to compulsory licences and allows the rights holder to prevent a state from using such information for a period of five to ten years.

The provisions of the US FTAs effectively prohibit actions that are permitted under TRIPS and undermine the Doha Declaration. Both the US and EU are aiming for a de facto right for clinical trial data relating to new pharmaceutical products^d. By bestowing exclusive rights on clinical trial results, the flexibilities of TRIPS become compromised. The use of original test data in clinical trials saves generic drug manufacturers considerable time and enables them to introduce the generic drug at a low price. The process of obtaining trial data would incur an additional expense on the drug. Essentially if the regulatory authority is unable to register a generic drug until the patent has expired, the compulsory licence is effectively redundant. It is prudent to note that if developing countries oppose these clauses seeking de facto rights for data, they may not gain favourable trade concessions from the EU and US. Professor Mercurio notes, “Many developing countries do not hesitate to trade off Intellectual Property Rights in exchange for market access” (10). He also adds that this is, in fact, the choice of developing nations and not the trading

nation as one might expect.

Perhaps there is some merit in the argument for data exclusivity rights? The information generated by the original investor involves considerable time and skill and is a substantial investment, and therefore it is one which should be protected. The volume of data required in the approval of a new drug is immense, and exhaustive information is required before a drug will be given approval. Regulatory approval can take 8-12 years to complete and can involve €800m. From 5,000 potential molecules, only one will become a marketable pharmaceutical. Invariably generic companies do not wish to engage in this costly R&D as this involves a large amount of time and money (11). However, from the perspective of developing countries, a restriction on the use of data represents a significant hurdle in the use of compulsory licences; yet, as Professor Mercurio notes, developing countries continue to negotiate FTAs as bilateral agreements with trading nations which can provide concrete gains (10). For developing countries, the provisions of bilateral and regional trade agreements significantly delay the registration of a generic drug even if a compulsory licence has been issued. Thus, if access to medicines is to succeed, WTO members must ensure that the restriction on data does not apply to compulsory licences. The US argue that this is their interpretation^d but essentially it results in an onerous TRIPS-plus standard on developing countries which have not achieved a level of development like that of the US^e.

A number of problems^f exist with regard to the US position (12). Although the US has argued that side letters to the FTA contain waivers in the event of national emergencies, these carry little legal weight. The side letters effectively contradict the FTAs and are effectively subordinate to such. The reference to particular diseases intimates that certain public health issues may not be covered. Disconcerting is the reference to “necessity,” a term rigidly defined in international law such that a country take only those steps “necessary”. Necessity indicates the least obtrusive option or where there is no alternative. Inevitably such speculative legal standing is deterring for generic companies.

BOLD MOVES TOWARDS UNIVERSAL ACCESS?

A number of factors may prevent universal access to medicines. PhRMA has erroneously argued that Brazil and Thailand are too rich to issue compulsory licences. There is also a danger that weaker, more vulnerable countries may not follow the lead of Brazil and Thailand particularly when pharmaceutical giants like Abbott are threatening to withdraw life-saving medicines from those countries that dare issue compulsory licenses^g.

c In regard to Article 39.3 of TRIPS.

d The US has sought to use bilateral agreements with its FTA partners as a means of enhancing IP rights. These TRIPS plus provisions appearing in the free trade agreements of the US mirror US domestic law.

e Similarly Russia has consented to onerous FTAs focusing on the enforcement of IPRs in order to join the WTO. In doing so Russia has succumbed to US demands and the IP standards surpass the WTO agreement on TRIPS. Particularly onerous are provisions regarding compulsory licences for essential medicines and is another example of the US persistence on the matter.

f Not content with FTAs, the US responded to the Thai TRIPS compliant licence by placing it on the Special 301 Priority Watch-List.

g Another factor weighing against universal access is that the international TRIPS framework has finally been implemented in India resulting in even more difficulty in sourcing post-1995 medicines. Due to the “mail box” system in operation in India the number of on-patent drugs is set to increase.

Solace can be found in the synergy between the Clinton Foundation HIV/AIDS Initiative's work with generic companies, UNITAID's funds and expertise, combined with the World Health Organization (WHO) pre-qualification service. The Clinton Foundation has been greatly aided by UNITAID's purchasing power sourced from a new airline tax initiative which has resulted in a straightforward acquisition of second-line medicines (13). National drug regulatory authorities can permit fast-track registration of medicines as a result of a pre-qualification service with the WHO, while UNITAID are proposing collective management of intellectual property rights through patent pools encompassing patents and registration of data rights. Furthermore, an intergovernmental working group has also been set up by the WHO to deal with public health and innovation and will present their findings in 2008.

An additional positive step is a response to complaints by Democrats in the US. A template was suggested in May 2007. It is proposed that generic drugs will come to market quicker through trade agreements with trading partners. The approach suggests protecting pharmaceutical test data in partner countries for as long as it is protected in the US, but no longer — thus allowing generics to come to market in both countries simultaneously. A public health exemption is also suggested to temper data exclusivity obligations. Further proposals aim to approve generics with no pre-requirement of non-violation of a patent. Finally and perhaps most significantly is a proposal for side letters on public health to have a formal legal basis within the FTA structure.

CONCLUSION

If the problem of access to medicines is to be tackled effectively, compulsory licences must be excluded from the remit of data exclusivity. The burdens of bilateral agreements serve as additional weight that undermines the TRIPS agreement and the potential of the Doha Declaration. International aid, combined with an increase in local technical expertise provided through developed nations, is necessary for developing countries to understand the flexibilities of TRIPS and how it can use these to tackle access to essential medicines. The words of Professor Frederick Abbott ring true: "The political will of governments as well as the private sector is essential to determining whether or not matters are effectively addressed....If the government and its private sector are not committed, very little may be possible" (14).

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