Strategies to Balance Patent Law and Low Cost Access to Medicines

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AN ESTIMATED SIX MILLION PEOPLE die of HIV/AIDS, tuberculosis, and malaria every year.[1] These diseases are much more than just a health problem. They constitute a global social crisis that seriously impedes the ability of developing countries to combat poverty and improve the lives of their citizens. HIV/AIDS, tuberculosis, and malaria are not the only diseases concerned, however. A number of other so-called neglected diseases such as leishmaniasis, onchocerciasis, lymphatic filariasis, and dengue occur only in developing countries and receive very little attention from pharmaceutical companies.

The threat to health and life posed by HIV/AIDS, tuberculosis, malaria, and neglected diseases reflects the grave global inequalities in access to disease prevention, treatment, and care. The challenge is complex and cannot be resolved by means of a single solution. It requires long-term investment in health systems, good governance, and education. It is also important to take a look at the social status of those affected. Who are they? Are they in a position to demand that action be taken for their benefit? We know that women and children are disproportionally affected by several diseases with a particular relevance to poverty.

One of the many issues that needs to be urgently addressed is the question of access to medicines that are effective against the above diseases, which affect vast numbers of poor people. Here, too, the challenge is complex. In some cases the problem is primarily one of limited access to existing medicines. This is partly related to prices. Also, we still lack sustained efforts to develop effective medicines against diseases, like malaria, that predominantly affect poor people or people in poor countries.

Patent systems were developed in the late nineteenth century both to protect

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the private interests of inventors so they could reap the benefits of their efforts, as well as to protect the public interest by stimulating innovation and investment. Patent rules stimulate the development of new medicines and have been conducive to the development of effective medicines for a number of diseases. Exclusive commercial rights do, however, result in a higher prices for products based on these inventions, since the patent right holders (patentees) set the price for the use of their inventions.

In the pharmaceutical industry, patents can therefore impede access to medicines for poor people by increasing prices. The inventor's exclusive right is finite, so prices decrease after a number of years when the invention becomes part of the public domain. But, for too many people, that may be too late. It can be argued that only a minority of essential medicines as defined by the World Health Organization are patent protected, and therefore the problem is of limited gravity. This argument is valid, but these protected medicines are typically the newest and most effective ones, including medicines for treating HIV/AIDS, so the issue is highly relevant for poverty reduction. Large investments and extensive testing are necessary before a patented drug can be sold on the market, and only a relatively small number of research and development projects actually succeed in producing patented medicines. The institution of patent protection for essential medicines therefore poses an ethical dilemma. If patents are too strongly protected, high prices and limited supply prevent the poor from gaining access to these medicines. [2] On the other hand, if medicines are too easily copied and no enforcement mechanism exists for protecting the patentee's rights, investors and inventors may find it too risky to devote time and resources to the development of new medicines.

Furthermore, patents have not proven to be a sufficient stimulus for the development of medicines to treat diseases that primarily affect those without purchasing power. For this we need inventive strategies to support research and development and ensure availability on a sustained basis.

Given the variation between countries in terms of economic development, national health care systems, and prevalence of diseases, the level of protection cannot and should not be the same everywhere. Any international framework for patent protection should provide national authorities with a sufficient degree of flexibility to enable them to safeguard access to affordable medicines for the poor.

TRIPS

The Trade Related Intellectual Property Rights (TRIPS) Agreement, concluded in the 1994 Uruguay Round of multilateral trade negotiations, provided for a mini-

mum level of intellectual property rights for all members of the World Trade Organization (WTO) and contained specific provisions on patent protection. Developed country members were expected to implement the agreement by 1 January 1996 while the least developed countries (LDCs) were initially given until 2006 to fully implement the agreement—a deadline extended until 2016 by the Doha Declaration on TRIPS and Public Health. Other developing countries were allowed a transitional period of up to 10 years,[3] which meant that these countries were expected to have fully implemented the agreement by 1 January 2005. As we are now well into 2005, we must be prepared for changes in the international market for generic medicines. Some of the developing countries that are now bound by the TRIPS agreement have been important sources of cheaper, generic medicines for poorer countries—countries that do not themselves produce medicines. Imports of cheaper, generic medicines to poorer countries from producing countries like India and Brazil could therefore decrease prices and increase access.

Flexibility

Since its inception, the TRIPS Agreement has been the object of much heated discussion concerning its effect on public health in developing countries. Several members, including my government, were of the opinion that the agreement initially paid too little attention to the problems of poorer developing countries with limited capacity to produce medicines themselves.

In 2001, the WTO Ministerial Conference[4] adopted a separate Declaration on the TRIPS Agreement and Public Health.[5] The Doha Declaration explicitly states that the TRIPS Agreement should be interpreted as supportive of the members' "right to protect public health and, in particular, to promote access to medicines for all." The Declaration thus sets the scene for differentiating intellectual property policies to protect public health. It explicitly recognizes "the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose." All members, including developing country members, are entitled to use the flexibility provided by the TRIPS Agreement to achieve national policy objectives for public health, such as providing affordable medicines for HIV/AIDS. The declaration is more than an expression of political ambition. It provides a legal basis for interpreting the TRIPS Agreement as consistent with public health objectives and for using the flexibility of the agreement for this purpose.

One area where member countries have some flexibility is in the scope of the patent protection granted at the national level. According to the TRIPS Agree-

ment, members must make patent protection available for "products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."[6] This means that all members are obliged to make patent protection available for new pharmaceutical inventions. However, there is no obligation to make patent protection available for new ways of using existing patented inventions. It is also up to the national authorities to assess what constitutes an "inventive step"; therefore the threshold for deciding whether a new medicine is eligible for patent protection is flexible. The scope of the exclusive rights conferred on the patentee is also flexible. For example, a country is at liberty to allow research to be carried out on the basis of the invention without compensation to the right holder, thus providing others with the opportunity to further develop the patented drug. The TRIPS Agreement does not oblige member countries to introduce penal sanctions for patent rights violations either. A country may leave it to the patentees to enforce their rights through civil remedies. A large multinational pharmaceutical company would probably be more reluctant to pursue its claim on patent protection if it had to go through a civil law suit rather than have the state prosecutor do the job.

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In many cases, developing countries have difficulty mustering the legal and technical expertise necessary to take advantage of the flexibility provided by the TRIPS Agreement. Moreover, the sheer complexity of setting up a patent protection scheme could prevent a country with inadequate resources from effectively using the flexibilities built into the TRIPS Agreement. Technical assistance[7] is thus needed to ensure that policy-makers are aware of the options available to them when they are amending patent legislation.

The TRIPS Agreement recognizes that the need to use an invention without the endorsement of the patent holder may arise, and thus, under special circumstances, national authorities are allowed the right to compulsory licensing.[8] Compulsory licensing schemes can be used to keep prices from increasing in developing countries as they implement the patent protection required by the TRIPS Agreement. Developing countries may, however, find it difficult to apply compulsory licensing for several reasons. Firstly, compulsory licensing requires an effective administrative system for processing applications. Many developing countries may not have the administrative capacity necessary to establish an independent and

effective system for compulsory licensing, hence the need for technical assistance mentioned above. Secondly, even when a license to produce a pharmaceutical product is granted, many of the poorer developing countries have limited facilities—or none at all—for the production of medicines. These are often countries that have serious public health problems or a high prevalence of diseases such as HIV/AIDS. They are in need of large volumes of imported medicines but at the same time have limited purchasing power.

Almost two years after the Doha Declaration, the WTO on 30 August 2003 finally adopted a system of compulsory licensing which addressed this problem of compulsory licensing in countries with insufficient domestic production capacity. The decision included a waiver of Article 31f of the TRIPS Agreement, and in so doing opened up for exportation to poor countries generic medicines produced on the basis of compulsory licencing. So far, only Canada and Norway have implemented the decision, but other countries are likely to follow suit in the near future. There is still some disagreement among members as to how the TRIPS Agreement should be amended to reflect the decision. Amending the TRIPS Agreement should be a purely technical exercise that would in no way alter the content of the 30 August 2003 decision. Deviation from the carefully drafted agreement could mean a reopening of the debate.

Considering the key role some middle-income countries play in supplying the developing country market with cheap generic medicines, it could be argued that these countries have a responsibility to ensure that their national legal framework and implementation do not entail a decrease in the accessibility of essential medicines for poorer countries.

Compulsory licensing schemes will obviously never be as effective in controlling the prices of medicines as unrestricted competition from generic copies. It appears, however, that compulsory licensing is an effective bargaining tool in negotiations with patent holders on the prices of essential medicines in developing countries. Several large pharmaceutical companies have had a change of heart regarding voluntary licensing. This may be due, at least in part, to the credible threat of compulsory licensing combined with political pressure. The number of voluntary licensing schemes has increased significantly over the last few years, delivering effective affordable medicines for HIV/AIDS to an increasing number of people each year.

According to studies carried out by Médecins Sans Frontières,[9] generic competition is the most effective way of lowering drug prices. The prices of antiretroviral medicines for HIV/AIDS have been falling steadily since 2000, particularly as a result of competition from generic products from India.[10] However, the price fall

has not been sufficient in degree or scope to ensure general access to affordable medicines.

New medicines are normally highly sophisticated. It is often argued that they cannot be easily or cheaply copied without the help of the inventor or patent right holder—thus, the quality of copy medicines may be inferior, and they may not have the intended effect or may cause serious side effects. The validity of this argument for the production of generic medicines has been questioned by both experts and public sector officials. The capacity to safeguard quality is, however, a bottleneck in most developing countries.[11] To compensate for this problem, the World Health Organization has established capacity for testing the quality of generic medicines for the treatment of HIV/AIDS, malaria, and tuberculosis.

Differential pricing of medicines—i.e. the adaptation of the prices charged by the seller according to the purchasing power in the respective countries—is frequently cited as an effective strategy for providing access to essential medicines. When prices are adjusted to the recipient market, the higher prices charged in rich countries compensate for low or zero-profit sales in poorer countries. Differential pricing schemes can be implemented by voluntary price differentiation on the part of pharmaceutical companies; bilateral negotiation of price discounts between governments and companies; and global partnerships between businesses, non-governmental organizations, and governments in the form of donations, bulk purchasing, and competitive tenders.[12] However, differential pricing will only be effective if there are stringent measures to prevent the re-exportation of cheap medicines to higher-priced markets. Differential pricing carries with it the risk of theft, smuggling, and corruption, and thus may undermine national health policy. Moreover, since differential pricing schemes depend heavily on the effective separation of markets, they do not address disparities in income levels within countries and markets. This approach therefore must be supplemented with public health schemes, such as subsidizing medicines for poor segments of the population. Also, many developing countries still rely on high import duties as an important source of public income. High customs duties may consequently reduce the advantages of price differentiation and subsidized imports. It is therefore important that developing countries ensure that fiscal policies do not limit access to affordable medicines.

Another problem is related to new generations of bilateral or regional trade agreements. In several cases, negotiating governments from developed countries have insisted that the flexibility provided by the TRIPS Agreement be limited through the introduction of higher standards of intellectual property rights protection—i.e. a TRIPS-plus obligation. In general, this development is negative.

National authorities in developed countries should ensure that trade negotiators do not safeguard the interests of their industries to the detriment of public health objectives in developing countries.[13] Developed countries must refrain from putting pressure on developing countries to take on TRIPS-plus obligations that limit the options available to them to safeguard public-health interests.

Only 10 percent of the world's resources for health research today are spent on 90 percent of the world's disease burden, which consists mainly of the so-called 'poverty diseases.' This is known as the 10/90 challenge. Financial incentives created by patents have not resulted in the development of efficient and affordable vaccines and medicines for these diseases. Governments must critically reassess how patent protection affects R&D and examine other ways of promoting the production of more effective medicines and vaccines for these diseases.

A number of private-public partnerships have emerged over the last few years to provide a capital base for funding R&D on vaccines and medicines for diseases that the pharmaceutical industry has not traditionally invested in to any appreciable extent. These partnerships also enhance the purchasing power of developing countries and thereby expand the market for relevant medicines. In addition, developed countries and multilateral development institutions should explore the possibility of guaranteeing a certain level of demand for a given medicine by setting aside funds for its purchase, then giving away such medicines free of charge. In the case of some critical diseases, this could provide a stimulus for more investment in poor-people's diseases.

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The development of cutting-edge technology in the fight against HIV/AIDS is among the efforts that have been impeded by market constraints. The development of an AIDS-vaccine and of products that can be controlled by women (so-called microbicides, i.e. gels, sponges, and films) and prevent the sexual transmission of HIV and other sexually transmitted diseases has been too slow. Yet products like these have the potential to make a difference in the fight against HIV/AIDS, and some governments and private foundations are trying to fill the void. Fundraising has been an uphill battle, but recent events are promising and more and more donors are rallying behind the efforts. For microbicides, the XV International AIDS Conference in Bangkok 2004 represented a turning point, but the shortfall of

funds is still huge. It is estimated that some $260 to 280 million is needed annually for the next five years; currently, the process is supported annually with some $140 million.

However, solving 10/90 problem will not only require the development of new medical products. Health systems and the research capacity of developing countries must be strengthened to the point where they are able to participate in research and seek solutions to medical problems which are adapted to their particular situations. When new drugs or vaccines are developed, clinical trials in disease-endemic countries are needed before the products can be made available for public use. The need for local expertise in epidemiology, statistics, and social sciences is often overlooked. The UNICEF-UNDP-World Bank-WHO Special Program for Research and Training in Tropical Diseases is a good example of a program that has adopted a holistic approach to address the 10/90 gap.

CONCLUSION

A number of strategies can be pursued to support access to affordable medicines for poor people. In order to address the inequalities inherent in unequal access to medicines, much more brainpower must be invested in the development of medicines for poor people. The incentives provided by patents have proven to be insufficient in this regard, and other sources of investment are needed.

There is a real danger of an increase in prices of essential medicines following the implementation of patent protection in countries that supply generic medicines from 1 January 2005.

The effective use of the flexibility provided by the TRIPS Agreement, such as scope of protection and compulsory licensing, could moderate a price increase for essential medicines in poor countries. In this respect, it is important that medicine-producing countries implement the WTO decision on compulsory licensing of drugs immediately, in a manner that makes compulsory licensing an effective measure to gain access to essential drugs when attempts to reach an agreement with the patentee fail. However, continued dialogue and cooperation with pharmaceutical companies on voluntary schemes are still the preferred approach to provide access to essential drugs. LDCs, for whom implementation of patent protection of pharmaceuticals is delayed until 2016, still have the option of producing generic copies of patented medicines. Some producers might even find it attractive to establish themselves in LDCs for that very reason. Developing countries should, at any rate, avail themselves of the flexibility provided by the TRIPS Agreement with respect to public health issues.

Finally, developed countries must refrain from putting pressure on developing countries to take on TRIPS-plus obligations that limit the options available to them in relation to patent protection of medicines that affect public health issues.

Rich and poor countries alike are challenged to address the serious health problems prevalent in a number of poor countries. It is vital that we monitor price development for essential medicines closely over the next few years and channel sufficient funding to the development of effective medicines for poor peoples' diseases. If we fail to do so, we will fail in one of the essential tasks we face in the fight against poverty. Millions of people will continue to die prematurely from or have their lives destroyed by diseases that could have been prevented. The challenge lies with governments as well as with industry.

Notes

1. Source: "Infectious Disease Report 2002," World Health Organization, Geneva.

2. While spending on pharmaceuticals accounts for less than one fifth of total public and private health spending in most developed countries, it accounts for 15 to 30 percent of health spending in transitional economies and 25 to 66 percent in developing countries. (Source: World Health Organization, Geneva)

3. If a developing country did not provide product patent protection in a particular area of technology when the TRIPS Agreement entered into force (1 January 1995), it was allowed up to 10 years to introduce such protection, see Article 65.

4. The Doha World Trade Organization Ministerial Conference, 9-14 November 2001.

5. See the WTO Document WT/MIN(01)/DEC/W/2, 14 November 2001.

6. Article 27.1.

7. Developing countries have received valuable technical assistance from the World Intellectual Property Organization (WIPO) in connection with their implementation of the TRIPS Agreement. It is nevertheless important that experts on intellectual property rights adequately address public health issues when giving advice to policy makers.

8. See Article 31 of the TRIPS Agreement.

9. Médecins Sans Frontières, "Untangling the Web of Price Reductions," February 2005.

10. According to Médecins Sans Frontières, of the 700 000 people who currently receive antiretroviral treatment in the developing world, 50 percent receive Indian generic medicines.

11. According to the WHO, fewer than one in three developing countries have fully functioning drug regulatory authorities. 10 to 20 percent of sampled drugs fail quality control tests in many developing countries. The failure to follow good manufacturing practices too often results in toxic, sometimes lethal, products.

12. One such example is the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), which is an independent international public-private partnership. The Global Fund has disbursed $1.5 billion in grants to 160 programs in 85 countries in its first and second round of grants.

13. The Norwegian Government has adopted a policy of restraint when it comes to pursuing TRIPS-plus obligations in relation to patents in free-trade negotiations with developing countries.