

The recent agreement on WTO patent rules

and access to medicines: a flawed deal?

In recent years international controversy has raged over the way in which global patent rules – as enshrined in the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) – are set to further restrict poor people's access to vital life-saving medicines by allowing companies to charge high prices for vital medicines. The WTO TRIPS Agreement requires all member countries, irrespective of their level of development, to provide a "minimum" of 20 years patent protection for all products and processes, thereby providing the pharmaceutical companies with an effective global monopoly for new medicines. Furthermore, the United States is using unilateral pressure and bilateral and regional trade agreements to ratchet up patent protection on medicines beyond the standards in TRIPS.

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Over 14 million people die each year from treatable infectious diseases such as HIV/AIDS, tuberculosis and malaria. More than forty million people are now living with HIV/AIDS, and close to 8,000 people die of AIDS every day in the developing world. Non-communicable diseases – such as cancers, asthmas diabetes and cardiovascular diseases – account for at least 40 per cent of all deaths in developing countries.

Much of this illness could be prevented if poor people had access to affordable medicines. But currently one third of the world's population does not. Moreover, because poor people lack purchasing power there is a lack of research into diseases

such as tuberculosis, malaria, and shigella. Less than 10 per cent of global spending on health research goes on 90 per cent of the global disease burden.

Many factors restrict access to medicines: poverty i.e. lack of money to buy medicines, lack of political will of governments, poor health infrastructures, inappropriate drug selection. But the price of medicines is also a key barrier in poor countries.

The main public focus has been on the excessively high price of patented HIV/AIDS medicines. But the problems caused by the TRIPS Agreement will extend beyond HIV/AIDS. There are many other diseases that ravage developing countries, for which new or improved treatments are, or will be, patented and expensive. Drug-resistant strains of tuberculosis, malaria, pneumonia and gonorrhoea are spreading fast, with enormous human cost. Non-communicable diseases pose an increasing burden in poor countries, and new diseases – such as SARS – can emerge.

As a result of a growing global concern, and the strong and united stance of developing countries, WTO members agreed the Doha Declaration on TRIPS and Public Health at the Doha ministerial meeting in 2001. This landmark Declaration affirmed the primacy of public health over private patent rights, and confirmed the rights of governments to use the existing public health safeguards in the Agreement, such as compulsory licensing, "to promote access to medicines for all". While the Declaration will not solve all the public health problems arising from the TRIPS Agreement, it was an important step forward in the struggle for affordable medicines, and a victory for developing countries at the WTO.

Activists of the Global Access Project during a protest in Cancún, Mexico, during the 5th WTO Ministerial Conference in September 2003. The AIDS activists are protesting against the current barriers for AIDS medicines and other medicines for other diseases and demand an accord on improving access to generic drugs.

A case of double standards?

Paragraph 6 of the Declaration on TRIPS and Public Health mandated WTO trade ministers to find a solution to one unfair and highly damaging double standard in the Agreement. This double standard prevents countries without drug production capacity – including most developing and least developing countries – from making effective use of compulsory licensing to gain access to affordable generic medicines. Currently rich countries can issue a compulsory license to produce a cheaper generic version of a patented medicine if the price is too high or supply limited. But most developing countries do not have the manufacturing capacity or market size to do so, and so rely on imports, at least for the active ingredients.

However, when the developing country drug-producing countries have to comply with WTO rules in 2005, it will be much harder for them to continue exporting. At this point countries without adequate drug production capacity will no longer be able to get access to cheaper generic medicines. They will have to pay the high price of the patented product – which they can ill afford – or leave patients without treatment.

A flawed deal?

Finding a solution to this double standard, should have been a purely technical matter, but the drug companies used their influence through the US and the EU, to try and backtrack on the promises they made at Doha. Rich countries exerted great pressure on developing countries to accept a deal which could only be used for certain diseases, emergencies or only by the poorest countries, even though the Doha Declaration contained no such restriction. They also tried to pressure developing countries to accept new layers of bureaucracy and legal hurdles. Finally, following two years of intense wrangling the WTO finally agreed a “solution” to this issue on 30 August, just before the 5th WTO ministerial meeting in Cancún. Supachai Panitchpakdi, WTO Director-General, was quoted as saying:

“This is a historic agreement for the WTO. The final piece of the jigsaw has fallen into place, allowing poorer countries to make full use of the flexibilities in the WTO’s intellectual property rules in order to deal with the diseases that ravage their people. It proves once and for all that the organization can handle humanitarian as well as trade concerns.” However, NGOs, including Oxfam, MSF, Third World Network and others, which had campaigned for a much simpler and fairer solution originally backed by the WHO and many developing and ACP countries, took a different view. In a joint statement at Cancún they said: “The August 30 WTO deal on exports of generic medicines is being presented as a gift to the poor. However, it is a “gift” bound tightly in red tape. As a measure of trade policy, it contradicts the basic principles of the WTO and free trade. The good news is that the developing countries resisted pressure from the United States, the European Union, Japan and other developed economies to limit the agreement to only a few diseases or for only extraordinary circumstances. But for a WTO “deal” to be more than a public relations exercise for a new round of trade rules, it should actually work in practice. The WTO took a 52-word mechanism that was endorsed by the European Parliament in 2002 and created a 3,200-word maze of red tape.”

The mechanism agreed by the WTO requires both the importing and exporting country to issue a compulsory license (if patents are in place), leaving most poor countries dependent on a political decision in another country to meet their health needs. Along with other restrictions, the double compulsory license also creates the possibility for uncertainty and delay, making the deal unnecessarily difficult for developing countries and generic companies to use. Moreover, ambiguities in wording leave the door open for the US and industry to restrict the scope of the deal by exerting bilateral pressures behind the scenes. However, despite these problems, the priority now must be for countries to implement it without any further restrictions, to try to make it work, and see if it can deliver the desired results. The NGO joint statement called upon every country that does not have “access to medicines for all” to begin to use the TRIPS public interest safeguards, and the 30 August 2003 WTO decision, to provide affordable medicines to the poor. This could still include simpler and more effective ways of allowing exports under TRIPS, for example under an Article 30 exception or Article 31k. The NGO joint statement noted that the current decision is only a temporary waiver, and the permanent amendment to TRIPS is scheduled for 2004. They called upon WTO member countries to draft an amendment to the TRIPS Agreement that simplifies and clarifies the procedures and removes unnecessary obstacles to the export of medicines to address public health problems.

The NGO statement also strongly urged countries to resist implementation of TRIPS-plus obligations in regional or bilateral trade agreements. Finally, the NGO joint statement said that if the framework imposed on countries by the WTO cannot be used effectively to promote public health and access to medicines for all, then poor countries should not be obliged to issue patents on medicines.

Deeper problems with TRIPS

The deal was supposed to remove restrictions on the export of affordable generic medicines – but it does nothing to address the 20-year patent period imposed by TRIPS which restricts the production of affordable medicines. Increasingly, in the future the supply of generic versions of newly patented medicines will rely on countries issuing compulsory licenses. Unless this can and is done in a routine and flexible way, or unless patent rules are relaxed in developing countries, it will become increasingly hard for generic companies to achieve the necessary markets and economies of scale to produce affordable, quality generic medicines. If this happens it will mean new improved medicines will remain priced out of reach for many of the world’s poor. For this reason the international community must continue to monitor the health impacts of the Agreement, and consider further future reforms to the TRIPS Agreement in order to give developing countries greater freedom to decide the appropriate length and scope of patent protection for medicines based on public health needs. More broadly, evidence from authoritative sources indicates the need for a substantive review of the entire TRIPS Agreement in the light of its detrimental impact on global intellectual property rules on innovation, access to knowledge-based goods and development. ¹ ■

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1. Powerful critiques of the one-size fits all, high level of intellectual property protection mandated by TRIPS can be found in the reports of the UK’s expert International Commission on Intellectual Property Rights and the UK-based Royal Society, and in World Bank studies.