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# Patents versus Patients

## Five years after the Doha Declaration

Oxfam Briefing Paper 95

### Questions and answers

#### **Why is 'Access to Medicines' an important issue for development?**

Improving both the accessibility and affordability of medicines would save millions of lives and improve people's health and welfare. Attaining the highest possible standard of health is also a human right. In many developing countries, poor people, especially women, do not receive treatment because of either lack of availability or expense.

Many factors affect access to medicines, including: research and development of medicines that are appropriate for use by women and children, whose reactions to drugs are different from those of men; selection and distribution of medicines; infrastructure, capacity, and adequate financing of public health services. In developing countries there is a strong need for increased investment in public health services, to improve health facilities and to ensure that there are enough qualified health workers within reach of people needing the service.

Oxfam believes that everyone who needs medicines and health care should be able to get them, regardless of their sex, age, or income level. Improving accessibility and affordability of medicines will save millions of lives and will help to relieve the suffering of women, men, and children in developing countries. Good quality generic medicines cost a fraction of the price of patented medicines. Poor people depend on generic medicines for their health needs, and therefore the production and distribution of these medicines should be encouraged.

If medicine has a low price, this can enable governments to use their limited health budgets more efficiently to deliver medicines and other health services to their citizens. Furthermore, for people who have to pay for their own medicines, a lower price is often the difference between life and death. An affordable price for medicines can also ensure that a sick person and his or her family are not driven into poverty and indebtedness as a result of the high cost of essential medicines.

#### **What does 'access' to medicines mean?**

Lack of access to medicines can be caused by either unavailability or inaffordability. When a medicine is **unavailable** this could be due to:

1. A lack of good government policies on selection or quality of essential medicines.
2. A failure in the delivery system: This means that the medicines are not getting to the patient who needs them due to, for example, lack of health infrastructure, such as clinics, not having enough staff with the knowledge to buy the right medicines, lack of qualified health workers, or insufficient government financing to buy the medicines.
3. Inappropriate medicines: this means, for example, a lack of knowledge on rational prescribing, or inappropriate storing conditions for the medicines (they have past their expiry date, or are not stored at the proper temperature).
4. A lack of research and development for medicines needed for poor countries. This is especially important for neglected diseases, where the appropriate medicines have not been developed due to no commercial market in developing countries. Usually medicines are developed for adults, and tested mainly on men. This means, for example, that there is an urgent need to develop HIV medicines that are suitable for babies and children. Many other

medicines have not been tested to determine if they are safe for breastfeeding mothers to use.

When a medicine is **unaffordable** this could be due to:

1. The inventor (a drug company) setting high prices for medicines, so that they can be unaffordable to governments and the majority of the population.
2. A lack of competition, leading to high prices. This is often because of inappropriately strict monopoly protection enforced by patent holders. Generic competition is the surest way to decrease prices.
3. A lack of adequate public funding to provide the medicines free of charge or at heavily subsidised prices, especially for poor people. Public health systems in developing countries often do not include high-cost medicines.
4. Inequality within populations, especially gender inequality. Seventy per cent of the world's poorest people are women and girls, and it is difficult for them to get to clinics or have the money to buy medicines.

### **Why does the price of medicines matter for developing countries?**

Medicines represent the greatest share of health-care expense for people in poor countries. Spending on pharmaceuticals ranges from ten per cent to 20 per cent of expenditure on health in the richest countries, and from 20 per cent to 60 per cent in poorer countries.<sup>i</sup> Most people in developing countries lack health insurance coverage, which means that buying medicines can be a major cause of economic and social hardship. Across Asia, medicines comprise between 20 per cent and 80 per cent of out-of-pocket health care costs, and according to some estimates, a significant number of individuals are driven into poverty every year due to the high cost of medicines.<sup>ii</sup> As a result, poor people, and especially women, are disproportionately affected by the unaffordable price of medicines. Lack of medicines also puts an extra burden on women, who usually have the caring role for sick family members.

### **Should we only be concerned about medicines for HIV and AIDS?**

HIV and AIDS have caused the single greatest human reversal in development over the last twenty years. While ensuring that access to affordable medicines for HIV and AIDS remains one of the highest priorities, other diseases also have serious consequences for the health, well-being, and economic security of poor people in developing countries. Among 15–24 year olds in sub-Saharan Africa, women are five times more likely to be infected than men, highlighting the need for women to gain access to medicines that are essential to their own and their children's health. However, there are other diseases which have enormous health and economic consequences for people and countries. These diseases also affect people who are HIV positive. There are three types of diseases in particular:

**Infectious diseases:** Tuberculosis (TB) and malaria claim the lives of two million people every year. Malaria has been estimated to cost Africa more than US\$12 billion every year in lost GDP, even though it could be controlled for a fraction of that sum.<sup>1</sup> Chest infections are still the main cause of mortality among children, even though they can be treated by simple medicines. Lack of treatment for TB and co-infection with HIV has led to the emergence of multi-drug-resistant TB, which is difficult and costly to treat. 'Silent infections', such as sexually transmitted and urinary infections, continue to cause suffering, especially for women. Other infectious diseases, such as Hepatitis C, also represent a severe burden for poor people in many developing countries.

**Non-communicable diseases:** Once considered a 'burden of the rich', the World Health Organisation (WHO) now estimates that over 80 per cent of deaths from non-communicable diseases (NCDs) occur in the developing world.<sup>iii</sup> By 2020, new cases of cancer in the developing world will have increased by 50 per cent more than the total number of cases in 2000.<sup>iv</sup> The number of people suffering from diabetes worldwide has leapt over the last two decades, from 30 million to 230 million, with most cases occurring in the developing world.<sup>v</sup> Besides causing severe morbidity and mortality, NCDs can cripple poor people economically and socially, because treatment often means a lifetime of paying for medicines, with an immense burden of care falling upon women.

<sup>1</sup> [http://www.rbm.who.int/cmc\\_upload/0/000/015/370/RBMInfosheet\\_3.htm](http://www.rbm.who.int/cmc_upload/0/000/015/370/RBMInfosheet_3.htm)

**Neglected diseases:** Because most people who suffer from diseases such as sleeping sickness and Bilharzia live in developing countries and are too poor to pay for medicines, the pharmaceutical industry has traditionally not bothered to engage in research and development to address these diseases. As a result, there is an acute scarcity of effective, affordable, safe, and easy to use medicines for such diseases.

### **What are Intellectual Property 'Rights', and what is a patent?**

The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) covers two categories of intellectual property: literary and artistic (copyright, and neighbouring rights) and industrial property (trademarks, geographic denominations, industrial designs and models, un-patented know-how, and patents). The WTO and TRIPS use the concept of 'rights' to describe this concept. However, given that Intellectual Property is not a natural right, Oxfam uses the term 'IP rules', or 'IP protection'.

Patents are part of 'intellectual property protection', which means that they are a legal creation. The patent system is designed by governments to encourage innovation, by giving inventors a guaranteed return on their investment. Because intellectual property is not physically tangible and can be used by many people simultaneously at no additional cost, a temporary monopoly licence is awarded, to prevent others from using it.

Patents are part of a social contract between the government, society at large, and the inventor. Basically, the inventor is given a temporary monopoly in exchange for (a) inventing new things, and (b) making them available to the public. All intellectual property systems have limited carve-outs (cash-raising mechanisms) to ensure that this balance between the interests of the inventor and those of society at large is not upset.

Although patents, and intellectual property rules in general, are one tool used by government to spur innovation, the pharmaceutical industry focuses on this tool as the only way to stimulate research and development (R&D). Governments have many other tools that can be used to stimulate R&D, such as direct funding, tax breaks, prize money, and advanced purchasing commitments. The recent reports by the WHO commission on IP and innovation, and the WHO resolution in May 2006, acknowledge the need to explore other tools beyond IP.

In rich countries, where there is the scientific and economic basis for innovation, there are incentives for inventors to continue innovating, knowing that they will be able to recuperate their investment. In such cases, there is (ideally) a balance between the proliferation of new inventions and the temporary cost of giving the inventor a monopoly.

In fact, developed countries introduced intellectual property rights when they reached the level of development adequate to benefit from assigning monopoly rights. The major industrial countries (Japan, Switzerland, Italy, etc.) adopted patent protection for pharmaceuticals at levels of per capita income of about \$20,000. However, developing countries will adopt intellectual property rules at levels of between \$500, in the case of the poorest, and about \$2000-\$4000 for the middle-income countries. By rich-country standards, forcing TRIPS on developing countries is about 50-100 years premature.<sup>vi</sup>

### **What is 'data exclusivity'?**

When companies apply to register a medicine in a country, they need to submit clinical data that shows the effectiveness and safety of the medicine, as shown by clinical trials. Generic producers have to provide evidence of bio-equivalence of their product to the original product, without having to repeat expensive and time-consuming clinical trials to prove how safe and effective the active chemical ingredient is.

Article 39.3 in TRIPS requires members of the WTO to protect such data submitted to health regulatory authorities against unfair commercial use. TRIPS does not require any period of market exclusivity. However, it does not define unfair use. The US law allows five years for data exclusivity and seeks to define that as a minimum protection against unfair use. The EU had to compensate for lack of strong patent laws in some of its countries (before TRIPS) by extending the data exclusivity rule to ten years. Currently all EU members are TRIPS compliant regarding the 20 years patent protection, but the EU kept the 10 years of data exclusivity.

While patent laws reward invention, clinical trial data is not 'intellectual property', and thus the data exclusivity provision protects profit rather than stimulating innovation. Currently there is strong pressure from the EU for new members to comply with the ten-year data exclusivity provision. Free Trade Agreements between the USA and developing countries have clauses for at least five years of data exclusivity.

With data exclusivity, generic companies will not be able to enter the market, as they generally are unable to afford repeating time-consuming and costly clinical trials. Above all, repeating clinical trials is unethical, because generic manufacturers would have to unnecessarily administer placebos to some patients, when the safety and clinical validity of a medicine is already established.

Currently, India is under great pressure to introduce a fixed period for data exclusivity, despite the fact that the current IP law, which is TRIPS compliant, does not provide a specific duration.

### **Are there any international regulations on patents?**

In 1995, the agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) was concluded as part of the creation of the World Trade Organisation. The TRIPS Agreement requires all WTO members to include certain minimum standards of intellectual property protection in their national laws. WTO members have to provide patents, in addition to copyright, trademark, and software protection. Under the TRIPS Agreement, patents on medicines are treated in the same way as patents on any other product, such as washing machines, cars, or MP3 players. However, medicines cannot be considered on the same basis as other goods because they are specifically important for people to realise a fundamental human right: the right to health. In addition, users or 'consumers' of medicines are not in a position to determine the quality of the product, and for that reason monitoring quality is a function of the state. Oxfam therefore believes that medicines should be classified as essential goods, which have to be accessible to all people.

The TRIPS agreement was pushed primarily by the USA and other rich countries, because their companies had much to gain from stricter international intellectual property standards. TRIPS was a significant victory for the pharmaceutical industry, since it meant that all WTO members will have to grant 20 years of monopoly rights to produce and market new medicines. Not even the USA granted 20 years of patent protection prior to TRIPS (it gave 17 years), so TRIPS represented international harmonization of IP at a very high level.

Less-developed WTO members were allowed more time to change their laws. Developing countries were given until 2005 to be TRIPS-compliant, and Least Developed Countries (LDCs) have been given a longer transition period to incorporate product patents for pharmaceuticals (until 'at least 2016').

Before having to incorporate the intellectual property protection required under TRIPS in their laws, developing countries were able to freely copy new medicines. Thus India has been able to produce inexpensive versions of expensive patented medicines and sell them to other developing countries. As of 2005, though, India had to implement TRIPS, and therefore generic production of new, patented medicines is no longer allowed. Health advocates are concerned that this important source of generics is drying up.

### **How do patents block access to medicines in developing countries?**

TRIPS gives the patent holder monopoly rights of 20 years to produce and sell their product. This means that because there is no competition they can charge higher prices in order to maximise their profit.

Although the big pharmaceutical companies say that they price their medicines differently in poor countries, pointing to agreements reached on lower prices with various governments, the prices that they offer are never as low as the prices resulting from generic competition. For example, after the Brazilian government began producing generic antiretroviral medicines for HIV, prices dropped by 82 per cent. In contrast, the prices of medicines with no generic

competitor dropped by only 9 per cent in the same time period. Indian generic companies, using the lack of strict IP before TRIPS implementation, managed to combine three antiretroviral medicines in one pill (Fixed Dose Combination), which is now the standard first-line treatment for HIV. This combination made it easier for patients to stick to the treatment regime and therefore improved HIV treatment. The three medicines are produced by three different originator companies and they all have different patents. Competition among generic companies reduced the price of this medicine to US\$ 140 a patient each year.

Since TRIPS implementation, generic competition for new medicines is not allowed. However, to remedy this, governments can use the TRIPS public health safeguards to protect public health. Unfortunately, their ability to do so is increasingly limited under the terms of free trade agreements with the USA, and due to political pressure by rich countries to protect intellectual property.

### **Are there any exceptions to the intellectual property protection in TRIPS?**

The TRIPS agreement includes a number of safeguards to protect public health. These safeguards are present in many intellectual property systems around the world, and are designed to maintain the balance between the interests of the public and those of the patent holder. Oxfam recommends that developing countries include them in their national laws. Examples of safeguards include:

**Compulsory licensing:** This can be used to temporarily override the patent for public health reasons. The government authorises production and/or importation of the generic medicines without the permission of the patent holder. To compensate the patent holder, reasonable royalties can be paid. Under the TRIPS Agreement, WTO members have the freedom to determine the grounds upon which to grant such a licence.

**Parallel importing:** In the case where a medicine is patented in a country, it can shop around and find the best price for that patented medicine on the global market, then import the patented medicine from another country. Permission of the patent holder is not needed and this process does not involve generics. Big pharmaceutical companies oppose this practice – which is allowed under TRIPS – because it undercuts their efforts to charge higher prices in markets that can afford it. For some countries, this can result in huge savings, because the price of patented medicines in a nearby country may be considerably lower. The EU allows this practice internally only.

**The Bolar provision:** This allows for testing and regulatory approval of generic versions of a medicine before its patent expires, to ensure that generic versions can be introduced immediately upon patent expiry. Without this provision, the introduction of a generic could be delayed for as long as is necessary for tests and to acquire regulatory approval, which is approximately one to three years after the patent expires.

### **Why are poor countries not implementing and applying these flexibilities?**

There are numerous reasons why most developing countries have not implemented TRIPS safeguards. After the TRIPS agreement, there was legal uncertainty created by rich countries and the pharmaceutical industry regarding the right of developing countries to use the safeguards. The USA and The Pharmaceutical Research and Manufacturers of America (PhRMA), in particular, have put intense pressure on developing countries, such as Brazil, Thailand, and South Africa, making it difficult for them to use the safeguards.

In fact, not only have they prevented use of these safeguards, the USA is enforcing even higher levels of intellectual property protection in developing countries (known as 'TRIPS plus' rules) through Free Trade Agreements (FTAs) with these countries. Developing countries must resist such pressure and introduce and enforce TRIPS safeguards in order to protect public health. Civil society has been exerting pressure in developing countries, such as Kenya, to implement the safeguards.

### **What is the Doha Declaration?**

The Doha Declaration **on the TRIPS Agreement and Public Health** was unanimously adopted on 14 November, 2001 at the WTO Ministerial Conference in Doha, Qatar. The Doha Declaration was a victory for developing countries.

The Declaration affirms that public health comes before commercial interest. The declaration stated that 'the (TRIPS) Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines to all'.

The Doha Declaration is a legal document, agreed after TRIPS, that can be used to interpret the TRIPS agreement. It has legal effects on the Member States and certain WTO bodies, particularly in terms of lodging complaints to the WTO Dispute Settlement Understanding.<sup>vii</sup> Above all, the Declaration is a moral and political commitment by all countries, but in particular the developed countries, to ensure that public health is protected before intellectual property rules.

### **Why do the Free Trade Agreements violate the Doha Declaration and hinder access to medicine:**

The USA is pursuing stricter intellectual property rules within the Free Trade Agreements, which undermine access to medicine because they include provisions to:

- expand the scope of pharmaceutical patents to include new indications, new formulations, and other minor changes;
- limit grounds for issuing compulsory licenses to emergencies, government non-commercial use, and competition cases only;
- prohibit parallel trade of on-patent drugs sold more cheaply elsewhere, where prohibited by contract;
- extend patent monopolies for administrative delays by patent offices and drug regulatory authorities;
- enhance protections for clinical trial data by providing at least five years of data exclusivity, and by linking drug registration rights to patent status, thereby preventing registration and sale of generics;
- enforce patent violations and grant drug companies investor-based rights to sue, including for improvidently granted compulsory licenses.

### **Will the production of affordable generic medicines for developing countries undermine innovation of new essential medicines?**

#### **1. Pharmaceutical companies recoup their costs primarily from developed-countries' markets.**

In 2003 the pharmaceutical market was worth \$468 billion worldwide. North America, Europe, and Japan accounted for 89 per cent of the market, while Africa accounted for barely one per cent. Furthermore, the pharmaceutical industry has been one of the most profitable, returning an average profit of 19 per cent per annum, as opposed to a five per cent average for other sectors of the Fortune 500 (the top 500 United States public corporations, as measured by gross revenue).<sup>viii</sup> In the last few years, emerging markets in developing countries, such as India, China, and Brazil, have become important markets for pharmaceutical companies. However, up to now they have concentrated only those who can afford to pay their prices. This is a new challenge for pharmaceutical companies: how to make a profit and at the same time fulfil their Corporate Social Responsibility on access to medicine in the emerging markets.

#### **2. R&D is directed more to maximising profit rather than true therapeutic innovation**

Companies tend to favour R&D for higher-priced and similar versions of existing medicines with little added therapeutic benefit. Companies also spend a lot of money on monopoly extensions and litigations.

### 3. Public sector funds a lot of R&D

According to the World Bank, half of the current R&D expenditure worldwide, estimated at \$70-\$90 billion, is funded publicly. Many of the medicines with high therapeutic value currently marketed by companies were also originally discovered with public funding. These include ARVs such as stavudine (d4T), zidovudine (AZT), didanosine (ddl), zalcitabine (ddC), abacavir, and ritonavir, as well as cancer medicines such as paclitaxel (Taxol).

### 4. Companies spend more on marketing than on R&D

Despite claims of profligate spending on R&D, 2004 figures show that companies spend, on average, only 14 per cent of their revenues on R&D, compared to 32 per cent on marketing and administration.<sup>ix</sup>

### 5. Intellectual property protection has not stimulated innovation for diseases that primarily affect poor countries

IP as a market mechanism has failed to stimulate innovation of medicines that would address those diseases that disproportionately affect poor people. The most recent medicine to treat TB is 30 years old. Only when the public and philanthropists (such as Bill Gates) intervened to create Public Private Initiatives has funding for R&D been made available for neglected diseases such as TB and malaria. It is clear that other mechanisms are needed to stimulate R&D in this important health arena.

### Are generic manufacturers stealing intellectual property and breaking the law?

No. Companies based in rich countries may claim that generics producers in developing countries are stealing their intellectual property. But patents are granted on a national basis and there is no such thing as an *international patent*. Therefore, just because a medicine is under patent in the USA, this does not mean that it is protected from competition in every other country; a patent in the USA only provides a monopoly for 20 years in connection with the US market. Therefore, if a medicine is not patented in a country, for example Kenya, it is perfectly legal for a generic company to produce or import a version of that medicine in Kenya. Companies in Kenya, which are producing the generic medicine, can export the generics to other countries where that medicine is not under patent, and none of this would be a violation of intellectual property rules. None of it would be 'stealing'. On the contrary, this situation could provide great benefits to patients in Kenya and elsewhere, because affordable versions of the medicine would be available. This has been the case of all generic medicines, such as ARVs, antibiotics, cancer medicines, and so on. In addition, patents are granted for twenty years, and when they expire it is both legal and appropriate for generics to enter the market at that time, which is the case for many medicines in Europe, the USA, and other developed countries.

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<sup>i</sup> WHO, 'The World Medicines Situation', Chapter 5, 2004.

<http://hinfo198.temppdomainname.com/medicinedocs/library.fcgi?e=d-0edmweb--00-1-0--010--4---0--0-10l--1en-5000---50-about-0---01131-00115ERnz+VC9ee84d6400000000436f372a-0utfZz-8-0-0&a=d&c=edmweb&cl=CL2.1.6&d=Js6160e.7>

<sup>ii</sup> Van Doorslaer, E. et al. (2005), 'Paying out of pocket for health care in Asia: Catastrophic and poverty impact', Equitap Project: Working Paper #2, May 2005.

<sup>iii</sup> World Health Organization, 'Chronic diseases and their common risk factors', accessed at [www.who.int/chp/chronic\\_disease\\_report/media/Factsheet1.pdf](http://www.who.int/chp/chronic_disease_report/media/Factsheet1.pdf)

<sup>iv</sup> Kerr, D., P. Boyle, M. Samiei (undated) 'Building Sustainable Cancer Capacity in Africa: Prevention, Treatment and Research', University of Oxford working paper.

<sup>v</sup> 'Poor nations struggle to cope with diabetes surge', Detroit Free Press, June 11, 2006.

<sup>vi</sup> Birdsall N., D. Rodrik, and A. Subramanian (2005) [www.ictsd.org/dlogue/2005-07-01/Docs/RODRIK-BRIDSALL\\_SUBRAMANIAN\\_what-rich-can-do\\_April2005.pdf](http://www.ictsd.org/dlogue/2005-07-01/Docs/RODRIK-BRIDSALL_SUBRAMANIAN_what-rich-can-do_April2005.pdf)

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<sup>vii</sup> C. Correa, 'Implications of the Doha Declaration on the TRIPS Agreement and Public Health', WHO, June 2002.

<sup>viii</sup> Public Citizen. " Rx R&D Myths: The Case Against the Drug Industry's R&D Scare Card". Congress Watch. July 2001.

<sup>ix</sup> Families USA (2005), 'The Choice: Health Care for People or Drug Industry Profits', September 2005 [www.familiesusa.org/resources/publications/reports/the-choice.html](http://www.familiesusa.org/resources/publications/reports/the-choice.html)