

Intellectual Property & Access to Medicines in Developing Countries

The Issue

Millions of people in developing countries do not have access to even the most basic healthcare services, including safe and effective medicines. This has led to a global healthcare crisis, in which diseases such as HIV/AIDS, tuberculosis (TB) and malaria are spreading in countries that have neither the resources nor the facilities to deal with them.

Poverty is the single biggest barrier to improving healthcare in the developing world. In many countries people do not have enough food, access to a clean water supply, hospitals or clinics in which to receive treatment, and healthcare professionals to care for them.

Nevertheless, there are some who prefer to blame intellectual property, and in particular patents, for the fact that many millions of people are denied access to the medicines they need.

This paper provides some background on the importance of Intellectual Property (IP) to biomedical innovation; addresses some of the accusations around how IP can act as a barrier to access; and sets out the real barriers and possible solutions to the access challenge in developing countries.

GSK's Position

- Improving healthcare in the developing world presents a complex challenge to the global community. It can only be addressed if the significant barriers that stand in the way of improved access are tackled as a shared responsibility by all sectors of global society - governments, international agencies, charities, academic institutions, the pharmaceutical industry and others.
- GlaxoSmithKline (GSK) is committed to playing a full part in addressing the healthcare challenges of the developing world by taking an innovative, responsible and, above all, sustainable approach. Our core business activity of developing and launching new medicines and vaccines significantly improves health. However, GSK is making a vital contribution to developing country healthcare through action in four areas¹:
 - preferential pricing of our antiretrovirals, anti-malarials and vaccines;
 - investing in research and development (R&D) that targets diseases particularly affecting the developing world;
 - community investment activities and partnerships that foster effective healthcare; and,
 - innovative partnerships and solutions, such as voluntary licensing.

¹ For more information, please see <http://www.gsk.com/responsibility/cr-review-2006/access-to-medicines.htm>

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- It is misleading and counter-productive to focus on patents in the access debate. Patent protection stimulates and fundamentally underpins the continued research and development for new and better medicines for diseases including those which occur in the developing world. Without adequate intellectual property protection, the medicines that are needed in the developing world are far less likely to be developed.
- The WHO estimates that adequate therapies do not exist for over 70% of the 2,500 currently recognised medical conditions, while many existing therapies could be improved. Market conditions must provide sufficient incentives to encourage the research required to address this need. Patents are a key incentive to the private sector to undertake the cost and risk of pharmaceutical development.

BACKGROUND

The Importance of Patents to the Pharmaceutical Industry

Developing an innovative pharmaceutical product or vaccine is a costly and risky activity. It requires:

1. the discovery of active substances suitable for treating or preventing the medical condition
2. developing them into formulations suitable for administration to patients
3. satisfying the regulatory authorities in all countries where the product is to be sold that the product is safe and effective.

Approximately 5-10,000 compounds are synthesised for every one that comes to market. Those that show some type of potential medical activity undergo pre-clinical and, if this is successful, large-scale clinical testing before applications to approve the product are made. Substantial numbers, often thousands, of patients undergo clinical trials. Following approval, post-marketing surveillance of the product is required.

The average cost of bringing a new pharmaceutical product to market has been estimated by Tufts University to be \$1.2 billion and only one in three drugs which are brought to market is profitable. Furthermore, approximately 70% of the cost of bring a product to market arises after discovery of the compound.

Patent Protection and Pharmaceuticals

Companies would not incur the risk and cost of innovative R&D if, shortly after launch of their products, a cheaper copy could be launched by a competitor who had the competitive advantage of not incurring developing costs and risk and who did not develop the market for the product.

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A period of freedom from competition from copies is therefore needed to provide the incentive to innovate and reward for innovation. Patents are a vital way of providing this incentive and reward. The period of exclusivity conferred by a patent relates to the specific patented product, not to therapeutic classes, for example. This means that novel products that do not infringe the original patent can still be launched to provide competition. So patented compounds from one company often compete with patented compounds from another, and unpatented (generic) products often compete with patented products.

Patents are granted for products and processes which are new (i.e. not known) and inventive (i.e. not obvious) at the time they are applied for. They give their owner the exclusive right to manufacture and market the product for (usually) 20 years from the date of application. In that 20 years, the innovator can prevent copy products from entering the market (although, as we shall see below, in practice the period of protection is very much shorter for pharmaceuticals.)

During this period of exclusivity, the innovator is given an opportunity to obtain the revenue needed to cover his costs, fund future R&D and obtain a reward for the cost and risk of his investment.

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The Doha Declaration and the 31f Agreement

The WTO TRIPs Agreement established minimum standards of IP protection which WTO Members have to comply with. Some argue that these standards create a barrier to access to medicines. This ignores the fact that the access crisis has existed since long before TRIPs came into force.

Further, in November 2001 the members of the World Trade Organisation agreed the Doha Declaration on TRIPs and Public Health. This Declaration recognised the importance of IP for the development of new medicines. It also clarified the public health safeguards in the TRIPs Agreement stating that "the TRIPs Agreement does not and should not prevent Members from taking measures to protect public health".

However, the Doha Declaration identified one outstanding issue. Art 31.f of TRIPs generally requires that a compulsory licence (CL) must be limited to predominantly supplying the local market. This meant that those countries that do not have the capacity to manufacture pharmaceutical products could not make use of the CL flexibility. The TRIPs Council was therefore asked to find a solution to the problems faced by those countries with insufficient or no manufacturing capacities in the pharmaceutical sector who could face difficulties in making effective use of compulsory licensing under the TRIPs Agreement. On 30 August 2003 the members of the WTO agreed unanimously on a solution to enable compulsory licensing of medicines for export.

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A formal amendment to the TRIPS Agreement was finally agreed in December 2005. The agreement reached allows for a workable solution for compulsory licensing for export but maintains respect for Intellectual Property. It strikes a balance in ensuring that GSK, and others, can invest in R&D for badly needed new vaccines and medicines for patients in the developing world, whilst allowing for compulsory licensing of patents where this is necessary to protect public health.

The Real Barriers to Access

There are many significant barriers to access in the developing world. The problem is rooted in poverty, which results in an inability to pay for even the cheapest medicines, including generics. Another key factor is a chronic under-investment in healthcare infrastructure which has led to a lack of clinics and hospitals, poor distribution networks, low numbers of trained healthcare providers, and high levels of patient illiteracy. Other factors that impede access are taxes and tariffs that raise prices unnecessarily, and cultural factors such as stigma and discrimination. This situation was neatly captured by the former WHO Director General, JW Lee who said:

“If all the money and all the drugs are available today, that will not solve the problem because it cannot be delivered. There are simply not enough doctors, nurses and infrastructure. It's very misleading (to say) that it is a lack of drugs that is making this crisis worse.”

According to the World Bank, a per capita spend on healthcare of at least US\$14 per year is required to provide a basic healthcare infrastructure. The expenditure on health of many sub-Saharan African countries is well below this. Significant additional external funding is essential for medicines and development of the infrastructure needed to deliver them. National healthcare systems must be strengthened, as current WHO Director General Margaret Chan said in her acceptance speech:

“Health systems are the tap root for better health. All the donated drugs in the world won't do any good without an infrastructure for their delivery.”

Patents as a Barrier to Access

To focus on patents as a barrier to access is misleading and counter-productive. Patent protection stimulates and fundamentally underpins the continued research and development for new and better medicines for diseases including those which occur in the developing world.

Few patents exist in many countries in Africa. In the context of the AIDS crisis in Africa, a study published in JAMA² looked at the existence or otherwise of patents for 15 ARVs in 53 African countries and concluded: “that patents and patent law are not a major barrier to treatment access in and of themselves”.

² Do patents for anti-retroviral drugs constrain access to AIDS treatment in Africa, 1886 JAMA, October 17, 2001 – Vol 286, No 15

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More broadly, over 95% of the 325 drugs on the WHO Essential Drugs List (EDL) are not patent protected and yet the WHO says that 30% of people in developing countries do not have access to these drugs. First line treatments for killer diseases like malaria and TB are available as generic products at very low cost, and yet many people are denied access to them.

Many people see tearing up intellectual property rules or expanding local manufacture, as a panacea. This is simplistic and counter-productive. If that were the answer, India would deal with AIDS better than any country in the developing world. Until recently, India had no IP protection for pharmaceutical products, and has the most developed generics industry in the world, and yet access to ARVS for those who need them is arguably no better than in Africa. And access to other essential drugs in India is lower than it is in Africa.

A Global Response

Access to medicines is a complex and multi-faceted problem. There is no simple answer. The challenges can only be properly addressed through partnership between developed and developing country governments, international organisations, the industry and charitable organisations.

- Increased Funding: Developed world governments need to provide additional resources for healthcare in the developing world through bilateral arrangements and support for multilateral organisations such as the Global Fund to Fight AIDS TB and Malaria.
- Retention of Healthcare Workers: Resources are needed to provide the infrastructure – hospitals, clinics, distribution networks – which will ensure that medicines reach patients. There also needs to be a concerted effort to discourage the export of a precious commodity - trained healthcare workers. More physicians from Benin practice in Paris than in the whole of Benin, and more Ghanaian doctors live in New York and New Jersey than Ghana. Uganda trains around 150 doctors every year, but about 30% of them leave the country. Recipient developed countries should take appropriate steps to monitor and reverse this activity.
- Price and Product Protection: Developed countries must undertake not to use the preferential prices offered to the developing world as benchmarks for their domestic drug prices. And, along with developing countries, they should act to prevent diversion of preferentially-priced product.
- No “free-riding”: Middle Income countries must accept their responsibilities and not seek the lowest prices offered to the world’s poorest countries. Compulsory licensing should only be considered as a last resort and the negative impact of widespread compulsory licensing on innovation must be taken into consideration.

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- Greater Political Commitment: Developing world governments need to show genuine political commitment of the kind shown by Uganda and Botswana. This means addressing stigma; it means removing import tariffs that raise prices; and it means prioritising healthcare in national budgets to deliver as much money as possible to reinforce the funding coming from the West. Developing countries must drive out inefficiencies in the procurement, storage, prescribing and use of drugs. The World Bank estimates that some African countries get the benefits of only \$12 worth of medicines for each \$100 spent on drugs by the public sector.
- Strategic Guidance and Support: International organisations such as UNAIDS and the WHO have an important role to play in providing strategic guidance and providing technical assistance to countries. Likewise, Non-governmental organisations (NGOs) play an important role in delivering healthcare to some of the poorest people who otherwise would have no access to healthcare services.
- An Appropriate Role for Generics: Generic companies have a role in addressing the AIDS crisis. But it would be counter-productive to ignore or undermine the role of the research-based industry. There is a fundamental truth about AIDS – we need new medicines and vaccines. We do not yet have a cure for AIDS. We do not have a vaccine for AIDS. Existing medicines are less and less effective as resistance to them grows. Intellectual property protection is of critical importance to the R&D-based industry. If there is no intellectual property protection, there will be no R&D. And if there is no R&D, there will be no new medicines and vaccines.

Improving access to treatment and healthcare is a shared responsibility between all sectors of national and global society, including national governments, industrialised donor countries, NGOs, industry and multilateral organisations such as the World Bank, WHO and UNAIDS.

At GSK, we believe we are playing our part through our efforts in R&D, preferential pricing community investment and innovative partnerships and solutions, such as voluntary licensing. We will continue with our efforts, improving our initiatives by applying lessons learned and looking for opportunities to do more.

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