Patent sense

Protecting intellectual property saves lives in the developing world, argues **Paul Herrling**.

Non-profit institutes funded by industry carry out R&D on drugs for neglected diseases.

Many diseases are endemic in the developing world, yet for a number of these there are few safe and effective treatments. This lack of medicines results from an industrial model that has been in place for more than 50 years. Basic scientific research carried out in the public sector is translated into life-saving medicines mainly by pharmaceutical companies. This is a lengthy, onerous and expensive process — taking about 15 years and costing hundreds of millions of dollars per drug — and comes with a high risk of failure. Nevertheless, more than 90% of new molecular entities discovered and developed as medicines between 1990 and 1999 originated from pharmaceutical companies[1,2].

Drug firms may be the main source of new therapies, but they remain commercial entities that can invest the considerable resources required to translate basic science into an effective medication only when there is a reasonable chance of financial return.

There is little opportunity to get an adequate return on investment for infectious diseases such as tuberculosis (TB), dengue fever, malaria, leishmaniasis and African trypanosomiasis (sleeping sickness), which mainly affect people living in resource-poor regions. In other words, market mechanisms fail in these cases, and there is insufficient drug-discovery research and development (R&D) for these common infectious diseases.

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No secrets

Some organizations interested in improving access to medicines in the developing world, such as Médecins Sans Frontières and Oxfam, think that a major impediment to affordable medicines is the patent system. But this is not the case. This system protects intellectual property in countries whose economies are based, to a large extent, on innovation. A patent is defined as a grant by the state of exclusive rights for a limited time in respect of a new and useful invention. These rights usually imply that, for a limited time, only the innovator, or a person or entity licensed by the innovator, can sell products based on the invention. This offers the innovator an opportunity to recover the investment needed to develop the invention into a practical product. Without this incentive, important discoveries would never be developed into useful products. Modern patent law provides protection for 20–25 years, which should be compared with the 15 years, on average, needed for the discovery and development of a new drug. In return for these rights, the innovator discloses a description of the invention that allows other experts to reproduce the key findings. This process is firmly based on the premise that knowledge is gained only through a full understanding and appreciation of previously published advances.

In the absence of a patent, the only way inventors can protect their inventions is throughtotal secrecy, which is counter to furthering innovation, a fact often ignored by those who consider that patents prevent research. It is only when patents are used excessively to protect information — to the extent that researchers cannot use a patent-protected invention in their studies — that the system is a considerable barrier to further innovation. To prevent such abuse of patents, several countries have implemented the 'research exemption', which allows scientists to use patent-protected technology freely for their research provided they do not exploit it commercially. In light of these issues, the protection of intellectual property with patents is crucial for pharmaceutical companies to discover and develop new drugs for the developing world.

Neglected no longer

In the past decade or so, the drug industry has formed partnerships with the public sector, generating pipelines of early-stage potential medicines for certain neglected diseases. These partnerships include the Global Alliance for TB Drug Development, the Drugs for Neglected Diseases Initiative (DNDi) and the Medicines for Malaria Venture. In 2004, 63 new drugs were being pursued by this approach[3].

Most of these drugs originate from R&D programmes in pharmaceutical companies and are patented accordingly. But these patents are not used to enforce unaffordable prices in the developing world or to prevent manufacturers from selling generic versions of these drugs in developing regions.

An example of this is Coartem, an artemisinin-based combination therapy. One of the most effective treatments for malaria

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at present[4], Coartem is included on the list of essential medicines by the World Health Organization[5]. One of its components was discovered by Chinese scientists, and this was then clinically characterized, and developed and produced as a combination therapy, by Novartis. Coartem is patented in 49 countries but is available at cost price to patients in all countries in which malaria is endemic. In 2006, Novartis delivered more than 62 million treatments of Coartem to more than 30 countries at cost price. A generic version of the drug is being manufactured by Indian pharmaceutical companies and sold in the developing world.

Another example is a new artemisinin-based combination therapy for malaria, developed by sanofi-aventis in collaboration with the DNDi. This treatment, also on the World Health Organization's list of essential medicines[5], will be available in most of sub-Saharan Africa next year. Sanofi-aventis has set aside its patent rights and will supply the medicine at cost price to the poorest populations in countries in which malaria is endemic.

In general, drugs developed by pharmaceutical companies as part of public–private partnerships are patented by industry, as it is the discoverer. But they are exclusively licensed for treating neglected diseases in agreements stipulating that the drugs will be available at cost price to the developing world.

Necessary system

So why are patents even necessary? There are three main reasons. First, commercial entities, including drug companies, can allocate resources to non-profit projects only if they are financially sound. Research- and innovation-based companies earn sufficient returns on their R&D investments only if they are permitted a marketing-exclusivity period — accorded by patents — for their innovative products. In countries without this protection in place, the drug industry is not research intensive and innovation based. Indeed, this was the case in India while there was no patent protection for new pharmacologically active molecules.

The randomness of evolution provides a second reason for patenting drugs for neglected diseases. Nature does not distinguish between the biology of diseases of the poor and the rich. So therapeutic molecules or pathways that are targeted by drugs for neglected diseases might also be relevant for treating diseases that affect people in more affluent regions. For example, the Novartis Institute for Tropical Diseases in Singapore takes all molecules that have activity against dengue virus and systematically tests them against the West Nile and hepatitis C viruses, which belong to the same family as dengue and cause disease also in developed countries. If a molecule has activity against dengue virus or another family member, it is developed and patented. Considerable financial returns could be generated in the developed world, and a portion of these is earmarked for refinancing, and for providing long-term sustainability to, the institute's non-profit initiatives.

A third reason to patent such drugs relates to emerging economies such as those of Brazil (see page 180) and India. In these countries, there are populations of very poor patients, and the non-profit model would certainly apply. But in the same countries, there are growing numbers of more affluent patients, who are increasingly able to buy their medication, either directly or through health insurance. For these patients, the company that developed the medicine could expect to generate revenue as a result of patent protection. Such differential pricing within a country (see page 176) would encourage further innovation not only by global companies but also by local enterprises. This model would require legislation that prohibits copying before patents have expired but that allows generic-drug production after patent expiry.

For the foreseeable future, the discovery and development of new medicines will be driven almost exclusively by commercial pharmaceutical companies. The only way that these firms can remain viable is through a robust intellectual-property protection system. This system, therefore, contributes to saving lives. Without it, there would be few new drugs for any disease, regardless of whether it afflicts the rich or the poor. ■

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Aid organizations such as Médecins Sans Frontières say that patents block access to medicines.

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