



Highlights of “Drug Patents Under the Spotlight” a new MSF report released at the WHA 56, Geneva 22 May, 2003

“Patents are not God-given rights. They are tools invented to benefit society as a whole.”

Dr Bernard Pécoul, MSF Campaign for Access to Essential Medicines.

DEMYSTIFYING PATENTS

Procurement of life-saving medicines is part of Médecins Sans Frontières’ (MSF) daily business. In poor countries, patents on pharmaceuticals can become obstacles to public health because drug patent holders are able to charge prices unaffordable for the majority of people.

In publishing this report, MSF hopes to help others make sense of the often complicated field of drug patents by listing and discussing patent data on 18 drugs in 29 countries. It is targeted at buyers of medicines such as non-governmental organizations, public health officials, or individuals working in developing countries.

The report explains:

- Patents were not created to enrich inventors but to benefit society as a whole by promoting innovation;
- Determining whether a drug is patented is a very complicated task, because patents don’t cover drugs as such but products, processes, medical indications, or combinations of products;
- Drug patents that need not be granted are being granted in developing countries right now;
- Drug patents can and should be challenged;
- Patentability requirements in developing countries should be amended to keep the number of patents granted to an absolute minimum in order to improve access to medicines.

SOME COMMON MISCONCEPTIONS:

Misconception 1: Patents are international

In reality, when a company is said to have patented a medicine worldwide, it means that they have a whole collection of different patents, one for each country or region of interest to them. Purchasers of medicines should therefore check patent status in their country rather than assume status on the basis of other countries.

Misconception 2: If a patent has been granted by a patent office, it is valid

In fact, a patent might not be valid even though it has been granted by a patent office. Some possible reasons: mistake in applying national rules of patentability, no examination of application, judgment made turns out to be incorrect, document might exist which is unknown to the patent office. In functioning patent systems, patents are regularly challenged. In the US and EU, for example, when challenged in court, patents are sometimes deemed invalid. Those wishing to purchase a medicine should not hesitate to check and challenge the validity of the patent.

Misconception 3: Patent infringement is a crime

In fact, almost everywhere, this is not the case. Patent rights are private rights, which means that the state is not obliged to police patents for patent holders. It’s the patent owner’s decision whether or not to stop any infringement by taking action before the competent court or authority. However, some countries are drafting text that is making infringement a crime. Since there is absolutely no requirement in the TRIPS Agreement to make any sort of patent infringement a crime, we recommend that countries not do this.

DESIGNING AND MANAGING PATENT SYSTEMS TO ADDRESS PUBLIC NEEDS

Each country must be able to design and operate its patent system in its own best national interest, using the flexibilities of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The World Trade Organization's (WTO) 2001 Doha Declaration on TRIPS and Public Health unequivocally states that the TRIPS Agreement "does not and should not prevent Members from taking measures to protect public health" and in particular "to promote access to medicines for all." WTO member countries have a margin of manoeuvre in designing what should and should not be patentable.

Unfortunately, although the TRIPS agreement gives countries these flexibilities, many developing countries' patent systems are still based on that of former colonial powers, or influenced by industrial country thinking through bilateral or international technical assistance. As a result, drug patents that need not be granted are being granted in developing countries right now. This is true for example for "new" uses of existing compounds. The TRIPS Agreement defines the minimum intellectual property standards Members must adhere to, but there is no reason for countries to expand patent protection beyond that.

To ensure that people in developing countries get their part of the patent bargain, patents should be granted only if a number of conditions are met: in particular, the invention should be new and inventive, and should be disclosed in the patent application.

Some developing countries are beginning to strike a better balance between inventors and public needs, revoking invalid patents (see box on the Thailand ddl case) or adapting their national patent system to protect access to medicines.

THAILAND CASE: REVOKING AN INVALID PATENT: THE CASE OF DDI IN THAILAND

In May 2002, a lawsuit was filed by a Thai AIDS Foundation and two people living with HIV/AIDS against Bristol-Myers Squibb (BMS). The court summoned the Thai Department of Intellectual Property (DIP) as co-defendant.

The plaintiffs alleged that BMS and DIP had "conspired to intentionally delete" the dosage restriction to the patent on ddl, an antiretroviral drug. BMS' original patent application in July 1992 specified a dosage range "from about 5 to 100 mg per dose", but BMS filed an amendment to remove this restriction 5 years later.

In the final verdict delivered on 1 October 2002, the court found in favour of the plaintiffs. The court noted that the Doha Declaration "insisted that TRIPS be interpreted and implemented so as to promote the rights of member states to protect countries' public health" and that "those in need of medicines are interested parties to the granting of a patent".

In principle, this means that the more convenient ddl dosage can now be made by other producers who will likely sell it at much lower prices. However, the case is currently under appeal.

We hope that this report will contribute to inform people in developing countries on how to design a patent system that better serves the public interest. However, there is clearly a further need for technical assistance to all developing countries to implement TRIPS in a pro-public health way, following the Doha Declaration.

PATENT TABLE COMPILED BY MSF

The table in the new MSF report shows some essential medicines for which patents already constitute a barrier to access or might do so in the coming years. MSF gathered this patent information primarily to guide its own purchasing practices and is now making it available to inform other purchaser choices. The countries selected are countries where MSF has field projects or is planning to open them.

The table in the report shows information gathered by MSF on patents on 18 medicines in 29 countries: Brazil, Cambodia, China, Guatemala, Kenya, Malawi, Peru, South Africa, Thailand, Uganda, Ukraine, Zambia, Zimbabwe and OAPI countries (Benin, Burkina Faso, Cameroon, Central African Republic, Congo, Ivory Coast, Gabon, Guinea, Guinea Bissau, Equatorial Guinea, Mali, Mauritania, Niger, Senegal, Chad and Togo).

The table illustrates the increasing patenting of pharmaceutical medicines. Some claim that patents are not a problem since there are few patents in developing countries. But most of the time, the lack of patent in a country is a consequence of pre-TRIPS patent legislation, which did not allow patents for pharmaceuticals. As

The full text of this report can be found at www.accessmed-msf.org

countries implement TRIPS, there will be more and more patents on medicines. For instance, patent protection for recent drugs such as AZT+3TC (Combivir®) and AZT+3TC+abacavir (Trizivir®) has been applied for in almost all countries in the table.

MSF appeals to the World Health Organization (WHO) and the World Intellectual Property Organization (WIPO) to complete this work by making essential drug patent information more readily available and accessible to a wider audience. This information should be accompanied by clear advice to countries on how to overcome patent barriers to medicines, and with technical assistance in doing so.