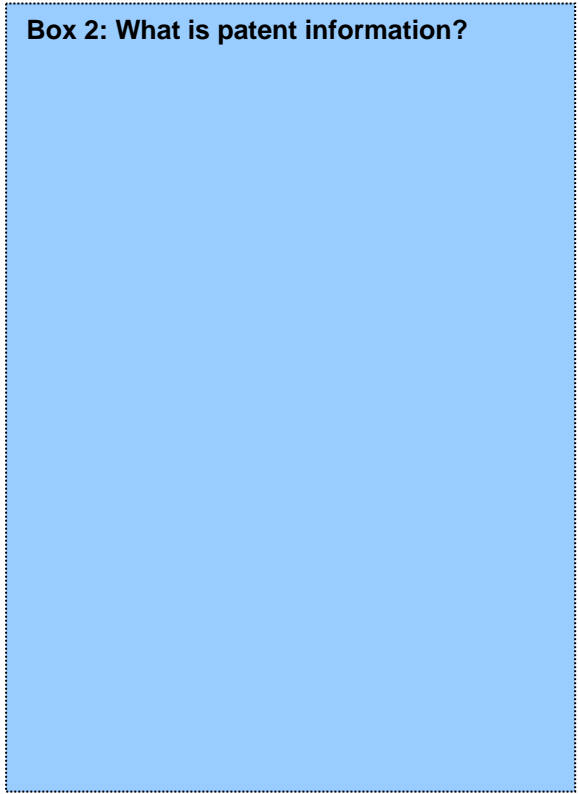


Box 1: Key issues

- Reliable domestic patent information is difficult to obtain in many countries
- Health authorities and other stakeholders face difficulties in assessing the status of patents related to medical products submitted in patent applications to aid patent searching
- Providing comprehensive patent information and enhancing access to national registers is the responsibility of national governments

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Box 2: What is patent information?



Access to Medicines,

made as the special expertise and information resources of each secretariat are made available to support the work of other organizations, in line with their own distinct mandates.

THE CONTEXT

The first session set the context for the discussion.

WHO described access and information needs from a public health perspective. Access to medicines is determined by four basic factors:

- rational selection of medicines;
- affordable prices;
- sustainable financing; and
- reliable health and supply systems.

Lack of access to essential medicines is still a major problem; although medications often exist, at relatively low prices and off-patent, many people in need still do not have access to them. New medicines remain inaccessible if priced out of reach of the majority of patients in developing countries.

According to WHO, reasons for such high prices include the patent regime introduced by the WTO TRIPS Agreement, and the conclusion of bilateral or regional free trade agreements that introduce more extensive levels of intellectual property protection. The public health community has four simple questions about patents on health technology:

- What is patented?
- Who owns the patent?
- Where is it patented?
- How long it is patented for?

Although the questions are simple, the answers are not.

In its presentation, the WTO focused on how to link empirical data to policy processes and strengthen the basis for policymaking on

CASE STUDIES, METHODOLOGIES AND SOURCES OF INFORMATION

For more than 30 years, the WHO has published a Model List of Essential Medicines, which is updated every two years. Most countries have adopted the concept and have developed their own national lists of essential medicines. One important question is to what extent the essential medicines on the WHO Model List are protected by patents. One of the projects presented at the symposium focused on assessing the patent status of the medicines that have been added to the WHO Model List in recent years. The study, based on data from the US Federal Drug Administration's Orange Book, identified relevant patent families for these medicines in countries where patent data were available.

Access to affordable generic medicines can be achieved through licensing agreements. A new approach to increase access this way is the creation of a patent pool for antiretroviral medicines, undertaken by the Medicines Patent Pool Foundation. This requires reliable patent information, including:

- knowing what patents cover the products to be used;
- what the patents exactly cover for these products;
- who holds the patents;
- the countries where the patent applications have been filed and where they have been granted; and
- the current legal status of those patents.

These are complex tasks. Many national and regional patent collections can only be consulted on-site. Information is often not updated or incomplete, especially on the legal status. With the support of WIPO and a wide range of national and regional patent offices, the Medicines Patent Pool has identified the

PRACTICALITIES OF PATENT INFORMATION – GAPS AND NEEDS

Patent information clarifies who owns which rights, at what time, and discloses the technical teaching contained in patents. During a patent's life span, a number of events determine its legal status. How much of that information is published is defined within each country. This varies considerably. In some countries, the complete dossier is available for public inspection on-line. Other countries only publish in a printed Gazette the simple fact that a patent has been granted — full information can only be retrieved by inspecting a physical file at the patent office. Patent offices' databases can usually be accessed free of charge. Commercial providers offer paid access, but provide value added services such as analysis and visualization tools, quality checks or enhanced abstracts. Overall, information on the legal status of patents is not easy to access in many countries. In some instances, the information is not reliable and may be expensive. This leads to difficulties in assessing the patent status, particularly in developing countries.

Box 4: What are "patent landscapes"?

A patent landscape is a report that researches and describes the patent situation for a specific technology in a given country, region or on the global level. Patent landscape reports usually start with a state of the art search addressing the technology of interest. In a second step the results of the search are analyzed to answer specific questions, such as those relating to the identification of certain patterns of patenting activity (who is doing what, and what is filed where?) or certain patterns of innovation (innovation trends, diversity of solutions).

Patent landscapes can be useful for policy discussions, strategic research planning, technology transfer and procurement. In a wider sense, some patent landscape reports may analyze the validity of patents by referring to legal status data and can therefore form a basis for freedom to operate analyses and decision-making.

These reports, however, only provide a *snapshot* of the patenting situation at a specific point in time.

The discussion pointed towards the need for policy makers and national governments to improve access to data in national registers and to allocate the necessary resources so that it is easier to compare available data internationally. This requires standardized approaches, and making the data more reliable and keeping it up-to-date. This is particularly important for databases in developing countries.

Procurement planning focuses on the quality and prices of products rather than on patent issues. However, procurement decisions require accessible and reliable patent information. Problems about the status of a patent often arise only late in the cycle, when procurement should actually start. If the patent information is not available at that time, delays can lead to emergency procurement so treatment is not disrupted, and stocks do not run out. Procurement agencies would benefit from an easy-to-use online database and consultation service for finding and interpreting patent information.

Speakers said international organizations should play their part to develop easily accessible online information tools and provide an automatically updated list of patents for active ingredients, which could avoid duplicating costly patent searches.

The discussion suggested that intellectual property education and capacity building should better reflect practical needs. Public discussion should not simply focus upon counting patents, as innovation could not be measured by the sheer number of patents, only by considering the substantive content of patent documents can an evidence-based understanding of innovation be gained.

Some speakers criticized the fact that regulatory agencies in some cases are confronted with demands to assess the patent status of medical products before authorizing generic versions. Regulatory agencies regularly do not have the capacity to do so. Lack of access to domestic patent information particularly in developing countries also presents challenges for the generic companies striving to prove to the regulatory agencies the absence of patents relevant to their products, where such a requirement exists. This impedes the registration of generics.

