



TECHNICAL SYMPOSIUM

DATE: JANUARY 20, 2011

Access to Medicines, Patent Information and Freedom to Operate

World Health Organization (WHO)
Geneva, February 18, 2011

(preceded by a Workshop on Patent Searches and Freedom to Operate,
in the afternoon of February 17, 2011 at WIPO)

BACKGROUND INFORMATION¹

INTRODUCTION

Access to patent information in relation to medical products has a major, and growing, importance for public health, both for practical health programs and for policymakers. Procurement agencies, research institutions, originator and generic pharmaceutical industry, and other stakeholders need to know about the patent status of specific products in specific markets in order to determine their

communication between the relevant authorities, and language barriers. Improving access to health-related patent information is therefore also part of element 5.1c of the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property which specifically addresses access to and further development of user-friendly global databases which contain public information on the administrative status of health-related patents.

The importance of facilitating the access to, and the use of, patent information is a key activity of WIPO. It is reflected in particular in WIPO's Development Agenda, specifically the projects on "Developing Tools for Access to Patent Information" and "Intellectual Property and the Public Domain" adopted by the WIPO Committee on Development and Intellectual Property (CDIP), Document CDIP/4/6, and as a core element of WIPO's Program on Global Challenges.

For the WTO, the Doha Declaration on the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and public health first addressed the interface between intellectual property rights and public health more specifically. Based on the recognition that the TRIPS Agreement is part

WORKSHOP IN THE AFTERNOON OF FEBRUARY 17, 2011, AT WIPO

Whereas the Symposium on “Access to Medicines, Patent Information and Freedom to Operate” of February 18, 2011 will focus on broader aspects related to patent information and freedom to operate, illustrated, among others, by specific patent landscape reports and freedom to operate case studies, the goals of this workshop are to introduce participants to the basic concepts of how to do patent searches and freedom to operate analysis. This will be illustrated by two 90 minute sessions, one focusing on how to search for patent information in different freely-accessible patent databases, and one focusing on how to conduct a freedom to operate. The former will also address added value of commercial patent databases, and resources for researching legal status of patents and related issues. The latter will be based on a prosthetic limb product which could have broad applicability to developing countries where landmine injuries are all-too-common. Searches will be conducted using both keyword and patent classification strategies. Both active and expired patents should be considered, as well as patent applications (e.g. PCT applications); the legal status of different members of patent families will be assessed. Results will be discussed broadly, both with respect to freedom to operate and the value of patent database searching generally as an important tool in the research and development and deployment of critical, inclusive innovations.

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FIRST SESSION: ACCESS TO MEDICINES, PATENTS AND FREEDOM TO OPERATE – THE CONTEXT SETTING

With a view to providing guidance for the subsequent discussion, this session will introduce what patent information means, covering technical, legal and business related aspects, what it is used for, and how it can be used. It will draw out the distinction between patent information (technical information, state of the art search), legal status information and freedom to operate analysis aimed at the development of an intellectual property strategy.

The session will explore the linkage between patent information and access to medicines and outline the concepts of access to medicines and freedom to operate: How to identify the patents linked to a specific pharmaceutical? Why do we need easy access to reliable information on patents and their (legal) status? Which conclusions can be drawn from that information for the practical context of research, production or procurement activity? How does the information facilitate better access to essential medical products? Do we have the necessary information resources and are they accessible?

SECOND SESSION: PATENT INFORMATION AND FREEDOM TO OPERATE: CASE STUDIES, METHODOLOGIES AND SOURCES OF INFORMATION

A number a case studies will illustrate the main issues with the view to familiarizing the discussion with underlying concepts, the relevant approaches and methodologies.

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identify e.g. the patent, owner and inventor, and allow retrieving patents or relating it to other patents. The term "bibliographic data" is traditionally used to address the information on the front page of a patent publication.

Legal information refers to the territorial scope, the terms of protection, the scope of protection and administrative and legal status of a patent as determined by legally relevant events or actions defined by the respective patent law and regulations. Patent legal status data are an important component of patent information. They are used to determine, inter alia

- whether examination of a patent application is still pending, or
- whether the application has been withdrawn or was rejected;
- whether a patent has been granted and is still valid, and for how long, or
- whether a granted patent has expired, lapsed, or been revoked.

As the legal status of patents is linked to legal events or actions, it may change over time and therefore poses particular problems to the availability and reliability of up-to-date information. The most prominent and direct sources of legal status in

- IP PANORAMA (E-learning) Module 6: Patent Information
<http://www.wipo.int/sme/en/multimedia>

What are "patent landscapes"?

Patent landscape is not a defined term and can come in different guises. In the context of this background paper and the joint technical symposium, the term is used to describe patent reports that show the patent situation for a specific technology in a given country, region or on the global level. Patent landscape reports usually start with an ordina

is one type of input among many that managers use to make strategic risk-management decisions in relation to research and development and product launch.

Freedom to operate usually starts with a search of the pertinent intellectual property information that intends to identify all the relevant intellectual property rights. Freedom to operate analyses are relevant at all stages of the product research and development as well as in the commercialization chain. Depending on the stage at which a freedom to operate analysis is carried out, different levels of detail and precision may be required. Following the identification of the pertinent rights, for example the relevant patents within the patent family, it is necessary to look at the scope, as identified, for example, by the claims of a patent, and the validity of the single rights identified in the respective countries or areas of interest.

At the outset, the mere existence of a patent right does not inform about the freedom to operate. If a freedom to operate opinion identifies intellectual property rights and, in a next step, assesses that their scope and validity is relevant for the planned research, production or distribution activity in the defined region, a variety of strategies and actions can be used to establish freedom to operate and to enable the planned activity. A conscious use of intellectual property information and related information about the legal and economic context is a prerequisite for any research, development, production and distribution activity.

Freedom to operate, informed by intellectual property information, supports a broad range of tools and relief which are established in, and are an integral part of the intellectual property system, and build the bridge with proactive management of intellectual property to enable broad access. Such access, and freedom to operate, can be obtained through a combination of two or more options will often be pursued concurrently. These are:

- Legal/intellectual property management strategies: license-in, cross-license, oppose third-party patents, seek non assert covenant, seek compulsory license
- Research and Development strategies: modify product, or invent around
- Business strategies: merge and/or acquire, wait and see, abandon project

In this sense, the existence of intellectual property rights, whereby patents are licensed with associated know-how and regulatory data that speed up the introduction of important drugs and vaccines, is rather an indication for an opportunity to get access to technology than a hindrance.

More detailed information can be found in:

IP Handbook of Best Practices, Section 14: "Freedom to Operate and Risk Management" and particularly Chapter 14.1 "Freedom to Operate, Public Sector Research, and Product-Development Partnerships: Strategies and Risk-Management Options" <http://www.iphandbook.org/handbook/ch14/>

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