



TECHNICAL SYMPOSIUM

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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 freedom to operate in research and development, manufacture and procurement, to design business and access strategies, to assess which products can be produced and marketed without infringing patents, and to determine with whom and the extent to which licenses have to be negotiated, with whom and for what markets.

However, assessing the patent status of medical products is not always easy. Up-to-date patent information, including information about the patent status, is still difficult to obtain in many countries, particularly in developing countries. These difficulties stem from a variety of reasons, including lack of

¹ This paper has been jointly drafted by the World Health Organization (WHO), the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO) in preparation for the joint technical symposium.

capacity and resources in national patent offices, lack of expertise in using the available information resources, lack of accessible patent and legal status information that can easily be accessed, lack of 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 of the wider national and international action to address public health problems, the WTO's work focuses on ensuring that intellectual property rights are actively used both as a tool to develop new medicines and to enhance access, as well as that the other relevant aspects, including procurement and technology transfer, are duly taken into account. Patent information provides an invaluable empirical basis for this work, as it clarifies the context and need for specific measures to promote access to medicines.

With regard to public health, access to reliable patent information is important in a number of ways:

Procurement of medicines: When the patent status of a medical product in a specific country is not clear, procurement agencies need to be able to verify the legal and administrative patent status to determine the sources from which they can legally procure the product, and to plan for specific access strategies. This information is also a prerequisite for the use of flexibilities provided by the WTO TRIPS Agreement, such as government use, or compulsory licenses that may be used, as necessary, to address public health needs. The difficulties in obtaining such information thus can compromise the procurement of the most cost-effective quality medicines.

Research and development, transfer of technology, production, and freedom to operate: At the outset of any project related to medical research and development, transfer of technology or production of a medical product, informational and legal obstacles to the activity have to be explored with the view to ensuring that the plan can be carried out without infringing any intellectual property or other rights, and to determine any specific steps that should be taken as early as possible to ensure freedom to operate. Before a medical product can be manufactured locally, it should be clarified whether the product and the intended manufacturing process are under patent protection in the respective country. If that is the case the local producer will aim at concluding a license agreement (which typically also allows for the transfer of know how) with the right holder which can be one step to achieve the freedom to operate. To identify countries to which locally produced products can be exported, again requires an assessment of the patent situation in the potential export markets. For the generic as well as the originator industry, it is key to know the patent situation of specific products in specific markets in order to assess which products can be produced and marketed without infringing patents and to which extent licenses might have to be negotiated.

Analyzing innovation activity and tracking developments with regard to Research and Development: Patent information is an important tool to look at and analyze development trends, research activity and actors since the filing of patent applications reflects the underlying innovation activity. Overviews on the patent situation for a specific technology or disease in a given country can show what is being patented in terms of disease targets and approach, who is doing the patenting (industry, biotech, academia) and the geographical coverage (where patents are filed). It enables an overview of trends over time in terms of the medical research and development focus, the changing directions of established players, and the growing role of new players in medical research and development.

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.

TECHNICAL SYMPOSIUM

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

- A joint project of the WHO, WIPO and University of New Hampshire School of Law to determine the patent status of the medicines on the WHO Model Lists of Essential Medicines.

For more than 30 years, WHO provides a Model List of Essential Medicines that is updated every two years². Most countries have since adopted the concept and developed national lists of essential medicines. An important question in the discussion around patents and access to medicines is to what extent essential medicines are patented. This project - based on previous research on the patent status of essential medicines - will provide an update on the patent status of essential medicines on the current WHO Model List.

- A patent landscape report on two ARVs, which WIPO is preparing in cooperation with the Medicines Patent Pool, will show, how patent protection evolves over subsequent generations of patents.

² <http://www.who.int/mediacentre/factsheets/fs325/en/index.html>

- A "Global patent landscape on patenting activities in the field of vaccines" under development by WIPO in collaboration with WHO/IVR and PHI. This report will show the overall patent situation in a set of countries with regard to a number of vaccines. It will provide an overview on what is being patented in terms of disease targets and approach, who is doing the patenting, where patents are filed and on how patent policies change over time.
- A freedom to operate analysis of dengue vaccines.
A vaccine or drug is either manufactured by the developer of the product or licensed to a third party for production, or both. In either case, the developer needs to have "assembled" all the intellectual property to have freedom to operate. Although the Pediatric Dengue Vaccine Initiative (PDVI) that commissioned this freedom to operate analysis is not a developer or manufacturer of vaccines, PDVI is concerned with vaccine access and needs to understand the probable development of both the market and the intellectual property landscape, including current licenses. These will determine licensing options from the developer of the vaccine to manufacturers, especially those in developing countries. The goal of this freedom to operate analysis, therefore, was to understand how intellectual property may affect access to the vaccine in developing countries, assess how some of the vaccine developers will be affected by intellectual property and what freedom they have to license the product to developing countries, and evaluate the freedom of the developing country developers to market their vaccines outside of their home countries.

THIRD SESSION: PRACTICALITIES OF PATENT INFORMATION – GAPS AND NEEDS

This session will introduce the kinds of patent information that are available, the sources, search tools and methodologies, as well as limitations with regard to availability and reliability, pointing out the differences and advantages and limitations for different forms of analysis and policy discussion. This session will contribute to raising awareness about the variety of data sources, both publicly available as well as commercial, methodology and expertise needed to use the data, but also about gaps, infrastructure, capacity and training needs in a number of countries.

FOURTH SESSION: PANEL DISCUSSION: STRENGTHENING THE PATENT INFORMATION BASE FOR ACCESS TO MEDICINES STRATEGIES – TAKING STOCK OF EXPERIENCE AND CHARTING FUTURE DIRECTIONS

A panel of different users of patent information discusses how freedom to operate analyses and patent analyses could directly assist in charting pathways for access to new medicines. They will review the importance of a functioning intellectual property infrastructure that enables gathering and making available pertinent information. In this way, the Panel may help to raise awareness about the challenge of having legal status data from developing and developed countries available in an accessible and usable form. This discussion could help create a practical feedback loop between the health policy community, on the one hand, and patent information experts and patent data initiatives, on the other hand, so that policymakers can base their action on a better founded ground. Equally, the discussion could highlight to policymakers why it is good policy to invest in the infrastructure needed to make available comprehensive and up to date patent information.

FURTHER INFORMATION

What is patent information?

The term patent information is used in this context to designate (i) information that is disclosed in patent documents and that can be derived from such documents, and (ii) information that is related to patent applications and can be derived from other sources, such as patent registers. Such documents, registers and other sources contain technical information, legal information and bibliographical data related to inventions that are claimed in the respective patent documents. With regard to its technical nature, patents have to describe the invention in a comprehensive and clear manner and thus constitute a source of valuable technical information. Bibliographic components

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 information are national patent registers or national patent gazettes or bulletins.

This use of the term “patent information” is distinguished from more general information related to patents. This broader context addresses information about the various aspects of the patent system, such as intellectual property legislation, guides on how to use various intellectual property rights, annual reports, statistics and the like. Such general information is important to support patent and freedom to operate analyses by contributing information about the legal and economic context in which patent rights are used.

More detailed information can be found in the following sources. This link list is not exhaustive and serves as a starting point for further orientation:

- WIPO Guide to Using Patent Information
http://www.wipo.int/freepublications/en/patents/434/wipo_pub_1434_03.pdf
- How to conduct patent searches for medicines - A step-by-step guide, World Health Organization - South East Asia Region and Western Pacific Region 2010
http://www.wpro.who.int/publications/PUB_9789290223757.htm
- Patent Information in Brief – FAQs on Patent Information
http://www.wipo.int/patentscope/en/data/patent_information.html
- PATENTSCOPE® Search International Patent Applications and WIPO Patent Information Services:
<http://www.wipo.int/pctdb/en/http://www.wipo.int/sme/en/documents/wpis.htm>
http://www.wipo.int/freepublications/en/patents/493/wipo_pub_493.pdf
http://www.wipo.int/patentscope/en/data/developing_countries.html
<http://www.wipo.int/patentscope/en/programs>
- WIPO Standards – WIPO Handbook on Industrial Property Information and Documentation
<http://www.wipo.int/standards/en>
- WIPO Standing Committee on the Law of Patents (SCP)
<http://www.wipo.int/patent-law/en/scp.htm>
Document SCP/13/5 – Dissemination of Patent Information
http://www.wipo.int/edocs/mdocs/scp/en/scp_13/scp_13_5.pdf
 - SCP/14/3 – Technical Solutions to Improve Access to, and Dissemination of, Patent Information
http://www.wipo.int/edocs/mdocs/scp/en/scp_14/scp_14_3.pdf
 - SCP/15/4 – Corrigendum of Documents: SCP/13/3 and 4 and SCP/14/2, 3 and 5
Corrigendum
http://www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_4.pdf

- 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 ordinary more or less broad 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, e.g. to identify certain patterns of patenting activity (Who is doing what? What is filed where?) or certain patterns of innovation (innovation trends, diversity of solutions). An important component of such reports is the visualization of the results of this analysis to facilitate their understanding. Patent landscapes provide only a snapshot of the patenting situation at a certain point in time and can be useful for policy discussions and strategic research planning. In a wider sense, some patent landscapes reports may analyze the validity of patents by referring to legal status data; and be a basis for freedom to operate analysis and decision finding.

Searching all the patents linked to a specific product or its manufacturing is difficult because information on the different technologies involved in manufacturing such a product is not easily available, unless they are disclosed by the manufacturer, as it is the case for active ingredients. Vice versa, patent landscape reports on pharmaceuticals focusing only on the active ingredient may not cover other components of patent protection of a particular product comprising the ingredient.

More detailed information and examples of patent landscape reports:

- Working Paper on Patent issues related to influenza viruses and their genes, prepared by WIPO at the request of the World Health Organization, October 2007
<http://www.wipo.int/export/sites/www/patentscope/en/lifesciences/pdf/influenza.pdf>
http://www.who.int/entity/csr/disease/avian_influenza/WIPO_IP_%20paper19_10_2007.pdf
- Annex to the Working Paper on Patent issues related to influenza viruses and their genes: Patent Landscape for the H5 virus
http://www.who.int/csr/disease/influenza/avian_flu_landscape.pdf
- Determining the patent status of essential medicines in developing countries - WHO Health Economics and Drugs Series No. 017, 2004 Author: MSF with support from WHO, UNAIDS
<http://apps.who.int/medicinedocs/documents/s14154e/s14154e.pdf>
- WIPO Symposium on Public Policy Patent Landscaping in the Life Sciences – April 7 and 8, 2008
http://www.wipo.int/meetings/en/2008/lifesciences/patent_landscaping
- WIPO Life Sciences Symposium: Patent Landscaping and Transfer of Technology under Multilateral Environmental Agreements – August 26, 2008
http://www.wipo.int/meetings/en/2008/lifesciences/ip_iss2_ge
- Shedding Light on the Life Sciences: Patent Landscaping for Public Policymakers
WIPO Magazine 4/2008
http://www.wipo.int/wipo_magazine/en/2008/04/article_0005.html

What is a "freedom to operate" analysis?

Freedom to operate is—first and foremost—a strategic management tool. It is the synthesis of scientific, legal, and business expertise coupled with strategic planning. Strictly speaking, however, freedom to operate is a legal concept. It is a legal opinion by a patent counsel on whether the making, using, selling, or importing of a specified product, in a given geographic market, at a given time, is free from the potential infringement of third-party intellectual property or tangible property rights. As such, it

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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