



TECHNICAL SYMPOSIUM

Access to Medicines, Patent Information and Freedom to Operate

Summary and key issues

TRILATERAL SYMPOSIA

On 18 February 2011, the World Health Organization (WHO), the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO) organized a joint

Technical Symposium on Access to Medicines, Patent Information and Freedom to Operate

The event, hosted by WHO, was the second in a series of symposia that WHO, WIPO and WTO are organizing in Geneva on issues relating to public health, trade and intellectual property. The symposia provide a platform for participants to exchange information and experiences and to discuss current issues. They enhance the dialogue between the relevant organizations and other key stakeholders, and foster a mutual understanding of public health and intellectual property policy. The series started with a symposium on *Access to Medicines: Pricing and Procurement Practices* hosted by the WTO on 16 July 2010.

This joint report summarizes the 2011 event. It is meant to provide an accessible overview of the issues discussed in the Symposium. All presentations as well as a video recording of the event are available on the Symposium's website (see "Further information") below.

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
- Collaborative efforts are needed to build capacity and improve availability of data, particularly in developing countries
- Patent information should be digitized and patent registers should be searchable online
- Where available, the International Non-proprietary Names (INN) should be submitted in patent applications to aid patent searching
- Providing comprehensive patent information and enhancing access to national registers is the responsibility of national governments
- Procurement agencies would benefit from tools to aid the search for patents relating to health technologies, as well as a consultation service on how to find and interpret patent information

INTRODUCTION

Access to patent information for medical products is becoming more important for public health. Procurement agencies, research institutions, the originator and generic pharmaceutical industries, and other stakeholders need to know about the patent status of specific products in specific markets — whether a patent application has been filed, what the legal and administrative status of that application is, whether a patent has been granted and what the legal status is of that grant. The information is needed for companies, institutions or individuals to determine whether they are free to undertake research and development, or to manufacture and procure the products, and to determine with whom and the extent to which they may have to negotiate licenses.

However, assessing the patent status of medical products is not always easy. Up-to-date domestic patent information, including the patent status, is still difficult to obtain in many countries, particularly in developing countries. This may be due to a number of reasons, including a lack of capacity and resources in national patent offices, as well as of accessible information on patents and their legal status information, a lack of communication between the relevant authorities, and language barriers.

Improving access to patent information related to health is also a concern of the WHO through its Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property which addresses access to user-friendly global databases containing public information on the administrative status of health-related patents.

WIPO's Development Agenda and the work of the WIPO Committee on Development and Intellectual Property (CDIP) also aim to make patent information easier to obtain and to use.

In the WTO with its Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), the 2001 Doha Declaration on the TRIPS Agreement and Public Health was a first specific step towards ensuring that the objectives of intellectual property rights and public health are aligned. In other words intellectual property rights should be used actively to develop new medicines and to enhance access, taking into account procurement, technology transfer, and other relevant aspects.

Box 2: What is patent information?

The term patent information describes information that is disclosed or that can be derived from patent documents, and information that can be derived from other relevant sources, such as patent registers. It includes technical and legal information and bibliographical data.

Patents have to describe the invention comprehensively and clearly. They are therefore a source of technical information.

Bibliographical data identify the patent, its owner and inventor, and allow patents to be retrieved or linked to other patents.

Legal information refers to the territory in which the patent is granted, the terms of protection, the scope of protection and the administrative and legal status of a patent as determined by legally relevant events or actions defined by the respective patent law and regulations.

For public health, access to reliable patent information is important for a number of reasons:

- **Procurement of medicines:** Procurement agencies need to be able to verify the patent status of a medical product in order to determine where they can legally procure it. This information is also necessary for using the flexibilities of the WTO TRIPS Agreement, such as government use or compulsory licenses. If the information is difficult to obtain, procuring the most cost-effective quality medicines may be compromised.
- **Research, development and production:** Anyone undertaking research and development, transfer of technology or the production of a medical product, has to explore the informational and legal obstacles. This is to ensure that the project can be carried out without infringing any intellectual property, including patents or other rights, and to determine any specific steps that should be taken as early as possible to ensure freedom to operate.
- **Analyzing innovation activity:** Patent information is important for analysing research activity since patent applications broadly reflect innovation. Reports on the patent situation for a specific technology or

disease in a given country can show what is being patented, what the disease targets and approach are, who is doing the patenting and where the patents apply.

Box 3: What is "freedom to operate"?

Freedom to operate is to have "assembled" all intellectual property and tangible property rights relating to a particular product. Freedom to operate is based on a synthesis of scientific, legal, and business expertise coupled with strategic planning. Strictly speaking, freedom to operate is a legal opinion on whether the making, using, selling, or importing of a specified product, in a given geographic market at a given time, is free from potential infringement of third-party intellectual property or tangible property rights. As such, it is one type of input that managers use to make risk-management decisions in relation to research and development, product launch, and commercialization.

Freedom to operate starts with a search of the pertinent intellectual property information in order to identify all relevant intellectual property rights. This includes the "deconstruction" of a product, including as may be applicable, methods used in the making of such product, the searching of potentially relevant patents, and the analysis of patent claims.

OBJECTIVES

The symposium's objective was to address the growing importance of patent information for public health, and more specifically to

- highlight that it is important to be able to obtain patent information easily in order to provide access to medicines;
- show how patent information can be used to determine the freedom to operate in improving access to medicines;
- explore what kind of patent information is required for this purpose;
- discuss to what extent this information is available and accessible; and
- identify information gaps that need to be filled.

KEY MESSAGES DIRECTORS-GENERAL

In the opening session, the three Directors-General paid tribute to the close co-operation between the three organizations, a relationship that has developed over the years and helped improve the understanding of each others' perspectives.

WHO Director-General Margaret Chan said the WTO TRIPS agreement had changed the landscape of health product purchasing and patenting. Before TRIPS, countries had been free to choose not to grant patents on medicines. Those days are over.

Financial constraints in the health sector have increased the pressure to use budgets more efficiently, including procuring lower-cost generic products. This situation has created a critical need to improve the ability to manage and use intellectual property in the developing world she went on.

The issues explored in the symposium included the need for more transparent and accessible data on patents in order to support decisions about freedom to operate.

WIPO Director-General Francis Gurry stressed that one of the justifications for patent protection is the disclosure of technology. While this did not function effectively in the age of paper copies, modern technology has made the information easily accessible.

Therefore, among WIPO's core functions in this area is the drive to make patent information available. Better tools are also being developed to overcome language barriers.

WTO Director-General Pascal Lamy envisaged an information platform that is accessible for all, usable by even those who lack technical or legal expertise, giving real-time information about the patent coverage of essential medicines. Citing his own experience working with these issues, he described this as a target well worth working towards. While acknowledging the practical difficulties that still have to be confronted, he recognized the significant progress that has been made, including by WIPO, to make patent information a useful tool for policymakers.

He also spoke of the challenge of making the work of the three organizations blend together better, welcoming the progress that has been

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 access to medicines. Protection and enforcement of intellectual property rights should be to the advantage of both producers and users of technological knowledge. Both need accessible, reliable, neutral and relevant patent information to develop practical innovation and procurement strategies.

All three organizations have been asked by their Member States to improve the current situation. The first step is to know what is patented. Next is to assess the implications for

research and development, access and procurement in the developing world. These clarify the options for the practical management of intellectual property, innovation policy, procurement strategies and the use of flexibilities and other available policy options. While the technology now allows patents to be searched much more easily, there are still huge data asymmetries between countries. These need to be adjusted.

WIPO focused on the importance of obtaining freedom to operate for access to medicines. If a freedom to operate analysis reveals the existence of relevant intellectual property rights, and their scope and validity is relevant for the planned research, production or distribution activity in a defined region, a variety of strategies can be used to obtain freedom to operate.

These include: legal and management strategies, such as licensing-in of patent rights, cross-licensing, opposing third-party patents, seeking non-assertion covenants (declaration of non-enforcement by the rights holder) or compulsory licensing; research strategies, such as modifying a product or process or inventing around; and business strategies, such as through merging with and/or acquiring rights holders, or abandonment of projects.

Freedom to operate is thus a plan that begins with an analysis of the intellectual property landscape of a potential product. Gradually, freedom to operate, to be useful, will evolve into an "attitude" throughout a product's research and development, and life cycle. Importantly, freedom to operate is a risk management tool as there rarely is total certainty of non-infringement.

Whether or not countries should report all relevant data directly to WIPO, which could then make it available, instead of relying on national publications, was discussed as a means of closing the information gap, especially on legal status data. The point was also made that, to improve patent information, countries have to live up to their responsibilities to make this information available.

Where companies have declared that they will not enforce their patents in certain countries, this leads to the question of whether this is enough to make procurement decisions.

The discussion highlighted the important role of the generic industry in providing affordable medicines.

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 legal status of 69 key patents for 23 antiretroviral medicines in 67 countries. A database has been launched in the meantime to allow open access to this resource (available at: <http://www.medicinespatentpool.org>). The discussion raised the question of whether patent pooling could be a general solution in cases of patent thickets, i.e. situations involving overlapping patents, which prevent competition.

In the field of vaccines, WHO is monitoring the patenting activity to identify the extent to which vaccines and production technologies are protected by intellectual property. When patents apply, in some cases WHO supports research on alternative technologies or negotiates licenses with the right holders on behalf of developing country manufacturers. For most existing vaccines, patents do not generally prevent production by competitors, but there are some notable exceptions, including reverse genetic engineering, a key technology for the production of pandemic influenza vaccines and the human papilloma-virus vaccine.

A major barrier to increasing the uptake of vaccine manufacturing in developing countries is the lack of know-how. Thus WHO also focuses on the transfer of vaccine production technology to these countries.

The Dengue Vaccine Initiative of the International Vaccine Institute presented a global freedom to operate analysis with different candidates for dengue vaccines. The goal was to understand how intellectual property may affect access to future vaccines in developing countries and to evaluate how free developing country developers are to market their vaccines internationally. The analysis revealed that the sponsors of different vaccine candidates seem to have all the intellectual property required to obtain regulatory agency approval for their vaccine candidates and to market them widely. However, in the future, problems might still arise from patent applications, which cover certain delivery mechanisms.

The concern was raised as to whether inventing around existing patents takes up too much time and research capacity which are both limited in developing countries. The example of pneumococcal vaccines was discussed, in which the difficulty lies less in inventing around existing patents, but rather in the scientific and technological complexity of the vaccine itself. Also highlighted were the increase in drug prices caused by taxes and tariffs, and the need for an international framework against fake medicines.

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 re-searches 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.

TAKING STOCK OF EXPERIENCE AND CHARTING FUTURE DIRECTIONS

The symposium's fourth session highlighted the need for access to reliable patent information, particularly in many developing countries. The discussion stressed a need to make better use of information technology, including the digitization of patent information to make it more accessible and user-friendly. As a further contribution to simplifying patent searches, it was suggested that applicants provide INNs (international non-proprietary names) where known at the time of filing the patent application. Another proposal was to establish a list of predefined search queries for pharmaceutical compounds in low income countries, which would link products with patents.

It was proposed that one possibility for making patent searches less repetitive could involve collecting the results of patent queries on specific medical products. This would then be made available in an accessible format, comparable to currently available data on prices and quality inspections. It was also suggested that right holders should be approached to obtain information about the status of patents. Experience shows that companies were often willing to cooperate. But despite the increasing digitization of data, the question was asked as to whether the growing number of patent applications will make it increasingly difficult to assess freedom to operate anyway.

The need for collaborative efforts in capacity building for developing countries was particularly emphasized. Alongside the facilitation of patent searches and improvements in the use of information obtained, the increased capacity could ultimately support the local production of pharmaceutical products. By integrating manufacturing in African countries into their business plans, where patents hardly ever constituted an obstacle, generic companies from emerging economies could also provide an important contribution to this objective.

Some speakers noted that sustainable business meant that products are made available at the right price, not at the lowest price, so that high quality can be guaranteed. Some called for a realistic view of the investments required: most research is funded by public money and the costs of clinical trials are often exaggerated. Simplified access to information would help fight any abuse by

dominant parties. In order to avoid patents becoming an obstacle to access to medicines, one company reported that it had deliberately decided to cease filing patents for its inventions in least developed and low-income countries.

CLOSING SESSION

In the closing session, WIPO's Deputy Director-General Johannes Christian Wichard noted the importance and the benefit of the trilateral cooperation between WHO, WIPO and the WTO. Addressing practical issues from the respective special expertise of each organization helped ensuring policy coherence at the multilateral level.

However, patent information is difficult to obtain and available tools are not yet completely reliable. More work is needed and done to build capacity and make complete and reliable patent information easier to access.

The public health community needs to provide policy guidance in identifying the essential technologies. The patent community can contribute the tools and help making sense out of the patent information. This is a complex task to which WIPO is prepared to contribute its part.

WHO's Assistant Director-General Marie-Paule Kieny recalled that, since the TRIPS Agreement came into force, the relationship between intellectual property and public health has been extensively discussed in many forums. Progress has been made, including through the Doha Declaration on the TRIPS Agreement and Public Health and the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.

However, discussions are often dominated by ideology rather than facts. The cooperation between WHO, WIPO and the WTO wants to bring more evidence to the debate. Accessible and reliable information about patents are key for health policy makers and procurement managers.

The issues raised at the symposium provided a good agenda for future work. By making patent information accessible and understandable to the public health community, freedom to operate can be promoted and, ultimately, access be improved. For this to happen, it is indispensable to combine the complementary expertise in WHO, WIPO and the WTO and to collaborate with all partners.

FURTHER INFORMATION

WEBSITE OF THE SYMPOSIUM

WHO: http://www.who.int/phi/access_medicines_feb2011/en/index.html

WIPO: http://www.wipo.int/meetings/en/2011/who_wipo_wto_ip_med_ge_11/index.html

WTO: http://www.wto.org/english/news_e/news11_e/trip_21jan11_e.htm

FREEDOM TO OPERATE:

IP Handbook of Best Practices, Section 14: "Freedom to Operate and Risk Management" <http://www.iphandbook.org/handbook/ch14/> and particularly Chapter 14.1 "Freedom to Operate, Public Sector Research, and Product-Development Partnerships: Strategies and Risk-Management Options" www.iphandbook.org/handbook/ch14/p01

PATENT INFORMATION:

WIPO Guide to Using Patent Information http://www.wipo.int/freepublications/en/patents/434/wipo_pub_l434_03.pdf

How to conduct patent searches for medicines - A step-by-step guide, WHO - 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/patentscope/en/>

WIPO patent legal status project: http://www.wipo.int/patentscope/en/programs/legal_status/index.html

WIPO Standing Committee on the Law of Patents (SCP):
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 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>

PATENT LANDSCAPES:

WIPO Patent Search Report on pandemic influenza preparedness (PIP)-related Patents and Patent Applications http://www.who.int/csr/disease/influenza/Influenza_FullReport_01Apr2011.pdf

Working Paper on Patent issues related to influenza viruses and their genes, prepared by WIPO at the request of the WHO, 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 <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

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

WIPO patent landscape project: http://www.wipo.int/patentscope/en/programs/patent_landscapes/pl_about.html

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