

SYMPOSIUM ON ACCESS TO MEDICINES:

Pricing and Procurement PRACTICES

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Current Developments and ingoing work in WHO/WTO/WIPO

Access to patent information, competition policy and arbitration and mediation

Konji Sebati

Department for Traditional Knowledge and Global Challenges

World Intellectual Property Organization

Directors General Pascal Lamy, Margaret Chan, and Francis Gurry, Hon. Ruth Dreifuss, distinguished colleagues, my co-panelists, Ladies and gentlemen, good morning.

My intention is to outline some of the intellectual property aspects that may be of relevance for procurement and pricing practices in a public health context. I shall not endeavor to talk about why intellectual property is important for access to health, since this is a topic that has been discussed over and over for years.

Access to medicines and intellectual property has been a central topic of the international policy discussions for years, as you have repeatedly heard; and as you heard from WIPO's Director General in his opening remarks. I shall however attempt to give you a practical impression about the wealth of information that is available from the intellectual property system; and WIPO's continuing challenge, an imperative in fact, to assess how intellectual property systems and policies can and should enable access to medicines, and not be seen as a barrier. This is why a symposium like this is an excellent opportunity for exchange of ideas; learn from each other's contributions, opinions and views.

WIPO has the potential to be *the* leading intergovernmental forum for addressing the intersection between intellectual property and global policy issues, one of which is public health and access to medicines; a continuing global challenge even today; But also exacerbated by the other global challenges the world is facing today like climate change, food security, the attainment of the Millennium Development Goals and protection of biodiversity.

Continued access to health solutions requires an active policy of promoting innovation, but ensuring that the results of this innovation are easily accessible to patients, doctors, governments, academics and others who play a role in promoting of public health. As Aristotle once said; "It is clearly better that property should be private, but the use of it common: and the special business of the law maker is to create in men this benevolent disposition".

We see ourselves at WIPO as that interface between encouraging strong intellectual property principles, and being the enabler of a benevolent disposition to share this intellectual property at some point for the common good. WIPO and WTO launched a joint initiative to assist LDCs in implementing the TRIPS Agreement and in using intellectual property as a tool for technological advancement, economic growth, and knowledge and wealth creation. WIPO is convinced that all developing countries, through effective use of the patent system, should be able to stimulate local research activities and make joint efforts to develop and produce medicines they need.

In providing such support, WIPO's aim is to help all countries to fully utilize the intellectual property system and patent system as a dynamic too. An adequate intellectual property system, respecting both the needs of creators of intellectual property as well as consumers, is especially important in the field of health care. The patent system as it is anyway requires significant disclosure of the information leading to the invention of new drugs. Without the patent system, such key technical information would remain unavailable or even secret. Many health care researchers and drug manufacturers, who depend heavily on such information for their work, would have to reinvent the wheel. An active policy to promote innovation and to make the results of this innovative activity accessible to patients, doctors, hospitals, governments, and all others that have a role in public health contributes to access to health.

.....but the big question this morning is what exactly can WIPO contribute to the accessibility of medicines? The topic today illustrates a very practical aspect of access to medicines; how do medicines reach the patient? And at what cost?

- Procurement contracts are awarded to eligible suppliers on the basis of general, transparent principles, that include the:
 - identification of the needs of the purchaser
 - identification of potential eligible suppliers through formal determined methods
 - competitive processes

- objective & transparent pre-established criteria for the evaluation of tenders
- fairness, integrity and transparency of the procurement process

So what is the role of intellectual property in procurement?

At the outset, one might think that intellectual property would not appear as an issue for procurement; however the provider would need to make sure that his offer does not infringe the rights of others, including intellectual property rights. The procurer too would trust that the provider is entitled to sell the product without infringing other people's rights, especially if this is an international procurement involving purchasing and distributing medicines in different countries. It may be necessary to ensure that this distribution activity does not have the possibility of infringing intellectual property rights.

What seems to be crucial, from an intellectual property perspective, is information; information about the laws applicable in the receiving countries, the existence or absence of rights, etc. All such information is generated and administered in local patent offices, and in fact most of what is required exists; information about innovation, inventors and related patent rights. In principle, all the information that may be requested in this respect exists. The challenge has been, especially in developing countries, that it is not always easy to obtain this information.

But how can the information be obtained?

This is where WIPO comes in. On June 1, 2010, WIPO launched WIPO GOLD, the Global Intellectual Property Reference Resource; a convenient portal which does not add any new functionality to the system, incorporates all of the existing WIPO services that provide information, and provides quick and easy access to a broad collection of data and easy accessible links to a number of further databases;

- searchable data and tools relating to technology
- brands
- designs
- intellectual property statistics
- WIPO standards
- intellectual property classification systems
- intellectual property laws and treaties.

WIPO's most highly developed database and gateway to patent services and activities is **PATENTSCOPE**, fully searchable repository service that allows a full-text search of over 3.7 million published international patent applications, from the first publication in 1978, and increasingly gives access to national patent documentation. **PATENTSCOPE** provides the latest information and documents available to the International Bureau.

It particularly features full-text search in bibliographical data, descriptions and claims; & allows viewing and downloading the available relevant documents. A new open source search engine has introduced some new features which help to improve the search results through, for example;

- automatic analysis by cluster for every search
- better relevance ranking
- multiple languages support
- machine translation of titles and abstracts
- full text descriptions and claims with embedded images.

And because of the challenge of the different languages and translations of certain technical terms, WIPO also recently launched what is called Cross-Lingual Information Retrieval (CLIR); a new exciting facility of the **PATENTSCOPE** Search system which will open up a new way of carrying out multiple linguistic searches of patent databases in different languages and will significantly enhance access to patent information throughout the world. The search query in one language will be translated at best into several other languages by special software which has been developed by WIPO. CLIR has extensive rich coverage in English, French, German and good coverage for Japanese and Spanish. The next languages to be considered are Chinese and Portuguese.

The international applications that can be found on the **PATENTSCOPE** Portal are however applications, not granted patents. For procurement purposes one would like to rather know about patents in force; but as you know, the grant of patents is under the national jurisdiction of the competent national or regional patent authority.

National offices increasingly provide us with information on international applications that have moved to national patent grant proceedings. At the moment we have information from 43 countries, and are seeking to increase it. As recent as September **PATENTSCOPE** was expanded to include data information from 8 national offices, namely; **ARIPO**, Cuba , Israel , Korea, Mexico, Singapore, South Africa and Vietnam. Soon to add data from Argentina, Philippines, Kenya

We see this as an essential role for WIPO to help countries to make patent information available, and to make that data better, easier and more effectively available.

Another service that WIPO can provide is in regards to information about a country's patent laws. WIPO's Collection of Laws for Electronic Access (CLEA), is a service that maintains a collection of all intellectual property legislative texts received by WIPO. The aim is to make available to the public a database of intellectual property treaties, laws and regulations that is authoritative, accurate and complete. Such texts include national laws from about 220 countries, as well as multilateral and bilateral treaties, and are available for consultation on request.

A new and improved version of CLEA in respect of content, format and usability is called **WIPO Lex**, an ambitious project which for some time will remain an on-going

process. The primary focus is the completion & updating of the national intellectual property legal systems of all WIPO, WTO and UN Members over the next few years. In the medium-term, WIPO Lex will also feature all IP-relevant treaties (other than WIPO treaties), at the international, regional and bilateral levels. Due to constraints in resources, English is the priority language of the WIPO Lex, although every effort will be made to provide translations in French and Spanish soon.

WIPO Lex, or for now CLEA, the Collection of Laws for Electronic Access, will be very useful in knowing more about patent law exhaustion in countries, especially in relation to procurement; whether when a medicine is sold and delivered by the holder of a patent right on the basis of a procurement contract, in the same market where they are bought, the patent may be exhausted, meaning that the purchaser is free to use the medicine and there should be no further problems for the distribution of the medicine from the intellectual property point of view. However, if the right is exhausted not only in the country of procurement but also in another country, the patent holder cannot prevent the exportation into another country. Whether the rights are exhausted or not though is a question of what the national law says, the exhaustion regime in the receiving country becomes relevant. WIPO Lex will become very useful.

I was also asked to speak on Competition Policies. The question again here is; is IP against competition? Does it inherently trump on competition? IP however does differentiate, and that in itself is the core of competition between businesses; be they multinational companies or the artisan in a flea market in Johannesburg. Thus the terms used in IP like novelty, inventiveness, distinctiveness, creativity, originality, priority etc., are so essential. IP is inherently pro-competition because without IP there is no differentiation, and with no differentiation there is no competition. However IP has to come in the right dosage!! Too little gives rise to confusion, with generalised imitation, indistinguishable products, and the danger of substandard products and consumer confusion. On the other hand too much IP and abuse of IP with suppression is just as self destructive. (e.g. protecting generic names as trademarks, patenting properties of nature).

Countries need to create an environment that ensures adequate and appropriate standards for competition. Fair or unfair competition has an impact on prices, and this will invariably affect procurement procedures.

In WIPO's Development Agenda, Member States approved a project on Intellectual Property and Competition Policy. (described in the WIPO Document CDIP4/4).

This project seeks to promote a better understanding of the interface between intellectual property and competition policy, particularly in developing countries and countries with economies in transition. WIPO's role is to undertake a series of activities aimed at collecting and scrutinizing recent practices, legal developments, jurisprudence and legal remedies available in selected countries and regions. Such activities are going to include;

- survey and analysis on the use of compulsory licenses to repress anticompetitive practices
- studies on intellectual property & competition in selected countries and regions
- meetings on intellectual property and competition at the regional level
- symposia on emerging challenges over the anti-competitive use of intellectual property
- WIPO training programs on technology licensing
- development of a guide on franchising
- publication of studies and proceedings of relevant meetings

To complete my presentation on availability of information and data, and WIPO's role in access to medicines, Procurement and Pricing practices, I would like to mention yet another area WIPO service; the Arbitration and Mediation Center, which provides services that deal with disputes.

Disputes are often neglected matters; however thinking about dispute resolution well in advance is essential for success. The WIPO Arbitration and Mediation Center was established in 1994. The Center promotes alternative dispute resolution other than court litigation, time and cost-effective resolution of commercial disputes involving intellectual property between private parties. Over the years the Center has gained considerable administering authority in resolving thousands of disputes over the years.

Some of the examples of Arbitration and Mediation cases that have been resolved, both contractual and non-contractual disputes, are;

- patent license agreements (e.g. payment of royalties, sharing test results)
- software and information technology
- research and development collaboration agreements
- distribution agreements for pharmaceutical products
- patent infringements
- joint ventures
- copyright collecting societies
- trademark coexistence agreements
- research institutes and NGOs and universities (including spin-offs).

The Center serves as resource for rules, contract clauses, and neutrals. It gives procedural guidance and offers tailored dispute resolution services, provides trainings and organizes conferences. The Center is also prepared to have a potential role in developing tailored alternative dispute resolution mechanisms and administering disputes relating to patent pools to facilitate access to medicines.

In conclusion L & G, I hope I have been able to illustrate to you the services that WIPO can provide, albeit being peripheral to procurement and pricing as such, yet these are services that are needed in some way or another;

- Within procurement processes, disclosures of patent information helps in the identification and selection of products and suppliers;

- WIPO's patent information systems, PATENTSCOPE as an example, is a valuable tool at various stages of procurement, providing world leading references sources, databases and portals for patent and licensing policies to maximize availability of innovation, including research tools and platform technologies for the development of products relevant to public health particularly in conditions prevalent in developing countries or affect developing countries disproportionately.
- A range of specific supporting activities, such as facilitating licensing agreements and dispute resolution; and

WIPO is committed to do whatever is within our possibility to enhance worldwide access to information related to innovation and connected intellectual property rights, and in turn access to medicines.

Thank you for your attention.