

Searching for Transparency: Improving Patent Information to Increase Access to Medicines

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The ability of developing and least-developed countries to procure affordable generic medicines continues to be hampered by a lack of transparency in patent information. While there has been an increase in electronic patent information since TRIPS, much more still needs to be done.

The globalisation of patent protection for medical products has meant changes for public health actors seeking to sustain and improve access to medicines. Under the WTO Agreement on Trade-related Aspects of Intellectual Property rights (TRIPS), member states that did not make available patent protection for pharmaceuticals when the treaty came into force were required to provide means for applicants to file such patents. WTO members with developing country status were subsequently required to start examining patent applications and providing patent protection on medicines either by 1 January 2000 or by 1 January 2005. Many developing countries implemented patent protection for medicines significantly earlier than required under the transitional provisions of TRIPS. Today, patents on medicines are being granted in developing and least-developed countries (LDCs).

Whereas previously health authorities and procurement bodies could make the decision to purchase more cost-effective generic versions of medicines without having to consider the question of patents, this is no longer the case. Procurement bodies must now establish in advance of purchasing decisions whether patents on a particular medicine have been applied for, granted or expired.

Aside from being able to monitor the status of patents for procurement purposes, relevant actors must also keep abreast of this information in order to determine suitable strategies and policy choices. This can include whether a country government should use TRIPS flexibilities, NGOs (and generic companies) raising concerns through patent oppositions, or generic companies deciding if they have the freedom to operate.

In order for organisations to tackle these issues, there is a critical need for transparent patent information. The question remains, however, whether enough is being done to accommodate this need.

A Decade of Searching for Transparency

Following the inception of TRIPS, very little attention was paid to the role played by patent information in ensuring continued access to affordable generic versions of medicines for developing countries and LDCs. As efforts to increase the procurement of generic antiretrovirals and related medicines began around 2000, the realisation set in that the lack of information on the status of patents would be an obstacle to increasing access. Indeed, the outbreak of avian flu in 2005 showed how farcical the situation could become without patent information: facing uncertainty about whether they could stockpile generic versions of oseltamivir, some developing countries began to consider voluntary and compulsory licenses – only to eventually be told by Roche that in some cases there were no patents.

Nevertheless, during the last ten years useful contributions have been made to improve transparency by landscaping the patent status of medicines (see box opposite).

Most of the efforts have concentrated on the area of antiretrovirals and are limited in the countries they cover. This is due to a number of factors, including: ongoing difficulties in obtaining patent information from developing country and LDC patent offices; the lack of human and capital resources to ensure continuity for keeping patent landscapes up to date; and indecision amongst some organisations as to whether there could be unforeseeable consequences to having transparent patent information. These reasons, and a lack of political will, partly explain why the WHO Patent Project appears to have stalled. This is despite Resolution

61.21 of the 2008 World Health Assembly, which urged the WHO to:

“compile, maintain and update a user-friendly global database which contains public information on the administrative status of health-related patents, including supporting the existing efforts for determining the patent status of health products in order to strengthen national capacities for analysis of the information contained in those databases and improve the quality of patents.”

Despite such setbacks, in the past two years patent information in an electronically searchable format has become increasingly available. More and more national patent offices are providing searchable databases, albeit with some providing more information than others.

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Patent Landscape Milestones: 2000–2010

- Patent Situation of HIV/AIDS-related Drugs in 80 Countries (UNAIDS/WHO, 2000)
- Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa (IPI/WIPO, 2000)
- Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa? (Attaran and Gillespie White, 2001)
- Drug Patents under the Spotlight (MSF, 2003)
- WHO Patent Project: Determining the Patent Landscape of Essential Medicines in Developing Countries (UNDP/UNAIDS/WHO/European Patent Office, 2005–2008; unpublished)
- Some Intellectual Property Issues Related to H5N1 Influenza Viruses, Research and Vaccines (Edward Hammond, The Sunshine Project and TWN, 2007)
- Patent Landscaping Report on Neglected Human Diseases (WIPO/CSIR, 2008)
- UNITAID Patent Pool Implementation Plan (UNITAID, 2009; unpublished)
- HIV Drug Patents in China (I-MAK, 2010)

Examples include Argentina, Brazil, China, Colombia, Egypt, India, Malaysia, Mexico, Philippines and Thailand. In the case of the Indian Patent Office, it was only after much public pressure that the database provided the full text of published and granted patents, as well as the status of applications.

WIPO's database, Patentscope, allows users to search for international patents using 11 different search fields, including the full text of patents. Working with national patent offices, Patentscope provides the national phase status of international applications in countries or regions including Argentina, the African Regional Intellectual Property Organisation, Cuba, Kenya, Mexico, Philippines, South Africa and Vietnam.

The European Patent Office (EPO) has also been adding information from developing country patent offices to its database Esp@cenet. It is understood that the EPO is considering tagging pharmaceutical patents to marketed products listed on the US Food and Drug Administration's Electronic Orange Book.

While the last decade has seen improvements in access to patent information and more detailed patent landscapes on medicines, there still remains a considerable lack of transparency. This is particularly so for civil society users not familiar with how to navigate the various sources of patent information.

It is unfortunate that where patent information on medicines has been gathered by organisations – such as UNITAID, the WHO and the Drugs for Neglected Diseases Initiative – they have not made the research available for public viewing. It would seem logical that by making such information available, other organisations across the world would be able to maintain the data and even build upon it. Such information could also improve research in the area, and thus help understand the role patents play in access to medicines.

Improving Patent Transparency

The obvious solution to the transparency problem is to have patent owners disclose the relevant patents they have on medicines. However, in most cases, pharmaceutical companies are unwilling to share this information, preferring to play a game of hide-

and-seek. This strategy gives originator companies an advantage and creates uncertainty in the marketplace for competitors.

Peter Drahos in his recent book *The Global Governance of Knowledge – Patent Offices and their Clients* rightly points out that patent offices have a greater obligation to diffuse information on inventions as a public good. Simply publishing patent information and offering databases for searching is not the same as actively promoting transparency.

Ideally, patent offices would make the information more easily accessible. For example, their databases could be linked to pre-searched company patent portfolios for active pharmaceutical ingredients. Such lists could be compiled and automatically updated by the relevant patent office through programmed algorithms combining all the various search techniques, including compound structure(s), compound names, keywords and citations. The list would also include details of patents that have expired or lapsed – information not so readily transparent in current databases.

Access to such information would help give more clarity to freedom-to-operate decisions and save considerable time now spent on repeat searches by organisations with limited resources.

Information of this nature would make transparent the patenting strategies of companies, such as the filing of patent clusters in order to deter competitors and prolong patent protection on existing medicines. This could lead to a better understanding of the type of innovation and patenting behaviour that is taking place, helping contribute to more solid evidence-based policies. It would also reduce unnecessary legal fees that lawyers and commercial patent database providers charge for repeating patent searches, which often return the same results.

Changing the pedagogy in IP education and training can also improve transparency. Current initiatives by WIPO and other institutions are either directed to patent office personnel only or provide a theoretical brand of teaching. However, experience in the field has shown that practical tools that relevant actors, in particular civil society, can use to help demystify the patent system can go long way to creating more transparency. Such tools can help build awareness of patent information systems and create a new network of users outside of the lawyers and search providers that currently monopolise the space. It is only by expanding knowledge and awareness outside of existing establishments that the patent system can truly serve the public.

A recent publication by the WHO offices of South-East Asia and Western Pacific Region on *How to Conduct Patent Searches for Medicines – A Step by Step Guide* is a useful starting point in this direction.¹ The guide, written primarily for beginners, provides various techniques on how to search for patents on medicines, including finding US patents listed in the US FDA Orange Book and tracing the corresponding and related patents in developing country patent offices. The guide also sets out the useful methodology adopted by the WHO Patent Project and UNITAID for their landscaping of patents on antiretroviral medicines.

Information asymmetry in the patent system makes procurement decisions for medicines inefficient. It also makes for blind policy decisions when implementing patent laws. The modern patent social contract, which was partly defined on the exchange and dissemination of the knowledge of inventions claimed in patent specifications, currently disproportionately favours patent holders. Much more needs to be done if we do not want another decade to go by in the dark.

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ENDNOTE

¹ http://www.wpro.who.int/publications/PUB_9789290223757.htm