11 How to conduct a patent search on a medicine

Identifying barriers to access and strategies to overcome these barriers often means being able to identify whether there are patents covering a medicine, and whether the patents are valid. A medicine can be covered by one patent or several – even several dozens in some cases (compounds, processes, combinations, etc.). The difficulty for health advocates is that there is no easy way to make the link between a medicine and the patents that cover it.

The obligation to disclose the invention covered by a patent is at the origin of the patent system. Therefore the patent is supposed to describe the invention. However, along the years and as a consequence of commercial strategies, things have changed. Today pharmaceutical companies, or the lawyer(s) that work for them, write patent applications in order to obtain a patent while at the same time avoiding providing any significant information on the invention. This is a significant perversion of the system and makes it very difficult to understand which patent(s) cover which medicine.

For policy makers, health advocates or activists, it is however important to be able to trace the patents covering a medicine. This factsheet identifies the steps one can undertake to conduct a patent search where the medicine is a chemical (patent and exclusivity searches for biologic products are not covered by this factsheet).

Step 1. Identify the patent(s) covering the patents in the US

One of the easiest ways to identify patents for chemical products (not biologics) is to use the "Orange Book" from the US. The Orange Book is the register of all drugs that the U.S. Food and Drug Administration has approved as safe and effective.[1] The Orange Book is of great interest for health advocates as it requires companies to declare their patents on the approved drugs. Therefore it indicates a clear link between patents and medicines.

➜ Practically to access the Orange Book, go to [http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm]. There you can search for a medicine by the name of the active ingredient (international non-proprietary name) or by the brand or proprietary name. For Tenofovir Disoproxil Fumarate, for instance, you can also use the proprietary name Viread.

➜ The result of the search will give you a list of all the products registered under that name or containing that active ingredient. Often the different products correspond to different dosages or to combinations.

➜ Each product has an application number. The application number is the same for different dosages of the same product. Click on the application number of the product you are interested in (N021356 for Viread 150 mg): a new window opens and will show you details about the product (Active ingredient, Proprietary name, Dosage, Strength, Approval date, etc.).

➜ At the bottom of the webpage there is an active link on "Patent and Exclusivity information". Click on it: a new page open with the patent data about the product. It is basically a list of all the patents that cover the product. For each patent there is a US patent number. For Viread, four patents appear with the following numbers: 5922695, 5935946, 5977089, 6043230. Pick the number of one patent, for example: 5922695.

1. Alternatively the Canadian Patent register can also be used: https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/patent-register.html.

Step 2. Search the EPO database to identity patent in a specific country

➜ Once you have identified the US patents on a medicine, the next step is to go to Espacenet, the patent search engine of the European Patent Office (EPO): [https://worldwide.espacenet.com].

➜ Use Smart search and enter the number of the US patent adding 'US' in front of the number (US5922695). The patent should appear as a result of the search under its title: **Antiviral phosphonomethyoxy nucleotide analogs having increased oral bioavarilability.**

➜ Click on it: a new window opens. On the left side of the screen is a menu. If you look at the description you will be able to read the patent itself.

➜ In this menu choose INPADOC patent family. Click on it: the list of all the countries where this patent is registered along with the country specific patent numbers will appear. With the help of the Espacenet Country Codes available here: [https://worldwide.espacenet.com/help?locale=en_EP &method=handleHelpTopic&topic=countrycodes], you should be able to identify the relevant patent application in your country from the list.

Step 3. Check the patent status and validity in a specific country

In order to know if a patent is valid you need to check whether it was granted (or if it is still under examination), whether it was opposed successfully or was amended or revoked, whether the annual fess that must be paid each year to ensure its validity have been paid, etc. Your national (or regional) patent office has this information. You can ask them, or check on their website if they have one.

➜ Let's take the example of a patent granted by the patent office in New Zealand: NZ333687 (that correspond to US5922695). Click on "INDAPOC legal Status" and you will get information about the legal status of the patent in New Zealand.

➜ Let's take the example of a patent granted by the EPO: EP0915894, the equivalent in Europe of US5922695. Once on the patent, choose the "INDAPOC legal Status" in the menu on the left. A new page open on which you will see "Designated Countries" which is the list of countries in Europe where the patent application was filed (according to the European Patent Convention that established the European Patent Office and the procedure to grant patent in the region) as well as all the administrative steps from the filing of the patent (request for examination, inventor changed before grant, examination reports, patent granted, opposition filed, etc).Under the title INDAPOC legal status: EP0915894, click on EP register. Then click on "Legal status" in the menu on the left. From there you can access the information about this patent on the website of the national patent offices of each of the European countries that where designated: this will tell you the status of the patent in each country, if the patent is valid, or expired, or cancelled, etc.

➜ Via Espacenet, in the list of the patents corresponding of a patent such as US5922695, you will find the WIPO international application filed by the patent applicant (here WO9804569).[2]

➜ Through the patent search engine of WIPO, Patentscope, you can also obtain the list of the countries in which the patent was filed: [https://patentscope.wipo.int/search/en/search.jsf].

➜ **An alternative and faster way for HIV, Hepatitis C and tuberculosis medicines in low- and middle-income countries** is to look into **Medspal, the Medicines Patent Pool search engine**, where experts already did the search: [http://www.medspal.org]. This tool can be used to do search by product or by country. It also enables free text searches, such as by patent numbers, product brand name, applicant name, patent status or any combination of these. For each patent applied for or granted in a given country, a patent card provides information about the application (patent status, date of application, expected expiry date, priority number, PCT related application, etc.), and links to further information.

FIND OUT MORE (SOURCES AND RESOURCES)

➜ UNDP, A Methodology for Patent Searches on Essential Medicines in Developing Countries, 2012, available at: [http://www.undp.org/content/undp/en/home/librarypage/hiv-aids/a-methodology-for-patent-searches-on-essential-medicines-in-deve.html].
➜ WHO, How to Conduct Patent Searches for Medicines. A Step-by-Step Guide, 2010 available at [http://apps.who.int/medicinedocs/en/d/Js17398e].
➜ WHO, updates patent information on treatments for Hepatitis C, available at: [http://www.who.int/phi/implementation/ip_trade/ip_patent_landscapes/en].
➜ WIPO, Patent Landscape Reports by Other Organizations, allows search in the field of public health. It is available at: [http://www.wipo.int/patentscope/en/programs/patent_landscapes/plrdb.html].

2. International application through WIPO are not leading to worldwide granted patent but they allow patent owner to seek patent protection simultaneously in a large number of countries by filing a single "international" patent application instead of filing several separate national or regional patent applications. The patent owner designate the countries in which the patent application to be sent. Such applications are possible due to the Patent Cooperation Treaty (PCT). 150 countries are currently members of this treaty.