Public Policy Patent Landscape in the Life Sciences: Public health policy context

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Background: TRIPS Agreement

- The WTO TRIPS Agreement introduced a multilateral framework for intellectual property protection, which requires WTO Member countries to implement prescribed minimum standards of intellectual property protection within their national legal systems.
- nearly all developing countries now provide patent protection for pharmaceutical products; some well ahead of their TRIPS deadlines.
- relevant information on which medicines are patented where, by how many patents, and for how long is needed for procurement and supply ;
- such information may be obtained from publicly-accessed sources

Background: WHO Project with partners

- WHO (TCM/HTP) had jointly-published with UNAIDS and MSF, a report on patent status of ARVs and HIV-related medicines in 29 developing countries in late 2004.
- WHO-UNAIDS Secretariat jointly published the report on "Patent Situation of HIV/AIDS-related Drugs in 80 countries", which provided a list of patents that have been applied for or granted on HIV/AIDS-related medicines in selected countries.

Rationale

- Developing countries have difficulties obtaining access to accurate and up-to-date information on the patent status of essential medicines
- There is lack of capacity in national patent offices to administer the patent system (including managing effective search mechanisms) and to respond to the public health needs
- WHO initiated a patent landscape project

Objectives

- Facilitate effective and efficient medicines procurement, by providing relevant information to Member States
- Facilitate informed policy decisions regarding medicines procurement and the use of the TRIPS flexibilities, as confirmed in the Doha Declaration;
- Respond to requests for patent data from Member States, UN agencies
- Increase transparency and access to patent information related to essential medicines.

Process

- Collaboration with World Intellectual Property Office (WIPO) and Patent offices in selected countries
- Technical consultations with experts at WIPO on the project design and methodology, as well as discussions on possible means of collaboration.
- Selection of a list of the relevant pharmaceutical products for which patent status is to be determined;
- Identification of a list of priority countries in which patent data on medicines is sought;
- Relevant information of valid patents for each of the identified pharmaceutical products in the priority countries

Collaboration

- There has been close and active collaboration with the European Patent Office (EPO) on the project through provision of technical support to the project since its inception.
- EPO provided training the methods of conducting searches on the EPO databases,
- The Office of Patented Medicines and Liaison, Therapeutic Products Directorate, of Health Canada, provided information relating to the listing of patents on essential medicines and has expressed willingness to explore further collaboration on this project.
- Other national patent offices, including the State Intellectual Property Office of China (SIPO), the African Intellectual Property Office (OAPI) and the South African Companies and Intellectual Property Registration Office (CIPRO), provided patent information .

Consultation

- UN agencies that procure medicines on behalf of governments, including UNICEF, UNDP and the Global Fund on the Fight Against AIDS, TB and Malaria (GFATM), were consulted and provided inputs regarding information gaps in the context of medicines procurement and intellectual property rights.
- Consultation with relevant departments/units in WHO

Process: Identification of pharmaceutical products

- Medicines or combinations of medicines for HIV/AIDS, tuberculosis, malaria and opportunistic infections (OI), based on WHO Model Essential Medicines List and WHO Treatment Guidelines,
- Consultations with technical departments/units within WHO (including HIV/HTM, STB/HTM, MMSS/HTM), UN and other organizations involved in medicine procurement (i.e., UNICEF, UNDP, the Global Fund and IDA).
- Commonly-procured medicines for HIV/AIDS, TB and malaria. Fixed-dose combinations and paediatric formulations of key medicines
- Provisional selection of pharmaceutical products for HIV/AIDS, tuberculosis and malaria.
- Selection of pharmaceutical products for antiretroviral treatment and verification at national level as part of the pilot phase.

Process: Identification of countries for which patent data is required

- Countries with actual and potential production capacity, countries with little or no manufacturing capacity, countries with high disease prevalence and low GDP.
- A list of 67 countries had initially been identified, on the basis of their meeting the criteria as stated above.
- For the first phase of the project, an initial list of 10 priority countries from the full list were identified as those countries for which the project will focus

Process: Identification of countries for which patent data is required

- Preliminary patent information in these countries, or patent offices in those countries had either indicated a willingness and ability to provide the information requested,
- Project partners (EPO and WIPO) had identified some countries as good candidates, in terms of their patent search capacity.

Countries

- African Intellectual Property Office/OAPI (16 Member States: Benin, Burkina Faso, Cameroon, Central African Republic, Congo, Cote d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal, Chad, Togo)
- African Regional Intellectual Property Organization /ARIPO
- (16 Member States: Botswana, the Gambia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Sierra Leone, Somalia, Sudan, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe
- Brazil
- China
- Kenya
- India
- South Africa
- Ukraine
- Indonesia

EPO-WHO Patent Database project: List of countries

Category 1	Category 2	Category 3	Category 4
Countries for which some patent data has been compiled (by MSF and EPO) but for which there is need to update data for list of 50 identified medicines	Countries for which patent data will have to be compiled for the list of 50 identified medicines	Countries for which patent data will have to be compiled for the list of 50 identified medicines	EPC members
1. Brazil 2. Cambodia 3. China 4. Guatemala 5. Kenya 6. Malawi 7. *OAPI 8. Peru 9. South Africa 10. Thailand 11. Uganda 12. Ukraine 13. Zambia 14. Zimbabwe	1. Argentina 2. Bolivia 3. Botswana 4. Chile 5. Colombia 6. Ecuador 7. Egypt 8. Ghana 9. Honduras 10. India 11. Indonesia 12. Israel 13. Jordan 14. Malaysia 15. Morocco 16. Nigeria 17. Pakistan 18. Philippines 19. Tanzania 20. Tunisia 21. Uruguay 22. Venezuela 23. Vietnam	1. Bangladesh 2. Belarus 3. Ethiopia 4. Iran 5. Laos 6. Russian Federation	1. Bulgaria 2. Estonia 3. Hungary 4. Latvia 5. Lithuania 6. Poland 7. Slovakia 8. Slovenia 9. Turkey

*OAPI Member states (16): Benin, Burkina Faso, Cameroon, Central African Republic, Congo, Cote d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal, Chad, Togo

Identification of priority patent information and corresponding patent families

- Patent information will be presented according to the relevant priority patents for each of the product, in selected countries.
- Patents may be granted on various aspects of a single pharmaceutical product; e.g.
  - the chemical compound, the derivative of compound (salts, esters, metabolites, etc.), the formulation (capsule, tablet, etc.), the use of compound or its derivatives for treatment of diseases (1st & 2nd use) and the different dosage regimens for administration, each product is expected to be covered by several patents.
- Analysis of the relevant patents and the different filing dates and thus, different expiry dates for each patent on a product, in order to provide an indication of how long patent protection will subsist.

Primary source of patent information on pharmaceutical products

- Preliminary patent data was derived from the on-line patent registries maintained by Health Canada and the US Food and Drug Administration (FDA).
- Canada and the US have a ‘patent linkage’ system, the medicines regulatory authorities in these 2 countries maintain patent registries that list patents submitted by pharmaceutical companies for pharmaceutical products that have obtained marketing approval, to prevent generic entrants from obtaining marketing approval prior to the expiry of the relevant patents.

Primary source of patent information on pharmaceutical products

- This patent information provides an initial list (not complete) of potentially relevant patents for further patent searches for identification of patent families.
- Patent families are the listing of patents from various countries that derive their origin from the priority patent; i.e., the first patent application to be filed.
- From the patent families identified, further analysis has to be made on: (1) whether the patent has been in fact granted; (2) whether the granted patent claims the relevant invention that affects the use and manufacture of the medicine.

Patent family search

- Once the primary patent information was sourced from the Health Canada and US FDA Orange Book, the project sought to identify the relevant patent families for each of the Canadian and US patents, in order to track where else in the world similar patent applications have been filed and granted.

European Patent Office searches

- Searches conducted at EPO generated much raw data (approximately 2000 pages) which were analysed.
- The completed analysis of the patent family searches indicates priority patent information for 19 antiretroviral drugs or combinations for the treatment of HIV/AIDS, as well as some patent information for patents granted at the national level.

Verification of patent information with national and regional patent offices

- Patent searches will have to be conducted at the national level in order to verify the patents that have been granted by national patent offices.
- A determination of validity of granted patents will also have to be made in each country.

Methodology

- Description of sources of patent data,
- Rationale for selecting specific patent sources,
- Method for collection and analysis of data.
- This is aimed at identification of limitations of the methodology and outlining alternative methods and the required resources.
- This should be considered against the background of urgent need to provide countries with essential, life-saving medicines that are patent protected, and the capacity in developing countries to obtain accurate information speedily.
- Phase II of the project planned for further work

Phase II

- National patent searches and consolidation of patent information
- Finalisation of the Project methodology document
- Determine approximate patent expiry and estimates timeframe for possibility of generic introduction
- Preparation of explanatory text on the rationale of database, its use and its limitations
- Design of database or web page for presentation of patent information obtained

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