UNDP WHO Workshop on the Examination of Pharmaceutical Patents: Developing a Public Health Perspective

Cape Town, 30 – 31 October 2008

Meeting Report

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I. Introduction[1]:

The TRIPS Agreement introduced minimum standards into intellectual property regimes previously unknown at a multilateral level. If utilized, it provides some flexibility for countries to balance the need to promote innovation through patents with the need to spread the benefits of that innovation, including through access to ARVs and other medicines. To ensure that the benefits of innovation can be assimilated by all WTO Member States, important flexibilities were introduced into the TRIPS Agreement. These, among other, enable WTO members to interpret the three criteria of patentability (novelty, inventive step, and industrial application).[2] Because a patent in essence amounts to a temporary monopoly granted to the inventor for a minimum period of 20 years, countries have retained the discretion to regulate the criteria and the conditions[3] under which patents will be granted, to ensure that developmental and public health concerns are adequately addressed.

There is however, growing evidence which points to the proliferation of patents over minor variants of existing products both in developed and developing countries. This trend has been noted with much concern by development stakeholders who are concerned about patents where only incremental changes have been made and the unjustified monopolies they result in. While the number of patents annually obtained to protect genuinely new pharmaceutical products is small and declining, thousands of patents are being granted for pharmaceuticals.[4] A large number of patents cover minor modifications of older existing drugs.[5] Therefore, while the number of approved new-developed chemical entities has lowered significantly in recent years, the number of patents being granted because of simple changes in the chemical formulation of existing pharmaceuticals, has led in many instances, to the exclusion of generic competition. This in turn, restricts the availability of affordable medicines and constitutes an important obstacle for the realization of the right to health. Beyond that, innovation expert as a whole warn against overbroad patent protection in both, North and South, as it is likely to function more as a deterrent of, rather than incentive for innovation.

The examination of pharmaceutical patents from a public health perspective is a very important issue for African as for other developing countries in the foreseeable future. While the patent status of most 1st line antiretroviral treatment (ART) and several

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[1] A large portion of this section is drawn from the concept note of this meeting and is not a reflection of the deliberations in Cape Town on 30-31 October 2008.

[2] Article 27.1 of the TRIPS Agreement.

[3] According to Correa, "A patent is a title granted by the public authorities conferring a temporary monopoly for the exploitation of an invention upon the person who reveals it, furnishes a sufficiently clear and full description, and claims this monopoly. The criteria for patentability require that a product or manufacturing process fulfils the conditions of novelty, inventiveness and industrial applicability (or utility)." See 'Guidelines for the Examination of Pharmaceutical Patents': Developing a Public Health Perspective', Correa, WHO-ICTSD-UNCTAD, 2007, available online at: http://ictsd.net/downloads/2008/04/correa_pharmaceutical-patents-guidelines.pdf

[4] According to Chapter 4 of the CIPIH Report, ever -greening occurs when, in the absence of any apparent additional therapeutic benefits, patent-holders use various strategies to extend the length of their exclusivity beyond the 20-year patent term.

essential medicines are no longer imperative, there are a range of patents on newer 2nd line treatment, with a strong likelihood that future-generation antiretrovirals (ARVs) will also be under patent protection. Given the price differences between patented and non-patented medication, countries where there are significant populations of people living with HIV and AIDS as well as any countries with a significant generics industry will be strongly affected by this trend. As a result the implementation of a robust understanding of patentability criteria, designed to reward real inventions but prevents the granting of (extended) monopoly rights for merely incremental innovation or obvious modifications to existing inventions has immediate impacts on how many people can have access to life saving medicines in many countries.

In this spirit UNDP and WHO put together a training session targeted at patent examiners and intellectual property experts from African countries. The session was held in Cape Town on 30-31 October 2008. Patent examiners from six African countries (Egypt, Ghana, Kenya, Malawi, Namibia and Zambia) participated in the session, as well as an official from the trans-national intellectual property office ARIPO. This report outlines the different sessions held during the training and highlights the discussions and recommendations put forward by participants during the meeting.

II. Objectives

The objective of the meeting was to raise the profile of pharmaceutical patent examinations from a public health perspective and contribute to the discussion of suitable guidelines for the examination of different types of patent claims relating to pharmaceuticals. An adequate examination of patent applications might avoid the need to resort to more controversial, costly and lengthy flexibilities such as compulsory licensing.

The facilitator of the consultation was Professor Carlos Correa from the University of Buenos Aires with technical support provided by Tenu Avafia from UNDP and two consultants, Chan Park and Johanna von Braun. The training was based on a working document drafted by Carlos Correa and published by the WHO, UNCTAD and the International Centre for Trade and Sustainable Development (ICTSD) called: *Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective. A Working Paper.*[6] In addition, participants discussed more general questions related to IP, development and public health, all of which will be outlined in this report.

III. Snapshots of selected patent offices in the region

Patent registration in Africa occurs in a number of ways. A small group of countries (Algeria, Egypt, Ethiopia, Kenya, Morocco, Mozambique and Zambia) have local patent offices with the capacity to examine patent applications at a national level. A larger group of countries rely on regional patent offices, such as the African Regional Intellectual

[6] http://www.iprsonline.org/resources/docs/Correa_Patentability%20Guidelines.pdf

Property Organization (ARIPO)[7] . The examination was conducted by ARIPO for Contracting States, and in some instances, observer countries.[8] Each Contracting State has a six month period from the granting of a patent by ARIPO to confirm or reject the application of the patent in its territory. A third group of countries belong to the Organisation Africaine de la Propriété Intellectuelle (OAPI) and are consequently, signatory to the Bangui Agreement. Established in 1962, OAPI has 16 Member States in West and Central Africa.[9] Unlike ARIPO, patents are granted by OAPI without prior substantive patent examination. Also in contrast to ARIPO, which allows its Member States the opportunity to accept or to reject a patent, once it is granted by the OAPI Secretariat, a patent becomes enforceable in all 16 Contracting States.

a) Kenya Industrial Property Institute (KIPI)[10]

KIPI reports to the Ministry of Trade and Industry and functions under the legal framework provided by the Industrial Property Act, 2001. The patent office itself has been in existence since 1989 and was reinvented as KIPI with the 2001 Act.

Section 2 of the Act gives KIPI the mandate to: *"consider applications for and grant industrial property rights including patents for inventions and certificates for trademarks for identification of goods, service marks for identification of services, utility models, technovations (rationalisation models) and industrial designs; (...) Screen technology transfer agreements and licences"* to facilitate appropriate technology transfer; *"Provide to public, industrial property information for technological and economic development"* and for the creation of public awareness in intellectual property rights; and *"[p]romote inventiveness and innovativeness in Kenya"* so as to encourage creativity to facilitate technological, industrial and socio-economic growth of the country.

KIPI is a receiving office and an elected office for PCT and ARIPO applications. Its patent division is divided into three sections: engineering, physical/chemical sciences and natural/biomedical sciences. Examination of patent applications in the pharmaceutical field is carried out in all sections of the patent division but engineering. KIPI employs 9 examiners who hold at least a BSc, mainly in biochemistry, chemistry, botany, zoology, physics, etc. with professional trainings in Kenya and abroad. These examiners carry out, on behalf of the Managing Director of KIPI, both formal and substantive examination of applications in the pharmaceutical field.

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[7] The Member States of ARIPO are: Botswana, the Gambia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Sierra Leone, Somalia, Sudan, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe. Some of ARIPO's member states are also able to engage in their own patent examination.

[8] In addition to the 16 Member States, there are 14 observer countries which are regarded as potential ARIPO members. These are: Angola, Algeria, Burundi, Egypt, Eritrea, Ethiopia, Liberia, Libya, Mauritius, Nigeria, Rwanda, Seychelles, South Africa and Tunisia.

[9] OAPI Member States are: Benin, Burkina Faso, Cameroon, Central African Republic, Congo, Côte d'Ivoire, Gabon, Guinea, Guinea Bissau, Equatorial Guinea, Mali, Mauritania, Niger, Senegal, Chad, and Togo.

[10] This section is based on the presentation made by representatives of KIPI.

The examination process includes a public interest examination for: filings done by Kenyan citizens; inventions relating to national security; inventions relating to public health and nutrition, morality and public order; exclusion of mere presentation of facts, discoveries and theories; methods of doing business; method of treatment, etc.

An application must meet novelty, inventive step and industrial applicability in order for a patent to be issued.[11] The decision to grant or reject an application for grant of a patent is solely dependent on the examiner handling the application, unless the decision is challenged by the applicant upon which the case may be referred to another examiner or a panel of examiners. Any applicant who is not satisfied by the decisions of the examiner may appeal to the Industrial Property Tribunal and thereafter to the High Court of Kenya.

For those patents that are notified through ARIPO, KIPI subjects them to public interest examination but not to substantive examination.

b) The Egyptian Patent Office (EGYPO)[12]

The Egyptian Patent Office was established in 1951 and today includes a total number of 100 technical examiners, 30 of whom are in the field of pharmaceuticals. The total number of applications during 2007 was approximately 1500. The Office is a PCT receiving office.

The legal framework of patent examination is based on Law 82 (2002) which was an amendment of Law 132 (1949). Egypt joined the WTO in 2002. Egypt's mail box was opened in 1995, to which approximately 2800 applications were submitted, 80% of which were in the pharmaceutical field. Their examination started in 2005 and the first mail box application receiving a patent grant was in 2007.

Pharmaceutical patent applications make the majority of applications received by EGYPO, and the percentage is increasing. Over the last few years the examination process has become increasingly critical, above all because of the growing proximity between the claimed invention and existing prior art and the fact that only few chemical entities are included in patent applications; most applications cover mere modifications of existing products. Patents can be granted on compounds; compositions (e.g. combinations, dosage forms, etc.) and manufacturing processes. Excluded from patentability are methods of treatment and diagnosis; secondary use of known compounds; naturally existing biological material (DNA, living cells, tissues and organs).

The actual examination includes a legal and technical part. The legal part examines whether all obligations by the patent applicant have been fulfilled. The technical part takes into consideration the three criteria of patentability: novelty, inventive step and industrial applicability. It involves a claim analysis, searching related prior art and

[11] Kenya's Patent Act also includes a unique provision that specifically exempts second use patents from having to pass all three patentability criteria in order to qualify for a patent. However, this provision is under constant debate and patent examiners do not implement it.

[12] Section based on presentation made by EGYPT representative during the workshop.

comparing application to relevant prior art. Patent examiners then give a primary feedback to the applicant who may make amendments to his/her application. The final decision is made by the examiner.

c) African Regional Intellectual Property Office (ARIPO)[13]

ARIPO was created by the Lusaka Agreement signed on 9 December 1976 (1978 into force). On 1 June 1981 the Organization established its own Secretariat. ARIPO operates based on two principal legal frameworks, namely the Harare Protocol on Patents and Industrial Designs, and the Banjul Protocol on Marks.

Section 1 of the Harare Protocol empowers ARIPO to grant and administer patents and to register utility models and industrial designs on behalf of the Contracting States (CS). Filing takes place either through ARIPO itself or through the patent office of a CS. ARIPO's patentability criteria are in line with TRIPS (novelty, inventive step and industrial applicability). ARIPO allows for both first and second use patents.

ARIPO examiners search to determine relevant prior art (everything made available to the public anywhere in the world by means of written disclosure, use or exhibition before the date of filing of application or where priority is claimed before the priority date). An invention is considered new/novel if it is not anticipated by prior art. Furthermore, ARIPO examiners evaluate the inventive step requirement based on the 'problem-solution' approach, i.e. they identify the technical problem and then analyze the solution offered by the invention. The invention is considered to contain an inventive step if the solution it offers is considered non-obvious to a person skilled in the art. The search and examination report is also published and contains the conclusions of the substantive examination of the application

Once a patent is granted by ARIPO, as mentioned, CSs have six months to make a written communication to ARIPO that the patent shall have no effect in its territory based on the respective national law. If after six months no notification has been sent to ARIPO the patent is considered granted in the CS. Once granted, an ARIPO patent becomes a "bundle of patents" each governed by the national law of the designated State(s). As a result, after a patent has been granted, a party who wishes to challenge the validity of the patent must seek redress in each of the CSs under the procedures set out in the national law. Some CS have indicated that the six months period is not enough for a well-functioning notification system, and that it should be extended to allow for to allow for proper analysis of the applications.

IV. Summary of discussions

Before going into the detailed technical discussions on different aspects of pharmaceutical patents, participants took part in a session on background information, in which the more specific debate on patent examination is embedded. Issues related to

[13] Section based on presentation of ARIPO representative during the workshop.

intellectual property and public health, innovation and development were discussed. The following section elaborates on the topics that were touched upon in this session.

1. Background

a) IP-health

The need for broad and sustainable access to affordable medication is particularly high in Sub-Saharan Africa, which has 10% of the world's population but is home to more than 60% of all cases of HIV/AIDS. In 2007 for every person put on treatment 2.5 new infections incurred. Furthermore, additional risks are posed by tuberculosis and malaria. Of the estimated 1 000,000 global malaria deaths 90% are in Africa, affecting mostly children.

One of the main factors influencing access to essential medicines is drug prices. A principal aspect influencing the price of medicines is a result of patent protection. Once patents expire, or in those countries where patent protection may not exist, generic competition often results in dramatic price reductions within a relatively short period of time. According to MSF, the prices of the most frequently used first line ART combination therapies, all of which are now available in generic form, have dropped by 99% over the last 8 years from US$ 10 000 per patient to approximately US$ 87 per patient.[14] In low and middle income countries, the prices of most first line medicines decreased by 30-64% from 2004 to 2007.[15] A number of factors, including more efficacious drug combinations and emerging drug resistance, have necessitated the introduction of second line ARVs, which cost up to nine times the price of first line therapies.[16] The median price of the four most widely used first line combinations was 170 USD per person per year in 2007, while the cost of the most widely used second line combination was 1214 USD per person per year in low income countries and 3306 USD per person per year in middle income countries.[17] The need for second (and potentially third) line regimens makes it all the more urgent for countries to utilize TRIPS flexibilities as a way of reducing prices and promoting access to treatment.