



**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. Introduction¹:

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 conditions³ 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

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.

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.

b) The role of the patentability criteria for public health

The number of countries utilizing TRIPS flexibilities to reduce the cost of improving the availability of essential medicines in recent years has increased and is growing. A number of countries in Africa¹⁸ have issued compulsory licenses or government use orders either

¹⁴ <http://www.doctorswithoutborders.org/events/symposiums/2008/aids/concerns/access.cfm>

¹⁵ Op cit 3

¹⁶ In addition, new and improved first line regimes that are more durable, efficacious and tolerable cost up to three times more than older first line therapies.

¹⁷ Op cit 3.

¹⁸ These include Brazil, Eritrea, Ghana, Indonesia, Malaysia, Mozambique, Philippines, Thailand, Zambia and Zimbabwe

to increase the availability or to reduce the prices of essential medicines. South African activists have also successfully used competition law to reduce the price of ART.¹⁹ While these developments are encouraging, reality remains that the majority of developing country WTO Member States are still in the process of amending their IP legislation to take full advantage of flexibilities contained in the TRIPS Agreement, or have yet to even begin this process. For instance, a study commissioned by UNDP in 2007 found that only six countries in sub-Saharan Africa had parallel importation provisions which incorporated the international exhaustion of rights, thus allowing them to import from the cheapest global source.²⁰ In the same vein, the TRIPS Agreement does not require the patenting of new uses of known products including pharmaceuticals.

An important flexibility in TRIPS stems from the discretion given to Member States to determine the criteria for the application of the patentability requirements. While Article 27.1 provides some basis for patentability as it calls for the protection of inventions (both products and processes) that are “...*new, involve an inventive step and are capable of industrial application*”, TRIPS leaves Members the space to define these three criteria. This flexibility was precisely maintained for the purpose that Members were allowed to adapt their definition of patentability criteria to domestic development and industrial policy. Some WTO Member States have been active in making use of this flexibility. For example, the Indian Patent Act revision of 2005 incorporated the much discussed Section 3d which tightened the criteria required to pass the test of novelty, inventiveness and industrial applicability. This has led to the rejection of a number of so called “new use” patents and is also regarded as reducing the likelihood of ever-greening of patents.

It should be emphasized that this flexibility is one of the most important flexibilities contained in the TRIPS Agreement because, unlike other mechanisms, it prevents the granting of ‘bad patents’, instead of challenging them once they already have been granted, or being forced to issue a compulsory license, which can carry unfortunate political repercussions. “Bad patents” are considered those products or processes that are not sufficiently innovative to deserve patent protection but often constitute obvious product improvements, or new applications to known products that have patents which are about to expire. Estimates today suggest that two thirds of patents in the pharmaceutical field constitute such ‘bad patents’ and are today seen as common business practices of many companies.

The abundance of such patents highlights the importance of a strict enforcement of patentability criteria. Given that the validity of patents is usually maintained until proven otherwise in court and the fact that these court cases are not only expensive, but can take

¹⁹ ‘The ability of select sub-Saharan African countries to utilise TRIPs Flexibilities and Competition Law to ensure a sustainable supply of essential medicines: A study of producing and importing countries.’ by Tenu Avafia, Jonathan Berger and Trudi Hartzenberg, tralac Working Paper No 12, University of Stellenbosch Printers, (2006).

²⁰ “Access to ART and other Essential Medicines in Sub-Saharan Africa: Intellectual Property and Relevant Legislations” UNDP, September 2007; “The use of flexibilities in TRIPS by developing countries: can they promote access to medicines?” by Sisule Musungu and Cecilia Oh, CIPIH Study 4C, available online at <http://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf> for a comprehensive discussion of the implementation of TRIPS flexibilities by various developing countries to reduce medicine prices.

up 10 years, the prevention of a ‘bad patent’ can result in providing access to the patented product in question many years in advance.

c) The responsibility of the patent examiner as a guardian of public health

The role of the patent examiner is to decide whether a patent application is deserving of a 20 year period of patent protection. With respect to pharmaceutical patent applications, above all in developing countries where 80% of citizens pay out of their pockets for medicines, patent examiners carry a tremendous amount of responsibility. Their decision has a huge influence on the availability and accessibility of the product in question in the domestic market. While they should grant patents to those applications that are truly new and innovative and have industrial application, they should apply very strict standards of these criteria to prevent the patenting of products that fail any of the criteria of patentability.

Patent examiners acknowledged that patent claims in the field of pharmaceuticals can be based on many different aspects of pharmaceutical products or processes. These include not only active ingredients but also mere formulations, salts, esters, polymorphs or simply new applications of existing products. It is frequent that new patents are based on these often sub-categories of known products in spite of the fact that many of them fail the strict application of novelty, inventive step and industrial application, above all when considered by a person ‘skilled in the art’. The aim of the below listed guidelines is to support patent examiners to identify real inventions and filter out those applications that are either obvious, or fail for other reasons the strict patentability test, for, as it was discussed above, their granting have considerable public health consequences.

2. Key public health guidelines for the examination of pharmaceutical patents²¹

a) Formulation and composition²²

○ **Discussion**

Participants discussed the fact that active ingredients are presentable in different formulations or compositions. Often, patents do not protect the active ingredient *per se*, but only the actual formulation or composition thereof. In many cases even though the special formulation of administering a specific active ingredient is new, participants argued that it would still fail the inventive step criteria as variations in composition and formulation are obvious to an average person skilled in the art. It is only in very rare cases where a new formulation or composition truly produces an unexpected result or

²¹ This section will touch briefly upon all the guidelines discussed during the training workshop. Its substance is heavily based on the principal text on which the workshop is based, namely “Guidelines for the examination of pharmaceutical patents: developing a public health perspective – A working paper” by Carlos Correa, ICTSD, UNCTAD, WHO (2006). While each section will be briefly described and its recommendation put forward a lengthier and more detailed analysis can be found in the above mentioned publication itself.

²² Ibid, see page 6.

substantially added benefit that could not have been anticipated by a person skilled in the art.²³

Participants highlighted that it was important to have good access to prior art in order to make judgement on inventive step with respect to such patents. Without such access, some patent examiners said, they would rely on judgements made by other patent offices.

- **Recommendation**

Participants endorsed the recommendation put forward in the Guidelines:

“New formulations and compositions, as well as processes for their preparation, should generally be deemed obvious in the light of the prior art, particularly when a single active ingredient is claimed in association with known or unspecified carriers or excipients. Exceptionally, claims of this type could be patentable if a truly unexpected or surprising effect is obtained, for instance, when a really difficult problem or a long standing need, such as a noticeable reduction in side effects, is solved in a non-obvious way, or when the solution found leads to a tremendous advantage compared to the state of the art.”²⁴

b) Combinations²⁵

- **Discussion**

Combinations of previously known substances are also increasingly subject to patent applications claims. Similar to compositions and formulations, the question with many of these claims is whether a real inventive step can be demonstrated. Furthermore, as the ‘synergies’ of new combinations often take place in the body of a patient rather than outside, they might be considered discoveries and not inventions, and therefore not subject to patent protection.

Participants argued that only if a new and non-obvious synergistic effect can be proven a patent may be justified. Furthermore, participants emphasised that bearing in mind the limited resources of patent offices, it is the responsibility of the patent applicants to demonstrate this synergistic effect and disclose it appropriately through the provision of biological evidence and other test results that may be necessary. The burden of proof must lie with the patent applicant not the patent office.

- **Recommendation**

Participants agreed with the recommendations put forward in the Guidelines :

²³ Ibid. See pages 6 & 7

²⁴ Ibid. Page 7.

²⁵ Ibid. Page 7.

“Combinations of known active ingredients should be deemed non-inventive. If, however, a new and non-obvious synergistic effect is considered a basis for patentability, it should be properly demonstrated by biological tests and appropriately disclosed in the patent specifications”²⁶

Some participants suggested that it could be useful to clarify in the recommendation that as “*demonstration*” could be done on paper rather than through the actual implementation of biological testing, by or on behalf of the patent office, the term “*disclosure*” would be more suitable. An alternative term suggested was “*demonstration by credible information.*”

c) Dosage and dose²⁷

○ Discussion

Next to patents on formulations and combinations, patents also sometimes claim for inventions that consist of a particular dosage, for example a dosage adapted to paediatric care, for administering a drug to patients. These patents tend to be formulated as product patents in spite of the fact that they refer to a certain way of administering the drug. Participants therefore discussed that they fall under method of treatment with is not patentable in many countries. Furthermore, as argued above, a dosage form in most cases does not pass the inventive step criteria.

○ Recommendation

After discussing a range of examples participants agreed with the recommendation provided by the Guidelines:

“New doses of known products for the same or a different indication do not constitute inventions, particularly (but not only) in countries where methods of medical treatment are not patentable as such.”²⁸

d) Salts, ethers, and esters²⁹

○ Discussion

Patent applications relating to new salts of previously known active ingredients have become common. Converting an active ingredient into its salt form may increase the stability and/or solubility of the drug, or have other beneficial properties that allow for easier manufacture or storage of the drug. However, the use of salts for this purpose is commonly known and are thus obvious. Anybody skilled in the art would consider the making of salts as very basic knowledge. It is only in very rare cases that the salts

²⁶ Ibid. p. 8

²⁷ Ibid. p.8

²⁸ Ibid. Page 8.

²⁹ Ibid. Page 9.

generate unexpected effects, in which case a patent may be considered. Participants mentioned that in some patent offices present at the meeting the protection of salts was not limited to these exceptional cases. Given that in many cases a patent on a salt will constitute a *de facto* monopoly on the active ingredient patents on salts make up one of the principle means of extending monopoly rights on a product beyond the original patent term – a practice also referred to as ‘ever-greening’ of patents. The same holds true for ethers and esters.

- **Recommendation**

Participants agreed with the recommendation put forward in the guidelines:

“New salts, ethers, esters and other forms of existing pharmaceutical products can generally be obtained with ordinary skills and are not inventive. This may not apply, exceptionally, when tests, appropriately conducted and described in the specifications, demonstrate unexpected advantages in properties as compared to what was in the prior art.”³⁰

e) Polymorphs/hydrate/solvates³¹

- **Discussion**

As described in the “Guidelines” active ingredients can exist in a variety of forms. If they are crystalline or amorphous solids they are referred to as polymorphs. While different polymorphs may add certain pharmaceutical value, it is important to note that their existence is inherent to a particular molecule and not man-made. Thus, their properties constitute a discovery (and not an invention) which is not generally patentable. In addition, the search and analysis for polymorphs is mostly subject to routine experimentation in the drug formulation process and thus fails the inventive step test.

Patents on polymorphs are frequent in a range of jurisdictions, including the EPO, and several European countries but often contested as they can end up postponing the entry of the generic equivalent product to the polymorphs’ active ingredient. Polymorph patents may be challenged based on the fact that they are a discovery, rather than an invention and fail the non-obvious test as it is obvious for a person working in the pharmaceutical sector to find the most appropriate polymorph for the formulation of a drug. . This also often results in patents being granted in African countries which heavily rely on EPO guidelines and decisions in their patent examination process.

- **Recommendation**

Participants agreed with the recommendation of the Guidelines:

³⁰ Ibid. Page 10.

³¹ Ibid. Page 10.

“Polymorphism is an intrinsic property of matter in its solid state. Polymorphs are not created, but found. Patent offices should be aware of the possible unjustified extension of the term of protection arising from the successive patenting of the active ingredient and its polymorphs, including hydrates/solvates. Processes to obtain polymorphs may be patentable in some cases if they are novel and meet the inventive step standard.”³²

Some participants stressed that it should be made clear that the last sentence relates to a process patent rather than a patent on the actual polymorph.

f) Markush claims³³

○ Discussion

Patent claims sometimes are very broad, containing entire families of possible compounds, which may include thousands or millions of them. These are referred to as ‘Markush claims’ (named after the first patent of such type being granted in the U.S. to Eugene Markush in 1920). Often they include a large number of compounds that have never been tested before and which properties are only claimed based on theoretical assumptions drawn from their equivalence to other compounds included in the claim. This leads to monopoly rights over a very broad range of compounds in spite of the fact that they have never been tested.

This broad range has been subject to increasing criticism, including in the US PTO where new guidelines were drafted in 2007 to force patent applicants to be more precise in their application.³⁴ Participants highlighted how in their offices applicants are often told to be more specific when it comes to Markush type applications and narrow down the claims. Many of the participants experienced a general tension between the patent applicant and patent office with respect to the overall scope of claims.

○ Recommendation

Participants endorsed the recommendation put forward by the Guidelines:

“Claims covering a large range of compounds should not be allowed. Patent offices should require patent applicants to provide sufficient information, such as fusion point, Infrared Absorption Spectrum (IR) or Nuclear Magnetic Resonance (NMR), obtained through true testing and experimentation to enable the reproduction by the disclosed method of each embodiment of the invention for which protection is sought. Claims of limited scope could be granted if evidence is provided at least that, with the substitution of any member within the same family class, the same disclosed result would be obtained.

³² Ibid. Page 11.

³³ Ibid. Page 12.

³⁴ See: <http://www.uspto.gov/web/offices/com/speeches/07-30.htm>

*The coverage of the patent should be limited to what is actually enabled by the disclosure in the specification.*³⁵

g) Selection patents³⁶

○ **Discussion**

In some cases patent claims are based on a selection of a group of elements out of a larger group previously disclosed, e.g. under a Markush claim. Usually the particular segment included in the patent claim has an additional characteristic or property that had not been made explicit in the broader previous patent. While in rare cases surprising and unexpected features can occur, selection inventions lack novelty.

○ **Recommendation**

Participants endorsed the recommendation put forward in the Guidelines:

“As a general rule, selection patents should not be granted if the selected components have already been disclosed or claimed and, hence, lack novelty. If unexpected advantages or existing products were deemed patentable under the applicable law, the patentability of a selection could be considered when an inventive step is present.”³⁷

h) Analogy Processes³⁸

○ **Discussion**

As described by the Guidelines, analogy processes are manufacturing processes that are utilized for the production of new or inventive but unpatentable compounds. Even though analogy processes may not be new or inventive by themselves they have been deemed patentable in some countries under a legal fiction. This may lead to the protection of non-patentable pharmaceuticals, since the TRIPS Agreement extends the protection of patents on a process to the products that are directly obtained by them. In the US, for example, analogy processes were originally only patentable with respect to particular biotechnological inventions under certain conditions. This has now been expanded to other fields.

○ **Recommendation**

Participants agreed with the recommendation put forward in the guidelines:

³⁵ “Guidelines for the examination of pharmaceutical patents: developing a public health perspective – A Working Paper” by Carlos Correa, WHO UNCTAD ICTSD (2006), page 12.

³⁶ Ibid. Page 14.

³⁷ Ibid. page 15.

³⁸ Ibid. page 16.

“Non-novel or obvious pharmaceutical processes, regardless of whether the starting materials, intermediaries or the end product are novel or inventive, should be considered non patentable as such.”³⁹

i) Enantiomers / Isomers⁴⁰

○ Discussion

Enantiomers are defined as molecules that are identical in chemical formula and structure, but are mirror images of each other. Often, a single enantiomer will exhibit different chemical properties, with one being more active than the other. The practice has been to patent first the “racemic” mixture (a combination of both enantiomers), and then subsequently patent one of the single-enantiomers, namely the more active component. This ‘ever-greening’ practice leads to continuation of the monopoly over the original product, in spite of the fact that the original patent has already expired.

Participants discussed that it was a well known practice among people skilled in the art to test enantiomers as one of them tended to be more active than the other. Thus, a patent claim on a single enantiomer lacks an inventive step. The fact that it previously was in a racemic mixture makes it also part of ‘prior art’. Participants commented that it was common practice in their patent office to only grant patents on enantiomers in the case that the process of isolation was deemed inventive, in which case the process would be patented but not the single enantiomer as such.

○ Recommendation

Participants agreed with the recommendation put forward by the guidelines:

“Single enantiomers should generally not be deemed patentable when the racemix mixture was known. However, processes for the obtention of enantiomers, if novel and inventive, may be patentable.”⁴¹

j) Active metabolites and prodrugs

○ Discussion

Active metabolites can result out of the administration of certain pharmaceutical compounds in the body. They are produced by the metabolism of the body. Thus metabolites themselves are not created and do not classify as invention. Participants suggested that given that metabolites are products of our own body they should not be patented.

³⁹ Ibid. Page 16.

⁴⁰ Ibid. page 16.

⁴¹ Ibid. Page 17.

Prodrugs are inactive compounds that, when metabolized in the body, can produce an active ingredient of therapeutic value. Patents usually cover both, the active ingredient that is metabolized as well as the inactive prodrug. There have been cases, however, where the patent on the active ingredient has expired, but the prodrug was patented later renewing a *de facto* monopoly over both, prodrug and active ingredient.

- **Recommendation**

Participants agreed with the recommendations put forward in the Guidelines:

a) Active metabolites of drugs should generally not be deemed patentable separately from the active ingredient from which they are derived.

b) Patents over prodrugs, if granted, should disclaim the active ingredient as such, if previously disclosed or otherwise non-patentable. Like other subject matter claimed in a patent, a prodrug should be sufficiently supported by the information provided in the specifications. In addition, evidence may be required that the prodrug is inactive or less active than the compound to be released, that the generation of the active compound ensures an effective level of the drug and that it minimizes the direct metabolism of the prodrug as well as the gradual inactivity of the drug.⁴²

Participants further discussed whether the use of certain “pro-moieties” that are commonly used to create prodrugs could be deemed to lack inventive step. The integration of such is still ongoing.

k) Methods of treatment⁴³

- **Discussion**

Participants debated about patents on methods of treatment, which are non-patentable in many, but not all jurisdictions. The TRIPS Agreement (Art. 27.2) allows Member States to exclude methods of treatment from patentability. Furthermore, methods of treatment do not have industrial application, but only the products they are based on. Participants highlighted how methods of treatment in some countries, where they are explicitly excluded from patentability, still may receive patents if they are masked as product claims. This could happen, for example, if a patent is formulated on a product that is not described by its chemical properties, but by the way it is administered to a patient. Participants claimed that on many occasions they have turned away product claims that actually turned out to be methods of treatment.

- **Recommendation**

Participants endorsed the recommendation put forward by the Guidelines:

⁴² Ibid. Page 19.

⁴³ Ibid. Page 19.

“Methods of treatment, including for prevention, diagnosis or prophylaxis should be deemed non patentable where industrial applicability is required as a condition for patentability (including in cases where the patentability of such methods is not expressly excluded).”⁴⁴

1) Use claims, including second indications⁴⁵

○ Discussion

Patent protection of a particular use of a known product (second indication) is particularly common in the pharmaceutical field in developed countries. However, the TRIPS Agreement does not require such patents. New use patents essentially maintain the monopoly over a product that is known. Some participants pointed out that in their jurisdiction they did not allow second use patents, based on lack of novelty. It may also be argued that new use patents fail the industrial applicability criterion as they are equivalent to patents on a method of treatment.

○ Recommendation

Participants agreed with the recommendation put forward by the Guidelines:

“Claims in relation to the use, including the second indication, of a known pharmaceutical product can be refused, inter alia, on ground of lack of novelty and industrial application.”⁴⁶

3. Available instruments to strengthen public health considerations in the examination of pharmaceutical patents

There are a range of instruments available to governments to strengthen public health objectives in the examination of pharmaceutical patents. Some of these are legal mechanisms while others relate more to the overall governance of the patenting process. The following consists of a list of some of these mechanisms.

a) Pre-grant and post grant opposition⁴⁷

Once a patent is granted anybody wanting to challenge the validity of a patent often has to go through the courts, with is not only a lengthy but also a very costly process. For many smaller and medium sized companies, let alone for not-for-profit-institutions, it is usually too costly and risky to enter into litigation. As a result many national patent laws allow for a certain period before (once the patent has been filed and published) and after

⁴⁴ Ibid. Page 20.

⁴⁵ Ibid. Page 21.

⁴⁶ Ibid. page 21.

⁴⁷ Ibid. page 24.

the granting of a patent in which observations on or opposition to the patent grant can be filed.

Essentially the process helps the examiners in their examination as competitors may be in a good position to spot prior art conflicts or lack of inventive step. However, in order to function smoothly, competitors or other interested parties, such as the Ministries of Health, have to be aware of these mechanisms and have access to the patent application or grant. The obligation of patent applicants to file the International Non-proprietary Name (INN) in their application that identifies the actual compound can help third parties in being more effective in their patent analysis. It is important that countries implement in their national laws pre- and post grant opposition mechanisms. The period of opposition should be sufficiently long to allow for national competitors or other third parties to gain access to the file, examine it and file their opposition.

b) Exclusive wording

Another mechanism discussed by participants that could support the examination of patents from a public health perspective is to specifically exclude certain matters such as second uses from patentability. However, a review of the legislations in the region indicates that out of 39 sub-Saharan African countries, only four (Democratic Republic of Congo (DRC), Malawi, Namibia and Zambia) have provisions to limiting therapeutic uses and/or new/second uses.⁴⁸

Exclusive wording in patent law can be a very useful mechanism as it provides the examiner with a default position of the patent office. Such wording could generally exclude from patentability any living substances, new methods of known substances, mere admixtures or combination drugs, or methods of treatment. Furthermore, some laws are even more specific with respect to some of the issue mentioned above. For example the Indian patent law includes specific restrictions to the patentability of salts, polymorphs, isomers and prodrugs. Patent offices and other governmental agencies should consider integrating some exclusive wording in the national patent legislation in order to facilitate the work of the patent examiners.

c) Need for patent guidelines by patent offices based on domestic interests

Participants also discussed the importance of guidelines that could support patent examiners in their day to day work. Many patent offices around the world, including the US, work with guidelines to provide patent examiners with certainty on their judgements, above all in fields such as the life sciences which continue to undergo technological change. As guidelines are easier to adopt and can be more detailed than legislation, they serve as a useful instrument to allow patent offices to stay on top of technological developments. Patent offices in developing countries should consider developing

⁴⁸ Ibid; UNDP study “Access to ART and other Essential Medicines in Sub-Saharan Africa: Intellectual Property and Relevant Legislations” September 2007.

guidelines that bear in mind domestic development objectives, including in the field of public health.

d) Use of Constitution

Participants also highlighted the possibility of making use of the constitution in order to challenge either patent applications or patents, once they have been filed or granted, respectively. Many countries have references to the right to health or medical treatment in their national constitution, which should be used in opposing patents through pre/post grant opposition, litigation, to issue compulsory licenses or even to seek legislative change.

4. Institutional Challenges

Participants also discussed the role of certain institutional challenges or issues of governance for strengthening public health objectives in the examination of pharmaceutical patents. The following is a list of issues that were touched upon in the discussions.

a) Enlarging the role of the national health authorities in the patent examining process

The issue of governance is important to bear in mind when it comes to designing a patent examination process that is inclusive of public health objectives. Ranging from the drafting of national legislation to the location and nature of the training of patent examiners, governments should consider the implications of the institutional set up on its outcome. Participants, for example, highlighted that many of their national patent laws (as are other parts of their legal systems) are based on the systems of their former colonial powers and continue to be heavily influenced by such in spite of the fact that national priority-setting on IP policy may differ substantially. Furthermore, the fact that many of their patent examiners are being trained at the EPO or other patent offices in developed countries inevitably makes them exam patents the way an EPO examiner would do.

In order to strengthen public health objectives in the examination process some countries have provided domestic health authorities with a formal role. In Brazil, for instance, the national drug regulatory authority (ANVISA) must provide its prior consent for the granting of pharmaceutical patents. Paraguay has implemented a similar process.⁴⁹

⁴⁹ Ibid, see page 25. It should be noted that the link between the drug regulatory authority and the patent office should only go in one direction and not be implemented in a reciprocal manner. While the role of the health authority is important for supporting the patent examination process the question of whether a drug has a patent or not should not interfere with the market approval of a drug after having passed the efficacy and safety procedures of the FDA. It is not the role of the FDA to function as a patent enforcement agency.

b) Limited funding and capacity in patent offices

Participants also highlighted the need for further funding into their patent offices as many of them are extremely stretched for resources and thus prevented from implementing appropriate examination processes. Indeed, many developing countries cannot conduct their own examination and rely to a large extent on the decisions made by other offices that are likely to have different priorities when it comes to the examination of patents.

Indeed, as mentioned above, a range of African countries rely on regional patent offices, such as ARIPO or OAPI, for substantive patent examinations. OAPI's and ARIPO's member states include both, developing and least developed countries, which have different obligations with respect to TRIPS and also may differ substantially with respect to domestic IP policy priorities. Regional patent offices must ensure that processes are set up that allow taking account of the different standards of development in the patent examination process.

c) Need for wider capacity building including civil society, and judges

Participants also noted the lack of judges specialised enough to make appropriate judgements on technical patent issues. More training needs to be provided to them emphasising also the impact their decisions may have on access to medicines.

Furthermore, it is important to provide training to civil society organisations (CSOs) on issues related to IP. CSOs can function as important watchdogs on patent applications and patent grants and even enter into litigation to challenge certain patents on public health grounds. They also can apply for compulsory licenses and support raising general awareness on issues related to IP. Participants noted that in Africa with the exception of South Africa, civil society is largely very weak on the issue and further capacity building in this field is desperately needed.

d) Need for greater transparency

Participants also noted a general lack of transparency with respect to patents. They argued that for many of them it is very difficult and expensive to find out whether a product is patented in a country or not. Some participants also highlighted that they were often not aware of valid patents that were registered through regional offices and that it took them long time to get feedback on the nature of a patent status from regional bodies.

It was highlighted that some UN agencies are currently working on developing a patent database on essential medicines that could facilitate the work of patent offices in this field. The work on this project is ongoing.

V. Conclusion

At the end of the workshop participants were asked to reflect on what they took away from the event. They highlighted that the workshop was of tremendous use to them and that indeed they would now approach patent examination from a very different angle. They referred to it as a real learning experience and an '*eye opener*'. Some even expressed anger about some of the patents they had granted in the past which they today would consider as failing the patentability criteria.

They further emphasised the importance of bringing the lessons learnt back to their governments to ensure they would be integrated into national policy. They stressed how the focus on public health in the examination process cannot be strengthened enough, bearing in mind the impact it may cause. In this sense they felt it was important to further integrate the Ministries of Health in the process, as well as CSOs.

Finally, aware of their responsibility they emphasised how they wished to continue learning about these matters, also from each other. Patent examiners suggested that maybe exchanges could be organised among patent offices in the region to support those with less financial means in their capacity building. Further regional collaboration was also highlighted with respect to addressing issues of access to medicines, including the need to look increasing regional manufacturing capacities.