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TECHNICAL CONSULTATION - ARAB STATES REGION
Examination of Pharmaceutical Patents from a Public Health Perspective

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MEETING REPORT

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List of Acronyms and Abbreviations

ANVISA	National Health Surveillance Agency
ARV	Antiretroviral
CAFTA	Central America Free Trade Agreement
CL	Compulsory Licensing
EGYPO	Egyptian Patent Office
EMRO	Eastern Mediterranean Regional Office
EPO	European Patent Office
GCC	Gulf Cooperation Council
HARPAS	HIV/AIDS Regional Programme in the Arab States
ICTSD	International Centre for Trade and Sustainable Development
INAPI	National Algerian Institute for Industrial Property
INNORPI	National Institute for Standardisation and Industrial Property
IP	Intellectual Property
IPRs	Intellectual Property Rights
JPO	Jordanian Patent Office
LA	Latin America(n)
OMPIC	Moroccan Office for Industrial and Commercial Property
MOH	Ministry of Health
TRIPS	Trade-Related Aspects of Intellectual Property Rights
USPTO	United States Patent and Trademark Office
WIPO	World Intellectual Property Organization
WHO	World Health Organization
WTO	World Trade Organization

Introduction

The World Trade Organization (WTO) Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement) introduced for the first time binding minimum standards of intellectual property protection at the multilateral level. In particular it required developing countries to grant patent protection on pharmaceutical products. Since then, attempts have been made to achieve an appropriate balance between the need to promote innovation through patents with the need to protect public health, in particular by providing affordable access to ARVs and other medicines.

Important flexibilities were introduced into the TRIPS Agreement to ensure that developing and least developed WTO Member States could address public policy objectives such as the protection of public health. These flexibilities enable WTO Members to determine how to apply the three criteria of patentability (novelty, inventive step, and industrial application), issue compulsory licenses and government use orders, and make use of the international exhaustion of rights to parallel import. Countries could also apply a number of general exceptions available under Article 30 of the TRIPS Agreement such as the early working or Bolar provision or the experimental use exemption and to make use of transitional arrangements. 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 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, for whom, the granting of patents where only incremental developments have been made, is a deterrent to, rather than a facilitator of, innovation. 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. A large number of patents cover minor modifications of older existing drugs. Therefore, while the number of 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.

In the Arab region, there are countries with strong pharmaceutical industrial capacities, such as Egypt and Jordan, and these are mostly dependant on manufacturing of generic and under-license products. Local pharmaceutical production comprises the bigger share of the pharmaceutical market in these countries, with substantial contribution to their national incomes and to public health, since it guarantees affordability. Patent registration of pharmaceuticals in the Arab region occurs in a number of ways. Most countries have their own local patent offices, but not necessarily the technical capacity to examine patent applications at a national level. Patent offices in countries like Egypt are particularly large in size, and have a good experience in patent examination. Countries of the Gulf Cooperation Council (GCC) have a common patent office in Riyadh, and a granted patent through the GCC Patent Office provides protection in all GCC Member States. Patent examination takes place only in the GCC Patent Office, whereas national patent offices of GCC Member States lack such capacity, so they simply forward applications to the GCC Patent Office. Some patent

offices, for example Morocco, do not examine patent applications, but rely on examination done at other bigger offices, such as the European Patent Office, (EPO) or follow the recommendations of the World Intellectual Property Organisation (WIPO).

Objectives of the meeting

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. Specific objectives included:

- Providing patent offices in the region with the opportunity to present and share their experiences and standards of patentability in pharmaceuticals;
- Discussing guidelines on patentability that should be implemented to take into consideration public health concerns, and exploring available mechanisms to enhance the examination of pharmaceutical patents from a public health perspective;
- Explaining typical claims in pharmaceutical patents, and discussing pharmaceutical patent examination rules and procedures;
- Reviewing cases in which other national bodies/ authorities (different from Patent Offices) intervene in the examination of pharmaceutical patents;
- Facilitating networking among patent examiners in the region so that they can share relevant information with each other and benefit from each other's expertise and experience

Executive Summary

The UNDP, WHO and ICTSD co-sponsored the workshop *“Examination of Pharmaceutical Patents from a Public Health Perspective”*, held in Cairo on 14-15 April 2009, hosted a total of 44 participants, including 26 patent examiners representing 7 patent offices in the Arab region (Algeria, Egypt, Gulf Cooperation Council, Jordan, Morocco, Syria and Tunisia).

This was the first time patent examiners in the region met to discuss public health related aspects of pharmaceutical patenting, and to exchange views and share experiences in relation to their work in this area. Over the two days of the workshop, participants and partnering organizations actively discussed several issues of relevance, both to the region and to the day-to-day examination challenges that examiners face. There were several presentations showing the implications of IP on public health, particularly in developing countries. Each patent office represented had the opportunity to give a brief overview of its history, size and work, particularly concerning pharmaceutical patenting laws and procedures.

The Patentability Guidelines

The Guidelines for the Examination of Pharmaceutical Patents¹ made a very useful tool for workshop examiners, providing solutions to problematic issues they regularly encounter with pharmaceutical applications. Participants also highlighted there is a need to translate the Guidelines to Arabic to guarantee that all patent offices and policy makers have access to them.

TRIPS-Plus Provisions

Patent offices in countries that signed Free Trade Agreements face the challenge of having to enforce restrictive provisions during examination (e.g. granting second use patents). Discussions have revealed the reliance of some patent offices on technical assistance from external bodies such as the EPO and WIPO when examining patent applications, which can challenge the analysis carried out by examiners. Often such advice does not sufficiently take into consideration national laws or public health interests.

Herbal Compositions

Some patent offices in the region receive large numbers of patent applications for herbal compositions and natural extracts or pharmaceutical preparations based on them. Participants expressed their interest in having access to guidelines for the examination of herbal products. This will be explored further by the meeting organising partners.

National Coordination

Finally, it was also suggested that stakeholders from Ministries of Health, pharmaceutical regulatory authorities and trade should be included in consultation meetings to start a dialogue and follow up at national level in each country in the region.

¹ ICTSD, WHO, UNCTAD (2006) Guidelines for the Examination of Pharmaceutical Patents: Developing a public health perspective – A Working Paper. Available from: http://www.iprsonline.org/resources/docs/Correa_Patentability%20Guidelines.pdf

Opening session

Dr. Khadija Moalla, HIV Practice Leader and Coordinator of the UNDP HIV/AIDS Regional Programme in the Arab States (UNDP/HARPAS) welcomed workshop participants in Cairo. She pointed out some of the challenges facing the Arab region in terms of access to medicines, stating that only 6% of people living with HIV/AIDS (PLWH) who need treatment in the region have access to it. Dr. Moalla explained the rationale of UNDP involvement in promoting access to treatment and provided an overview of UNDP initiatives in the Arab region.

Dr. Belgacem Sabri, Director of Health Systems and Services Development, WHO/EMRO, stated that the WHO works on promoting values of equity, access and universal coverage of treatment, particularly antiretroviral (ARV) treatment. Dr. Sabri welcomed the recommendations that would result of this meeting, and any requests for technical cooperation from WHO/EMRO.

Dr. Zafar Mirza, Regional Advisor, Essential Medicines & Pharmaceutical Policies, WHO/EMRO greeted the workshop participants and conveyed greetings from Dr. Hussein El-Gezairy, Regional Director of EMRO/WHO. Dr. Mirza introduced Professor Carlos Correa, praising his tremendous expertise in the field of intellectual property (IP) protection. Dr. Mirza said that international public health is becoming very important, and that patent examiners are becoming relevant actors in the promotion of public health concerns in the examination of patents. . He pointed out the uniqueness of this meeting in terms of the fruitful cooperation of organisations represented, which resulted in producing the patentability guidelines to be discussed in the context of the meeting. Dr. Mirza expressed his wish that the interface created in this meeting continues, and that a regional network of patent examiners is established to facilitate exchange of knowledge and experiences.

Mr. Ahmed Abdel Latif, Intellectual Property Programme Manager, International Centre for Trade and Sustainable Development (ICTSD), gave an introduction on the work of ICTSD and on their regional research agenda on access to treatment following IP protection of medicines. Mr. Abdel Latif touched on the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement) and its flexibilities, while introducing the “Guidelines for the Examination of Pharmaceutical Patents” (hereinafter, Guidelines). He said that different countries and regions will have to tailor their own national approaches and criteria. Mr. Abdel Latif expressed his wish to establish a network to follow up on this work.

Professor Carlos Correa welcomed participants and introduced the Guidelines, saying that they were the results of extensive consultation among various organisations and experts in the field. Prof. Correa expressed his expectations to learn from the participants’ experiences in pharmaceutical patenting in their home countries, and to consult with them about the recommendations in the Guidelines.

Developing a Public Health Perspective for the Examination of Pharmaceutical Patents

Dr. German Velásquez, Director of WHO Secretariat on Public Health, Innovation and Intellectual Property

In his presentation, Dr. Velásquez discussed some of the public health concerns and tensions created by the TRIPS Agreement in developing countries, stressing the importance of access to

treatment, particularly essential medicines and ARV treatment. Implications of the TRIPS Agreement include high prices for newly patented drugs, delayed generic competition and eventually weakening of local pharmaceutical industry in countries where it exists².

He explained the key elements of the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property. Dr. Velásquez also gave an overview of the TRIPS flexibilities that could be used by developing countries for the protection of public health. He pointed out that the number of new clinically significant medicines, for which patent protection is sought, is small and declining³. This has raised the importance of developing patent examination guidelines which consider the public health aspect of pharmaceutical patents, with the aim of improving the patent system.

Defining Patentability Criteria and Disclosure

Prof. Carlos Correa, University of Buenos Aires, Argentina

Prof. Correa explained the three patentability criteria: novelty, inventiveness and industrial applicability. He distinguished between an invention and a discovery, and discussed inventiveness standard, which has been relaxed by patent offices in the last decades. For instance, the level of inventiveness required in the USA in the 1940's was higher than that required now.

There is a decline in the number of new chemical entities invented despite the availability of new scientific and technological tools, but surprisingly, the number of pharmaceutical patents is on the increase. Around 180,000 patents are granted annually in the USA, including pharmaceuticals, which creates an overload to patent examiners who can only devote a short time for examination of each application.

Prof. Correa also discussed patenting strategies that companies apply in order to delay competition. These include blanketing, flooding, fencing, surrounding and combination into patent networks. The Australian Congress has issued a particular provision to prevent evergreening of patents. A determination of anticompetitive practices by Bristol-Myers Squibb in the USA was given as an example of abuses by pharmaceutical companies. The role of patent offices is to protect public interest rather than to serve patent applicants, according to the US Federal Trade Commission.

In establishing the level of inventiveness governments should consider a set of policies:

1. **Innovation/development policy.** The argument that a low level of inventive step is desirable because it will allow local company to have their share of patents is misleading and may have negative effects.
2. **Competition policy.** Competition authorities should be vigilant about abuses of patents.
3. **Public health policy,** preventing the grant of protection to minor or trivial developments, hence protecting access to drugs and public health.

² Only 3 million PLWH receive ARV treatment, out of a total of 9 million who need treatment. Each year, 10.3 million children in developing countries die because of lack of access to essential medicines.

³ According to the National Institutes of Health in the USA, clinically significant drugs amount for only 15% of drug approvals.

Discussion

Several issues were raised by participants; among these were:

- **National statistics about patent applications of pharmaceutical or chemical health-related products in relation to total number of applications.**
Prof. Correa answered saying that they are generally high in developing countries.
- **Whether national patent laws explicitly govern patentability criteria.**
Prof. Correa said that generally there is no specificity in the law on how it should be applied; however, there are guidelines in Argentina, Brazil and India. Article 1 of the Japanese law, for instance, clearly states that its purpose is to promote industrialisation. A study revealed high consistency in pursuing this objective and that many patent examiners came from the ministries of industry and trade. Many countries do not have a clear policy, and ministries of health generally do not participate in drafting or implementing the IPRs laws.
- **Applying for a patent in several countries with different levels of patentability standards, and whether countries are cooperating in this regard.**
Prof. Correa mentioned that there is little coordination between developing countries in this area. European Patent Office (EPO) and patent offices in Australia, Japan and USA have provided training and advice to developing countries that do not necessarily take the legislation and needs of the receiving country fully into account.
- **On the effect on accessibility in countries with low standards,** Prof. Correa said that foreign companies will react to the standards locally applied. The number of foreign applications will certainly be more than that of local ones, which gives room for evergreening of patents.
- **For countries that do not conduct substantive examination,** Prof. Correa stressed the importance of regional cooperation in the case of Africa in order to avoid a risk of monopoly for years for matters that are not inventive.
- **On the Patent Cooperation Treaty (PCT) and how it fits with TRIPS,** Prof. Correa explained that the PCT preliminary patent examination report is not based on the specific provisions of the applicable national laws, under which a patent could be rejected. It should not be the only basis for decisions regarding patent grants.

The Impact of FTAs on Public health and Access to Medicines

Dr. Mohammed El Said, University of Central Lancashire, UK

Dr. El Said outlined the main principles and flexibilities of the TRIPS Agreement. Then, he explained the concept of TRIPS-plus, mentioning some of the bilateral and regional free trade agreements (FTAs) in the region e.g. Jordan, Morocco, Bahrain and Oman have signed US-FTAs, Egypt, Lebanon and Tunisia have signed European FTA, and several other Arab countries have signed European Union Association Agreement. He then gave a detailed explanation of TRIPS-plus provisions in these agreements and their impact on public health supported by evidence from developing countries, including some Arab countries.

1. *Elimination of transition periods*

Some FTAs deprive developing countries of transitional periods that they are entitled to under the TRIPS Agreement e.g. EU-Jordan Association Agreement. In this case, developing countries do not have enough time to prepare their domestic setting in terms of IP enforcement, and patented drugs enter the market earlier.

2. *Data exclusivity*

The US-Morocco FTA provides data protection for pharmaceutical products for a minimum of five years. Data exclusivity delays entry of generic competitors to the market, hence delays lowering of medicine prices which could be as low as 30% of innovator drug price, according to the WHO.

3. *Extending patent term beyond 20 years*

FTAs require countries to extend patent protection term beyond 20 years to compensate for delays stemming from the filing of the patent application e.g. Jordan, Bahrain and Oman.

4. *Restricting parallel importation*

The US-Morocco FTA set restrictions over parallel importation.

5. *Allowing patentability of new uses*

The TRIPS Agreement contains no obligation to patent new uses of known substances. The US-Oman FTA requires patenting of such new uses⁴.

6. *Restricting compulsory licensing and government use*

The US-Jordan FTA puts restrictive measures on compulsory licensing and government use, hence giving grounds for monopoly and eliminating flexibilities that could have been otherwise available for Jordan to use.

7. *Patentability criteria*

The US-Morocco FTA provides relaxed definition of patentability criteria in terms of industrial applicability.

Dr. El Said ended his presentation by asking whether it is too early now to start assessing the impact of FTAs on medicine prices, vis-à-vis some arguments which say that the full impact of FTAs will be not be felt until 15 years after an FTA comes in force. He leaves few final thoughts on the need for national innovation agendas, and for regional and international collaboration.

Egyptian Initiative for Personal Rights

Mr. Hossam Bahgat

Mr. Hossam Bahgat introduced the Egyptian Initiative for Personal Rights (EIPR) as a human rights organisation working in Egypt. EIPR has a standing division dedicated to health and human rights, which aims at building bridges between health and human rights.

Egypt has a dual obligation towards the protection of intellectual property rights (IPRs) and the right to health. In other words, Egypt has to maintain the balance between the TRIPS on one hand, and the International Covenant on Economic, Social and Cultural Rights. EIPR works on highlighting this link between IP and health, and exploring the potential tensions between them. This programme started in 2004, few months before the enforcement of the TRIPS Agreement was due in Egypt. Mr. Bahgat mentioned that Egypt has a long standing civil society movement; however, when it comes to IP and trade policy impact on development, there is not enough awareness. The scope of

⁴ According to Prescrire (2005) 68% of the products approved in France between 1981 and 2004 brought “nothing new” compared to previous preparations.

advocacy of EIPR went beyond the TRIPS Agreement to monitor FTA negotiations through its engagement with the Ministries of Foreign Affairs and Foreign Trade. Egypt rejected a number of provisions in the European Free Trade Agreement (EFTA). EIPR monitors court cases and intervenes, wherever relevant. The way the Pfizer and Eli Lilly cases ended up was not in the favour of the multinational companies. EIPR is currently documenting these cases in order to share them.

Mr. Bahgat mentioned that EIPR is learning from the experiences of other Arab and international NGOs. They are mapping research conducted by academia and UN organisations, and particularly focusing on human rights analysis of existing drug policy.

Country Presentations

Algeria

Mr. Bechar Abderrahman, National Algerian Institute of Industrial Property (INAPI)

Mr. Abderrahman gave a presentation on INAPI, explaining its strategic role in promoting creativity and innovation with the ultimate aim of industrial development. INAPI also acts as a public access point to technologies contained in granted patents. Mr. Abderrahman explained the steps involved in patenting an invention in INAPI, starting from filing for a patent application, patentability criteria applied during examination, and finally, issuing of the patent. He mentioned that patent applications in Algeria are not subjected to substantive technical examination, since INAPI is merely a registration body. A patent is issued under the responsibility of its holder, with no guarantee on INAPI's side regarding its novelty, inventiveness or full disclosure and accuracy of the description; and disputes are to be resolved in court. He closed by saying that INAPI aims at protecting industrial property more efficiently, using all available capacities and expertise.

Egypt

Ms. Aliaa El-Behery, Pharmacist and Patent Examiner, Egyptian Patent Office (EGYPO)

Ms. El-Behery introduced EGYPO, which has 30 legal examiners, 115 technical examiners and 30 pharmaceutical examiners. Egypt had a grace period until 2005 before the TRIPS Agreement was enforced. The EGYPO received 2800 applications in the mail box until January 2005, 80% of which were for pharmaceutical products. Ms. El-Behery then explained the phases of examination in EGYPO:

1. **Formality examination**, which is conducted by technical and legal examiners
2. **Preliminary examination**, which is done by legal examiners
3. **Substantive examination** by the relevant technical department, and it includes searching prior art, claim analysis, application of patentability criteria and finally decision making.
4. **Publication** in the patent gazette, allowing for 60 days of opposition
5. **Patent issuing**

Ms. El-Behery closed her presentation by giving a brief overview of selected articles of the Egyptian patent law.

Gulf Cooperation Council

Mr. Rashid Al-Ghatarifi, Assistant Director, Patent Examination Department, Gulf Cooperation Council Patent Office (GCCPO)

Mr. Al-Ghatarifi introduced the Gulf Cooperation Council (GCC). Member states of GCC are United Arab Emirates, Bahrain, Kuwait, Oman, Saudi Arabia and Qatar. The GCCPO is based in Riyadh, and began its operation in 1998, and the patents granted there are valid in all GCC Member States. An Executive Board of the GCC Health Ministers is responsible for central drug registration in GCC Members through the GCC Central Committee for Drug Registration.

The GCCPO staff is 50 in total, half of which are patent examiners, including 5 pharmacists. In 2008 alone, the office received 2,748 patent applications, out of which 256 patents were granted.

Pharmaceuticals comprise 33% of patent applications. Until March 2009, GCCPO granted 152 pharmaceutical patents, making 17% of total granted patents. Top five pharmaceutical companies filing for patenting are multinational companies.

The GCC Patent Law was amended in 1999 to comply with the TRIPS Agreement, and came into force in 2000. Patentability criteria are universal novelty, inventive step and industrial applicability. The GCCPO is currently considering some patent law modifications which would be in favour of pharmaceuticals, allowing for parallel importation and Bolar exception, and preventing second use patents.

Jordan

Ms. Lina Haddad, Head of Jordanian Patent Office (JPO)

Ms. Haddad provided an overview of the cases where patents shall not be granted according to Article 4 of the Jordanian Patent Law, followed by an explanation of the procedures executed by JPO. Ms. Haddad discussed the three stages that patent applications go through: 1) Formal examination; 2) Preliminary substantive examination; and 3) Substantive examination. Pharmaceutical applications received by the JPO are either applications that claim priorities, or ones submitted by local applicants. For those claiming priorities, follow-up is done using free databases, and the decision is made in the office. Applications submitted by local applicants undergo preliminary substantive examination, and are then either sent to WIPO for examination or proceed to substantive examination at the office. Ms. Haddad then highlighted the fact that most of local pharmaceutical patent applications received by JPO are herbal in nature. Herbal compositions have to fulfil the three patentability criteria by being novel, that is, a whole new composition; inventive, with a particular surprising effect and not simply an aggregation of features; and industrially applicable.

Morocco

Ms. Nabila Khassal, Moroccan Commercial and Industrial Property Office (OMPIC)

Ms. Khassal first gave a brief overview of OMPIC. Its mission involves supporting economic decision makers, and dissemination of information (there are 12,400 published patents available for this purpose). Ms. Khassal discussed some statistics on patent applications received by OMPIC. From 1999 till 2008 there was nearly 400% increase in the number of patent applications. The number of foreign applications is about four times the number of Moroccan ones. Medical preparations comprised 33% of total patent applications in 2008.

Ms. Khassal explained the procedural steps that a patent application undergoes before the patent is granted and published in the official patent catalogue: 1) Filing of a patent application; 2) Amending and completing the application, if needed, in a given period of three months; 3) Examination; 4) Granting of patent and publishing. Pharmaceutical products were not patentable under Article 25 of the old Moroccan law of year 1916. Following the TRIPS Agreement, pharmaceutical products were to be patentable and OMPIC started receiving applications in a mailbox until the new law came into force.

Ms. Khassal shared that OMPIC is considering launching a feasibility study for a system where written research reports for patent applications could be produced. OMPIC will establish this system in collaboration with the EPO.

Syria

Ms. Aline Ghanem, Patent Examiner, Syrian Patent Office

Ms. Ghanem listed the intellectual property conventions and agreements that Syria has signed to, starting from the Paris Convention for the Protection of Industrial Property in 1924 till Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks in 2004. Ms. Ghanem then gave an overview of the patenting process in the Syrian Patent Office. After prior art search, patent applications are sent to relevant scientific authorities e.g. research centres or universities, for specialised scientific opinion regarding the application. In case of pharmaceutical patent applications, they are sent to the Faculty of Pharmacy, which provides the patent office with support in the decision of whether to grant the patent, or not. Ms. Ghanem showed some statistics on granted patents in the Syrian Patent Office. The most noticeable thing is that the number of patents granted per year ranged from 165 in 1999 to 69 in 2008, which is relatively low compared to other Arab countries. Statistics clearly show that the number of local patents is continuously decreasing compared to foreign patents, which are increasing.

The Syrian Patent Office lacks specialized patent examiners for pharmaceutical applications. However, the office is currently developing the capacity of its examiners through training seminars and workshops that are relevant to pharmaceutical and chemical patents.

Tunisia

Ms. Emna Lahmar, National Institute for Standardisation and Industrial Property (INNORPI)

Ms. Lahmar first introduced the history of INNORPI which was established in 1982. Tunisia amended its IP legislation after joining the WTO in 1994. She pointed out that additional experienced human resources are needed to address the needs of patent examinations. Ms. Lahmar then gave an overview of the patent granting procedure, starting from filing the application. INNORPI has received around 1750 applications related to pharmaceuticals from 1995 till 2008. Statistics showed that there is a continuous increase in the number of patents during the period from 1999 till 2008, with a wide gap between the number of local and foreign patents, where the number of foreign patents is nearly five times that of local ones. At the end of 2008, INNORPI has managed around 5,550 patents. INNORPI local partners include research centres and universities. Others include WIPO, EPO and patent offices in Algeria, France, Morocco and Syria.

Discussion

Local vs. foreign pharmaceutical patents and technical consultation

One of the participants raised the issue of patent offices not seeking technical advice from competent national bodies, giving the example of Articles 17 and 21 of the Egyptian and Jordanian IP laws respectively, where the law allows seeking technical advice from relevant ministries. Pharmaceutical industry in Jordan is very export oriented; however, JPO mainly refers to WIPO although the Jordanian Food and Drug Administration (JFDA) has 400 staff members.

The participant also commented on the dichotomy between the number of local and foreign patent applications in some countries, which is often influenced by public policy, and asked about the percentage of pharmaceutical patent applications. In Jordan, 60-70% of patent applications are for pharmaceuticals, out of which 60-70% are of foreign origin, and usually filed elsewhere before

Jordan. Most local applications are related to engineering rather than to pharmaceuticals. In Morocco, foreign applications are also higher in number. Government encourages local applications by offering tax reductions for local enterprises, encouraging and sponsoring research, offering training on database search and encouraging research in universities. OMPIC seeks advice from EPO and receives training from them on database searching.

The surprising low number of patents in Syria compared to other countries brought up a question on whether this means that there are a lot of patents in the public domain.

Human rights and IP

Another participant raised the issue of the apparently conflicting IP and human rights, and whether one of them should take precedence over the other. In response to this, EIPR believed that human rights should take precedence over IP, following Article 4 of the Doha Declaration, as Prof. Correa explained. Compulsory licence could be used to protect public health. The US has the highest number of compulsory licenses, and in many cases without royalties, considering that there is wrong doing on the patent holder's side.

Consultations with health authorities and scientific institutions

One participant mentioned that in the majority of countries there is no link between the patent office and drug registration, that is, no linkage. In countries where there is linkage, there is the possibility of blocking generic production. In few countries, prior consent by health authorities is required, which is the case in few LA countries where this is stipulated in legislation. Some national laws allow patent offices to seek advice from universities, as in Chile for example, where there is a network of university professors who provide advice. On the other hand, some offices consult WIPO, which could be useful, but there remains the risk that national laws will not be fully considered. It is always better to have national experts.

Compulsory Licenses

It was underlined that no compulsory licensing (CL) has ever been issued in any Arab country. Parallel importation is an automatic exception, but CL requires a decision, and its procedure needs clarification at national level. There are no clear guidelines to follow in case a CL is to be issued though the requirements and procedures might vary from one country to the other.

Regional patent laws and FTAs

There is some ambiguity regarding FTAs in GCC. The GCC countries have a common patent law, but still each GCC country has its own patent law. The Bahraini Patent Law allows for patent term extension, following the US model. Prof. Correa further explained that the TRIPS Agreement applies the principle of most favoured nation, meaning that privileges given to any country through bilateral FTAs (e.g. with the US or EU) have to be applied to the remaining WTO members.

Typical Claims in Pharmaceutical Patents

Prof. Carlos Correa, University of Buenos Aires, Argentina

Prof. Correa reviewed the conceptual background for every type of claim, including a discussion on relevant patent examples in the Guidelines annex.

Conclusions and Recommendations

Dr. Zafar Mirza facilitated the last session and asked participants and organisers to share their ideas and final impressions. The following is a summary of the discussion.

General feedback on the workshop

- All participants, particularly junior examiners, found the workshop to be a very useful training opportunity, and the content to be relevant to their work.
- More time was needed; some participants found two days to be too short for the amount of information presented and discussions raised during the workshop.

The Guidelines

- The Guidelines were found to be a very useful document by all participants.
- Participants from EGYPO said that they received answers to pharmaceutical problems they used to face, particularly regarding enantiomers and selection patents. The Guidelines will be used as a reference tool during examination at their office, especially that EGYPO is considering developing its own examination guidelines.
- Prof. Correa mentioned that Guidelines will continue to be improved, and that they are intended to guide rather than to prescribe.
- There was consensus on translating the Guidelines to Arabic, which is important to make them accessible throughout the region, and to involve policy makers at national level. There was also a suggestion to have a bilingual version in Arabic and English.
- Prof. Correa mentioned that the document is also available in Spanish, and is currently being translated to Chinese and French, which will be useful in the francophone Arab countries.

Herbal compositions

- Participants from EGYPO and JPO expressed a strong need for the development of guidelines for the examination of herbal compositions, which constitute a major part of their work.
- Prof. Correa responded to this request⁵ saying that if this is pursued, it would be necessary to get the technical support of a pharmacist with knowledge in this area, and develop a draft and initiate a consultation similar to the one for the Guidelines. Patent examiners specialized in this field at the Chinese patent office could make an important contribution. For this purpose, he suggested an interesting paper on Chinese practice by Xuan Li and Weiwei Li, 'Inadequacy of Patent Regime on Traditional Medicinal Knowledge—A Diagnosis of 13-Year Traditional Medicinal Knowledge Patent Experience in China', *JWIP*, vol. 10 issue 2.

⁵ This was in an email exchange few days after the workshop, after ICTSD shared the workshop evaluation results based on feedback sheets filled in by the participants. The evaluation report is attached in the report annex.

Policy coherence at national level

- Dr Zafar mentioned that the aim of this meeting went beyond those two days; it was to bring everybody on the same page and to involve higher IPR senior policy makers at national level.
- Health officials and representatives from health authorities, trade and industry should be involved in such meetings in the future. According to JPO delegates, the process of decision making in JPO does not follow any guidelines; usually seniors take those decisions, even if their effect goes beyond patenting, to the extent of affecting the pharmaceutical industry.

Coordination at regional level

- JPO suggested establishing a multilevel personal and official network between patent offices in the Arab region, for better communication and exchange of experiences.
- EMRO is about to launch an important policy guide on FTAs and agreements with EU, which are pushing up patent protection standards in the region.
- Given the burden of covering six countries, GCCPO participants expressed their wish of further collaboration in follow up to this meeting. Dr. Mirza asked them to explore the possibility of holding a meeting for the six GCC countries with the WHO/EMRO assistance.
- Dr. El-Said suggested the dissemination of legal guidelines or a newsletter to share experiences and the latest developments in this area in other regions.

Cooperation with international organizations

- From the WHO HQ side, Dr. Velásquez mentioned that he was impressed by the participation and by the interventions made by the patent examiners. Collaboration with EMRO in this field is going well, and will continue.
- Mr. Abdel Latif expressed the interest of ICTSD in wider work on the flexibilities of the TRIPS Agreement in the region, and also referred the elaboration of a policy guide with EMRO on FTAs and TRIPS flexibilities and their impact on public health.
- Ms. Luciana Mermet, UNDP, said that an equitable access to essential medicines is a key target of the global partnership to achieve the MDGs, and is often hindered by the complex web of IPRs and trade agreements. UNDP aims at contributing to building national capacity of patent offices, as well as ensuring the necessary backward linkages with other relevant national authorities involved, such as line ministries (public health, trade, etc), both through regional capacity building activities, advocacy and key policy messaging through human development national and regional reports.

Need for capacity development

- All patent examiners present shared that they would like more of these technical meetings in the future. JPO delegation expressed their need for infrastructure and capacity development given the large number of applications they receive vis-à-vis the number of staff in their office. INNORPI is currently recruiting more patent examiners, and more of this kind of technical training will be necessary for them.

APPENDICES

I. Agenda

Tuesday 14 April 2009

08:30-09:00AM	Registration
09:00-09:45AM	Opening Address <ul style="list-style-type: none">- Khadija Moalla, HIV/AIDS Regional Programme in the Arab States, United Nations Development Programme (UNDP)- Germán Velásquez, World Health Organization (WHO)- Belgacem Sabri, WHO Regional Office for the Eastern Mediterranean (EMRO)- Ahmed Abdel Latif, International Centre for Trade and Sustainable Development (ICSTD)- Carlos Correa, University of Buenos Aires (UBA) <i>An Overview of the Consultation</i>
09:45-10:00AM	Patents in the Context of Public Health: Balance between protection and access to medicines Germán Velásquez, WHO
10:00-10:30AM	Defining Patentability Criteria and Disclosure: TRIPS vs. local flexibilities Carlos Correa, UBA
10:30-10:45AM	<i>Tea/coffee break</i>
11:30-01:00PM	TRIPS-Plus health-related provisions under Free Trade Agreements Mohammed El Said, University of Central Lancashire Presentations from region's country patent offices experiences: Algeria, Egypt, GCC Patent Office
01:00-02:00PM	<i>Lunch</i>
02:00-03:15PM	Typical Claims in Pharmaceutical Patents <ul style="list-style-type: none">- Formulation and Composition- Combinations- Dosage and Dose
03:15-03:30PM	<i>Tea/coffee break</i>
03:30-04:30PM	Typical Claims in Pharmaceutical Patents (continued)

- Salts, ethers, and esters
- Polymorphs/Hydrate/Solvates
- Markush Claims
- Selection Patents

04:30-05:00PM Discussion and Q&A

06:30-08:00PM *Welcome Reception*
Semiramis Intercontinental Hotel

Wednesday 15 April 2009

09:00-10:30AM Presentation by the Egyptian Initiative for Personal Rights (EIPR)

Presentations from region's country patent offices experiences:
Jordan, Morocco, Syria and Tunisia

10:30-10:45AM *Tea/coffee break*

10:45-12:30AM Typical Claims in Pharmaceutical Patents (continued)

- Analogy Processes
- Enantiomers
- Active metabolites and pro-drugs

12:45-01:45PM *Lunch*

01:45-02:30PM Typical Claims in Pharmaceutical Patents (continued)

- Methods of treatment
- Use claims, including second indications
- TRIPS requirements
- Experiences in developed countries and problems arisen

02:30-03:30PM Mechanisms to enhance the examination of pharmaceutical patents from a public health perspective:

- Pre-grant and post grant opposition: the need for a balance of opportunity
- Examination Rules and Procedures

03:30-03:45PM *Tea/coffee break*

03:45-05:00PM Summing up, experience sharing and conclusions

II. List of Participants

Name	Organization	Phone Numbers	Email
Lina Haddad	Head of Jordanian Patent Office Industrial Property Protection Directorate Ministry of Industry and Trade, Jordan	Tel: 00 962 6 562 90 60 ext: 326	lina.h@mit.gov.jo Website: www.mit.gov.jo
Hussam Abukhiran	Patent Examiner Jordanian Patent Office, Industrial Property Protection Directorate Ministry of Industry and Trade, Jordan	Tel: 00 962 6 562 90 60	hussam.kh@mit.gov.jo
Maha Al Quda	Patent Examiner Jordanian Patent Office, Industrial Property Protection Directorate Ministry of Industry and Trade, Jordan	Tel: 00 962 6 562 90 60	maha.q@mit.gov.jo
Aliaa El-Behery	Patent Examiner (Pharmacist) Egyptian Patent Office	Tel: +202 27921272 Mob: +20195747093	aliaa_elbehery@yahoo.com Website: www.egypt.gov.eg
Eman Ragab	Patent Examiner (Pharmacist) Egyptian Patent Office	Tel: +202 27921272 Mob: +20127176199	Besky84@hotmail.com
Fatma Samir El- Sebae	Patent Examiner (Pharmacist) Egyptian Patent Office	Tel: +202 27921272 Mob: +201017959631	Fatma.samir@gmail.com
Reham Dewedar	Patent Examiner (Biochemist) Egyptian Patent Office	Tel: +202 27921272	Lovelyangle6@yahoo.com
Sally Mohamed Odah	Patent Examiner (Pharmacist) Egyptian Patent Office	Tel: +202 27921272 Mob: +20124653141	leadinthefield@hotmail.com
Yasmin Samy Talaat	Patent Examiner (Pharmacist) Egyptian Patent Office	Tel: +202 27921272 Mob: +2 0122755767	dr.yasmin@hotmail.com
Amira Ahmad Abdelrahman	Patent Examiner (Pharmacist) Egyptian Patent Office	Tel: +202 27921272 Mob: +2 0116146311	amiraelakhal@yahoo.co.uk
Heba Abdelrehim Mohammed	Patent Examiner (Pharmacist) Egyptian Patent Office	Tel: +202 27921272 Mob: +2 0106212069	h_elrehim@hotmail.com
Ashraf M. Kamel	Pharmacist, Registration Department Central Administration of Pharmaceutical Affairs Ministry of Health and Population Egypt	Mob: +2012 42 65 917	Ashraf_dppc@hotmail.com
George Nabil	Pharmacist, Registration Department Central Administration of Pharmaceutical Affairs Ministry of Health and Population Egypt	Mob: +2012 425 4531	georgeissace@yahoo.com

Name	Organization	Phone Numbers	Email
Soraya Saidani	Head of Office Algerian National Institute of Industrial Property (INAPI)	Tel: +213 21 73 01 42/ 60 84 ☒Fax: +213 21 73 55 81/ 96 44	saysory8864@yahoo.fr
Rima Abderrahim	State Engineer, Algerian National Institute of Industrial Property (INAPI)	Tel: +213 21 73 01 42/ 60 84 ☒Fax: +213 21 73 55 81/ 96 44	rima.abderrahim@gmail.com
Bechar Abderrahman	State Engineer, Algerian National Institute of Industrial Property (INAPI)	Tel: +213 21 73 01 42/ 60 84 ☒Fax: +213 21 73 55 81/ 96 44	a.bechar@hotmail.fr
Nabil Masry	Patent Examiner, Syrian Patent Office Directorate of Property Protection Ministry of Economy and Trade, Syria	Tel: +963 11 516 1139/ +963 11 8822053/ +963 966084615 Fax: +963115161144	khaledpat@yahoo.com , ipr@syrencon.org
Aline Ghanem	Patent Examiner, Syrian Patent Office Directorate of Property Protection Ministry of Economy and Trade, Syria	Tel: +963 11 516 1139/ +963 11 4719980/ +963 988223763 Fax: +963115161144	alineghanem@yahoo.com , ipr@syrencon.org
Osama Mokhaibr	Patent Examiner, Syrian Patent Office Directorate of Property Protection Ministry of Economy and Trade, Syria	Tel: +963 11 516 1139/ +963 933227321 Fax: +963115161144	Osama_mk@ymail.com , ipr@syrencon.org
Nabila Khassal	The Moroccan Commercial and Industrial Property Office (OMPIC)	Tel: +212 522 33 54 86 Fax: +212 522 97 24 99	khassal@ompic.org.ma
Abderrahmane Bakhouya	The Moroccan Commercial and Industrial Property Office (OMPIC)	Tel: +212 522 33 54 86 Fax: +212 522 97 24 99	a.bakhouya@ompic.org.ma
Emna Lahmar	National Institute for Standardisation and Industrial Property (INNORPI), Tunisia	Tel: +216 7180 67 58	innorpi@planet.tn , innorpi.dre@planet.tn Website: www.innorpi.tn
Haroun Grami	National Institute for Standardisation and Industrial Property (INNORPI)	Tel: +216 7180 67 58	innorpi@planet.tn , innorpi.dre@planet.tn
Amir Babi	National Institute for Standardisation and Industrial Property (INNORPI)	Tel: +216 7180 67 58	innorpi@planet.tn , innorpi.dre@planet.tn
Rashid Khamis Ali Al-Ghatarifi	Assistant Director of Technical Examination Department Gulf Cooperation Council Patent Office, Riyadh	Tel: +966 503228359	ralghatrifi@gcc-sg.org
Majed Ibrahim AlRufayyig	Patent Examiner (Pharmacist) Gulf Cooperation Council Patent Office, Riyadh	Tel: +966-505483187	mrufayyig@gcc-sg.org
Nada Moqbel Albahigi	Patent Examiner (Pharmacist) Gulf Cooperation Council Patent Office, Riyadh	Tel: +966-507478708	nalbehajji@gcc-sg.org
Nouf Saleh Alnassban	Patent Examiner (Biochemist) Gulf Cooperation Council Patent Office, Riyadh	Tel: +966-504449077	nalnassban@gcc-sg.org
Mohammed Kamel El-Said	Lecturer in International Trade Law, Lancashire Law School University of Central Lancashire, United Kingdom	Tel: +974 5145403	mel-said@uclan.ac.uk

Name	Organization	Phone Numbers	Email
Hossam Bahgat	Director of Egyptian Initiative for Personal Rights (EIPR)	Tel/fax: + (202) 2794 3606- 2796 2682	hossam@eipr.org
Dina Iskander	Researcher on the Accessibility of Medicines, Health and Human Rights Program Egyptian Initiative for Personal Rights (EIPR)	Tel/fax: + (202) 2794 3606- 2796 2682	dina@eipr.org
Carlos Correa	Director of the Centre for Interdisciplinary Studies on Industrial Property and Economics Law School of Law, University of Buenos Aires, Argentina	Tel: +5411 4809-5600 ext 5558	quiess@gmail.com
German Velásquez	Director of Secretariat on Public Health, Innovation and Intellectual Property World Health Organization	Tel: +41 22 791 3509 Direct: +4122 791 27 24	Velásquez_g@who.int
Belgacem Sabri	Director of Health Systems and Services Development Eastern Mediterranean Regional Office World Health Organization	Tel +202 2765309/10 Fax +202 2765416 Mob+20 103333413	sabrib@emro.who.int
Zafar Mirza	Regional Adviser Essential Medicines & Pharmaceutical Policies, Eastern Mediterranean Regional Office World Health Organization	Tel: +202 27 655 61/ 27 650 00, fax: 00-202-2765416 Mobile: +2010 19 00 329	mirzaz@emro.who.int
Lamiaa M. El-Sayed	Senior Administrative Support Essential Medicines & Pharmaceutical Policies Health Systems & Services Development, Eastern Mediterranean Regional Office World Health Organization	Direct: +202-22765320 Fax: +202-26702492/94 Mobile: +20123258224	elsayedl@emro.who.int
Mohammed Ramzy	Technical Officer Essential Medicines & Pharmaceutical Policies Eastern Mediterranean Regional Office World Health Organization	Tel:(202) 2276 5 356 Mobile: +20 10 52 62 991	ramzym@emro.who.int
Mohamed Abdelhakim	Technical Assistant Essential Medicines & Pharmaceutical Policies Eastern Mediterranean Regional Office World Health Organization	Tel:(202) 2276 5526 Mobile: +20 10 46 19 107	abdelhakimm@emro.who.int
Ahmed Abdel Latif	Programme Manager Intellectual Property International Centre for Trade and Sustainable Development (ICTSD)	Tel: +41 22 917 8492 Direct tel: +41 22 917 8921; fax: +41 22 917 8093	aabdellatif@ictsd.ch www.ictsd.org
Khadija Moalla	HIV Practice Leader and Regional Coordinator, HIV/AIDS Regional Programme in the Arab	Mobile: +2010 140 20 16 Fax: +202 25784847	khadija.moalla@undp.org www.harapas.org www.chahama.org

Name	Organization	Phone Numbers	Email
	States United Nations Development Programme		
Luciana Mermet	Policy Specialist, Trade & Human Development, Poverty Group, Bureau for Development Policy United Nations Development Programme	Ph.: +1 212 906 5089 Fax: +1 212 906 5313	maria.luciana.mermet@undp.org
Ahmed Moustafa	Programme Manager Arab Trade and Development Programme United Nations Development Programme	Mobile: +2010 006 96 88/ +2012 717 82 68	ahmed.moustafa@undp.org
Heba Wanis	United Nations Development Programme	Mobile: +2012 318 0314	heba.wanis@undp.org , h.wanis@gmail.com