

Standing Committee on the Law of Patents

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**PATENTS AND HEALTH: COMMENTS RECEIVED FROM MEMBERS AND
OBSERVERS OF THE STANDING COMMITTEE ON THE LAW OF PATENTS (SCP)**

Document prepared by the Secretariat

Pursuant to the decision of the Standing Committee on the Law of Patents (SCP) at its seventeenth session held in Geneva from December 5 to 9, 2011, the Secretariat invited the members and observers of the SCP, through Note C.8076, to submit comments on the topic of patents and health. This document contains, in the Annex, the comments received.

[Annex follows]

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COMMENTS RECEIVED FROM MEMBER STATES

COSTA RICA

With regard to the subject of “patents and health”, the Industrial Property Registry welcomes the proposal put forward by the Delegation of South Africa on behalf of the African Group and the Development Agenda Group, since this proposal will enable the objectives of the SCP to be achieved, through the preparation of studies, the exchange of information and experience, and the provision of technical assistance.

The Industrial Property Registry is also grateful for the proposal submitted by the Delegation of the United States of America, since that proposal makes clear that not only the patent system has an impact on the availability of medicines. Its proposal containing three elements for a work program complements the proposal submitted by the Delegation of South Africa and will enrich the discussions at the next session of the SCP.

DOMINICAN REPUBLIC

The National Industrial Property Office (ONAPI) welcomes the proposal submitted by the Delegation of South Africa on behalf of the African Group and the Development Agenda Group. ONAPI supports this proposal, since we trust it will be of benefit to developing countries and least developed countries (LDCs).

RUSSIAN FEDERATION

In order to address fully the issue of availability of medicines, a topic that was raised for the first time on the agenda of the 16th session of the Standing Committee on the Law of Patents (SCP), the Delegation of the United States of America has submitted certain elements of a patents and health work program (document SCP/17/11) for the consideration of SCP Member States. The work program focuses in particular on the following:

- (1) conducting a comprehensive study on the availability of generic medicines and the reasons for their scarcity (discovering the effect of falsified medicines on availability is an important element of this research);
- (2) conducting a comprehensive study on the positive impact of patent systems in providing access to medicines (the study would evaluate the role of patent protection in providing incentives for scientific research leading to innovative medicines and developing the technologies required to guarantee the availability of generic medicines in developing and least developed countries).

The Russian Federation considers the issue of availability of medicines to be of the utmost importance. The work program proposed by the Delegation of the United States of America would allow all barriers to the availability of medicines to be comprehensively analyzed, and would provide objective data on the effect of patent systems.

1. Barriers to the availability of medicines

In conformity with the World Health Organization (WHO) interpretation, “availability of medicines” is approached in terms of (a) physical availability and (b) economic availability, or affordability. Moreover, physical availability assumes the supply of quality, effective and safe medicines to consumers. Affordability covers the State system to regulate pricing and the system that shapes demand for medicines.

(a) Resolving the problem of physical availability of medicines

The availability of safe and effective medicines is a multifaceted problem that touches on many aspects of law, national policy, physical infrastructure, social amenities, education and economics. Resolving the problem of physical availability of medicines is linked in particular to:

- improving the regulatory framework for the circulation of medicines (regulating the quality required of medicines placed on the market and preventing the use of counterfeit medicines);
- improving coordination of the activities of all relevant ministries and agencies;
- strengthening controls on the import of medicines;
- strengthening the personal responsibility of distribution network staff;
- mobilizing international cooperation on medicine quality control;
- providing information on advances in medicines;
- developing measures to support pharmaceutical manufacturers.

Falsified medicines undermine public trust in medical treatments and the health system in general, and represent a serious threat to the health and lives of patients taking such medicines, due to the absence of therapeutic effect or toxicity. Absolutely all falsified medicines pose potential dangers to patient health, since they are not subjected to the quality controls required of legal products at the production stage and in practice cannot be identified by end users.

The steady rise in the scale of international trade in medicines, as well as Internet sales has further enabled the penetration of counterfeit products in the medicine supply chain. Moreover, the danger from international organized crime groups involved in the circulation of counterfeit medical products threatens international security in general. This situation gives rise to the need to develop and implement a single policy to combat false medical products, found transnational health associations, and develop cooperation among and harmonization of national legislative and law enforcement systems.

In 2004, the concept of “falsified medicine” was introduced in Russian legislation (Federal Law No. 86-FZ on Medicines, of June 22, 1998). While developing legislation to protect the public interest, concepts such as “falsified medicine” and “counterfeit medicine,” were introduced in the new Federal Law No. 61-FZ on Circulation of Medicines, of April 12, 2010.

Furthermore, an express prohibition on importing falsified, substandard and counterfeit medicines into the country, a ban on their manufacture and sale, and provisions to withdraw them from circulation and destroy them were introduced in the new Federal Law.

The State medicine quality control system involves:

- evaluating the effectiveness, safety and compliance with quality standards of medicines on registration;
- evaluating the quality of the first batch of medicines manufactured or imported on authorized entry into circulation;
- examining the quality of medicines found in circulation (sampling);

- monitoring the quality, effectiveness and safety of medicines in circulation;
- quality inspections.

Thanks to a range of control and monitoring measures, including interagency and international cooperation, the quantity of falsified medicines discovered has fallen to 25 per cent of the levels found in 2005.

In Russia, the Federal Supervision Service for Healthcare and Social Development (Roszdravnadzor) is responsible for monitoring the quality of medicines. Roszdravnadzor has created a system to uncover substandard and falsified medicines and remove them from circulation. This system comprises:

- the regional Offices of Roszdravnadzor;
- testing laboratories;
- a joint information system;
- quality systems within medicine manufacturers, and pharmaceutical retailers and wholesalers.

In order to improve the effectiveness of State monitoring of medicine quality, Roszdravnadzor is creating eight modern laboratory complexes in each Federal District of the Russian Federation and organizing mobile express laboratories based at the complexes. Action to prevent the spread of falsified and substandard medical products involves close cooperation between the customs and law enforcement agencies. Experience of combating falsified medicines reveals the need to develop active interagency and transnational cooperation, as well as the importance of creating a single information space for regulators in different countries, and of taking steps towards international legislative harmonization.

Since 2005, Russia has taken an active role in international organizations and initiatives that aim to suppress the trade in falsified medicines. The importance of drafting an international document regulating the fight against falsified medicines is reflected in the decisions of transnational meetings at every level. The need to develop an international legal instrument to combat counterfeit medical products was identified in the Moscow Declaration developed at the International Conference Europe against Counterfeit Medicines, held jointly with the European Directorate for the Quality of Medicines and HealthCare during the Russian Presidency of the Committee of Ministers of the Council of Europe, on October 23-24, 2006.

In 2007, the Committee of Ministers of the Council of Europe formed a Group of Specialists on Counterfeit Pharmaceutical Products, in which Russian specialists played an active role. The Group prepared a draft Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (Medicrime), and the Council of Europe Committee of Ministers adopted the final text of the Convention in 2010.

The Convention requires signatories to stipulate criminal liability for: the manufacture, counterfeiting of documents, trade, advertising and illegal transportation of falsified medical products. The opening of the Convention to countries that are not members of the Council of Europe creates objective conditions for transforming it into an inter-regional instrument in the fight against the criminal trade in medical products.

Positive results achieved regarding the availability of medicines in Russia

The first step to modernize the Russian pharmaceutical industry was taken in 2010, with the development and adoption of the Development Strategy for the Pharmaceutical Industry for the period up to 2020 (Pharma 2020 Strategy). To provide State economic support for scientific and technical development in this sector of domestic industry, in 2011, the Government of Russia developed and adopted a targeted federal program, Development of the Pharmaceutical

and Medical Industry of the Russian Federation for the period up to 2020 and beyond (Pharma 2020). Legal provisions for the program to modernize the pharmaceutical industry and accelerate improvements in the circulation of medicine in general were set out in Federal Law No. 61-FZ on Circulation of Medicines, of April 12, 2010.

The introduction, in Federal Law, of an essentially new organization of the State system to regulate the circulation of medicines has led to significant changes in the activities of all stakeholders in the circulation of medicines throughout the country, including the activities of the federal executive authorities. Firstly, this makes the Ministry of Health and Social Development of the Russian Federation (Russian Minzdravsotsrazvitia), responsible for the priority task of developing State policy and the legal framework for the circulation of medicines for medicinal purposes (Instruction of the Government of the Russian Federation No. 321, of June 30, 2004, on Approval of the Regulations of the Ministry of Health and Social Development of the Russian Federation - version of June 3, 2011).

To resolve the challenges of strategic management of the circulation of medicines, a special, new federal body was created under the Russian Minzdravsotsrazvitia: the Department for State Regulation of the Circulation of Medicines. The main task of the Department is exercising the State's authority to register medicines and examination organizations carrying out the State registration of medicines (Order No. 722 of the Russian Minzdravsotsrazvitia, of August 25, 2010, on Approval of the Regulations of the Department for State Regulation of the Circulation of Medicines).

Alongside these changes to the structure and functions of the federal executive authorities regarding the circulation of medicines, the relevant State examination institutions were reorganized. Therefore, by Order No. 1316-r of the Government of the Russian Federation, of August 4, 2010, , the Roszdravnadzor Federal State Institute the Research Centre for the Examination of Medical Products and the Federal State Institute, L.A. Tarasevich State Scientific Research Institute for the Standardization and Control of Biological Medicines were brought under the authority of the Russian Minzdravsotsrazvitia.

Furthermore, under Instructions No. 2058-r of the Government of the Russian Federation of November 17, 2010 the decision was taken to reorganize the Research Centre for the Examination of Medical Products and the L.A. Tarasevich State Research Institute for the Standardization and Control of Biological Medicines, both federal State-financed institutes under the authority of the Russian Minzdravsotsrazvitia, in order to merge them into one combined institution with separate structural subdivisions. Therefore, following reforms to regulatory bodies and on the basis of the two examination institutes that had previously belonged to different agencies, a single institute was created to carry out examinations of all medicines, including medicinal immunobiological drugs.

Order No. 750n of the Russian Minzdravsotsrazvitia, of August 26, 2010, on Approval of the Regulations for Examination of Medical Products intended for Medicinal Purposes and the Format for the Conclusions of the Examination Commission following the Examination of Medical Products (registered with the Russian Ministry of Justice on August 31, 2010, No. 18315), was drafted on the basis of the relevant regulations of the Federal Law and approved by the Regulations on Conducting Examinations of Medical Products intended for Medicinal Purposes (the Regulations).

In accordance with the Regulations, the examination of medical products intended for medicinal use is based on the principles of legality, observance of human and citizen rights and freedoms, the rights of legal entities, the independence of examiners, objectivity, complete and comprehensive research conducted using modern achievements of science and technology, and the responsibility of federal State-financed institutes for conducting examinations of medicines and of examiners for the performance and quality of examinations.

In November 2007, WHO decided to include the Russian Federation in the WHO Program for International Drug Monitoring. Moreover, the agency in Russia responsible for monitoring the safety of medicines and taking administrative steps to regulate the circulation of medicines with reference to their changing safety profiles, Roszdravnadzor, was invited to participate in active cooperation, involving access to the WHO international database that holds over four million reports on adverse side effects of drugs.

Priority tasks to provide access to medicines are fostering the conditions for gradual, stable development of the pharmaceutical industry, providing State guarantees that patients receive high quality medicines, improving the quality of monitoring at every stage of medicine circulation, and reducing the burden of administrative barriers. Steps to adapt regulatory requirements to international standards are intended to make the Russian pharmaceutical market a part of the global medicine market.

In order to guarantee the quality of information about medicines authorized for medicinal use in Russia, the Ministry of Health and Social Development of the Russian Federation adopted basic regulations on State information standards in 2001. This is a standard set of regulatory documents containing official information about medicines authorized for medicinal use that is a primary information source. In addition, advertisements for medicines are regulated by Federal Law No. 38-FZ on Advertisements of March 13, 2006, and Federal Law No. 61-FZ on Circulation of Medicines of April 12, 2010,. This legislation establishes the prohibition on advertising unregistered medicines and prescription drugs to the public (these medicines can only be advertised to healthcare specialists).

One problem facing us today is that the legislation focuses only on standards for advertisements and does not touch upon other promotion methods, such as the activities of medical representatives.

(b) Resolving the problem of affordability of medicines.

In Russia, the State only regulates the price of medicines, of both domestic and import origin, that are on the list of vital and essential medicines. In fact, price regulation is a way for the State to register the maximum cost price for medicines from Russian and foreign manufacturers of such preparations. There are also limits on the retail and wholesale markups of pharmaceutical products. The scale of markups is approved by Acts of the Federal Executive Authorities of Subjects of the Russian Federation. Medicines whose price is registered are entered into the State register of maximum cost prices.

According to the evaluations of various organizations of experts, up to 80 per cent of patients purchase medicines with their own resources. Those with low and middle incomes are unable to treat themselves with modern, and therefore expensive, medicines. In Russia there are currently programs to provide medicines to those receiving social benefits that covers around 4.3 million people. This is the format for medicine insurance in Russia and it is used by those receiving benefits – around three per cent of the population.

The introduction of a compulsory medicine insurance system should become an important element of Russian healthcare reforms. This is the only way to improve the public's poor access to treatment with modern, effective medicines. Reimbursing a significant part of the cost of medicines should become the main tool of the system to supply modern medicines. The compulsory medical insurance fund has prepared a concept, the main thread of which is that all holders of compulsory medical insurance policies should be charged only half the cost of prescription medicines at the pharmacy, the rest being covered by other sources, including State funding. The introduction of a medicine insurance system implies a pivotal role for the State as the main user and purchaser, as well as the legislator. Nonetheless, the legislation

and mechanisms for medicine insurance are currently at the development stage and the system of such insurance may appear no earlier than 2013. The prices of next generation medicines used to treat various illnesses effectively are often too high. Striving for high quality while resolving the problems of affordability of pharmaceutical products limits the need for cost cutting and cheaper manufacture.

Given the market-led medicine supply system, great significance is also attached to the development of the List of essential medicines authorized for purchase with State funds. This List offers support for the health of those with non-fatal illnesses who do not have the resources to purchase expensive medicines. The provision of this type of access is directly reflected in the patients and has great social significance, since it improves doctor's prescription practices, which are, after all, also a basic factor defining the accessibility and effectiveness of the healthcare system.

When considering the factors that aggravate the elevated prices of medicines, it is worth noting the low return rate of innovative development and the blockbuster strategy, employed by companies seeking to create blockbuster drugs with sales in the billions. Among the measures that help to minimize high medicine costs are the introduction of generics and improvements in the mechanisms for their registration, and the substitution of generics for original medicines under compulsory programs, including the programs to supply additional medicines. Additional resources to tackle the funding deficit might be attracted through international exchanges of experience and technical know-how, holding economically viable events on the availability of medicines, and offering financial support to low income countries by providing more credit and a greater number of grants and preferential loans.

2. Effects of the patent system on the availability of medicines

Patent policy and practice regarding pharmaceutical products varies widely from country to country. In Russia, legal protection is accorded to products related to medicines, medical solutions, including using medicines for new purposes, and also treatment methods, including the use of medicines. The Russian Civil Code provides the possibility of extending the term of application of a medicine patent. This possibility is afforded by the fact that a medicine requires official authorization for use. That authorization is awarded in the manner stipulated by the Federal Law No. 61-FZ on Circulation of Medicines, of April 12, 2010.

The rules for extending a medicine patent's period of application are in accordance with the Regulations for defining the term of additional legal protection provided in European Union Council Regulations No. 1768/92 of June 18, 1992 and No. 1610/96 of July 23, 1996. Russian legislation permits the granting of a patent for a new usage of a known substance. Furthermore, Russian legislation regulates the issues of broadening the scope of the patent system and extending the application of a medicine patent in a balanced manner. In order to prevent the misuse of patenting rules applicable to known substances, the methods for verifying the patentability of such items is specified. Medicines that offer no new therapeutic effect compared to known analogues may be regarded as unpatentable.

Under the legislation in force, issues with the use of patented medicines are resolved on a case-by-case basis through voluntary or compulsory licensing. Russian legislation allows parallel importing of medicines. In addition to this, Russia shares the concerns of a number of countries regarding the development of pricing policies by monopoly producers of patented medicines. Patent monopolies could impede further innovation, such as the development of fixed-dose combination drugs or other formats for medicines.

The Russian Federation supports the proposals to reduce the high prices of patented medicines by changing the financing mechanisms for scientific research and development (R&D). At the heart of these proposals lies the elimination of a reciprocal link between the prices of medicines

and scientific openness to creating new medicines. The difficulties of developing the Russian pharmaceutical industry are linked to:

- the high level of innovation and technology used in the development and manufacture of medicines;
- creating progressive financing mechanisms for medicine development;
- eliminating gaps in the critical cycle of interaction that ensures new, domestic and innovative brands are created;
- broadening cooperation among manufacturers of pharmaceutical products;
- eliminating uneven development in the different sectors of technology involved in developing medicines;
- bringing Russian patent legislation and law enforcement practice into line with international standards.

At present, the Russian Federation is working on a range of proposals for amendments to various individual laws aimed at promoting R&D. In particular, the focus is on laws regulating the drafting of Government tasks for R&D, including in medicine, instructions on the rights to the results of scientific and technical activities performed using federal funds, and laws regulating the investment of State funds to develop and modernize the facilities and equipment of leading scientific institutes.

One alternative model for cooperation on innovation and financing for medical R&D is the patent pool. An area in which the creation of a patent pool could lead to clear advantages is the development of first-line fixed-dose combination drugs as advocated in the new WHO recommendations for treatment regimes. Creating patent pools that could grant non-exclusive licenses to use patented medicines in exchange for royalty fees would greatly boost the development of the pharmaceutical industry and increase its effectiveness, while also providing a great flow of inexpensive generics to the consumer market.

A patent pools system:

- reduces the transaction costs of licensing, since the system does away with the need to conclude several separate agreements;
- eliminates the barriers to the use of medicines blocked by patents;
- encourages innovation and development based on patented products;
- eases the transfer of technology and provides for an economically stable expansion of facilities and availability of medicines, including in developing countries.

Therefore, a patent pools system presents the most attractive resolution to the problem of availability of medicines.

EURASIAN PATENT OFFICE (EAPO)

The Eurasian Patent Office (EAPO) fully supports the proposal of the United States of America (document SCP/17/11) concerning the need to conduct research, within the World Health Organization (WHO), in order to identify the factors affecting the population's health and constituting barriers to the accessibility of reliable and effective medicines, as well as to determine the share of influence of a patent monopoly, in both positive and negative terms, on the health of the population, including on the provision of accessibility of medicines.

At the same time, it should be pointed out that the patent system plays a uniquely important role in the development of research activities in relation to devising new medicines; there are numerous examples of this in the successful battle against diseases, namely through the creation of new patented medicines (for example, against the HIV infection). The issue of the

need to carry out additional research, within the Standing Committee on the Law of Patents (SCP), in order to confirm the positive influence of the patent system on the health of the population, is therefore a controversial one. It is more appropriate to carry out the analysis proposed by the United States of America, in order to provide a general overview of the factors influencing the health of the population and the accessibility of medicines.

Such research would serve as a starting point in determining the future work of the SCP on the subject of patents and health.

As regards the joint proposal put forward by the Delegation of South Africa (document SCP/16/7), it should be pointed out that the patent system incorporates many mechanisms allowing access and the supply of the national market with the requisite medicines to be regulated (compulsory license according to the TRIPS Agreement, TRIPS flexibilities allowing States to define situations independently, which require the grant of a compulsory license, including for the purposes of regulating prices for medicines, and the Bolar exception which promotes the accelerated establishment of the production of generics), but, as shown by the research results published, most countries in need of medicines rarely make use of these regulatory possibilities. Since the work aimed at studying the problem in question is conducted both by other WIPO committees and also in other international organizations, it is not appropriate to duplicate such work also within the SCP.

As regards the exhaustion of rights, it should be noted that the work in question is already being done by the SCP; the results of the 2011 questionnaire on exceptions and limitations could be used for further analysis of the issue of the parallel import of medicines.

In relation to the two remaining issues of the first proposed element, we consider it useful to conduct a study within the SCP.

It is also appropriate to focus the activities of the SCP on issues which are directly connected to the patent system and to patent protection of medicines. This issue is closely connected with the problem of quality of patents, since in the past few years a trend towards patenting inventions relating to medicines and their use, which constitute minor modifications (improvements) of pre-existing medicines, has clearly been observed. The development of more precise standards for assessing the patentability of such inventions is one of the effective means of limiting an unjustified patent monopoly on the market for medicines.

KNOWLEDGE ECOLOGY INTERNATIONAL (KEI)

During the 16th Session of the Standing Committee for the Law of Patents (SCP), South Africa, on behalf of the Africa Group and Development Agenda Group (DAG), introduced a proposal on the topic of Patents and Health (SCP/16/7). In response, the United States submitted its own proposal (SCP/17/11) during the 17th session which took place from 5-9 December 2011. KEI affirms our support for African Group/DAG proposal, which we have described in our submission to the SCP on 12 September 2011.¹ KEI also expresses concern regarding the attempts by the United States government to minimize the challenges and barriers for patient access created by patents on medical technologies.

Proposals before SCP should be placed in the context of existing international instruments that lay out commitments and obligations. The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) set an important global norm for intellectual property protection. After

¹ <http://keionline.org/node/1260>.

the TRIPS came into effect, subsequent international commitments have been made with respect to public health that are also important.

The Doha Declaration on the TRIPS Agreement and Public Health (referred to here as the Doha Declaration) stated that TRIPS “can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all.” Similarly, the World Health Organization Global Strategy and plan of action on public health, innovation and intellectual property, adopted in 2008, calls upon member states to promote access to medicines for all (para 15.e).

The United States proposal says that studies and presentations are needed with regard to non-patent barriers, and wants to document the positive impact of the patent system and the factors affecting access to medicines that are not related to patents to determine “the effect, if any, of patents on the availability of medicines.” That the patent system provides for monopoly rights over life-saving medicines, and such monopolies lead to high prices is well-known and extensively documented. By calling on the SCP to focus only on exculpatory evidence that paints a rosy picture for a system of strong patent rights, the United States is seeking to undermine the attention given to implementing the changes that are necessary to achieve “access to medicine for all.”

The World Health Organization Essential Medicine List (EML)

To support its proposal, the United States notes that only four percent of medicines on the WHO List of Essential Medicines (EML) are currently protected by patents, and implies that the paucity of patented drugs on the WHO list is evidence that patents on drugs are not important for patients. The comments on the EML illustrate at best that the U.S government is poorly informed about the access to medicines issue. Outside of drugs for HIV/AIDS, which were only added to the EML after extensive campaigning by AIDS activists, there are almost no patented drugs on the EML. But why is this? Does the U.S. Government claim that there are not patented medicines that poor people living in developing countries would use if they were affordable? Consider a few data points on cancer drugs.

In 2011, Paul Miano examined 100 cancer drugs considered important by the US NIH. See Cancer: Approval, ownership, market structure, and placement on WHO Model Essential Medicines List, for 100 new molecular entities (NMEs) on the NCI alpha list of cancer drugs and vaccines, KEI Research Note 2011:1.

According to Miano, of the 100 important cancer drugs, more than half were first registered for sale by the US FDA after January 2000, and about two thirds of the drugs were sole source products, suggesting they were protected from competition by patents or other intellectual property rights. If someone who worked on the United States submission was diagnosed with cancer, or one of their loved ones was diagnosed with cancer, would they want to have access to all of the drugs on that list, or only one third of the drugs?

In the 2011 WHO Model EML, there were zero cancer drugs on the main list, and 20 products on the complementary list. The newest product on the WHO EML that was among the NIH 100 most important products, was registered by the FDA in 1996, and all of the EML cancer products were off patent. To suggest that no patented cancer drugs are “essential” is to say either that the lives of poor people who have cancer are not essential, or that the products were just too expensive to justify their use in resource poor settings. But when the products go off patent, they often find themselves on the list. What the US is saying is that poor people can wait until patents expire before having access. For many patients with cancer, that means dying.

If the United States was more broadly consulting with health groups, it would never have made claims in the WIPO SCP submission that the paucity of patented drugs on the EML is evidence for anything other than the fact that patents make drugs too expensive. The fact that there are

not patented cancer drugs on the EML does not mean that poor people do not get cancer or that the new drugs do not work. It means the patents drive the prices up so high that poor people do not get them.

In other parts of its filing, the United States compulsory licenses on patents will not “gain the cooperation of the patent owner” and the party receiving the compulsory license “may not be able to successfully manufacture the medicine.” This is certainly true as stated, but everything in the statement also applies to the facts when patents expire. In both cases, there is the legal freedom to manufacture generic versions, and compete. There is certainly ample evidence that the elimination of legal barriers is an effective way to promote competition and lower prices. This is certainly true the United States where, according to the GphA, 10,072 of the 12,751 drugs listed in the FDA's Orange Book have generic counterparts, and generic medicines account for 69 percent of all prescriptions, but only 16 percent of outlays on prescription drugs. The United States might ask how many of the cancer drugs on the NIH list of 100 important cancer drugs are available from generic suppliers, and ask what needs to be done to expand that number, rather than to suggest that generic sources are impossible.

Questions that could be asked about the EML

If the WIPO SCP examines the WHO EML, there are many different directions that are possible for such a review. For example, one could ask these questions:

1. How many persons living with HIV/AIDS died in developing countries before the WHO agreed to put patented AIDS drugs on the EML?
2. What would the WHO EML look like if there was a new category for for “product that are cost effective if available from generic suppliers?”
3. What percent of women with HER2+ breast cancer have access to Herceptin in developing countries?
4. What percent of women with HER2+ breast cancer have access to Herceptin in high income countries?
5. How many developing countries have sufficient medical infrastructure to provide Herceptin to women with HER2+ breast cancer, if the product was available at lower biogeneric prices?
6. Would Herceptin be on a WHO EML if the price was much lower?
7. Should the WHO provide pre-qualification for generic and biosimilar cancer drugs?

Additional Issues

Countries have the sovereign right to grant TRIPS-compliant compulsory licenses and the Doha Declaration on TRIPS and Public Health explicitly affirmed that member states have the “right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.”²

It should be noted that the United States has issued several judicial compulsory licenses in the years since the Supreme Court held in *eBay v. MercExchange*, 547 U.S. 388 (2006) that permanent injunctions do not automatically issue in cases where patent infringement occurs. In

² WT/MIN(01)/DEC/2, Declaration on the TRIPS agreement and public health (Nov. 14, 2001), http://www.wto.org/english/thewto_e/minist_e/min01_e/mindeedl_trips_e.htm.

subsequent case law with respect to patent infringement of medical devices or inventions, courts have denied injunctive relief and granted monetary damages and royalties instead.

Judicially imposed compulsory licenses issued in the United States concern the denial of injunctions as a remedy to patent infringement. In 2011 these cases have included denials of injunctions on a patent used for manufacturing and exporting a medical device to treat aortic stenosis³ and for contact lenses.⁴ Several other cases following the *eBay v. MercExchange* case have also resulted in the denial of a permanent injunction of medical patents including for an angioplasty guide catheter, method of genotyping the hepatitis C virus, a prosthetic vascular graft, and patents related to devices and methods used by spinal surgeons.⁵ Although the United States has issued its own compulsory licenses, it appears to discourage other countries considering such options.

We refer back to our comments on the African Group/DAG proposal and reaffirm our support for the request to organize a technical workshop on the practices of issuing compulsory licensing of medical technologies:

We note that technical assistance experts often fail to distinguish between compulsory licenses that are granted under the procedures of Part II of the TRIPS, concerning patent rights, and those granted under Part III of the TRIPS, concerning the remedies for infringement of those rights. For example, the most commonly used mechanisms for obtaining a compulsory license in the United States are those associated with Part III of the TRIPS, including in particular Article 44 of the TRIPS. Under the structure of the TRIPS agreement, Article 44 compulsory licenses are not subject to the restrictions that exist for Article 30 and 31 of the TRIPS, an issue not explored in the experts reports. Consequently, we support the African Group/DAG request for the International Bureau of the World Intellectual Property Organization (WIPO) to “Organize a technical workshop on state practice involving the compulsory licensing of medical technologies, including the application of TRIPS Articles 30, 31 and 44.

The United States proposal appears to minimize the barriers created by patents, and presents a variety of humanitarian AIDS programs and voluntary actions as a substitute for government policies that guarantee access. The US proposal echoes the views of the large pharmaceutical companies and ignores the views of the public health, development and consumer groups working on the access to medicines issues. KEI is extremely disappointed that the United States government would make such a submission to the SCP.

Additionally, although the United States notes its concern regarding non-patent barriers to access to medicines, it ignores those non-patent mechanisms that give additional rights to right-holders. For example, the United States proposal does not take into account exclusive rights over test data, a practice that effectively extends monopoly power over medicines. The United States proposal does not address the justification for or consequences of its efforts to change global norms on intellectual property outside of multilateral institutions such as WIPO and the WTO. The United States has asked smaller market country to trade preferential market access for higher levels of patent protection and enforcement than are required under international obligations. The most recent example is the secret negotiation for a Trans-Pacific Partnership Agreement (TPPA). The United States also has an annual unilateral rating of countries for its annual Special 301 Report, often for not implementing intellectual property standards on

³ James Love, The CoreValve compulsory license on patent to treat aortic stenosis, (Sept. 1, 2011), <http://keionline.org/node/1218>.

⁴ Anne Mira Guha, *The Johnson & Johnson Acuvue Compulsory License* (Sept. 1, 2011), <http://keionline.org/node/1219>.

⁵ Anne Mira Guha, *U.S. Compulsory licensing of medical inventions as a limit on remedies under eBay v. MercExchange*, (June 7, 2010), <http://keionline.org/node/862>.

pharmaceutical test data and patentability of medicines that go beyond the requirements of international agreements such as TRIPS, and which violate medical ethics and increase prices for medicines.

LATIN AMERICAN ASSOCIATION OF PHARMACEUTICAL INDUSTRIES (ALIFAR)

1. The WIPO Development Agenda requires that the patent system should be consistent with fundamental public policy priorities and, in particular, with the promotion and protection of public health, as rightfully stated in the Proposal by the Delegation of South Africa (document SCP/16/7).

The patent system, and the intellectual property as a whole, are not ends in themselves that should be blindly maximized; instead, they represent one more of the diverse political, economic and legal tools aimed at promoting development and, therefore, they should be assessed and applied taking into account the characteristics of each country. In particular, it is necessary to emphasize that patent laws should seek to achieve an adequate balance with public health interests and policies, and ensure the population's right to health and, specially, their access to essential medicines.

Failure to make use of the flexibilities provided for in the TRIPS Agreement, and the adoption of a more rigorous patent system that includes, for instance, the extension of the patent protection term, the increase of patentable subject matter, the adoption of border measures in respect of patents, or the introduction of exclusive rights on test data submitted to the regulatory authorities, will necessarily convey negative consequences on public health.

A more strict patent system will bring about a deep restriction in the pharmaceutical market, as well as an increase in the prices of medicines and in government and social public health costs, which shall hinder any action aimed at ensuring public health and access to medicines.

2. Having in mind the goal of achieving a balance between the patent system and the promotion of public health, ALIFAR could not share the proposal submitted by the delegation of the United States of America concerning patents and health (document SCP/17/11).

First, ALIFAR must point out that it is not correct to state that “the lack of effective patent protection is one factor which prevents the appropriate medicines from reaching the neediest patients in DC and LDCs”. Conversely, there is wide international consensus on the negative implications that the adoption of laws that tend to maximize the strictness of the patent system may have on public health.

This has been emphasized in the WTO Ministerial Declaration on the TRIPS Agreement and Public Health, adopted on November 14th 2001. The Doha Declaration recognizes the gravity of the public health problems experienced by many developing and least developed countries (paragraph 1), stresses the need for the TRIPS Agreement to be part of the wider national and international efforts to address such problems (paragraph 2), recognizes the concerns on the intellectual property effects on medicine prices (paragraph 3), and states that the TRIPS Agreement does not and should not prevent WTO members from taking measures to protect public health and promote access to medicines for all (paragraph 4), while reaffirming the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose (paragraph 4).

In line with this analytical perspective, the WHO's Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH), in its report entitled “Public Health, Innovation and Intellectual Property Rights”, analyzed the diverse effects of intellectual property rights on upstream research, the subsequent development of medical products and the possibility of

ensuring access to them in developing countries, and included, as well, a wide range of recommendations related to compulsory licenses, exceptions to patent rights, pro-competitive measures and access to medicines.⁶

It is to be noted that the report of the Commission on Intellectual Property Rights, Innovation and Public Health of the World Health Organization was expressly acknowledged and adopted by the World Health Assembly in May of 2006.⁷

Second, ALIFAR considers that it is not correct to state that “weakening the patent rights granted to pharmaceutical researchers and manufacturers in certain markets (...) leads manufacturers to keep already developed medicines out of those markets” and that “more goods become available in developing countries when IP rights are strengthened there”.

In this regard, ALIFAR is compelled to point out that the problem of access to medicines in DC and LDCs is not based on the availability or lack of medicines, but in the fact that, when medicines are available, their prices must be affordable for the public and for the national public health budgets.

In this regard, the 14th edition of the report “Untangling the Web of Antiretroviral Price Reductions”, published by the well-known international humanitarian organization Médecins Sans Frontières in July 2011, clearly shows that, in the case of antiretroviral medicines, patents work as strong barriers to medicine access, while the promotion of competitiveness for generic drugs and policies that tend to flexibilize pharmaceutical patent rights has a positive and direct effect on market prices and, therefore, on the extension and strengthening of more and improved public health programs.⁸

Third, ALIFAR considers that the proposal submitted by the Delegation of the United States of America presents a misconception in its attempt to make the expressions “weakening patent protection” and “greater use of flexibilities” equal concepts.

In fact, proposals that seek to make a connection between patents and public health –and development as a whole-, which emphasize the flexibilities of the international patent system, do not attempt, by any means, to make patents “weak”; instead, they emphasize the idea that more patent protection not always implies better and improved patents as well as more innovation and development; instead, they seek to prevent patent protection strictness from increasing out of proportion, which would affect competitiveness and public policies.

Similarly, such proposals intend to guarantee DC and LDCs the widest scope of freedom to outline their own intellectual property systems, as developed countries have always done in the past and continue doing at present.

⁶ Cfr. Commission on Intellectual Property, Innovation and Public Health (CIPIH): *Intellectual Property, Innovation and Public Health*, World Health Organization, Geneva, 2006. See, *inter alia*, recommendations 2.7, 2.9, 2.10, 4.10, 4.13, 4.14, 4.16, 4.18, 4.19, 4.20, 4.23, 4.24, 4.25, 4.26, 4.27, on the need to promote further flexibilities on exceptions and limitations of patent rights and compulsory licenses, and to adopt measures to benefit access to medicines and technology transfer, among other aspects.

⁷ See WHA 59.24. For a further analysis on the resolutions adopted by the World Health Assembly regarding the relationship between the TRIPS Agreement and Public Health see WHA52.19, WHA53.14, WHA56.27, WHA57.14, and WHA60.30. See, also, the institutional website of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG) <http://www.who.int/phi/igwg/en/index.html#>.

⁸ Available at <http://www.doctorswithoutborders.org/publications/article.cfm?id=5448&cat=special-report>.

Fourth, regarding the alleged positive effects of the patent systems in terms of encouraging research and development to create innovative drugs, ALIFAR notes that such incentives have been clearly insufficient to treat a wide variety of diseases that affect DC and LDCs, which leads to the problem of neglected diseases. This only proves that public health, innovation and development policies of the different WTO member countries should not be restricted to proposing a stricter patent system, expecting that such unilateral legislative reforms automatically improve population's health.

Fifth, ALIFAR considers that it is inadequate to analyze the "other factors external to patent protection" that "are at play in limiting the availability of medicines". Such "other factors" exceed the SCP's and WIPO's goals and mandates. The problems of access to medicines not related to intellectual property are analyzed more deeply and exhaustively in other fora. However, WIPO does have the authority and obligation to analyze the relationship between patents and public health. WIPO is naturally linked to the patent system and, by virtue of such connection, it must focus on that relationship. However, this does not imply that WIPO should analyze public health matters in general, if these are unrelated to patents.

Sixth, ALIFAR believes it is necessary to emphasize that measures to promote a more active use of flexibilities are, in fact, useful to improve the availability of medicines.

Compulsory licenses, for instance, have proved their effectiveness to reduce the price of patented drugs and, the mere fact that there is a possibility of using them has led to more fruitful negotiations between countries and patentees.⁹ Similarly, the adoption of strict provisions on patentable subject matter by WTO member countries has proved that it is possible to implement policies aimed at preventing patent evergreening and patents on minor innovations that only affect competitiveness in a negative way.¹⁰

Seventh, regarding the alternative approaches proposed by the Delegation of the United States of America to improve the availability of medicines, ALIFAR considers that it is not possible to affirm that those approaches are "more useful" than the use of the flexibilities at an international level. Instead, it is only possible to affirm that they are just "useful" and that they can be used as a complement to other public policy tools.

Without prejudice thereof, ALIFAR needs to address the implementation problems that some of the above mentioned "alternative approaches" present. In fact, patent pools prove to be limited since they strongly depend on the patentees' will, which has not been positive in all the cases. This is the case of Johnson & Johnson, a corporation that has recently announced its refusal to enter into negotiations with the Medicine Patents Pool created by UNITAID, which decision will affect the access to three key antiretroviral drugs.¹¹ At the same time, the tiered pricing program also depends too much on the patentee's will, with the difficulties that this implies. In this regard, the policies of certain pharmaceutical companies to exclude developing countries from their tiered pricing programs are widely known.¹²

⁹ For example, since 2001, Brazil has resorted to compulsory licenses on several occasions to obtain price reductions on antiretroviral medicines. See Shadlen, Kenneth C. (2009) "The politics of patents and drugs in Brazil and Mexico: the industrial bases of health policies", *Comparative politics*, 42 (1). pp. 41-58.

¹⁰ E.g., article 3 (d) of India's patent law.

¹¹ <http://www.ip-watch.org/2012/01/12/johnson-johnson-denies-patent-pool-licences-for-hiv-medicines-for-the-poor/>.

¹² Regarding antiretroviral drugs, the discriminations included in the tiered pricing policies are explained in the report by Medicinès Sans Frontières "Untangling the Web of Antiretroviral Price Reductions", above mentioned.

3. The proposal submitted by the delegation of the U.S.A. also includes, in their enforcement section, the subject of the trade of falsified and substandard drugs, which quality is below the standards of health regulations. The national member associations of ALIFAR and their associated laboratories have been supporting the efforts undertaken by the national authorities of their respective countries to eliminate this true scourge. Also, ALIFAR has been actively involved in all the actions and efforts promoted by the Pan American Network for Drug Regulatory Harmonization / WG – Combat Counterfeit Medicines.

Without prejudice of the above, ALIFAR considers that the topic of trade of counterfeit and substandard medicines widely exceeds the authority vested in SCP and WIPO and, also, is absolutely unrelated to patents and the enforcement thereof. In fact, we should remember that “a counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, with insufficient active ingredient or with fake packaging”.¹³ Therefore, by definition, the problems with counterfeit and substandard medicines affect both patented drugs as well as medicines in the public domain. For such purposes, fighting counterfeit drugs does not demand the enforcement of intellectual property regulations but, instead, the strict enforcement of laws and regulations on manufacturing and marketing of drugs, including criminal rules, if existing in the local legislations.

On the other hand, ALIFAR warns about the dangers of assimilating an eventual drug patent infringement under the legal concept of counterfeit or substandard drugs trading which underlies in the U.S.A. proposal. An important cornerstone of the patent system in the area of public health is the role of competitors in seeking non-infringing alternatives to a drug patent or a patent being declared invalid in order to offer consumers alternatives with the same therapeutic efficacy and without paying monopoly prices. This policy is incorporated in the legal systems of many WIPO members and has been particularly promoted by the United States¹⁴ with significant success in terms of having access to medicines before the expiration of their patent term, and of savings for consumers and governments.¹⁵

The fact of including medicines authorized by the competent health authority under the category of “counterfeit drugs”, which challenge the validity or infringement of a patent, would seriously endanger the use of policies such as the ones described above, which have been successfully implemented by many countries of the international community, including U.S.A.

4. Among the wide spectrum of issues that link patents to public health, ALIFAR is particularly concerned about the extension of patenting practices usually known as “evergreening” and, in particular, about the proliferation of pharmaceutical patents, generally obvious, awarded on minor modifications on drugs or on drugs manufacturing processes. We consider that such phenomenon seriously affects competition and, as a direct consequence thereof, it has negative effects on the access to medicines and on public health policies.

Therefore, ALIFAR considers it necessary that SCP makes progress in the approval of the work program proposed by the South African Delegation, on behalf of the African Group and the

¹³ WHO, Department of Essential Drugs and Other Medicines, *Counterfeit Drugs – Guidelines for the development of measures to combat counterfeit drugs*, Geneva, 1999, p. 8.

¹⁴ See *Drug Price Competition and Patent Term Restoration Act of 1984*, Pub. L. No. 98-417, 98 Stat. 1585h

¹⁵ See Federal Trade Commission, *Generic Drug Entry Prior To Patent Expiration: An FTC Study 15 (2002)*, p. 9, available at <http://www.ftc.gov/reports/index.shtm#2002>; and Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry (1998)* p. 28, available at <http://www.cbo.gov/publication/10938>.

Development Agenda Group (document SCP/16/7), without subscribing the proposal of the Delegation of the United States of America (document SCP/17/11).

In the same sense, ALIFAR agrees with the inclusion of the preventions and activities proposed by The Third World Network (document SCP/17/INF/3, paragraphs 55 through 57) in the SCP work program.

Also, with a view to strengthening and collaborating with the SCP work program proposed by the Delegation of South Africa, ALIFAR emphasizes that the frame study to be designed by eminent independent experts, within the frame of the so-called “Element I”, should also cover an analysis on costs and benefits to public health and practices on the admissibility of the following types of claims and/or pharmaceutical patents.¹⁶

- (iv) Selection patents.
- (v) Methods of treatment
- (vi) Use claims and second pharmaceutical indications
- (vii) Pharmaceutical formulations and compositions.
- (viii) Combinations of active principles.
- (ix) Dosage forms.
- (x) Salts, ethers and esters.
- (xi) Polymorphs.
- (xii) Analogy processes
- (xiii) Enantiomers
- (xiv) Active metabolites and prodrugs.

MEDICINES PATENT POOL (MPP)

At the Sixteenth Session of the Standing Committee on the Law of Patents, under the Agenda item on “Patents and Health”, it was agreed that Member States and Observers would be invited to submit any comments to the Committee by February 28, 2012.¹⁷ The present submission responds to that invitation and provides the perspective of the Medicines Patent Pool (“The Pool”) on the issues being discussed under that agenda item, with a specific focus on HIV/AIDS.

Patenting of HIV Medicines in Developing Countries

One of the issues raised by WIPO Member States during the discussion on “Patents and Health” is the extent to which needed medicines are patented in developing countries and the impact of such patents on access to medicines. Since its establishment in 2010, the Pool has made considerable efforts to collect up-to-date patent information on HIV medicines to have a clear picture of what is patented where.

The data gathered by the Pool, with the collaboration of WIPO and many national and regional patent offices, has been published in the Patent Status Database on Selected HIV Medicines, available on the Pool’s website.¹⁸ The data shows that many HIV medicines have been widely patented in developing countries. Patents have been granted on the drug compounds, on new forms of drug compounds, on new formulations (such as formulations appropriate for children),

¹⁶ The work paper entitled “Guidelines for the Examination of Pharmaceutical Patents. Developing a Public Health Perspective”, by Carlos Correa, sponsored by the WHO, ICTSD and UNCTAD, 2006, has addressed the analysis of the topics mentioned in these comments. We understand that the SCP is an adequate frame to continue and intensify such analysis.

¹⁷ See document SCP/16/7.

¹⁸ <http://www.medicinespatentpool.org/LICENSING/Patent-Status-of-ARVs>.

on manufacturing processes and on combinations of several drugs into one pill.¹⁹ Many patent applications are also pending in many developing country jurisdictions and may be granted sometime in the future.

Data gathered by the Pool also shows an increase in the number of developing countries in which newer medicines for the treatment of HIV are patented. While patents for many of the older compounds have expired in many jurisdictions, or were never filed or granted, newer HIV medicines are more widely patented, including in countries where generic manufacturers for HIV medicines are based. Examples of such medicines are etravirine, raltegravir, rilpivirine and several investigational drugs. This is likely due to changes in national patent laws in many countries following the entry into force of the TRIPS Agreement, as well as to changing patenting practices of applicants.²⁰

Among the medicines for HIV that are included in the WHO Model List of Essential Medicines (widely referred to as the EML),²¹ some are patented in several developing country jurisdictions.²² In addition, there are medicines that have so far not been included in the EML that are also patented or for which patent applications are pending, including those currently recommended by the WHO as part of a third-line regimen for the treatment of HIV.²³

The patent landscape report undertaken by WIPO on key HIV medicine ritonavir confirms the trend of widespread patenting of ARVs in developing countries.²⁴ It identified 805 patent families claiming ritonavir, many of which are either pending or granted in some developing countries. The landscape also noted that at least 400 such patents were on combinations of ritonavir with other compounds.

The changing patent landscape for HIV medicines is at the heart of the decision taken by UNITAID to support the establishment of the Medicines Patent Pool in 2010, an initiative mentioned by a number of delegations during the discussions on “Patents and Health” in the Committee. The Pool’s mandate is to negotiate public-health-oriented voluntary licences with a view to enhancing access to patented HIV medicines and promoting the development of fixed-dose combinations and adapted formulations for the treatment of HIV.²⁵ As a mechanism to enhance innovation and access, it must be seen as complementary to other mechanisms and initiatives that are being discussed by the Committee, including the use of flexibilities available under international agreements on intellectual property. Its success depends on the voluntary participation of patent holders that need to be willing to agree to licences that meet the public health needs of developing countries.

¹⁹ It is important to note that combinations of various products into a single pill (known as “fixed dose combinations” or FDCs) are particularly important for the treatment of HIV and a large number of patents on FDCs have been granted or are pending in many developing countries.

²⁰ A detailed analysis of the patent status of different HIV medicines in developing countries is available in the working paper “ARV Priority List for the Medicines Patent Pool” available at <http://www.medicinespatentpool.org/WHAT-WE-DO/Target-Medicines>.

²¹ According to the WHO, “Essential medicines are those that satisfy the priority health needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness”.

²² Examples include atazanavir, efavirenz, lopinavir, ritonavir and tenofovir disoproxil fumarate.

²³ These include darunavir, etravirine and raltegravir.

²⁴ See WIPO, *Patent Landscape Report on Ritonavir*, 2011.

²⁵ Since its establishment in 2010, the Pool has signed agreements with two patent holders and is currently in negotiations with five others. The agreements have been published on the website of the Medicines Patent Pool.

Patent Status Databases

One of the proposals being discussed by the Committee concerns the development of patent status databases for diagnostic tools and medicines in relation to ten diseases.²⁶ This is an area in which the Pool has some experience that may be of interest to the Committee.

In April 2011, the Pool published its patent status database on HIV medicines. It covers 24 compounds and approximately 69 developing countries. Obtaining accurate, up-to-date patent status data in many developing countries is often a difficult task as such information is not readily available from public databases. The Pool, therefore, initially worked on identifying the most important patents relating to 23 antiretroviral products (subsequently expanded to 24) and then collaborated with WIPO and national and regional patent offices to obtain patent status information on those patents. The database is periodically updated with information obtained from the relevant patent offices. Also, as new HIV medicines are developed, they too are added to the database.

The Pool's database is limited to one disease: HIV; and to one type of medical technology: antiretroviral medicines. It only includes those patents considered to be most important in relation to each medicine. Its geographical coverage is gradually expanding, as data is obtained from more patent offices or other sources.²⁷ But despite its limitations, it has proven that with the collaboration of patent offices, this kind of database is not only feasible, but also extremely useful. The database is being used today by a wide range of actors in the public health field including UN agencies, donor agencies, civil society institutions and many others. Initiatives of this kind can play an important role in enhancing the transparency of the patent system and are of great importance for public health actors around the world.

THIRD WORLD NETWORK (TWN)

Introduction

The Africa Group and the Development Agenda Group (DAG) presented a specific proposal on Patents and Public Health during the 16th session of the SCP (SCP/16/7). This proposal received significant support from a number of countries as well as non-governmental organizations. The Third World Network also made a submission supporting the proposal presented by the Africa Group and the DAG.²⁸

In response to this proposal, the United States submitted its own proposal (SCP/17/11) during the 17th session. This proposal is disappointing as it makes a number of frivolous observations and attempts to trivialise the impact of patents on access to medicines. Further by raising issues such as substandard/unsafe medicines which are not relevant to the mandate of the SCP, the US is attempting to confuse matters and distract member states from discussing the linkages between patents and public health, and possible WIPO activities in this regard raised in the proposal put forward by the Africa Group and DAG.

Comment on specific issues raised by the US

The US proposal argues that a number of factors affect the availability of medicines in developing countries. While this may be the case, it is also important to acknowledge that the "price" factor can singularly be determinative of life or death, where a deadly disease is

²⁶ Paragraph 10, document SCP/16/7.

²⁷ The most recent additions to the database are Mongolia and Pakistan.

²⁸ See http://www.wipo.int/scp/en/meetings/session_17/health/twn.pdf.

treatable.²⁹ It can determine whether patients will have or will not have access to the treatment it requires.

Today the world has been able to scale-up HIV/AIDS treatment largely due to the fact that the price of ARVs dropped dramatically in the past decade from more than US\$10,000 per person per year (pppy) in 2000 to less than \$150 pppy today. This price reduction has made lifesaving drugs accessible to millions of people in developing countries. By the end of 2010, 6.6 million people in low- and middle-income countries – 47% of the total number eligible – had access to antiretroviral therapy, a dramatic increase from the 300 000 (2.7% of those eligible) on antiretroviral therapy in 2002.³⁰

This is very much the result of competition from suppliers of generic drugs principally from India. The transitional period in place in India allowed firms to produce affordable generic versions of ARVs and even more importantly to produce easier to administer combinations of antiretrovirals not already available from brand-name companies. This single example shows how the removal of patent barriers as well as the use of TRIPS flexibilities has had an enormous positive impact in improving access to medicines in developing countries.

To support its proposition that many other factors and not patents directly affect the availability of medicines, the US proposal relies on WHO's List of Essential Medicines, adding that only about 4% of the medicines are presently protected by patents. It is indeed disappointing that despite evidence of how patents on medicines affect access to affordable medicines, the US has chosen to insist that patents don't matter. It is a well-known fact that drugs for HIV/AIDS were only added to the EML after extensive campaigning by AIDS activists and that the WHO Model List is underinclusive because it excludes some expensive newer treatments that remain covered by patents such as in the case of cancer treatments.

In addition, just because other factors may affect access, this does not preclude the need to also address patent barriers. In fact, while US refers to WHO's EML, WHO Secretariat itself has recognized that patents can impact access to medicines and has issued/commissioned various publications on the matter that encourage the use of TRIPS flexibilities to overcome the patent barrier. See http://www.who.int/phi/publications/category_ip_trade/en/index.html for a full list of WHO publications on intellectual property and health.

It is also worth recalling that the Doha Declaration on TRIPS and Public Health itself recognizes "the concerns about its [TRIPS Agreement] effects on prices".

In recognition of the potential adverse effect of IP on public health, the Declaration states: "We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all." The Declaration also reaffirms the right of WTO member states to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted, the right to determine what constitutes a national emergency or other circumstances of extreme urgency (mentioned in Article 31 of the TRIPS Agreement) and the freedom to determine its own regime of exhaustion of rights.

²⁹ WHO member states have agreed in the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property adopted through WHA 61.21 in 2008 that "The price of medicines is one of the factors that can impede access to treatment" (para 11).

³⁰ DOHA+ 10 TRIPS Flexibilities and Access to Antiretroviral Therapy: Lessons from the Past, Opportunities for the Future; UNAIDS Technical Brief 2011 available at http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2260_DOHA+10TRIPS_en.pdf.

Moreover the simple fact that a number of governments have taken action to override the patent barriers through the use of public health relevant flexibilities (e.g. transitional period, strict interpretation and application of patentability criteria including prohibiting patenting of new uses of pharmaceuticals, parallel importation, exception to patent rights, compulsory license and government use orders) to improve access to medicines is evidence that patents can be a barrier to access to medicine in a particular country.

Role of public health relevant TRIPS flexibilities in improving access to medicine

The US proposal undermines the role of TRIPS flexibilities particularly compulsory licensing in improving access to affordable treatments. Clearly the US has deliberately chosen to ignore concrete evidence available today³¹ on the positive impact of the use of public health relevant flexibilities on public health.

The example highlighted above provides solid evidence on how the use of transitional period in India facilitated the availability of generic medicines, which in turn enabled scaling up of HIV/AIDS treatment. Use of flexibilities such as pre-grant opposition and prohibition on patenting of new uses of existing pharmaceuticals available in India's Patent Act has also facilitated access. For instance, in March 2006, a coalition of public-interest groups filed an opposition against GlaxoSmithKline (GSK)'s application for a patent on Combivir (a FDC of zidovudine+lamivudine) arguing that the product is a combination of two drugs in one pill and thus not entitled to a patent under the Indian patent law. Following filing of the pre-grant opposition, GSK withdrew its pending patent applications in India as well as in other countries, thus enabling improved access to generic versions of Combivir.

A number of countries have also used compulsory licensing to overcome the patent barrier and improve access to medicines. This includes Malaysia, Zimbabwe, Brazil, Thailand, Indonesia, Ecuador and evidence available suggests that overall the compulsory licenses improved access to medicines in the country issuing the license by either allowing the production or importation of more affordable generic versions of medicines.³²

For instance Malaysia's issuance of a government use order to import three ARVs including Combivir from India to supply public hospitals led to an average cost reduction of about 81% per month per patient for the Ministry of Health.³³ The number of patients that could be treated in government hospitals and clinics increased from 1,500 to 4,000. The government-use order also resulted in reduction of the prices of the originator companies. By 2004, GSK reduced its ARV prices by 53–80% compared with 2001 prices, and Bristol-Myers Squibb dropped the price of its product didanosine (100mg formulation) by 49% and the price of the 25mg formulation by 82%.

In 2002, Zimbabwe's Minister of Justice, Legal and Parliamentary Affairs issued a notice declaring a period of emergency on HIV/AIDS for the purpose of enabling "The State or a

³¹ See for e.g. South Centre/WHO. The use of flexibilities in TRIPS by developing countries: can they promote access to medicines? Geneva: South Centre/WHO, 2006; DOHA+ 10 TRIPS Flexibilities and Access to Antiretroviral Therapy: Lessons from the Past, Opportunities for the Future; UNAIDS Technical Brief 2011 available at http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2260_DOHA+10TRIPS_en.pdf.

³² Country Experiences in Using TRIPS Safeguards, WHO, 2008 available at http://www.searo.who.int/LinkFiles/IPT_Briefing_note_4_country_experiences.pdf.

³³ Chee Yoke Ling, "Malaysia's Experience in Increasing Access to Antiretroviral Drugs: Exercising the 'Government Use' Option", Third World Network, IPR Series 9, available at <http://www.twinside.org.sg/title2/IPR/pdf/ipr09.pdf>.

person authorised in writing by the Minister to make or use any patented drug, including any antiretroviral drugs, used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS related conditions; and/or to import any generic drug used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS related conditions.” Following the emergency declaration, in April 2003, Varichem Pharmaceuticals [Pvt] Ltd, a Zimbabwe-registered company, was granted authority to use relevant patents. Under the terms of this authorization, Varichem was to “produce antiretrovirals or HIV/AIDS-related drugs and supply three quarters of its produced drugs to state-owned health institutions”.

At the start of production, Varichem reportedly agreed to supply the government with its generic version of Combivir at US\$ 15 per patient per month and to meet 75% of the government needs for this drug. Two other companies later received authorization. Datlabs, a pharmaceutical manufacturer, was authorized to import antiretroviral medications from Ranbaxy in India, while Omahn, an agent for the Indian manufacturer Cipla, was authorized to import Cipla products.³⁴

The Government of Brazil has used compulsory licensing strategically in price negotiations, and it has also issued licences when price negotiations failed. Using the threat of compulsory licensing, the Brazilian Government negotiated significant price reductions for efavirenz and nelfinavir in 2001, lopinavir in 2003, the combination of lopinavir and ritonavir in 2005, and tenofovir in 2006. It has been estimated that the Brazilian Government’s policies, including the use of TRIPS flexibilities have saved the country about US\$ 1.2 billion on antiretroviral purchasing costs between 2001 and 2005.³⁵

In 2007 after protracted negotiations with the patent holder, Brazil issued a compulsory licence for efavirenz an important antiretroviral drug used by a third of Brazilians on treatment through the national programme. It is reported that after the licence was issued, the price dropped from US \$1.60 per dose to US \$0.45 per dose for the imported generic version of the drug.³⁶

In late 2006 and early 2007 Thailand issued compulsory licences for a number of pharmaceutical products: efavirenz, lopinavir/ritonavir and clopidogrel (a drug used for heart disease). It is reported that by early 2008 the number of patients using lopinavir/ritonavir had tripled. In early 2008 the Thai Government issued additional compulsory licences for letrozole (a breast cancer drug), docetaxel (a breast and lung cancer drug) and erlotinib (a drug used for treating lung, pancreatic and ovarian cancer).³⁷

Compulsory licenses have not only benefitted developing countries but also developed countries. For instance Canada made extensive use of compulsory licensing to promote the production of generic pharmaceuticals, and this scheme reportedly produced some of the lowest consumer drug prices in the industrialized world. Between 1969 and 1992, there were 1 030 applications to import or manufacture medicines under such licences, of which 613 were granted.³⁸

³⁴ DOHA+ 10 TRIPS Flexibilities and Access to Antiretroviral Therapy: Lessons from the Past, Opportunities for the Future; UNAIDS Technical Brief 2011 available at http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2260_DOHA+10TRIPS_en.pdf.

³⁵ See http://www.who.int/phi/phi_trips_policybrief_en.pdf.

³⁶ See http://www.who.int/phi/phi_trips_policybrief_en.pdf.

³⁷ See http://www.who.int/phi/phi_trips_policybrief_en.pdf.

³⁸ ICTSD/UNCTAD, 2003. Non-voluntary licensing of patented inventions: historical perspective, legal framework under TRIPS, and an overview of the practice in Canada and the USA available at <http://www.iprsonline.org/resources/docs/Reichman%20-%20Non-voluntary%20Licensing%20-%20Blue%205.pdf>.

In March 2007, the Italian Competition Authority ordered Merck & Co. Inc. to provide free licences for the manufacture and sale in Italy of the active ingredient finasteride (used in the treatment of prostate hypertrophy) and related generic drugs.³⁹ In an earlier investigation in 2005, the Competition Authority had already obliged Merck to grant licenses for its antibiotic combination imipenem+cilastatin, in order to rectify alleged abuse of a dominant market position, while in February 2006 its investigations led GSK to license its migraine drug sumatriptan succinate.

The above examples clearly show that US's assertions about TRIPS flexibilities including compulsory license are baseless and that these flexibilities can be an effective mechanism for promoting access to medicines and boosting local production capacity. In fact while the US is discouraging the use of compulsory license, the US itself has issued several judicial compulsory licenses following the *eBay v. MercExchange*, 547 U.S. 388 (2006) decision, whereby in cases pertaining to patent infringement of medical devices or inventions, courts have denied injunctive relief and granted monetary damages and royalties instead.⁴⁰

The adverse effect of IP on the entry of generic competition and prices as well as the value of using TRIPS flexibilities to promote access to medicines has also been observed in international instruments as well as by various international organizations.⁴¹

For instance the WHO Global Strategy and Plan of Action on public health, innovation and intellectual property (GSPOA) adopted by all WHO member states including the US in 2008 through resolution WHA 61.21 states in para 12 that: "International intellectual property agreements contain flexibilities that could facilitate increased access to pharmaceutical products by developing countries. However, developing countries may face obstacles in the use of these flexibilities. These countries may benefit, inter alia, from technical assistance."

This same instrument calls on for the provision of "technical support...to countries that intend to make use of the provisions contained in the Agreement on Trade- Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the TRIPS agreement, in order to promote access to pharmaceutical products." (see para 5.2 of GSPOA).

The UNGA Political Declaration on HIV/AIDs adopted in 2011⁴² also states: "Commit to remove before 2015, where feasible, obstacles that limit the capacity of low- and middle-income countries to provide affordable and effective HIV prevention and treatment products, diagnostics, medicines and commodities and other pharmaceutical products, as well as treatment for opportunistic infections and co-infections, and to reduce costs associated with life-long chronic care, including by amending national laws and regulations, as deemed appropriate by respective Governments, so as to optimize: (a) The use, to the full, of existing flexibilities under the Trade-Related Aspects of Intellectual Property Rights Agreement specifically geared to promoting access to and trade of medicines..."

³⁹ See <http://www.twinside.org.sg/title2/health.info/twninfohealth086.htm>.

⁴⁰ See James Love, The CoreValve compulsory license on patent to treat aortic stenosis, (Sept. 1, 2011), <http://keionline.org/node/1218>; Anne Mira Guha, The Johnson & Johnson Acuvue Compulsory License (Sept. 1, 2011), <http://keionline.org/node/1219>; Anne Mira Guha, U.S. Compulsory licensing of medical inventions as a limit on remedies under *eBay v. MercExchange*, (June 7, 2010), <http://keionline.org/node/862>.

⁴¹ See DOHA+ 10 TRIPS Flexibilities and Access to Antiretroviral Therapy: Lessons from the Past, Opportunities for the Future; UNAIDS Technical Brief 2011 available at http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2260_DOHA+10TRIPS_en.pdf.

⁴² <http://daccess-dds-ny.un.org/doc/UNDOC/LTD/N11/367/84/PDF/N1136784.pdf?OpenElement>.

“Urge relevant international organizations, upon request and in accordance with their respective mandates, such as, where appropriate, the World Intellectual Property Organization, the United Nations Industrial Development Organization, the United Nations Development Programme, the United Nations Conference on Trade and Development, the World Trade Organization and the World Health Organization, to provide national Governments of developing countries with technical and capacity-building assistance for the efforts of those Governments to increase access to HIV medicines and treatment, in accordance with the national strategies of each Government, consistent with, and including through the use of, existing flexibilities under the Trade-Related Aspects of Intellectual Property Rights Agreement, as confirmed by the Doha Declaration on the TRIPS Agreement and Public Health..”

The 2011 UNGA Political Declaration on the Prevention and Control of Non-communicable diseases also notes the link between access and use of flexibilities:

“45. Promote, establish or support and strengthen, by 2013, as appropriate, multisectoral national policies and plans for the prevention and control of non-communicable diseases, taking into account, as appropriate, the 2008-2013 WHO Action Plan for the Global Strategy for the Prevention and Control of Non-communicable Diseases, and the objectives contained therein and take steps to implement such policies and plans; (p) Promote access to comprehensive and cost-effective prevention, treatment and care for the integrated management of non-communicable diseases, including, inter alia, increased access to affordable, safe, effective and quality medicines and diagnostics and other technologies, including through the full use of trade-related aspects of intellectual property rights (TRIPS) flexibilities”.

In 2002, the Global Fund board, specifically adopted an approach designed to encourage countries to use TRIPS flexibilities to achieve the lowest possible price for products of assured quality.⁴³

UNITAID, whose mission is to contribute to scaling up access to medicines for HIV/AIDS, tuberculosis and malaria in low-income countries also provides in its constitution that “Where intellectual property barriers hamper competition and price reductions, it will support the use by countries of compulsory licensing or other flexibilities under the framework of the Doha declaration on the Trade-Related Aspects on Intellectual Property Rights (TRIPS) Agreement and Public Health, when applicable.”⁴⁴

Comment on alternative approaches proposed

The US argues that alternative approaches such as voluntary licensing and tier pricing are preferred to use of flexibilities in providing availability of medicines.

Voluntary licences are contract negotiations between private parties. Terms in a voluntary licence may set price ranges, or include other terms that maintain prices at or near the same level as those offered by the patent holder. Or, terms may limit how many patients or which categories of patients are eligible to benefit from the lower prices provided by the licensee. In short, voluntary licensing arrangements depend crucially on the terms of the licence.

For instance in the case of the voluntary licenses developed under the Medicines Patent Pool, there are certain restrictions attached to the licenses. This includes that licences to manufacture are granted only to Indian manufacturers and a number of developing countries

⁴³ See the Report of the Third Global Fund Board Meeting held in October 2002 available at <http://www.theglobalfund.org/en/board/meetings/third/>.

⁴⁴ See Article 1.2 of the UNITAD Constitution. http://unitaid.eu/images/governance/en_constitution_rev6july2011.pdf.

with high HIV burdens are excluded from the scope of the licences. Also MPP acknowledges that “it is not in a position to dictate terms and conditions to licensors”.⁴⁵ Further in the case of MPP, in Dec. of 2011, Johnson & Johnson refused to license its patents on the HIV drugs to the MPP.

In short in a voluntary licensing arrangement much depends on the terms of the license and this in turn depends on the willingness of the patent holder. It is also worth noting the observation made on voluntary licensing in a report of WHO mission i.e. that “Voluntary licensing arrangements, at the discretion of the patent holder, are usually made for strategic reasons (e.g. market entry) rather than as price gestures and they may, in certain cases, not entail any price reduction at all. In developing countries, due to the lack of negotiating capacity of the licensee, voluntary licensing does not always translate into price reductions.”⁴⁶

The US proposal also promotes “tier-pricing” as a solution. On this it is worth noting the observation made in the WHO Commission Report on Intellectual Property, Innovation and Public Health i.e.

“The differential pricing approach undertaken by pharmaceutical companies varies significantly in response to price elasticity and other factors. Where they exist, open market prices usually respond to local market conditions. Companies do generally set different prices that take account of market conditions, willingness to pay and local regulations. Companies may be concerned that lower priced drugs in low income nations may be channelled back, one way or the other, to higher income countries, undermining their profits there even if, as is currently the case in most of the developed world, patented products from elsewhere (known as parallel trade – see below) are generally not permitted to be imported. Even if there is no physical leakage of product between different markets, they may be concerned that governments in developed countries, under pressure from drug purchasers, may use prices in low income countries as a reference point for their own price setting or purchasing decisions. Moreover, because incomes are very unequally distributed in most developing countries, companies may find it best for their profitability to concentrate only on high income segments in developing countries, in particular because it is more difficult to apply a differential pricing policy within developing countries than it is between them.”⁴⁷

This comment clearly shows that tier-pricing is an inadequate tool for resolving the access problems of a particular country.

Intellectual Property, Public Health and Innovation

The US also argues in its paper that “weakening the patent rights” “in certain markets not only removes or reduces the incentive to develop new medicines but also leads manufacturers to keep already developed medicines out of the market” adding that “a new drug is more likely to be launched in a country where patent protection is strong”.

This argument has simply no basis. Firstly no data is presented to support the co-relation between the use of flexibilities and reduced incentive for development of new products. Secondly it is now acknowledged that the existing incentive system is unable to address the R&D needs of many people living in developing countries.

⁴⁵ See <http://www.medicinespatentpool.org/LICENSING/Current-Licences/Medicines-Patent-Pool-and-Gilead-Licence-Agreement/Q-and-A-Gilead-Licences#14>.

⁴⁶ Improving Access to Medicines in Thailand: The use of TRIPS flexibilities, Report of a WHO Mission, 31 January-6 February 2008, available at <http://www.moph.go.th/hot/THAIMissionReport%20FINAL15feb08.pdf>

⁴⁷ See <http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf>, pg. 129.

On this an expert WHO report has noted that: “Where there is no purchasing power – either on the part of the government or the patient – the market is not an adequate determinant of value. Thus too few resources are likely to be devoted to developing drugs, vaccines and diagnostics that address the needs of people living in developing countries, because they are inherently unprofitable, or the relationship between investment and risk, in relation to potential profit, is unattractive to the private sector. The market alone, and the incentives that propel it, such as patent protection, cannot by themselves address the health needs of developing countries. That is the principal reason why new initiatives have sprung up in recent years, such as public-private partnerships.”⁴⁸

Thirdly just having a new drug available makes little sense if it is unaffordable to the majority of the patients that need the drug. Thus to ensure that the needed pharmaceuticals are available to the majority of people in developing countries it is important to use all measures available to reduce the cost of the product and to make it affordable.

The US proposal also calls for a study to evaluate the role of patent protection in providing incentives for research and development and in fostering technology transfer necessary to make generic and patented medicines available in developing countries.

In 2003, the World Health Assembly created a Commission that undertook a thorough review of the linkages between intellectual property rights, innovation and public health and emerged with a detailed report on this matter in 2006.⁴⁹ This report is widely known as the CIPIH report. This report also led to the adoption in 2008 of a Global Strategy and Plan Of Action on public health, innovation and IP (GSPOA).⁵⁰

On the relationship between patents and R&D in the context of developing countries, the CIPIH report notes: “Intellectual property rights have an important role to play in stimulating innovation in health-care products in countries where financial and technological capacities exist, and in relation to products for which there are profitable markets. However, the fact that a patent can be obtained may contribute little or nothing to innovation if the market is too small or scientific and technological capability inadequate. Where most consumers of health products are poor, as are the great majority in developing countries, the monopoly costs associated with patents can limit the affordability of patented health-care products required by poor people in the absence of other measures to reduce prices or increase funding. Because the balance of costs and benefits of patents will vary between countries, according to their level of development and scientific and technological infrastructure, the TRIPS agreement allows countries some flexibility in finding a balance more appropriate to their circumstances.”

Noting the extensive work done in WHO to investigate the linkages between IP, public health and innovation as well the adoption of the GSPOA, the SCP should build on this work as per its mandate rather than to duplicate it.

Comment on Enforcement

The US in its proposal raises the issue of falsified and other substandard medicines adding that the SCP work program should address to what extent the presence in a market of falsified medicines hinders the availability of genuine medicines, both generic and patented.

The issue of falsified and substandard medicines has absolutely NO connection whatsoever with patent issues and thus WIPO does not have the mandate to discuss this issue. A

⁴⁸ See <http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf>.

⁴⁹ See <http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf>.

⁵⁰ http://apps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf.

pharmaceutical product is granted a patent on the basis whether it fulfills the patentability criteria used nationally and not on the basis of quality and safety of medicines.

Further the topic of proliferation of poor quality medicines is the mandate of the World Health Organization. In the WHO there is already an ongoing intergovernmental process that is working on this matter.

US attempts to raise this issue in the SCP is devious as it is aimed at confusing issues, and to distract the attention of the SCP from the actual issues that the SCP should be working on.

US suggestion that WIPO analyse all factors that affect the availability of off-patent medicines is absolutely ludicrous. As noted by the US, these factors are “unrelated to patents” and thus definitely not within the mandate of the SCP or of WIPO. Accommodating US suggestion would basically expand the mandate of WIPO to all other health issues.

Comment on US's specific Proposals

First the US proposes that WHO be invited to make a presentation to the SCP on the availability of generic medicines in DC/LDCs, on the non-patent barriers to availability of safe and effective medicines that are encountered in many countries, and on the effect of falsified medicines, both generic and patented, on the availability of proper medicines. This is aimed at putting “in context the potential effect of patents, as compared to the effect of other factors, on the availability of medicines”.

This proposal of the US makes little sense as US is proposing inviting WHO to present at the SCP on issues SCP has simply no mandate to work on while refusing to discuss patent issues that SCP has a mandate on. Clearly it is an attempt to trivialize the impact of patents and to avoid any discussion on the impact of patents on public health.

Second - The US proposal also calls for a study to evaluate the positive role of patent systems in providing lifesaving medicines to developing countries adding that the study would evaluate the role of patent protection in providing incentives for research and development and in fostering technology transfer necessary to make generic and patented medicines available in developing countries.

The study proposed by the US is one-sided as it focuses only on the positive role of the patent systems. Further it has been noted above that in 2003, the World Health Assembly created a Commission that undertook a thorough review of the linkages between intellectual property rights, innovation and public health and emerged with a detailed report on this matter in 2006.⁵¹ This report is widely known as the CIPIH report. This report also led to the adoption in 2008 of the GSPOA mentioned above.

Noting the extensive work done in WHO to investigate the linkages between IP, public health and innovation as well the adoption of the GSPOA, the SCP should build on this work as per its mandate rather than to duplicate the work.

Third- The US proposes conducting a comprehensive study to examine the availability of lifesaving medicines that are not protected by patents, and the reasons for their lack of availability adding that an important factor to be reviewed is the effect of falsified medicines, which circumvent any regulatory and enforcement regime. In support of its proposal the US argues that the availability of safe and effective medicines is a multifaceted problem and that informed analysis on how the patent system may or may not affect the availability of medicines is only possible with an understanding of these additional factors that affect the problem.

⁵¹ See <http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf>.

As has been noted above, this proposal of the US goes beyond the mandate of the SCP and should not be accepted. The proposal is about examining issues that have nothing to do with the patent system. The US argues that “the SCP would not be expected to take action on these non-patent issues which are not within its mandate but would benefit from an understanding of where its action fits within the broader range of factors influencing access to medicines”.

It has been mentioned above that just because other factors may affect access, this does not preclude the need to address issues that arise in the context of patents and public health. Thus it makes little sense to discuss issues that the SCP has no mandate to work and that has nothing to do with the patent system.

It is strange that the US only wants to examine availability of medicines not protected by patents. This approach is selective. It also suggests that if patients don't have access to affordable medicines due to patents, and die as a result, this is not an issue that concerns the US.

Conclusion

As noted above the US proposal is based on frivolous points aimed at trivialising the issue of the impact of patents on access to medicines. In addition, the proposals made by the US falls outside the mandate of the SCP and thus should not be accepted.

On the other hand, the proposals of the Africa Group and Development Agenda Group should be adopted. In its earlier submission, the Third World Network had also made a number of observations on the proposal of the Africa Group and DAG and provided additional proposals for consideration. We reiterate those observations and proposals.

Below are some brief inputs on the joint proposal of the Africa Group and DAG:

(i) On Element 1 pertaining to Studies, we welcome the proposal for a framework study. However, to ensure that the experts are fully informed about the challenges and constraints faced in using the flexibilities, we would also urge that Member states ensure that the experts commissioned to undertake the framework study do obtain inputs from public interest civil society groups by way of a public hearing as well as written submissions through web-based hearings. Civil society participation from developing countries to attend the public hearing should be facilitated with funding support from WIPO.

(ii) On Element II pertaining to Information Exchange, we are supportive of proposals contained in paragraph 9 to 12. These proposals (e.g. on developing a database on the patent status in WIPO member states (see para 12) are indeed justified in view of the challenge of information asymmetry faced by developing countries.

(iii) On Element II on technical assistance, we welcome the call to develop targeted technical assistance program following from the outcomes of the studies and information exchange. However we should also stress on the need to avoid conflicts of interest and to have proper reporting, monitoring and evaluation of these technical assistance programmes to ensure that these programmes are indeed consistent with public health objectives of the countries participating in the programmes.

Further proposals on Patents and Public Health

In view of the issues raised above in the introductory section, we are of the view that the SCP should also consider the following activities as part of their work-programme:

- (i) Establish a panel of experts on patents and development to review patent provisions in bilateral and plurilateral trade and investment agreements and its impact on public health. To facilitate the review, public hearings and/or other forms of consultations with Member states and civil society should be conducted.
- (ii) Conduct a study on patenting strategies and practices employed by pharmaceutical companies to prevent or delay generic competition. To facilitate information gathering and the preparation of study, Member states and civil society should be given the opportunity to make written submissions.
- (iii) Conduct a web-based hearing on patent examination practices to facilitate the grant good quality patents and prevent the grant of frivolous pharmaceutical patents. The hearing could be followed up with a discussion in the SCP.
- (iv) Setup a database to facilitate prompt dissemination of information pertaining to pre-and post grant oppositions to patent applications and grants related to pharmaceutical products filed in WIPO member states. The database should be publicly accessible and contain information on the patent oppositions filed including the rationale for opposition, responses to the oppositions, appeals filed (if any) and the final decision made on the opposition.
- (v) Compile information on the legislative implementation of the 30th August 2003 Decision by WIPO Member states and to convene a discussion panel at the next SCP on the operation and use of the 30th August 2003 decision of the World Trade Organization.

[End of Annex and of document]