## Report of

# Side Event to the Twenty-Fourth Session of the World Intellectual Property Organization Standing Committee on the Law of Patents

Title: PATENTS AND PUBLIC HEALTH: EXPLORING OPTIONS FOR FUTURE WORK IN THE WIPO

Date/Time: 29 June 2016 from 13h00 to 14h45

Venue: Room B, WIPO Headquarters, Geneva



**Description:** The South Centre organized an event on the sides of the WIPO SCP. The panel discussed options for future work in WIPO on patents and public health. The SCP is a relevant forum for the discussion in the context of the international patents system and its relation to meeting the public policy objective of ensuring access to medicines for all. The panel discussed how this policy objective can be achieved, in compliance with the World Trade Organization Agreement on Trade Related Aspects of Intellectual Property Rights and the Doha Declaration on TRIPS and Public Health.

#### **SUMMARY**

Chair: Dr. Viviana Muñoz Tellez, Coordinator DIIP, South Centre

The WIPO SCP is in the process of defining its future work plan. A balanced work plan should include the issue of public health and patents. WIPO as a specialized agency of the United Nations is mandated to contribute to the achievement of the Sustainable Development Goals, including SDG 3 on health. The complex interlinkages around issues of public health, intellectual property, innovation and building local industrial capacity, trade and human rights are being discussed in a number of multilateral fora. The SDGs are the framework to seek greater policy coherence. The WIPO Secretariat has undertaken initiatives on

intellectual property and public health, including cooperation with WHO and WTO, publications and seminars. Yet more guidance from Member States is necessary. Member States need to direct WIPO initiatives in the area of public health. They also need a space to discuss and forge common understandings, particularly around access to medicines. The SCP is an ideal forum on the interrelation between the patent system and public health.

WIPO can produce more factual, evidence-based research and analysis and tools to inform national policy making, international discussion and technical assistance activities. This should include empirical work on the effect of patents and other forms of IP on R&D investment and affordable medical product innovations. It should also extend to their effects on incremental innovation and the production and availability of low-cost generic medical products, and the role of flexibilities within the patent system in promoting affordable access to medical products. The African Group proposal in the SCP is a good way forward.

### **Speakers:**

Ms. Chichi Umesi, First Secretary, Permanent Mission of the Federal Republic of Nigeria to the United Nations, Geneva

Nigeria is currently the African Group coordinator at the WIPO. At the 16th session of the SCP in 2011, the African Group and Development Agenda Group submitted a proposal aimed at enhancing the capacity of developing and least developed countries (LDCs) to adapt their patent regimes and make full use of flexibilities in the international patent system to address public policy priorities related to public health. The African Group submitted an update to the proposal, as document SCP/24/4 to the 24<sup>th</sup> session of the SCP in June 2016. This takes into consideration the continued challenge of access to medicines. Developed countries as well as developing countries and LDCs are affected by lack of access and high prices. The revised proposal also considers developments since 2011. These include the extension by the WTO TRIPS Council of the transition period for LDCs, meaning that LDCs are not required to grant patents for pharmaceutical products at least until 2033. This is an important recognition that the implementation of patent protection for pharmaceutical products in LDCs will be detrimental to their public health challenges of securing access to affordable medicines. The proposed work program seeks to enhance the capacities of Member States, and particularly developing countries and LDCs, to adapt their patent regimes to make full use of the flexibilities available in the international patent system and to promote public policy priorities related to access to health care. The African Group requests support to the inclusion of patents and health in the future work plan of the SCP and the specific activities proposed in document SCP/24/4.

Ms. Hu Yuan Qiong, Legal and Policy Advisor, Access to Medicines Campaign, Médicins Sans Frontières

The MSF views access to medicines from two angles: access to existing medicines, and the development of and access to new medicines. The core dimensions of access and innovation are affordability,

availability and suitability. There are several challenges to access and innovation. These include patent barriers in the new WHO essential medicines list (EML), patent ever-greening and TRIPS-plus provisions that are harmful for public health, limitations on voluntary licensing measures, political pressures on national laws and policies, and a broken model of incentivizing research and development for new medicines.

MSF research shows that increased competition is associated with a drop in prices, demonstrated in the case of first-line combination drugs for HIV/AIDS. The price of the newer third-line regimen is more than 14 times higher than the recommended first-line, associated to delayed generic competition entry due to patents. MSF recommends that WIPO studies be evidence-based and factual. MSF has given detailed comments on a recent WIPO report on patent-based analysis of the WHO EML of 2013. The MSF report finds that the WIPO study disregarded the trend of disease burden and development of new EML, used a contestable methodology, presented wrong and limited usefulness of the data for public health decision making, and presents misleading conclusions.

### Mr. Thiru Balasubramaniam, Geneva Representative, Knowledge Ecology International

The function of the patent system is to serve the public interest. Developed countries have a number of mechanisms in their national patent laws to limit the exercise of patent rights, while in compliance with their international obligations. These mechanisms are regularly implemented. This reflects concerns on high pricing in relation to patented medicines, as well as anti-competitive effects of patent monopolies. There are a number of examples that can be provided of how such mechanisms are used in developed countries. These include the use of compulsory licensing as a remedy to anti-competitive practices in the United States and in Europe, potential use of compulsory licensing to import cheaper generic drugs, and limitations to issuance of injunctions for public interest purposes. The SCP should take into consideration these experiences.

### Mr. K. M. Gopakumar, Legal Advisor and Senior Researcher, Third World Network

Developing countries and LDCs face a number of challenges in access to medicines. These include the regulatory constraints that patent systems pose to their ability to implement policy and measures aimed at ensuring access to medicines. Even though LDCs are not required to implement the TRIPS Agreement, and developing countries can make use of TRIPS flexibilities for policy space in patent law, there are real political and practical constraints. These constraints include the continued pressure from developed countries, e.g. free trade agreements, bilateral mechanisms such as the US Section 301 list, not to make use of flexibilities. The WIPO has not been able to produce an effective work program on use of flexibilities and tools to assist countries for this purpose. This is due to the reluctance of developed countries. The SCP should set a concrete work program on patents and public health that promotes use of flexibilities in the patent system, and also expands tools available for policy makers to use these flexibilities.