

Standing Committee on the Law of Patents

Sixteenth Session

Geneva, May 16 to 20, 2011

PROPOSAL SUBMITTED BY THE DELEGATION OF SOUTH AFRICA ON BEHALF OF THE AFRICAN GROUP AND THE DEVELOPMENT AGENDA GROUP

Document prepared by the Secretariat

1. The Annex to this document contains a proposal submitted by the Delegation of South Africa on behalf of the African Group and the Development Agenda Group in respect of a work program on patents and health, for consideration under item 9 of the revised draft agenda: Patents and Health.

2. The members of the Standing Committee on the Law of Patents (SCP) are invited to consider the contents of the Annex.

[Annex follows]

**JOINT PROPOSAL BY THE AFRICAN GROUP AND THE DEVELOPMENT AGENDA GROUP
SCP WORK PROGRAM ON PATENTS AND HEALTH
SCP 16, 16-20 MAY 2011**

Introduction

1. At the 15th session of the Standing Committee on the Law of Patents (SCP) the African Group proposed that the Committee should undertake a work program on the topic "patents and health." The African Group and the Development Agenda Group are of the view that the patent system should be consistent with fundamental public policy priorities, and in particular the promotion and protection of public health.

Context

2. The issue of patents and its impact on public health has been the subject of discussion in many fora. In 2003, the 56th World Health Assembly of the World Health Organization (WHO) had urged Member States "to reaffirm that public health interests are paramount in both pharmaceutical and health policies," and "to consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)." Furthermore, the 2001 Doha Ministerial Declaration on the TRIPS Agreement and Public Health affirmed, *inter alia*, that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health.
3. The WHO Global Strategy and Plan of Action (GSPOA) on Public Health, Innovation and Intellectual Property adopted in 2008 states that while international IP agreements contain flexibilities that could facilitate increased access to pharmaceutical products by developing countries, they may face obstacles in the use of flexibilities. Thus, there is a need to address this problem and remove obstacles faced by developing countries in making full use of the public health related flexibilities. The GSPOA also states that IPRs should not prevent Member States from taking measures to protect public health, and that international negotiations on issues relating to IPRs and health should be coherent in their approaches to the promotion of public health.
4. In order to protect public health, the flexibilities and safeguards contained and allowed by the TRIPS Agreement would need to be incorporated in the national legislation. There is equally the need to ensure that international commitments, including regional and bilateral arrangements, do not restrict these flexibilities and safeguards. Moreover, these safeguards and flexibilities have to be workable in practice, particularly with respect to ensuring access to medicine.
5. In this context, it will be pertinent for the Committee to discuss the issue of patents and health and draw up a work program that assists countries in adapting their patent regimes and make full use of the patent flexibilities. In this regard, the African Group and the Development Agenda Group are presenting the following work program.

Work Program

6. The proposed work program seeks to enhance the capacities of Member States, and particularly developing countries and least developed countries (LDCs), to adapt their patent regimes to make full use of the flexibilities available in the international patent system to promote public policy priorities related to public health. This work program is composed of three interlinked elements that are to be pursued simultaneously.

7. These three elements are respectively: (i) the elaboration of studies to be commissioned by the WIPO Secretariat, following consultations with the Member States at the SCP, from renowned independent experts; (ii) information exchange among Member States and from leading experts in the field; and (iii) the provision of technical assistance to Member States, and particularly developing countries and least developed countries (LDCs), in relevant areas, and building upon work undertaken in the first two elements of the work program.

Element I – Studies

8. Commission a framework study by leading independent experts to examine the challenges and constraints faced by developing countries and least developed countries (LDCs) in making full use of the public health related patent flexibilities both in the pre-grant and in the post-grant stage. This study should also include:
 - (a) A component on the law and practices with regard to compulsory and government use licenses in WIPO Member States. Such a study will also provide as detailed information as possible, as to Member States that have issued or that have attempted to issue compulsory and government use licenses, the details of the license issued, the challenges faced as well as the impact on public health. This should also include the provision of empirical data on the royalty rates set in each case.
 - (b) An examination on the extent to which countries use exhaustion of rights to allow parallel trade in medicine.
 - (c) An assessment of the benefits of mandatory disclosure of International Non-Proprietary Names (INNs) in the abstract or title of patent applications. This would enable an easier identification of the generic name of the medical product subject of the patent application.
 - (d) Conduct a cost-benefit analysis of the admissibility of Markush claims (broad patent claims that may apply to a broad range of compounds). It could be worthwhile to analyze whether such claims based merely on theoretical inference can be considered to satisfy the criteria for patentability.

Element II – Information Exchange

9. Invite the UN Special Rapporteur on the Right to Health, Mr. Anand Grover, to the seventeenth session of the SCP, to present his report to the Human Rights Council on Intellectual Property Rights and Access to Medicines.
10. Organize during SCP 17 and 18, experience sharing sessions on countries' use of patent flexibilities for promoting public health objectives. The specific health related flexibilities to be discussed in those sessions should be determined in consultation with Member States.
11. Organize a technical workshop on state practice involving the compulsory licensing of medical technologies, including the application of TRIPS Articles 30, 31 and 44.
12. Develop a database on the patent status in WIPO Member States of relevant diagnostic tools and medicines for at least 10 non-communicable and communicable diseases. Such information will also include information on the availability of generic versions of the tools and medicines. The list of 10 non-communicable diseases and communicable diseases will be identified in consultation with Member States with the support of the WHO. The database will be useful in identifying the patent status of medicines for both communicable and non-communicable diseases and how access to these medicines can be better

ensured by making full use of the available flexibilities. It should be noted that this request is not new, where in 2003 the WHO had requested the WIPO Secretariat to provide information about the patent status of essential medicines.

Element III – Technical Assistance

13. Flowing from the outcomes of the studies and information exchange as contained in elements I and II above, the WIPO Secretariat, in consultation with Member States, should develop targeted technical assistance programs.
14. Develop a technical assistance module that explicitly demonstrate the difference between compulsory licenses that are granted under the procedures of Part II of the TRIPS Agreement, concerning patent rights, and those granted under Part III of the Agreement, concerning the remedies for infringement of those rights. These technical assistance programs would explain both approaches, and focus on the flexibilities afforded to both systems, noting that 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 Agreement. These targeted technical assistance programs would proceed from the study identified in paragraph 8 above.

Development Agenda Links

The proposed work program has links to Development Agenda recommendations 1, 7, 9, 14, 31 and 40.

15. WIPO technical assistance shall be, inter alia, development-oriented, demand-driven and transparent, taking into account the priorities and the special needs of developing countries, especially LDCs, as well as the different levels of development of Member States and activities should include time frames for completion. In this regard, design, delivery mechanisms and evaluation processes of technical assistance programs should be country specific.
16. Promote measures that will help countries deal with intellectual property-related anti-competitive practices, by providing technical cooperation to developing countries, especially LDCs, at their request, in order to better understand the interface between IPRs and competition policies.
17. Request WIPO to create, in coordination with Member States, a database to match specific intellectual property -related development needs with available resources, thereby expanding the scope of its technical assistance programs, aimed at bridging the digital divide.
18. Within the framework of the agreement between WIPO and the WTO, WIPO shall make available advice to developing countries and LDCs, on the implementation and operation of the rights and obligations and the understanding and use of flexibilities contained in the TRIPS Agreement.
19. To undertake initiatives agreed by Member States, which contribute to transfer of technology to developing countries, such as requesting WIPO to facilitate better access to publicly available patent information.
20. To request WIPO to intensify its cooperation on IP related issues with United Nations agencies, according to Member States' orientation, in particular UNCTAD, UNEP, WHO, UNIDO, UNESCO and other relevant international organizations, especially the WTO in order to strengthen the coordination for maximum efficiency in undertaking development programs.

[End of Annex and of document]