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PROPOSAL BY THE AFRICAN GROUP FOR A WIPO WORK PROGRAM ON PATENTS AND HEALTH

Document prepared by the Secretariat

1. The Annex to this document contains a proposal submitted by the Delegation of Nigeria on behalf of the African Group for a WIPO Work Program on Patents and Health, for consideration under item 7 of the 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]

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INTRODUCTION

1. At the 15th session of the SCP, the African Group proposed that the Committee should undertake a work program on the topic "patents and health". 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 is of the view that a fundamental public policy priority related to the promotion and protection of public health is the affordable access to health care and medicines internationally. The African Group submits this document as an update of the 2011 joint proposal contained in document SCP/16/7 and SCP/16/7.Corr.

CONTEXT

2. There has been significant international focus on the role of patents in public health, specifically a persistent lack of access to health technologies (medicines, diagnostics, medical devices, vaccines, etc.), which includes lack of access to medicines in developing and least-developed countries. Challenges to public health continue to emerge, including pandemics such as the Ebola virus that gravely affected Africa in 2014-15, and more recently (since May 2015) the Zika virus in the Americas and the Caribbean, for which there is currently no cure; the serious threat of Anti-Microbial Resistance (AMR); and the need for new ways to finance and incentivize Research and Development (R&D) and innovation to address global health challenges, particularly neglected diseases or diseases prevalent in developing countries and LDCs. Many reports and global initiatives have directed serious attention to these and other issues.

3. It is instructive that in May 2015, the WHO published a revised Model List of Essential Medicines that included new ground-breaking treatments for *inter alia*, Hepatitis C, a variety of Cancers and Tuberculosis, many of which are patented, very expensive and hardly affordable for patients worldwide. This signaled a new approach since medicines on the WHO Model List were, hitherto, those that could be made widely available at low cost.

4. In November of 2015, the United Nations Secretary-General, Mr. Ban Ki-moon, convened a High-Level Panel (HLP) on Access to Medicines. The proposed objective of the HLP is "*to review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies.*" Thus, the need to prioritize public health interests in pharmaceutical and health policies is paramount, particularly in the context of the Sustainable Development Goals (SDGs).

5. Also in November 2015, the WTO TRIPS Council extended to 2033 the transition period for LDCs in respect of pharmaceutical products, recognizing that implementation of patent protection for pharmaceutical products in LDCs (most of which are in Africa) will be detrimental to their public health challenges of securing access to affordable medicines. At this juncture, the African Group recalls the range of flexibilities contained in the TRIPS Agreement concerning IPRs and Public Health; the 2001 Doha Declaration on the TRIPS Agreement and Public Health; the 2008 WHO Global Strategy and Plan of Action (GSPOA)

on Public Health which underscored that IPRs should not prejudice protection of public health; and reiterates the important moral principle that international commitments (including bilateral and regional) should not hinder use of the flexibilities and safeguards provided in the international patent system.

6. Anti-Microbial Resistance (AMR) has become one of the foremost global health concerns, resulting in several engagements to develop relevant, coherent international public health policy and actionable steps to mitigate the challenge. The WHO Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) continues to work towards filling gaps in the health R&D needs of developing countries and LDCs, including neglected diseases or diseases that disproportionately affect such regions, and for which R&D gaps remain unaddressed due to market failures.

7. The WHO CEWG Report reiterated the need for further investment in Health R&D, which should be needs-driven, evidence-based, guided by the core principles of affordability, effectiveness, efficiency, and equity; and considered a shared responsibility. The WHO also recently adopted a Global Action Plan on Anti-Microbial Resistance (GAP) and assisted to launch the Global Antibiotic Research and Development (GARD) Partnership with the Drugs for Neglected Diseases Initiative (DNDi), which aims to develop new antibiotic treatments addressing AMR and to promote their responsible use while ensuring equitable access to low and middle-income countries.

8. Furthermore, the post 2015 SDGs adopted by the United Nations places emphasis on the achievement of universal health coverage, including access to affordable essential medicines for all as one of the targets to be achieved under SDG Goal 3. The SDG specifically states that countries should support R&D of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries and LDCs, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, and, in particular, provide access to medicines for all.

9. Given the ever increasing global focus on R&D, innovation and public health, including the role of the patent system as a tool for spurring innovation in health technologies, it is important for the SCP to be a significant facilitator in the critical work of analyzing the patent-related challenges and questions at the intersection of public health, access to medicines and patent rights. The Committee should draw up a work program that assists countries in adapting their patent and health regimes to ensure affordable access to medicines. In this regard, the African Group presents the following work program.

WORK PROGRAM

10. 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. This work program is composed of three interlinked elements that are to be pursued simultaneously.

11. 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 LDCs, in relevant areas, and building upon work undertaken in the first two elements of the work program.

ELEMENT I – STUDIES

12. Commission a study by leading independent experts to examine the challenges faced by developing countries and LDCs in incentivizing innovation in healthcare technologies where patents have proved to be an insufficient motivator. This study should include:

(a) An examination of regulatory and other incentives that could spur innovation without promoting overuse of antibiotics, including non-patent incentives to drive drug committees to invest in AMR research. This includes consideration of a 'pay or play' levy on the pharmaceutical sector which would require companies to either pay the levy or invest in R&D that is deemed useful for AMR.

(b) An assessment on possible adjustments to the patent system to encourage innovation in healthcare technologies related to reducing AMR, including improved diagnostics to better pinpoint infection and antibiotic treatment in humans, and modifying plant patents to incentivize reduced antibiotic use in agriculture. Such an exercise could include an assessment of the de-linkage principle related to research funding and drug price.

(c) Study on the relationship between patent systems and challenges related to the availability of medicines in developing and least developed countries, including fostering of the requisite technology transfer to facilitate access to affordable generic and patented medicines in developing countries and LDCs.

13. Commission a study to examine the challenges and opportunities faced by developing countries and LDCs in using licenses for healthcare technologies. This study should 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.

(b) An examination on the extent to which countries use exhaustion of rights to allow parallel trade in medicine.

(c) An analysis of the interface of competition law and patent rights in the context of pharmaceuticals in different countries, including a compilation of statutory and case law on anti-competition grounds for compulsory license on pharmaceuticals. Experience from countries where the intersection of competition law and patent law has been used to facilitate access to medicines should be documented.

(d) A study and evaluation of the law and practice of WIPO Member States with regard to voluntary licenses.

(e) The feasibility of a globally accessible license database for compulsory and voluntary licenses.

ELEMENT II – INFORMATION EXCHANGE

14. Appoint a balanced Working Group or Task Force to study and synthesize the reports and recommendations from the HLP and commitments in the WHO GAP, in relation to the patent system; and to consider how the SCP can contribute to advancing the innovation and health related SDGs.

15. At a half-day Information Exchange session during SCP 26, invite the UN Special Rapporteur on the Right to Health to present the report to the Human Rights Council on Intellectual Property Rights and Access to Medicines. Also invite WHO to present WHO CEWG and GAP reports, and the Co-Chairs of the UN HLP to share their views on the HLP's objectives and findings.

16. Organize a technical workshop on state practice involving the compulsory and voluntary licensing of medical technologies, including the application of TRIPS Articles 30, 31 and 44.

17. Periodic information exchange on the margins of the SCP, involving leading experts, on identified development-oriented issues related to patents and health.

18. WIPO development of an international patent register, in consultation with Member States and the support of WHO, for essential medicines to facilitate determination of the patent status of a medicine internationally, including those for communicable and non-communicable diseases. Currently, there is no efficient or accurate way to determine the patent status of medicines, including those on the WHO Model List of Essential Medicines. This lack of transparency in the patent status of essential medicines (and other medicines) negatively affects efforts of governments and procurement agencies to negotiate terms and conditions of access to medicines.

19. Development of an international license registry for licensed medicines to facilitate access to a medicine internationally.

ELEMENT III – TECHNICAL ASSISTANCE

20. Flowing from the outcome 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. These programs should provide a clear synergy between the studies and information exchange and include:

(a) A series of workshops on negotiating and drafting license agreements for generic manufacturers, taking due cognizance of flexibilities in the international patent system.

(b) A development-oriented guide for the issuance of compulsory licenses on medical patents, based on successful case studies.

(c) Periodic workshops to facilitate more rigorous interpretation and application of patentability criteria by patent examiners with regards to patent applications covering health technologies in developing countries and LDCs.

(d) Development of a technical assistance module that explicitly demonstrates 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. This module 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.

DEVELOPMENT AGENDA (DA) RECOMMENDATION LINKS

21. The proposed work program has links to DA recommendations 1, 7, 9, 14, 31, 32 and 40:

1. 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.

7. Promote measures that will help countries deal with intellectual property-related anticompetitive 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.

9. 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.

14. 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.

31. 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.

32. To have within WIPO opportunity for exchange of national and regional experiences and information on the links between IPRs and competition policies.

40. 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]