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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 sixteenth session held in Geneva from May 16 to 20, 2011, the Secretariat invited the members and observers of the SCP, through Note C.7998, to submit comments on the topic of patents and health. This document contains, in the Annex, the comments received.

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COMMENTS RECEIVED FROM MEMBER STATES

COSTA RICA

1. With regard to the topic of "Patents and Health", it should be pointed out that the patent system must be in line with public policies, in particular in the field of public health. The proposed program consists of three elements:

- Preparation of studies by experts to determine the situation in the Member States (Compulsory licenses, exhaustion of rights to allow parallel trade in medicine, Markush claims, among other issues).

- Information exchange and experience-sharing between Member States.

- Provision of technical assistance to the Member States with regard, for example, to differences between compulsory licenses that are granted under Parts II and III of the TRIPS Agreement.

2. In Costa Rica, there are no serious problems regarding access to medicine. However, these kinds of studies are always beneficial, as are the exchange of related information and the provision of technical assistance.

INDONESIA

3. Regarding the proposal of the Delegation of South Africa on behalf of the African Group and the Development Agenda Group, which be the basis of the discussion on the topic of Patents and Health in the 17th session of the SCP, we support the proposal.

KYRGYZSTAN

4. The Patent Law of the Kyrgyz Republic provides the following regulations:

- Possibility to renew a patent term of validity for invention, related to pharmaceutics up to 25 years; for other inventions the maximum term is 20 years;
- Possibility to conduct a scientific research or experiment with a subject matter of industrial property; it shall not be considered as infringement of exclusive right of a patent owner;
- Possibility to issue a compulsory license by the Government of the Kyrgyz Republic at extraordinary situation or for national safety with payment of a compensation to a patent owner;
- Possibility for any person interested to use a protected IP subject matter in the case of a patent owner refusal to conclude a license agreement with this person.

5. The Kyrgyz Republic is a member of the World Trade Organization (WTO) since December 1998 and observes the norms of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to provide minimum standards of IPRs protection in all fields of technology, including:

- Products (medicines);
- Methods (receipt of medicines).

6. Taking into consideration the importance of mentioned question and supporting the idea of limitation of patent monopoly for medical products, we believe to be possible the variant of excluding from the Patent Law the norm regarding a prolongation of validity term for pharmaceutical patents for five years. Obviously there is a necessity of detailed study of this question and concordance with all interested parties.

MEXICO

7. IMPI welcomes the proposal submitted by the Delegation of South Africa on behalf of the African Group and the Development Agenda Group. The Institute is convinced that, based on the program suggested by these Groups, as well as on the undertaking of the study, the exchange of information and technical assistance, it will be possible to achieve the goals set within the SCP.

8. Furthermore, IMPI wishes to thank the WIPO Secretariat for the important document to be presented at the Seventeenth Session of said Committee, a document which will include those activities relevant to cooperation with other international organizations regarding this topic, in order to rule out duplication of efforts. The Institute reiterates its interest in continued discussions on this issue and we hope that the talks will be productive and that agreement will be reached at the next Session of the SCP.

KNOWLEDGE ECOLOGY INTERNATIONAL (KEI)

9. In November 2001, the World Trade Organization (WTO) Ministerial Conference in Doha, Qatar adopted the Doha Declaration on the TRIPS Agreement and Public Health affirming that the "TRIPS Agreement does not and should not prevent members from taking measures to protect public health". This landmark declaration marked a watershed in global trade governance, by singling out public health and in particular, health technologies, from other trade-related issues. The Doha Declaration reiterated that health technologies are not just another commodity and may be differentiated from other inventions as underscored by paragraph four of the Declaration,

> *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.*

10. The Doha Declaration was precipitated by a request made by the African Group in April 2001 for the WTO to hold a special session of the TRIPS Council to clarify the relationship between intellectual property and access to medicines. In its request, the African Group observed,

> *[a]s the recent upsurge of public feelings and even public outrage over AIDS medicines has shown, there is now a crisis of public perception about the IPR system and about the role of TRIPS which is leading to a crisis of legitimacy for TRIPS. Whilst this storm is raging outside the WTO, and legitimately so, we as Members inside the WTO cannot shut our eyes and ears. Each of us, from developing and developed countries, must respond, and respond adequately and appropriately.*

11. Nearly ten years on from Doha, it is perhaps appropriate that the African Group and the Development Agenda Group (DAG) tabled their paper on a work program for patents and health (SCP/16/7) at the 16th session of the Standing Committee on the Law of Patents (SCP) with the over-arching objective that the, "patent system should be consistent with fundamental public

policy priorities, and in particular the promotion and protection of public health". This objective is further fleshed out in the context session of the African Group/DAG submission,

> *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.*
>
> *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.*

12. To preface our contribution on patents and health, we observe that recommendation 14 of WIPO Development Agenda (http://www.wipo.int/ip-development/en/agenda/recommendations.html) states:

> *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.*

13. 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.*

14. KEI supports the African Group/DAG proposal for the International Bureau to "commission a framework study by independent experts" to document state practice on compulsory licensing including the provision of empirical data on the royalty rates set in each case and an "examination on the extent to which countries use exhaustion of rights to allow parallel trade in medicine".

15. In addition, under the mandate of recommendation 14, we request the International Bureau to undertake technical studies on the following:

- Current implementation of Paragraph 7 of the Doha Declaration on TRIPS and Public Health, regarding patents in LDCs,
- The methods of implementing Paragraph 6 of the Doha Declaration

- In the area of patent quality, WIPO should also consider gathering statistics and creating a database of challenges to patent validity, so that it is easier for residents of one country to learn about a patent validity dispute in another country, and possibility to even consider patent reexamination when claims are overturned in another country.

16. The discussion of the relationship between patents and health in WIPO's patent committee is timely as nearly ten years from the passage of the Doha Declaration, negotiations on the Political Declaration for the United Nations High Level Meeting (HLM) on Non-Communicable Diseases (NCDs) to be held in New York on 19-20 September 2011 have witnessed the European Union and the United States endeavoring to purge all references to the Doha Declaration.

17. KEI observes that the Doha Declaration explicitly states the following,

In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

18. As KEI noted in its analysis[1] of the NCD negotiations in New York,

The 2001 Doha Declaration came about largely because of the very visible crisis surrounding access to patented medicines to treat AIDS. The Bush Administration and the European Commission sought to narrow the understanding about health and intellectual property so it only applied to AIDS, or a limited set of infectious diseases. That effort failed in 2001 and again in 2003, during an interpretation of another section of the agreement. Since then, the U.S. and the European Commission have generally accepted references to the Doha Declaration on TRIPS and Public Health in World Health Resolutions, such as WHA61.21, in 2008, an in several bilateral and regional trade agreements, including in the final text of the AntiCounterfeiting Trade Agreement (ACTA), which was completed in December of 2010. However, in a number of cases, the US and the EU have also asserted that the Doha Declaration is in fact limited to AIDS, infectious diseases or epidemics. These backtracking interpretations have always been strategic, when the US and the EU wanted to push back against a developing country effort to use compulsory licensing of patents for anything other than drugs for AIDS.

19. The proposed framework study of independent experts that the African Group and the Development Agenda Group requested to examine the challenges faced by developing countries and LDCs in making full and effective use of public health related flexibilities should analyze why the European Union and the United States would seek to eliminate all references to the Doha Declaration in the Outcome Document United Nations High Level Meeting on Non-Communicable Diseases (NCDs). We posit that the European Union and the United States endeavor to purge references to the Doha Declaration is motivated by the desire to rewrite history by asserting that the “access to medicines” provisions in the Doha Declaration do not apply to medicines for cancer and other non-communicable diseases and to raise doubts about the application of other elements of the Doha Declaration, including paragraphs 5, 6 and 7 to non-communicable diseases, if not legally, at least politically. In WIPO's documentation of state practice on compulsory licensing, the International Bureau may wish to catalog the following two

[1] 10 September 2011, Obama Administration wants to Eliminate References to Doha Declaration in UN Political Declaration on Non-Communicable Diseases, Krista Cox, http://keionline.org/node/1252.

compulsory licenses recently issued in the United States, for contact lenses[2] as well as a device to treat aortic valve stenosis[3].

THIRD WORLD NETWORK (TWN)

A. GENERAL

20. Today billions of people worldwide do not have access to the medicines they need. In some of the lowest-income countries particularly in Africa and Asia this figure rises to more than half of the population.

21. These statistics reveal that despite significant technological advances made by humankind in the medical field, getting medicines to those who need them remains a major challenge for the international community.

22. The "price" factor can singularly be determinative of life or death, where a deadly disease is treatable. It can determine whether the government will be able to provide treatment to its people or whether an individual will be able to obtain the treatment it requires.

23. The problem of high prices has been observed by the international community in the context of treatable infectious diseases such as HIV/AIDS and malaria. For example in 2000, for a triple-combination antiretroviral (ARV) treatment of Stavudine (d4T) + Lamivudine (3TC) + Nevirapine (NVP) the price of the lowest branded treatment was about US$ 10 439 for a year's supply.[4] The high price tag meant patients living with HIV/AIDS would not be able to afford treatment and would be condemned to death.

24. The entry of generic versions of branded medicine led to significant price reductions. In 2001, Cipla Ltd., a generic producer based in India, offered the same combination for US$ 350. Overtime with more competition, this cost has been reduced to US$ 99.[5] Reduced prices for ARV treatment, has been a crucial factor in the scaling up of HIV/AIDS treatment.

25. Clearly competition among multiple manufacturers is essentially the reason for reduced prices. However, the existence of competition has very much been threatened by the coming into force of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in the World Trade Organization (WTO) in 1995 which globalised minimum standards of IP protection.

26. Many development experts are of the view that TRIPS has very significantly tilted the balance in favour of IP holders, most of who are in developed countries, *vis-à-vis* consumers and local producers in developing countries and *vis-à-vis* development interests.[6]

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2 1 September 2011, The Johnson & Johnson Acuvue Compulsory License, Anne Guha, http://keionline.org/node/1219.

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

4 See Médecins Sans Frontières, "Untangling the Web of Price Reductions" (July 2007) available at www.accessmed-msf.org.

5 See Médecins Sans Frontières, "Untangling the Web of Price Reductions" (July 2007) available at www.accessmed-msf.org.

6 See Carlos Correa "Intellectual Property Rights, the WTO and Developing Countries, The TRIPS Agreement and Policy Options" (2000), Zed Books Ltd and Third World Network; Report of the Commission on Intellectual Property Rights, "Integrating Intellectual Property Rights and Development Policy", (September 2002) available at http://www.iprcommission.org/graphic/documents/final_report.htm.

27. The minimum 20-year patent protection required by TRIPS allows a pharmaceutical company monopoly over the production, marketing and pricing of patent-protected medicines. This period can be further extended by the company through the use of various strategies such as applying for patents on usage, dosage or combination form – a practice commonly known as "evergreening"[7], thus keeping the drug free from competition and enabling high pricing.

28. While the situation was problematic prior to 2005, it is anticipated that it will worsen in the years to come. For example in the case of ARVs, Médecins Sans Frontières (MSF), is already talking about the "return of the price crises" that was seen about in 2000 when life-saving ARVs were priced out of reach of those in need. Introducing more recent drugs in anti-AIDS combination therapy because of the emergence of resistance to older treatment would today increase the annual cost of treating an adult for one year in a developing country from US$ 99 to US$ 426. Since everyone on therapy today is expected to need these newer therapies at some point, the escalation in cost will have dire consequences for AIDS programmes.

29. The main reason why cheaper generic alternatives were possible for older ARV products is that there were no patents in some developing countries with vibrant generic pharmaceutical industries. India, for example free from product patents for medicines used to manufacture and supply generic medicines to the rest of the world. However, India, known as the pharmacy of the world, has had to comply, beginning in 2005 with its TRIPS obligations and permit the patenting of pharmaceutical products. Therefore, the possibility of supply of affordable generic medicines in the future for new drugs for HIV/AIDs and other diseases seems rather bleak.[8]

30. The situation is made worse by the range of patent related TRIPS plus measures being pushed onto developing countries, through north-south bilateral/plurilateral trade and investment agreements and IP enforcement initiatives pushed by developed countries and international organizations as well as patenting strategies by pharmaceutical companies aimed at delaying generic competition.

31. Against this background, it is important to have a frank and evidence based discussion on the relationship between patents and health. In particular it is important to initiate a process that provides independent evidence, data and guidance in relation to issues pertaining patents and health in particular the use of flexibilities.

32. Many independent and highly esteemed experts as well as Member driven processes have made observations on the relationship as well as on flexibilities. For some examples see Box 1.

33. Noting this and additionally that WIPO is mandated to deal with patent issues and is tasked to provide technical assistance on the matter it is critical to have an evidence based discussion as well as a concrete work-plan on the subject matter in WIPO. See also Part B below on *"Why should WIPO discuss Patents & Public Health"*

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7 Evergreening is a term popularly used to describe patenting strategies that are intended to extend the patent term on the same compound. See Report of the WHO Commission on Intellectual Property, Innovation and Health (April 2006), p. 148 available at http://www.who.int/intellectualproperty/report/en/index.html.

8 See Médecins Sans Frontières, "Untangling the Web of Price Reductions" (July 2007) available at www.accessmed-msf.org.

Box 1

In 2001, a Commission set up by the UK government on IP and Development noted that "for most developing countries any benefits in terms of the development of new treatments for diseases that afflict them will be, at best, long term, while the costs of implementing a patent system are both real and immediate".[9] It then recommends a variety of measures that can be taken by countries, including that developed countries strengthen parallel importation; developing countries *inter alia* provide international exhaustion of rights, establish workable laws and procedures to give effect to compulsory licensing, and government use, exception for "early working" to patent rights; and that they avoid granting data exclusivity.[10]

In 2006 the Report of WHO's Commission on Intellectual Property, Innovation and Public Health (CIPIH) (at pg. 196) made the following observation: "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."[11]

In *2008, the WHO Global Strategy and Plan of Action (GSPOA) on Public Health, Innovation and Intellectual Property* adopted via WHA 61.21 noted:

"The price of medicines is one of the factors that can impede access to treatment" and 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."

In 2009, the UN Special Rapporteur on the Right to Health on his submission to the UN General Assembly concluded[12] *inter alia:*

"The framework of the right to health makes it clear that medicines must be available, accessible, acceptable, and of good quality to reach ailing populations without discrimination throughout the world. As has been evident, TRIPS and FTAs have had an adverse impact on prices and availability of medicines, making it difficult for countries to comply with their obligations to respect, protect, and fulfil the right to health."

"Similarly, lack of capacity coupled with external pressures from developed countries has made it difficult for developing countries and LDCs to use TRIPS flexibilities to promote access to medicines".

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9 pg. 39, "Integrating Intellectual Property Rights and Development Policy, Commission on Intellectual Property Rights", 2002. See www.iprcommission.org.

10 Integrating Intellectual Property Rights and Development Policy, Commission on Intellectual Property Rights, 2002. See www.iprcommission.org.

11 See http://www.who.int/intellectualproperty/report/en/index.html.

12 A/HRC/11/12; See http://www2.ohchr.org/english/bodies/hrcouncil/docs/11session/A.HRC.11.12_en.pdf.

B. WHY SHOULD WIPO DISCUSS PATENTS & PUBLIC HEALTH

34. At the 16th session of the SCP several members states from Group B (composed of developed countries) said that the "Committee should concentrate on the added value WIPO had brought, and could bring, to global challenges such as health from the point of view of its technical expertise, and should not attempt to import discussions held in other fora".[13]

35. The statement of Group B suggests that the SCP should only address patents and health if there is an added value to the discussion (presumable from discussions taking place in the WHO) from the perspective of WIPO's technical expertise.

36. We would argue that WIPO's basic documents (i.e. the WIPO Convention, the WIPO-WTO Agreement and the UN-WIPO Agreement) as well as the TRIPS Agreement suggests that WIPO has the mandate and duty to analyse, reflect and provide guidance on issues pertaining to patents and public health.

37. The WIPO Convention (signed in 1967, amended in 1979) lists the objectives of WIPO as "to promote the protection of intellectual property throughout the world through cooperation among States and, where appropriate, in collaboration with any other international organization".

38. This objective is further elaborated in Article 4 (on Functions) of the Convention. Some of the relevant functions are to "promote the development of measures designed to facilitate the efficient protection of intellectual property throughout the world"; "offer its cooperation to States requesting legal–technical assistance in the field of intellectual property"; "assemble and disseminate information concerning the protection of intellectual property, carry out and promote studies in this field, and publish the results of such studies"; "take all other appropriate action".

39. Broadly the Convention mandates WIPO with "efficient protection of IP", "technical assistance on IP"; and disseminating (presumably evidence-based) information about the protection of IP.

40. However it is important to not interpret this mandate narrowly. In the context of patents such protection involves not only rights for the patent holder but also what is now commonly known as "flexibilities". For example, the Paris Convention, a treaty administered by WIPO states in Article 5 of the "right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work." This clearly shows that compulsory licenses are part of the package of patent protection. Thus WIPO also has a mandate to undertake an adequate work-plan on "flexibilities" such as compulsory licenses, including its use in specific areas such as health.

41. The Convention must also be read in conjunction with the UN-WIPO Agreement signed once WIPO became a specialized agency of the UN. Article 1 of this Agreement stresses on "promoting creative intellectual activity" and "facilitating the transfer of technology related to industrial property to the developing countries in order to *accelerate economic, social and cultural development*".

42. It is apparent that WIPO must also address within its remit, sectoral issues pertaining to "economic, social and cultural development". This would include issues pertaining to health.

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[13] Draft report of the16th SCP session available at http://www.wipo.int/export/sites/www/scp/en/meetings/session_16/documents/scp_16_9_prov.pdf.

43. Further this Convention cannot be read in isolation from the key provisions of the WTO-TRIPS Agreement, in particular Article 7 (on Objectives) and Article 8 (on Principles) which are hereby reproduced.

44. Article 7 (Objectives): "The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations".

45. Article 8 (Principles): "Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement".

> "2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology."

46. Article 7 of TRIPS is explicit on the need for IP protection and enforcement to not only contribute to technological innovation, dissemination of technology but also be conducive to social and economic welfare.

47. On the other hand, Article 8 provides the freedom to Members to formulate and amend their laws and regulations, adopt measures necessary to protect public health and nutrition and to promote the public interests.

48. Accordingly the TRIPS Agreement contains a variety of flexibilities for Member states to take measures necessary to protect their national interests as envisaged by Article 7 and 8 of TRIPS. Some such "flexibilities" are found in Article 6 on "Exhaustion"; Article 27 on "Patentable subject Matter"; Article 30 on "Exceptions to Right Conferred"; Article 31 "Other Use Without Authorization of the Right Holder"; Article 44 on "Injunctions".

49. In the context of health, the Doha Declaration on TRIPS and Public Health reaffirmed the right of WTO members to take measures to protect public health. It 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."

50. At this point it is worth recalling the WTO-WIPO Agreement signed on the desire to "establish a mutually supportive relationship between them, and with a view to establishing appropriate arrangements for cooperation between them". This Agreement establishes the basis of WIPO granting legal technical assistance and technical cooperation to WTO members and non-members on the TRIPS Agreement.

51. From these points, three conclusions can be made:

> (i) IP/Patent protection is not just about the rights of the patent holders but also involves flexibilities such as exhaustion of rights, compulsory licenses, patentable subject matter. Thus WIPO's mandate on IP issues extends not just to issues that affect the right

holder but also to flexibilities that form part of the system including the use of such flexibilities in specific sectors.

(ii) WIPO has a mandate on technical assistance as stated in its basic instruments as well as in the WIPO-WTO Agreement on TRIPS related matters. As a result WIPO is bound by the legal objectives and principles that underpin the TRIPS Agreement i.e. by Article 7 and 8 of the Agreement. Thus its mandate includes assisting countries in implementing Articles 7 and 8 as per national interests and accordingly all the other patent related flexibilities found in the TRIPS Agreement including implementing the Doha Declaration on TRIPS and Public Health.

(iii) Article 8 of TRIPS recognizes that IP protection can have adverse impacts. The Doha Declaration on TRIPS and Public Health also expressed concern about IP protection and "its effects on prices". As such WIPO in discussing patent protection should also address the adverse impacts of patent protection. Such discussions are important not only to protect public health but also to ensure that intellectual creativity is not hindered.

52. Thus it is not a matter of WIPO adding value to the discussion on patents and health. The issue of patents is interlinked with the ability to take measures to protect health as noted in Articles 7 and 8 as well as in the Doha Declaration on TRIPS and Public Health. It is thus time to reflect on the development of patent law trends and whether such development is advantageous or disadvantageous for health.

53. Moreover WIPO's mandate on technical assistance is linked to its ability to comprehend and address the relationship between patents and public health. As such we would argue that it is not only within WIPO's purview but it is also WIPO's obligation under its numerous basic instruments to address these interlinkages by undertaking studies, collating data, facilitating exchange of information and appropriate technical assistance programmes.

54. Developing countries face many challenges in the use of TRIPS flexibilities, e.g. lack of institutional capacity, information asymmetry, undue pressure from pharmaceutical companies. We are of the view that WIPO has a critical role to play to address these challenges and to enhance the use of flexibilities to ensure fulfillment of the right to health.

C. JOINT PROPOSAL BY THE AFRICA GROUP AND THE DEVELOPMENT AGENDA GROUP

55. The proposal on patents and health by the African Group and the DAG is indeed timely and an important step forward in initiating discussions on patents and public health in WIPO.

56. Below are some brief inputs on the joint proposal:

(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.

D. FURTHER PROPOSALS ON PATENTS & PUBLIC HEALTH

57. 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]