

## SHARING SESSION ON COUNTRIES' USE OF HEALTH-RELATED PATENT FLEXIBILITIES

### Summary<sup>1</sup>

*Document prepared by the Secretariat*

1. Pursuant to the decision of the Standing Committee on the Law of Patents (SCP) at its nineteenth session, held in Geneva from February 25 to 28, 2013, the present document is a summary of a sharing session on countries' use of health-related patent flexibilities, which was held on January 28, 2014, under agenda item 8 of the twentieth session of the SCP.
2. In total, 20 Member States and three non-governmental organizations made interventions during this session.
3. The Delegation of India expressed its strong support for the proposal submitted by the Delegation of South Africa on behalf of the African Group and the Development Agenda Group (DAG), in respect of a work program on patents and health (document SCP/16/7). In the view of the Delegation, the components of the study and other actions proposed in the work program were most relevant and should be given due consideration by the Committee.
4. The Delegation of Pakistan, while recognizing the role of patents in fostering innovation and creativity, stated that the patent rights have a direct impact on the right to health, especially in developing countries where pharmaceutical products were highly priced. The Delegation, *inter alia*, stressed that intellectual property protection should not inflate price and put the right to health beyond the reach of developing countries.
5. The Delegation of Algeria, speaking on behalf of the African Group, underlined that the agenda item on patents and health represented the highest priority for its Group. It stated in particular, that the proposed work program aimed at assisting Member States, particularly developing countries and least-developed countries in adopting and adjusting their patent systems in order to take full advantage of the flexibilities in the international patent system and to promote their policies on public health. While recognizing that some of the activities undertaken by WIPO, such as technical assistance, had been, in general, beneficial for developing countries, the Delegation noted that there had been some other activities which raised serious concerns regarding their development orientation from public health perspectives. Therefore, the Delegation noted that one of the main objectives of the proposal was to give direction to the work of WIPO on that issue.
6. The coordinators of other groups, namely of Central European and Baltic States (CEBS), Group B and the European Union, stressed that patents provided important incentives in supporting innovation in the pharmaceutical industry. They called for a balanced approach in discussing the issue of patents and health at the SCP, taking into account interests of all stakeholders and various interfaces and factors relevant to patent and health. In this regard, the European Union referred to the Trilateral Study entitled "Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and

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<sup>1</sup> The full interventions of the sharing session will be recorded in the report of the 20<sup>th</sup> Session of the Standing Committee of the Law of Patents (SCP). In case of discrepancy between this Summary and the Report, the latter should prevail.

Trade” where it was highlighted that lack of access to medical technologies was rarely due to a single isolated factor such as patents, but included other factors, such as affordable prices, sustainable financing and reliable health and supply systems with quality as an underpinning element.

7. Further, the coordinators of CEBS, Group B and the European Union shared the view that duplication of work within other WIPO bodies relating to this topic, i.e., the CDIP and other international organizations such as WHO and WTO should be avoided. Considering that any policy making should be evidence-based, they called for evidence-based justifications for policies implemented or being prepared regarding the flexibilities.

8. Noting that the important role of the patent system lied in the incentives it provided to pharmaceutical companies, the Delegation of Japan stated that denying the contributions of the patent system toward enhancing public health would prevent medicines from being developed in the future. In its view, the existing patent system was well balanced and that any work should not shift that balance toward creating greater flexibilities.

9. A number of delegations shared experience of their countries in the use of health-related patent flexibilities. The Delegation of Kenya stated that the Kenyan patent law, which contained various flexibilities, had been helpful in addressing public health problems in its country, including facilitating access to affordable medicines through the significant reduction of price for medicines. Further, the Delegation shared a particular case related to the use of compulsory licensing in its country and acknowledged that there were some challenges in the use of flexibilities which needed further study.

10. The Delegation of Zimbabwe, presenting the case of its country regarding the public health and patents, stated that the Zimbabwe Patent Act contained all the key flexibilities as provided in the TRIPS Agreement. However, only one flexibility, namely the compulsory license for government use had been utilized, which had not achieved its objectives. Therefore, the Delegation called for the need of technical assistance on how countries could best utilize the TRIPS flexibilities to promote public health and how the governments could also make use of those flexibilities that were in the national legislation but not implemented.

11. Similarly, the Delegation of Zambia reported on the unsuccessful experience with compulsory licensing implementation in its country. It noted, *inter alia*, that public health issues required commitment from all stakeholders and holistic approach which was practical, balanced and sustainable.

12. The Delegation of Algeria informed the Committee that, to date, its country did not have any problems in implementing exceptions and flexibilities, as prescribed in its law. While stating that some exceptions and limitations were easy to implement, the Delegation, however, noted that compulsory licenses in respect of medicines had not been used. Considering that they may use compulsory licenses in the future, the Delegation proposed the Committee to examine whether there should be a legal assistance to strengthen the human resources of offices, so that countries could better cope with the implementation of the provisions under their law.

13. The Delegation of Colombia explained the connection between competition law and patents. It further wished to reiterate that the purpose of the patent system was to deal with the higher costs and risks related to research and development. Protecting inventions against imitation encouraged further innovation. The social responsibility of pharmaceutical companies would be to make their products available to the society. If they failed, a compulsory licensing

mechanism could be used by governments. However, the Delegation pointed out that that did not imply that the States should get involved in the way in which an individual pharmaceutical company used its resources, unless there were some indications that the commercial or marketing practices infringed the law of the country concerned. Furthermore, the Delegation noted that one should not, in advance, assume misappropriation or misuse of a patent because that would be an infringement of the principle of good faith. The Delegation also talked about the role of the regulatory body in fixing the problems related to access to medicines.

14. The Delegation of Brazil stated that, in its country, the universal access to health was an individual right present in the constitution. In the international debate, Brazil supported different initiatives and processes aimed at promoting universal access to health. The Delegation stated, *inter alia*, that the Brazilian law, in certain aspects, provided broader protection when compared to the protection granted by multilateral treaties. Brazil supported a balanced system that would, at the same time, support innovation and guarantee to the society the benefits of innovation. The Delegation did not agree that the discussion on that topic at the SCP duplicated discussions in other WIPO bodies or other organizations.

15. The Delegation of Belarus expressed its support to the work of the SCP on patents and health in view of, *inter alia*, its socio-humanitarian significance. In this regard, Belarusian policy was aimed at progressive modification of national legislation in order to achieve the balance of interests of both the patent-holders and the general public via use of patent flexibilities. Noting that the endeavors to establish such a balance required thorough study and analysis of existing flexibilities and the best practices of their implementation, the Delegation expressed its belief that a WIPO study of the topic would be a very helpful assistance to the Member States.

16. The Delegation of the United States of America, *inter alia*, stated that patent flexibilities contained in the Drug Price Competition and Patent Term Restoration Act, informally known as the “Hatch-Waxman Act”, created a balanced approach to flexibilities. In particular, the Delegation noted that the Hatch-Waxman Act resulted in continued innovation in new medicines as well as strong generic drug industry in the United States of America.

17. The Delegation of Iran noted, *inter alia*, that the issue of public health and patents and having access to medicines at an affordable price were important issues for developing countries, and suggested that the SCP explore practical ways to respond to existing challenges. The Delegation believed that WIPO, as a specialized agency of the United Nations, had the mandate to address the topic of patents and public health. The Delegation was of the view that the proposal submitted by the African Group and the DAG would not constitute a duplication with any other processes within or outside of WIPO.

18. The Delegation of South Africa informed the SCP that its government had been working on the national policy on intellectual property rights which focused heavily on health reform to address the particular health challenges. In this regard, the Delegation stated that the leak by the multinational pharmaceutical industry to undermine that effort was unfortunate. The Delegation stressed that it was imperative that the SCP substantively discussed the issue of patents and public health, and drew up a work program which would assist countries in adapting patent laws to make full use of patent-related flexibilities in accordance with their public health needs. The Delegation was also of the view that WIPO, as a specialized agency of the United Nations, had a key role to play within its mandate to facilitate access to medicines.

19. The Delegation of Argentina stated that, under the TRIPS Agreement, countries had flexibility in defining the term “invention”, as well as other patentability requirements. The

Delegation noted that flexibilities enable governments to elevate the negative impact that intellectual property rights may have on the right to health. Consequently, in the view of the Delegation, it was important to develop the study on flexibilities contained under the TRIPS Agreement and their implementation based on the proposal made by the African Group and the DAG.

20. In addition to the above mentioned Member States who supported the proposal made by the African Group and the DAG, the Delegation of China also expressly stated that the work of the SCP on this issue could be based on the work program contained in that proposal.

21. On the other hand, the Delegation of Greece, speaking on behalf of the European Union, emphasized that further work in this area should reflect a balanced approach and draw, for instance, inspiration from the proposal of the Delegation of the United States of America.

22. Further, the Representatives of Knowledge Ecology International, Inc. (KEI), Third World Network (TWN), and Médecins sans Frontières (MSF) also joined countries which supported the proposal made by the African Group and the DAG.

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