

## **Standing Committee on the Law of Patents**

**Seventeenth Session**  
**Geneva, December 5 to 9, 2011**

### **WIPO ACTIVITIES ON PATENTS AND HEALTH**

*Document prepared by the Secretariat*

#### **I. INTRODUCTION**

1. At its sixteenth session held from May 16 to 20, 2011 in Geneva, the Standing Committee on the Law of Patents (SCP) requested that the Secretariat prepare, for the seventeenth session of the SCP, a document describing the activities of the World Intellectual Property Organization (WIPO) on patents and health, including the relevant cooperation activities with other international organizations (see paragraph 15(c) of document SCP/16/8).
2. Accordingly, this document is submitted to the seventeenth session of the SCP, to be held from December 5 to 9, 2011. The document aims at providing comprehensive information regarding the activities of WIPO in the area of patents and health in order to assist informed discussions within the Committee on this topic.
3. WIPO's determination to serve as a leading intergovernmental forum for addressing the intersection between intellectual property, innovation and global policy issues is expressed by one of the nine strategic goals of the Organization: "Addressing IP in relation to global policy issues".
4. More specifically, based on the mandate established by the Program and Budget for the 2010/11 biennium under Program 18 on IP and Global Challenges, WIPO created the Global Challenges Division to carry out work under that Program in close cooperation with relevant WIPO programs, other agencies and substantive engagement with other relevant stakeholders, namely, the United Nations and other intergovernmental organizations (IGOs), civil society and non-governmental organizations (NGOs), as well as the private sector and academia. Together with other stakeholders, WIPO aims at contributing to the shared search for solutions to the major challenges facing humanity, including challenges relating to public health. The objective

of the Program is to lead and inform policy deliberations, to facilitate access to, and use of, information and to support the assessment of policy, legal and practical options concerning IP and global issues, such as climate change, food security and public health. The work under the Global Challenges program builds on previous health related activities carried out by the former Global Issues Division in connection with Program 5 (Life Sciences) under the Program and Budget for the 2008/09 biennium.

5. WIPO's activities on patents and health, however, go beyond the work carried out under Program 18. Many activities of WIPO directly or indirectly relate to the topic of patents and health. Therefore, this document intends to capture the wide range of activities covered by WIPO that relates to patents and health.

6. WIPO is a specialized agency of the United Nations dedicated to intellectual property issues. As WIPO alone does not have a comprehensive competence in the area of health, and in view of the complexity of the challenges relating to the area of health, the Organization works closely with other IGOs and NGOs, having different, but relevant competencies. The cooperation and the enhanced dialog with WIPO's international organization partners, such as the World Health Organization (WHO), the World Trade Organization (WTO) and the United Nations Conference on Trade and Development (UNCTAD), but also with regional and national organizations as well as with NGOs, civil society, the private sector and academia is an important part of the strategy addressing public health and intellectual property issues. Consequently, many of WIPO's activities, be it at the policy level or at the practical level, have been undertaken in cooperation with other stakeholders. This document illustrates the wide range of partners with whom WIPO works together in the field of patents and health.

7. Following this Section, Section II briefly illustrates patent-related activities of WIPO which may not be directly addressing health issues, but which may have an indirect relevance in improving the contribution of the patent system in the area of health. Sections III to VII provide information on WIPO activities that directly relate to patents and health. These WIPO activities are categorized as follows: (i) WIPO Development Agenda and CDIP projects; (ii) seminars and conferences in Geneva; (iii) technical and legal cooperation; (iv) cooperation with WTO and WHO; and (v) other activities.

## **II. GENERAL ACTIVITIES**

8. Many activities relating to patents undertaken by WIPO are not specifically addressing the health area. Nevertheless, they may be relevant to the issues relating to patents and public health, since the general objectives of the patent system, i.e., the promotion of technological innovation and the transfer and dissemination of technology, are of fundamental importance for improving public health. Legal and institutional frameworks which adequately balance incentives to innovate and access to technology, taking into account the interest of both technology holders and technology users, support innovation, dissemination and transfer of technology in the health area as well.

9. In a way, all efforts to improve the patent system have a positive impact, either directly or indirectly, on the contribution of the patent system to health issues. For example, a high quality of granted patents, sufficient disclosure of inventions in patent applications, or an adequate scope of protection with the necessary exceptions and limitations are some essential elements for the patent system to fulfill its objectives also in terms of innovation and transfer of technology in the health area. An improved infrastructure for accessing patent information and improved technical infrastructure of patent offices increase the efficiency of disseminating technological information relating to health as well as the legal information necessary for technology transfer, such as who owns which health-related technology in which country (or countries) for how long. In order to ensure the quality of health-related patents and the sound enforcement of law, the

capacity of patent officers, patent examiners, judges, enforcement officers and patent professionals, such as patent attorneys, needs to be constantly enhanced so that they are equipped with the necessary knowledge and skills in a fast-moving society. Therefore, it may be worth briefly mentioning those general activities relating to patents, carried out by WIPO, which may be relevant to health.

10. In the context of the SCP, the Committee agreed, at its sixteenth session, to establish a questionnaire on exceptions and limitations to patent rights. Answers received from Member States to this comprehensive questionnaire have been compiled in a document submitted to the seventeenth session of the SCP. The questionnaire includes certain exceptions and limitations that are often referred to in the discussions on health, such as compulsory licenses and government use, exhaustion of patent rights, research and experimental use exemptions and the exception relating to acts for obtaining regulatory approval from a governmental authority. In addition, the Committee also discusses issues concerning the quality of patents and transfer of technology.

11. As an international patent filing system, the well functioning of the Patent Cooperation Treaty (PCT) is important for the international patent system in all fields of technology, including technologies relating to health. Due to its global reach, the timeliness and quality of international work products under the PCT, such as the international publication of PCT international applications and the preparation of international search reports, written opinions and international preliminary examination reports, are an integral part of the factors that determine the quality of national and regional patent systems in many countries.

12. With respect to the development dimension of the topic “patents and health”, the WIPO Development Agenda aims to ensure that development considerations form an integral part of WIPO’s work. As such, it is a cross-cutting issue which touches upon all activities of WIPO, including those that relate to patents and health. Generally speaking, many Development Agenda recommendations address, for example: (i) the promotion of a fair balance between intellectual property protection and the public interest; (ii) consideration of the priority and the special needs of developing countries and least developed countries (LDCs); and (iii) flexibilities in international intellectual property agreements, which should be supportive of the development goals agreed within the United Nations system, including those contained in the Millennium Declaration. At the project level, for instance, the projects relating to transfer of technology, patents and the public domain (including consideration of national patent registry databases) and competition policy as well as the establishment and development of Technology and Innovation Support Centers (TISCs) have been carried out with a view to taking concrete steps that contribute to development. Indeed, public health is recognized as one of the key areas in many Development Agenda projects.

13. Since innovation, commercialization and transfer of technology are essential for the development of health-related technology and products, WIPO’s activities in this area should also be mentioned. For instance, WIPO assists Member States in formulating national IP and innovation strategies and developing institutional intellectual property policies, including the establishment of transfer of technology offices in universities and public institutions. For the effective use of the intellectual property system for development in developing countries, LDCs and countries with economies in transition, WIPO has been organizing workshops and seminars on innovation and its commercialization, such as patent drafting, licensing and IP management. In addition, the activities specifically targeted to small and medium enterprises (SMEs) to successfully use IP for commercialization have been conducted through providing supportive information and organizing seminars, workshops etc. It is expected that those activities positively support innovation, commercialization and transfer of technology in the health area as well.

14. Further, technical assistance and capacity building in other patent-related areas, such as legislative advice, training government officers and modernizing IT infrastructure of patent offices, are also part of the core activities of WIPO. A number of educational programs for enhancing the understanding of intellectual property issues, for example, summer schools, distance learning courses and Master programs are also conducted by WIPO.

15. Technologies relating to health can be very complex, and may require a high level of expertise in examining patent applications in that field. WIPO's International Cooperation on Examination (ICE) service, a remodeled service of the International Cooperation for Search and Examinations of Inventions (ICSEI), will explore the provision of coordination services and make arrangements between donor and requesting IP offices for delivery of search and examination reports on patent applications and for organizing training and other capacity building programs to develop skills in utilizing such reports.

16. Patent information, i.e., published patents (and published patent applications in many countries) as well as information associated with those patents (and patent applications), is an important source of valuable technical information as well as legal information about the ownership and the scope and term of patent protection, among others. With a view to facilitating access, retrieval, use and dissemination of patent information, including health-related patent information, the International Patent Classification (IPC) and WIPO standards have been constantly reviewed and developed by the relevant WIPO bodies. Further, information and communication technology has created opportunities for more effective access to the output of the patent system. In this regard, WIPO develops global IP databases (for example, PATENTSCOPE) and voluntary platforms (for example, "Access to Research for Development and Innovation" (aRDi) and "Access to Specialized Patent Information" (ASPI)); (ii) assists digitization of patent collections; and (iii) supports capacity building to facilitate the use of various patent information tools and databases.

17. Lastly, the WIPO Arbitration and Mediation Center offers alternative dispute resolution options for the resolution of international commercial disputes between private parties. Such dispute resolution mechanisms are available for solving disputes in the area of health, and indeed, 15% of arbitration and mediation cases filed with the Center were in the field of pharmaceuticals.<sup>1</sup>

### III. DEVELOPMENT AGENDA AND CDIP PROJECTS

18. While many Development Agenda recommendations and projects under the CDIP may be relevant to patents and health at the general level, the Patent Landscape Reports Project<sup>2</sup> specifically identifies public health as one of its priority areas. As an implementation of the Development Agenda project DA\_19\_30\_31\_01 ("Developing Tools for Access to Patent Information"), adopted by the CDIP at its fourth session, held from November 16 to 20, 2009 (document CDIP/4/6<sup>3</sup>), a series of patent landscape reports in the area of public health<sup>4</sup> is being prepared.

19. In particular, two patent landscape reports on the HIV antiretrovirals (Ritonavir and Atazanavir) have recently been published in cooperation with the Medicines Patent Pool and UNITAID.<sup>5</sup> These reports illustrate not only the diversity and interdependence of various

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<sup>1</sup> <http://www.wipo.int/amc/en/center/caseload.html>.

<sup>2</sup> [http://www.wipo.int/patentscope/en/programs/patent\\_landscapes/pl\\_about.html](http://www.wipo.int/patentscope/en/programs/patent_landscapes/pl_about.html).

<sup>3</sup> [http://www.wipo.int/edocs/mdocs/mdocs/en/cdip\\_4/cdip\\_4\\_6.pdf](http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_4/cdip_4_6.pdf).

<sup>4</sup> [http://www.wipo.int/patentscope/en/programs/patent\\_landscapes/pl\\_ongoingwork.html](http://www.wipo.int/patentscope/en/programs/patent_landscapes/pl_ongoingwork.html).

<sup>5</sup> [http://www.wipo.int/patentscope/en/programs/patent\\_landscapes/reports/ritonavir.html](http://www.wipo.int/patentscope/en/programs/patent_landscapes/reports/ritonavir.html) and [http://www.wipo.int/patentscope/en/programs/patent\\_landscapes/reports/atazanavir.html](http://www.wipo.int/patentscope/en/programs/patent_landscapes/reports/atazanavir.html).

patents related to this compound, but also the various approaches for studying drug developments through patents. They also constitute examples of access to and utilization of patent information. The patent landscape report related to Ritonavir identifies a number of innovation tracks that spun off from the first Ritonavir patent application. These innovation tracks illustrate the continuation of important protection related to Ritonavir, as subsequent generations of patents continue to narrow the scope of protection while still maintaining protection from the first Ritonavir patent. The report also includes an analysis of statistical trends. The Atazanavir patent landscape report additionally illustrates various patent search methodologies, using various proprietary and non-proprietary indexing systems, showcasing the challenges related to the different chemical, clinical, manufacturer, generic and brand designations which may be used to identify a specific chemical compound.

20. Further, in the framework of the collaboration of WIPO with the WHO cluster on Innovation, Information, Evidence and Research (IER), a patent landscape report on vaccines currently under preparation intends to contribute to the implementation of several of the eight elements of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA) of WHO. The report will provide an overview of patenting activity in the area of vaccines by means of a statistical analysis, complemented by a separate section on patenting related to vaccines for three selected diseases of high economic and health burden importance: (i) streptococcus pneumonia conjugate vaccines; (ii) typhoid conjugate vaccines; and (iii) influenza vaccines. The first two of the selected diseases are targets for facilitated technology transfer to developing country vaccine manufacturers, and the third, while being well-known and already a target of technology transfer, is a disease of immense public health importance for which there appears to be a wide range of patents being applied for. The report will include a special focus on the respective patenting activity in the emerging economies of Brazil, China and India. A further patent landscape report in the area of disabilities is envisaged

21. In the framework of actions for implementation of recommendation 14 under the WIPO Development Agenda, two documents describing patent-related flexibilities in the multilateral legal framework and their legislative implementation at the national and regional level (documents CDIP/5/4 Rev. and CDIP/7/3) were submitted to the CDIP. These documents examine the implementation and use of flexibilities in national/regional laws and regulations, including flexibilities relating to compulsory licenses and government use, exhaustion of rights, research exemption, regulatory review exception, transitional periods and the patentability of substances existing in nature, among others.

#### **IV. SEMINARS AND CONFERENCES IN GENEVA**

22. Since 2007, WIPO has organized a series of Life Sciences Symposia, inviting speakers who represent a wide range of stakeholders, including organizations, policymakers, government agencies, legislators, delegates, and civil society actors. The symposia provided a forum for exchanging information and experiences in making use of the intellectual property system in life sciences. They explicitly did not aim at assessing or influencing discussions in any other forum and, therefore, did not produce any formal outcome.

Those which are most relevant to public health include:

- IP and Bioethics; September 4, 2007.<sup>6</sup> The Symposium looked at implications of intellectual property rights and their ethical underpinnings. WIPO has been an active member of the UN Inter-Agency Committee on Bioethics (UNIACB) since its inception. The Committee provides a forum for debate and exchange of information in the field of bioethics and related issues and promotes coordination and cooperation among UN

<sup>6</sup> [http://www.wipo.int/meetings/en/2007/lifesciences/sym\\_bioethics/](http://www.wipo.int/meetings/en/2007/lifesciences/sym_bioethics/).

agencies and other regional and international inter-governmental groups that deal with the field of bioethics. WIPO has also prepared an issues paper "Intellectual Property and Bioethics An Overview" which is published on WIPO's website.<sup>7</sup>

- Current Issues in Intellectual Property and Public Health, September 19, 2007:<sup>8</sup> A half-day Symposium in which representatives of WIPO Member States (Chile, France, Thailand), WHO, WTO, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) and Médecins sans frontières (MSF) (Doctors without Borders) discussed current issues in the area of IP and public health.
- Intellectual Property and Life Sciences Regulations, November 16, 2007:<sup>9</sup> Organized by WIPO in cooperation with the Stockholm Network, this Symposium discussed the IP dimension of protecting regulatory data related to pharmaceutical and agricultural products. It addressed exceptions to patent rights for regulatory processes, the grant of patent term extensions to compensate for regulatory requirements, and the challenge of regulating new technologies as well as biological pharmaceuticals and diverse approaches to linking patent protection with regulatory approval mechanisms.
- Public Policy Patent Landscaping in the Life Sciences, April 7 and 8, 2008:<sup>10</sup> Organized in cooperation with the Food and Agriculture Organization (FAO), this Symposium included a peer review of a WIPO-FAO Patent Search Project on plant genetic resources for food and agriculture and a comparative review of public policy patent landscaping in other fields of life sciences, with a special focus on public health landscaping.
- Public Sector Intellectual Property Management, December 15, 2008:<sup>11</sup> This Symposium explored different national approaches, institutional policies and public-private partnerships in public sector management of IP in the life sciences. The speakers included representatives from WIPO Member States (Cuba, Germany, South Africa, United States of America), the International Centre for Genetic Engineering and Biotechnology (ICGEB), WHO, the Medicines for Malaria Venture (MMV) and the Drugs for Neglected Diseases Initiative (DNDI).
- Symposium on Future Challenges of International Law: the Way Forward in Patenting Biotechnology, November 25, 2009:<sup>12</sup> Organized in cooperation with the University of Berne and the World Trade Institute (WTI), this Symposium addressed the interface between biotechnology, IP rights and international trade, and explored options for the international patent system following the WTO Doha Round. The Swiss National Centre of Competence in Research (NCCR) presented work conducted in the framework of its International Trade Project on Biotechnology. The program presented aspects of human genetic resources, human rights, ethics and practical research issues which are of particular relevance also in the debate on public health and health related biotechnology research. The Symposium looked as well at future challenges regarding the international regulation of IP rights and biotechnology from the WIPO and WTO perspectives.

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<sup>7</sup> [http://www.wipo.int/export/sites/www/freepublications/en/life\\_sciences/932/wipo\\_pub\\_b932ipb.pdf](http://www.wipo.int/export/sites/www/freepublications/en/life_sciences/932/wipo_pub_b932ipb.pdf).

<sup>8</sup> [http://www.wipo.int/meetings/en/2007/lifesciences/sym\\_health/](http://www.wipo.int/meetings/en/2007/lifesciences/sym_health/).

<sup>9</sup> [http://www.wipo.int/meetings/en/2007/lifesciences/sym\\_regulation/](http://www.wipo.int/meetings/en/2007/lifesciences/sym_regulation/).

<sup>10</sup> [http://www.wipo.int/meetings/en/2008/lifesciences/patent\\_landscaping/](http://www.wipo.int/meetings/en/2008/lifesciences/patent_landscaping/).

<sup>11</sup> [http://www.wipo.int/meetings/en/2008/lifesciences/ip\\_lss3\\_ge/](http://www.wipo.int/meetings/en/2008/lifesciences/ip_lss3_ge/).

<sup>12</sup> [http://www.wipo.int/meetings/en/2009/wipo\\_ls\\_biot\\_ge\\_09/index.html](http://www.wipo.int/meetings/en/2009/wipo_ls_biot_ge_09/index.html).

- The Evolution of the Regulatory Framework on Pharmaceutical Test Data, February 8, 2010.<sup>13</sup> This Symposium focused on legal practice and experience in test data protection in the pharmaceutical industry. Participants included representatives of intergovernmental organizations, regulatory agencies and industry.

23. In addition, during the last decade, the topic of patents and health has been frequently addressed in the conferences organized by WIPO, such as: (i) Conference on the International Patent System, March 25 to 27, 2002, Geneva; (ii) International Seminar on Intellectual Property and Development, May 2 and 3, 2005, Geneva;<sup>14</sup> and (iii) Open Forum on the Draft Substantive Patent Law Treaty (SPLT), March 1 to 3, 2006, Geneva.<sup>15</sup> More recently, a Conference on Intellectual Property and Public Policy Issues, held on July 13 and 14, 2009, in Geneva,<sup>16</sup> addressed issues relating to the interface of intellectual property with other areas of public policy, including health. With respect to public health, the participants discussed issues such as how to strengthen multilateral cooperation, how to promote access to medicines through balancing patent rights and responsibilities and what are innovation models that meet the challenges of neglected diseases.

## V. TECHNICAL COOPERATION

### TECHNICAL ASSISTANCE

24. All technical assistance activities relating to patents are also relevant to innovation, dissemination and transfer of technology in the area of health in the general sense, and are carried out in accordance with the spirit of the Development Agenda recommendations. Some of the most recent events organized by WIPO in cooperation with national authorities, which specifically addressed health issues,<sup>17</sup> are highlighted as follows:

- WIPO Seminar for Certain Arab Countries on Facilitating Access to Innovative Pharmaceuticals through the Creative Implementation of International Industrial Property Obligations, May 11 to 13, 2009, Muscat, Oman: The seminar was organized in cooperation with the Ministry of Health of the Sultanate of Oman, and its objective was comprised in the scope of recommendation 22 of the Development Agenda. The purpose of the seminar was to discuss with a number of member States the impact of intellectual property on national public policies related to the promotion of access to pharmaceuticals, namely, the encouragement of the establishment of local generic industries without undermining the incentive effect for research-based companies.
- Workshop on Intellectual Property Business Strategies in the Pharmaceutical Industry and Training for Trainers on IP Business Strategies, May 18 to 22, 2009, Rio de Janeiro, Brazil: The Workshop was organized in cooperation with the National Institute of Industrial property of Brazil and Fundação Oswaldo Cruz. The Workshop implemented an initiative that stimulated the sharing of best practices on commercialization of IP results.
- Training Course on Intellectual Property Strategies in the Health and Pharmaceutical Sector, June 8 to 12, 2009, Havana, Cuba: This Training Course implemented an

<sup>13</sup> [http://www.wipo.int/meetings/en/2010/wipo\\_ip\\_iss1\\_ge\\_10/](http://www.wipo.int/meetings/en/2010/wipo_ip_iss1_ge_10/).

<sup>14</sup> [http://www.wipo.int/meetings/en/details.jsp?meeting\\_id=7523](http://www.wipo.int/meetings/en/details.jsp?meeting_id=7523).

<sup>15</sup> [http://www.wipo.int/meetings/en/2006/scp\\_of\\_ge\\_06/](http://www.wipo.int/meetings/en/2006/scp_of_ge_06/).

<sup>16</sup> [http://www.wipo.int/meetings/en/2009/ip\\_gc\\_ge/index.html](http://www.wipo.int/meetings/en/2009/ip_gc_ge/index.html).

<sup>17</sup> WIPO's technical cooperation activities that were held in cooperation with WHO and WTO are found in Chapter VI.

initiative that stimulates the sharing of best practices on commercialization of IP results in the health and pharmaceutical sector.

- The WIPO Regional Seminar on Intellectual Property, Software and E-Health: Trends, Issues, Prospects, June 3 and 4, 2010, Kigali, Rwanda: In the context of e-health, the Seminar looked at intellectual property issues relating to software, including the patentability of software-implemented inventions.
- WIPO National Seminar on the Role of Patents and Intellectual Property Rights (IPRs) in Medical and Pharmaceutical Science, Technology Transfer and Commercialization, April 26 to 28, 2010, Tehran, Islamic Republic of Iran: The Seminar was organized in cooperation with the State Organization for Registration of Deeds and Properties and the Tehran University of Medical Sciences. It provided information to, and enhanced the awareness of, professors, students and researchers in the field of medical and pharmaceutical sciences, concerned officials and experts on the basic principles of intellectual property rights, technology transfer and commercialization in medical and pharmaceutical science.
- WIPO Sub-Regional Workshop for Central American Countries and the Dominican Republic on the Legal Impact of FTAs on Industrial Property Laws, December 15 and 16, 2010, Panama: The objective of this regional workshop was to analyze the impact of the Regional Free Trade Agreements in the national law of Central American countries, as well as to hold consultations with those countries on the future revision of their legal frameworks.
- WIPO National Workshop on Industrial Property, the TRIPS Agreement and Flexibilities, April 3 to 7, 2011, Damascus, Syrian Arab Republic: The Seminar was part of the on going process of the accession of the Syrian Arab Republic to the WTO. The program covered, among others, the multilateral legal framework and flexibilities available in a patent law, such as the patentable subject matter, exceptions and limitations and the transitional period.
- Regional Workshop on Innovation, IP Asset Management and Successful Technology Licensing (IP and Pharmaceuticals), December 2011, Muscat, Oman (to be organized in cooperation with the Islamic Development Bank (IDB)).

25. In addition, a number of policy forums organized by WIPO included discussions on intellectual property and public health issues. For example, during the International Conference on IP and Development, held from October 17 to 19, 2010, in Alger, Algeria, several topics discussed covered issues concerning patents and health. Further, WIPO organized high-level forums for LDCs that included discussions on intellectual property and public health issues, among others. WIPO Regional Forums on the Use of Intellectual Property for Development for the English speaking African LDCs, for French speaking African LDCs, for Portuguese speaking LDCs and for Asia and the Pacific LDCs were held between December 2009 and November 2010. A Ministerial Declaration adopted during the High-Level Ministerial Conference organized by WIPO on the occasion of the Fourth United Nations Conference for the Least Developed Countries (UN LDC IV), held from May 9 to 13, 2011, in Istanbul, Turkey, sought to capture the deliberations and recommendations of all thematic issues that had been discussed at the above Regional Forums.

26. Moreover, the WIPO Academy organizes a number of educational programs which also contains the topic of patents and health,<sup>18</sup> for example:

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<sup>18</sup> Other colloquia and courses organized with WTO are found in paragraph 40.

- Master of Laws (LLM) in Intellectual Property, Turin, Italy;
- Master in Intellectual Property, Mutare, Zimbabwe;
- Master of Laws in Intellectual Property, Yaounde, Cameroon;
- WIPO Summer Schools on Intellectual Property (Geneva, Dubrovnik, Daejeon, Odessa, Saint Petersburg, Washington D.C., Mexico-City, Sao Paulo, Cape Town, Suva);
- WIPO-Sweden Advanced Training Course on Industrial Property in the Global Economy, Stockholm, Sweden.

## LEGISLATIVE ADVICE AND FLEXIBILITIES

27. Upon request by its Member States, WIPO provides legislative assistance and policy advice in relation to national patent laws and regulations. The assistance provided includes advice on the proper utilization of flexibilities available within the multilateral legal system. In particular, legislative advice relating to the implementation of the Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) is underpinned by the provisions of the Agreement between WIPO and WTO which entered into force on January 1, 1996. Such advice includes the implementation of the Doha Declaration on the TRIPS Agreement and Public Health, the Decision of the WTO Members on the “waiver” in 2003 and the subsequent amendment of the TRIPS Agreement at the national and regional levels.

28. During the period from June 2009 to June 2011, WIPO has provided legislative and policy advice in response to requests from the authorities of 18 countries<sup>19</sup> and one regional body.<sup>20</sup> The advice generally covers all fields relating to the patent, utility model and trade secret systems. Among them, those that are closely related to health policies include, for example, the effective implementation of a patent system that promotes innovation; the identification of patentable subject matter and the use of available flexibilities, i.e., medical inventions (surgical, therapeutic and diagnostic methods); and the scope of the patent rights and its exceptions and limitations, i.e., research and regulatory review exceptions. Further, advice was also provided with respect to different options available under the multilateral legal instruments, namely, the recourse to compulsory licences, the identification of the proper level of exhaustion, the use of general transitional periods for certain countries (LDCs) or object specific transitional periods (i.e., pharmaceutical and agricultural chemical products), the adoption of the prosecution system for patent applications and ways and means for its enforcements. In certain cases, requests are more focused on the assessment of the compatibility of a given law with a treaty that the country is going to join or of a number of flexibilities, including health-related ones, implemented under the law of a given country. Frequently, Member States pay particular policy attention to the protection of test data, either because of general TRIPS commitments or due to more precise obligations under bilateral or regional agreements.

29. During the period mentioned above, the following activities have been undertaken by WIPO with respect to legislative and policy advice in the area of patents: (i) the elaboration of 22 comments on draft laws prepared by Member States and submitted for WIPO comments; (ii) six draft laws were prepared by WIPO and sent for the authorities’ consideration; (iii) eight short-term missions on legislative advice for consultations in capitals with competent authorities and stake holders; (iv) two consultation meetings with authorities at the WIPO Headquarters in

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<sup>19</sup> Bangladesh, Bosnia and Herzegovina, Cook Island, Colombia, Dominican Republic, Ecuador, Egypt, Jamaica, Grenada, Iraq, Lebanon, Lithuania, Maldives, Mauritius, Nigeria, Sudan, Yemen and United Arab Emirates.

<sup>20</sup> Common Market for Eastern and Southern Africa (COMESA).

Geneva; and (v) the preparation of documents CDIP/5/4 Rev. and CDIP/7/3 (see paragraph 21) which have been useful materials for the provision of legislative advice.

30. During the sixth session of the CDIP, the request was made to provide regional seminars, and to ensure or facilitate the exchange of practical experiences among Member States in the implementation of flexibilities. Consequently, WIPO organized a Regional Seminar on the Effective Implementation and Use of Several Patent-Related Flexibilities,<sup>21</sup> jointly with the Department of Intellectual Property of Thailand (DIP), from March 29 to 31, 2011, in Bangkok, Thailand. The Regional Seminar was attended by 23 participants from 16 countries of Asia and the Pacific region, in addition to local participants from Thailand. Speakers included two regional speakers (from Singapore and the Philippines) and two representatives from the private sector (from a Japanese generic pharmaceutical industry association and a research-based pharmaceutical industry association from Thailand).

## LEGAL STATUS SERVICE

31. Upon request from developing countries, LDCs or competent intergovernmental or non-governmental organizations, WIPO provided, in cooperation with relevant national and regional patent offices, legal status information, as follows:

- Legal status information on a number of patents related to antiretroviral medicines in some national developing countries' jurisdictions was made available to the Medicines Patent Pool. The data provided assisted the Medicines Patent Pool to verify and publish this information on its Patent Status Database for Selected HIV Medicines.<sup>22</sup>
- Patent information related to Moxifloxacin, an antibiotic used against multi-drug resistant tuberculosis (MDR TB), was provided for the StopTB Partnership in order to facilitate the procurement process for a clinical trial using Moxifloxacin in Vietnam.

## TECHNOLOGY PLATFORMS

32. In order to facilitate the sharing of knowledge and the adaptation, transfer and diffusion of technologies, WIPO has been developing platforms that build on partnerships and collaborations between technology holders and technology users. In the area of health, WIPO Re:Search – *Sharing Innovation in the Fight Against Neglected Tropical Diseases*<sup>23</sup> was formed in 2011, and creates a partnership among WIPO, pharmaceutical companies, research and academic institutions and a non-governmental organization, BIO Ventures for Global Health. It provides access to intellectual property for pharmaceutical compounds, technologies, and – most importantly – know-how and data available for research and development for neglected tropical diseases, tuberculosis and malaria. WIPO Re:Search creates a searchable, public database of available intellectual property assets and resources to facilitate new partnerships and to support organizations that conduct research on treatments for neglected tropical diseases, tuberculosis and malaria.

33. In addition, WIPO is developing a web-based patent data retrieval environment that provides access to patent information related to essential health-related technologies on a jurisdiction-by-jurisdiction basis with the working title “WIPO Essential”. Improving access to

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<sup>21</sup> Discussions primarily covered five distinct topics, namely, (i) patentable subject matter; (ii) compulsory licenses; (iii) exhaustion of rights; (iv) research exemption; and (v) regulatory review exception.

<sup>22</sup> <http://www.medicinespatentpool.org/LICENSING/Patent-Status-of-ARVs>.

<sup>23</sup> <http://www.wiporesearch.org>.

pertinent patent information is the key to devising appropriate health programs and making effective policy decisions that enhance access and delivery in developing countries. The primary objective of WIPO Essential is to enable relevant users to access pertinent patent information on essential health-related technologies so that users will be able to engage in informed discussions, debates and communication relating to access and delivery of such technologies in developing countries.

## VI. COOPERATION WITH WHO AND WTO

### COOPERATION WITH WHO

34. WIPO has been actively participating in WHO meetings and providing substantive inputs with respect to intellectual property and innovation issues.

(a) WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH)

35. WIPO had been invited to provide preliminary comments during the process of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH). Following this invitation, the WIPO Secretariat made a presentation entitled "Intellectual property rights, innovation and public health: prospective WIPO inputs" at the WHO CIPIH on April 5, 2004.<sup>24</sup> Further, a document entitled "Preliminary Comments of WIPO to the WHO Commission on Intellectual Property Rights, Innovation and Public Health"<sup>25</sup> and a document "Follow-on Innovation and Intellectual Property"<sup>26</sup> were submitted to WHO.

(b) Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG)

36. In 2006, the 59<sup>th</sup> World Health Assembly (WHA) established the IGWG with the mandate to prepare a Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA) to secure an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries, proposing clear objectives and priorities for research and development, and estimating funding needs in this area<sup>27</sup>. The WIPO Secretariat participated, as an observer, in all meetings of the IGWG and the related sessions of the WHO Executive Board (WHO EB) and the WHA.

(c) Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA)<sup>28</sup>

37. The GSPOA requested the WHO Director-General "to coordinate with other relevant intergovernmental organizations, including WIPO and WTO, to effectively implement the global strategy and plan of action."<sup>29</sup> The three organizations meet regularly, exchange information on their respective work programs and discuss and plan, within the possibilities of their respective mandates and budgets, common activities. The coordination is intended to ensure the exchange of data, experiences and other information and best use of the available resources.

<sup>24</sup> <http://www.who.int/intellectualproperty/events/WIPO.pdf>.

<sup>25</sup> [http://www.wipo.int/export/sites/www/patentscope/en/lifesciences/pdf/who\\_comments.pdf](http://www.wipo.int/export/sites/www/patentscope/en/lifesciences/pdf/who_comments.pdf).

<sup>26</sup> [http://www.wipo.int/export/sites/www/patentscope/en/lifesciences/pdf/who\\_wipo.pdf](http://www.wipo.int/export/sites/www/patentscope/en/lifesciences/pdf/who_wipo.pdf).

<sup>27</sup> Resolution WHA 59.24, [http://apps.who.int/gb/ebwha/pdf\\_files/WHA59-REC1/e/Resolutions-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA59-REC1/e/Resolutions-en.pdf).

<sup>28</sup> [http://www.who.int/phi/implementation/phi\\_globstat\\_action/en/index.html](http://www.who.int/phi/implementation/phi_globstat_action/en/index.html).

<sup>29</sup> Resolution WHA 61.21, par. 4.(5), [http://apps.who.int/gb/ebwha/pdf\\_files/A61/A61\\_R21-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf).

(d) Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and other Benefits (PIP)

38. WIPO was invited, as an observer, to a number of WHO meetings relating to the WHO negotiation process on “Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and other Benefits” (PIP). In this context, based on WHA Resolution 60.28, WHO requested WIPO to prepare an expert paper. This expert paper provided the background to the WHO Report on “Patent issues related to influenza viruses and their genes” (document A/PIP/IGM/3), submitted to the WHO “Intergovernmental Meeting on Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits”, held from November 20 to 23, 2007, in Geneva. The Paper is published on the WIPO website<sup>30</sup> and, together with an Annex containing a “Patent Landscape for the H5 virus”, on the WHO website.<sup>31</sup>

39. In December 2010, WHO Member States requested the WHO Director-General to seek information from WIPO on Pandemic Influenza Preparedness-related patents to support the WHO “Open-Ended Working Group of Member States on Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and other Benefits (OEWG)”. WIPO prepared this report, and presented it to the meeting of the OEWG in April 2011. The report is published on the WHO website<sup>32</sup> and on the WIPO website.<sup>33</sup>

#### WHO-WIPO-WTO TRILATERAL COOPERATION

40. The participation of WIPO and WTO, as observers, in the WHO negotiation processes has over time contributed to build up and enhance a well working relationship between the three organizations on issues around public health, intellectual property and trade. This working relationship, supported by Development Agenda Recommendation 40 to intensify cooperation on IP related issues with UN agencies, matured into an informal, practical and well functioning trilateral cooperation between WHO, WIPO and WTO at the working level, whereby the three organizations meet regularly, exchange information on their respective work programs and discuss and plan, within the possibilities of their respective mandates and budgets, common activities. The trilateral cooperation is intended to contribute to enhancing the empirical and factual information basis for policy makers and supporting them in addressing intellectual property issues in relation to public health.

41. In the specific context of the trilateral cooperation, the following events have been organized:

- Joint Technical Symposium on Access to Medicines: Pricing and Procurement Practices, July 16, 2010:<sup>34</sup> This Symposium presented in a factual manner the experiences of international and regional agencies in the pricing and procurement of medicines as important determinants of access.
- Workshop on Patent Searches and Freedom to Operate, February 17, 2011:<sup>35</sup> The workshop introduced participants to the basic concepts of how to do patent searches and freedom to operate analysis.

<sup>30</sup> <http://www.wipo.int/export/sites/www/patentscope/en/lifesciences/pdf/influenza.pdf>.

<sup>31</sup> [http://www.who.int/csr/disease/avian\\_influenza/wipo\\_ipdoc/en/](http://www.who.int/csr/disease/avian_influenza/wipo_ipdoc/en/).

<sup>32</sup> [http://www.who.int/csr/disease/influenza/Influenza\\_FullReport\\_01Apr2011.pdf](http://www.who.int/csr/disease/influenza/Influenza_FullReport_01Apr2011.pdf).

<sup>33</sup> <http://www.wipo.int/globalchallenges>.

<sup>34</sup> [http://www.wipo.int/meetings/en/2010/wipo\\_wto\\_who\\_ge\\_10/](http://www.wipo.int/meetings/en/2010/wipo_wto_who_ge_10/).

<sup>35</sup> [http://www.wipo.int/meetings/en/details.jsp?meeting\\_id=22342](http://www.wipo.int/meetings/en/details.jsp?meeting_id=22342).

- Joint Technical Symposium on Access to Medicines, Patent Information and Freedom to Operate, February 18, 2011.<sup>36</sup> The Symposium addressed the growing importance of patent information for public health with respect to freedom to operate strategies, procurement of medicines, technology transfer and setting of research priorities and strategies. In this context, a case study looked into the patent status of medicines that had been recently included in the WHO Model List of Essential Medicines. Further, preliminary results of the WIPO patent landscape reports on the two antiretrovirals and vaccines as well as the Patent Status Database for Selected HIV Medicines, which had been established by the Medicines Patent Pool in collaboration with WIPO, were presented at the Symposium.

42. Further, in the context of the enhanced trilateral cooperation, WHO, WIPO and WTO have been increasingly engaged in providing inputs in their respective training activities. For example, since many years, speakers from WHO, WIPO and WTO participate in national and regional seminars and training courses organized by one or more of those organizations, for example:

- WTO-WIPO National Seminar on TRIPS, January 12 and 13, 2010, Dakar, Senegal;
- WTO-WIPO National Workshop on TRIPS, February 23 and 24, 2010, Kampala, Uganda;
- WTO-WIPO Regional Workshop on TRIPS Standards and Options for Public Policy, January 25 to 29, 2010, Singapore;
- WTO Regional Workshop for Central and Eastern European Countries, January 26 to 28, 2011, Vienna, Austria;
- WTO Regional Workshop for Latin America, March 8 to 11, 2011, Costa Rica;
- WTO National Workshop on IP and Public Policies, May 11 to 13, 2011, Ecuador;
- WTO Annual Workshop on the TRIPS Agreement and Public Health, September 21 to 24, 2010 and WTO Workshop on Intellectual Property and Public Health, October 10 to 13, 2011, Geneva;
- WTO Regional Workshop for Francophone African Countries on the TRIPS Agreement, Public Health and Traditional Medicine, planned for November 29 to December 1, 2011, Douala, Cameroun;
- WIPO-WTO Advanced Course on Intellectual Property for Government Officials, May 16 to 27, 2011, Geneva;
- WIPO-WTO Colloquium for Teachers of Intellectual Property, June 20 to July 1, 2011, Geneva.

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<sup>36</sup> [http://www.wipo.int/meetings/en/2011/who\\_wipo\\_wto\\_ip\\_med\\_ge\\_11/](http://www.wipo.int/meetings/en/2011/who_wipo_wto_ip_med_ge_11/).

## VII. OTHER ACTIVITIES

### UNITAID

43. Between 2008 and the establishment of the Medicines Patent Pool, WIPO participated, as an observer, in UNITAID meetings related to the UNITAID Medicines Patent Pool initiative, such as the UNITAID Executive Board and meetings of the UNITAID Expert group on the Patent Pool. It contributed to the discussions on various intellectual property related aspects of the setting up of the Patent Pool, such as general information on the intellectual property system, specific information on the functioning of the patent system, patent information, licensing practices and arbitration and mediation.

44. In cooperation with UNITAID, a group of experts was convened in September 2010 at WIPO to discuss and help define specific in-licensing and out-licensing terms in support of UNITAID in preparing for the setup of the Medicines Patent Pool.

### AFRICAN UNION

45. WIPO participated in meetings organized by the African Union (AU) on the AU Pharmaceutical Manufacturing Plan for Africa, namely, the first and second meetings of the Technical Committee on the Pharmaceutical Manufacturing Plan for Africa, held in October 2007 in Addis Ababa, Ethiopia and in February 2008 in Johannesburg, South Africa, respectively. The WIPO Secretariat gave a presentation on “Issues on Intellectual Property and Public Health” to the Technical Committee.

### AFRICAN NETWORK FOR DRUGS AND DIAGNOSTICS INNOVATION (ANDI)

46. WIPO supported the initiative of the Special Programme for Research and Training in Tropical Diseases (TDR) to develop an African Network for Drugs and Diagnostics Innovation (ANDI). WIPO participated in ANDI task force meetings as an observer. As part of the preparatory steps, ANDI mapped the health research and development (R&D) landscape of the African continent to better understand ongoing activities, available capacity as well as challenges and opportunities. With the help of WIPO, this mapping exercise also provided useful information on the African IP landscape based on available patent literature and interviews with several investigators. WIPO has also provided a case study on IP and benefit-sharing in the development of drugs based on traditional knowledge, a questionnaire for the ANDI audit on existing IP management capabilities as well as elements for an ANDI IP strategy. Most recently, WIPO participated in the ANDI stakeholder meeting and high level forum, which was held from October 11 to 13, 2010, in Nairobi, Kenya.

### AFRICAN LEADERS' MALARIA ALLIANCE (ALMA)

47. The African Leaders' Malaria Alliance (ALMA), working to end malaria-related deaths, was founded by African Heads of State. WIPO participated in an ALMA Conference on Local Manufacturing in Africa, which was held from May 26 to 31, 2011, in Nairobi, Kenya.

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