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Standing Committee on the Law of Patents

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REPORT OF THE SHARING SESSION REGARDING THE EXPERIENCES ON CAPACITY BUILDING ACTIVITIES RELATED TO NEGOTIATING LICENSING AGREEMENTS

Document prepared by the Secretariat

1. Pursuant to the decision of the Standing Committee on the Law of Patents (SCP) at its thirtieth session, held in Geneva from June 24 to 27, 2019, the present document contains, in its Annex, a report of the sharing session regarding the experiences on capacity building activities related to negotiating licensing agreements, which was held at the thirtieth session of the SCP on June 24, 2019, under agenda item 8: Patents and Health. All presentations are available at: https://www.wipo.int/meetings/en/details.jsp?meeting_id=50419.

[Annex follows]

Report of the Sharing Session regarding the Experiences on Capacity Building Activities related to Negotiating Licensing Agreements (Thirtieth Session of the SCP, June 24, 2019)

AUTM's capacity building activities relating to negotiating licensing agreements Mr. Marc Sedam, Chair-Elect of AUTM

AUTM is a non-profit global institution in educating, developing, promoting and inspiring technology transfer practitioners to make the world a better place through the commercialization of academic research. It comprises about 3,000 members representing businesses and government organizations and more than 800 universities, research institutions and hospitals. The mission of AUTM is to support and advance technology transfer worldwide. When AUTM was started in 1976, most people in the universities of the United States of America did not know what to do with their intellectual property (IP) and that only around 5 percent of 28,000 pieces of IP funded by the Federal government had been licensed. Currently, AUTM represents 65 countries with 20 percent of its members located outside the United States of America.

As technology transfer is more than licensing, activities of AUTM includes: (i) analyzing the marketplace, developing business plans, and understanding patent/licensing issues; (ii) assisting with patent application process; (iii) seeking venture/angel capital; (iv) boosting start-ups through campus-based accelerators, incubators and proof-of-concept programs; (v) matching researchers with companies looking to license new technologies; and (vi) helping faculty grow their technology pipeline.

The role of policymakers in supporting technology transfer is: (i) to provide strong and sustained basic research funding to provide pipeline of great ideas; (ii) ensure that patent rights are protected for a given university, researcher and the government; (iii) encourage policies that would attract venture capital support; and (iv) support laws that promote technology transfer. While compulsory licensing was an important contribution in overall IP strategy, it is a choice of the last resort. While the Bayh-Dole Act provides for a compulsory licensing provision, there has never been a need to invoke that provision over the last 45 years.

Several key factors for the successful licensing of IP are: (i) to have dedicated technology transfer and support team; (ii) understanding the marketplace and the local regional economy; (iii) establishing university-private sector relationships that may involve additional research funding; (iv) bridging the gap between an invention and its commercialization; (v) valid patents; (vi) outstanding researchers doing outstanding research; and (vii) long-term financial commitment.

As regards to technology transfer statistics, licensing of academic patents over the last 22 years contributed up to 1.7 trillion United States dollars to the US economy, up to 865 billion to the US GDP and supported creation of 5.9 million jobs. In addition, the technology transfer has resulted in creation of 6,050 start-ups and 755 new products.

With over 30 years in professional development experience, AUTM offers trainings in the following seven fundamental areas: invention disclosure and assessment; IP management; marketing; licensing; start-ups; operations; and leadership. AUTM delivers high-quality professional development to a global audience, such as AUTM members, practitioners, policy makers, industry and collaborating organizations.

AUTM's training programs are also developed for international audience and such programs could be customized for cooperating partners. For example, AUTM collaborates, *inter alia*, with Asia-Pacific Economic Cooperation (APEC). The goal of that collaboration is to increase capacity of the APEC region in technology transfer and licensing of life sciences and healthcare innovations. The focus is on training and education with a view to creating registered technology transfer professionals (RTTP) in each country. The regular trainings started in 2014. Over five years, around 20 training sessions have been provided to hundreds of attendees. The program is particularly appreciated in Thailand, in which the licensing volume and value have been increasing.

AUTM provides professional development programs in various formats, such as standard courses, annual meetings, regional meetings, short courses and webinars. Training could be delivered on-site, and students could earn credits toward professional certification. The experienced instructors with extensive international experience are being drawn from relevant universities and research institutions. The standard courses offered by AUTM are: (i) Essentials of Academic Technology Transfer; (ii) Technology Operations and Organization Licensing Skills; (iii) Technology Valuation; (iv) Negotiation; (v) Marketing; (vi) Startup Business Development; and (vii) Software. Two certifications of professionals in technology transfer exist: Certified Licensing Professional (CLP) (www.licensingcertification.org) and RTTP (www.attp.info).

Furthermore, AUTM provides quantitative data and real-world examples about licensing activities of universities, hospitals and research institutions. AUTM has been approached to help other countries to collect such data. It also provides TransACTDatabase, which is searchable database of various transactions and their terms and conditions, as well as STATT Database, which contains 25 years of statistical data relating to licensing activities, such as funding, staff size, legal fees, patent applications filed, royalties earned and other information.

Capacity building activities relating to negotiating licensing agreements by the Licensing Executive Society International (LESI)

Mr. Stefan Kohler, LES Switzerland

LESI is a non-profit professional organization, founded in 1972. It is an umbrella organization of national and regional associations for licensing executives. The LESI's missions are: creating and maintaining national LESI Societies and supranational Committees; setting and promoting consistent, high professional standards for licensing on a global basis; facilitating professional networking between licensing professionals; providing quality educational content and facilitating the sharing of such content; and informing and interacting with global organizations and policy forums concerning the economic significance and importance of licensing, technology transfer and intellectual property rights. The national and regional LES Societies are: Andean Community, Arab Countries, Argentina, Australia & New Zealand, Austria, Benelux, Brazil, Britain & Ireland, Chile, China, Chinese Taipei, Czech Republic & Slovakia, France, Germany, Hungary, India, Israel, Italy, Japan, Korea, Malaysia, Mexico, Philippines, Poland, Russian Federation, Scandinavia, Singapore, South Africa, Spain & Portugal, Switzerland, Thailand, Turkey, United States of America & Canada. LES Societies have also established regional activities in Americas, Asia Pacific and Europe.

In order to build capacity in the licensing field, LESI organizes conferences and licensing training courses. Licensing topics have been discussed at its Annual International Conferences and regional and national conferences as well as the LES Global Technology Impact Forum (GTIF). The GTIF is dedicated to improving knowledge on licensing in developing countries, in particular.

With regard to training courses, LESI provides LES100 Training Course, which is a one-day introductory course for those who are relatively new to licensing. LES100 is specifically aimed at those people who is considering a career in licensing and technology transfer, lawyers and patent and trade mark attorneys looking for greater familiarity with the business of IP licensing. small- and medium-sized enterprises (SMEs) that are required to have an introduction to licensing, students interested in learning the basics of IP and how to commercialize IP through licensing. LES100 is divided into five Modules: (i) Introduction & IP Basics; (ii) Basics of IP Commercialization and Licensing; (iii) Determining Reasonable License Fees and Royalty Rates; (iv) Managing Risks; and (v) Mock Negotiation Workshops replicating real world situations. In addition, LESI collaborates with the EPO and jointly developed two-days training course for people with advanced knowledge on licensing. In particular, that training is targeting participants coming from SMEs, start-ups, spin-outs, emerging enterprises, multinational corporations, and technology transfer and research organizations. The joint course provides a comprehensive, professional set of tools and techniques to implement and profit from IP in the business strategy, as well as a platform for networking among licensing and technology commercialization professionals from Europe and overseas.

LESI quarterly publishes a journal called "Les Nouvelles", targeting over 10,000 members of LESI. The journal is designed to improve knowledge and skills of those members in licensing and protecting IP. LESI also conducts surveys. For example, the 2016 Global "Life Sciences" Royalty Rates and Deals Terms Survey provided information on 117 licensing agreements.

As regards to challenges, licensing agreements in life science area are extremely complex. It requires profound scientific knowledge of the technology as well as experience regarding target markets, administrative rules and IP-related issues to be able to identify economic opportunities and risks. Additionally, the legal questions in that area, such as relating to the cross-border situation, regulatory issues etc., are multifaceted. Having profound knowledge on all those aspects and building a capacity to draft such complex agreements are quite challenging. Noting that different legal systems and cultures need to be taken into account in drawing up licensing agreements, the choice of applicable law and jurisdiction usually favors countries with developed and stable legal systems. Therefore, capacity building in licensing area included various elements, such as: (i) profound legal education; (ii) professional experience and training in legal/IP departments; and (iii) continued further education and training.

Experiences of the Brazilian Forum of Innovation and Technology Transfer Managers (FORTECH)

Ms. Elizabeth Riter, Director, FORTEC

In 1997 when Ms. Riter was invited to establish a technology transfer office at the Federal University of Rio Grande do Sul, neither legislation supporting technology transfer activities nor the tradition of university-company cooperation existed. After a long period of discussions throughout the country, in 2004, the Technological Innovation Law was signed. That Law became a prominent landmark in the technology transfer and IP management at universities. It acknowledged the role of academic institutions in the innovation process, and reinforced the importance of university-company cooperation, aiming at technical development of the country. The Law also had not only removed some obstacles, but also established a mandatory requirement that each academic institution should have a technology transfer office. In 2016, that Law was amended, allowing, *inter alia*, more autonomy and flexibility for universities to negotiate R&D and licensing agreements.

In 2006, FORTEC was created with an idea to improve the technology transfer activities and to provide support to the TTO managers in terms of learning and sharing best practices. It has an important role to play in technology transfer activities in Brazil. In parallel with the training activities put into practice by FORTEC, in collaboration with the National Institute of Industrial Property (IMPI) and WIPO, FORTEC disseminated the Successful Technology Licensing program (STL) of WIPO. Since 2006, FORTEC has trained more than 400 professionals in negotiation skills and IP licensing. In addition to the Master and Ph.D. program offered by the Academy of Intellectual Property of IMPI, FORTEC also runs its Master's program, which is based on a mix of various teaching methodologies, including distance learning. From 2006 to 2015, due to an increased funding for trainings, many training events were organized not just by FORTEC, but also other institutions in Brazil, including by the Association of Innovative Companies. AUTM's materials on technology transfer, which have been translated into Portuguese language, are widely used in Brazil. For example, during the annual meeting of FORTEC in 2010, they were made available to each participant.

While the results of the above efforts depend on local capacity, better research infrastructure and business environment as well as increase in technology transfer activities in Brazil were reported. In order to evaluate the results of the implementation of the Technological Innovation Law, annual surveys have been conducted. In particular, each university or academic institution has to inform the Ministry about their activities in terms of IP protection, technology transfer agreements, and R&D agreements. From 2000 to 2004, only four Brazilian universities protected their research results, whereas after the implementation of the Law, 177 institutions reported their activities in those areas. There has been an increase in the number of patent applications filed by and granted to the academic institutions during the period from 2012 to 2016. Specifically, in 2016, more than 2,000 patent applications were filed and 800 patents granted to such institutions. In addition, the number of technology agreements were doubled between 2012 and 2016. A number of projects relating to technology transfer are conducted by various Brazilian institutions, including FIOCRUZ, INPA, EMBRAER and UNICAMP. While the technology transfer activities in Brazil has been improving, there is a need to generate the multiplier effect in order to further increase those activities.

Experiences of the European Institute for Enterprise and Intellectual Property (IEEPI) Mr. Antoine Dintrich, Director General, IEEPI

IEEPI was created in 2004 by the French Ministry of Industry and French Institute of Industrial Property (INPI) to respond to the lack of training on IP in France. Two missions of the IEEPI are: (i) promoting IP awareness within companies, with a specific focus on SMEs; and (ii) creating and providing training sessions on the other aspects of IP.

In the framework of mission (ii), the following subjects have been taught by the IEEPI: management of IP rights; open innovation and collaborative research; licensing and technology transfer contracts; IP rights valuation; and litigation strategy. IEEPI provides a full range of IP trainings: trainings from the catalog and custom-made trainings; Master in "IP and Innovation" and technology transfer; advanced technology transfer courses; and e-learnings. Around 2,000 people have been trained each year in the above-mentioned subjects. IEEPI is involved in EU projects, and has partnerships with China, Belgium, Morocco, Switzerland and other countries. It has been certified by ISO 9001 certification.

New trainings and development of IP competencies are in much need, due to the growing number of issued patents each year, growing role of emerging countries (i.e., Brazil, China, India and Republic of Korea), and growing number of litigations around the world. Furthermore,

development of IPR market as well as growing impact of digital economy require new professions with new skills. In particular, trainings are needed in the areas of IP valuation, technology transfer, software and digital technology. More people should be trained on IP issues in R&D, marketing and procurement.

Attendees of the training courses often express the needs for professionalization (acquiring new competencies), recognition (visibility of competencies by certificates and diplomas) and mobility (i.e. transferability of competencies in different environments (public/private, national/international)). The competencies needed by the technology transfer managers are technical skills, i.e. understanding of scientific issues, contract laws, IP laws and finance issues. In addition, soft skills, such as negotiation skills, project management skills as well as understanding of multicultural settings are required. Because of such a wide range of skills involved, oftentimes, customized training is necessary.

For example, IEEPI Advanced Licensing Course, organized in collaboration with LES France, is a 10 days high-level training program. Main topics taught are: Patent Rating / Patent Mapping; IP valuation; Contracts; and Licensing negotiation. Around 200 experts have been trained since the creation of that course. The Master course, mentioned above, lasts six weeks (3 or 5 days per month), and covers the following five modules: (i) Overview of Intellectual Assets Management and Open Innovation; (ii) Project Management and Information Analysis; (iii) Technology Transfer and Licensing Techniques; (iv) Managing Communication and Marketing; and (v) Business Development and Negotiating.

The challenges in technology transfer trainings are the difficulty in finding trainers with specific technical expertise and skills, who are willing to teach at affordable remuneration.

In conclusion, IPR market is growing fast and needs both IP professionals and non-IP professionals. Therefore, there is a need for designing advanced trainings on various technology transfer related subjects. That could not be achieved in isolation by one institution alone. There is a need to enhance cooperation between training providers and professional associations. In particular, institutions such as AUTM, WIPO and EPO could help in the creation of a course format, which often requires a lot of investment.

Experiences of the United Nations System Organizations

Based on document SCP/30/6, the experience of the World Intellectual Property Organization (WIPO) on capacity building activities relating to negotiating licensing agreements was presented. The WIPO Academy, in cooperation with other institutions, organizes a number of training courses, workshops and summer schools, which address the issue of IP licensing. In addition, some distance learning courses include IP licensing matters. During the period from 2014 to 2018, approximately 20,000 people participated in the courses relating to negotiating licensing agreements. Over 50 percent of those participants came from Asia and Pacific Region, 18 percent from the Latin America and the Caribbean, following by Arab Region and certain countries in Europe and Asia. The participants were mostly from the private sector (26 percent), government (25 percent) and academia (21 percent).

In addition, WIPO carries out capacity building programs based on the WIPO Successful Technology Licensing (STL) Manual. The Manual addresses two aspects of licensing: key terms and negotiation techniques. A new edition was issued in 2010 with the part on procompetitive licensing, adding the issues regarding competition law and licensing. Participants are predominantly national and regional academic institutions, although participants from businesses, including SMEs, often attend the trainings.

The Representative of the World Health Organization (WHO) made a presentation on the WHO's current work to achieve universal health coverage, with particular focus on IP licensing and access to medicines and health technologies. Among other issues, the Representative focused on public health-oriented terms and conditions in voluntary licenses, and explained the best practices relating to licensing terms for delivering meaningful access to health products. In addition, she spoke about socially responsible licensing by universities and public research institutions.

The Representative of the World Trade Organization (WTO) made a presentation on the WTO's capacity building activities relating to the TRIPS Agreements and Public Health. While the WTO does not focus its technical assistance activities on patent licensing specifically, the subject has been covered by the technical assistance activities conducted in the context of the Agreement of the Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and public health, IP and competition law, as well as in the context of discussions on Article 66.2 of the TRIPS Agreement focusing on transfer of technology. During the last five years, the WTO Secretariat organized 18 Geneva-based courses, four regional workshops and seven national workshops. All WTO courses related to public health are open to officials of Ministries of Trade, IP and Health as well as representatives of civil society and industry.

The Representative of the United Nations Conference on Trade and Development (UNCTAD) made a presentation on its capacity building activities for technology transfer and R&D collaboration. Among other issues, he spoke about the recent experiences of its organization in training on IP, pharmaceutical production and public health, including licensing and technology transfer negotiations. As the lessons learned from those experiences, he noted that negotiation skills are only one part of successful technology transfer and collaboration, and stressed the importance of overall policy and institutional coordination among various key players. In addition, he informed the Committee about its recent activities, such as general consultations with African pharmaceutical producers, involving IP licensing experts, industry representatives and academia, and two training on technology transfer and R&D collaboration in 2019.

Q&A session1

2. The issues discussed during the Q&A session concerned, *inter alia*: the use of March-in rights provision provided in Section 203 of 35 U.S.C.; non-suit clauses found in sample licensing agreements; details of the licensing agreements terms and to what extent licensing terms actually improved public interests and promoted access to the technology; the definitions of "licensing technology" and "technology transfer"; restrictive clauses in contracts that would go beyond the period of patent protection; and importance of the requirement of sufficiency of disclosure for dissemination of invention.

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Discussions during the Q&A session are reported in the draft Report of the thirtieth session of the SCP (document SCP/30/11 Prov.).