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PATENTS AND TRANSFER OF TECHNOLOGY: EXAMPLES AND EXPERIENCES

Document prepared by the Secretariat

INTRODUCTION

1. At its seventeenth session held from December 5 to 10, 2011 in Geneva, the Standing Committee on the Law of Patents (SCP) agreed that the Secretariat would expand its study on patent-related incentives and impediments to transfer of technology (SCP/14/4 Rev.2) through practical examples and experiences (see paragraph 25(e)(ii) of document SCP/17/12). The present document contains the requested information.

2. The practical examples contained in this document are neither comprehensive, nor do they aim to fully reflect patent-related incentives and impediments to transfer of technology. Further, the examples presented in this document neither suggest nor imply the Secretariat's agreement with any conclusions, recommendations or suggestions contained therein or in the original publications that contained those examples.

PRACTICAL EXAMPLES AND EXPERIENCES

A. CASES IN THE WIPO IP ADVANTAGE DATABASE

3. The WIPO IP Advantage database, available on the WIPO website,[1] provides a gateway to case studies that chronicle the intellectual property (IP) experiences of inventors, creators, entrepreneurs and researchers from across the globe. The case studies offer insights into how

[1] http://www.wipo.int/ipadvantage/en/.

IP works in the real world and how its successful exploitation can contribute to development. Four case studies that involve transfer of patented technology are summarized in the following paragraphs.

Electrical shark repellent technology[2]

4. A particular kind of electrical shark repellent – the Shark Protective Oceanic Device (Shark POD) – was first invented in the 1990s by the Kwazulu Natal Sharks Board (KZN), which was the tourism and research center on the south coast of South Africa. The SharkPOD had three main components: a main body containing a 12 volt battery pack, one electrode attached to the diver's oxygen cylinder, and another electrode attached to the diver's fins. The two electrodes created an electrical field around the diver which repelled sharks by disrupting their sensory and neuromuscular system. KZN marketed Shark PODs through its spin-off company, Shark POD Holdings Ltd. in 1996. While the technology had tremendous potential for applications, Shark Pods were big, heavy and expensive, and their distribution ended in 2001.

5. Recognizing the potential of the technology, an Australian diver and entrepreneur, Mr. Mike Wescombe-Down, acquired an exclusive worldwide license agreement with KZN for further development of the Shark POD device. Mr. Wescombe-Down co-founded Sea Change Technology Holdings (Sea Change) in Australia, and working together with other technology partners, Sea Change launched a new device called "Shark SHIELD" in 2002, which was compact in size and usable by recreational divers. Subsequently, Sea Change went into production for a wide range of new protective products against all predatory shark species, and changed its name to Shark Shield Pty Ltd.

6. As regards patents, desiring to further their invention, KZN ceded its patent of Shark POD technology to what was then called Shark POD Holdings Ltd, a company in which KZN was a shareholder. Shark POD Holdings in turn licensed its IP to Sea Change Technologies, in order to develop a new product for divers. Sea Change became Shark Shield, and the commercialization of the invention proceeded apace. KZN, however, still maintains a close contact with its IP and the board carries out tests and approves prototypes of all new Shark SHIELD applications. Having invested much time and effort in developing its invention, in 2002, Shark Shield filed a patent application for its shark repelling device with the Intellectual Property Office of Australia (IP Australia). With a view to marketing its products worldwide, the company filed six international patent applications under the Patent Corporation Treaty (PCT).

7. Having stalled in their plan to market their technology, KZN board members quickly licensed it to an entrepreneur with a clear vision for the product. More than 17,000 Shark SHIELD personal units have been providing protection to ocean-goers in Australia, and the technology is also used by militaries and coast guards of a number of countries.

Water disinfection unit using UV light[3]

8. Dr. Ashok Gadgil, an Indian-born physicist, began searching for a way to purify water cheaply in developing countries after an outbreak of "Bengal cholera" in 1993 in North India. He was searching a way to design a water disinfector that was robust, efficient, simple and inexpensive. The ability of ultraviolet (UV) light to kill bacteria and viruses has been known to scientists since the early 1900s. However, a water treatment device using UV light had not been successfully implemented before Dr. Gadgil, because of frequent lamp fouling, complexity of handling it and high maintenance costs. In 1996, Dr. Gadgil invented an innovative water disinfection unit, the UV Waterworks (UVW), which solved the problems by suspending the lamp above the surface of the water and attaching an aluminum reflector above the hanging light.

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2 http://www.wipo.int/ipadvantage/en/details.jsp?id=2695.

3 http://www.wipo.int/ipadvantage/en/details.jsp?id=2564.

The device developed by Dr. Gadgil can treat approximately 15 liters of water a minute. Each unit can deliver safe drinking water to a village of 2,000 for under US$2 per person per year, including amortized capital costs.

9. Initially Dr. Gadgil considered putting up his invention on the Internet for all to use freely. However, the Technology Transfer Department of his employer, the University of California/ Lawrence Berkeley National Lab (UC/LBNL), convinced him of the advantage of patenting. He realized that even if he did not want to benefit from his invention, patenting would protect against badly manufactured copies which would not be as functional as the genuine ones. Following the advice of LBNL's patent attorneys, a PCT application was filed with a view to protecting the invention abroad. In accordance with the conditions of Dr. Gadgil's employment contract, UC/LBNL owns the patent rights of the UVW.

10. The performance and feasibility for practical use of the UVW system prompted about a dozen companies to approach UC/LBNL, each asking for an exclusive license. Following due processes for entering into contracts, UC/LBNL's Technology Transfer Office selected WaterHealth International (WHI), as the licensee for the UVW system. Hundreds of UVW systems are now being used around the world in some 15 countries including India, Mexico, and the Philippines. Since the systems developed by WHI are modular, they can be used in different ways, for example, as community water systems in remote villages, as water refilling stores, household systems, or to provide water for hospitals or schools.

CarbonFiberStone (CFS)[4]

11. Mr. Kolja Kuse, an electrical engineer at Aachen University specializing in energy production, had the idea to make a polished stone stove top with invisible induction coils hidden beneath the surface. However, he was not successful, as the stone always expanded and cracked when the surface got above a certain temperature. After he learned that carbon fiber shrunk longitudinally when heated, together with a fiber specialist, he coated granite with carbon fiber. The result: the stone never fractured. Through further research, CarbonFibreStone (CFS), consisting of a slice of granite with a fine laminate of carbon fiber on either one or both sides, was developed by TechnoCarbon Technologies (TechnoCarbon). CFS is elastic, strong and light, has a high resistance to corrosion and can be easily processed by conventional stone industry methods and tools.

12. After filing a national patent application with the German Patent and Trademark Office (DPMA), in order to protect the invention internationally, in 1995, Mr. Kuse filed an international patent application under the PCT for his first CFS-based technology: the granite and carbon fiber stove top. In total, by July 2010, 12 PCT applications had been filed. TechnoCarbon decided that licensing its technology was the best way to market it and reach the most customers. As CFS may be used in many different industries in which TechnoCarbon itself does not have any expertise and experience, licensing out the patented technology, on the one hand, secures royalty income for TechnoCarbon, and on the other hand, allows each licensee to develop future applications of CFS technology in its industry based on its specific expertise.

13. Partnering with Granidus, a non-governmental organization (NGO) based outside of Berlin, TechnoCarbon is also exploring technology transfer opportunities. It plans to channel profits from commercial licensing deals into subsidizing the transfer of CFS to developing countries, and is looking into cross-licensing arrangements with technology companies in developing countries. For TechnoCarbon and Granidus, the ideal model is to encourage companies in those countries to develop their own new CFS applications for local needs, and help them with patenting.

[4] http://www.wipo.int/ipadvantage/en/details.jsp?id=2593.

SuperAdobe construction method[5]

14. Mr. Nader Khalili (1936-2008) was an architect, teacher and inventor of the SuperAdobe construction method. Combining the philosophy of Rumi – the 13th century sufi mystic poet – with ancient Middle Eastern architecture building methods that he had encountered on a five-year motorcycle ride across his homeland in the Islamic Republic of Iran, and modern building technology and know-how, he developed the SuperAdobe – also called the super block system – using layers of sand-filled bags that are coiled and placed one upon the other. The bags are securely attached into a dome-shaped structure using barbed wire. For extra stability, the blocks of adobe (a structure made of sun-dried clay or soil bricks) are held together using cement, lime, or asphalt emulsion. The adobe structure is strong and resistant to floods, fires, hurricanes and earthquakes, provides insulation against both heat and cold, and can be quickly constructed by men, women and young adults.

15. In order to convert his idea into a viable project, Mr. Khalili approached the National Aeronautic and Space Agency (NASA) in the United States of America for R&D support. NASA was interested in developing simple yet secure habitats on the moon and on Mars. In 1986, Mr. Khalili continued his R&D by founding the Geltaftan Foundation whose aim is to create earth-based ceramic houses. By 1991, the entrepreneur incorporated the foundation into a new non-profit and charitable organization – The California Institute of Earth Art and Architecture (Cal-Earth) – where he taught SuperAdobe building technology based on Rumi's philosophy. Prototypes of SuperAdobe were built and have been tested successfully and passed industry building standards for California (a region known for earthquakes). Because SuperAdobe technology is easy to build, secure and both cool and warm, the buildings are used in developing countries and for emergency shelter, especially for people displaced by conflict or natural disasters.

16. Recognizing the potential for his invention to help poor and vulnerable people around the world, Mr. Khalili sought to protect it against commercial exploitation for purposes that may deny access to those who need it most. As he wanted his invention to be offered freely to the poor, but available to be commercially licensed, in 1998 the inventor filed a patent with the United States Patent and Trademark Office (USPTO). Seeking to propagate SuperAdobe across the world without leaving it vulnerable to usurpers, he also filed an international patent application under the PCT in 1999. The architect patented his technology to ensure that it could be distributed and commercialized for the benefit of the poor, demonstrating that private financial reward is not the only reason why inventors may wish to protect their inventions with intellectual property rights (IPRs).

B. OECD BUSINESS SURVEY ON THE LICENSING-OUT PATENTS

17. The Organisation for Economic Co-operation and Development (OECD), together with the European Patent Office (EPO) and the University of Tokyo, carried out a business survey on the licensing-out of patents in 2007. 612 European firms and 1640 Japanese firms responded to the survey. The survey was carried out with a view to gathering statistical evidence that would address licensing transactions from a quantitative perspective. Its objectives were to investigate the intensity of licensing to affiliate and non-affiliate companies, its evolution, the characteristics, motivations and obstacles met by companies willing to license. The background, methodology and initial analysis of the survey responses were put together in a Science,

[5] http://www.wipo.int/ipadvantage/en/details.jsp?id=2716.

Technology and Industry (STI) working paper 2009/5, entitled "Who licenses out patents and why? Lessons from a business survey", published by the OECD (hereinafter referred to as the "survey report").[6]

18. The survey report concluded that licensing markets were less developed than they could be, in view of the willingness of patent holding companies to license more of their portfolios. While both market-based and government solutions could be envisaged, the report stated that a proper evaluation of the private and public mechanisms that could help solve market failures in the patent market had yet to be made. The following paragraphs introduce major findings from the survey report with a particular attention to patent-related incentives and impediments to transfer of technology.

Licensing activities by European and Japanese firms

19. Licensing out was practiced by a significant share of firms holding patents: 35% of firms in Europe and 59% of Japanese respondents. Focusing on the licensing out of patents to non-affiliated parties, 20% of the European firms declared to license patents to non-affiliated parties, while the corresponding figure for Japanese firm was 27%. The share of the patent portfolio that companies license out to non-affiliated partners was usually high: more than half of the licensing companies in Europe and almost three out of four in Japan licensed 80 to 100% of their portfolio.

20. The relationship between the size of the firm and the probability to license out was U-shaped: small firms and large firms were more likely to license out their patented inventions. The survey report explained this finding as follows: (i) small companies often lack manufacturing or commercial facilities, and thus license out their inventions rather than exploiting them themselves; (ii) larger firms often play the role of technology integrator, thus entering into licensing deals (including cross-licensing) to secure access to all technologies needed for their products. Other explanations for the higher share of large firms licensing out their patents given by the survey report were market strategy and revenue generation.

21. As regards the share of cross-border licensing among total licensing, among the European firms licensing out their patents, 64% of them licensed less than 20% of their (licensed) patents to entities located in different countries. 85% of Japanese firms doing licensing out licensed less than 20% of their patents to foreign affiliated companies.[7]

22. Companies that license patents to non-affiliated companies seemed to more frequently integrate transfer of know-how (41% of companies declared to integrate it in more than 20% of their IPR contracts).

Motivation for licensing out patents

23. According to the survey report, the first motivation, by far, to license patents to third parties was "earning revenue" for both European and Japanese firms. The financial motivation was far stronger for smaller than for larger firms in Europe, while there was no significant difference between smaller and larger firms in Japan.

24. The second motivation for both European and Japanese firms was "entering into cross licensing deals", which was far more important for larger companies than for smaller companies.

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6 Document DSTI/DOC(2009)5, available at: http://www.oecd.org/dataoecd/47/16/42477187.pdf.

7 In the EPO survey, licensing abroad concerns "partners located abroad", while in the Japanese survey, the question referred to licensing out to foreign affiliated companies.

25. In Europe, the third motivation was to ”stop others from infringing your patents” (this item was not included in the Japanese survey), indicating that underlying exclusive rights derived from patents motivated firms to license out. Both larger and smaller firms considered this important. The fourth motivation in Europe was setting the inventor’s technology as standard.

26. In Japan, “establishing your technology as a standard” and “outsourcing manufacturing” came in the third place, while the latter was a very weak motivation in Europe.

Obstacles to licensing out patents

27. Twenty-four per cent of European firms stated that they had patents that they had been willing to, but could not, license out (53% of the firms in Japan). It was found that there was a positive relationship between being an active licensing company and the number of patents that companies would be willing to license. The survey report, however, noted that these figures had to be interpreted carefully, as they reflected only the viewpoint of potential licensors and not potential licensees. If there is no demand, licensing activities cannot be carried out.

28. The main obstacle that companies had been confronted with when attempting to license their technologies was by far the difficulty of finding partners. Twenty-five per cent of European companies and 18% of Japanese companies considered it a very important factor. Other factors, such as the complexity and cost of drafting and negotiating contracts, the lack of readiness of the invention (technology has not been developed enough for licensing out), low prices offered by potential licensees, were deemed less important impediments by both European and Japanese firms. In Europe, all factors were considered more important by smaller companies than by larger companies. In particular, 30% of smaller European firms underlined the difficulty of identifying a partner as being a very important impediment to licensing. In contrast, a lower level of difficulty in identifying a partner was reported by Japanese SMEs compared to larger firms (13% and 23%, respectively). The survey report assumed that the National Center for Industrial Property Information and Training (INPIT), an agency of the Japanese government, had been playing a crucial role in providing information and facilitating patent licensing for Japanese SMEs.

C. CO-OWNED PATENTS AND TRANSFER OF TECHNOLOGY

29. Greater collaboration between firms in the innovation process is seen as one important element of the changing face of innovation.[8] In addition, in order to accelerate innovation and commercialization of public-funded research results, policy makers have started to explore a better interface between the private sector and the public research sector (universities and public research organizations). Where patents which result from such joint research activities are under co-ownership, exploiting the co-owned patent through self-exploitation, licensing or transfer of ownership may become complicated, if co-owners have different interests in utilizing the co-owned patents. This could happen, for example, in the case of joint research between a private entity and a public entity as well as between an upstream, research-based firm and a downstream, manufacturing firm.

30. While national laws regarding joint ownership are different, stakeholders seek practical solutions and arrangements under their respective national legal systems, as national laws generally provide flexibility for joint patent owners to mutually agree on case-by-case solutions. The differences in national laws, however, may affect international research collaborations reaching beyond national borders. The following paragraphs provide examples of national laws and practical solutions sought under different legal frameworks.

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8 WIPO Intellectual Property Report 2011 – the Changing Face of Innovation http://www.wipo.int/econ_stat/en/economics/wipr/.

31. Generally speaking, four types of rules regarding the right of co-owners to exploit or assign their (share of) co-owned patent *vis-à-vis* other co-owner(s) are applied:

(i) Each co-owner is entitled to work his invention on his own without the consent of the other co-owner(s). However, no co-owner may grant a license under, or assign his share in, the co-owned patent, without the consent of all the other co-owner(s). For example, Japan and the United Kingdom apply this type of rule.

(ii) Each co-owner is entitled to work his invention on his own and assign his share in the co-owned patent, without the consent of the other co-owner(s). However, no co-owner may grant a license under the co-owned patent without the consent of all the other co-owner(s). This type of rule is applied, for example, in Germany.

(iii) Each co-owner is entitled to work his invention on his own, grant a license under the co-owned patent and assign his share in the co-owned patent, without the consent of the other co-owner(s). This type of rule is applied, for example, in the United States of America.

(iv) Each co-owner may work the invention for his own benefit, but only if he equitably compensates the other joint owners who do not personally work the invention or who have not granted a license. If one of the co-owners wishes to grant a non-exclusive license to a third party, he may do so subject to granting equitable compensation to the other co-owners who do not personally work the invention or who have not granted a license. An exclusive license by a co-owner may only be granted with the agreement of all the co-owners or subject to authorization of the court. Where a co-owner wishes to assign his share in the co-owned patent, the other co-owners have priority to buy that share. For example, France applies this type of rule.[9]

In general, the above rules apply in the absence of any contrary agreement among co-owners.

32. Although co-owners may derogate the above rules by means of a joint ownership agreement, since it is not always easy to conclude an agreement on possible future joint research results before starting the joint research, the different legal rules prompt different challenges.

33. In Japan, issues relating to the joint ownership of patents have been discussed in conjunction with the promotion of public-private joint research activities with a view to accelerating the innovation process. Following the Intellectual Property Action Plan 2008, the Kyoto Comparative Law Center issued a detailed report regarding the exploitation of patented inventions derived from joint research conducted by universities and the private sector, which included extensive survey results.[10] Various points addressed in the report come from the fact that universities do not have expertise in commercializing, manufacturing and selling products developed from the results of the joint research conducted with firms. The only way to "exploit" their share of IP is either to license to third parties or to assign their rights. However, if universities wish to do so, they have to obtain consent from their partner, unless a prior agreement to the contrary has been concluded. Whether requiring the other co-owner's consent in the absence of a contrary agreement hindered the efficient use of co-owned patents or not was one of the main questions raised.

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9 According to the French Intellectual Property Code, L613-29, in addition, where one of the joint owners wish to grant a non-exclusive license to a third party, the draft licensing agreement must be notified to the other joint owners accompanied by an offer for transfer of the share at a specified price. Within three months of such notification, any of the joint owners may oppose the granting of a license on condition that he acquires the share of the joint owner wishing to grant the license.

10 http://www.jpo.go.jp/shiryou/toushin/chousa/pdf/zaisanken/200500all.pdf.

34. According to the results of the survey in the report, the absolute number of cases where a co-owner company refused licensing or assignment of rights sought by a co-owner university was very small. At the same time, the number of cases where the co-owner university seeks to license out or assign its share in the patent seems to be small as well. Some universities commented that if a company decided to use the co-owned patent defensively (preventing third parties from using the patented invention without using it itself), further innovation on the invention resulting from the joint research would be hampered. On the other hand, some universities considered that the current principle was favorable as it would allow them to make sure who the other co-owners were and to whom a license may be granted by the co-owners. Around one out of five universities responded that their current provisions on the co-owner licenses and assignments should be reviewed.

35. In view of the fact that co-owner universities are not able to work and commercialize the invention on their own, but co-owner companies may do so without the consent of co-owner universities under the default rule, in practice, when entering into a joint research activity, universities try to negotiate with a potential company partner the sharing of benefits that may derive from future joint research results. According to the survey, 60% of universities were in favor of introducing a legal provision concerning such sharing of benefits between working and non-working co-owners.

36. In the United Kingdom, in order to encourage universities and industry collaboration and the sharing of knowledge, the Lambert Toolkit was prepared by the Lambert Working Group on Intellectual Property.[11] It consists of a set of five Model Research Collaboration Agreements (two parties) and four Consortium Agreements (multiple parties). In the Guidance Notes of the Toolkit, the members of the Lambert Working Group recommend that joint ownership be avoided, where possible. If it is important that more than one party owns some IP, a better way might be to consider the sole ownership of some of the IP by one party and of the other IP by the other party. Consequently, the Model Research Collaboration Agreements are based on either IP ownership by one party or on separate IP ownership by each party. Model Consortium Agreement A contains a joint ownership clause (5.4), which applies only where it is not possible to distinguish between the multiple parties' contribution to the result of joint research. Clause 5.7 allows all joint owners to deal with and exploit the jointly owned IP as though it were a sole owner, without accounting to the other joint owners for any money made. However, no joint owner may grant any third party any rights that detract from any other joint owner's right to deal with any jointly owned IP as it sees fit.

37. In France, publicly funded research projects are often carried out through the collaboration of a number of organizations and universities. The complex rules governing the co-ownership of patents does not necessarily accelerate the licensing activities of joint research results. Seeking better IP management, some public entities tried to split the ownership according to the dedication of each party to the joint project that led to the invention, and one of the parties was designated as the manager responsible for IP licensing. However, it was still difficult, in most cases, to get an agreement as each party was reluctant to fully empower another party, and not all public entities are equipped with specialists who can deal with IP and innovation at large.

38. Against this backdrop, the French government started a project to create new entities (*Société d'accélération du tranfer de technologies (SATT)*) which would be in charge of technology transfer for public research entities. It is part of an initiative called "*Investissements d'avenir*" dedicated to innovation for the future with a budget of 35 billion Euros. The SATTs are private companies which are expected to become regional actors working closely with, in particular, local universities and SMEs. Their main activities will be supporting innovation activities management of IP, such as licensing. They are expected to be self-sufficient after 10

[11] http://www.ipo.uk/whyuse/research/lambert.htm.

years through their innovation service, technology transfer and licensing service, start-up creation support etc. After the call, five SATTs have been created so far.

39. At the European level, an Expert Group on intellectual property issues in publicly-funded research was organized by the European Commission in the context of a series of activities supporting the European Research Area (ERA) activities. A report[12] issued by the Expert Group in 2004 touched upon the issues of joint ownership for public research organizations (PROs). It pointed out that while in theory, all European statutes had enough flexibility to allow the provisions on co-ownership to be changed by mutual consent of the parties, in practice, these provisions were very difficult to negotiate, even among PROs. The Group proposed the following guidelines: (i) the exclusive use by one of the joint owners requires the consent of all parties and should be consented by royalties or other form of compensation; (ii) each joint owner should be allowed to use, directly or indirectly, the joint IPR, including the right to grant non-exclusive licenses, provided that first option for exclusivity has been proposed to the industrial co-owners; and (iii) in the event one of the joint owners obtains significant benefits from the use of the non-exclusive IPRs, the other parties should receive an equitable share of such benefits.

40. In the United States of America, since the default rule is that each co-owner may, in principle, freely work the co-owned invention on his own, grant a license to third parties or assign his share in the co-owned patent, there is a strong incentive, particularly for companies, to agree on clear self-exploitation, licensing and assignment rules. As an example, a Model Sponsored Research Agreement prepared by Stanford University states that technology that is jointly developed by university personnel and industry sponsor personnel will be jointly owned. Further, an industry sponsor may exclusively license the university's rights in the jointly owned technology. The model agreement states that such exclusive license (and any other exclusive or non-exclusive license of university-owned technology) is effective as of the date the parties negotiate and sign a separate licensing agreement. On the University's website, it is explained that, in general, licensing terms cannot be pre-set in the Sponsored Research Agreement, since (i) it is very difficult to set licensing terms for an invention that does not exist; and (ii) in accordance with the Internal Revenue Code and Regulations, granting rights to sponsored research intellectual property that does not yet exist is considered a "private business use" of facilities funded with tax-exempt bonds. While each agreement between a university and an industrial sponsor may be tailor made to reflect the unique conditions of each case, model agreements may reflect the general policy of the university concerned.

D. MENINGITIS VACCINE PROJECT (MVP)[13]

41. The Meningitis Vaccine Project, established in 2001, is a partnership between Program for Appropriate Technology in Health (PATH) and the World Health Organization (WHO). Its mission is to eliminate epidemic meningitis – a bacterial infection of the brain - in sub-Saharan Africa through the development, testing, introduction and widespread use of conjugate meningococcal vaccines.

42. To develop an affordable and effective vaccine, MVP first focused on understanding the constraints that had limited the introduction of new vaccines in Africa. After consulting African public health officials who indicated that the cost of more than US$0.50 per dose would be unsustainable, this ceiling price became the key driver in negotiations. MVP analyzed the costs

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12 http://ec.europa.eu/research/era/pdf/iprmanagementguidelines-report.pdf.

13 The information regarding this Project was obtained from the websites of the Meningitis Vaccine Project, the World Health Organization and the National Institutes of Health of the United States of America. http://www.mwningvax.org http://www.who.int/immunization/newsroom/events/menafrivac_partners/en/index.html http://www.ott.nih.gov/.

of constructing the manufacturing capacity, process development and clinical and regulatory activities for licensing a meningococcal A conjugate vaccine in Africa. The project investigated two approaches: (i) subsidizing a vaccine manufacture in the United States of America or Europe for the cost of development in return for the right to purchase a low-price vaccine; or (ii) purchasing raw materials, developing the conjugation process, and transferring the technology to a developing country manufacturer for large-scale production and low-price sale of vaccine.

43. When it became clear that the price US$0.50 per dose would not be possible under the first approach, MVP focused on the second approach: a consortium model. It identified two suppliers of the main components of the conjugate vaccine, a research laboratory that was willing to develop and transfer a conjugation technology (Center for Biologics Evaluation and Research of the U.S. Food and Drug Administration (CBER/FDA)) and a vaccine manufacturer who could accept the technology transfer and was willing to make a conjugate vaccine that would cost less than US$0.50 per dose (Serum Institute of India Ltd.). In addition to a low vaccine cost, the consortium model allowed development of a vaccine with specific characteristics tailored to particular needs in Africa.

44. The conjugation technology developed by Dr. Che-Hung Robert Lee and Dr. Carl Frasch of the U.S. Food and Drug Administration was licensed from the US National Institutes of Health (NIH) to the Serum Institute in December 2003. The collaboration agreement includes transfer of relevant technology patented in India. The clinical trials, coordinated by MVP with a wide range of partners, started in 2005. In January 2010, following a review supported by Health Canada, the Drug Controller General of India (DCGI) granted Serum Institute marketing authorization to export and use MenAfriVac™. In June 2010, the WHO announced prequalification of MenAfriVac™. Massive vaccination campaigns have been launched in sub-Saharan regions since late 2010. Almost 55 million people have received the new vaccine to date. MVP hopes to vaccinate an additional 265 million people throughout the African “meningitis belt” by 2016.

45. With respect to the successful collaboration in developing MenAfriVac™, an Executive Director of the Serum Institute is quoted as saying in *SciDev.Net*. "The key was the transfer of technology from NIH". A list of MVP partners shows the involvement of various public and private entities across the world with expertise in pharmaceutical development, vaccine manufacturing, clinical and laboratory work, regulatory issues, disease surveillance, vaccine introduction and supply etc. as well as donors making financial contributions. Since its inception of the project in 2001, MVP’s strategy has been based on the following principles:

- the project aims to achieve a sustainable public health impact and is not simply about making vaccines available;
- decisions about vaccine development are linked to introduction strategies and likely financial constraints;
- African public health officials and other stakeholders in Africa are closely involved with MVP.

E. LOCAL PRODUCTION OF PHARMACEUTICALS AND RELATED TECHNOLOGY TRANSFER TO DEVELOPING COUNTRIES

Case studies on local production and related technology transfer in developing countries

46. A series of case studies on local production and related technology transfer in Argentina, Bangladesh, Colombia, Ethiopia, Indonesia, Jordan, Thailand and Uganda was undertaken by the United Nations Conference on Trade and Development (UNCTAD) under a joint project with the WHO and the International Center for Trade and sustainable Development (ICTSD) and

published in 2011.[14] The case studies provide examples of local production and related transfer of technology which were either patented or not patented in the country where pharmaceutical products were locally produced. Although they do not necessarily focus on technology transfer and its association with patents, the case studies provide rich examples of how local producers had obtained and developed the technological capacity to produce medicines in different countries. Three LDCs, Bangladesh, Ethiopia and Uganda, which have different requirements regarding the patentability of pharmaceutical inventions, are included in the case studies. A case from Thailand illustrates a local vaccine production project being carried out by a state enterprise with the full support of WHO. From Argentina, Colombia and Jordan, further cases where local pharmaceutical manufactures had established themselves were presented in the publication.

(i) Argentina

47. *Laboratorio Elea S.A.C.I.E y A. (ELEA)*, founded in 1939, is a major local pharmaceutical firm in Argentina with a diverse product portfolio. Its technological capacity principally comes from in house R&D, licensing agreements with foreign firms and strategic alliances with universities and public research centers in Argentina and Cuba. ELEA has filed patent applications and obtained patents on its innovation not only in Argentina, but also at the global scale. It was analyzed that close geographical, linguistic and cultural relationships with other Latin American countries was an important element in favor of the Argentinean industry. In the case study, it was noted that the high technological capability of the domestic pharmaceutical industry was not necessarily sufficient to establish a pharmaceutical sector with a self-sufficient active pharmaceutical ingredients (APIs) production. It was considered that the main impediment was the volume of the Argentine market which did not facilitate the ability of local firms to compete with Indian and Chinese pharmaceutical laboratories.

(ii) Bangladesh

48. The patent law of Bangladesh excludes pharmaceutical products from patentable subject matter although process inventions regarding pharmaceuticals may be patented, provided that all the relevant requirements under the law have been met. Two companies examined, Beximco Pharmaceuticals Ltd. (BPL) and Square Pharmaceutical Ltd. (Square), built their capacity at the early stage through technical collaboration with multinational companies operating in Bangladesh, and followed it up with licensing agreements and contractual manufacturing and sale to develop further capacity. In the early stage of its operations, Square acquired its expertise from India, and attributed the success of the company to its initial licensing arrangements with various multinational companies. Following the implementation of the national Drug Policy of 1982, which put restrictions on local production of drugs by multinational companies, Square and Beximco started their own generic brands. Both companies continued to engage in acquiring expertise of companies from developed countries for advancing their capability to produce new drugs and for upgrading facilities and manufacturing practices to meet the standards of developed countries with a view to tapping in their market. In 2010, the government of Bangladesh submitted a communication to the Council for TRIPS which identified its priority needs for technical and financial cooperation in order to implement the TRIPS Agreement. With respect to the export of pharmaceutical products produced under compulsory licenses, the said communication referred to an amendment of the compulsory license provision in its national law to be in line with the Protocol Amending the TRIPS Agreement of December 5, 2005.

[14] http://www.who.int/phi/publications/Local_Production_Case_Studies.pdf.

(iii) Colombia

49. *Tecnoquímicas S.A. (Tecnoquímicas)* is the largest pharmaceutical laboratory in the Colombian market in terms of value of sales. Founded in 1934, it started with the distribution of raw materials, medicines and personal care products. In the 1950's *Tecnoquímicas* became a licensee of several multinational pharmaceutical companies, allowing it to acquire technology and know-how of those companies. In the 1990s, *Tecnoquímicas* lost important licenses due to globalization and the departure of the large multinational laboratories. The company developed a strategy, including diversification of its product line, investment on its own trademark, enhancement of its generic products line and increase in exports. Through acquisition and branding strategy, Tecnoquímicas grew as the generic market grew in Colombia.

50. The in-house R&D laboratory was created in 1995. The main source of information used to support R&D was (i) information supplied by the API manufacturers; (ii) paid databases; and (iii) patent information. The company had applied national and PCT applications on its in-house innovation. It also provided financial support to universities and research centers. While it was based on the company's corporate social responsibility policies, it benefited from the better chance to recruit from, and train staff at, those institutions and to undertake technical collaboration. Even if the competition with other international players in the Colombian generic market might grow, *Tecnoquímicas* has competitive advantages such as its large distribution network and its ability to understand, and adapt to, the needs of local consumers. *Tecnoquímicas* perceived the small Central American market as the best prospect for the short term, because the large international pharmaceutical companies did no pay as much attention to those markets as they did to bigger markets, and the cultural similarity might facilitate the expansion into those markets easier than others.

51. The patent protection of pharmaceuticals has been strengthened in the Andean Community since the 1990s, first by Decision 311 of 1991 which allowed, in principle, the patenting of pharmaceutical products except for those included in the WHO list of essential medicines in November 1991, and second, by Decision 486 of 2000 which made any pharmaceutical products patentable subject matter. This, however, was not sufficient to prevent the closure of factories and the departure of multinational companies during the 1990s and thereafter. In the case study, it was noted that insecurity and political violence, the trend in the multinational companies to concentrate production in fewer places and increased local good manufacturing practice (GMP) standards requiring higher costs seemed to have been more important factors resulting in a withdrawal of foreign investments.

(iv) Ethiopia

52. Since Ethiopia is not a Member of the WTO, it has no obligation to comply with the TRIPS Agreement. Nevertheless, patents are available for pharmaceutical products for the duration of 15 years with the possibility of additional five-year protection. According to the case study, the absolute number of patents in force, however, is very low. The case of Sino-Ethiop Associate (Africa) Private Limited Company (SEAA) was presented in the publication. SEAA is a joint venture established in 2001 by an Ethiopian company and two Chinese companies, which is exclusively involved in the manufacturing and marketing of empty hard gelatin capsules (EHGCs), The Chinese partners were producers of the equipment and machinery used by SEAA and brought in know-how and experience in the production and international marketing of EHGCs. The Ethiopian partner contributed in marketing the product locally and managing the operation of the company. Seventy per cent of the produced EHGCs were sold to Ethiopian pharmaceutical companies and the rest was exported mainly to other African countries. SEAA competes well in the region with large EHGC manufacturers in India and China, as the cost of transporting high quality EHGCs over long distance is relatively high. The government of Ethiopia has been making an active effort to strategically target foreign investment in the pharmaceutical sector.

(v) Indonesia

53. From Indonesia, PT Eisai Indonesia (PTEI) was selected for a case study by UNCTAD. Pharmaceutical products and processes are patentable subject matter under the patent law of Indonesia. According to the case study, although exact figures are not available, R&D based pharmaceutical firms generally seek patent protection for new chemical entities in Indonesia due to the potential of the large domestic markets. Established in 1970, PTEI is a subsidiary company of EISAI Co. Ltd. (Eisai), one of Japan's major R&D-based pharmaceutical companies. Technology transfer had taken place from the parent company Eisai to PTEI in all aspects, including dissemination of manuals, training staff and frequent communication between PTEI and Eisai. Efforts were made to keep the technology in-house, although, according to the case study, not only Eisai but also other Japanese pharmaceutical companies that had established subsidiaries in Indonesia had helped the growth of the local industry through spillover of skilled human resources and in-licensing. Staff of both PTEI and EISAI considered technology transfer projects to have been completed successfully, and Japanese expatriate staff are no longer stationed in PTEI. PTEI produces a wide range of products mostly for EISAI, which are destined to local consumption and exportation. Most products are off-patent, although a number of patented products are produced as well. According to the analysis of the case study, the decision of multinational pharmaceutical companies to set up a subsidiary in Indonesia appeared to have been primarily driven by the size of the market and its potential of further growth.

(vi) Jordan

54. Local firms in Jordan have become a major supplier of high quality pharmaceutical products in the Middle East and North African region. The case study presented the case of the Jordan Pharmaceutical Manufacturing Co. PLC (JPM) which produced wide range of generic products with the company's brand names. JPM had benefited significantly from the high level of education in Jordan. It allowed JPM to build a solid technical base with the capacity to absorb technologies, produce high quality products and serve both domestic and export markets. Pharmaceuticals represented 8.2% of Jordan's exported goods in 2009. When Jordan acceded to the WTO in 2000, it agreed to make patent available for pharmaceutical products. A bilateral Free Trade Agreement (FTA) was concluded with the United States of America in 2001, in which a number of provisions concerning intellectual property rights were found. In the case study, it was noted that pharmaceutical manufacturers expressed the problem they had with the data exclusivity practices introduced by Jordan-US FTA. Further, the case study referred to the Trade Policy Review Report by Jordan submitted to the WTO in 2008, according to which 7% of all pharmaceuticals produced in the country were patent-protected products produced under license. The case study also showed that JPM and its domestic subsidiaries actively filed patent applications on the inventions resulted from in-house R&D on which the JPM management recently placed a strategic focus.

(vii) Thailand

55. The publication contains another case from Thailand regarding a project in respect of local production of influenza vaccines. The Government Pharmaceutical Organization of Thailand (GPO) is the amalgamation of the Government Pharmaceutical Laboratory (established in 1942 to serve as a domestic pharmaceutical factory to reduce reliance on imported medicines and to produce medicines for national emergencies) and the Department of Medical Depot, which was responsible for the procurement of medical products for the Thai government (founded in 1901). The GPO influenza vaccine project started in 2007 with a grant of US$1.9 million from WHO for the purpose of establishing pilot facilities for the production of seasonal and pandemic influenza vaccine. Before the GPO project, there was no domestic production of influenza vaccine. Technical and advisory support from WHO in facilitating the acquisition of technology for

influenza vaccine production helped to resolve many of the issues and challenges. Transfer of technology for the development and production of influenza vaccine was considered as the most effective route to secure sustainable access to high quality influenza vaccine technology. One of the major considerations in that context was to address the related intellectual property rights issues.

56. The first stage of the project started with R&D into the development of the virus strain for the production of vaccines. Technical assistance from the external consultant and transfer of technical know-how related to the production processes from the International Technology Platform for influenza Vaccine (ITPIV), which had been established by the Netherlands vaccine Institute with WHO support, were provided. In the second stage, GPO started developing the live attenuated influenza vaccine (LAIV). Reporting on the progress of the Global Pandemic Influenza Action Plan to Increase Vaccine Supply (GAP), WHO noted that a major barrier in the influenza vaccine project was to find manufacturing partners to transfer technology.

57. The WHO had conducted patent landscaping under the GAP framework in order to identify the most feasible approach for vaccine development both from a technical and legal (intellectual property) point of view. It found that the technology to produce egg-based inactivated vaccines had existed for a long time, although a number of patents relating to recent improvements to the process and final composition were identified. It was concluded that, most likely, patents would not create an absolute barrier to the production of vaccines via that well-known process. Access to LAIV technology and the Leningrad attenuated virus strain was made possible through a licensing agreement negotiated by WHO with Nobilon International BV in 2008. Nobilon international BV granted the WHO a non-exclusive license to develop, register, manufacture, use and sell LAIV produced in embryonated chicken eggs. It also allowed the Institute of Experimental Medicine in Russia to supply WHO with LAIV reassortants. WHO was permitted to grant a sub-license to vaccine manufacturers in developing countries working within the framework of WHO/GAP. Such vaccine manufacturers would be able to manufacture and distribute influenza vaccines royalty-free to the public sector in developing countries.

58. WHO noted that a major barrier in the influenza vaccine project was to find manufacturing partners who would transfer relevant manufacturing know-how and information in the regulatory dossiers. In the case study, it was noted that, with respect to influenza vaccine production, manufacturing know-how and access to regulatory dossiers might present more significant challenges than patent issues. It was stated that a joint venture initiative between GPO and Sanofi Pasteur to promote domestic vaccine development through transfer of technology and know-how had not been fully realized, due in part of to the lack of clarity in the technology needs and priority of the GPO.

(viii) Uganda

59. While Uganda is an LDC WTO Member, the Patent Act of Uganda does not exclude pharmaceutical inventions from patentable subject matter. In other words, both pharmaceutical products and processes may be patented in Uganda, provided that all the relevant requirements under the Act have been complied with. In the publication, the case of Quality Chemicals Industries Limited (Quality Chemicals) was presented. Quality Chemicals is a joint venture between Indian generic manufacturer Cipla and Ugandan local firm, Quality Chemicals Limited, which had been a local distributor of imported drugs. The joint venture was initiated in 2007, and Quality Chemicals has been producing and supplying drugs for HIV/AIDS and malaria for the markets in Uganda and neighboring countries. The government of Uganda introduced investment incentives to Cipla, such as free land to build the plant, free set-up of the entire infrastructure and remuneration of Cipla's pharmaceutical experts for their training activities with local staff. In addition, the Ugandan government agreed with Cipla to procure from the new plant in Kampala ARVs worth US$30 million per year for seven years. Cipla, in return, provided a range of hardware technologies required for production and all the tacit know-how related to

the running of the plant, including quality control and organizational skills. Quality Chemicals is responsible for providing capital to finance the operation of the production plant and local employees, and for strategic direction and marketing.

IFPMA Publication "Technology Transfer: a Collaborative Approach to Improve Global Health"

60. The International Federation of Pharmaceutical Manufactures & Associations (IFPMA) issued a publication entitled *"Technology Transfer: a Collaborative Approach to Improve Global Health"*[15] in 2011. In the Foreword, the Director General of IFPMA writes:

> "In an increasingly globalised world, the promise of technology transfer is a key consideration for all countries whether in low, middle and high income countries and many multilateral organizations, including the UN, World Bank, WTO, WIPO, have a role to play in creating the necessary conditions for global growth and poverty reduction. For the WHO and the broader public health policy making community, technology transfer as it applies to medicines and vaccines is of major importance. To contribute to these discussions and with a view to informing the debate, we have brought together in this publication over 50 examples of successful pharmaceutical technology transfers."

61. In the IFPMA publication, it was noted that, for all investors, political stability and the rule of law are prerequisites for transferring pharmaceutical technologies. It identified the following eight critical factors that research-based pharmaceutical companies were looking for in prospective technology recipient countries:

- promising market scale and accessibility;
- political stability and good, transparent governance;
- appropriate capital markets;
- innovation-friendly environment with sound intellectual property protection and enforcement;
- proper access to information;
- adherence to regulatory standards;
- skilled workforce; and
- alignment with economic development priorities.

A number of concrete examples of knowledge transfer from IFPMA members, including (i) manufacturing and know-how transfer; (ii) scientific collaboration and knowledge sharing; and (iii) capacity building, are found in the publication.

[End of document]

15 http://www.ifpma.org/fileadmin/content/Publication/IFPMA_Technology_Transfer_Booklet_2011.pdf.