US RESPONSE TO WIPO CIRCULAR C 8261

Exceptions and limitations to patent rights

Member States and Regional Patent Offices are invited to provide input on the implementation of the following five exceptions and limitations in their countries or regional systems, respectively: (i) private and/or non-commercial use; (ii) experimental use and/or scientific research; (iii) preparation of medicines; (iv) prior use; and (v) use of articles on foreign vessels , aircrafts and land vehicles.

In particular, they are invited to submit information additional to, or updating, the information contained in their responses to the questionnaire on exceptions and limitations to patent rights. Member States and Regional Patent Offices which have not yet submitted their responses to the questionnaire are invited to do so. The questionnaire and the responses to it can be found at: http://www .wipo.intlscp/en/exceptions/.

The United States responses to the questionnaire are up to date and can be found at: http://www.wipo.int/scp/en/exceptions/replies/usa.html.

Quality of Patents

Member States and Regional Patent Offices are invited to submit information on work-sharing programs among patent offices and on the use of external information for search and examination. The latter may include , for example , information on utilization of external search and examination reports and use of various external databases for retrieving information relevant to search and examination, such as prior art and information concerning corresponding foreign applications.

Member States and regional Offices have sought ways to re-use the search and examination results completed on related or cross-filed applications, to minimize duplication of work, enhance examination efficiency and quality and to deliver real benefits to end users, such as more predictable patent rights. The present environment of limited funding in many large and small offices, and the need to process applications efficiently and in a timely manner, make it even more imperative to avoid wasting resources.

Many offices have been involved in decades of cooperation on work sharing. In terms of multilateral cooperation, the Trilateral Offices (USPTO, EPO and JPO) have been involved in work sharing since 1983, and the Five IP Offices - a forum of the five largest offices (USPTO, EPO, JPO, KIPO, and SIPO) - since 2007. There have been also many instances of bilateral cooperation, including the many agreements under the Patent Prosecution Highway (PPH), examiner exchanges, symposia, information sharing and various work sharing pilot programs.

Patent Prosecution Highway

One example of successful work sharing program is the Patent Prosecution Highway (PPH). The PPH began in 2006 as a pilot between the USPTO and JPO, and since then has been embraced by many other offices. Under the PPH, when claims are determined to be allowable in one participating office, a corresponding application with corresponding claims filed in a second participating office is fast-tracked for examination. In this manner the second office can utilize the search and examination results of the first office, thereby avoiding duplication of work and expediting the examination process. The PCT PPH expands the program to applications that obtained a positive examination result in a PCT search or preliminary examination.

The PPH facilitates work sharing, since participating offices can more effectively reutilize work to avoid duplication, improve processing efficiency, and increase quality. The PPH also incentivizes applicants by providing faster processing and earlier patentability determinations in multiple jurisdictions. Significant cost savings also encourage applicants to participate. The program continues to be revised and improved to increase the quality of granted patents and the efficiency of the process.

An important principle of the PPH is that every participating office conducts its own search and examination according to its national law. There is no deference to the search results or legal conclusions reached by another office. The work product of the office that first examined the application is simply used to provide a better starting point to the office conducting the later examination.

Collaborative Search & Examination

In June 2010, a pilot was launched within the IP5 framework, involving the EPO, USPTO and KIPO. Its aim was to test the feasibility of establishing an International Search Report (ISR) and Written Opinion of the International Search Authority (WO-ISA) where examiners from the participating offices with complementary skills would work together to produce a high-quality ISR and WO-ISA.

In the pilot, the examiner from the office acting as ISA for a given PCT application (the first examiner) analyzed the application, defined a search strategy, conducted the search and drafted a provisional ISR and WO-ISA. The provisional ISR and WO-ISA were then transmitted to two peer examiners in the other offices. The peers commented on or supplemented the provisional work of the first examiner, who considered those comments when drafting the final ISR and WO-ISA.

The successful completion of the first CS&E pilot program spurred a second follow up pilot program of a larger scale, which built on the lessons learned during the first pilot project to provide qualitative and quantitative information.

From the two pilot programs it was learned that differences between office procedures for analyzing claims directed to medical use or to methods of treatment affected the collaboration, due to differences between offices on what is considered patentable subject matter. Different classification schemes contributed to complicating the reutilization of searches performed by other offices.

USPTO-UKIPO Work Sharing Initiative

On November 10, 2010, the USPTO and the UKIPO commenced a program for reutilizing each other's search and examination work products on corresponding patent applications, to assess the benefits of work sharing. By sharing and reutilizing work products, the Offices aimed to increase the efficiency and quality of their respective patent search and examination processes. This program included initiatives to educate examiners on the respective patent systems and examination practices of the other office.

This project suggested that further cooperation would be beneficial in exploring the differences in practice between the Offices, particularly regarding novelty and inventive step/non-obviousness. Collaboration on these issues could facilitate a deeper understanding among examiners and lead to more effective reutilization of work products.

The potential benefits of work sharing could also be exploited more effectively by gaining a better understanding regarding the applicability of prior art. These results suggest that the USPTO and UKIPO should continue their work sharing cooperation, with a focus on increasing examiner understanding of each office's practice and on helping examiners better understand the other office's rules, particularly with respect to novelty and obviousness/inventive step.

USPTO KIPO SHARE pilot

In 2008, the Korean Intellectual Property Office (KIPO) and the United States Patent and Trademark office (USPTO) engaged in a comprehensive program to foster increased bilateral cooperation between the offices. This included the Strategic Handling of Applications for Rapid Examination (SHARE) pilot, under which, when corresponding applications were filed in two offices, the Office of First Filing (OFF) conducted a search and examination and shared its findings with the Office of Second Filing (OSF), such that the OSF could maximize reutilization of the work performed by the OFF and minimize duplication of work.

Prior to beginning the pilot, examiners from KIPO visited the USPTO as part of an examiner exchange program, in which each Office presented an overview of its search and examination practices. The exchange was a great success, and the offices developed a deeper understanding of each other's rules and procedures.

An analysis of the pilot revealed that in general, a reference could be reutilized at least in part, but that different examination practices in each Office resulted in examiners applying the references differently. Therefore, it appears that addressing differences in office procedures through examiner exchange programs is one element leading to successful work sharing.

Tools for Work Sharing

Many work sharing programs rely on tools to help the examiners communicate, exchange references, access information etc. In some cases these tools exist, but more often better tools are needed to carry out basic work sharing functions. Examples include tools to provide machine translation, to provide access to family data and search results, and to share search strategies.

Collaborative Patent Classification

The Cooperative Patent Classification (CPC) was initiated as a joint partnership between the USPTO and the EPO which agreed to harmonize their existing classification systems (ECLA and USPC, respectively) and migrate towards a common classification scheme. This strategic decision by both offices is an important step towards advancing the efforts currently being undertaken through the IP5's Working Group on Classification. The migration to CPC was developed based in large part on the existing European Classification System (ECLA) modified to ensure compliance with the International Patent Classification system (IPC) standards administered by the World Intellectual Property Organization (WIPO). It is expected that this project will result in a more effective search process for all offices taking part.

Common Citation Document

The Common Citation Document (CCD) application aims to provide single point access to up-to-date citation data relating to the patent applications of the IP5 Offices. It consolidates the prior art cited by all participating offices for the family members of a patent application, thus enabling the search results produced by several offices for the same invention to be visualized on a single page. The creation of the CCD application is part of an ongoing process of technical harmonization at international level aimed at establishing an appropriate infrastructure to facilitate greater integration of the global patent system.

Machine Translation

Use of machine translation, which is part of an IP5 foundation project, is expected to eventually become routine. While today a human translation of the application and claims provided to an office of second filing is necessary to ensure consistent scope of protection, in the future machine translation is expected to be adequate.

Confidentiality of communications between clients and their patent advisors

Member States and Regional Patent Offices are invited to submit information on laws and practices on, and experiences relating to, the issue of confidentiality of communications between clients and their patent advisors.

In particular, Member States and Regional Patent Offices are invited to submit information additional to, or updating, the information contained in documents SCP/14/2, SCP/16/4 Rev., SCP/17/5, and SCP/18/6.

The status of the law in the United States regarding the confidentiality of communications between clients and their patent advisors remains unchanged, and is described in documents SCP/17/5 and SCP/18/6, which can be found at:

http://www.wipo.int/edocs/mdocs/scp/en/scp_17/scp_17_5.pdf

http://www.wipo.int/edocs/mdocs/scp/en/scp_18/scp_18_6.pdf

Transfer of technology

Member States and Regional Patent Offices are invited to provide practical examples and experiences on patent-related incentives and impediments to transfer of technology.

Patent-related incentives for TT:

1. Legal environment that provides strong, predictable and enforceable patent rights

a. *Strong patent protection stimulates technology transfer*
It has been shown by empirical evidence that stronger IPR protection, and in particular, patent protection, stimulates technology transfer to developing countries as it positively affects foreign direct investment (FDI) and imports. See Technology Transfer and the Economic Implications of the Strengthening of Intellectual Property Rights in Developing Countries by Walter G. Park and Douglas C. Lippoldt available at http://nw08.american.edu/~wgp/park_lippoldt08.pdf; and Challenges to Technology Transfer: A Literature Review of the Constraints on Environmental Technology Dissemination by Daniel K. N. Johnson and Kristina M. Lybecker available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1456222 .

b. *Clarity with respect to the property rights and ownership of publically-funded inventions promotes patenting and licensing*
The Bayh-Dole Act passed in the United States in 1980 accelerated the increase in patenting by universities and the technology transfer from universities to industry. This was done by allowing universities to elect to take title to federally-funded inventions and by simplifying the procedures for such election. For example, before 1980, fewer than 250 patents were issued to U.S. universities each year . Discoveries were seldom commercialized for the public's benefit. In contrast, in fiscal year 2011, members of the Association of University Technology Managers (AUTM), which represents university technology transfer offices, reported that 4,700 patents were issued. In addition, in fiscal year 2011, 4,899 new license agreements were signed, 19,905 total U.S. patent applications were filed and 671 startups were formed, related to university research. See http://www.autm.net/FAQs.htm . Many countries have adopted ownership provisions similar to those specified in the Bayh-Dole Act.

2. Federal programs provide many incentives to technology transfer

National Institutes of Health (NIH) technology transfer activities provide an example of patent-related incentives related to health technologies. The 2012 US Report on the implementation of Article 66.2 of the TRIPS agreement states: “The NIH was the first contributor to the Medicines Patent Pool (MPP) in licensing US government-owned patents related to the use of HIV anti-retroviral (ARV) protease inhibitor drugs. The MPP promises to enhance access to ARV treatment for people living with HIV/AIDS in developing countries and enable the development of new combinations of ARVs and adapted

formulations for developing countries. The patents licensed by NIH resulted from research undertaken by the NIH and the University of Illinois in Chicago. The licence is seen as a first step for an expected ongoing collaboration as NIH's Office of Technology Transfer and the MPP consider additional potential licence agreements to add other NIH-managed patents to the pool for technologies that may have potential as new HIV therapeutics.

In 2011, the NIH became a founding contributor and active participant in the World Intellectual Property Organization (WIPO) Re:Search initiative, established to share innovation in the fight against neglected tropical diseases (NTDs), malaria and tuberculosis, by providing access to intellectual property for pharmaceutical compounds, technologies, know-how and data available for research and development for these NTDs. On behalf of the NIH and FDA, the NIH contributed intellectual property from its internal research programmes for over 70 technologies. These technologies are made available for licensing to help in the development of diagnostics, vaccines, and therapeutics to improve public health in the LDCs. The initial NIH Re:Search participation effort was highlighted in an Office of Science and Technology Policy (OSTP) blog entry on 27 October 2011, noting that the NIH's participation aligns with the Presidential Policy Directive on Global Development, which calls for greater efforts to leverage the power of research and development to improve disease treatment.

In February 2012, the USPTO launched the Patents for Humanity Pilot Program to reward companies who bring life-saving technologies to underserved people of the world. The program provides business incentives for patent owners and licensees to apply their patented technology to address humanitarian needs. The program is structured as a voluntary prize competition. Participants submitted applications describing how they have used their technology to combat global challenges in four areas: medical technology, food and nutrition, clean technology, and information technology. Volunteers from academia served as judges, selecting the best examples for awards. Winners received a certificate to accelerate select matters before the USPTO on any technology in their portfolio. They also received public recognition from the USPTO and media publicity of their efforts. The first ten winners were announced in early 2013, and were recognized in a ceremony at the US Capitol

For complete report please see document IP/C/W/580/Add.6 available on the WTO website.

Many authors agree that the real impediments to technology transfer are not related to patents or IPR per se. For example, inadequate, weak or unclear domestic laws, regulation and practices; high tariffs; inadequate scope of patent protection and weak patent enforcement in recipient countries; "taking" of patent rights, for example through compulsory licensing, were identified as barriers for innovation and technology diffusion.

See, for example, Promoting Technology Transfer by Protecting Intellectual Property Rights available at http://www.thecied.org/; Promoting Technology Diffusion To The Developing World available at www.theglobalipcenter.com; Challenges to Technology Transfer: A Literature Review of the Constraints on Environmental Technology Dissemination by Daniel K. N. Johnson and Kristina M. Lybecker available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1456222 .