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Introducing our Newsletter

Welcome to the first issue of the *Newsletter* of the Intellectual Property Interest Group. Our initial format will generally comprise several pages of news and an opinion piece by an ASIL colleague on a current topic. In future issues we can include information on upcoming events and our members' publications and activities. We plan to publish generally mid summer and in time for the annual meeting of the ASIL (and of our interest group).

In this issue we are grateful for the contribution of Enrico Bonadio, Lecturer in IP and IT Law at the University of Abertay Dundee. His comment is on the EPO's recent decision clarifying the rules on patentability of surgical methods. Much of the rest of the materials in this initial issue have been prepared by the interest group's new co-chair, Aaron Fellmeth.

Materials for publication in the *Newsletter* can be submitted to its editor, Carter Eltzroth, at celtzroth@helikon.net. While submissions are welcome, they are subject to space constraints as indicated by this first issue. We are always happy to receive notices of the publications and activities of our members.

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PATENT COOPERATION TREATY REFORM*

In May 2009, the WIPO presented to the Patent Cooperation Treaty (PCT) Working Group a document entitled “The Future of the PCT,” which outlined various perceived problems in the PCT. A few weeks later, the United States presented a proposal to reform the PCT by creating a new treaty (PCT II). Amendment of the existing PCT was not proposed. In this case, the U.S. PTO rather than the USTR is taking the lead on the negotiations. The forum is the WIPO Committee on Reform of the PCT rather than the Doha Round of World Trade Organization (WTO) negotiations.

The WIPO document (PCT/WG/2/3, Apr. 3, 2009) identifies several main problems with the operation of the PCT system at present. The first problem is backlogs in processing PCT applications among the national patent offices. WIPO identified needless duplication of patent searches, both within national offices and between offices, as a root cause of these backlogs. A related problem is that the cost of obtaining multinational patent protection through the PCT is prohibitive for individual inventors, developing country inventors, and small and medium-sized business firms even in the developed world. Duplication of work increases the delay inherent in and cost of using the PCT.

Relatively few international patent applications proceed directly to the national stage; most result in parallel proceedings on the national and international stages. Moreover, no major examining office accepts the work of any other national office without performing its own national examination. As a result, an international patent application may be subject to search and examination four or even five times, depending on how it is processed and what level of deference is given to the international search report. Among the solutions suggested by WIPO are the integration by International Searching Authorities (ISAs) of their international search with their own national search (assuming the applicant is seeking a patent from the patent office acting as an ISA, as is usual), so that only a single search is necessary. WIPO recommended examining why patent applicants find inefficient parallel national and international applications beneficial.[†]

WIPO also recommended increasing the quality of the international search reports so that other patent offices would feel more comfortable relying on them instead of conducting their own independent searches during the national stage. The duplication is partly fostered by many patent offices having adopted reservations or notices of incompatibility to the PCT (at present, some 150) that create discrepancies in international standards for the content and effect of the patent application. The WIPO recommended examining these reservations and notices with a view to their reduction and ultimate withdrawal.

In addition, many states with a registration system do not examine patent validity. A negative international preliminary examination report (IPER) can leave such countries in the position of granting a patent that is probably invalid. WIPO proposed no specific

* For background information on the PCT, see Jay Erstling & Isabelle Boutillon, *The Patent Cooperation Treaty: At the Center of the International Patent System*, 32 WM. MITCHELL L. REV. 1583 (2006).

[†] On this question, see PETER DRAHOS, *THE GLOBAL GOVERNANCE OF KNOWLEDGE: PATENT OFFICES AND THEIR CLIENTS* (2010).

solution to this problem. A related problem is that PCT users have criticized the national patent offices for granting too many invalid patents due to inadequate examination procedures and the absence of an efficient mechanism for invalidating such patents. Increasing the reliability of the international search could help foster reliance on negative reports and reduce the incidence of inaccurate positive reports.

The WIPO took the position that these problems do not require significant amendment of the PCT legal framework, but rather reformation of the practices of the national patent offices, as discussed above. WIPO reported that the “general consensus” in the PCT Working Group favored these suggestions “in principle,” although more detailed proposals would be needed.

Three weeks after the presentation of the WIPO report, the United States proposed its own “Comprehensive Proposal for PCT Reform” (WIPO Doc. PCT/WG/2/12, Apr. 24, 2009). The U.S. proposed a new PCT (“PCT II”) in response to its position that the PCT framework “hampered” the cooperation of national patent offices and thereby failed in its task of eliminating redundant work by the offices. The PCT II would have two key features:

- (1) combined national and international search and examination accomplished through collaboration among the national patent offices; and
- (2) allowing the applicant as well as third parties to submit prior art to the international searching authority to improve the quality of the search.

The U.S. PTO argued that the resulting significant improvement in quality of the international search report would eliminate redundancy and greatly increase the confidence of national patent offices in the international search or IPER. It would also save money for the national and regional patent offices by removing the need to conduct an independent, duplicative national examination.

Of course, the cost savings to national patent offices would only be realized if they were to rely on a search and examination by the international searching authorities, which are mostly the more developed patent offices such as the U.S. PTO, the European Patent Office, and the Japan Patent Office. Developing countries generally distrust WIPO efforts to harmonize patent application processing and substantive patent law. Both developing countries and most Group B countries* strongly opposed the U.S. proposal as tampering with the basic structure of the PCT. The main concern appeared to be that the U.S. proposal would have removed some of the flexibility in implementing the multinational patent applications in favor of more control by the receiving offices and international searching authorities.

Soon after the proposal, the Obama Administration assumed office, and with it came a change in the PTO’s attitude toward the PCT. The U.S. PTO is no longer actively pushing for PCT II and appears to be distancing itself from the Bush Administration’s

*“Group B” is the term used at WIPO to denote the principal IP-exporting countries, such as the European Union and its most economically developed member states, Australia, Canada, Japan, New Zealand, Norway, Switzerland, and the United States.

proposal. Nonetheless, there appears to be a consensus among members of the PCT Working Group that the PCT does not function optimally. The Group has endorsed the idea that future study and proposals are needed, but no work is proceeding at this time. The prospects for over 140 countries agreeing on significant changes to the structure of the PCT seem distant, especially in light of a perception that many countries do not trust the intentions of others. In the meantime, both the U.S. PTO and the Japan Patent Office have begun cooperating more by allowing a positive PCT International Search Report to accelerate the examination process, whereas previously these offices gave the report no weight. Greater international cooperation could lead to reduction in the inefficiencies of the PCT process without necessitating major treaty reform.

COMMENT: European Patent Office rules on patentability of surgical methods

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On 15 February 2010 the Enlarged Board of Appeal (EBA) of the European Patent Office (EPO) released an important decision regarding the exclusion from patentability of certain surgical methods (in the case G1/07).^{*} Under the European Patent Convention (EPC), methods of treatment by surgery are not patentable. Yet the exact scope of this exclusion has never been clear, as to date the EPO Technical Boards of Appeal seems to have reached different decisions on this matter.

The patent application examined by the referring board regarded magnetic resonance methods for imaging pulmonary and cardiac vasculature and assessing blood flow using dissolved polarised ¹²⁹Xe. In the context of these methods an embodiment relies on directly delivering such polarised ¹²⁹Xe to an area of the heart through injection, and said methods may be applied before either surgery or a drug therapy for the treatment of pulmonary and cardiac problems. During surgery they may provide useful real-time feedback in order to confirm success (e.g. surgically induced variations in blood perfusion). In the context of therapy they may permit the effect of the drug to be determined.

The EBA was asked *inter alia* whether the above methods should be excluded from patent protection as a “*method for treatment of the human or animal body by surgery*” (exception now contained in Article 53-c) EPC), even if the above described step – i.e. the injection of a contrast agent into the heart – does not *per se* aim at maintaining life and health.

^{*}For a more thorough comment of this decision see Enrico Bonadio, *Medical Methods, Risks to Public Health and Exclusion from Patentability*, in EUROPEAN J. OF RISK REG. 2010/2.

The EBA initially noted that the claimed methods involve physical interventions on the body which require professional medical skills to be carried out and involve substantial health risks even when executed with the required medical professional care and expertise. The said board held that the presence of such risk-related factors – e.g. harmful side effects or health risks for the subject – is material when verifying whether invasive surgical methods (as the one in G1/07) should be excluded from patentability, regardless of whether they have no curative purposes or effects.

The EBA concluded that methods having purely or mainly non therapeutic aims which include a substantial intervention on the body and do involve health risks should be excluded from patentability under the surgery-related exception (now contained in Article 53-c) EPC). The EBA also clarified that with reference to such risky inventions the rationale for the exception – i.e. to free doctors from being potentially prevented by patents in the application of the best possible treatment on their patients – clearly applies and justifies their exclusion from protection. In the decision the EBA took pains to give some examples of the above methods: i.e. (i) sex change operations, (ii) elimination of wrinkles, (iii) breast enhancement, (iv) embryo transfer, (v) organ transplantation, (vi) cosmetic surgery, (vii) sterilization and (viii) castration.

On the other hand, uncritical methods involving only a minor intervention and no substantial health risks (when carried out with the required care and skill) are to be considered patentable. Indeed, the EBA stressed that the progress and advance in safety and *“the now routine character of certain, albeit invasive techniques, at least when performed on uncritical parts of the body, have entailed that many such techniques are nowadays generally carried out in a non-medical, commercial environment like in cosmetic salons and in beauty parlours and it appears, hence, hardly still justified to exclude such methods from patentability”*. Examples of such uncritical methods could be (i) hair removal by optical radiation, (ii) micro abrasion of the skin, (iii) piercing, (iv) tattooing, etc.

The lesson we can draw from this decision is that risk-related factors are paramount when it comes to deciding whether medical methods are to be excluded from patentability. These factors are amongst those socio-ethical and public health related considerations which must be taken into account when dealing with the inventions in question. This is therefore a relevant decision from EBA, which is the most important body in EPO. Indeed, it is competent to take decisions only when the case law of the Technical Boards of Appeal (TBA) – i.e. lower boards of the EPO – becomes inconsistent or an important point of law arises, thus ensuring uniform application of patent law across Europe.

ANTI-COUNTERFEITING TRADE AGREEMENT NEGOTIATIONS

On the Anti-Counterfeiting Trade Agreement currently under negotiation, see the May 2010 ASIL Insight by Aaron Fellmeth. Relatedly, on May 5, 2010, the U.S. International Trade Commission initiated an investigation into Chinese IP enforcement practices at the behest of Congress. The study will focus on the effect of Chinese counterfeiting and piracy on the U.S. economy.

STALLED SUBSTANTIVE PATENT LAW TREATY NEGOTIATIONS

In 2002, the United States proposed in the WIPO's Standing Committee on Patents the adoption of a substantive patent law treaty (SPLT) that would move beyond the harmonization found in the TRIPs Agreement and the WIPO Patent Law Treaty.* At the time, the WIPO issued a document (A/37/6, Aug. 19, 2002) pointing out some advantages of a "global patent," but expressing skepticism of its prospects in the near term. That skepticism has so far proven justified.

The current consensus among Group B countries is for a "reduced package" of harmonization in four issue areas: the definition of prior art; a harmonized definition of novelty; a harmonized definition of inventive step or nonobviousness; and a grace period after public disclosure of the subject matter in a patent application. In 2006, the working group claimed to have arrived at a tentative agreement on the definitions of prior art (anything in the public domain) and novelty. They also stated that they are "largely in agreement" on the third, except for the matter of "secret prior art." Secret prior art is technology that is available to the patent examiner but not publicly available to inventors (e.g., because it was disclosed in a prior, unpublished, pending patent application by someone other than the patent applicant at issue). Disclosure of prior art in a senior patent application will probably negative novelty, but the working group has not resolved whether secret prior art can be combined with publicly known prior art to render an invention obvious and, therefore, ineligible for a patent.

Regarding the grace period, this subject has occasioned disagreement as well. Currently, the United States is the only country in the world with a first-to-invent registration system. In exchange for abandoning the first-to-invent system and switching over to the first-to-file system used elsewhere, the United States has tried to negotiate for a one-year grace period to allow senior inventors to delay somewhat before filing a patent application. The grace period has been a troublesome issue in the Group B country negotiations at WIPO for a SPLT. In a move to increase its bargaining leverage, the United States later requested an 18-month grace period. Europe and Japan oppose a grace period of more than a year, the former arguing that in any case a grace period will be less important in some industries than in others and that perhaps the treaty should differentiate.

* For background information on the terms of these treaties, see AARON XAVIER FELLMETH, *THE LAW OF INTERNATIONAL BUSINESS TRANSACTIONS* 44-49 (2009).

There is a special working group on development issues. The EU has stated that it favored the integration of development issues into the SPLT, and this is a subject on which developing countries are adamant. Key developing countries wish to tie technology transfer, prohibitions on anticompetitive licensing and exploitation practices, and the protection of genetic resources and traditional knowledge into any SPLT. The Asian Group took this position early on.

WIPO's International Bureau produced a draft treaty in 2004 as the basis for negotiations, and the SPLT dominated the Standing Committee on Patent's agenda in 2006. Nonetheless, very little has been accomplished since 2006. After several failed attempts to move forward with a Substantive Patent Law Treaty, the deputy director of the PTO office of public affairs commented that "the U.S. intends to pursue harmonization of prior art issues within the group of developed countries, and will evaluate in the future whether an agreement may be possible in WIPO at some point."

ONGOING U.S. PATENT LAW REFORM EFFORTS: INTERNATIONAL ASPECTS

Congress has been considering significant changes to the 1952 Patent Act for several years. While several bills have passed one house, no one bill has gathered majority consensus in both houses. Few of the controversial provisions, however, related to international patent matters. This is not to say that the reforms proposed with respect to international issues were minor; on the contrary, they were extremely consequential.

The current U.S. patent law combines a first-to-invent standard with a statutory bar system in Section 102. Like its predecessor bills, the 2010 Patent Reform Bill now before the Senate (S.B. 515^{*}) would replace this system with a first-to-file system similar to that used in most other countries, except that it would have included a one-year grace period for a patent or prior publication (or otherwise publicly known) anywhere in the world directly or indirectly by the inventor(s). As this section is currently written, it follows that a foreign patent application filed by another and published less than one year before the U.S. patent application would not be anticipatory prior art under this section unless a priority dispute arises. However, given the U.S. position in its negotiations of the SPLT (above), the unilateral adoption of a first-to-file system by the U.S. Congress would tend to undermine the Executive Branch's leverage in any SPLT negotiations.

In any case, the shift to a first-to-file system would necessitate a redefinition of the "effective filing date" for the patent application (Section 100) to mean either the filing date of a nonprovisional patent application or, if the application is for a foreign invention entitled to priority, the earliest foreign application in which the claimed invention is fully disclosed under Section 112. In addition, the current Patent Act contains special rules for priority of foreign inventions in Section 104. Priority under Section 104 depends on whether the inventor is domiciled in (or is a citizen of) a state party to the NAFTA or

^{*} See <http://judiciary.senate.gov/legislation/upload/PatentReformAmendment.pdf>.

WTO Agreements. This section is repealed as unnecessary in light of the amendments to Section 102.

In addition, the United States is currently the only country to have a “best mode” requirement in its disclosure rules (Section 112). Previous versions of the bill would have repealed this requirement, but the 2010 bill takes a different approach. It leaves the requirement intact, but failure to fulfill the best mode requirement would no longer invalidate the patent. This amendment is expected to reduce patent litigation substantially and to vitiate the number of patents invalidated for Section 112 reasons. It would also further harmonize U.S. law with foreign practice (although not as much as previous versions of the bill). At the same time, it reduces the value to the public of a disclosure of the invention in the patent application.

Finally, previous versions of the bill would have added a post-patent grant opposition procedure as Chapter 32 to Part III of Title 35 in order to allow anyone seeking to invalidate a newly-issued patent to challenge its validity before an administrative agency rather than a court. The European Patent Office has a similar procedure. However, the 2010 bill omits this feature.

BLOCKED EUROPEAN PATENT COURT

Under the European Patent Convention (EPC), most European states have agreed to a procedure for granting multiple national patents through a single “European” application filed at the European Patent Office. The EU has long been working on developing a project for a single, Europe-wide patent, along the lines of the now-available Community Trade Mark. In the meantime, a recurring problem within the European system is that different national courts could interpret identical patents differently, so that, for example, infringement litigation could result in invalidity of the patent in one jurisdiction, “not invalidity” and no finding of infringement in another, and “not invalidity” and a finding of infringement in a third. In 1999, the state members of the European Patent Organization began consideration of a proposal to adopt an optional protocol to the EPC that would commit state parties to an “integrated judicial system, including uniform rules of procedure and a common appeal court” for national patents granted under the EPC procedure.

In 2007, the parties agreed upon what was thought to be a final draft “European Patent Litigation Agreement” (EPLA) that would create a European Patent Court of First Instance with jurisdiction over controversies involving state parties to the Agreement primarily relating to:

- actual or threatened infringement of an EPC patent;
- a declaratory action of non-infringement of an EPC patent; and
- actions or counterclaims for revocation or invalidity of an EPC patent.

Under Article 45(1), the national courts of the EPLA contracting states retain jurisdiction to grant provisional protective measures under applicable national law. Applicants must, however, bring an action on the merits before the European Patent Court within 31 days. The EPLA also sets up a Court of Appeal to hear all appeals from the Court of First Instance.

At present, the path to widespread adoption of EPLA is blocked by a legal conflict with the EU's existing organizational structure. The EPLA would set up the Court as an independent entity outside of the EU framework. The court would be accessible to all EPC contracting states, some of which are not EU members, such as Switzerland. However, the European Commission wants the patent court's statutes to closely mirror the European Union's legal framework, and several EU members "take the view that creating a new jurisdiction in parallel to the Community jurisdiction would be complicated and risk creating inconsistencies. In the case of the creation of the Community patent it would lead to duplication of EU-wide patent courts."* It appears that the impasse will not be broken for several more years, despite the acknowledged advantages of an EU-wide unified patent system.

WIPO TREATY FOR IMPROVED ACCESS FOR THE BLIND

In May 2009, the World Blind Union – an NGO representing some 600 different organizations of blind and partially sighted persons from 158 countries – formally proposed a draft treaty to the WIPO's Standing Committee on Copyright and Related Rights. The Treaty For Improved Access For Blind, Visually Impaired And Other Reading Disabled Persons ("Treaty for the Blind") would limit the scope and enforcement of copyrights in order to accommodate the needs of visually impaired persons. Because the TRIPs Agreement, via Articles 8 and 12 of the Berne Convention (which are incorporated into the TRIPs Agreement), gives authors of copyrighted works exclusive rights to prepare derivative works, all authors of works protected by copyright in WTO member states have the legal right to prevent closed captioning, transcription to braille, audio recording, or other adaptations of their works for the benefit of the visually impaired. The Treaty for the Blind, if widely adopted, would address some of the impediments created by this right to the full enjoyment of copyrighted works by the visually impaired.

More specifically, the core of the draft treaty is Article 4, which creates "limitations and exceptions" to exclusive rights under copyright law for the blind or persons so visually impaired as to be unable to obtain normal access copyright protected works:

- (a) It shall be permitted without the authorisation of the owner of copyright to make an accessible format of a work, supply that accessible format, or copies of that format, to a visually impaired person by any means, including by non-commercial lending or by electronic communication by wire or wireless means,

*Communication from the Commission to the European Parliament and the Council – Enhancing the Patent System in Europe, EU Doc. COM/2007/0165 final (Apr. 3, 2007), EurLex Doc. 52007DC0165-EN.

and undertake any intermediate steps to achieve these objectives, when all of the following conditions are met:

1. the person or organisation wishing to undertake any activity under this provision has lawful access to that work or a copy of that work;
2. the work is converted to an accessible format, which may include any means needed to navigate information in the accessible format, but does not introduce changes other than those needed to make the work accessible to a visually impaired person;
3. copies of the work are supplied exclusively to be used by visually impaired persons; and
4. the activity is undertaken on a non-profit basis.

(b) A visually impaired person to whom a work is communicated by wire or wireless means as a result of activity under paragraph (a) shall be permitted without the authorisation of the owner of copyright to copy the work exclusively for his or her own personal use. This provision is without prejudice to any other limitations and exceptions that a person is able to enjoy.

(c) The rights under paragraph (a) shall also be available to for-profit entities and shall be extended to permit commercial rental of copies in an accessible format, if any of the following conditions are met:

1. the activity is undertaken on a for-profit basis, but only to the extent that those uses fall within the normal exceptions and limitations to exclusive rights that are permitted without remuneration to the owners of copyright;
2. the activity is undertaken by a for-profit entity on a non-profit basis, only to extend access to works to the visually impaired on an equal basis with others; or
3. the work or copy of the work that is to be made into an accessible format is not reasonably available in an identical or largely equivalent format enabling access for the visually impaired, and the entity providing this accessible format gives notice to the owner of copyright of such use and adequate remuneration to copyright owners is available.

(d) In determining if a work is reasonably available in (c)(3), the following shall be considered:

1. for developed economies, the work must be accessible and available at a similar or lower price than the price of the work available to persons who are not visually impaired; and
2. for developing countries, the work must be accessible and available at prices that are affordable, taking into account disparities of incomes for persons who are visually impaired.

Article 4(c)(3) is the only derogable provision of the treaty.

Several other provisions ensure that the Article 4 rights can be effective. Article 6 allows the circumvention of digital rights management measures for the beneficiaries of Article 4, which would either conflict with or carve out an exception to the current draft of the

ACTA. Article 7 nullifies contrary contractual provisions, which would prevent copyright owners from using a common tactic of using contracts of adhesion to deprive consumers of statutory or common law rights. Article 7 would nullify contrary provisions even in negotiated contracts. Article 8 ensures that import and export measures do not deprive the beneficiaries of Article 4 of the right to international trade in adaptations of copyrighted works for the visually impaired.

The draft treaty does try to balance the interests of the visually impaired with those of copyright owners and authors. Article 5 preserves moral rights of authors. Article 9 provides that users of adaptations under Article 4 should try to notify rights owners of the use so that they may obtain remuneration or challenge the use, facilitated by a database of copyright protected works to be kept by WIPO. Perhaps most important for copyright owners, Article 11 commits the parties to developing a method for ensuring “adequate” remuneration to copyright owners under Article 4(c)(3) in the absence of agreement between the owner and user.

The standing committee has been considering reports from stakeholders and has not given any definite indication of its intentions with respect to the draft. It is clear, however, that numerous delegations support the treaty in principle, and none has expressed outright opposition. The United States has implied concern that digital access for the visually impaired to copyright-protected materials not undermine the ability of copyright owners to prevent large scale copying through digital rights management techniques.* The next session of the standing committee will be in June 2010, at which time the committee will continue consideration of the draft treaty.

* U.S. Statement on Improving Accessibility to Copyrighted Works for Blind and Visually Impaired Persons Delivered to the WIPO Standing Committee on Copyright and Related Rights, Geneva, Switzerland, May 26, 2009, at 4, *available at* <http://www.copyright.gov/docs/sccr/statement/us-intervention.pdf>.