The Hague Agreement: It May Save You Money

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On December 19, 2012, President Obama signed the Patent Law Treaties Implementation Act of 2012 (Act of 2012) into law. The Act of 2012 serves to implement two patent law treaties: (1) the Geneva Act of the Hague Agreement Concerning the International Registration of Industrial Designs (Hague Agreement) and (2) the Patent Law Treaty. By signing the Act of 2012 into law, President Obama paved the way for the U.S. to become a member of the Hague Agreement one year after enactment or when the U.S. provides the World Intellectual Property Organization (WIPO) with its implementing legislation. The implementation of the Hague Agreement moves the U.S. design patent laws to more closely follow the international community. In addition, U.S. inventors will now have increased flexibility when filing their design patent applications.

Although the President signed the Act of 2012 into law last December, the U.S. Patent and Trademark Office (USPTO) has not yet issued rules of practice in accordance with the Hague Agreement for international design applications. With the one-year deadline looming, it is expected that the USPTO will issue final rules for filing and examining international design patent applications in the near future. Once implementation of the Hague Agreement is complete, international design applications designating the U.S. will have the same legal effect as a U.S. national design application.

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So, what does this mean to the U.S. inventor? Following implementation of the Hague Agreement in the U.S., an inventor will be able to file a single international design application to obtain protection in other selected member countries or regions of the Hague Agreement. This procedure is similar to the Madrid Protocol process used for trademarks. Currently there are approximately 60 contracting parties, including 58 member countries, the European Union and the African Intellectual Property Organization. The member countries and regional systems cover many of the world's markets; however, many large industrial nations (e.g., Japan, Canada, South Korea and China) are not members. Commentators have speculated that now that the U.S. has become a member and is implementing the Hague Agreement, other countries will follow suit and commence or accelerate their respective internal legislative processes to also become members of the Hague Agreement.

As noted above, the key element of the Hague Agreement is the ability to file a single design application, which may occur for U.S. applicants either indirectly through the USPTO or directly with WIPO. Once the U.S. implements the Hague Agreement, applicants from member countries or regions will be able to file design patent applications in their home country and designate the U.S. for examination of their applications.

Under the Hague Agreement, there are generally two types of design patent systems: non-examination and substantive examination. In countries with non-examination systems, the filed applications are not substantively examined by the patent office. This means they are not reviewed and compared to the available prior art. Rather, non-examination systems publish and register the design patent applications only. Once a design patent is registered or issued in a non-examination system, the applicant obtains the right to enforce their rights against third-party infringers. However, enforcement will likely lead to the infringers challenging the validity of the registered design. Countries that employ a substantive examination system will individually review each design patent application under that country's own patent laws. For example, in the U.S., design patent applications are currently examined, and any filed under the Hague Agreement will be reviewed to determine whether the claimed invention is novel and non-obvious with respect to the available eligible prior art. Under the substantive examination systems, design applications that issue after the substantive examination will become enforceable against infringers upon publication.

As noted above, one of the major benefits of the U.S. becoming a member country to the Hague Agreement is that applicants will now be able to file a single design patent application either indirectly through the USPTO or directly with WIPO. This may enable applicants to save significant money on design patent application filing, publication and examination fees. The money savings arise due to the ability

to file a single design patent application in English, which designates a number of countries or regions. For example, a single application may save money by decreasing the fees paid to foreign attorneys for translating and filing design patent applications, as well as possibly decreasing filing fees paid to foreign patent offices. The cost savings will increase as the number of countries designated by the applicant increases. However, one needs to remember that in the event a particular country's patent office that performs substantive examinations on international design patent applications issues a rejection as to the pending application, the applicant will likely need to engage an attorney in that particular country to respond to the rejection. Thus, all foreign attorney fees may not be eliminated by the ability to file a single design patent application.

The Hague Agreement can potentially deliver significant cost savings and increase filing efficiencies for the applicant.

In addition to the ability to file a single design patent application under the Hague Agreement, several other important changes to U.S. design patent law will come into effect. For example, the U.S. design patent term will change from 14 years to 15 years from issuance. Extending the life of the design patent may be very important to a company trying to keep its competition out of the marketplace. Further, U.S. international design patent applications will be able to claim priority to other related U.S. applications, foreign applications and prior international design applications if filed within six months of the prior filing.

Another interesting twist added by the new law and the Hague Agreement is that international design patent applications will publish within six months following WIPO's completion of its review of the application's formal requirements. The application publication is similar to how PCT utility patent applications currently publish. Because of the publication requirements, design application publications will have provisional rights that are similar to the ones that exist for published utility patent applications. Specifically, when a design patent is issued that is substantially similar to the international design patent application publication, the patent owner may be entitled to a reasonable royalty from any third party that infringed the design patent during the time between the date of publication of the design application and the date the design patent application issued.

When considering whether to file a single international design patent application, it is important to be cautious as the laws in each designated country must be taken into consideration. An example of this is, under the Hague

CMS Issues Proposed Decision Memo for Percutaneous Image-guided Lumbar Decompression for Lumbar Spinal Stenosis

The U.S. Centers for Medicare & Medicaid Services (CMS) proposes that Percutaneous Image-guided Lumbar Decompression (PILD) for LSS is not reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act. Therefore, CMS proposes that PILD for LSS is non-covered by Medicare.

The scope of the national coverage analysis (NCA) included a review of evidence on whether the procedure in question provides improved health outcomes in Medicare beneficiaries. This included Vertos Medical's proprietary mild® procedure. CMS initiated this NCA in early 2Q13 and met with Vertos in 2Q and 3Q13.

Per Vertos Medical press releases, the efficacy and safety of mild have been demonstrated in 11 clinical trials and 16 physician-reviewed clinical journal articles. The brief outpatient procedure is performed through an incision the size of a baby aspirin and requires no general anesthesia, no implants and no stitches.

CMS cited several fundamental limitations of the evidence that supported conclusions that disagree with those of the studies that have been used to support claims of clinical benefit:

- Absence of diagnostic consensus leads CMS to question whether enrolled study subjects indeed have LSS, and if so to what degree
- Absence of diagnostic consensus constrains any significant consensus on treatment
- General reliance on case series rather than robust randomized sham controlled clinical trials with explicit protocol driven criteria further limits the persuasiveness of the evidence

CMS noted that these limitations are particularly challenging with back pain, in light of the subjective nature of patients' symptoms and the failure to adequately account for the biases and confounding that arise from placebo effects/spontaneous symptom improvement.

CMS summarized, "In reviewing the evidence on PILD we are confronted with weak studies, questions about missing information, questions about adverse events and conflicts of interest. After thoroughly reviewing the evidence for PILD for LSS, we have determined the evidence does not support a conclusion of improved health outcomes for our Medicare beneficiaries."

Comments on the proposed decision are slated for collection through mid-November, after which CMS will respond in a final decision memorandum.

REFERENCES

Proposed Decision Memo for Percutaneous Image-guided Lumbar Decompression for Lumbar Spinal Stenosis (CAG-00433N), October 17, 2013, CMS.gov

Agreement an international design application may include up to 100 designs as long as all the designs belong to the same international classification for industrial designs (i.e., Locarno classification). However, in some countries, the patent laws include unity of design requirements which may make it so an application cannot include the up to 100 designs that are allowed under the Hague Agreement. For example, under U.S. patent law, design patents must be directed to a single design invention, and if the application includes more than one patentably distinct design, then the U.S. patent office will issue a restriction requirement.

Another note of caution when filing a single international design patent application would be to know the drawing requirements for each designated member country or region. The reason for this is that some of the drawing requirements will vary among countries, including the number of views needed or allowed, whether shading or broken lines may be included in the figures and if colors or photographs can be used. Finally, the specification requirements for design patent applications may vary from country to country. For example, some require more robust descriptions in design patent applications than others.

Once implementation of the Hague Agreement in the U.S. is complete, applicants wishing to file international design patent applications should ensure that the patent attorney filing their applications is well-versed in the design patent laws of each country where the applicant is seeking protection in order to ensure mistakes are avoided.

Used properly, the Hague Agreement can potentially deliver significant savings and increase filing efficiencies for the applicant. However, these next few years may bring uncertainty as the new law is implemented and administered by USPTO. Applicants will need to be cautious as they start utilizing the Hague Agreement to procure U.S. and international design patent protection.

The contents of this article are for informational purposes only and should not be interpreted or construed as legal advice. Please consult with a licensed patent attorney if you have any questions.

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Surgeons Describe Anterolateral Ligament in the Human Knee

Knee surgeons in Belgium have provided the first full anatomical description of a human knee ligament that may play a role in anterior cruciate ligament tears. Research indicates that the anterolateral ligament (ALL) is present in 97% of all human knees, and that pivot shift is caused by an injury in that ligament.

The research could bring on changes to methods of treatment for serious ACL injuries. The surgeons, Dr. Steven Claes and Professor Dr. Johan Bellemans of University Hospitals Leuven, are studying a technique to correct ALL injuries.

Dr. Al Getgood, an associate professor at Western University Schulich School of Medicine & Dentistry and an orthopaedic surgeon at the Fowler Kennedy Sport Medicine Clinic in Canada, notes that the anterolateral ligament "is not a new ligament as many media reports have suggested," but that "only recently has its function and its role in ACL injury and reconstruction been better understood."

Dr. Getgood and his colleagues at Western's Interdisciplinary Development Initiative in Bone & Joint Health are collaborating with Drs. Claes and Bellemans to further understand the ligament's function. In 2014, Dr. Getgood will lead a multi-center randomized study in Canada and Europe, supported with grants from the International Society of Arthroscopy, Knee Surgery and Orthopaedic Sports Medicine and the Orthopaedic Research and Education Foundation, to investigate whether the addition of ALL reconstruction to standard ACL reconstruction will help to reduce graft failure after ACL surgery.

REFERENCES

Surgeons describe new ligament in the human knee, KU Leuven, November 2013.

Orthopaedic surgeon says anterolateral ligament not "new" but promising for ACL injuries, Western University, November 3, 2013.