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Three Ways to Challenge Patent Validity Under the America Invents Act

By Joseph D. Rossi

The U.S. patent system, as modified by the Leahy-Smith America Invents Act of 2011, allows for multiple options in challenging the validity of competitors' patents after they have been granted – all while avoiding the significant costs of litigation. Three options, each of which presents strategic advantages, are post-grant review (PGR), inter partes review (IPR) and ex parte re-examination (EPR). Of these three options, PGR and IPR were created by the America Invents Act (AIA) and take place before the newly commissioned Patent Trial and Appeal Board (PTAB) at the U.S. Patent and Trademark Office. Ex parte re-examination has existed since 1981, and takes place before a patent examiner.

A. The Options

1. Post-Grant Review

Section 6 of the AIA establishes the post-grant review procedure in which a party may seek cancellation of patents on any validity ground that could be raised under paragraph (2) or (3) of Section 282(b) of the Patent Act, 35 U.S.C. § 282(b). In layman's terms, this means that a patent can be challenged on any grounds of

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Should You Join the 'HAVANA CLUB'? Trademarks in Cuba

By Kevin Casey

Following President Barack Obama's recent announcement that the U.S. is normalizing relations with Cuba, we encourage clients to consider registering at least their most important trademarks in Cuba. Although patents and trademarks can be protected in Cuba on behalf of U.S. individuals and corporations, the question has long been "Why do so?" given that U.S. individuals and corporations have not been conducting business in Cuba. One reason is to avoid "brand theft," the unfortunate experience of having a Cuban individual or company register marks of a U.S. trademark owner in bad faith, anticipating a change in the political climate that would allow U.S. entry into Cuba. When the U.S. trademark owner does decide to do business in Cuba, and to use and register its trademarks there, such use and registration may be precluded by the Cuban individual's or company's prior registration. U.S. trademark owners confronted a similar experience when South Africa lifted its practice of apartheid, allowing for U.S.

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invalidity that otherwise could be asserted as a defense in a patent litigation (except failure to disclose best mode). Thus, a PGR does not have to be based on prior art but could be based on, for example, issues regarding a patent's insufficient disclosure or claims directed to nonpatentable subject matter.

The time period for filing a PGR is within nine months after the patent is issued. The procedure applies only to patents issuing from applications having an effective filing date after March 16, 2013 (i.e., those subject to the AIA's first-to-file provisions). The PTAB may grant post-grant review of a patent where it is more likely that at least one claim is unpatentable, or the petition raises a novel or unsettled legal question that is important to other patents or patent applications.

2. Inter Partes Review

Section 6 of the AIA also established the inter partes review procedure in which any person other than the patent owner may petition the PTAB requesting to cancel at least one claim as unpatentable under Section 102 or 103 of the Patent Act based on patent(s) or printed publication(s). A petition for inter partes review is available for any enforceable patent at any time during the life of the patent; however, for patents issued from applications filed post-AIA (i.e., first-to-file), a petition may not be filed until the later of nine months after grant or after a post-grant review proceeding has terminated.

The PTAB may grant inter partes review of a patent when there is a reasonable likelihood that the petitioner would prevail as to at least one challenged claim. Inter partes review may not be instituted if the petitioner has filed a civil action challenging the patent's validity, or if the petition is filed more than one year after the petitioner is served with a complaint alleging infringement.

If it can be filed within a year from service of the complaint, the IPR procedure is very attractive for a defendant facing patent infringement litigation if the defendant believes that the ultimate outcome depends on the validity of the asserted claims. If an IPR petition is filed by a defendant, however, a stay in the litigation is not automatic and is granted solely at the court's discretion. Both the PTO and court proceedings will continue in parallel absent a stay. Statistics have shown



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that approximately two-thirds of requests for litigation stays have been granted to allow the validity issues to be decided by the PTO in an IPR procedure.

3. Ex Parte Re-examination

Either the patent holder or another party can request an ex parte re-examination. Regardless, the review process itself involves only the PTO and the patentee. In an ex parte re-examination – as in an IPR – the review of a patent is based solely on prior art patents and printed publications.

The standard for instituting ex parte re-examination is a substantial new question of patentability, which is whether there is a substantial likelihood that a reasonable examiner would consider the prior art patent or printed publication important in deciding whether or not the claim is patentable. The ex parte re-examination procedure is available at any time as long as the patent is enforceable.

B. Strategy – Which Procedure Is Best for You?

Stradley Ronon's IP attorneys can advise you on the strategic advantages of selecting one type of proceeding versus another. For example, if the requester wants to remain anonymous, only the ex parte re-examination procedure should be considered. In the IPR and PGR procedures, the real parties in interest must be disclosed not only so the judges of the PTAB can determine whether they have a conflict of interest but also because the AIA created estoppel provisions for these proceedings. Under the estoppel provisions of the AIA, a petitioner in an inter partes review or a post-grant review may not request or maintain a subsequent proceeding before the PTO with respect to any challenged patent claim on any ground that was raised or reasonably could have been raised in the inter partes or post-grant review. Similarly, a petitioner in an inter partes review or a post-grant review may not assert in a subsequent district court action that a claim is invalid on any ground that the petitioner raised or reasonably could have raised in the inter partes or post-grant review. There is no legal estoppel in an ex parte re-

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examination procedure. Thus, a prospective challenger may have limited options if anonymity is important.

Post-grant review carries with it an important strategic consequence. Because PGR allows as its basis all grounds of invalidity that would otherwise be available in litigation, an estoppel could preclude an accused infringer from raising any invalidity defense during litigation. Thus, a third-party is “all in” for a PGR, and it may be difficult thereafter to raise invalidity defenses in a later dispute involving the patent in a district court.

Timing is an important strategic consideration. An *ex parte* re-examination may take up to three years to be resolved. In contrast, the AIA dictates that the PGR and IPR procedures must be completed in one year but allows for a six-month extension upon request of the parties. If your business needs a quick resolution to a potential patent infringement issue, then the PGR or IPR procedures will have an advantage over *ex parte* re-examination.

Although all three options are ultimately less expensive than litigation, cost is another strategic consideration. Both IPR and PGR tend to cost more because each procedure allows for limited discovery, settlement, oral hearings, protective orders and other litigation-style mechanics. In contrast, in *ex parte* re-examination, the requester is not involved in the proceeding after the

petition is granted. If, on the other hand, the requester wants to be more involved in the proceeding and the challenge will be based on printed publication prior art, then IPR would be the better option.

C. Strategy Regarding the Initiating Petitions

Once the best post-grant attack option is identified, a new strategy applies in optimizing the requester’s chances of success in getting the petition granted to institute the procedure. Each of post-grant review, *inter partes* review and *ex parte* re-examination is initiated by filing a petition and paying the required fee. Although about 87 percent of petitions for IPR, for example, have been granted, it is important to understand the strategy involved in preparing a successful petition. For example, the statistics have shown that about 75 percent of petitions (for any of these procedures) are supported by an expert witness declaration, and that by including an expert witness declaration with the petition, the odds of having a successful petition are increased by about 10 percent. Moreover, the statistics have shown that including a claim construction in the petition also increases the odds of success by about 15 percent. Statistics have also shown that petitions with a more focused attack, i.e., a smaller number of claims and fewer prior art references and invalidity theories, are more likely to be successfully received by the PTAB. Given these recent changes in the law, patent holders and challengers should employ counsel with both exceptional patent prosecution and patent litigation skills for post-grant proceedings. ■

Trademarks in Cuba

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expansion into that country in the 1990s. U.S. trademark owners still confront this experience in certain Asian countries today.

The current policy change is likely to generate a new wave of applications to register trademarks in Cuba. Before a U.S. trademark owner joins the charge, however, at least two cautions should be noted. First, changes in the political status quo are likely to be slow — the opportunity to do business in Cuba may not open for some time. Second, like the United States, Cuba has a legislative requirement that trademarks must be used in commerce to avoid claims of abandonment. Specifically, although use is not required to obtain a trademark registration in Cuba, a third party can petition to cancel a registered trademark if the mark is not used for three



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consecutive years after registration. Therefore, the inability of U.S. trademark owners to use their trademarks to promote goods or services in Cuba renders them vulnerable to attack. This caution is tempered somewhat: Our colleagues knowledgeable about Cuban trademark law advise that in more than 30 years of filing applications in Cuba on behalf of U.S. and European companies, they have never seen a cancellation action filed by a third party on the basis of nonuse. ■

IP Client Spotlight

Stradley Ronon is proud to handle all matters involving patent, trademark, copyright, trade secrets and related areas of IP law for Pentec Health Inc. Headquartered in Boothwyn, Pennsylvania, and founded in 1983, Pentec Health is an industry leader in providing specialty infusion services nationwide to patients who require access to complex pharmaceutical products and services outside of the hospital setting. Pentec Health is focused on providing renal nutritional products and services to dialysis centers for their malnourished dialysis patients, and offering specialty in-home infusion services for highly complex conditions that are underserved by traditional home care providers.

One aspect of Stradley's representation has been to secure worldwide patent protection for Pentec Health's PROPLETE® product, an effective treatment for hemodialysis patients. Recently, Stradley partner Brian



Cocca, along with the inventor of the PROPLETE® product, Eileen Moore, and Clinical Researcher Jerry Van Bolt, traveled to the U.S. Patent and Trademark Office in Alexandria, Virginia, to discuss rejections levied against the U.S. patent application protecting Pentec Health's PROPLETE® product. Based on this meeting and follow-up discussions with the patent examiner who was scrutinizing the application, Brian and the team were able to secure an important patent. PROPLETE® Intradialytic Parenteral Nutrition solutions are uniquely formulated to meet the needs of the protein-malnourished hemodialysis patients who may consume adequate calories but inadequate protein. ■

SPEAKING OF . . .



Congratulations to Brian Cocca, Ph.D., who was recently elected to Stradley Ronon's partnership. Brian focuses his practice on drafting and prosecuting patent applications in the biotechnology and pharmaceutical fields. His experience includes counseling biotechnology and pharmaceutical clients in all aspects of product development, patent procurement and portfolio development strategies, risk management strategies, and patent invalidity and non-infringement assessments, as well as research agreements and licensing strategies. ■

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