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Using Post-Grant Proceedings To Challenge Pharma Patents

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Thanks to the Leahy-Smith America Invents Act, there are now a variety of ways to challenge the validity of a U.S. patent, such as inter partes reviews, covered business method proceedings, postgrant reviews, derivation proceedings and ex parte re-exams. It is still early in the game for many of these proceedings, and it can be difficult for a company to establish a strategy for challenging a patent, particularly in the biological/pharmaceutical space, since far fewer PTAB postgrant proceedings to date have involved biological/pharmaceutical patents than electrical/computer patents. Still, some conventional wisdom is beginning to emerge about this array of options, including whether and how these proceedings can provide effective means for challenging patents in the biological/pharmaceutical space.

Companies often wonder if and when they need to be concerned about a particular patent they may be infringing on and what their options are for dealing with the patent. It is still difficult and expensive to invalidate a patent via a U.S. Patent and Trademark Officepostgrant proceeding, although this is far less expensive than being involved in litigation — often by a factor of 10 or more. The decision to challenge a patent is not frivolous, and a party that is seriously considering challenging a patent has typically either been engaged in a licensing discussion with the patent owner or is otherwise concerned it is about to be sued for patent infringement, or has already been sued. The prospect of being held liable for up to triple damages for willful infringement of a patent may motivate a company to seek invalidation of the patent via postgrant challenge even before being sued by the patent owner.

Depending on the jurisdiction and a variety of other factors, stays of litigation may be granted in court cases where an IPR, CBM or even an ex parte re-exam is in progress. Thus, a defendant may be able to buy time and reduce litigation expense by filing a request for postgrant proceeding with the USPTO. Ex parte re-exams are typically the least expensive option, and they do not share the onerous estoppel provisions of IPRs. However, after an ex parte re-exam is filed by a third party, the third party plays no further role in the proceeding with the USPTO. Thus, there is ample opportunity for the patent owner to counter the arguments of the third party, and even make new claim amendments to address those arguments, without further opportunity for rebuttal by the third party. The third-party requestor may wind up inadvertently sanitizing the patent claims over the prior art he cites, making the patent even stronger than before.

Life Science IPRs May Gain Momentum From Gnosis Decision

IPRs are generally more effective than ex parte re-exams at invalidating patents, but they need to be comprehensive, since all possible arguments of invalidity that are based on prior art patents or other printed publications must be raised during the IPR proceeding — they cannot be presented later during a court proceeding. For example, a challenger cannot file an IPR while reserving a novelty destroying prior art publication to present later in court. Similarly, it is a poor strategy for a defendant to skimp on a prior art search when preparing an IPR. A defendant that has filed an IPR is estopped from later raising additional publication-based invalidity defenses in court. However, because IPRs are limited to prior art publication-based arguments, there may be other invalidity arguments available which are not subject to the estoppel provisions of IPRs and which can, in fact, be raised in court.

Furthermore, many more IPRs to date have involved patents in the electrical/computer space than the biological/pharmaceutical space — 71.8 percent vs. 5.3 percent of all IPR petitions fall into these two categories, respectively, as of Aug. 14, 2014. However, pharmaceutical companies are more seriously considering IPRs following the recent June 20, 2014, Gnosis decisions, in which the PTAB invalidated on obviousness grounds many claims of four patents directed to compositions and methods of using certain folate compounds as food supplements.

Comparing Other Options

PGRs and DERs, while they will surely play a greater role in the future, still have a much lower profile than IPRs and CBMs because PGRs and DERs are only available to challenge patents with effective filing dates on or after March 16, 2013.

Between IPRs and CBMs, IPRs currently have a higher profile than CBMs because CBMs are limited to challenges of patents directed to covered business methods, as that term is defined by the AIA. Furthermore, petitions for CBM review can only be filed after a party is sued or charged with infringement, whereas a petition for IPR can be filed in the absence of litigation. However, where a party has been sued, a CBM should be considered over an IPR if the CBM subject-matter requirement is met, because CBMs offer certain advantages over IPRs. For example, CBMs have less onerous estoppel provisions than IPRs, and, unlike an IPR, a CBM may be filed against a patent more than one year after service of the complaint alleging infringement of the patent. Furthermore, the USPTO has been rather liberal in its determinations that the CBM subject-matter requirement is met. Moreover, validity challenges may be made in CBMs on additional grounds that are not available to IPRs, such as subject-matter grounds (35 U.S.C. § 101) and indefiniteness grounds (35 U.S.C. § 112). However, it should be noted that the March 7, 2014, PTAB decision in the Blackberry Corporation v. Mobilemedia Ideas LLC, case shows that in an IPR, the board may take it upon itself to find that the claims at issue are indefinite, even though the challenger is technically limited to making only prior art publication-based novelty and obviousness arguments. This opens up the prospect of various “backdoor” arguments available to IPR patent challengers.

In the biological/pharmaceutical space, CBMs would initially appear to be almost entirely irrelevant; however, a group of generic drug manufacturers — Amneal Pharmaceuticals LLC, Par Pharmaceutical Inc. and Roxane Laboratories Inc. — recently filed a petition for CBM patent review of U.S. Patent No. 7,895,059. The July 15, 2014, petition argues the ‘059 patent qualifies for CBM review because it includes at least one claim directed to a “financial product or service” that is not a “technological invention.” The petitioners argue that, in this case, the “financial product or service” is a centralized distribution program to reduce abusive and illicit uses of a particular drug (i.e., the patent is an Orange

Book-listed patent covering Risk Evaluation and Mitigation Strategies). Drug manufacturers will be closely watching what the PTAB does with this case.

Emerging Wisdom for Life Sciences

In 2013, there were 514 petitions filed for IPRs, 48 for CBMs, one for DERs and zero PGRs. These figures have increased in 2014 to 1083 petitions filed for IPRs, 148 for CBMs, five for DERs and one PGR in the period from Jan. 1, 2014, to Aug. 14, 2014. The vast majority — 71.8 percent — of these petitions were in the electrical/computer space, with 15.4 percent mechanical, 7.1 percent chemical, 5.3 percent biological/pharmaceutical and 0.4 percent design. Thus, the type of postgrant proceeding about which there is the most emerging collective experience is the IPR, particularly those filed against patents in the electrical/computer space.

In summary, a postgrant proceeding should be considered by a patent challenger if he thinks he is about to be sued for patent infringement.

- A postgrant proceeding offers the possibility of a stay of litigation and a reasonable, less expensive forum for invalidation of the patent than federal court.

- The most effective, best-tested option for challenging patentability is probably the IPR, particularly for patents in the electrical/computer space, though momentum is gaining for IPRs of biological/pharmaceutical patents.

- If a party has already been sued for patent infringement, he should consider filing a CBM rather than an IPR if there is an argument that the CBM subject-matter requirement is met.

- An ex parte re-exam may be an effective way to challenge a patent, however there is greater risk that patentability of the claims will be upheld in an ex parte re-exam, or that the patent owner will find a way to amend the claims to patentably distinguish them from the challenger's cited art while keeping the challenger's product or system within the scope of the claims.

- PGRs and DERs will become more prevalent as more patents issue from applications filed on or after March 16, 2013.

- While most postgrant proceedings to date involve patents in the computer/electrical field, there will likely be an increasing number of postgrant challenges to biological/pharmaceutical patents in light of the recent high-profile Gnosis IPR decisions and the Amneal CBM filing.

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