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AIA & Paragraph IV Litigation: What's Next?

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On Sept. 16, 2011, President Obama signed into law the Leahy-Smith America Invents Act ("AIA"), which introduced numerous changes to the United States patent laws. Since its introduction, there has been considerable debate within the pharmaceutical industry as to how the AIA will affect the management of patent portfolios that protect innovator drugs and litigations related to those patents.

Two new proceedings introduced by the AIA are *inter partes* review ("IPR") and post grant review ("PGR"), which are scheduled to go into effect in 2012 and 2013, respectively. These proceedings offer generic drug companies an alternative forum to challenge patent validity, through short, trial-like proceedings at the United States Patent and Trademark Office ("PTO"). Exploring whether and to what extent generic drug companies may use these proceedings can provide insight into what innovator drug companies should consider doing in response to protect the patent portfolios covering their drugs.

Paragraph IV litigation finds its origins in the Drug Price Competition and Patent Term Restoration Act ("Hatch-Waxman Act"). The Hatch-Waxman Act allows the first generic company to file an Abbreviated New Drug Application ("ANDA") containing a "paragraph IV" certification asserting that the innovator company's patent is invalid, unenforceable or not infringed, with eligibility for 180 days of marketing exclusivity. This exclusivity translates into significant profits for first-filer generic drug companies and is a major driver of Hatch-Waxman litigation. Arguably, whether IPR or PGR will be employed by generic companies will depend in large measure on whether they affect a generic company's eligibility for the 180-day exclusivity.

Understanding the details and differences of IPR and PGR proceedings help to understand which proceeding might be used. IPR is available beginning nine months after a patent is issued or after termination of PGR. A petition by a generic company for IPR requires that the PTO make a threshold determination that the petition presents a "reasonable likelihood" that the petitioner will prevail with respect to at least one of the patent claims challenged in the petition. This threshold is higher than the standard for *inter partes* reexamination (a proceeding that *inter partes* review will replace) and should result less than 95% of petitions being granted.

Unlike IPR, PGR is only available for a short time period as the petition must be filed within nine months of the patent's grant date or issuance of a reissue patent. PGR proceedings are initiated where the petitioner establishes that it is "more likely than not" at least one of the claims challenged is unpatentable.

Both proceedings contain estoppel provisions, which limit the ability of the petitioner to make arguments and present evidence in federal court that were (or reasonably could have been) raised during IPR or PGR proceedings. PTO fees for those proceedings start at $35,800 for PGR and $27,200 for IPR, for a patent with up to 20 claims.

To illustrate how PGR and IPR may affect paragraph IV litigation, three hypothetical scenarios are presented below. These scenarios assume that both PGR and IPR are in effect.

Scenario #1

The Food and Drug Administration ("FDA") approves a New Drug Application ("NDA") for an innovator drug which is awarded New Chemical Entity ("NCE") status, meaning that the innovator drug enjoys five years of marketing exclusivity, and that the first date on which a generic company could file an ANDA with a paragraph IV certification is four years from approval of the innovator drug. The innovator drug is covered by patent no. 1 that was granted yesterday.

Today, a generic company could file a petition for PGR, or, in nine months, a petition for IPR. Because PGR and IPR are accelerated proceedings, it is possible that by year four, patent no. 1 has been invalidated, leaving the generic with no opportunity to file a paragraph IV certification and no opportunity to obtain 180-day exclusivity. Thus, if maximizing profit is the goal of the generic, it may not make sense for it to initiate PGR or IPR early into a NCE period of exclusivity.

Initiating IPR in year four may not make sense to the generic either. In year four of NCE, a generic company can file an ANDA having a paragraph IV certification, and could also initiate IPR. Assuming that the innovator company initiated a paragraph IV litigation, a civil action and IPR could proceed simultaneously. However, the generic company would then run the risk that the federal court could stay the civil action pending outcome of the IPR to avoid contradictory results, potentially jeopardizing access to early summary judgment and an ultimate determination of non-infringement or patent invalidity.

Furthermore, current experience with *inter partes* reexamination teaches us that there is a 45% chance that the claims will be modified during the proceeding. Similar results may be expected for IPR. These claim modifications may or may not be beneficial to the generic company in terms of a new non-infringement argument. Nevertheless, in this hypothetical scenario, at the end of this year-long (with an additional six months for good cause) process (excluding appeal to the Federal Circuit), the generic company may still have to wrestle with issues of estoppel as well as infringement and validity issues in federal court. Thus, by initiating an IPR, the generic company may

have lengthened its time to market and spent more money than it would have spent simply going forward with the paragraph IV litigation in federal court.

Scenario #2

Assume the same facts as above, but in year two of NCE exclusivity, the innovator drug company obtains a second patent, patent no. 2, protecting its drug. Here, it may be more likely that one of the two patents becomes subject to an early PGR or IPR petition, simply because the generic company no longer jeopardizes its opportunity to file a paragraph IV certification, *i.e.*, in year four of NCE there will still be an extant patent against which to certify. Interestingly, however, it is possible that the closer to year four that a patent is granted covering a drug product, the less likely a generic company is to file a PGR or IPR petition due to the uncertainties discussed above, namely estoppel issues, the potential of a stay and the likelihood that the claims are either confirmed or changed, necessitating further litigation in federal court.

Scenario #3:

Assume the same facts as either Scenarios 1 or 2, but now there are two generic companies, the first filer and the second filer, who are interested in filing ANDAs on the same drug product. In this scenario, it is given that the first filer will be eligible for the 180-day exclusivity and that the second filer will not.

Second filers that join a litigation involving a first filer usually seek to minimize legal expenditures by relying on the litigation work done by the first filer. If the first filer fails in some way, for example by failing to obtain tentative FDA approval within 30 months, the first filer will lose its eligibility for 180-day exclusivity and the second filer has a path forward to market its generic drug either before or at the same time as the first filer. In this scenario, it would make little sense for the second filer to seek PGR or IPR on either patent because such proceedings would require the second filer to spend more than simply relying on the first filer to litigate the patents. Also, invalidating the patent via PGR or IPR does nothing for the second filer if the first filer has already secured its 180-day exclusivity.

The above scenarios suggest that PGR and IPR petitions may be more likely when there are multiple patents protecting an innovator drug that has been awarded NCE status. What this in turn suggests for innovators is that it may no be longer safe to wait to defend against patent challenges in year four of NCE exclusivity.

The accelerated schedule for PGR and IPR proceedings may leave participants with little time to fully assess their strategic positions. Therefore, innovator companies may wish to be prepared, as they obtain patent protection for their drugs to counter early validity challenges, both at the PTO and in court. To do so, innovator companies should consider obtaining the advice of outside counsel with expertise in both patent prosecution and patent litigation earlier than before. Such early preparation is a small price to pay for protecting a patent estate that protects an innovator drug company's products.