An Unintended Consequence Of The Liberal IPR Standing Requirement: Is A Legislative Fix Needed?

On February 10, 2015, the Coalition for Affordable Drugs (ADROCA) filed an IPR petition against US Patent No. 8,663,685 owned by Acorda Therapeutics, Inc. Seventeen days later, on February 27, 2015, ADROCA filed another IPR petition against US Patent No. 8,007,826 also owned by Acorda. Both patents cover aspects of the drug Ampyra®, sold by Acorda to treat multiple sclerosis (MS). However, these petitions are not the consequence of routine cases in which the petitioner is either involved in infringement litigation with the patent owner or is concerned that future activities might infringe the relevant patent. Rather, the petitions were filed by an entity whose name is meant to suggest some altruistic motive, but whose initials (Acorda spelled backwards is ADROCA), suggest a greater concern with making a quick buck for the company’s investors.

Behind petitioner ADROCA is the hedge fund Hayman Credes and hedge fund manager and principal, Kyle Bass. Thus, ADROCA’s petitions shine a spotlight on the impact of the liberal standing requirements for seeking inter partes review and raise the question of whether such an open-door policy is consistent with the legislative goals of post grant trial proceedings at the PTAB.

ADROCA is certainly not the first entity without an infringement risk to file an IPR. These petitions are concerning, however, because they likely have less to do with improving the quality of patents and limiting unnecessary litigation costs and everything to do with making money for a hedge fund investor. In addition, because the filing of these petitions appears to validate that money making-strategy, there are likely more to come. Specifically, Kyle Bass has stated that he is far from finished attacking pharmaceutical patents.
In January, Bass announced he would launch a campaign to lower drug prices by challenging drug patents using IPR proceedings. ADROCA’s petitions in this case, however, will not likely result in the market entry of one or more Ampyra® generics any earlier than would have happened had such petitions not been filed. As noted above, Kyle Bass and his hedge fund have filed separate IPR petitions against two patents owned by Acorda. The patents cover methods of treating MS using sustained release aminopyridine compositions and particular dosing regimens to achieve particular pharmacokinetic parameters. But the IPR petitions are directed to just two of five patents listed in the Orange Book for Ampyra®. Abbreviated New Drug Applications (ANDAs) have been filed by at least 8 generic companies, and Hatch-Waxman suits filed by Acorda against each generic company are pending in Delaware.

Thus, while it is possible that the PTAB could invalidate all claims in both of the patents attacked by Bass prior to a district court decision on the same patents, no generic company will receive final approval unless the asserted claims from all five patents are held to be invalid or not-infringed. In addition, Ampyra® is protected by orphan drug exclusivity until January 22, 2017. Thus, Bass and his hedge fund would need to do quite a bit more work to pave the way for generic entry any earlier than the generics themselves may be able to secure through the pending litigation in Delaware – if that is indeed their goal. Perhaps, however, there are more petitions directed at Ampyra® to come.

Though appearing at first to be foolproof, any strategy by a third party advocacy group that is focused on lowering the price of drugs by attempting to accelerate generic entry may suffer from a serious downstream flaw. A third-party petitioner, such as ADROCA, may be unable to appeal a decision by the PTAB to uphold the relevant patent(s). Although the AIA puts no express limits on who may file an IPR petition, a recent high-profile case in the biotechnology area may have a chilling effect on the use of IPRs by 3rd parties without a direct infringement risk.

Consumer Watchdog requested inter partes reexamination of a US Patent directed to human embryonic stem cells owned by the Wisconsin Alumni Research Foundation (WARF) in 2006 (Control No. 95/000, 154). Consumer Watchdog describes itself as a "nonprofit organization dedicated to providing an effective voice for taxpayers and consumers . . . ." The group claimed that the WARF patent is impeding life-saving stem cell research. Specifically, Consumer Watchdog stated that "WARF’s ‘913 patent has put a severe burden on taxpayer-funded research in the state of California and is

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2 A single suit against Mylan was filed in the Northern District of West Virginia as a backup due to a potential jurisdictional issue in Delaware.
3 Expiration dates of the patents range from July 30, 2018 to May 26, 2027. Two of the patents listed but not challenged by Bass expire in 2025 and 2026.
4 http://www.consumerwatchdog.org/about
The Board eventually upheld the validity of the patent and Consumer Watchdog appealed.

On June 4, 2014, the Federal Circuit dismissed the appeal because Consumer Watchdog could not establish an injury in fact sufficient to confer Article III standing. Consumer Watchdog v. Wisconsin Alumni Research Foundation, 753 F.3d 1258 (Fed. Cir. 2014). The court noted that “although Article III standing is not necessarily a requirement to appear before an administrative agency, once a party seeks review in a federal court, the constitutional requirement that it have standing kicks in.” Id. at 1261. The court suggested that certain requirements of standing could be relaxed where “Congress has accorded a procedural right to a litigant, such as the right to appeal an administrative decision,” however, the injury in fact requirement is “a hard floor of Article III jurisdiction that cannot be removed by statute.” Id. In dismissing the appeal, the court reasoned that Consumer Watchdog had alleged only a general grievance concerning the WARF patent – not an injury in fact to an economic or other interest. The court recognized the group’s concern with the burden being placed on taxpayer-funded research but stated that such concern was “not enough to make the dispute justiciable.” Id. at 1263.

While the AIA does not limit who can file a petition seeking post grant review of a patent, a more rigorous conventional standing requirement will likely be applied on appeal. Thus, it is possible that patient advocacy groups and groups concerned about the impact of patents on drug prices and research may be less likely to file petitions knowing that an appeal may not be possible. This chilling effect, however, will not likely extend to IPRs such as the petitions filed by ADROCA because it appears that the primary reason for filing these petitions is to make a profit by betting on a falling stock price. 6

As events actually unfolded, Acorda’s stock dropped about 10% following the press-release informing investors of the first IPR filing. Acorda lost about $200 million in market capitalization during the course of the afternoon after the first IPR was filed – the result of six times the normal one-day trading volume. Following the filing of the second petition 17 days later, the stock took another dive and lost approximately another 5% of its value. As noted above, practically speaking, these petitions by themselves are unlikely to accelerate generic entry beyond what might occur as a result of the pending Hatch-Waxman cases in Delaware; however, because Ampyra® makes up about 91% of Acorda’s revenue, investors are apparently spooked easily.

The Hatch-Waxman cases were filed in July of last year; thus, investors have been well aware for some time of the potential exposure to generic competition. In fact, the

6 To short sell a stock, a broker lends you the stock. The shares are sold and the proceeds are credited to your account. At some point, you must close the short by buying back the same number of shares and returning them to your broker. If the price drops, you can buy back the stock at the lower price and make a profit on the difference.
active ingredient in Ampyra®, 4-aminopyridine, has been known for nearly 100 years, its pharmacological properties have been studied since 1924, and more than 30 years ago the compound was shown to have efficacy in MS patients (ACORDA petitions at 15). Given the dismal statistics associated with upholding secondary patents in Hatch-Waxman litigation, investors should be aware of the risks associated with relying on patents such as those listed for Ampyra® for exclusivity. If investors were in fact attuned to these statistics, however, such risks should have already been factored into the stock price such that the mere filing of these IPR petitions should not have moved the stock so dramatically.

As is the case with many pharmaceutical products, the patent portfolio and the different types of regulatory exclusivity protecting Ampyra® paint a complicated picture. General investors do not likely understand or pay attention to these complexities and to the potential fragility of the various types of exclusivity. Thus, the IPR petitions were likely to – and did – send up a red flag to the investment community and highlight a potential weakness in the portfolio, and so the market reacted.

Unfortunately, now that the Bass hedge fund strategy has been validated by an over-reactive investment community, it is likely Bass will target patents owned by other companies. In fact, Bass has indicated that these petitions are the first two in a planned series of similar filings. Specifically, he has stated that he may challenge patents covering Biogen Idec’s Teclidera® (responsible for 30% of the company’s revenue) as well as Celgene’s Revlimid® (responsible for 38% of that company’s revenue).7

In the context of pharmaceutical patents, many observers had accurately predicted that generic drug companies would use the IPR route as an alternative to or in addition to Hatch-Waxman litigation with innovator companies. Somewhat surprising, however, has been the use of the IPR avenue by third parties who – at least publicly – have an altruistic motive and are not directly impacted by the patent at issue. Probably even more surprising (although a recent BIO meeting discussion suggests perhaps this is not so surprising) is an IPR filing strategy that is motivated by attempts to negatively impact the stock price of a pharmaceutical company. One of the stated purposes of the AIA IPR procedure is to help establish a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counter-productive litigation costs. Indeed, IPRs have long been touted as the product of an effort to create a timely, cost-effective alternative to litigation. See In re Cuozzo Speed Technologies, LLC, No. 2014-1301, 2015 WL 448667, at *12 (Fed. Cir. Feb. 4, 2015). Instituting trials on IPR petitions filed either as part of a strategy to move a stock price or even as a demonstration of concerns about drug prices does not seem consistent with these stated goals. Regardless, the Bass petitions beg the question of whether a legislative fix should be considered which, at the very least might involve changes to level a playing field that many believe significantly favors the petitioner – or whether the PTAB should

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simply exercise its considerable discretion under 35 U.S.C. § 325(d) to deny institution of trials on such petitions.

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