

Consumer Watchdog Puts a Leash on Appealing USPTO Decisions to Federal Court

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Despite being dismissed by the Federal Circuit before reaching its highly anticipated substantive issues regarding patent eligibility, the ruling in *Consumer Watchdog v. Wisconsin Alumni Research Foundation* nonetheless significantly alters the patent litigation landscape. Consumer Watchdog (CW), a nonprofit waging a seven-year campaign to invalidate the Wisconsin Alumni Research Foundation (WARF) stem cell patent, saw its battle come to an abrupt end when the Federal Circuit held that it did not have an injury in fact sufficient to confer Article III standing to appeal a United States Patent and Trademark Office (USPTO) decision in federal court. The ruling limits the reach of the statute permitting appeals of USPTO rulings to the constitutional boundaries set by Article III, leaving some third-party challengers stuck with the USPTO as their only available forum.

The case arose from an *inter partes* reexamination of U.S. Patent No. 7,029,913 (the '913 patent) initiated by CW in 2006 on novelty and obviousness grounds. The invention is directed to in vitro culturing of human embryonic stem cells (hESCs). The USPTO initially allowed the claims, then reversed upon appeal, but eventually held that amendments made by WARF rendered the claims of the '913 patent valid. Following the USPTO decision, CW appealed to the Federal Circuit on an additional ground for invalidity based on the recent *Myriad* decision by the Supreme Court (arguing that, just like isolated genomic sequences, isolated hESCs should not be patent-eligible).

Article III Standing

Before reaching any substantive issue, the Court *sua sponte* asked the parties to address if CW had standing to appeal the USPTO decision in federal court. While 35 U.S.C. § 141 provides the procedural right to appeal an adverse ruling by the USPTO Patent Trial and Appeal Board (PTAB), any party bringing a dispute to federal court still needs to satisfy the three Article III standing requirements: 1) the party must have personally suffered an "injury in fact" that is concrete, particular, and actual or imminent; 2) this injury must be a consequence of the alleged grievance; and 3) a favorable decision by the court must be capable of remedying the injury. The Court noted that the latter two conditions can be relaxed in this context, but the injury requirement "is a hard floor of Article III jurisdiction that cannot be removed by statute."

Some Third-party Challengers May Not Appeal PTO Decisions in Federal Court

The Federal Circuit sided with WARF, finding that CW had not suffered an injury in fact from the USPTO's adverse decision and did not have a personal stake in the issue. CW's alleged injury (namely, the USPTO's decision in favor of WARF) was deemed insubstantial: while a party is provided the right to initiate a proceeding at the USPTO, the law does not "guarantee a particular outcome favorable to the requester." Thus, CW was not denied anything it had a right to. Further, CW did not claim a present or future commercial or research interest in hESCs, nor did it assert that it was or could be a licensee or competitor of WARF's intellectual property. Rather, CW charged that WARF's "broad and aggressive assertion of the '913 patent has put a severe burden on taxpayer-funded research." The Court found this "general grievance" to be an insubstantial injury for Article III standing purposes. Nor did the Court agree with CW's view that the estoppel effects of *inter partes* review constitute injury. The Court judged this grievance speculative and hypothetical, and noted that the facts did not support CW being a party to a

future infringement suit. However, the Court left open the possibility that "the preclusive effect of the estoppel provisions could constitute an injury in fact" and left the question to be answered by "future panels...under other circumstances."

Future Outlook

While those with patents directed towards biological material may be breathing a sigh of relief, others worry that the ruling will reduce the incentive of third parties to institute challenges before the USPTO. However, given that these parties cannot initiate declaratory judgment actions due to their lack of a concrete stake, the USPTO is often their only available venue. And the Court's indication that different circumstances may confer standing based on estoppel provisions provides some level of optimism for third party challengers. An even better strategy going forward may be for parties, such as advocacy groups, that have not suffered sufficient injury in fact to consider joining parties that would have Article III standing should appeal to the Federal Circuit be necessary.

This update was prepared by Nutter's Intellectual Property practice. For more information, please contact your Nutter attorney at 617.439.2000.

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