Axinn IP Update: District of Delaware Magistrate Judge Recommends Dismissal of Claims of Induced Infringement in Skinny Label Case

June 28, 2023

ATTORNEYS

Clegg, Rebecca

Landmon, Chad

Murphy, Matthew

Savit, PhD, Aaron

PRACTICE AREAS

Intellectual Property

Patents

Chad Landmon, Matthew Murphy, Rebecca Clegg, and Aaron Savit

In the first decision to issue following the Supreme Court's denial of certiorari in *Teva Pharms. USA, Inc. v. GlaxoSmithKline, LLC*, 22-37, Magistrate Judge Sherry R. Fallon of the United States District Court for the District of Delaware recommended that a complaint be dismissed, which asserted induced infringement of method claims directed to a use carved out of the ANDA product's label. *Zogenix, Inc. v. Apotex Inc.*, C.A. Nos. 21-1252-RGA, 22-1232-RGA, slip op. (D. Del. June 16, 2023). The decision highlights "[t]he narrow scope of the Federal Circuit's holding in *GlaxoSmithKline*" and signals that infringement claims against some ANDA product labels with a section viii carveout may be resolved via a Rule 12 motion.

In this case, Zogenix, Inc. and Zogenix International Ltd. (collectively, "Zogenix") asserted that an ANDA filed by Apotex Inc. and Apotex Corp. (collectively, "Apotex") would induce infringement of U.S. Patent No. 11,406,606 ("the '606 patent") under 35 U.S.C. § 271(e)(2)(A). The '606 patent, which is listed in the Orange Book for Fintepla® (fenfluramine), is directed to methods of treating patients having Dravet syndrome (a form of epilepsy) by administering reduced dosages of fenfluramine along with stiripentol. Apotex's ANDA contained a section viii statement to the '606 patent and a corresponding "skinny" label that removed references to administering fenfluramine with stiripentol. Apotex moved to dismiss the complaint for lack of subject matter jurisdiction and failure to state a claim under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), respectively.

Magistrate Judge Fallon recommended denying Apotex's Rule 12(b)(1) motion because "Federal Circuit precedent establishes that a Paragraph IV certification specific to the [asserted patent] is not required before the complaint is filed to confer subject matter jurisdiction." *Id.* at 6-7. More significantly, Judge Fallon also recommended that the court grant Apotex's Rule 12(b)(6) motion, finding that "the complaint does not plausibly allege

that Apotex's ANDA label encourages or instructs an infringing use because Apotex's label carves out references to fenfluramine administered concomitantly with stiripentol." *Id.* at 11.

To reach its determination concerning Apotex's Rule 12(b)(6) challenge, the court considered three aspects of the ANDA label identified by Zogenix: (1) the warnings and side effects of fenfluramine, (2) the dosing instructions, and (3) the clinical study data. None of these disclosures "show[ed] that Apotex took affirmative steps to induce infringement." *Id.* at 12. Specifically, the court found that warnings about the side effects of fenfluramine "do[] not amount to an instruction to use a reduced amount of fenfluramine in combination with stiripentol" and, even if physicians reduced the dose, there was nothing in the ANDA that endorsed such an approach. *Id.* Moreover, the dosing instructions in the label were specifically for patients taking fenfluramine "without concomitant stiripentol" and thus "cannot plausibly be construed to encourage a physician to prescribe fenfluramine in conjunction with stiripentol." *Id.* at 13. Finally, although the ANDA label references data from a study involving concomitant use of fenfluramine and stiripentol, it omits the clinical trial identifier and noted that all patients received "between 2 and 4 concomitant [anti-epileptic drugs]." *Id.* at 15. Therefore, while some users might infringe, the ANDA label does "not instruct users on the patented indications" and they "would have to go beyond the ANDA label to arrive at infringing uses." *Id.*

Even in the aftermath of the *GSK* decision, a proper "skinny" ANDA label can avoid a claim of induced infringement under 35 U.S.C. § 271(e)(2). As Judge Fallon noted, however, "ANDA label[s] may induce infringement despite the attempt at a carveout." *Id.* at 16. Disclosing side effects is likely insufficient to induce infringement of a specific method of reducing those side effects. Likewise, disclosing that a drug may be taken without another, and even noting that dosing differences exist between the two regimens may be insufficient. Instead, plaintiffs will need to show that the defendant took affirmative steps to induce infringement in order to survive a motion to dismiss. ANDA applicants considering a section viii carveout should continue to carefully consider the patented indication that they are striving to excise from their ANDA label. But the Magistrate Judge's recommendation in *Zogenix* joins *Amarin* in showing that an early dismissal of infringement claims post-*GSK* when a label properly carves a patented indication is possible.