

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

PAR PHARMACEUTICAL, INC. and
ALKERMES PHARMA IRELAND LTD.

v.

TWI PHARMACEUTICALS, INC.

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Civil No. CCB-11-2466

MEMORANDUM

Now pending is the motion of defendant TWi Pharmaceuticals, Inc. (“TWi”) for an exceptional case determination and attorneys’ fees under 35 U.S.C. § 285.¹ Plaintiffs Par Pharmaceutical, Inc. and Alkermes Pharma Ireland Limited (collectively, “Par”) have filed a response in opposition to the motion. For the reasons that follow, TWi’s motion will be denied.

BACKGROUND

Par acquired U.S. Patent No. 7,101,576 (“the ‘576 patent”) in 2006.² The patent relates to Par’s Megace ES drug, a nanoparticulate formulation of megestrol acetate used to treat anorexia, cachexia, and unexplained weight loss in patients with HIV and AIDS. After Par acquired the ‘576 patent, TWi filed an ANDA seeking FDA authorization to market a generic version of Megace ES. TWi timely notified Par of this filing, and, under 21 U.S.C. § 355(b)(2)(A) (a “Paragraph IV” certification under the Hatch-Waxman Act), asserted that the ‘576 patent “is invalid or will not be infringed by the manufacture, use, or sale of the new drug

¹ The parties also have filed motions to seal (ECF Nos. 326 and 339), which will be granted.

² The court assumes familiarity with the facts of the case, which are discussed at length in previous opinions. *See* ECF No. 140 (summary judgment); 212 (first invalidity determination); 257 (first injunction request); 279 (second injunction request); 304 (second invalidity determination); and 311 (third injunction request).

for which the application is submitted.” Par filed suit in September 2011 to block the sale of TWi’s generic product on the ground that it infringed the ‘576 patent.

After a five-day bench trial, the court ruled on February 21, 2014, that the ‘576 patent was invalid as obvious. (Memorandum & Order, ECF Nos. 212, 213.) Par requested, and this court granted, an injunction pending resolution of the case on appeal, and Par posted a \$10 million bond as security. (Memorandum & Order, ECF Nos. 257, 258.) On appeal, the Federal Circuit vacated the court’s judgment and remanded the case “for further analysis of the food effect limitation consistent with [the Federal Circuit’s] precedent on inherency.” *Par Pharm., Inc. v. TWi Pharms., Inc.*, 773 F.3d 1186, 1200 (Fed. Cir. 2014). On March 9, 2015, the court granted another injunction while it considered the case on remand and ordered Par to post an additional \$6 million bond. (Memorandum & Order, ECF Nos. 279, 280.) On July 28, 2015, the court ruled that the ‘576 patent was invalid as obvious and for lack of enablement. (Memorandum & Order, ECF Nos. 304, 305.) Par noted an appeal that same day and moved for another injunction, which this court denied. (Memorandum & Order, ECF Nos. 311, 312.) The Federal Circuit affirmed the invalidity determination on December 15, 2015. *Par Pharm., Inc. v. TWi Pharms., Inc.*, 624 Fed. App’x 756 (Fed. Cir. 2015) (mem.).

ANALYSIS

Section 285 of the Patent Act authorizes district courts to award attorneys’ fees to prevailing parties in “exceptional cases.” 35 U.S.C. § 285. In 2014, the Supreme Court overturned “unduly rigid” Federal Circuit precedent to hold that an “exceptional” case is “simply one that stands out from others with respect to the substantive strength of a party’s litigating position (considering both the governing law and the facts of the case) or the unreasonable

manner in which the case was litigated.” *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 134 S. Ct. 1749, 1755, 1756 (2014).³ An award of fees may be justified where a case “present[s] either subjective bad faith or exceptionally meritless claims,” or where a party has engaged in misconduct, even if that conduct is not independently sanctionable. *Id.* at 1757. The non-exclusive list of factors a district court may consider includes “frivolousness, motivation, objective unreasonableness (both in the factual and legal components of the case) and the need in particular circumstances to advance considerations of compensation and deterrence” when determining whether to award fees. *Id.* at 1756 n.6 (quoting *Fogerty v. Fantasy, Inc.*, 510 U.S. 517, 534 n.19 (1994) (internal quotation marks omitted)). District courts “may determine whether a case is ‘exceptional’ in the case-by-case exercise of their discretion, considering the totality of the circumstances,” *id.* at 1756, and a movant must establish an exceptional case by a preponderance of the evidence, *id.* at 1758. “There is no precise rule or formula for making these determinations, but instead equitable discretion should be exercised.” *Id.* (quoting *Fogerty*, 510 U.S. at 534).

Viewing the evidence in light of the totality of the circumstances, TWi has not established that this case is exceptional under the standard articulated in *Octane Fitness*.⁴ TWi first argues that Par’s case “lacked substantive strength,” contending that the ‘576 patent was weak and that Par’s arguments were “specious,” “disingenuous and unsustainable,” and “inconsistent with its own prior statements, actions, and positions.” (Mem. Supp. Mot. Att. Fees 22-24, ECF No. 325.) TWi also argues that the procedural history of the case “reflects a lack of substantive merit.” (*Id.* at 23-24.) But the evidence to which TWi points suggests only that Par

³ *Octane Fitness* overturned *Brooks Furniture Mfg., Inc. v. Dutilier Int’l, Inc.*, 393 F.3d 1378 (Fed. Cir. 2005).

⁴ The court expresses no opinion regarding whether TWi is entitled to attorneys’ fees for litigation in any other forum.

had the weaker case, not that its arguments were “exceptionally meritless.” *See Octane Fitness*, 134 S. Ct at 1757. As Par points out, it is not enough for TWi to show that it prevailed on the merits. *See LendingTree, LLC v. Zillow, Inc.*, 54 F. Supp. 3d 444, 458-61 (W.D.N.C. 2014). Nor has TWi demonstrated, by a preponderance of the evidence, that Par acted in subjective bad faith or with objective unreasonableness. *See Octane Fitness*, 134 S. Ct at 1757, 1758.

Turning to the other pathway to attorneys’ fees under *Octane Fitness*, TWi argues that Par acted in an “unreasonable manner” by, *inter alia*, asserting positions it could not support at trial, concealing information from the patent office, and engaging in “forum shopping” by filing a separate lawsuit in Delaware. (Mem. Supp. Mot. Att. Fees 24-26, ECF No. 325.) To the extent that these allegations are supported by the record, I am not convinced that they fall outside the normal range of conduct by adversaries in litigation. Further, many of TWi’s reasonableness arguments appear to relate to Par’s substantive claims, which have been addressed above, rather than its litigation tactics. (*See, e.g., id.* at 25 (referring to various positions taken by Par as “scorched earth tactic[s]”).) In short, this is not one of the “rare case[s]” in which attorneys’ fees are warranted by the manner of litigation. *See Octane Fitness*, 134 S. Ct at 1757.

Finally, there is no need to award attorneys’ fees in the interest of deterrence, compensation, or any other purpose associated with the “inherently flexible” text of Section 285. *See id.* at 1756. In particular, it is unlikely that other patent-holders will view this lengthy and fact-intensive adjudication as encouragement to pursue frivolous claims or engage in misconduct.

CONCLUSION

For the reasons stated above, TWi's motion for attorneys' fees will be denied. A separate order follows.

9/27/16
Date

/s/
Catherine C. Blake
United States District Judge