

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

IN RE KERYDIN (TAVABOROLE) TOPICAL
SOLUTION 5% PATENT LITIGATION

MDL No. 19-md-2884-RGA

ANACOR PHARMACEUTICALS, INC.,

Plaintiff,

v.

C.A. No. 18-1606-RGA

LUPIN LIMITED, et al.,

Defendants.

REPORT AND RECOMMENDATION¹

Pending before the Court is Defendant FlatWing Pharmaceuticals, LLC’s (“FlatWing’s”) Motion for Fees pursuant to 35 U.S.C. § 285. (No. 18-1606-RGA, D.I. 98; No. 19-md-2884-RGA, D.I. 79.)² For the reasons stated in more detail below, I recommend that the Court DENY the motion.

I. BACKGROUND

This is an ANDA case. Plaintiff Anacor Pharmaceuticals, Inc. markets Kerydin® (tavaborole), a topical solution indicated for the treatment of toenail fungus. Anacor is the assignee of U.S. Patent Nos. 9,549,938, 9,566,289, 9,566,290, and 9,572,823 (collectively, the “patents-in-suit”). The patents-in-suit claim methods and formulations for treating fungal infections in

¹ Posttrial motions for attorney fees are treated as dispositive motions. *See* Fed. R. Civ. P. 54(d)(2)(D); Fed. R. Civ. P. 54 advisory committee’s note to 1993 amendment; *see also Magnetar Techs. Corp. v. Six Flags Theme Parks, Inc.*, No. 07-127-LPS-MPT, 2017 WL 962760, at *5 (D. Del. Mar. 13, 2017). Accordingly, my opinion is issued in the form of a Report and Recommendation.

² For ease of reference, citations to the record will refer to the docket in Civil Action No. 18-1606 unless otherwise indicated.

humans. Each patent contains at least one dependent claim that recites treatment with a formulation comprising 5% tavaborole.

An ancestor to the patents-in-suit, U.S. Patent No. 7,582,621 (“the ’621 patent”), also claimed methods of treating fungal infections with tavaborole. On February 23, 2017, before Anacor filed this suit, the Patent Trial and Appeal Board (PTAB) had reviewed and found invalid all claims of the ’621 patent. (D.I. 100, Ex. C.) In particular, after reviewing expert testimony and making various findings of fact, the PTAB found that the ’621 patent claims were obvious in view of the combination of the references Austin and Brehove and in view of the combination of the references Austin and Freeman.³ (*Id.* at 37, 42.) On appeal, the Federal Circuit affirmed the PTAB’s determination that the claims were obvious in view of Austin and Brehove.⁴ *Anacor Pharms., Inc. v. Iancu*, 889 F.3d 1372, 1385 (Fed. Cir. 2018).

While the IPR of the ’621 patent was pending, the patents-in-suit were being prosecuted before the PTO. During prosecution, the Austin, Brehove, and Freeman references, as well as the petition for IPR of the ’621 patent and the PTAB’s decision to institute that IPR, were cited to the PTO. (*See* D.I. 103, Exs. 3-8.) The PTO issued the four patents-in-suit in early 2017 (before the PTAB’s IPR decision on the ’621 patent). Anacor listed them in the Orange Book for Kerydin®.

³ According to the PTAB, Austin teaches (among other things) that oxaboroles, tavaborole among them, have effective antifungal properties for use with industrial plastics. (D.I. 100, Ex. C at 10-11.) The PTAB found that Brehove teaches (among other things) the use of boron-based compounds to treat a fungal infection and states that the topical treatment compound should “exhibit powerful potency for pathogens, be permeable through the nail barrier, and be safe for patient use.” (*Id.* at 11-12.) Freeman discloses phenylboronic acid (PBA) and related boronic acid compounds for treating fungal infections. (*Id.* at 37.)

⁴ FlatWing points out that Anacor primarily challenged procedural issues on appeal, as opposed to challenging the substance of the PTAB’s obviousness determination. (D.I. 99 at 5, 12.) But given the Federal Circuit’s deferential standard of review of the PTAB’s factual findings, I do not think that Anacor’s strategy to focus its appeal on legal/procedural issues says that much about the strength of Anacor’s substantive positions.

In November 2017, FlatWing petitioned for *inter partes* review of the patents-in-suit. The PTAB instituted review of all claims of all four patents-in-suit in June 2018.

On September 7, 2018, while the IPRs were pending, FlatWing filed an ANDA seeking to market a generic version of Kerydin®. (D.I. 100, Ex. I.) On October 17, 2018, Plaintiff filed this action against FlatWing and two other generic drug manufacturers that had also filed ANDAs. (D.I. 1.) FlatWing moved to stay this action pending resolution of its IPR. (D.I. 23.) Anacor did not oppose the stay and, in fact, filed a cross-motion to stay other actions it had filed against other generic manufacturers seeking to market generic versions of Kerydin®. (D.I. 34.) All of the defendants except FlatWing opposed a stay. (D.I. 41.) On March 1, 2019, the Court denied FlatWing's motion to stay and denied Anacor's cross-motion. (D.I. 55.)

Three months later, on June 5, 2019, the PTAB issued its Final Written Decisions, which concluded that the claims of each of the four patents-in-suit were obvious. (D.I. 100, Exs. J-M.) Although Anacor had maintained that claims containing a 5% tavorole limitation were valid, the PTAB found that FlatWing had established by a preponderance of the evidence that they were obvious over the combination of Austin, Brehove, and Samour (another reference that had been cited to the PTO during prosecution of the patents-in-suit).⁵ (D.I. 100, Ex. J at 33; Ex. K at 34 (also in combination with the Excipients Handbook); Ex. L at 34; Ex. M at 33.) In coming to its decisions, the PTAB considered the evidence and expert testimony presented by both sides and made findings of fact. (*See, e.g.*, D.I. 100, Ex. J at 14, 30; Ex. K at 15, 31; Ex. L at 15, 31; Ex. M at 14, 30.) While the PTAB ultimately ruled against Anacor, nothing in the PTAB's lengthy written decisions suggests that it found Anacor's arguments to be baseless, frivolous,

⁵According to the PTAB, Samour discloses a formulation that can be used to treat or prevent fungal infections, at a range of active ingredient concentrations that includes 5%; however, the active ingredient in Samour is econazole, not tavorole. (D.I. 100, Ex. J at 13.)

unreasonable, or deficient in any way that was out of the ordinary. FlatWing did not ask the PTAB to assess attorney fees against Anacor.⁶

Anacor appealed the PTAB's decisions. The parties requested to stay this action pending Anacor's appeal, and the Court granted their request. (D.I. 90.)

On August 27, 2020, the Federal Circuit affirmed the PTAB's decision. *Anacor Pharms., Inc. v. FlatWing Pharms., LLC*, 825 F. App'x 811, 816 (Fed. Cir. 2020). Among other things, the Federal Circuit reviewed the PTAB's factual findings underlying its obviousness determination for substantial evidence and concluded that the PTAB had "reasonably credited testimony from FlatWing's expert." *Id.*

Two weeks later, on September 10, 2020, the parties in the coordinated actions before this Court requested that final judgment be "entered in favor of Defendants [including FlatWing] and against Anacor on Anacor's claims of infringement, and on Defendants' counterclaims of invalidity." (D.I. 95 at 2.) The Court entered final judgment on September 11, 2020. (No. 18-1606, D.I. 96; No. 19-md-2884, D.I. 77.)

On October 26, 2020, FlatWing filed the pending motion for fees. (D.I. 98.) FlatWing wants Anacor to pay it \$687,295.04, which includes \$584,276.00 in fees incurred by FlatWing in connection with the IPRs, \$93,973.75 in fees related to this action, and \$9,045.29 in expenses. (D.I. 99 at 19.)

⁶ The PTAB may impose sanctions pursuant to 37 C.F.R. § 42.12. Sanctions may include "attorney fees" and may be awarded for "[a]dvancing a misleading or frivolous argument or request for relief" or "[a]ny other improper misuse of the proceeding, including actions that harass or cause unnecessary delay or an unnecessary increase in the cost of the proceeding." § 42.12(a)(2), (7), (b)(6).

II. LEGAL STANDARD

Section 285 of the Patent Act provides that “[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party.” 35 U.S.C. § 285. The Supreme Court has defined an “exceptional” case as “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.*, 572 U.S. 545, 554 (2014). Whether a case is exceptional is left to the discretion of the district court, which should make a case-by-case determination based on the totality of the circumstances. *Id.*

III. DISCUSSION

To determine whether this case is exceptional, the Court must consider the totality of the circumstances and make a discretionary decision. I have reviewed and considered FlatWing’s arguments, as well as the record before me. Having done so, I cannot conclude that this case is exceptional. I find that it is not exceptional and, thus, attorney fees are not warranted.

In particular, I cannot conclude based on the record before me that the substantive positions taken by Anacor were out of the ordinary or that the manner in which it litigated this case was unreasonable. As to the former, I have reviewed Anacor’s non-obviousness argument and, although it was ultimately unsuccessful, I do not think that it was objectively unreasonable or that it was so weak as to render it out of the ordinary.

FlatWing’s primary argument for exceptionality is that Anacor’s case lacked substantive strength. According to FlatWing, when Anacor filed this action, it “knew” that all claims of the patents-in-suit were “almost certainly invalid” because the PTAB and Federal Circuit had already determined that the ancestor ’621 patent claims were invalid over Austin and Brehove, and the

only new limitation was the 5% concentration limitation (which the PTAB subsequently found was taught by Samour). (D.I. 99 at 12, 15.)

I disagree with FlatWing's contention that this case stands out with respect to the substantive strength of Anacor's litigating position. As an initial matter, the record demonstrates that, during prosecution of the patents-in-suit, the PTO examiner was made aware of the Austin, Brehove, and Samour references and the then-pending petition for IPR of the ancestor '621 patent (which made the case for why the '621 claims were obvious in view of Austin and Brehove). The examiner allowed the claims of the patents-in-suit anyway, and once that happened, they acquired a presumption of validity.

What's more, each of the patents-in-suit contained a claim with a limitation that the '621 patent claims lacked. And Anacor reasonably focused its non-obviousness arguments before the PTAB on that limitation. The record before me does not suggest that Anacor's non-obviousness arguments before the PTAB or the Federal Circuit were particularly weak. Rather, the record indicates that the parties submitted conflicting expert testimony, and the PTAB made factual findings—including crediting the testimony of FlatWing's expert—in reaching its conclusion.⁷ Of course, Anacor lost the IPR. But losing is not an unusual occurrence—someone loses in every case—and it certainly does not by itself entitle the winner to fees.

FlatWing also argues that Anacor litigated this case in an unreasonable manner, but there is nothing in the record to support that. In reality, this case was barely litigated at all. Although a scheduling order was entered, the parties had only exchanged initial disclosures before the PTAB

⁷ The PTAB's Final Written Decisions did not suggest that it found Anacor's position particularly weak as opposed to simply less persuasive. *Cf. Munchkin, Inc. v. Luv n' Care, Ltd.*, 960 F.3d 1373, 1380 (Fed. Cir. 2020) (reversing fee award and noting that the requestor failed to "point to any statement by the Patent Board suggesting that it viewed [the patentee's] position to be frivolous or anything out of the ordinary").

issued its decisions, and the Court subsequently stayed this case pending appeal from the PTAB. FlatWing’s real point seems to be that it was unreasonable for Anacor to file suit in the first place (which triggered a 30-month stay of FDA approval of FlatWing’s ANDA), but I reject that argument for the reasons already explained.⁸

IV. CONCLUSION

For the reasons stated above, I conclude that the totality of the circumstances does not support a finding that the case is exceptional. I recommend that FlatWing’s motion for attorney fees be DENIED.

Dated: June 23, 2021



Jennifer L. Hall
UNITED STATES MAGISTRATE JUDGE

⁸ Anacor also contends that the Court cannot award fees under 35 U.S.C. § 285 for the work that FlatWing’s attorneys performed in the IPR proceedings. But if this case is not exceptional, the Court does not need to decide that issue. *Cf. Dragon Intell. Prop., LLC v. Dish Network LLC*, 956 F.3d 1358, 1362 (Fed. Cir. 2020) (remanding and declining to decide “in the first instance” whether fees incurred during *inter partes* review can be assessed under § 285 by a district court in a parallel action, but “see[ing] no basis in the Patent Act for awarding fees under § 285 for work incurred in *inter partes* review proceedings that the [fee requestors] voluntarily undertook”); *see also id.* (“Should the district court determine that this is not an exceptional case, there would be no need to reach the additional issue[] regarding fee-shifting in *inter partes* reviews . . .”).