IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

In Re: ENTRESTO (SACUBITRIL/VALSARTAN) PATENT LITIGATION	Civil Action No. 20-md-2930-RGA
NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. ALKEM LABORATORIES LTD., *et al.* Defendants.	Civil Action No. 19-cv-1979-RGA

MEMORANDUM ORDER

On September 3, 2019, Nanjing Noratech Pharmaceutical Co. ("Noratech") notified Novartis Pharmaceuticals Corporation ("Novartis") by letter that it had submitted to the FDA ANDA No. 213671 for sacubitril/valsartan tablets ("the ANDA Products"). (D.I. 1 ¶ 88; D.I. 3; D.I. 372-2). Noratech informed Novartis that Noratech had filed Paragraph IV certifications for two of Novartis's patents related to its drug Entresto (sacubitril/valsartan), United States Patent No. 8,877,938 ("the '938 Patent") and United States Patent No. 9,388,134 ("the '134 Patent") (collectively, "the Asserted Patents"). (D.I. 372-2 at 2). On October 17, 2019, Novartis brought a patent infringement suit against Noratech and other defendants, alleging Noratech's ANDA products would infringe the Asserted Patents. (D.I. 1 ¶¶ 86-92, 300-01).

On December 8, 2021, Novartis provided Noratech with a covenant not to sue on the Asserted Patents and the parties stipulated to dismissal of Novartis's claims against Noratech for lack of subject matter jurisdiction. (D.I. 360). Noratech now moves for attorney fees under 35 U.S.C. § 285.[1] (D.I. 370). I have considered the parties' briefing. (D.I. 371, 387, 398).

I. Legal Standard

"The court in exceptional cases may award reasonable attorney fees to the prevailing party." 35 U.S.C. § 285. An "exceptional" case is "one that stands out from others with respect to the substantive strength of a party's litigating position (considering both the governing law and 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). In determining whether a case is "exceptional," a court should consider the totality of the circumstances, including "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." *Id.* at 554 n.6. "[A] case presenting either subjective bad faith or exceptionally meritless claims may sufficiently set itself apart from mine-run cases to warrant a fee award." *Id.* at 555.

"[T]he fact that the party's position does not prevail – or would not have prevailed if it had been litigated to conclusion – is insufficient by itself to warrant an award of fees." *Sun Pharm. Indus. Ltd. v. Saptalis Pharm., LLC*, 2020 WL 5077412, at *2 (D. Del. Aug. 26, 2020).

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[1] A party may be considered the prevailing party for purposes of 35 U.S.C. § 285 where the opposing party provides a covenant not to sue and stipulates to dismissing its claims. *Blackbird Tech LLC v. Health in Motion LLC*, 944 F.3d 910, 914-15 (Fed. Cir. 2019) (affirming § 285 award after voluntary dismissal and a covenant not to sue).

II. Analysis

Noratech argues this case should be deemed exceptional because (1) Novartis's case lacked "substantive strength," and (2) Novartis filed and litigated its suit in bad faith. (D.I. 371 at 13-19). I address each of these arguments in turn.

A. Substantive Strength

Noratech argues Novartis's suit was baseless because, "Novartis performed no pre-suit investigation and never had any basis to believe that it could show that its infringement claims ha[d] evidentiary support." (D.I. 371 at 13). I disagree.

"[T]he Hatch-Waxman Act gives a drug patent owner the right to bring an action for infringement upon the filing of a paragraph IV certification." *Bristol-Myers Squibb Co. v. Royca Lab'ys, Inc.*, 69 F.3d 1130, 1135 (Fed. Cir. 1995) (citing 35 U.S.C. § 27(e)(2)(A)). Noratech's paragraph IV certification and Novartis's good faith belief that Noratech's ANDA Products contained sacubitril and valsartan in a form that could potentially convert to the claimed co-crystalline form of sacubitril and valsartan provided a sufficient basis for Novartis to bring its infringement suit. *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litigation*, 693 F. Supp. 2d 409, 416 (D. Del. March 12, 2010) (in Hatch-Waxman litigation, the submission of an ANDA serves as an "'artificial' act of infringement," as "the usual methods of supporting an allegation for infringement (e.g., securing and evaluating the accused product) are not immediately available to the patentee")).

Novartis was under no obligation to forgo discovery by relying on Noratech's representation in its notice letter that Noratech's ANDA Products contained physically separate sacubitril and valsartan, rather than the co-crystal of sacubitril and valsartan ("TSVH") claimed in

the Asserted Patents. (*See* D.I. 371 at 13). Nor was Novartis required to accept Noratech's pre-suit Offer of Confidential Access to its ANDA under terms it considered unreasonable.[2] *See In re Cyclobenzaprine*, 693 F. Supp. 2d at 416-17 (Rule 11 does not prohibit a patentee from bringing an infringement action based upon the submission of an ANDA, without reviewing the ANDA, where the ANDA filer has attached "unacceptable conditions to its offer of access"); *Salix Pharms., Inc. v. Mylan Pharms.*, 2017 WL 11681685, at *19 (N.D. W.V. Sept. 12, 2017) (denying motion for fees under § 285 where moving party's "main contention is that, had the plaintiffs reviewed its ANDA prior to filing suit, they would have discovered that Mylan's ANDA product" did not infringe). I credit Novartis's argument that it believed attempting to negotiate reasonable terms for access to Noratech's ANDA within the 45-day window prior to filing suit would have been fruitless, especially here where seventeen different defendant groups were eventually consolidated into a single MDL and negotiating a protective order acceptable to all parties took close to four months and intervention by this Court. (D.I. 387 at 12; D.I. 388-2 Ex. 9 (Novartis sent first draft protective order on May 5, 2020); D.I. 119 at 63:21-66:10 (Court ruling from the bench deciding protective order disputes); D.I. 122 (final stipulated protective order filed Aug. 31, 2020)).

When Noratech filed its ANDA submission, Novartis became entitled to perform its own review of Noratech's ANDA and related materials to assess the strength of its infringement contentions. (D.I. 372-11 (Novartis explaining in its initial infringement chart, "On information

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[2] Noratech's Offer of Confidential Access included "default prohibitions against experts or Novartis's in-house counsel in charge of patent litigation having any access to the ANDA and provisions barring Novartis's entire outside law firm from engaging in any prosecution or FDA regulatory work for Novartis, regardless of subject matter." (D.I. 387 at 12 (citing D.I. 372-2 at 3)).

and belief," Noratech's ANDA Products contain TSVH "in crystalline form," and Novartis "will supplement this response as Novartis reviews with its experts Noratech's ANDA and research and development documents, . . . and, if necessary, conducts appropriate testing on samples of Noratech's ANDA Products and/or their ingredients")). That Novartis ultimately determined, after discovery and review of Noratech's ANDA and related materials, that its infringement theory was not viable does not mean Novartis's claims were "exceptionally meritless." *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545, 548 (2014) (fees are not "a penalty for failure to win a patent infringement suit" but are "appropriate only in extraordinary circumstances") (cleaned up).

B. Bad Faith

Noratech's arguments regarding Novartis's bad faith litigation conduct rely heavily on speculation and are premised on the assumption that Novartis's claims were baseless. (D.I. 371 at 16). Because, as I have explained above, I do not believe that Novartis's suit was baseless, I do not think that Novartis's litigation conduct makes this case exceptional.

III. Conclusion

For the reasons stated above, Noratech's motion for fees is DENIED.

IT IS SO ORDERED.

Entered this 17th day of June, 2022.

United States District Judge