

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PHARMACYCLICS LLC and
JANSSEN BIOTECH, INC.,

Plaintiffs,

v.

ALVOGEN PINE BROOK LLC
and NATCO PHARMA LTD.,

Defendants.

Civil Action No. 19-434-CFC

MEMORANDUM

Pending before me is the Motion for Attorneys' Fees and Experts' Fees (D.I. 389) filed by Plaintiffs Pharmacyclics LLC and Janssen Biotech, Inc. (collectively, Pharmacyclics). Pharmacyclics markets Imbruvica[®], a brand-name drug used to treat patients with small cell lymphomas.

I.

This case arose out of the submission to the U.S. Food & Drug Administration (FDA) by Defendants Alvogen Pine Brook LLC and Natco Pharma Ltd. (collectively, Alvogen) of an Abbreviated New Drug Application (ANDA) for approval to market generic versions of Imbruvica[®] tablets. Pharmacyclics filed this suit against Alvogen pursuant to the Hatch-Waxman Act, 21 U.S.C. § 355(j), for infringement of eighteen patents. Pharmacyclics had listed the asserted patents

in the so-called Orange Book administered by the FDA to cover Imbruvica®.

Section 271(e)(2)(A) of the Patent Act, 35 U.S.C. § 1 *et seq.*, defines the filing of an ANDA as an act of infringement of the patents listed in the Orange Book. *See Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1325 (Fed. Cir. 2012).

This suit against Alvogen was litigated alongside a related action involving other defendants seeking approval for generic versions of Imbruvica® capsules (the Capsule Action). *See* D.I. 114; *Pharmacyclics LLC v. Sandoz Inc.*, No. 18-192. The Capsule Action and this action were not fully consolidated, but parts of the suits were coordinated with respect to discovery, and the actions were tried together in October 2020.

At the time the parties filed the Pretrial Order on September 18, 2020, Pharmacyclics was still asserting against Alvogen fifteen claims across nine patents. D.I. 276 ¶ 45. At some point after the September 23, 2020 Pretrial Conference, Pharmacyclics winnowed its case to nine claims across four patents: U.S. Patent Nos. 8,008,309 (the #309 patent), 8,754,090 (the #090 patent), 9,655,857 (the #857 patent), and 9,725,455 (the #455 patent). D.I. 276 ¶ 45. In a stipulation filed the day before trial, Alvogen stipulated that its ANDA product infringed one asserted claim in each of the #309, #090, and #455 patents. D.I. 295. At the seven-day bench trial in October 2020, Alvogen pursued various invalidity defenses with respect to those asserted claims and various noninfringement and

invalidity defenses with respect to the two claims of the #857 patent Pharmacyclics asserted. D.I. 374; D.I. 352 at 3.

I ruled at trial that Alvogen infringed the asserted claims of the #857 patent. 10-21-2020 Trial Tr. 1976:8–1977:6, 1978:12–19, 1980:19–24 (docketed as D.I. 380). In a posttrial Memorandum Opinion, I found that all the asserted claims of the #309, #090, #857, and #455 patents were not invalid. D.I. 352 at 31, 57, 70, 90. I entered final judgment in Pharmacyclics’ favor on August 30, 2021. D.I. 357.

Alvogen appealed that judgment to the Federal Circuit, D.I. 359, and the Federal Circuit affirmed the judgment in November 2022. *Pharmacyclics LLC v. Alvogen, Inc.*, 2022 WL 16943006 (Fed. Cir. Nov. 15, 2022); D.I. 406-1 at 2–27. Pharmacyclics filed the pending motion in February 2023 and the parties completed briefing of the motion in April 2023. D.I. 426.

II.

The Patent Act provides that “in exceptional cases [the court] may award reasonable attorney fees to the prevailing party.” 35 U.S.C. § 285. “[A]n ‘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. District courts may determine whether a case is ‘exceptional’ in the case-

by-case exercise of their discretion, considering the totality of the circumstances.”
Octane Fitness, LLC v. ICON Health & Fitness, Inc., 572 U.S. 545, 554 (2014)
(footnote omitted).

There is no question in my mind that Alvogen engaged in vexatious conduct in this case. By way of example: In its posttrial reply brief, Alvogen stated that I should exclude twenty-four of Pharmacyclics’ proposed factual findings because Pharmacyclics had not relied upon those facts in its posttrial answering brief. D.I. 341 at 11 n.2. Alvogen did not identify or describe in its reply brief the challenged factual findings. Instead, it directed me to Exhibit C, which it attached to its reply brief. In Exhibit C, Alvogen again did not identify or describe the challenged factual findings. *See* D.I. 341 at 46. Instead, it simply listed paragraph numbers from Pharmacyclics’ proposed findings of fact, D.I. 332, thus requiring me to go through Pharmacyclics’ filing to identify the challenged proposed factual findings. Once I matched up Alvogen’s Exhibit C with Pharmacyclics’ filing, I was able to determine that all twenty-four of Alvogen’s objections were unfounded. Most of the objections were also confounding. Alvogen, for example, objected to Pharmacyclics’ assertion that “[t]his is an action for patent infringement arising from the submission to FDA by Defendants of an ANDA seeking approval of generic versions of Plaintiffs’ Imbruvica® Tablets.” D.I. 332 ¶ 1. Of course, this case is precisely what Pharmacyclics said it was—a patent

infringement case arising from Alvogen’s filing with the FDA an ANDA for Imbruvica®. Indeed, Alvogen itself stated in the Pretrial Order that “[t]hese actions for patent infringement (C.A. No. 18-192, C.A. [No.] 19-434), arise under the patent laws of the United States, Title 35, and are brought pursuant to the Hatch-Waxman Act, arising out of the filing by each of Defendants Alvogen, Zydus, and Sandoz with the U.S. Food & Drug Administration (‘FDA’) of an Abbreviated New Drug Application (‘ANDA’), seeking approval for generic versions of either Plaintiffs’ Imbruvica® Tablets (Alvogen) or Capsules (Sandoz and Zydus), pursuant to 21 U.S.C. § 355(j) prior to the expiration of one or more of the [asserted] patents.” D.I. 276 ¶ 1.

Alvogen also objected in its posttrial briefing to Pharmacyclics’ statement that “[t]his matter came before the Court for a bench trial on October 13–21, 2020.” *See* D.I. 341 at 46; D.I. 332 ¶ 12. But we did have a bench trial on October 13 through October 21, 2020! I was at the trial. And so was Alvogen’s counsel. Alvogen objected as well to Pharmacyclics’ assertion that “Alvogen does not contest jurisdiction or venue”—even though Alvogen has never contested jurisdiction or venue! *See* D.I. 341 at 46; D.I. 332 ¶ 14. Alvogen similarly objected to Pharmacyclics’ statement that “Alvogen stipulated that, under the Court’s claim construction, its ANDA Products infringe the asserted claims of the

[#]309, [#]090, and [#]455 Patents,” even though Alvogen signed and filed with the Court a stipulation to that effect. *See* D.I. 341 at 46; D.I. 332 ¶ 16; D.I. 295.

Alvogen also argued in its posttrial reply brief that “[c]ertain of Plaintiffs’ exhibits should be excluded because Plaintiffs did not substantively discuss them at trial.” D.I. 341 at 1 n.2. Alvogen did not identify or describe in its reply brief the challenged exhibits. Instead, it pointed me to Exhibit A, a table attached to its reply brief that listed thirty-one trial exhibits cited in Pharmacyclics’ proposed findings of fact. I scheduled a teleconference with the parties to discuss how to address Alvogen’s objections to exhibits. In the meantime, I arbitrarily selected three of the challenged exhibits to see for myself if they were discussed at trial. All three exhibits were in fact discussed in detail at trial, and as I explained during the ensuing teleconference, the question of whether they were discussed at trial was “not a close call.” 1-15-2021 Hr’g Tr. 32:19–24 (docketed as D.I. 382). I was tempted, based on Alvogen’s misrepresentations of the record with respect to these three exhibits to overrule its objections to the remaining twenty-eight challenged exhibits, but I gave Alvogen an alternative: if it wanted to maintain an objection to any of the twenty-eight exhibits, it had to agree up front that if I overruled the objection, Alvogen had to pay Pharmacyclics’ legal fees for defending against the objection. Alvogen declined this offer and dropped its objections. In doing so, it saved me and Pharmacyclics from further work, but both Pharmacyclics and I had

already spent time and energy (and, in Pharmacyclics' case, money) addressing Alvogen's objections.

Another part of Alvogen's vexatious litigation strategy was to require Pharmacyclics (and the Court) to engage in unnecessary claim construction. Alvogen assured me at the Rule 16 scheduling conference that it was "not looking to unnecessarily reconstrue terms or have the Court spend resources to reconstrue terms unnecessarily that ha[d] already been addressed" by me in the Capsule Action. 9-4-2019 Hr'g Tr. 31:3-9 (docketed as D.I. 365). In counsel's words: "If we have the same position as the defendants in the capsule case, we're not going to ask [the Court] to reconstrue those terms." 9-4-2019 Tr. 31:11-13. But that is exactly what Alvogen asked me to do for four of the ten claim terms litigated in the *Markman* hearing in this case. See 1-13-2020 Hr'g at 21:11-14; 21:20-21 (docketed as D.I. 176) ("That was the same argument that was made to me, right, in the capsule hearing."); 22:21-23:3 ("I've already heard this argument . . . So I read the briefs very carefully, and for the reasons that I stated at the capsule Markman hearing . . ."); 25:17-23 ("There was extensive briefing [on the disputed term]. . . We went back and we reread the transcript of the Markman hearing in the capsule case. We looked again at the briefing in the capsule Markman hearing carefully and I don't think [Alvogen's purportedly new argument on the same disputed term] will advance the ball."); 26:20-22 ("I've

dealt with that argument before, and, again, you can make it to the Federal Circuit.”); 38:4–20 (“I’ve heard this argument. I’ve ruled on this argument. Right?”).

Alvogen argues that it “was not barred by res judicata from seeking to clarify the meaning of key claim terms” and that it “was incumbent upon [its] counsel to be heard on claim construction and to preserve claim[]construction arguments for appeal.” D.I. 422 at 7–8. But relitigating the exact arguments I rejected in the Capsule Action is not “seeking clarification,” and Alvogen could have preserved any objection to my claim construction in the Capsule Action without demanding *Markman* briefing and a hearing in this case for issues I had already decided in the Capsule Action. (As it turned out, Alvogen did not challenge my claim construction in its appeal to the Federal Circuit.)

I could go on. But I won’t, because Pharmacyclics is also guilty of vexatious conduct in this action, and therefore, having considered the totality of the circumstances, I do not think an award of attorney fees is appropriate in this case.

III.

In the operative Amended Complaint, Pharmacyclics accused Alvogen of infringing eighteen patents. It asserted approximately 150 claims of those patents in its Final Infringement Contentions, *see* D.I. 406-1 at 151, 162, and as of January 16, 2020—ten months before trial—it was still asserting eighty-two claims,

D.I. 406-1 at 161–62. Pharmacyclics “narrowed” the number of asserted claims to forty-four claims across ten patents on February 25, 2020. D.I. 406-1 at 161–62. By the time it filed the Pretrial Order on September 18, 2020, Pharmacyclics was still asserting fifteen claims across nine patents. D.I. 276 ¶ 45. Pharmacyclics’ insistence on litigating so many patents and claims was unreasonable and placed undue and unnecessary burdens on Alvogen and the Court.

Like Alvogen, Pharmacyclics has also been guilty of burdening the Court with misleading argument. For example, it complains in its opening brief filed in support of its fee application that “Alvogen forced [it] to continue litigating infringement of the [#]309, [#]090, and [#]455 Patents until the eve of trial, finally stipulating [to infringement] the day before trial.” D.I. 405 at 10. It says fees are warranted for this conduct because “Alvogen acknowledged [in the stipulation] that it had no basis to contest infringement ‘[i]n view of the Court’s Claim Construction Order,’ which had issued *over eight months prior*,” and Alvogen’s delay in agreeing to the stipulation required Pharmacyclics to serve “needless expert reports . . . for which Alvogen did not serve any rebuttal, including for the [#]309, [#]090, and [#]455 Patents.” D.I. 405 at 10 (emphasis in the original) (citations omitted). But Pharmacyclics failed to disclose in its brief that *nine days* after I issued the Claim Construction Order, Alvogen sent Pharmacyclics a proposed draft stipulation in which Alvogen stated that “[i]n view of the Court’s

Claim Construction Order, and the current posture of the case, [Alvogen] agree[s] to stipulate to infringement” of the asserted claims of the #309, #090, and #455 patents “so long as those claims are not determined in a final and unappealable decision to be invalid, unpatentable, or unenforceable.” D.I. 423 at 247–48. Pharmacyclics also failed to mention that it waited nearly three weeks before responding to this proposed stipulation, and that when it did respond, it unreasonably insisted on deleting from the stipulation the phrase “so long as those claims are not determined in a final and unappealable decision to be invalid, unpatentable, or unenforceable.” Notwithstanding that unreasonable response, while the parties negotiated about the language of a mutually acceptable stipulation, Alvogen stated in an email to Pharmacyclics on March 11, 2020 that “[Pharmacyclics] know[s] the claims that [Alvogen] [is] willing to stipulate are infringed based on the current claim construction, *so there is no reason for Plaintiffs’ experts to address those claims in their reports.*” D.I. 423 at 271 (emphasis added). Thus, any harm from the service of “unnecessary” expert reports by Pharmacyclics was self-inflicted.

IV.

The imposition of attorney fees under § 285 is an exercise of a district court’s equitable discretion. *Octane Fitness*, 572 U.S. at 554. Thus, the equitable maxim that “he who comes into equity must come with clean hands” applies here.

See Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 814 (1945) (“The guiding doctrine in this case is the equitable maxim that he who comes into equity must come with clean hands. This maxim is far more than a mere banality. It is a self-imposed ordinance that closes the doors of a court of equity to one tainted with inequity or bad faith relative to the matter in which he seeks relief, however improper may have been the behavior of the defendant. That doctrine is rooted in the historical concept of court of equity as a vehicle for affirmatively enforcing the requirements of conscience and good faith. This presupposes a refusal on its part to be the abetter of iniquity. Thus while equity does not demand that its suitors shall have led blameless lives, as to other matters, it does require that they shall have acted fairly and without fraud or deceit as to the controversy in issue.”) (internal quotation marks and citations omitted).

Alvogen was a vexatious litigant in this case. Its hands were dirty in this regard. But so were Pharmacyclics’. I will therefore deny Pharmacyclics’ request for attorney and expert fees.

The Court will issue an Order consistent with this Memorandum.

4.30.24

Date


CHIEF JUDGE

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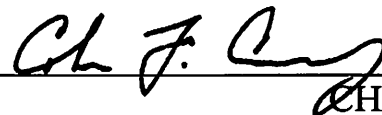
Defendants.

Civil Action No. 19-434-CFC

ORDER

At Wilmington on this Thirtieth day of April in 2024:

For the reasons set forth in the Memorandum issued this day, **IT IS
HEREBY ORDERED** that Plaintiffs Pharmacyclics LLC and Janssen Biotech,
Inc.'s Motion for Attorneys' Fees and Experts' Fees (D.I. 389) **IS DENIED**.



CHIEF JUDGE