

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

SUN PHARMACEUTICAL INDUSTRIES §
LTD. and RANBAXY SIGNATURE, LLC, §

Plaintiffs, §

v. §

SAPTALIS PHARMACEUTICALS, LLC, §

Defendant. §

Civil Action No. 18-648-WCB

Filed Under Seal

MEMORANDUM OPINION AND ORDER

Before the Court is Defendant Saptalis Pharmaceuticals, LLC’s Motion for Exceptional Case Determination and Attorneys’ Fees Pursuant to 35 U.S.C. § 285. Dkt. No. 160; Dkt. No. 161. Plaintiffs Sun Pharmaceuticals Industries Ltd. and Ranbaxy Signature, LLC (collectively, “Sun”) oppose. Dkt. No. 168. Saptalis replies. Dkt. No. 175. Saptalis’s motion is denied. Also before the Court is Sun’s Motion to Strike New Evidence and Arguments Raised in Saptalis’s Reply. Dkt. No. 180. Sun’s motion to strike is denied as moot.¹

BACKGROUND

In 2003, the U.S. Food and Drug Administration (“FDA”) approved New Drug Application No. 021591 by Sun for the drug protected by U.S. Patent No. 6,890,957 (“the ’957 patent”). Dkt. No. 143, at 2. The ’957 patent “relates to a liquid formulation of metformin and salts thereof” and to the use of that formulation “in treating hyperglycemia and/or diabetes.” ’957 patent, col. 1, ll.

¹ Saptalis filed a request for oral argument on its motion for attorney fees and Sun’s motion to strike. Dkt. No. 184. Saptalis’s request was filed more than 7 days after service of its reply brief in support of its motion for attorney fees, and is therefore untimely with respect to that motion. *See* D. Del. L.R. 7.1.4. In any event, I conclude that oral argument would not be helpful with respect to either motion, and I therefore deny Saptalis’s request.

15–17. After approving the New Drug Application, the agency then listed the patent in the FDA publication entitled *Approved Drug Products and Therapeutic Equivalence Evaluations*, as covering Sun’s product bearing the trade name Riomet®. Dkt. No. 143, at 2–3. Saptalis subsequently submitted an Abbreviated New Drug Application (“ANDA”) seeking approval to market a generic version of Riomet®. *Id.* at 3. Sun then filed this action under the infringement provision of the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2), alleging that Saptalis’s ANDA product infringes the ’957 patent.

Early in the case, Saptalis filed a motion for summary judgment of noninfringement. During the summary judgment proceedings, Saptalis attacked Sun’s theory of infringement with respect to two claim limitations that are present in the only independent claim of the ’957 patent. Dkt. No. 143, at 6. One of those limitations recites “a polyhydroxy alcohol present in an amount of about 15 to about 55% by weight.” Saptalis challenged Sun’s assertion of infringement with respect to that limitation on multiple grounds. One of those grounds was that the doctrine of prosecution history estoppel precluded Sun’s theory of infringement under the doctrine of equivalents. After an extensive analysis of that issue, I concluded that Saptalis was correct and that summary judgment of noninfringement was therefore warranted. *See id.* at 29–49. I rejected Saptalis’s reliance every other ground that purportedly justified summary judgment.

LEGAL STANDARD

Section 285 of the Patent Act, 35 U.S.C. § 285, authorizes district courts to award reasonable attorney fees to the prevailing party “in exceptional cases.” In *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, the Supreme Court held that 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 the facts of the case) or the unreasonable manner in which the case

was litigated.” 572 U.S. 545, 554 (2014). The Court added that 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.* While there is “no precise rule or formula for making these determinations,” courts may consider factors such as “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.

DISCUSSION

Saptalis asserts that this case should be found exceptional for two primary reasons. First, Saptalis contends that this case stands out from other patent cases with respect to the lack of substantive strength in Sun’s litigating position. According to Saptalis, Sun had no chance of proving infringement of the polyhydroxy alcohol limitation because there was no evidence supporting Sun’s theory of infringement under the doctrine of equivalents. Saptalis also argued that Sun’s theory of infringement under the doctrine of equivalents was clearly precluded by the doctrine of prosecution history estoppel. In Saptalis’s view, “Sun filed and maintained this case with no hope of ultimately prevailing, but simply to obtain a 30-month stay on FDA’s approval of Saptalis’s ANDA, and to use the stay and the expense of litigation to leverage delay in the launch of Saptalis’s ANDA Product.” Dkt. No. 161, at 1.

Second, Saptalis contends that this case stands out from other patent cases with respect to the manner in which Sun litigated the case. In support of that argument, Saptalis identifies several examples of Sun’s allegedly “unreasonable and vexatious” litigation tactics that Saptalis believes were “designed merely to keep the case on life support in order to maintain FDA’s statutory 30-month stay on the approval of a competing product.” *Id.* at 12–13.

1. I am not persuaded that Sun’s infringement theories were so unwarranted as to render this case exceptional. In evaluating whether a party has taken unreasonable litigating positions, it is important to note at the outset that the 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. *Octane*, 572 U.S. at 548 (fees are not “a penalty for failure to win a patent infringement suit,” but are appropriate only “in extraordinary circumstances”). The legislative purpose behind 35 U.S.C. § 285 is to prevent a party from suffering a gross injustice, not to punish a party for losing. *Munchkin, Inc. v. Luv n’ Care, Ltd.*, 960 F.3d 1373, 1378 (Fed. Cir. 2020).

Considering that legal framework, Sun’s theory of infringement of the polyhydroxy alcohol limitation under the doctrine of equivalents was not so meritless as to render this case exceptional. To begin with, I found that Sun’s evidence of infringement under the doctrine of equivalents was legally sufficient to create a disputed issue of material fact. Saptalis appears to disagree with that decision. Saptalis repackages arguments it made at the summary judgment stage, asserting that Sun’s theory of infringement under the doctrine equivalents “would not succeed at trial.” Dkt. No. 161, at 11. Saptalis further contends that “[s]urviving summary judgment . . . is not sufficient to avoid an exceptional case finding.” *Id.* at 11–12.

While Saptalis is correct that a denial of summary judgment is not always entitled to “decisive weight” in defeating a section 285 fee-shifting motion, it is an important factor in this case. *Eko Brands, LLC v. Adrian Rivera Maynez Enters., Inc.*, 946 F.3d 1367, 1375 (Fed. Cir. 2020). Saptalis has not identified any new considerations bearing on my previous determination that there was a disputed issue of material fact as to the polyhydroxy alcohol limitation. After considering the circumstances of this case, I find no reason to fault Sun for taking the positions

that I accepted at the summary judgment stage. *See Checkpoint Sys., Inc. v. All-Tag Sec. S.A.*, 858 F.3d 1371, 1376 (Fed. Cir. 2017); *Munchkin*, 960 F.3d at 1381.

In addition to finding that Sun’s evidence was sufficient to create a disputed issue of material fact as to the polyhydroxy alcohol limitation, I rejected all but one of Saptalis’s summary judgment arguments that the doctrine of equivalents was unavailable to Sun as a matter of law. Sun’s response to Saptalis’s one successful argument—that prosecution history estoppel barred Sun’s doctrine of equivalents theory—was not so far beyond the pale as to render this case exceptional. As I previously expressed, I had difficulty resolving the parties’ dispute regarding the applicability of the prosecution history estoppel doctrine. *See* Dkt. No. 93. The issue was factually complex, had tricky aspects to it, and required “extra time and attention.” *Id.* The complexity of the issue is evidenced by the extensive analysis that I had to devote to it. *See* Dkt. No. 143, at 29–49.

Sun’s efforts to persuade me that the doctrine of prosecution history estoppel was inapplicable here was thus not a frivolous venture for which a fees sanction would be appropriate. *See Medtronic Navigation, Inc. v. BrainLAB Medizinische Computersysteme GmbH*, 603 F.3d 943, 957 (Fed. Cir. 2010) (“we do not regard the issue [of prosecution history estoppel] as being so clear-cut that it was unreasonable for Medtronic to litigate the question until it obtained a ruling from the district court on the matter”); *Reckitt Benckiser LLC v. Aurobindo Pharma Ltd.*, No. CV 14-1203, 2017 WL 4613643, at *2 (D. Del. Oct. 16, 2017), *aff’d*, 737 F. App’x 537 (Fed. Cir. 2018) (“That the nature of the narrow dispute presented by the parties turned out to be amenable to summary judgment does not inevitably correlate to an exceptionally weak substantive position or an unreasonable manner of litigation.”); *EON Corp. IP Holdings, LLC v. FLO TV Inc.*, No. CV 10-812, 2014 WL 2196418, at *2 (D. Del. May 27, 2014) (finding that the “substantive strength

of EON's case was not so conspicuously deficient as to justify the award of attorney's fees," and noting that the "case turned on a complex and evolving area of law" and that the decision to invalidate the asserted claims "was not an easy one"); *Indivior Inc. v. Dr. Reddy's Labs. S.A.*, No. 14-CV-1451, 2020 WL 1955433, at *2 n.2 (D. Del. Apr. 23, 2020) (denying motion for attorney fees in a case in which "it was not clear to [the Judge] at trial that Plaintiffs' infringement position was completely meritless," and the disputed issue was "a close one, and one with which [the Judge] struggled during the litigation"). For the same reasons, Sun cannot be faulted for appealing my prosecution history estoppel ruling.

2. I am also not persuaded that this case stands out from other patent cases with respect to the manner in which Sun litigated it. Saptalis identifies six categories of conduct that purportedly demonstrate that Sun litigated this case in an unreasonable manner: (1) Sun took inconsistent positions regarding what constituted "polyhydroxy alcohols"; (2) Sun abandoned its proposed construction of the claim term "by weight"; (3) Sun abandoned its appeal; (4) Sun falsely reported the expiration date of the asserted patents; (5) Sun failed to disclose its expert in violation of the court's protective order; and (6) Sun attempted to delay or avoid summary judgment proceedings. Dkt. No. 161, at 12–20. In Saptalis's view, those "litigation tactics were 'unreasonable and vexatious,' designed merely to keep the case on life support in order to maintain FDA's statutory 30-month stay on the approval of a competing product." *Id.* at 13.

(i) As noted, claim 1 of the asserted patent recites "a polyhydroxy alcohol present in an amount of about 15 to about 55% by weight." In its initial infringement contentions in this case, Sun alleged that two ingredients in the accused product, sucralose and xanthan gum, are polyhydroxy alcohols. Sun subsequently served a first amended set of infringement contentions. Sun's amended infringement contentions retreated from the position that sucralose and xanthan

gum are polyhydroxy alcohols, and contended instead that they are equivalent to the polyhydroxy alcohol recited in the asserted patent. Saptalis contends that Sun's amendment was improper, and that there is no support for Sun's amended position that sucralose and xanthan gum are not polyhydroxy alcohols, but are equivalent to polyhydroxy alcohols.

Neither of those contentions is persuasive. In a previous order, I expressly held that the first amendment to Sun's infringement contentions was permissible. In that order, I stated that "Sun amended its infringement contentions early in the case, giving Saptalis ample time to address Sun's new allegations in its motion for summary judgment, and there is no suggestion that Sun's amended infringement contentions were the product of bad faith on Sun's part." Dkt. No. 97, at 4. Thus, contrary to Saptalis's suggestion, Sun's first amendment to its infringement contentions was not "eleventh-hour abandonment" of a position motivated by bad faith. Dkt. No. 161, at 13–14. It was an amendment early in the case that I expressly held was permissible.

Likewise, there is no force to Saptalis's contention that Sun's new position was "frivolous" and unsupported. As I previously explained:

Whether xanthan gum and sucralose are polyhydroxy alcohols remains a disputed issue of material fact in this case. First, as noted, the Court has already determined not to hold Sun to its statement in the original infringement contentions that xanthan gum and sucralose are polyhydroxy alcohols. Second, the summary judgment record discloses that there is an unresolved factual dispute as to whether xanthan gum and sucralose are polyhydroxy alcohols.

Dkt. No. 143, at 21. Although Saptalis contends that there is no question that "sucralose and xanthan gum are polyhydroxy alcohols," Dkt. No. 161, at 14, Saptalis has not provided a persuasive justification for me to revisit my previous decision on that issue.

Saptalis also contends that Sun unreasonably amended its position a second time. I disagree. On the last day of discovery, Sun served a second amended infringement claim chart on Saptalis, in which Sun amended its infringement contentions for a second time. Dkt. No. 131-1,

Exh. U, at 5–9. In the second amended infringement contentions, Sun alleged that xanthan gum, sucralose, and/or Strawberry Flavor WONF Natural are equivalent to the polyhydroxy alcohol recited in the '957 patent. *Id.* at 5. More specifically, Sun alleged that if the function of the polyhydroxy alcohol recited in the asserted patent is solely to increase the viscosity of the formulation, then xanthan gum alone is equivalent to the recited polyhydroxy alcohol limitation. *Id.* at 6. However, Sun alleged that if the function of the polyhydroxy alcohol recited in the asserted patent is to increase both the viscosity and the sweetness of the formulation, then xanthan gum, in combination with sucralose and/or Strawberry Flavor WONF Natural, are equivalent to the polyhydroxy alcohol limitation. Contrary to Saptalis's contention, that second amendment to Sun's infringement contentions does not reflect the type of misconduct that would warrant a fee award.

Although, Saptalis had the opportunity to challenge the propriety of Sun's second amended infringement contentions during the summary judgment proceedings, it did not. Dkt. No. 143, at 4 ("Saptalis has not challenged the permissibility of the second amended infringement contentions."). Consequently, the parties submitted briefing addressing Sun's theory of equivalence as set forth in those contentions. And my summary judgment order also addressed the theory of equivalence advocated in Sun's second amended infringement contentions. Because Saptalis failed to object to Sun's second amended infringement contentions until now, I give little weight to Saptalis's argument that this case is exceptional because that amendment was allegedly improper. *Stone Basket Innovations, LLC v. Cook Med. LLC*, 892 F.3d 1175, 1181 (Fed. Cir. 2018) ("[A] party cannot simply hide under a rock, quietly documenting all the ways it's been

wronged, so that it can march out its parade of horrors after all is said and done.” (citation and internal quotation marks omitted)).²

In sum, I reject Saptalis’s contention that Sun’s “constantly changing DOE theory provide[s] more than sufficient basis to deem this case exceptional.” Dkt. No. 161, at 15.

(ii) During claim construction proceedings, Sun decided to stipulate to a construction of the claim term “by weight,” after originally disputing Saptalis’s proposed construction. In general, the “reduction of the issues by its stipulation” is a “praiseworthy step, beneficial to the courts and the parties.” *Lindemann Maschinenfabrik GmbH v. Am. Hoist & Derrick Co.*, 895 F.2d 1403, 1408 (Fed. Cir. 1990). In this case, there was nothing improper about Sun’s decision to stipulate to a proposed construction. It is apparent to me that Sun had a good faith basis for originally disputing Saptalis’s proposed construction. Although Sun eventually agreed to stipulate to Saptalis’s proposed construction, such push-and-pull over the scope of claim language is common in patent litigation. Here, Sun believed it could win its case under Saptalis’s proposed construction. Saptalis has provided no persuasive reason to fault Sun for conceding an issue that Sun believed “would not advance this litigation[.]” Dkt. No. 79, at 13.

(iii) I also do not think there was anything exceptional about Sun’s decision to voluntarily dismiss its appeal. As noted, Sun cannot be faulted for seeking to appeal my prosecution history estoppel ruling, because Sun had a reasonable basis for its position on that issue. The fact that a party decides not to pursue an appeal, or to abandon an appeal after initiating it, does not by itself indicate that the appeal was meritless. Sun asserts that it dismissed its appeal because the

² Saptalis also contends that Sun altered its theory of equivalence yet again on appeal. *See* Dkt. No. 161, at 15. It appears to me, however, that Sun’s theory of equivalency on appeal was not inconsistent with the position that Sun took during the summary judgment proceedings. *See* Dkt. No. 143, at 4. At a minimum, any inconsistency was not so great as to warrant a fee award.

appeal no longer made “economic sense.” It is not uncommon or unreasonable for a party to voluntarily dismiss its appeal if the party believes that any benefit that might be obtained no longer justifies the cost.

Saptalis contends that “[w]hether the appeal or the case made ‘economic sense’ for Sun has nothing to do with the merits, but everything to do with Sun’s motivation.” Dkt. No. 177, at 9. According to Saptalis, “Sun pursued a case in which it had no chance” solely because Sun wanted to delay the entry of Saptalis’s generic drug into the market. District courts are alert to the possibility that branded drug companies might file frivolous Hatch-Waxman lawsuits for the sole purpose of obtaining a stay of FDA approval to generic market entrants. *See Reckitt*, 2017 WL 4613643, at *3. An award of attorney fees might be justified if a party filed a frivolous suit solely to obtain an automatic stay of FDA approval. But here, Sun’s litigation positions were not frivolous. Considering the circumstances of the case as a whole, I am not persuaded Sun’s “committed strategy of protecting [its] intellectual property rights” and branded products was pretextual and therefore warrants an exceptional case finding. *Indivior*, 2020 WL 1955433, at *4; *see also Reckitt*, 2017 WL 4613643, at *3 (“Reckitt’s litigation position was not frivolous, and as the market here already included generic competitors at the time this suit was filed. The Court finds no basis here to conclude that Reckitt chose to file a frivolous case to delay entry of an additional generic manufacturer.”); *Bayer Schera Pharma AG v. Sandoz, Inc.*, No. 08 CIV. 03710, 2012 WL 13071816, at *4–6 (S.D.N.Y. Aug. 27, 2012) (rejecting argument that case was exceptional because plaintiff allegedly filed suit to delay defendant’s market entry where plaintiff’s patent infringement case was not frivolous).

(iv) Saptalis next appears to suggest that Sun intentionally reported the incorrect expiration date of the asserted patent to the FDA based on “an improper motive.” Dkt. No. 161,

at 18–19. I am not persuaded. The most likely explanation is that Sun mistakenly failed to account for a terminal disclaimer limiting the patent term when Sun calculated the expiration date. Sun later corrected that mistake without the need for court intervention. That conduct does not reflect that type of “extraordinary circumstances” that would justify an award of attorney fees.

(v) Saptalis also asserts that Sun failed to disclose the identity of its expert in violation of the court’s protective order, and thus “ambushed Saptalis with a summary judgment expert declaration.” Dkt. No. 161, at 19. According to Saptalis, that failure demonstrates that “Sun engaged in gamesmanship or simply failed to give the matter the serious attention it deserved.” *Id.* Sun responds that its expert “reviewed and signed the protective order before receiving any Saptalis confidential information,” but that Sun “inadvertently failed to serve the disclosure” in a timely fashion because Saptalis was in the process of changing counsel at the time. Dkt. No. 168, at 19. According to Sun, the conduct at issue did not require court intervention and caused no prejudice to Saptalis.

Again, I find that the conduct Saptalis identifies does not reflect the type of “extraordinary circumstances” that would justify an award of attorney fees. I am not persuaded that Sun was acting in bad faith, and I conclude that Saptalis suffered little, if any, prejudice from the untimely disclosure, because Saptalis ultimately raised no objection under the protective order to Sun’s expert. Moreover, there is little force to Saptalis’s contention that Sun “ambushed” Saptalis, and deprived Saptalis of the opportunity to develop a fulsome response to Sun’s expert declaration “given the short time to reply” to Sun’s opposition to the summary judgment motion. Dkt. No. 166-2, Exh. J, at 1. Saptalis never asked for an extension of time to remedy the alleged prejudice; instead, Saptalis has raised the issue for the first time in its fees motion. Saptalis’s contention that it was harmed by Sun’s “ambush” is thus not persuasive. Even if Saptalis had been harmed, I am

not convinced that Sun's untimely disclosure was intentional and was the type of conduct that would warrant an award of fees.

(vi) Finally, Saptalis asserts that Sun engaged in misconduct because it attempted to delay or avoid summary judgment proceedings by filing the present action in Delaware. I disagree. Saptalis initially challenged Sun's forum of choice, filing a motion to transfer this case to the Eastern District of New York. Dkt. No. 11. But Saptalis later voluntarily withdrew that motion and agreed to litigate the case in the District of Delaware. It was not misconduct for Sun file the present lawsuit in its forum of choice if it had a right to litigate in that forum. In light of Saptalis's decision to voluntarily withdraw its objection to Sun's forum of choice, I am satisfied that Sun was permissibly exercising its legal rights rather than engaging in misconduct. Nor do I think this case stands out from others because of Sun's decision to file a "protective suit" in the Eastern District of New York. *See* Dkt. No. 177, at 10. As one judge in this district has stated, "the ambiguities in the Hatch–Waxman Act put patent holders 'between a jurisdictional rock and a hard place: file suit in the forum of choice but risk losing patent protection if the suit is dismissed for personal jurisdiction, or file suit in the only known safe forum.'" *Pfizer Inc. v. Sandoz Inc.*, No. CIV.A 09-742, 2010 WL 256548, at *3 (D. Del. Jan. 20, 2010) (quoting *Abbott Labs. v. Mylan Pharm., Inc.*, No. 05 C 6561, 2006 WL 850916, at *8 (N.D. Ill. Mar. 28, 2006)). Consequently, patent holders have been "filing 'protective' ANDA suits with increasing frequency." *Id.* It is difficult to conclude that this case stands out from others because the patentee engaged in a practice that has apparently been going mainstream.

3. Although I find that none of Saptalis's claims by themselves is sufficient to merit an award of fees, *Octane Fitness* requires that Court evaluate all of the evidence as a whole to determine whether the case is exceptional. I conclude that none of Saptalis's claims, either viewed

alone or in conjunction with Saptalis's other claims, merits an exceptional case finding and an award of attorney fees.

4. Aside from the merits, Sun moves to strike a portion of Saptalis's reply brief, as well as several corresponding exhibits. Dkt. No. 180. Saptalis opposes, and requests an award of attorney fees for the cost of the additional briefing on the motion to strike. Dkt. No. 183. Sun's motion to strike is denied as moot. Even considering the material Sun requests me to strike, my conclusion is that the case is not exceptional. I also reject Saptalis's assertion that the motion to strike was improper and further demonstrates the exceptional nature of the case. Saptalis stretched a characterization far enough in its reply brief that the characterization could plausibly be interpreted as a new argument. It was not unreasonable for Sun to file a motion to strike.

CONCLUSION

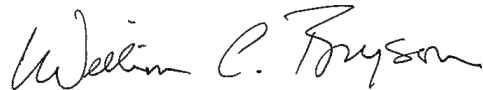
For the foregoing reasons, Saptalis's motion for attorney fees is denied. Sun's motion to strike is denied as moot.

This Memorandum Opinion and Order has been filed under seal because the parties filed their briefs under seal. Given the strong policy against non-public judicial proceedings, however, I will revisit the question of sealing this order. Accordingly, within seven days of the filing of this order, each of the parties shall advise me whether they believe any portions of this order need to remain sealed. If either party does not object to the unsealing of this order, that party can so advise my law clerk, Ryan Teel, by email at teelr@cafc.uscourts.gov. If either party objects to the unsealing of the order, in whole or in part, that party should so indicate in a filing with the court. With respect to any portion or portions of the order that a party believes should remain under seal, that party should explain, with specificity, why sealing that portion or portions of the order is necessary and justified. Before requesting that any portion of the order be sealed, counsel should

review my recent order in *Lipocine Inc. v. Clarus Therapeutics, Inc.*, C.A. No. 19-622, 2020 WL 4569473(D. Del. Aug. 7, 2020).

IT IS SO ORDERED.

SIGNED this 26th day of August, 2020.

Handwritten signature of William C. Bryson in black ink.

WILLIAM C. BRYSON
UNITED STATES CIRCUIT JUDGE