IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SILVERGATE PHARMACEUTICALS, INC., ***Plaintiff*,** ***v.*** **BIONPHARMA INC.,** ***Defendant.***	**Nos. 18-cv-1962, 19-cv-1067**

MEMORANDUM OPINION

GOLDBERG, J. **October 4, 2024**

Azurity Pharmaceuticals, Inc.[1] ("Azurity") brought this lawsuit against Bionpharma Inc. ("Bionpharma") for patent infringement based on Bionpharma's filing of an abbreviated new drug application ("ANDA"), No. 212408. Azurity claimed that Bionpharma's ANDA would infringe Azurity's U.S. Patent Nos. 9,669,008 (the "'008 patent"), 9,808,442 (the "'442 patent"), 10,039,745 (the "'745 patent"), and 10,154,987 (the "'987 patent").

After a five-day bench trial, the Honorable P. Leonard Stark found that Bionpharma did not infringe the asserted patents. See Silvergate Pharms. v. Bionpharma Inc., 2021 U.S. Dist. LEXIS 86207 (D. Del. Apr. 29, 2021). Bionpharma now brings a motion for attorneys' fees under 35 U.S.C. § 285, arguing that Azurity pursued the litigation for an improper purpose, made arguments that were objectively baseless, and acted in an unreasonable manner in litigating the

[1] Azurity was formerly known as Silvergate Pharmaceuticals, Inc., and is referred to as such in the case caption and various court documents.

case. On March 2, 20222, this matter was reassigned to me from Judge Stark's docket.[2] For the reasons set out below, Bionpharma's motion will be denied.

I. BACKGROUND

Azurity is the holder of New Drug Application ("NDA") No. 208686 for the oral liquid medication known as Epaned®, which was approved by the Food and Drug Administration ("FDA") for treating high blood pressure and other conditions. The active ingredient of Epaned® is enalapril, in the form of enalapril maleate. Enalapril was initially approved by the FDA in a tablet form in 1985, and Azurity created the liquid form Epaned® because children and elderly patients had difficulty swallowing tablets.

Bionpharma submitted an Abbreviated New Drug Application ("ANDA"), No. 212408, seeking approval for a generic version of Azurity's Epaned® product. Bionpharma's submission contained a "Paragraph IV certification" claiming that its product would not infringe Azurity's patents because it lacked certain elements recited in Azurity's patent claims. See Celgene Corp. v. Mylan Pharms., Inc., 17 F.4th 1111, 1117 (Fed. Cir. 2021). (D.I. 265 in 19-1067, Ex. 1.) Bionpharma also notified Azurity of the factual and legal bases for its noninfringement position, starting a 45-day window for Azurity to decide whether to employ a statutory provision that would place Bionpharma's ANDA on hold while infringement challenges were litigated. Azurity sued Bionpharma for patent infringement under the Hatch-Waxman Act, triggering an automatic stay on the FDA's approval process, for 30 months or until the infringement case was resolved. See 21 U.S.C. § 355(j)(5)(B)(iii)(I).

[2] Pursuant to 28 U.S.C. § 292(b), I have been designated to serve as a visiting judge for the District of Delaware to handle this matter and other District of Delaware cases.

In its Paragraph IV certification and throughout litigation, Bionpharma maintained that there was no infringement because, among other reasons, its product did not contain certain limitations present in Azurity's patent claims: (1) the "buffer" limitation, and (2) the "preservative" limitation. The "buffer" limitation recited "a buffer comprising about 0.8 to about 3.5 mg/ml citric acid and about 0.1 to about 0.8 mg/ml sodium citrate." The "preservative" limitation recited "about 0.7 to about 1.2 mg/ml sodium benzoate." Silvergate Pharms., 2021 U.S. Dist. LEXIS 86207, at *23. Azurity conceded that these claim limitations were not literally present in Bionpharma's ANDA product, but maintained that they were present as equivalents, invoking the "doctrine of equivalents." See Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 21 (1997). Specifically, Azurity asserted that the enalapril maleate (active ingredient) in Bionpharma's ANDA product would split apart to yield a buffer made from maleic acid, which would be equivalent to the buffer in the claim. Azurity also argued that a mixture of methylparaben and propylparaben in Bionpharma's ANDA satisfied the preservative limitation.

Under the scheduling order, either party was required to seek leave before filing a case-dispositive motion. Bionpharma sought permission to do so, and both parties now place substantial weight on those proceedings to support their respective positions in the present motion. I therefore summarize them here.

Judge Stark addressed Bionpharma's leave request in a May 5, 2020 telephone conference. (D.I. 123 in 19-1067 (May 5, 2020 Hr'g Tr).) During this conference, Bionpharma focused on two arguments: (1) "prosecution history estoppel" prevented Azurity from arguing the buffer limitation was satisfied under the doctrine of equivalents; and (2) Bionpharma's chosen preservative could not be equivalent to Azurity's sodium benzoate due to the "disclosure-dedication doctrine." Bionpharma's estoppel position was that Azurity, while attempting to secure its patents, made

statements and amendments that surrendered any right it might otherwise have had to claim ownership of equivalent buffers. As to the disclosure-dedication doctrine, Bionpharma argued that Azurity had disclosed a preservative made from methylparaben and propylparaben but did not claim it, which meant that such a preservative was "dedicated to the public" and could not be asserted as an equivalent. See Toro Co. v. White Consol. Indus., Inc., 383 F.3d 1326, 1333 (Fed. Cir. 2004).

Judge Stark denied Bionpharma leave to file its motion, stating, among other grounds, that he would benefit from expert testimony "to understand the full context of the totality of the prosecution history, … [and whether] those arguments rise to the level of clear and unmistakable disclaimers, [and] whether amendments … were made for reasons substantially related to patentability." (D.I. 123 in 19-1067 at 71:18-25.) Judge Stark stated that there remained "fact disputes that will be relevant to the resolution of one or perhaps all of the defendants' defenses [and that he would] greatly benefit from expert assistance at trial." (Id. at 69:17-22. 70:22-71:2.) Judge Stark further noted that Bionpharma would have the opportunity to argue that leave should have been granted and that "there was really never any merit … , likelihood [that] plaintiffs were going to win, … plaintiffs had to have known that, and that this … is an exceptional case [warranting an award of fees]." (Id. at 73:3-17.) The case then proceeded to discovery and trial.

After a five-day bench trial, Judge Stark entered judgment in favor of Bionpharma, finding that Azurity had not proved by a preponderance of the evidence that Bionpharma's ANDA infringed any of Azurity's asserted claims. Silvergate Pharms., 2021 U.S. Dist. LEXIS 86207. Judge Stark based this conclusion on five independent grounds. First, as to the buffer limitation, Judge Stark found that by amending that limitation while prosecuting the patent, Azurity had surrendered the ability to claim maleic acid as an equivalent to a citrate buffer. Second, Judge Stark

found that arguments Azurity made to the patent examiner had disclaimed buffers other than the one contained in the claim. Third, Azurity had not demonstrated that Bionpharma's product even contained a buffer at all. Fourth, to the extent there was a buffer, it was not equivalent to a citrate buffer because it did not function in the same way to achieve the same result. Finally, as to the preservative limitation, Judge Stark found that a methylparaben/propylparaben preservative was disclosed in Azurity's patent specification as an alternative to sodium benzoate and, therefore, could not be captured under the doctrine of equivalents. Azurity appealed Judge Stark's decision to the Court of Appeals for the Federal Circuit, which affirmed without an opinion. See Azurity Pharms., Inc. v. BionPharma Inc., No. 2021-1926, 2022 WL 703903 (Fed. Cir. Mar. 9, 2022).

Bionpharma now moves for attorneys' fees under 35 U.S.C. § 285, arguing that Azurity pursued this litigation for an improper purpose, made arguments that were objectively baseless, and litigated this case in an unreasonable manner.

II. LEGAL STANDARD

Under Section 285 of the Patent Act, a district court may award reasonable attorneys' fees "in exceptional cases." 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." Octane Fitness, LLC v. ICON Health & Fitness, Inc., 572 U.S. 545, 554 (2014). In assessing whether a case qualifies as exceptional, a district court exercises its discretion and considers the totality of the circumstances. Id. "A party's success on the merits of an ultimate issue in a patent case does not automatically render a case 'exceptional' for purposes of the attorney fee statute." Lighting World, Inc. v. Birchwood Lighting, Inc., 382 F.3d 1354, 1367 (Fed. Cir. 2004).

The party requesting fees must prove its entitlement by a preponderance of the evidence. OneSubsea IP UK Ltd. v. FMC Techs., Inc., 68 F.4th 1285, 1294 (Fed. Cir. 2023).

III. DISCUSSION

Bionpharma argues that fees should be awarded because Azurity's arguments were exceptionally meritless and it engaged in exceptionally unreasonable conduct in advancing those arguments. Those grounds are discussed below.

A. Merits of Azurity's Infringement Position

Bionpharma argues Azurity's lawsuit was exceptionally meritless because Azurity never had a plausible way to satisfy the "buffer" limitation. In Bionpharma's view, Azurity never had a colorable theory for overcoming amendment-based and argument-based estoppel. Bionpharma contends Azurity tried to compensate for a lack of merit by changing its position throughout the litigation, and that Azurity showed disinterest in the merits by refusing to review Bionpharma's ANDA pre-suit. Bionpharma argues these facts demonstrate that Azurity brought this lawsuit solely to obtain a stay and exclude Bionpharma from the market.

As described above, the "buffer" limitation required a "buffer comprising about 1.82 mg/ml citric acid and about 0.15 mg/mL sodium citrate dihydrate … ." '008 patent, claim 1. At trial, Azurity argued that the active ingredient in Bionpharma's ANDA, enalapril maleate, "dissociated" (broke apart) to yield a buffer made from maleic acid, which was purportedly equivalent to the citric acid buffer in the claims. Judge Stark found that Azurity was estopped from taking that position based on: (1) amendments made during the prosecution of the asserted patents, and (2) arguments made in response to the patent examiner's initial rejection. Additionally, Judge Stark found that even if estoppel did not apply, Azurity's proposed maleic acid buffer was: (a) not a buffer, and (b) not equivalent to a citric acid buffer. Although Bionpharma prevailed on several

grounds at trial, Bionpharma's present motion argues that just two of those grounds render this case exceptional, justifying attorneys' fees: (1) that Azurity was estopped due to amendments made during prosecution, and (2) that Azurity was estopped due to arguments made to the patent examiner.

1. Amendment-Based Estoppel

Throughout this litigation, Bionpharma asserted Azurity was estopped from claiming that a maleic acid buffer was equivalent to a citric acid buffer because Azurity had made amendments to its buffer limitation during patent prosecution. When a patentee responds to a patent examiner's preliminary rejection by narrowing a claim, the doctrine of "prosecution history estoppel" prevents the patentee from later arguing that the original, broader claim is equivalent to the narrower one. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 727 (2002). To invoke this doctrine, there must be a narrowing amendment made for purposes of patentability, and the accused equivalent must be within the surrendered subject matter. See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 344 F.3d 1359, 1366-67 (Fed. Cir. 2003) (en banc). Where these conditions are met, the doctrine will still not apply if the reason for the amendment had no more than a "tangential relation" to the accused equivalent. Pharma Tech Sols., Inc. v. LifeScan, Inc., 942 F.3d 1372, 1380 (Fed. Cir. 2019).

In applying for enalapril liquid patents, Azurity originally sought a buffer limitation of "about 1.82 mg/mL of citric acid." Silvergate Pharms., 2021 U.S. Dist. LEXIS 86207, at *74. The examiner rejected this claim as obvious, finding that the inventive step required sodium citrate dihydrate, which was absent from the claim. In response, Azurity amended the claim to read a buffer comprising "about 1.82 mg/mL of citric acid and about 0.15 mg/mL of sodium citrate dihydrate." Id. At trial, Azurity argued this was not a narrowing amendment because adding

sodium citrate to the claim merely "ma[de] express what had been implicit in the claim as originally worded" by Azurity. Interactive Pictures Corp. v. Infinite Pictures, Inc., 274 F.3d 1371, 1377 (Fed. Cir. 2001). Expert testimony was offered by Azurity to show that citric acid and sodium citrate dihydrate create identical ingredients when added to water. Silvergate Pharms., 2021 U.S. Dist. LEXIS 86207, at *75. Azurity reasoned that because citric acid would create sodium citrate, sodium citrate was implicitly contained in the earlier version of its claim. While Judge Stark agreed with Azurity's view of the science, he nevertheless found the amendment was narrowing because it increased the total number of molecules in the product: whatever amount of sodium citrate was created through the original claim, the amended claim increased that amount, making it narrowing. Judge Stark also found that Azurity's expert undermined his credibility by refusing to concede this basic mathematical fact. Id. at *91 n.12.

Azurity alternatively argued that estoppel should not apply because adding sodium citrate to the claim language bore no more than a tangential relation to the purported maleic acid buffer in Bionpharma's ANDA product. In Azurity's reading of the prosecution history, the amendment was made to clarify what was claimed—i.e., a buffer with both an acid and a salt—not to distinguish it from buffers made from entirely different acids and salts. According to Azurity, this clarification was achieved by making the inclusion of sodium citrate explicit rather than implied. Azurity relied on Eli Lilly & Co. v. Hospira, Inc., which found that the tangential-relation exception applied where "narrowing 'antifolate' to 'pemetrexed disodium' could not possibly distinguish the art cited in the obviousness ground of rejection," as pemetrexed disodium was known in the art. 933 F.3d 1320, 1330-31 (Fed. Cir. 2019). There, the Federal Circuit found that a narrowing amendment was made to avoid a specific prior art and did not disclaim other "functionally identical, pemetrexed salts"—i.e., those without disodium. Id. at 1330-31. Azurity

thus argued that adding sodium citrate to the claim made it clear that both an acid and a salt were present but had nothing to do with which acid and which salt. Judge Stark disagreed with Azurity's reasoning, concluding that "the objectively apparent reason for the narrowing amendment … is that both the identity and concentration of **both** components of the claimed buffer—[citric acid] **and** [sodium citrate]—are important to maintaining the long-term stability of the overall composition." Silvergate Pharms., 2021 U.S. Dist. LEXIS 86207, at *82 (emphasis in original).

Bionpharma now argues it was exceptionally meritless for Azurity to try to avoid amendment-based estoppel, focusing on Azurity's position that the amendment was non-narrowing. In Bionpharma's view, the "narrowing" could have been decided on the law pre-trial, meaning Azurity acted in bad faith by refusing to concede the obvious and insisting that expert testimony was needed. (Bionpharma's Brief, D.I. 323 in 18-1962, at 18.)

I am not convinced that this conduct was so exceptional as to warrant the imposition of fees. First, I note that Azurity did concede its amendment was narrowing for purposes of Bionpharma's motion for leave to file a dispositive motion, meaning the "narrowing" issue was not the basis for Judge Stark deciding the case should proceed to trial. (D.I. 123 in 19-1067, May 5, 2020 Hr'g Tr., at 43:11-16, 67:15-19.) Instead, Judge Stark determined that expert testimony could be relevant to Azurity's other arguments, such as that the amendment was not made for reasons of patentability. (Id. at 71-72.) Bionpharma does not presently argue that Azurity failed to offer relevant expert testimony on those points.

Additionally, even with the amendment being narrowing, Azurity could still potentially have succeeded in avoiding the effect of amendment-based estoppel had it prevailed on its theory that adding sodium citrate was tangential to the choice of acid—citric or maleic. Bionpharma has not offered a bright-line rule for when an amendment falls within the tangential relation exception.

See, e.g., Eli Lilly, 933 F.3d at 1331 (discussing the exception in the context of an amendment that narrowed the claim to one salt of the drug's active ingredient). Bionpharma does not cite a case that would have clearly demonstrated, ahead of trial, that adding sodium citrate was not tangential to the type of acid.

While Azurity's argument against the amendment being narrowing was weaker, it is not unusual for attorneys to assert alternative arguments, some stronger than others. See Centex Corp. v. United States, 486 F.3d 1369, 1375 (Fed. Cir. 2007) (noting that the defendant's "position as a whole was sufficiently supported by fair argument" even though "weak arguments were [also] raised"). In view of the "totality of [these] circumstances," Azurity's efforts to avoid amendment-based estoppel, while ultimately unsuccessful, do not warrant the imposition of fees. Octane Fitness, 572 U.S. at 554.

2. Argument-Based Estoppel

Bionpharma alternatively insists Azurity's infringement position was exceptional because Azurity lacked a colorable theory for overcoming argument-based estoppel. During the litigation, Bionpharma maintained that statements Azurity made in patent prosecution estopped it from claiming ownership of formulations that, like Bionpharma's, included ingredients not listed in Azurity's claims. Bionpharma prevailed on this argument at trial and now asserts that Azurity's efforts to rebut it were exceptionally meritless.

Bionpharma's argument-based estoppel defense rested on statements in Azurity's patent prosecution that: (1) "[i]n contrast [to the prior art formulations], the formulation of the present claims has only ***four*** ingredients along with enalapril and water"; and (2) "additional excipients in the [prior art] formulations are not needed or contemplated in the claimed enalapril liquid formulations as ***none of them are needed or necessary*** to produce an enalapril liquid formulation

of the present claims that is stable." Silvergate Pharms., 2021 U.S. Dist. LEXIS 86207, at *84 (quoting PTX-5 (D.I. 38-2) at SLVGT-EPA_0000873) (emphasis added by Judge Stark). Azurity's response to these statements was to claim they did not "evince a clear and unmistakable surrender of subject matter." Intendis GmbH v. Glenmark Pharms., Inc., 822 F.3d 1355, 1365 (Fed. Cir. 2016) (quotation marks omitted). Azurity relied on authority "that argument-based estoppel [is only] appropriate when the patentee has explicitly disavowed a specific feature in the prior art," whereas "additional statements meant to further distinguish the claimed invention from prior art do not constitute clear and unmistakable surrender." Baseball Quick, LLC v. MLB Advanced Media L.P., No. 11-cv-1735, 2014 WL 6850965, at *9 (S.D.N.Y. Dec. 4, 2014).

Judge Stark disagreed with Azurity's reading of the prosecution history, finding instead that "[Azurity]'s arguments … clearly and unmistakably disclaim[ed] buffers not containing citric acid and sodium citrate dihydrate at the claimed concentrations." Silvergate Pharms., 2021 U.S. Dist. LEXIS 86207, at *87. In doing so, Judge Stark found persuasive the testimony of Bionpharma's expert Dr. Moreton on how a person of skill in the art would read Azurity's statements to the examiner. Id. at *83-84.

Having reviewed the proceedings before Judge Stark, I conclude that Azurity's response to argument-based estoppel does not warrant the imposition of fees. Azurity relied on the fact that the standard for argument-based estoppel was high, and pointed to context from the prosecution history that it read as suggesting the statements in question were only meant to point out differences between Azurity's invention and specific prior art references—differences which did not include the presence or absence of citric acid. This argument was unpersuasive, but not so exceptional as to make a fee award appropriate.

B. Refusing to Review Bionpharma's ANDA

Bionpharma also argues Azurity could not have reasonably believed in its choice for an equivalent buffer because it had not reviewed Bionpharma's ANDA before filing suit. When this case was filed, and for some time after, Azurity only had access to Bionpharma's paragraph IV certification, which included no information about the ANDA product other than that it used enalapril maleate in an oral solution at a proposed strength of 1 mg/mL, and, in Bionpharma's opinion, it did not contain a buffer. Bionpharma had offered to let Azurity view the ANDA pre-suit subject to certain confidentiality conditions, but Azurity declined, and the parties now dispute whether Azurity acted reasonably in doing so. Bionpharma takes the view that Azurity failed to conduct a pre-suit investigation and brought the case without a basis for believing the product was infringing—in particular that it contained an equivalent to Azurity's citrate buffer.

Azurity's proffered reason for declining to view Bionpharma's ANDA was its objection to the conditions Bionpharma placed on access. Bionpharma argues that these objections were pretextual because the conditions were reasonable, reflecting instead Azurity's attempt to remain willfully blind. Bionpharma asserts that Azurity later agreed to the "essentially same confidentiality terms," meaning those terms could not have been objectionable. (Bionpharma's Brief, D.I. 323 in 18-1962, at 25.)

Having reviewed both the confidentiality terms Azurity rejected and those it later accepted, Bionpharma has not persuaded me that they are so similar as to justify an award of fees. Bionpharma originally offered terms that would have prevented Azurity's outside counsel from engaging in "any patent prosecution or any … work before or involving the FDA"—the area in which Azurity's lawyers have expertise. (See D.I. 265 in 19-1067, Ex. 1, at 45.) Those terms would have barred not just FDA regulatory work but prevented Azurity's attorneys from engaging in "any FDA counseling, litigation or other work before or involving the FDA." (Id.) In contrast,

under the terms Azurity later agreed to, its lawyers could continue to engage in patent prosecutions unrelated to the patents at issue in this lawsuit. (D.I. 34 in 18-1962, § 4(b).) Bionpharma has not sufficiently established that Azurity could not view the earlier terms as "unacceptable" given that they would have "barr[ed] … [an] entire outside law firm from engaging in any prosecution or FDA regulatory work … regardless of subject matter." In re Cyclobenzaprine, 693 F. Supp. 2d 409, 416-17 (D. Del. 2010); Novartis Pharms. Corp. v. Alkem Lab'ys Ltd. (In re Entresto (Sacubitril/Valsartan) Patent Litig.), 2022 U.S. Dist. LEXIS 112796, *15 n.2 (D. Del.).

I also note that, before filing suit, Azurity had a limited time to review the potential merits. See 21 U.S.C. § 355(c)(3)(C) ("[A]pproval [of an ANDA] shall be made effective immediately unless, before the expiration of 45 days . . . an action is brought for infringement of the patent . . . .) While Bionpharma had told Azurity that its product did not contain a buffer, Bionpharma has not explained why it would be unreasonable for Azurity to disbelieve that representation, given that Bionpharma's product was stable. See Novartis Pharms. Corp. v. Alkem Lab'ys Ltd., 2022 U.S. Dist. LEXIS 112796, *14 (D. Del.). I do not view it as exceptional conduct for Azurity to rely on the discovery process to verify its inference that the product contained an ingredient equivalent to a citrate buffer. Although that inference ultimately proved mistaken, given the above constraints, Azurity's conduct does not warrant the imposition of fees.

C. Changing Infringement Theories

Bionpharma further argues that Azurity delayed in identifying what ingredients of Bionpharma's ANDA product were equivalent to a citrate buffer, initially positing equivalents other than the one it settled on for trial (maleic acid). Bionpharma reasons that until Azurity identified an equivalent, it had no basis believing it would find one tangentially related to the sodium citrate amendment. Bionpharma asserts it took Azurity "over a year and a half after it

started filing the First Wave Suits" to identify maleic acid as its chosen equivalent, during which time Azurity repeatedly switched theories. (Bionpharma's Reply, D.I. 318 in 19-1067, at 3.) In Bionpharma's view, for Azurity to bring a lawsuit without first identifying all necessary claim limitations indicates that Azurity asserted infringement without a good-faith belief in the merits. In addition to claiming that this conduct was unreasonable, Bionpharma asserts that Azurity's delay in identifying an accused equivalent, is evidence of the weakness of its infringement position at trial.

While Azurity did change its position on the equivalent buffer, I am not convinced that Azurity's conduct demonstrates unreasonable conduct that warrants attorneys' fees. "It is not unusual," in the abstract, "for a party to refine and revise its [litigation] positions over the course of litigation." Sarif Biomedical LLC v. Brainlab, Inc., No. 13-846-LPS, 2016 WL 5422479, at *2 (D. Del. Sept. 27, 2016). ANDA litigation requires parties to compare patent claims against the product the defendant will ultimately market, and when more information is necessary to form an infringement theory, patentees may legitimately rely on the discovery process to obtain it. See Hoffmann La Roche, Inc. v. Invamed Inc., 213 F.3d 1359, 1364 (Fed. Cir. 2000) ("In the absence of [defendant's manufacturing] information, plaintiffs resort to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to confirm their belief and to present to the Court evidence that each and every defendant infringes one or more claims of the [asserted patents].").

While Azurity proposed several different ingredients as the possible buffer, those theories had a common theme: some ingredient in Bionpharma's ANDA product such as maleate, enalapril, or the parabens had natural buffering capacity that obviated the need for a separately added buffer. As Azurity proceeded through discovery, it attempted to identify the specific ingredient and

eventually settled on maleate. While Bionpharma accuses Azurity of taking "over a year and a half" from the filing of the complaint to make this decision, it was actually only eight months after the initial scheduling order and seven months before trial. I am not pursuaded that this conduct was exceptionally unreasonable, nor do I find the delay to be suggestive of an exceptionally meritless infringement position on the part of Azurity.

D. Obtaining the Automatic Stay

Bionpharma also asserts that Azurity brought this lawsuit not on the merits but only to obtain the automatic 30-month stay.

While a party's reasons for initiating litigation are relevant to an exceptional case finding, enforcing a statutory patent right is not improper in itself. Checkpoint Sys. v. All-Tag Sec. S.A., 858 F.3d 1371, 1375 (Fed. Cir. 2017). By contrast, improper motives could include bringing a case in bad faith, asserting meritless positions, or engaging in unreasonable litigation conduct. See Octane Fitness, 572 U.S. at 545, 555. For example, a party may act in bad faith by repeatedly promising to produce necessary evidence but then "fail[ing] to produce any written document or other credible evidence" on a key issue. Raniere v. Microsoft Corp., 887 F.3d 1298, 1301-02 (Fed. Cir. 2018).

Bionpharma asserts that Azurity's infringement position was so tenuous that the only benefit Azurity could have derived from this lawsuit was a stay precluding FDA approval of Bionpharma's ANDA. As described above, Bionpharma claims that Azurity failed to conduct a pre-suit investigation, repeatedly shifted its infringement theories, and refused to concede an "indisputable" point. For the reasons discussed previously, I am not persuaded by Bionpharma's interpretation of the litigation history. While Azurity likely did benefit from the automatic stay,

the mere assertion of that "statutory patent right" based on a "reasonable belief in infringement" would not, without more, render this case exceptional. Checkpoint Systems, 858 F.3d at 1375.

E. Discovery Conduct

Finally, Bionpharma asserts that Azurity's litigation conduct was exceptionally unreasonable. Most of Bionpharma's criticisms of Azurity's litigation conduct are intertwined with the merits and are therefore addressed above; for the reasons stated, I conclude that they do not make this case exceptional. Bionpharma's remaining argument is that Azurity pursued an unreasonable amount of discovery.

In alleging that "the amount of discovery Azurity sought was grossly excessive and intended to financially prejudice Bionpharma," Bionpharma points to the number of discovery requests without explaining why any of them were unnecessary to obtain relevant information. (Bionpharma's Brief, D.I. 323 in 19-1067, at 17.) Patent cases, especially those brought under the Hatch-Waxman Act, are typically complicated and may require extensive discovery, and Bionpharma does not claim that the amount of discovery in this case was exceptionally different from other cases. Bionpharma also fails to explain how the quantity was "grossly excessive." The mere number of requests sheds little light on whether they were appropriate. While I did not preside over the discovery process, I have reviewed what occurred and I conclude that Bionpharma has not demonstrated that Azurity's litigation conduct was exceptional.

IV. CONCLUSION

For the foregoing reasons, Bionpharma's motion for attorneys' fees will be denied.

An appropriate order follows.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SILVERGATE PHARMACEUTICALS, INC., ***Plaintiff*,** ***v.*** **BIONPHARMA INC.,** ***Defendant*.**	**Nos. 18-cv-1962, 19-cv-1067**

ORDER

AND NOW, this 4th day of October 2024, upon consideration of Defendant's Renewed Motion for Attorney Fees, Defendant's Brief in Support, Plaintiff's Brief in Opposition, Defendant's Reply in Support, and for reasons stated in the accompanying opinion, it is hereby **ORDERED** that the Motion is **DENIED**.

BY THE COURT:

/s/ Mitchell S. Goldberg
MITCHELL S. GOLDBERG, J.