IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVEN PHARMACEUTICALS, INC.,	:	
	:	
Plaintiff,	:	
	:	
v.	:	C.A. No. 18-699-LPS
	:	
AMNEAL PHARMACEUTICALS LLC,	:	
	:	
Defendant.	:	

MEMORANDUM ORDER

At Wilmington this **3rd** day of **September, 2021**:

Pending before the Court is Defendant Amneal Pharmaceuticals LLC's ("Amneal") motion for attorneys' fees filed pursuant to 35 U.S.C. § 285. (D.I. 232) Having reviewed the parties' briefs, declarations, exhibits, and notice of subsequent authority (*see, e.g.*, D.I. 233-34, 238-39, 243, 247), and having heard the parties' argument during the teleconference on April 20, 2021 (D.I. 248) ("Tr."), for the reasons stated below, **IT IS HEREBY ORDERED** that Amneal's motion (D.I. 232) is **DENIED**.

BACKGROUND

This case arose from Amneal's submission of Abbreviated New Drug Application ("ANDA") No. 211396, pursuant to 21 U.S.C. § 355(j), to the United States Food and Drug Administration ("FDA"), seeking approval to market a generic version of Plaintiff Noven Pharmaceuticals, Inc.'s ("Noven") Minivelle® estradiol transdermal patch. (D.I. 1 ¶ 5) On May 8, 2018, Noven sued Amneal, alleging infringement of U.S. Patent Nos. 9,833,419 (the "'419 patent"), 9,730,900 (the "'900 patent"), and 9,724,310 (the "'310 patent"). (*Id.* ¶ 4) Noven's filing of this lawsuit triggered an automatic regulatory stay of FDA approval of Amneal's ANDA

for up to 30 months, pursuant to 21 U.S.C. § 355(j)(5)(B)(iii). On May 22, 2018, Amneal answered the complaint, contending that its proposed drug product would not infringe the claims of the asserted patents and that those claims are invalid. (*See* D.I. 7)

In November 2019 and January 2020, the Court held a six-day bench trial on the parties' claims and defenses. (D.I. 200-06) On September 2, 2020, the Court issued a lengthy Opinion, finding that:

> (1) Amneal's product literally infringes the '419 patent; (2) Amneal's product does not infringe the '900 patent under the doctrine of equivalents ("DOE"); (3) Amneal's product does not infringe the '310 patent under the DOE; (4) the asserted patents are invalid for lack of enablement and written description under 35 U.S.C. § 112; and (5) the asserted patents are not invalid due to the on-sale bar of 35 U.S.C. § 102(b).

(D.I. 219 at 1-2) Relevant to the pending motion, the Court found, with respect to the lack of written description under 35 U.S.C. § 112, that:

> The record shows, instead, that, in light of everything a POSA [person of ordinary skill in the art] would have known (and would not have known) about ***transmucosal*** drug delivery systems, a POSA reading the specification would not have understood the inventor of the patents-in-suit to be in possession of the ***transmucosal*** embodiments.

(*Id.* at 76) (emphasis added)

Amneal filed the pending motion on November 20, 2020, seeking attorneys' fees on the ground that this case is "exceptional" within the meaning of 35 U.S.C. § 285, due to Noven's substantively weak litigation positions and unreasonable litigation conduct. (*See* D.I. 233)

LEGAL STANDARDS

In "exceptional" patent cases, a court may award "reasonable attorney fees" to the "prevailing party." 35 U.S.C. § 285. The Supreme Court has 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." *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545, 554 (2014). A party moving for attorneys' fees must demonstrate, by a preponderance of the evidence, that a case is "exceptional." *Id.* at 557-58. Ultimately, the Court must make a discretionary decision based on the totality of the circumstances. *See id.* at 554.

DISCUSSION

The parties do not dispute that Amneal is the prevailing party in this case. (*See* D.I. 233 at 4; D.I. 238 at 2) The Court must, therefore, determine whether this case is "exceptional" for purposes of attorneys' fees pursuant to Section 285.

Amneal's arguments for why this case is exceptional fall primarily into two categories. First, Noven's litigation positions – in particular on the asserted patents' lack of written description and enablement – were "objectively unreasonable." (*See* D.I. 233 at 5-14) Second, Noven brought and maintained this lawsuit against Amneal in bad faith in order to delay market competition. (*See id.* at 15-16) Viewing the record in its totality, the Court does not find by a preponderance of the evidence that this case is "exceptional" within the meaning of Section 285, for either or both of Amneal's reasons.

With respect to the purportedly exceptional weakness of Noven's litigation positions, Amneal contends that Noven "knew or should have known from the outset" that the asserted patents were invalid for lack of written description. (*Id.* at 2) Specifically, Amneal insists that three "undisputed" "invalidating facts" were "readily available" to Noven before it filed the complaint in May 2018: (1) the asserted patents claimed transmucosal patches; (2) the specification of the patents contained no description of transmucosal patches; and (3) Noven

knew that its inventor had never contemplated transmucosal patches.[1] (*See id.* at 5) Being aware of facts "from the outset" that later turn out to be determinative in the Court's analysis does not necessarily make a case "exceptional." *See, e.g.*, *Chrimar Sys., Inc. v. Foundry Networks, Inc.*, 976 F. Supp. 2d 918, 925 (E.D. Mich. 2013). Amneal falls short of showing how this case "stands out from others when judged without the benefit of the Court's resolution of contested issues." (D.I. 238 at 6)

Amneal's contention that the facts purportedly known by Noven "virtually ensured that the Asserted Claims in this case were invalid for lack of written description" (D.I. 233 at 6) is unpersuasive.[2] "Written description analyses are highly fact specific." *Nuvo Pharms. (Ir.) Designated Activity Co. v. Dr. Reddy's Labs. Inc.*, 923 F.3d 1368, 1383 (Fed. Cir. 2019); *see also Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1377 (Fed. Cir. 2017) ("[E]ach case involving the issue of written description must be decided on its own facts."). "[T]he level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010). That some courts have found invalidity for lack of written description in cases involving facts that are similar to those emphasized by Amneal here does not mean that there is "clear and well-settled" law that would "virtually ensure[]" a finding of invalidity. (*See* D.I. 233 at 6-7) (citing *Wyeth v. Abbott Labs.*, 2012 WL 175023, at *7-8

[1] Noven appears to dispute that it knew, at the time it filed the complaint, that its inventor had never contemplated a transmucosal embodiment. (*See* D.I. 238 at 12 n.8) If, as Noven suggests, it did not learn of this fact until the inventor's deposition during this litigation, that would further undermine Amneal's contention that Noven knew all along that invalidation based on lack of written description was an inevitability.

[2] Amneal was unable to cite any case which has been found exceptional based wholly or predominantly on a § 112 defense. (*See* Tr. at 15-16)

(D.N.J. Jan. 19, 2012), and *Boston Sci. Corp. v. Johnson & Johnson, Inc.*, 679 F. Supp. 2d 539, 554-55 (D. Del. 2010))

Given the fact-intensive inquiry of the written description defense, and the other evidence presented, Amneal's argument that "the facts known to Noven fully negated the presumption" of validity also fails.[3] (*See* D.I. 243 at 3) Because none of the facts Amneal alleges Noven "knew or should have known" would – either individually or in combination – necessarily "negate" the validity of the asserted patents, it follows that Noven's reliance on the presumption of validity was not objectively unreasonable.[4] Nor does the Court's decision to deny Noven's petition for a temporary restraining order ("TRO") against Mylan in an earlier-filed ANDA case involving the same asserted patents (*see* C.A. No. 17-1777 ("*Mylan*") D.I. 176) demonstrate that it was unreasonable for Noven to rely on the presumption of validity. In that decision, the Court noted that "the specification says very little about [transmucosal] embodiments," and concluded that it

[3] None of the cases cited by Amneal found a patentee's reliance on the presumption of validity was unreasonable, and none of these cases involved the fact-laden issue of written description. *See, e.g., IA Labs CA, LLC v. Nintendo Co. Ltd.*, 2012 WL 1565296, at *3 (D. Md. May 1, 2012) (on sale bar); *Rock Bit Int'l, Inc. v. Smith Int'l, Inc.*, 82 F. Supp. 2d 677, 677-78 (S.D. Tex. 1999) (on sale bar); *In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 2016 WL 9774861, at *3 (S.D. Ohio Sept. 28, 2016) (invalidating prior art); *Magnetar Techs. Corp. v. Six Flags Theme Parks, Inc.*, 2017 WL 962760, at *9 (D. Del. Mar. 13, 2017) (inventorship).

[4] Amneal's arguments in support of exceptionality rely heavily on its assertion that "Noven knew or should have known that its inventor had never contemplated or attempted, and certainly never in any sense 'possessed' the claimed transmucosal patches." (D.I. 233 at 8) However, assessing the sufficiency of written description "requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." *Ariad*, 598 F.3d at 1351. The Court did not treat the inventor's subjective testimony as dispositive evidence, instead finding it "corroborates [the Court's] conclusions." (*See* D.I. 219 at 75) Nor, indeed, did Amneal view the inventor testimony as dispositive; rather, it described it as "icing" and did not rush to present its written description defense upon obtaining the inventor's deposition testimony. (Tr. at 13; *see also id.* at 9 ("When we discovered the Mantelle [inventor] testimony, we started to get a whiff of this, we did not rush off and cut-and-paste because we wanted to work with our experts because we knew that invalidity turns on experts, not on some very unfortunate, nevertheless, not legally binding deposition testimony."))

could not "say at this point that Mylan's written description defense lacks substantial merit." (*See Mylan* D.I. 176 at 6-7) The TRO decision, however, was only a preliminary assessment that Noven could not demonstrate that Mylan was unlikely to succeed; it was not a final decision on the merits. A party is not necessarily acting unreasonably when it continues to litigate an issue after failing to prevail on that issue in connection with a preliminary motion seeking extraordinary relief.[5] Further support for the Court's conclusion that Noven reasonably litigated the written description issue is found in the facts that Amneal did not raise the written description (transmucosal) defense in its Paragraph IV notice, in its answer to the complaint, or in its initial invalidity contentions[6] – even after the *Mylan* TRO decision and after the deposition of the inventor. (*See* D.I. 238 Ex. 10 at 17; D.I. 7 at 24-25, 29-32; D.I. 238 Ex. 11 at 143-45)

Noven asserted reasonable, non-frivolous bases for the purported sufficiency of the patents' written description. It provided expert testimony from Dr. Richard Guy, an experienced pharmaceutical scientist, who testified that a POSA would understand from the prior art cited on the face of the patents, in combination with the specifications' references to "bioadhesive

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[5] Amneal directs the Court to *Innovation Scis., LLC v. Amazon.com, Inc.*, 842 F. App'x 555, 557-58 (Fed. Cir. 2021), in which the Federal Circuit affirmed an "exceptional case" finding based, at least in part, on the patentee's conduct after issuance of the claim construction order. (*See* D.I. 247) The district court had found that "Innovation's continued litigation after the *Markman* order issued was unreasonable" because "the *Markman* order notified Innovation that the '140 patent was legally insufficient either as patent ineligible subject matter or because it lacked a written description." *Innovation Scis., LLC v. Amazon.com, Inc.*, 2020 WL 4934272, at *2 (E.D. Va. Feb. 18, 2020). Every Section 285 case is fact-specific, so the *Innovation* analysis does not automatically mean that any other case is necessarily exceptional as well. More importantly, a definitive ruling from a court as to claim scope (via a claim construction order) is more likely to render certain arguments unreasonable thereafter than is a preliminary determination in the context of a TRO motion.

[6] In its November 2, 2018 initial invalidity contentions, Amneal merely listed "transdermal drug delivery system," in nearly-identical boilerplate language, as one of five limitations that were purportedly not described or enabled, without any discussion of the transmucosal embodiments. (*See* D.I. 238 Ex. 11 at 143-45)

polymer" and "adhesive polymer," that the inventor possessed the claimed transmucosal invention. (*See* D.I. 219 at 73-74) (citing D.I. 197 at 19-21; Guy Tr. 575) Noven also adduced evidence of the state of the art, which it contended may have informed "a POSA's understanding of the patents." (*See* D.I. 238 at 9; *see also* D.I. 215 at 3-15; Guy Tr. 571-86) The Court did not treat these arguments as unreasonable or frivolous and did not find resolving the parties' disputes to be an easy task. To the contrary, in its post-trial Opinion the Court devoted 15 pages to the issue of written description (and the related issue of enablement), which was nearly half of the entire Discussion section of the Opinion. (*See* D.I. 219 at 62-76) While Noven did not prevail on the written description issue, its position was not objectively unreasonable. Instead, the defense presented a triable issue on which Noven just happened to lose.[7]

Turning to Amneal's second broad basis for exceptionality, Amneal has failed to persuade the Court that Noven engaged in bad-faith litigation conduct. Amneal's arguments focus on Noven's "relentless pursuit of its claimed thirty months" regulatory stay despite the "knowledge that its claims were invalid." (D.I. 233 at 16) As already explained, however, Noven's litigation positions were not exceptionally meritless, and the Court has not found that Noven knew (or even should have known) that its claims were invalid. Noven's proposal of a trial date approximately six months prior to the end of the 30-month regulatory stay is within the

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[7] While the scheduling order in this case did not permit summary judgment motions without the Court's leave, had Amneal moved for summary judgment on its written description defense it is almost certain the Court would have denied the motion.

Amneal further contends that "[t]he facts known to Noven from the outset also rendered it extremely likely that its claims were invalid for failure to meet the enablement requirement." (D.I. 233 at 12) The Court's analysis and conclusions with respect to the reasonableness of Noven's position on enablement, and why Amneal's contentions do not make this an exceptional case, are essentially the same as explained above in connection with written description. The Court will not repeat them here.

range of this Court's typical practice in ANDA cases. The fact that there was already a generic drug on the market competing with Noven's branded drug further cuts against Amneal's assertion that Noven exploited the regulatory stay in bad faith to delay market competition. (*See* D.I. 238 at 13-14)

Amneal's other attempts to persuade the Court that Noven's litigation conduct renders this case exceptional are even weaker. For example, contrary to Amneal's suggestion, Noven's opposition to the consolidation of Amneal's case with earlier-filed cases was not unreasonable, as the Court agreed with Noven that "[the] Amneal [case] is in a materially different situation." (*See* D.I. 33) Nor was it unreasonable for the Amneal and Actavis (C.A. No. 18-758) cases to proceed on the same schedule, given the temporal proximity of their filing dates. Amneal also faults Noven for delaying the trial due to its expert witness' unavailability. (*See* D.I. 233 at 15) That scheduling conflict, however, was apparently created by the alternate trial dates proposed by the Court (*see* D.I. 172 ¶ 10, D.I. 199 at 15), and the trial eventually proceeded as scheduled.[8]

In sum, Amneal has not shown that this case stands out from others based on the substantive strength of Noven's litigation positions or the manner in which Noven litigated. These considerations – alone, in combination, and in the context of the totality of the circumstances – fail to render this case "exceptional" within the meaning of Section 285. Accordingly, the Court denies Amneal's motion for attorneys' fees.

HONORABLE LEONARD P. STARK
UNITED STATES DISTRICT JUDGE

[8] Given Amneal's failure to show that Noven litigated unreasonably, it is not necessary for the Court to consider Noven's contentions that Amneal pursued frivolous litigation positions. (*See* D.I. 238 at 15-18)