UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

GENENTECH, INC., a Delaware corporation,

Plaintiff,

v.

ELI LILLY AND COMPANY, an Indiana corporation,

Defendant.

Case No.: 18-CV-1518 JLS (JLB)

ORDER DENYING DEFENDANT'S MOTION FOR ATTORNEYS' FEES UNDER 25 U.S.C. § 285

(ECF No. 80)

Presently before the Court is Defendant Eli Lilly and Company's Motion for Attorneys' Fees Under 25 U.S.C. Section 285 ("Mot.," ECF No. 80-1). Plaintiff Genentech, Inc. filed a Response in Opposition to ("Opp'n," ECF No. 82) and Defendant filed a Reply in Support of ("Reply," ECF No. 83) the Motion. The Court took the matter under submission without oral argument pursuant to Civil Local Rule 7.1(d)(1). *See* ECF No. 84. After considering the Parties' arguments and the law, the Court **DENIES** Defendant's Motion.

BACKGROUND

Plaintiff Genentech, Inc. is the owner of U.S. Patent No. 10,011,654 (the "'654 patent"), entitled "Antibodies Directed to IL-17A/IL-17F Heterodimers." First Amended Complaint ("FAC") ¶¶ 3, 18, ECF No. 29. The '654 patent claims "methods of making

antibodies, including humanized antibodies, to the newly discovered IL-17A/F antigen." Opp'n at 2 (citing Ex. A, ECF No. 80-14 at 66:34-79:6, Example 1). Presently, Plaintiff does not have a product covered by the '654 patent. *See* Mot. at 7.

On July 2, 2018, simultaneous with the issuance of the '654 patent, Plaintiff commenced this action alleging Defendant Eli Lilly and Company infringed the '654 patent. FAC ¶¶ 3, 5, 26–43. Defendant markets a formulation of an antibody called ixekizumab as a treatment for moderate to severe plaque psoriasis and psoriatic arthritis in adults under the trademark Taltz. *Id.* ¶ 3. Plaintiff alleged that the ixekizumab antibody in Defendant's Taltz falls within the scope of protection of the '654 patent. *Id.* ¶ 26.

This action is part of a global dispute between Plaintiff and Defendant over the rights to this discovery. The Parties have litigated numerous international actions over Plaintiff's European patents related to the '654 patent, and foreign courts have examined the validity of Plaintiff's European patents. *See, e.g.*, *Eli Lilly & Co. v. Genentech, Inc*, [2019] EWHC 387 (Pat), Ex. Y, ECF No. 80-38 (finding Plaintiff's EP 1,641,822 B1, a European counterpart related to the '654 patent, invalid for obviousness); *Eli Lilly & Co. v. Genentech, Inc*, [2020] EWHC 261 (Pat), Ex. Z, ECF No. 80-39 (finding Plaintiff estopped from arguing EP 2,784,084 B1 claims are valid based on findings related to EP '822 patent). The findings of the UK courts are on appeal. Opp'n at 17.

After Plaintiff filed the present action, Defendant filed a motion to dismiss the original complaint and strike allegations therein. ECF No. 24. Before Plaintiff filed a response, the Parties jointly moved for leave to file an amended complaint, ECF No. 27, which the Court granted, ECF No. 28. Plaintiff then filed its FAC on October 17, 2018. ECF No. 29. On November 13, 2018, Defendant filed a second motion to dismiss alleging failure to state a claim and improper venue and moving to strike portions of Plaintiff's FAC. ECF No. 30. Shortly after Defendant filed the second motion to dismiss, Plaintiff filed an *ex parte* application for leave to seek expedited discovery related to Defendant's contentions that venue was improper in this District. ECF No. 34. The Court granted the motion and allowed limited discovery on the issue of venue. ECF No. 39. On September

12, 2019, the Court granted in part and denied in part Defendant's motion to dismiss, declining to strike portions of the FAC and finding venue was proper in this District, but also finding that Plaintiff's allegations as pleaded in the FAC were insufficient to support a claim for willful infringement. ECF No. 59. On October 4, 2019, Defendant filed its Answer and Affirmative Defense, pleading that the "asserted claims of the '654 patent are invalid under 35 U.S.C. § 112 for a lack of written description." ECF No. 63 at 7.

On April 2, 2019, Defendant filed a petition for Post Grant Review ("PGR") before the Patent Trial and Appeal Board ("PTAB"), challenging the patentability of all claims of the '654 patent as unsupported by written description and enablement under 35 U.S.C. § 112 and as anticipated under 35 U.S.C. § 102. *See generally* Ex. B, ECF No 80-15. On October 7, 2019, the PTAB issued an Institution Decision finding that it is more likely than not that the '654 patent claims are unpatentable based on a lack of written description. *See* Ex. E, ECF No. 80-18 at 11–12, 22–25.

On November 21, 2019, the Parties jointly moved to stay the instant case, ECF No. 69, and this Court granted the stay on November 26, 2019 pending a decision by the PTAB regarding the patentability of patent '654, ECF No. 72. Plaintiff requested four extensions on the deadline to file its Patent Owner Response before the PTAB, and Plaintiff ultimately never filed a response. Declaration of Katherine Helm ("Helm Decl.") ¶ 10, ECF No. 80-2. Plaintiff moved for an adverse judgement in the PTAB proceeding without ever making substantive arguments in favor of patent '654's validity before this Court or before the PTAB. Mot. at 1.

On February 26, 2020, Plaintiff moved for voluntary dismissal of this case with prejudice. ECF No. 73. On March 16, 2020, this Court granted Plaintiff's motion and declared Defendant the prevailing party. ECF No. 77. On March 30, 2020, the Parties filed a joint motion to bifurcate the "exceptional case" determination and attorneys' fees motion under Federal Rule of Civil Procedure 54(d)(2). ECF. No. 78. The Court granted the joint motion, ECF No. 79, and Defendant subsequently filed the instant Motion seeking a determination that this case is exceptional, ECF No. 80-1.

LEGAL STANDARD

Under 35 U.S.C. § 285, the court "in exceptional cases may award reasonable attorneys' fees to the prevailing party" in a patent infringement lawsuit. The Supreme Court construed this language in *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545, 553–54 (2014). Specifically, the *Octane* Court rejected the Federal Circuit's pre-*Octane* interpretation of the "exceptional case" language as "rigid and mechanical," holding that the prior method "impermissibly encumber[ed] the statutory grant of discretion to district courts." *Id.* at 553. *Octane* established a flexible approach: "[A] district court may award fees in the rare case in which a party's unreasonable conduct—while not necessarily independently sanctionable—is nonetheless so 'exceptional' as to justify an award of fees." *Id.* at 555.

Under *Octane*, a case may warrant a fee award if the litigation is objectively baseless, or if the litigation is brought in subjective bad faith. *Id.* In particular, a case is "exceptional" when it "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." *Id.* at 554. Courts may look to pre-*Octane* case law for guidance on whether a case was litigated in an unreasonable manner. *SFA Sys., LLC v. Newegg Inc.*, 793 F.3d 1344, 1349 (Fed. Cir. 2015). 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*, 572 U.S. at 554. To guide its discretion, a court may consider a non-exclusive list of factors, including: "frivolousness, motivation, objective unreasonableness (both in the factual and legal components of the case) and the need in particular circumstances to advance considerations of compensation and deterrence." *Id.* at n.6 (citing *Fogerty v. Fantasy, Inc.*, 510 U.S. 517, 534 n.19 (1994)). Additionally, *Octane* rejected the former requirement that patent litigants establish their entitlements to attorneys' fees by "clear and convincing evidence" in favor of a lower, preponderance of the evidence standard. *Id.* at 557–58.

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Finally, *Octane* does not mandate attorneys'-fee awards in all exceptional cases; *i.e.*, even if a court determines that a case is "exceptional," the court still has discretion to deny attorneys' fees. *See Ion Health & Fitness, Inc. v. Octane Fitness, LLC*, Nos. 2011–1521, 2011–1636, 2014 WL 4194609, at *3 (Fed. Cir. 2014) ("The Supreme Court's decision in *Octane* did not, however, revoke the discretion of a district court to deny fee awards even in exceptional cases."); *see also S.C. Johnson & Son, Inc. v. Carter-Wallace, Inc.*, 781 F.2d 198, 201 (Fed. Cir. 1986) ("Even an exceptional case does not require in all circumstances the award of attorney fees.").

ANALYSIS

The parties do not dispute that Defendant is a prevailing party as required by § 285. Therefore, the award of attorneys' fees turns on whether Defendant has carried its burden to establish this case is exceptional.

Defendant raises several arguments why this case is exceptional. Defendant argues that this case is exceptional because (1) Plaintiff's case was objectively baseless because the '654 patent claims are facially invalid; and (2) Plaintiff acted with subjective bad faith in initiating and persisting in these proceedings. *See* Mot. at 12–22. The Court discusses Defendant's arguments in turn, addressing Plaintiff's counterarguments where relevant.

I. Substantive Strength of Litigation Position

Defendant argues that Plaintiff's case was baseless because the '654 patent claims are facially invalid under controlling law. Mot. at 13–14. "To be objectively baseless, the infringement allegations must be such that no reasonable litigant could reasonably expect success on the merits." *Dominant Semiconductors Sdn. Bhd. v. OSRAM GmbH*, 524 F.3d 1254, 1260 (Fed. Cir. 2008) (citation omitted). Defendant contends that functional genus claims like those claimed in the '654 patent "have been specifically repudiated by both the Federal Circuit and corresponding PTO Guidance." Mot. at 4. Specifically, the Federal Circuit in *Amgen Inc. v. Sanofi* rejected the "newly characterized antigen test" as "flout[ing] basic principles of the written description requirement." 872 F.3d 1367, 1378 (Fed. Cir. 2017), *cert. denied*, 139 S. Ct. 787 (2019). Defendant argues that the patent

examiner applied the rejected newly characterized antigen standard to Plaintiff's application for the '654 patent, and mistakenly issued the patent on this basis. Mot. at 4–5.

Plaintiff argues that the '654 patent was issued by the United States Patent and Trademark Office ("USPTO" or "PTO"), and therefore it is presumed valid. Opp'n at 5. Plaintiff states that Defendant "points to no authority finding the presumption of validity is reduced by subsequent case law developments," and it is Defendant's burden to prove invalidity. *Id.* at 6 (citing *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 95 (2011)).

The Federal Circuit decided *Amgen* on October 5, 2017, while prosecution of the '654 patent was still ongoing. In response to *Amgen*, the USPTO issued a Memorandum on February 22, 2018 that instructed examiners not to allow claims based on the newly characterized antigen test:

> In view of the *Amgen* decision, adequate written description of a newly characterized antigen alone should not be considered adequate written description of a claimed antibody to that newly characterized antigen, even when preparation of such an antibody is routine and conventional.
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> . . .
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> The [earlier] training materials [utilizing the newly characterized antigen test] are outdated and should **not** be relied upon as reflecting the current state of the law regarding 35 U.S.C. §§ 101 and 112.

Ex. X. at 2–3, ECF No. 80-37 (emphasis in original).

It cannot be reasonably disputed that Plaintiff was aware of the *Amgen* decision while prosecution of the '654 patent was ongoing. In addition to *Amgen* being "widely publicized and discussed in the patent law community," Mot. at 6, Plaintiff's Assistant General Counsel sat on a panel on April 11, 2018, that described how "[t]he Federal Circuit's decision in *Amgen Inc. v. Sanofi* eliminated the 'well-characterized antigen' test for compliance with the written description requirement for antibodies[,]" Ex. 7 at 10, ECF

No. 80-9. Moreover, Plaintiff argued in another action that a patent covering antibodies lacked sufficient written description. *See Baxalta Inc. v. Genentech, Inc.*, No. CV 17-509-TBD, 2018 WL 3742610, at *7 (D. Del. Aug. 7, 2018).

Therefore, the question before the Court is whether the *Amgen* decision affected the validity of the '654 patent and placed Plaintiff in an exceptionally weak litigation position.

A. Presumption of Validity

Section 282(a) of the Patent Act provides that "[a] patent shall be presumed valid," and that "[t]he burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity." 35 U.S.C. § 282(a). The party asserting invalidity "has the added burden of overcoming the deference that is due to a qualified government agency presumed to have properly done its job, which includes one or more examiners . . . whose duty it is to issue only valid patents." *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1304 (Fed. Cir. 2008) (quoting *Am. Hoist & Derrick Co. v. Sowa & Sons*, 725 F.2d 1350, 1359 (Fed. Cir. 1984)); *see also Hyatt v. Kappos*, 625 F.3d 1320, 1334 (Fed. Cir. 2010) (en banc) (recognizing the deference owed to the USPTO as "the knowledgeable agency charged with assessing patentability"). "The party supporting validity has no initial burden to prove validity, having been given a procedural advantage requiring that he come forward only after a prima-facie case of invalidity has been made." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983).

Defendant argues that Plaintiff "ignored controlling law and relied on what it knew to be a rejected legal standard . . . as the basis to overcome written description rejections by the PTO." Mot. at 4. Therefore, Plaintiff "repeatedly evaded its duty to notify the Examiner," and as a result, the "Examiner mistakenly allowed the patent on this rejected standard[.]" *Id.* at 4–5. Plaintiff counters that Defendant "has never alleged that the '654 patent is unenforceable due to inequitable conduct . . . [and Defendant] cites no authority that [Plaintiff] had a duty to disclose the *Amgen* decision during prosecution." Opp'n at 16. Defendant argues that the Court need not determine whether Plaintiff's actions during patent prosecution amount to inequitable conduct to find that this case is exceptional. *See*

Reply at 5–6. While Defendant correctly states that the "exceptional case analysis . . . considers whether a plaintiff's conduct is unreasonable with respect to the factual and legal components of the case," *id.* at 6, Defendant argues that Plaintiff's litigation was baseless from its inception, *see id.* at 20. Given that Plaintiff initiated litigation immediately upon issuance of the '654 patent, it is reasonable for Plaintiff to rely on the '654 patent's presumption of validity unless the patent was invalid. Therefore, the Court will examine whether inequitable conduct invalidated the '654 patent, which would render Plaintiff's initiating this action objectively unreasonable. Otherwise, the presumption of validity provides Plaintiff with some basis for suing Defendant for patent infringement.

An otherwise valid patent may be rendered unenforceable by virtue of inequitable conduct committed during the prosecution of the patent application before the USPTO. *Glaverbel Societe Anonyme v. Northlake Marketing & Supply, Inc.*, 45 F.3d 1550, 1556 (Fed. Cir. 1995). Patent applicants "have a duty to prosecute patent applications in the [USPTO] with candor, good faith, and honesty." *Honeywell Int'l Inc. v. Universal Avionics Sys. Corp.*, 488 F.3d 982, 999 (Fed. Cir. 2007). "A party asserting inequitable conduct must prove by clear and convincing evidence that a patent applicant breached that duty by (1) 'fail[ing] to disclose material information or submit[ting] materially false information to the PTO' with (2) 'intent to mislead or deceive the examiner.'" *Advanced Magnetic Closures, Inc. v. Rome Fastener Corp.*, 607 F.3d 817, 829 (Fed. Cir. 2010) (quoting *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897, 913 (Fed. Cir. 2007)) (alterations in original). The nondisclosure or misrepresentation must meet threshold levels of both materiality and intent. *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995). Because a patent is presumed valid under 35 U.S.C. § 282, inequitable conduct requires proof by clear and convincing evidence. *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 551 (Fed. Cir. 1990).

Materiality is not limited to prior art, but instead embraces any information that a reasonable examiner would be substantially likely to consider important in deciding whether to allow an application to issue as a patent. *GFI, Inc. v. Franklin Corp.*, 265 F.3d

1268, 1274 (Fed. Cir. 2001) (citing *Akron Polymer Container Corp. v. Exxel Container, Inc.*, 148 F.3d 1380, 1382 (Fed. Cir. 1998)). Pursuant to 37 C.F.R. § 1.56(b),

> information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and
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> (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim, or
>
> (2) It refutes, or is inconsistent with, a position the applicant takes in
>
> (i) Opposing an argument of unpatentability relied on by the Office, or
>
> (ii) Asserting an argument of patentability . . .

Here, the patent examiner previously rejected claims of the '654 patent for failure to comply with the written description requirement. Ex. O at 6, ECF No. 80-28. In August 2016, Plaintiff argued the '654 patent claims were supported by adequate written description and overcame the examiner's rejection by explicitly relying on the newly characterized antigen test. *Id.* at 6–7 (citing Ex. W at Example 13, page 46, ECF No. 80-36). Therefore, it appears the patent examiner would not have found the claims patentable but for the application of the newly characterized antigen test. After the *Amgen* court rejected the newly characterized antigen test in October 2017, it stands to reason that the patent examiner should have reexamined these claims for their validity under the written description standard articulated in *Amgen*. It is unclear from the evidence before the Court whether the patent examiner did reevaluate the '654 patent claims in light of *Amgen*.

Defendant argues Plaintiff failed to disclose the change in law to the patent examiner, despite having numerous opportunities to do so before the patent was issued on July 3, 2018. Mot. at 7–8. Plaintiff had interviews with the examiner on December 12, 2017 and January 2, 2018. Exs. Q, R, ECF Nos. 80-30, 80-31. Plaintiff had further contact with the examiner after the USPTO issued the February Memorandum on *Amgen*, including filing corrected application papers. *See* Exs. S, T, U, V, ECF Nos. 80-30–80-35.

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The patent examiner, whose "duty it is to issue only valid patents," *PowerOasis, Inc.*, 522 F.3d at 1304, already should have been aware of *Amgen* during prosecution of the '654 patent because of the USPTO's memorandum on the subject. Indeed, other courts have found that it was reasonable for a patent applicant to assume that the examiner was aware of important legal decisions issued while the patent was still undergoing prosecution, and therefore "it was not unreasonable for [the plaintiff] to begin its litigation analysis with the presumption of validity that initially attached to such patents." *CertusView Techs., LLC v. S & N Locating Servs., LLC*, 287 F. Supp. 3d 580, 586 (E.D. Va. 2018); *see also DietGoal Innovations LLC v. Chipotle Mexican Grill, Inc.*, No. 2:12-CV-00764-WCB, 2015 WL 1284826, at *2 (E.D. Tex. Mar. 20, 2015) (finding that patent "issued well after [relevant Supreme Court] decisions came down is prima facie evidence against" position that patent was "obviously invalid"). Here, the patent was undergoing prosecution for eight months after the Federal Circuit issued its decision in *Amgen* and four months after the USPTO issued the memorandum advising examiners not to use the newly characterized antigen test. This refutes Defendant's assertion that the litigation was "baseless." It was not unreasonable for Plaintiff to assume its patent was valid because the examiner presumably examined and issued the patent under *Amgen*.

Defendant has not met the threshold burden of showing materiality, and there is no evidence before the Court that Plaintiff intended to deceive the examiner. In light of the memorandum on *Amgen* issued by the USPTO, Plaintiff's disclosure of the *Amgen* decision would have been cumulative under 37 C.F.R. § 1.56(b). Therefore, Plaintiff was not required to disclose the *Amgen* decision to the patent examiner because such a disclosure would have been cumulative and therefore immaterial.

To overcome the presumption of validity, Defendant must prove by clear and convincing evidence that Plaintiff committed inequitable conduct. Here, Defendant has not carried its burden. Accordingly, the Court finds that Plaintiff could rely on the '654 patent's presumption of validity and there was a reasonable basis to bring this infringement action.

When the newly characterized antigen test was rejected in *Amgen*, Plaintiff was on notice that the '654 patent claims were susceptible to attack under the written description requirement. However, the Court finds Plaintiff's position immediately after the issuance of '654 patent was not exceptionally weak because the '654 patent was presumptively valid. *See CertusView Techs., LLC*, 287 F. Supp. 3d at 587 (finding that infringement claims were not "objectively unreasonable" where "there were no governing precedents to guide [the plaintiff] that found nearly identical claims invalid"). It was not "clear that the case should never have been brought from the outset." *Effective Expl., LLC v. BlueStone Nat. Res. II, LLC*, No. 216CV00607JRGRSP, 2018 WL 466246, at *2 (E.D. Tex. Jan. 18, 2018). Therefore, it was reasonable for Plaintiff to initiate the present action based on the '654 patent.

B. Developments After Patent Issuance

Having found that Plaintiff's patent was not invalid for inequitable conduct, Plaintiff "ha[d] the right to vigorously enforce its presumptively valid patent." *Homeland Housewares LLC v. Sorensen Research & Dev. Trust*, 581 Fed. Appx. 877, 881 (Fed. Cir. 2014). With this presumption in mind, Defendant next argues that Plaintiff persisting in this litigation was objectively unreasonable because the '654 patent was invalid under *Amgen*. *See* Mot. at 13–14.

While Plaintiff is afforded a presumption of validity in the '654 patent, Plaintiff "must continually assess the soundness of pending infringement claims." *Taurus IP, LLC v. DaimlerChrysler Corp.*, 726 F.3d 1306, 1328 (Fed. Cir. 2013). The statutory presumption of validity does not relieve Plaintiff of its obligation under Federal Rule of Civil Procedure 11 to certify that the claims set forth in its First Amended Complaint are warranted by existing law. Indeed, "all plaintiffs have a duty to critically assess the merits of their case prior to suit. . . . The issuance of a patent cannot and should not be a license to sue with abandon." *Finnavations LLC v. Payoneer, Inc.*, No. 1:18-CV-00444-RGA, 2019 WL 1236358, at *2 (D. Del. Mar. 18, 2019) (granting attorneys' fees because the plaintiff asserted "clearly patent ineligible claims").

Cases where subsequent changes in the legal landscape called into question the validity of a patent are instructive here. In *Inventor Holdings*, the district court granted attorneys' fees based on the weakness of the plaintiff's patent after the Supreme Court decision in *Alice Corp. v. CLS Bank International*, 573 U.S. 208 (2014), and the need to deter future "wasteful litigation." *Inventor Holdings, LLC v. Bed Bath & Beyond Inc.*, No. CV 14-448-GMS, 2016 WL 3090633, at *3 (D. Del. May 31, 2016), *aff'd*, 876 F.3d 1372 (Fed. Cir. 2017). The *Inventor Holdings* district court held that "by the time of the *Alice* decision, [the plaintiff] was on notice that its claims, much like the claims in *Bilski* [*v. Kappos*, 561 U.S. 593 (2010),] and *Alice*, covered an abstract idea and that the introduction of a computer into these claims did not alter the analysis," meaning that the business method claims were objectively ineligible under 35 U.S.C. § 101 by the time of *Alice*. *Id.* at *4–5. The Federal Circuit concluded that the claims at issue were "manifestly directed to an abstract idea" and agreed with the district court that the "asserted claims were plainly invalid in view of *Alice* and its reasoning." *Inventor Holdings, LLC*, 876 F.3d at 1378–79. The Federal Circuit affirmed the district court's award of attorneys' fees and held that "[i]t was [the plaintiff]'s responsibility to reassess its case in view of new controlling law." *Id.*

Here, Plaintiff argues that the *Amgen* court did not establish a bright-line rule invalidating all functional antibody genus claims, so Plaintiff was monitoring multiple developments to assess the continuing soundness of its infringement claims. *See* Opp'n at 6–7, 13–14. First, Plaintiff claims that it was waiting for the outcome of the *Amgen* remand trial and renewed motion for judgment as a matter of law. *See id.* at 13–14. The *Amgen* remand trial concluded in February 2019, and the jury found *Amgen*'s patent claims, by Plaintiff's own admission "the claims most similar to the '654 patent claims," lacked written description support and were invalid. Opp'n at 13; *see Amgen Inc. v. Sanofi*, No. CV 14-1317-RGA, 2019 WL 4058927, at *1 (D. Del. Aug. 28, 2019), *aff'd sub nom. Amgen Inc. v. Sanofi, Aventisub LLC*, 987 F.3d 1080 (Fed. Cir. 2021). Plaintiff contends it also was waiting for the district court's decision on Amgen's renewed motion for judgment as a matter of law as to the written description support for the broader claims.

Opp'n at 13–14. The district court dismissed the JMOL motion as moot on August 28, 2019. *See generally Amgen*, 2019 WL 4058927.

Second, Plaintiff claims it was "monitoring the Federal Circuit's general trend toward requiring a higher level of disclosure to satisfy the written description requirement." Opp'n at 14. Plaintiff cites to three cases that demonstrate this "general trend." Opp'n at 14 (citing *Idenix Pharm. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149 (Fed. Cir. 2019); *Purdue Pharma L.P. v. Iancu*, 767 F. App'x 918 (Fed. Cir. 2019); *Quake v. Lo*, 928 F.3d 1365 (Fed. Cir. 2019)). These cases invalidated patent claims based on lack of written description support. *Idenix Pharm. LLC*, 941 F.3d at 1165–66; *Purdue Pharma L.P.*, 767 F. App'x at 923–25; *Quake*, 928 F.3d at 1367, 1374. Defendant points out that these post-*Amgen* cases are consistent with the law that existed at the time Plaintiff initiated the present action. Reply at 2. Additionally, the decisions Plaintiff cites were issued months before Plaintiff voluntarily dismissed this action. The Federal Circuit decided *Purdue* in April 2019, *Quake* in July 2019, and *Idenix* in October 2019.

Finally, when the PTAB instituted the PGR, Plaintiff was faced with defending the '654 patent at a lower standard of proof than before a jury. Opp'n at 14–15. Although Defendant would have needed to prove invalidity by clear and convincing evidence in this Court, Defendant would only need to meet the preponderance of the evidence standard in the PGR. Opp'n at 15 (citing 35 U.S.C. § 326(e); *Microsoft Corp.*, 564 U.S. at 95). Plaintiff claims this "changed the calculus considerably." *Id.*

Plaintiff admits that these subsequent developments "cast considerable doubt over whether [Plaintiff] would succeed in defending the validity of the '654 patent claims." Opp'n at 14. By Plaintiff's own admissions, Plaintiff was aware of its weakened litigating position by August 2019 at the latest. This was almost six months before Plaintiff moved to voluntarily dismiss this action. Plaintiff persisted litigating a case it had "considerable doubt" over for months, during which time this Court decided Defendant's second motion to dismiss, Defendant filed an answer, the PTAB issued its institution decision, the parties

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moved to stay the present action, and Plaintiff requested four extensions to file its Patent Owner Response before the PTAB.

This case is unusual because the significant change in the law that weakened Plaintiff's patent occurred during prosecution instead of after issuance. Therefore, the '654 patent's presumption of validity is in tension with Defendant's assertion that the '654 patent is clearly invalid for lack of written description. Ultimately, the Court has made very little in the way of substantive findings in this case. *See Munchkin, Inc. v. Luv n' Care, Ltd.*, 960 F.3d 1373, 1375 (Fed. Cir. 2020) (reversing district court grant of attorneys' fees where the merits of certain arguments were never fully adjudicated before the court). The Court has not undertaken claim construction or examined the validity of Plaintiff's patent in light of *Amgen*. A significant body of law has developed around *Alice*, whereas the same is not yet true for *Amgen*. The *Amgen* court held that "[a]n adequate written description must contain enough information about the actual makeup of the claimed products—'a precise definition, such as by structure, formula, chemical name, physical properties, or other properties, of species falling within the genus sufficient to distinguish the genus from other materials,' which may be present in 'functional' terminology 'when the art has established a correlation between structure and function.'" *Amgen Inc.*, 872 F.3d at 1378 (quoting *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1350 (Fed. Cir. 2010)). Further, the *Amgen* court reminds us that "[a] determination that a patent is invalid for failure to meet the written description requirement of 35 U.S.C. § 112, ¶ 1 is a question of fact[.]" *Id.* at 1379 (quoting *Ariad*, 598 F.3d at 1355). The Court did not undertake this fact-based inquiry on the '654 patent, and it does not endeavor to do so here. While the facts tend to indicate Plaintiff's litigation position was weakened, the Court cannot go so far as to find that the patent was facially invalid, as Defendant claims. Unlike the issuance of *Alice* in *Inventor Holdings*, no single event after issuance "plainly invalid[ed]" the '654 patent's asserted claims. *See Inventor Holdings, LLC*, 876 F.3d at 1378–79. Therefore, the Court does not attempt to draw lines as to when it became unreasonable to continue

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litigating the present action when Plaintiff's case was founded on a presumptively valid patent.

Additionally, Defendant is seeking an estimated $10 million in attorneys' fees. Mot. at 25. Plaintiff argues that Defendant "incurred such high costs for the PGR precisely because the written description issues and the science in the case are complex." Opp'n at 5. Defendant claims that, contrary to Plaintiff's assertion, the expense of the PGR petition "reflect[s] how important Taltz® is to [Defendant] and the patients it serves, and the high stakes associated with a petition that . . . requires a single presentation of all of the evidentiary and legal arguments up front." Reply at 5 (citation omitted). The Court agrees with Plaintiff. Although it is true that the PGR petition must be comprehensive, the length and cost tend to show that this is not so straightforward a case as Defendant would have this Court believe. It would be speculative for the Court to find Plaintiff's patent clearly invalid under *Amgen* when the Court has not undertaken the fact-intensive examination necessary to support such a finding.

Although it appears that Plaintiff likely should have terminated this action sooner, Plaintiff was not unreasonable in instituting the instant litigation because the '654 patent is afforded the presumption of validity. Although Plaintiff's litigation position was weak after *Amgen*, without more from Defendant, "[s]uch a superficial case cannot support a finding of exceptionality." *Munchkin, Inc.*, 960 F.3d at 1380. Accordingly, this factor weighs against an exceptional case finding.

II. Manner of Litigation

Turning to the second factor, the manner in which the case was litigated, Defendant argues that Plaintiff acted in subjective bad faith in prosecuting the '654 patent, initiating this litigation, and then maintaining what Plaintiff knew was an "unwinnable" case. Reply at 1.

The Federal Circuit has affirmed findings of litigation misconduct based on the patentee's destruction of relevant documents and lodging of incomplete and misleading extrinsic evidence. *Eon-Net LP v. Flagstar Bancorp*, 653 F.3d 1314, 1324–25. (Fed. Cir.

2011). Other factors tending to show the case was litigated in an unreasonable manner include "a pattern of litigation abuses characterized by the repeated filing of patent infringement actions for the sole purpose of forcing settlements, with no intention of testing the merits of one's claims," *SFA Sys., LLC*, 793 F.3d at 1350, and "an overall vexatious litigation strategy and numerous instances of litigation misconduct," *Monolithic Power Sys., Inc. v. O2 Micro Int'l Ltd.*, 726 F.3d 1359, 1366 (Fed. Cir. 2013).

First, Defendant argues that Plaintiff engaged in bad faith conduct in procuring the '654 patent. Mot. at 5. Defendant contends that Plaintiff "made no mention of the binding legal precedent that eviscerated its patentability arguments to the Examiner." *Id.* at 7. In response, Plaintiff maintains that "[i]t properly obtained the '654 patent in good faith." Opp'n at 19.

Although the Court found that Plaintiff was not required to disclose the *Amgen* decision to the USPTO, *see supra* Section I.A., Plaintiff's failure to do so was not in the spirit of good faith patent prosecution. *Amgen* was a highly relevant legal development that explicitly invalidated Plaintiff's previous arguments. Although the Court presumes that the patent examiner reexamined Plaintiff's claims under *Amgen* based on the USPTO's memorandum, the '654 patent's prosecution history indicates that but for the application of the newly characterized antigen test, the patent examiner would have found the claims unpatentable for lack of written description. Therefore, a patent applicant acting in good faith would have updated the examiner about a subsequent legal development that invalidated its previous argument. Waiting to see if the patent examiner made the connection between *Amgen* and Plaintiff's previous position does not demonstrate candor before the USPTO. *See, e.g.*, *Kingsland v. Dorsey*, 338 U.S. 318, 319 (1949) ("[T]he relationship of attorneys to the [USPTO] requires the highest degree of candor and good faith." (quotations omitted)). The Court does not condone Plaintiff's behavior. Although Plaintiff's patent was presumptively valid, Plaintiff's actions before the USPTO were unreasonable.

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Second, Defendant argues that Plaintiff engaged in bad faith conduct by initiating the '654 patent dispute before this Court when it had notice from Defendant that the claims of the '654 patent would be held invalid under controlling law. Mot. at 14. Defendant argues that the PTAB PGR institution decision confirmed that the claims of the '654 patent were more likely than not unpatentable under *Amgen* for lack of written description, but Plaintiff continued to pursue this infringement action. *Id.* at 16–17. In response, Plaintiff responds that its "litigation positions were not unreasonable, as evidenced by the substantial effort required to mount an invalidity challenge at the PGR and the hard-fought battle between the parties in the UK on related patents." Opp'n at 19.

As an initial matter, the Court is not persuaded by Plaintiff's argument that the "hard fought battle between the parties in the UK on related patents" is evidence of good faith litigation before this Court. Opp'n at 19. The '654 patent is subject to different standards of patentability than Plaintiff's European patents. Therefore, while Plaintiff may have stated a feasible claim in a foreign jurisdiction, Plaintiff still had a duty to litigate in good faith before this Court. Part of Plaintiff's duty includes ensuring that its claims are viable under the law of this jurisdiction. *See Taurus IP, LLC*, 726 F.3d at 1328. However, the Court has already determined that Plaintiff was entitled to a presumption of validity in the '654 patent because the patent was issued by the USPTO immediately before Plaintiff initiated this litigation. *See supra* Section I.A. Therefore, Plaintiff did not have an improper motive to bring this action. *See Checkpoint Sys., Inc. v. All-Tag Sec. S.A.*, 858 F.3d 1371, 1375 (Fed. Cir. 2017) ("[M]otivation to implement the statutory patent right by bringing suit based on a reasonable belief in infringement is not an improper motive.").

As further evidence of Plaintiff's bad faith, Defendant points to Plaintiff never litigating any substantive aspect of the '654 patent before this Court or the PTAB. Mot. at 15. Plaintiff did not offer a preliminary response to Defendant's PGR petition on the merits, and Plaintiff did not file a patent owner response or any substantive paper defending the patentability of the '654 patent claims. *Id.* at 17–18. Defendant argues that Plaintiff's "posturing and tactical maneuvering" was a tactic to hide that Plaintiff's positions were

"unreasonable and untenable." *Id.* at 18. Defendant claims Plaintiff's avoidance of litigating on the merits "was part of an unceasing worldwide strategy to extract a royalty" from Defendant's sales of Taltz. *Id.* at 1. Plaintiff argues that "[a]t the PGR institution stage, the patent owner is not even required to file a preliminary response." Opp'n at 8.

It does not appear that Plaintiff's motivation in bringing this action was "to harass or burden an opponent[.]" *Checkpoint Sys., Inc.*, 858 F.3d at 1375. Those cases that courts have found exceptional include "fil[ing] over fifty other lawsuits in the District Court to exploit the high cost to defend complex litigation to extract nuisance value settlements from various defendants." *Rothschild Connected Devices Innovations, LLC v. Guardian Prot. Servs., Inc.*, 858 F.3d 1383, 1386 (Fed. Cir. 2017) (internal quotation marks and citations omitted); *see also Shipping & Transit, LLC v. Hall Enterprises, Inc.*, No. CV 16-06535-AG-AFM, 2017 WL 3485782, at *7 (C.D. Cal. July 5, 2017) (granting attorneys' fees where the plaintiff "repeatedly dismissed its own lawsuits to evade a ruling on the merits and yet persists in filing new lawsuits advancing the same claims"). Although there are multiple international actions between Plaintiff and Defendant, the Parties have zealously litigated those foreign actions on the merits. In a 142-page judgment, the UK judge stated the case concerning Plaintiff's European counterpart to the '654 patent was "one of the most complex patent cases I have ever tried (and I have considerable experience of trying complex patent cases)." Ex. Y at 639 (¶ 3). This observation does not imply a series of nuisance cases, but instead suggests two juggernauts battling over the international rights to this invention. It does not appear that Plaintiff has a pattern of filing baseless lawsuits and then dismissing before litigating on the merits. While a pattern of repeatedly dismissing could suggest Plaintiff was leveraging the high cost of litigation to extract a royalty from Defendant, the Parties' litigation history does not support this finding. Although the Court does find it concerning that Plaintiff did not test the merits of its infringement claims, it is not clear that it brought this action to harass Defendant. Additionally, a substantive response from Plaintiff was not required until the Patent Owner Response was due before the PTAB.

Next, Defendant points to contrary litigation positions Plaintiff took as early as May 2018—before the present action was filed—wherein Plaintiff argued that a patent's functional genus claims were invalid for lack of written description. Mot. at 16 n.6 (quoting Brief for Defendant at 21-22, *Baxalta Inc.*, 2018 WL 3742610, (May 15, 2018)). Plaintiff concedes that Defendant "correctly notes [Plaintiff] was taking a defensive position on the written description issue in other litigation." Opp'n at 15 n.4 (citations omitted). Plaintiff argues its "awareness of potential issue conflicts provides another good-faith reason for [Plaintiff]'s decision to terminate this case." *Id.*

Judicial estoppel "prevents a party from prevailing in one phase of a case on an argument and then relying on a contradictory argument to prevail in another phase." *Pegram v. Herdrich*, 530 U.S. 211, 227 n.8 (2000). To find judicial estoppel, "a party's later position must be 'clearly inconsistent' with its earlier position." *New Hampshire v. Maine*, 532 U.S. 742, 750 (2001). In *Baxalta*, Plaintiff argued that "the patent lacks sufficient written description to support the breadth of claim 1 under 35 U.S.C. § 112" because the patent "fails to disclose a species representative of the structural breadth" and "fails to disclose species representative in terms of diversity of functional effect." 2018 WL 3742610, at *7–8. However, "[a] determination that a patent is invalid for failure to meet the written description requirement of 35 U.S.C. § 112, ¶ 1 is a question of fact[.]" *Amgen Inc.*, 872 F.3d at 1379 (quoting *Ariad*, 598 F.3d at 1355). It is not clear that Plaintiff's position in this litigation would be "clearly inconsistent" with its arguments in *Baxalta*, as the written description requirement is a fact-intensive inquiry specific to a particular patent. Because the Court did not reach the merits of Plaintiff's '654 patent, it is not clear how similar the '654 patent is to the patent at issue in *Baxalta*. Therefore, the Court does not find Plaintiff necessarily took contradictory positions in this litigation and *Baxalta*.

Finally, Defendant argues that Plaintiff's seeking of an adverse judgment against itself in the PGR and the proceedings before this Court does not excuse Plaintiff's bad faith conduct. *Id.* at 19. Defendant contends Plaintiff seeking an adverse judgement was merely

the result of Defendant "forcing [Plaintiff]'s hand" after Defendant incurred substantial costs. *Id.* Plaintiff pursued this action and participated in the PGR for twenty months "before coming to an abrupt stop, without notice[.]" *Id.* In response, Plaintiff contends it "honored its duty to reassess its case and acted in good faith to withdraw from the proceedings and minimize litigation expenses for all involved." Opp'n at 19.

The Court finds that staying the present action pending proceedings before the PTAB and moving to dismiss the case based on the findings of the PTAB was not, in light of the record before this Court, unreasonable. *See Pathway Innovations & Techs., Inc. v. IPEVO Inc.*, No. 17-CV-312-CAB-BLM, 2020 WL 1983485, at *2 (S.D. Cal. Apr. 24, 2020) (finding the plaintiff "agreeing to a stay while proceedings before the [United States International Trade Commission ("]ITC[")] and PTAB were ongoing, and then dismissing the case based on the outcome of those proceedings—was not unreasonable"). Rather, the facts tend to indicate Plaintiff reevaluated its claims and rightfully moved to dismiss the case based on the PTAB's institution decision, which the Court encourages when a party finds its litigation position is weakened.

While Plaintiff acted unreasonably in aspects of this litigation, most notably before the USPTO during patent prosecution, the Court does not find these actions rise to an overall level of unreasonableness or bad faith such to warrant an exceptional case finding. Therefore, this factor weighs against an exceptional case finding.

CONCLUSION

Based on the foregoing, the Court concludes that under the totality of the circumstances, Defendant has not shown that this case is exceptional such that an award of attorneys' fees is justified. The Court therefore **DENIES** Defendant's Motion for Exceptional Case Finding and Attorneys' Fees.

IT IS SO ORDERED.

Dated: March 23, 2021

Janis L. Sammartino
Hon. Janis L. Sammartino
United States District Judge