

dynamic capacity of a HIC column. (*Id.*) After the examiner continued to maintain the rejection (*id.* Ex. 1 at 1, 4), Amgen reiterated that Holtz did not teach a combination of salts or disclose increasing the dynamic capacity of a HIC column (*id.* Ex. 1 at 5-6). The examiner allowed the claims.

In August 2016, Coherus filed an abbreviated Biologics License Application (“aBLA”) seeking FDA approval to manufacture and market a biosimilar version of Amgen’s pegfilgrastim product NEULASTA. (D.I. 1 at ¶¶ 9-10, 30-34) Pursuant to the pertinent sections of the Biologics Price Competition and Innovation Act (“BPCIA”) (42 U.S.C. §§ 262(l)(2)-(5)), Coherus and Amgen exchanged patent information (i.e., “patent dance”) and agreed that the ’707 patent should be included in Amgen’s ensuing infringement lawsuit. (D.I. 94 Ex. 4)

On May 10, 2017, based on Coherus’ aBLA, Amgen initiated this lawsuit, alleging that one of the purification steps in Coherus’ manufacturing process infringed claims 1-4 and 7 of the ’707 patent. (D.I. 1 at ¶ 50) Because the salts involved in Coherus’ purification step were not literally claimed by the ’707 patent, Amgen’s infringement theory relied on the doctrine of equivalents (“DOE”). (D.I. 10 at 11-12) Coherus moved to dismiss Amgen’s complaint under Federal Rule of Civil Procedure 12(b)(6), arguing that prosecution history estoppel precluded the invocation of the DOE. (D.I. 9; D.I. 10 at 12-13)

On December 7, 2017, Magistrate Judge Burke issued a report recommending that Coherus’ motion to dismiss be granted. (D.I. 50 at 1) Judge Burke found that during prosecution of the ’707 patent, Amgen “clearly and unmistakably . . . indicated to competitors that it surrendered processes using combinations of salts different from the *‘particular* combinations of salts recited in the claims.” (*Id.* at 12) Therefore, “prosecution history estoppel bars Amgen from now attempting to reassert surrendered ground involving other combinations

of salts.” (*Id.* at 17) On March 26, 2018, this Court adopted Judge Burke’s recommendation and granted Coherus’ motion to dismiss. (D.I. 72 at 2) This Court found an additional, independent basis to dismiss Amgen’s infringement claim: that Amgen had dedicated Coherus’ salt combination to the public by disclosing that particular combination in the ’707 patent and then not claiming it. (*Id.* at 6-7)

Amgen appealed and the Federal Circuit affirmed. (D.I. 79, 84) In doing so, the Federal Circuit held that “prosecution history estoppel bars Amgen from succeeding on its infringement claim under the doctrine of equivalents.” *Amgen Inc. v. Coherus BioSciences, Inc.*, 931 F.3d 1154, 1161 (Fed. Cir. 2019). Coherus now seeks attorneys’ fees on the basis that this case is exceptional, within the meaning of § 285, due to Amgen’s weak litigation positions and unreasonable litigation tactics. (*See* D.I. 91 at 6-11)

LEGAL STANDARDS

In “exceptional” patent cases, a court may award “reasonable attorney fees” to the “prevailing party.” 35 U.S.C. § 285. Federal Circuit law applies when interpreting and applying § 285. *See Highway Equip. Co. v. FECO, Ltd.*, 469 F.3d 1027, 1032 (Fed. Cir. 2006).

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). Ultimately, a court must make a discretionary decision based on the totality of circumstances. *See id.* A party moving for attorney fees must demonstrate, by a preponderance of the evidence, that a case is “exceptional.” *Id.* at 557-58.

DISCUSSION

As a preliminary matter, there is no dispute that Coherus is the prevailing party. The Court granted Coherus' motion to dismiss and entered final judgment in favor of Coherus and against Amgen. (D.I. 72, 78) That judgment was affirmed on appeal. (D.I. 84) Coherus undisputedly "receive[d] at least some relief on the merits, which alter[ed] the legal relationship of the parties." *Inland Steel Co. v. LTV Steel Co.*, 364 F.3d 1318, 1320 (Fed. Cir. 2004) (internal quotation marks and alterations omitted). Therefore, the Court must determine whether this case is exceptional.

Coherus' arguments for why this case is exceptional fall into two primary categories. First, Coherus contends that Amgen's litigation positions were exceptionally weak. (*See, e.g.*, D.I. 91 at 6-9) Second, Amgen purportedly engaged in vexatious litigation tactics designed to prevent or delay Coherus' market competition. (*See, e.g., id.* at 7-10) 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 § 285, for either or both of Coherus' reasons (or any others).

In arguing that Amgen's litigation positions were exceptionally weak, and that this case therefore stands out from other patent cases, Coherus focuses on the fact that the non-infringement issue was resolved on a motion to dismiss. (D.I. 91 at 8-9) Citing case disposition data analysis, Coherus emphasizes that this is a "truly rare occurrence." (D.I. 91 at 8) (citing *Cosmo Techs. Ltd. v. Actavis Lab'ys. Fl, Inc.*, 2019 WL 1417459, at *2 (D. Del. Mar. 28, 2019)) The Court agrees with Coherus' factual predicate but not its conclusion. The "rare occurrence" of dismissal of infringement claims on a Rule 12(b)(6) motion does not necessarily make a case "exceptional." *See generally Reckitt Benckiser LLC v. Aurobindo Pharma Ltd.*, 2017 WL 4613643, at *2 (D. Del. Oct. 16, 2017) (denying § 285 motion notwithstanding "rare occurrence")

of ANDA patent case being resolved on summary judgment). The Court's decision to grant the motion to dismiss was based on its resolution of two issues of law: prosecution history estoppel and disclosure dedication doctrine, both of which may be (but are not always) amenable to resolution on a Rule 12 motion. (D.I. 72 at 2-7; *see also Spectrum Pharms., Inc. v. Sandoz Inc.*, 802 F.3d 1326, 1337 (Fed. Cir. 2015) (prosecution history estoppel is question of law); *Eagle Pharms. Inc. v. Slayback Pharma LLC*, 958 F.3d 1171, 1177 (Fed. Cir. 2020) (disclosure dedication doctrine is question of law)) That this case was resolved on a question of law on a motion to dismiss does not "inevitably correlate to an exceptionally weak substantive position." *Reckitt*, 2017 WL 4613643, at *2; *see also Stone Basket Innovations, LLC v. Cook Med. LLC*, 892 F.3d 1175, 1180 (Fed. Cir. 2018) ("A party's position on issues of law ultimately need not be correct for them to not stand out, or be found reasonable.") (internal quotation marks omitted).

As importantly, Amgen's litigation positions were not exceptionally weak. Although Amgen did not prevail, its positions were not entirely meritless. In arguing that prosecution history estoppel should not apply, Amgen pointed out that its prosecution arguments referring to the particular combinations of salts had failed to overcome the examiner's prior art rejection. (*See* D.I. 53 at 5-8) The '707 patent, Amgen's argument continued, was allowed based on the "increased dynamic capacity" of the HIC column, not the particular combinations of salts. (*See id.*) To Amgen, then, this case presented a situation distinctly different from those governed by binding precedent, as in the prior cases relied on by Coherus multiple independent arguments provided sufficient bases to overcome a prior art rejection, so each argument also gave rise to an estoppel. (*Id.* at 7) (citing *PODS, Inc. v. Porta Stor, Inc.*, 484 F.3d 1359, 1367-68 (Fed. Cir. 2007))

Amgen's attempted distinction of precedential prosecution history estoppel cases was not frivolous. *See generally Medtronic Navigation, Inc. v. BrainLAB Medizinische Computersysteme GmbH*, 603 F.3d 943, 957 (Fed. Cir. 2010) (“[W]e do not regard the issue [of prosecution history estoppel] as being so clear-cut that it was unreasonable for [the plaintiff] to litigate the question until it obtained a ruling from the district court on the matter.”); *see also Fraunhofer-Gesellschaft Zur Forderung der Angewandten Forschung E.V. v. Sirius XM Radio Inc.*, 2019 WL 1091386, at *2 (D. Del. Mar. 8, 2019) (“[The] facts of this case present a unique situation not directly addressed [by binding precedents].”). Hence, although Amgen lost the dismissal motion based on prosecution history estoppel, Amgen's litigation positions were not “objectively unreasonable.” *Id.*; *see also CentusView Techs., LLC v. S&N Locating Servs., LLC*, 287 F. Supp. 3d 580, 587 (E.D. Va. 2018) (finding that infringement claims were not “objectively unreasonable” where “there were no governing precedents to guide [the plaintiff] that found nearly identical claims invalid”). Furthermore, as Amgen states, “this is not a case that never should have been brought.” (D.I. 94 at 4)

Coherus contends that the weakness of Amgen's litigation positions is further demonstrated by Amgen's failure to “articulate[] any equivalency argument” in the complaint. (D.I. 91 at 6) This is unpersuasive. Had the case survived the motion to dismiss, Amgen could likely have amended its complaint and, in all events, would have been required to carefully detail its infringement theory through contentions and discovery. The complaint, by itself or in combination with the totality of factors, does not render this case exceptional.

Turning to Coherus' second broad basis for exceptionality, Coherus has failed to persuade the Court that this case is “exceptional” due to Amgen's supposedly unreasonable and vexatious litigation tactics. Coherus identifies examples of Amgen behaviors it contends were

wrongly designed to drag Coherus, a market competitor, into “years of” “quixotic litigation.” (D.I. 91 at 8, 10) Specifically, Coherus contends that Amgen misused the BPCIA’s “patent dance” mechanism and should never have brought this infringement action. (D.I. 91 at 7-8; D.I. 96 at 8) Coherus also asserts that Amgen needlessly prolonged the litigation by pursuing discovery, claim construction, and appeal. (D.I. 91 at 9-10; D.I. 96 at 8-9)

Amgen’s conduct during the “patent dance” did not amount to a misuse of that mechanism. The misuse Coherus alleges is that Amgen, after being on notice for months (via the patent dance) of Coherus’ non-infringement position, should have acknowledged it did not have a viable claim and should not have asserted the ’707 patent in litigation against Coherus. (D.I. 91 at 7-8; D.I. 96 at 8) This is simply a rehash of Coherus’ contention that Amgen’s litigation positions were exceptionally weak, a contention the Court has already rejected. That Amgen voluntarily dropped one of the two patents it had initially asserted, after learning of Coherus’ non-infringement arguments, further undermines Coherus’ contention that Amgen misused the “patent dance” mechanism in bad faith. (D.I. 94 at 5-6; *id.* Ex. 3)


Amgen’s pursuit of discovery and claim construction in connection with the motion to dismiss does not raise suspicions about Amgen’s good faith. Although prosecution history estoppel is an issue of law, it is not uncommon for courts to require context – and sometimes even trial – before deciding it. *See, e.g., MorphoSys AG v. Janssen Biotech, Inc.*, 358 F. Supp. 3d 354, 362 (D. Del. 2019) (considering prosecution history estoppel on motion for summary judgment, after claim construction); *ICU Med., Inc. v. Ryimed Techs., Inc.*, 2013 WL 5435820, at *1 (D. Del. Sept. 30, 2013) (considering prosecution history estoppel at bench trial).

This is all the more so with respect to Amgen’s decision to appeal this Court’s dismissal decision. There is no evidence whatsoever that Amgen pursued its appeal – which was its right

to pursue – in bad faith. It is only with hindsight that Amgen’s appeal can even arguably be viewed as “doomed” or “hopeless,” as Coherus characterizes it. (D.I. 96 at 8) The Federal Circuit’s treatment of the appeal confirms the Court’s conclusion that Amgen’s decision to appeal was entirely reasonable. The Federal Circuit heard oral argument, indicating that the panel did not unanimously view the “appeal [as] frivolous” or think that “the dispositive issue or issues have been authoritatively decided.” Fed. R. App. P. 34(a)(2). Then the Federal Circuit designated its opinion affirming this Court’s decision as precedential, indicating it addressed new or significant issues of law or fact. (*See* D.I. 94 Ex. 11 at 23-24)

Finally, Coherus argues that this case is “exceptional” because Amgen’s “fundamentally anticompetitive litigation strategy” unfairly burdens nascent biosimilars manufacturers like Coherus, who are financially disadvantaged. (D.I. 91 at 10-11; D.I. 96 at 9-10) Coherus cites no authority for finding a case exceptional based on disparity of financial resources of litigants. Nor did Coherus provide evidence of a pattern that Amgen has selectively asserted patents against companies that are financially disadvantaged. Again, neither this contention – nor the totality of circumstances – supports a finding that this case is “exceptional.”

The Court has considered Coherus’ other arguments, both individually and in combination with the totality of circumstances, and concludes, again, that Coherus has failed to show that this case is “exceptional” within the meaning of § 285. Therefore, the Court must deny the motion for attorneys’ fees.


HONORABLE LEONARD P. STARK
UNITED STATES DISTRICT JUDGE