IN THE UNITED STATES DISTRICT COURT
FOR THE DISTICT OF DELAWARE

AMGEN INC. and AMGEN MANUFACTURING, LIMITED,

Plaintiffs,

v.

HOSPIRA, INC. and PFIZER INC.,

Defendants.

C.A. No.: 20-cv-00201-CFC

[redacted]

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DEFENDANTS' OPENING BRIEF IN SUPPORT OF MOTION TO DISMISS

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Other Authorities

NATURE AND STAGE OF THE PROCEEDINGS

Amgen filed this patent-infringement case under the Biologics Price Competition and Innovation Act of 2009 ("BPCIA") against Defendants (together, "Pfizer") alleging that Pfizer's abbreviated biologics license application ("aBLA") to market a biosimilar of Amgen's pharmaceutical Neulasta® (pegfilgrastim) infringes U.S. Patent No. 8,273,707 ("the '707 patent"). Pfizer moves to dismiss.

SUMMARY OF ARGUMENT

This is the second time Amgen has sued a biosimilar manufacturer in this Court alleging infringement of the '707 patent. The first lawsuit, against Coherus, ended with a dismissal under Rule 12(b)(6), affirmed by the Federal Circuit, based on Amgen's concessions made during patent prosecution. *See Amgen Inc. v. Coherus Biosciences Inc.*, No. 17-546-LPS-CJB, slip op. at 17-18 (D. Del. Dec. 7, 2017) (Burke, M.J.) ("*Coherus I*") (Ex. A), 2018 WL 1517689 (D. Del. Mar. 26, 2018) (Stark, C.J.) ("*Coherus II*") (adopting report and recommendation), *aff'd* 931 F.3d 1154, (Fed. Cir. 2019) ("*Coherus III*"). For similar reasons, Amgen's complaint against Pfizer should be dismissed.

Amgen alleges that Pfizer's purification process for its pegfilgrastim product infringes the '707 patent (Ex. B).[1] Each patent claim is directed to processes for purifying proteins that require, among other limitations, using two specified salts

[1] All exhibits are attached to the Declaration of Claire A. Fundakowski.

"wherein the concentration of *each* of the first salt and the second salt in the mixture is between about 0.1 M and about 1.0 [M]." Ex. B at cls. 1, 10 (emphasis added). Pfizer's process does not meet the concentration limitation as a matter of law.

In its complaint, Amgen references its pre-suit "detailed statement" submitted under the BPCIA, which contends that Pfizer (according to its FDA application) uses [redacted]. D.I. 1 ¶¶ 48, 63; Ex. C at 19.[2] Critically, as Amgen admits, [redacted] which is plainly below 0.1 M. Ex. C at 19. Amgen nonetheless contends that this [redacted] is literally "about 0.1 M," even though it is [redacted]. Alternatively, Amgen contends that the [redacted] "meets this claim element equivalently." *Id.*

This case should be dismissed because, during prosecution, Amgen distinguished the prior art on the ground that it used a low acetate salt concentration of only 0.040 M—thus surrendering [redacted], such as Pfizer's [redacted]. As the Federal Circuit has made clear, "after relinquishing subject matter to distinguish a prior art reference asserted by the PTO during prosecution, [a patentee] cannot during subsequent litigation escape reliance [by the defendant] upon this unambiguous surrender of subject matter." *Spectrum*

[2] The Court can consider Amgen's detailed statement because Amgen "referenced and relied" on this document in its complaint to "form[] the basis for Amgen's patent infringement claims." *See* Ex. A, *Coherus I*, slip op. at 6 n.6 (citation omitted).

Int'l Inc. v. Sterilite Corp., 164 F.3d 1372, 1379 (Fed. Cir. 1998) (quotation omitted). Prosecution history estoppel legally bars "a patentee from using the doctrine of equivalents to recapture subject matter surrendered from the literal scope of a claim during prosecution." *Coherus III*, 931 F.3d at 1159 (citation omitted).

In *Coherus*, Judge Burke, Chief Judge Stark, and the Federal Circuit addressed the prosecution history related to the '707 patent—in particular, Amgen's arguments distinguishing a prior-art patent, U.S. Patent No. 5,231,178 ("Holtz")—in connection with a different claim limitation. *See, e.g.*, *Coherus III*, 931 F.3d at 1157-58. As the prosecution history makes clear, Amgen distinguished Holtz on multiple bases, including not only the claim limitation at issue in *Coherus*, but also the concentration limitation. As held in *Coherus III*, "while Amgen did assert multiple reasons for why Holtz is distinguishable, our precedent instructs that estoppel can attach to each argument." 931 F.3d at 1160.

Amgen is estopped from arguing that [redacted] fall within the claimed range. During prosecution of the parent patent, Amgen argued that Holtz did not "teach or suggest" salt concentrations "between about *0.1 M and 1.0 M*"—i.e., the same concentration limitation in the '707 patent-in-suit. Ex. D at 0111-12 (emphasis in original).[3] Instead, Amgen argued that Holtz taught

[3] The Court can take judicial notice of the prosecution history. *See, e.g.*, Ex. A, *Coherus I*, slip op. at 6 n.6 (citations omitted).

"*lower* concentrations of sodium acetate and phosphate"—in particular, "40 mM [0.040 M] sodium acetate [and] 40mM [0.040 M] sodium phosphate." *Id.* (emphasis added). Amgen surrendered "lower concentrations" of 0.040 M acetate salts and tied its surrender to the same concentration limitation it now asserts is satisfied by Pfizer's [redacted]. *Id.*; Ex. C at 19. Because both the parent and '707 patents "contain the same claim limitation," Amgen's clear and unambiguous surrender of salt concentrations below 0.040 M applies "with equal force" to the '707 patent-in-suit. *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 980 (Fed. Cir. 1999).

This motion thus raises a discrete legal question consistent with the *Coherus* decisions: Did Amgen surrender [redacted] concentrations of 0.040 M and below—and thus surrender Pfizer's [redacted]—when arguing that Holtz's use of an acetate salt concentration of 0.040 M did not "teach or suggest . . . the [claimed] concentrations of between *0.1 M and 1.0 M*?" The answer is yes. As "a matter of law," Amgen cannot now assert that Pfizer's [redacted] satisfies the '707 patent claims either literally or under the doctrine of equivalents. *Spectrum*, 164 F.3d at 1379.

Amgen's complaint should be dismissed with prejudice.

CONCISE STATEMENT OF FACTS

I. The ’707 patent

The ’707 patent is directed to a process of purifying proteins used as active ingredients in biologic drug products. Ex. B at 1:19–21. The patent focuses on hydrophobic interaction chromatography (“HIC”) and is “directed to a process for purifying proteins during which the dynamic capacity” of the HIC column “is increased by using a combination of two salts in the loading solution.” *Coherus II*, 2018 WL 1517689 at *1 (citing Ex. B at 2:39-42, 3:38-41). According to the specification, the claimed methods “maximize the amount of protein which can be loaded and retained by an HIC column” through the use of salt combinations that reduce protein loss and increase dynamic capacity. Ex. B at 3:38-41, 4:46-60.

The ’707 patent discloses prior-art methods that taught adding “a high concentration of a salt to a low concentration buffer solution.” *Id.* at 3:20-31. In one prior-art process, 1.4 M of ammonium sulfate, a high salt concentration, was “added to a *0.024 M* phosphate buffer”—a low concentration salt [redacted] used in Pfizer’s process—to purify proteins. *Id.* at 3:25–27 (emphasis added). The patent distinguishes this prior art from the claimed invention by claiming salts at intermediate concentrations: “[t]he present invention differs from these practices in the use of an *intermediate concentration* of a buffering salt in combination with an *intermediate concentration* of a second buffering salt, or

in combination with an *intermediate concentration* of a second non-buffering salt, to achieve increased dynamic capacity." *Id.* at 3:31–34 (emphases added).

Each patent claim requires that "the concentration of each of the first salt and the second salt in the mixture is between about 0.1 M and about 1.0"—i.e., intermediate salt concentrations. This excludes both the high-salt concentrations (e.g., 1.4 M) and the low-salt concentrations (e.g., 0.024 M) used in the prior art. Ex. B at 15:15–18, 16:15–18. Claims 1 and 10 are the only independent claims, and both recite this concentration limitation. *Id.* at cls. 1, 10.

II. Prosecution history

The '707 patent resulted from U.S. Application No. 12/822,072, which is a divisional application of No. 10/895,581 that issued as U.S. Patent No. 7,781,395 ("the '395 patent" or "parent patent"). Both patents recite the identical limitation "the concentration of each of the first salt and the second salt in the mixture is between about 0.1 M and about 1.0." Ex. B at cls. 1, 10; Ex. E at cls. 1, 10. Unlike the '707 patent—which claims three salt combinations—the '395 patent claims only citrate/phosphate salt combinations. Ex. B at cls. 1, 10; Ex. E at cls. 1, 10.

On February 14, 2008, the examiner rejected all pending claims of the '395 patent for both anticipation and obviousness over Holtz. Ex. D at 0121, 0123. The examiner found that Holtz taught "salts which improve the hydrophobic interaction" of proteins, including sulfate, phosphate, acetate, chloride, and citrate

salts. *Id.* at 0122. The examiner further found that Holtz generally taught salt concentrations "in the ranges of about 0.2 up to 2.0m; with salt content of about 0.4 up to 1M being preferred." *Id.* In support, the examiner cited various portions of Holtz's specification, including an example at columns 26-27. *Id.*

In a response dated July 14, 2008, Amgen sought to overcome these rejections by arguing that Holtz failed to teach three limitations: (1) "comprising mixing a preparation containing the protein *with a combination of a first salt and a second salt*," (2) "*wherein the first and second salts are citrate and phosphate salts*," and (3) "wherein the concentration of *each of* the first salt and the second salt in the mixture *is between about 0.1 M and about 1.0*." *Id.* at 0111 (emphases in original).

As relevant to the concentration limitation, Amgen specifically distinguished its invention from the Holtz example (at columns 26-27) cited by the examiner. Ex. D at 0112. Amgen argued that the salt concentrations used in the Holtz example—i.e., "40 mM [i.e., 0.040 M] sodium acetate" and "40 mM [i.e., 0.040 M] sodium phosphate"—were "lower" than the claimed range. *Id.* Amgen distinguished Holtz on this basis, among others, arguing that "Holtz et al. at columns 26 and 27 does not teach or suggest combining the protein to be purified with the particular *combination of two salts, citrate and phosphate salts* at concentrations of between about *0.1M and 1.0M* before loading the protein on the HIC column." *Id.* (emphases in original). As Amgen's italics make clear, it made two independent arguments: (1) the Holtz

example does not teach the claimed combination of citrate and phosphate salts; and, regardless, (2) the Holtz salts fall outside the claimed concentration range (i.e., they are "*lower concentrations*"). *Id.* (emphasis added). Amgen thus argued that Holtz did "not anticipate the claimed subject matter." *Id.* at 0113.

Amgen further argued non-obviousness, arguing "it would require more than 'routine' optimization to bridge the gap between what is disclosed in Holtz et al. and the instant claimed method," including determining "the optimum concentration range." Ex. D at 0114. That is, Amgen emphasized that there was a "gap" between the 0.040 M salt concentrations used in Holtz and the low end of the claimed range, i.e., "about 0.1 M." *Id.* Amgen thus expressly distinguished Holtz during prosecution, in part, on the ground that Holtz used a "*lower concentration[]* of sodium acetate" than the concentration required by the proposed claims, i.e., "lower" than about 0.1 M to about 1.0 M. *Id.* at 0112 (emphasis added).

The examiner subsequently withdrew the anticipation rejection, but continued to reject the pending claims for obviousness over Holtz. Ex. D at 0092-0097. The examiner ultimately allowed the '395 patent to issue after Amgen "maintain[ed] again that a *prima facie* case of obviousness has not been made." *Id.* at 0034, 0055.

During prosecution of the '707 patent-in-suit, Amgen sought claims reciting additional salt combinations—including, for example, acetate and sulfate salts—but with the same concentration limitation. The same examiner continued to reject the

pending claims over Holtz. *See* Ex. F at 0080, 0128. As recognized in *Coherus*, "Amgen distinguished Holtz on the basis that Holtz did not teach or suggest the '*particular* combination of salts' recited in Amgen's claims." *Coherus III*, 931 F.3d at 1160. Although Amgen did not repeat its arguments distinguishing the proposed concentration limitation from the salt concentrations disclosed in the Holtz example described above, at no point did Amgen rescind any of its prior arguments from the prosecution of the '395 patent. *See generally* Ex. F.

The examiner ultimately allowed the '707 patent to issue based on submissions unrelated to the concentration limitation. *See id.* at 0015, 0042-46.

III. The parties' pre-suit exchanges under the BPCIA

The BPCIA created an abbreviated pathway for the FDA to approve biosimilar versions of approved biologic drugs and contemplates pre-suit disclosures. *See generally* D.I. 1 ¶¶ 7-14. On August 10, 2019, Pfizer provided Amgen with its aBLA and related process information. D.I. 1 ¶ 12. In response, Amgen identified the '707 patent as the only patent allegedly implicated by Pfizer's process. D.I. 1 ¶¶ 14, 45.

On October 30, 2019, Pfizer provided Amgen with a "detailed statement" with pre-suit non-infringement and invalidity contentions. D.I. 1 ¶¶ 45-46. Pfizer contended, among other things, that it did not infringe the '707 patent claims because its process uses [redacted]

[redacted] Ex. G at 13-19; *see also* note 2, *supra*.[4]

On December 27, 2019, Amgen responded with a detailed statement alleging infringement. D.I. 1 ¶¶ 45-46. Amgen accurately described Pfizer's process as using [redacted] Ex. C at 10 (emphasis added). Although [redacted] is below 0.1 M, Amgen contended literal infringement based on the term "about"—and, alternatively, infringement under the doctrine of equivalents. *Id.* at 19.

The parties completed the remaining pre-suit steps under the BPCIA. Amgen sued for infringement of the '707 patent on February 11, 2020. *See* D.I. 1 ¶¶ 49-50.

LEGAL STANDARD

A complaint should be dismissed under Fed. R. Civ. P. 12(b)(6) if it does not allege "enough facts to state a claim to relief that is plausible on its face." *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 234 (3d Cir. 2008) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). While a court must accept as true the

[4] Pfizer seeks dismissal at this procedural juncture only with regard to the concentration limitation in view of the file history but reserves its right to assert additional defenses, including but not limited to defenses consistent with its detailed statement, should this case continue.

allegations in the complaint, a claimant must still plead sufficient facts that, if true, satisfy the elements of the relevant cause of action. *Jang v. Boston Sci. Scimed, Inc.*, 729 F.3d 357, 367 (3d Cir. 2013); *see also, e.g.*, *Coherus II*, 2018 WL 1517689 (granting motion to dismiss based on prosecution history estoppel); *cf. Eagle Pharm. Inc. v. Slayback Pharma LLC*, 382 F. Supp. 3d 341, 346 (D. Del. 2019) (CFC) (granting motion for judgment on the pleadings; analogizing issue to prosecution history estoppel) (citing *Coherus II*, 2018 WL 1517689 at *4 n.5).

ARGUMENT

As shown below, Amgen surrendered acetate salt concentrations below 0.040 M during prosecution. It cannot now maintain an infringement claim based on Pfizer's use of [redacted].

I. A party cannot recapture subject matter surrendered during prosecution.

As a matter of law, "after relinquishing subject matter to distinguish a prior art reference asserted by the PTO during prosecution, [a patentee] cannot during subsequent litigation escape reliance [by the defendant] upon this unambiguous surrender of subject matter." *Spectrum*, 164 F.3d at 1379. Courts enforce this principal through two related doctrines: prosecution history disclaimer and prosecution history estoppel. *See id.* at 1379-80.

Prosecution history disclaimer sets forth "the same standard applicable, in the context of the doctrine of equivalents, to the doctrine of argument-based estoppel."

Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1326 n.1 (Fed. Cir. 2003). In the context of literal infringement, "where the patentee has unequivocally disavowed a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender." *Id.* at 1324. The test for prosecution history disclaimer asks whether "the alleged disavowing actions or statements made during prosecution [are] both clear and unmistakable." *Id.* at 1326. Likewise, "[p]rosecution history estoppel applies as part of an infringement analysis to prevent a patentee from using the doctrine of equivalents to recapture subject matter surrendered from the literal scope of a claim during prosecution." *Coherus III*, 931 F.3d at 1159 (citation omitted).

The doctrines of prosecution history disclaimer and estoppel work together, such that where a patentee has "clearly relinquished" claim scope during prosecution to preclude a finding of literal infringement, "[t]hese actions [also] trigger application of prosecution history estoppel, precluding infringement under the doctrine of equivalents as a matter of law." *Spectrum*, 164 F.3d at 1379-80. A court's conclusion that prosecution history estoppel bars a finding of equivalency likewise bars a conclusion that a product can literally satisfy the claims. *See id.*; *Alpex Comput. Corp. v. Nintendo Co.*, 102 F.3d 1214, 1221, 1223 (Fed. Cir. 1996) (reversing finding of infringement literally and under the doctrine of equivalents based on prosecution history estoppel and disclaimer).

II. Amgen surrendered salt concentrations, [redacted], below 0.040 M during prosecution.

In *Coherus*, this Court granted a motion to dismiss in light of Amgen's repeated arguments that Holtz failed to teach "increasing the dynamic capacity of the HIC column(s) through the novel use of *particular combinations* of only two salts." *Coherus II*, 2018 WL 1517689, at *2-3 (quoting Ex. D at 0114). The Federal Circuit affirmed, holding that "during prosecution of the '707 patent, Amgen clearly and unmistakably surrendered salt combinations other than the particular combinations recited in the claims." *Coherus III*, 931 F.3d at 1159. Although not addressed in *Coherus*, Amgen also clearly and unmistakably surrendered salt concentrations—[redacted]—below 0.040 M by distinguishing Holtz on that basis during prosecution of the parent application.

A. During prosecution of the parent '395 patent, Amgen argued that Holtz's 0.040 M salt concentrations were "lower" than the claimed concentration range.

During the prosecution of the '395 patent, Amgen distinguished Holtz by arguing that the 0.040 M concentrations of acetate and phosphate salts used in Holtz did not "teach or suggest," among other things, "concentrations of between about *0.1M and 1.0 M*." Ex. D at 0112 (citing Holtz at cols. 26–27) (emphasis in original). Amgen argued that Holtz taught "a protein solution containing lower concentrations of sodium acetate and sodium phosphate," containing only "40 mM [0.040 M] sodium acetate" and "40 mM [0.040 M] sodium phosphate." *Id.* That is, according

to Amgen, there was a "gap" between the 40 mM (0.040 M) acetate and phosphate salt concentrations used in Holtz and the "the optimum concentration range," i.e., between about 0.1 M and 1.0 M. *Id.* at 0112, 0114.

These representations clearly and unmistakably surrendered salt concentrations of 0.040 M and lower. Amgen distinguished Holtz's use of "lower concentrations of sodium acetate and sodium phosphate" and tied this surrender to the claimed concentration limitation of "about *0.1M and 1.0M*." *Id.* Amgen thus "relinquish[ed] subject matter to distinguish a prior art reference asserted by the PTO during prosecution," and "cannot during subsequent litigation escape reliance [by Pfizer] upon this unambiguous surrender of subject matter." *Spectrum*, 164 F.3d at 1379; *see also PODS Inc. v. Porta Star Inc.*, 484 F.3d 1359, 1366-68 (Fed. Cir. 2007) (holding that patentee's argument that prior art "clearly lack[ed] the teachings" of a claim limitation "clearly and unmistakably . . . surrendered" subject matter).

Importantly, Amgen was not even claiming [redacted] salts at the time—only citrate and phosphate salts. Ex. D at 0109-10. So when Amgen argued that Holtz's 0.040 M concentrations of [redacted] salts were "lower" than the claimed range, Amgen was not limiting its arguments to the claimed salts. Instead, it was clearly and unmistakably telling the PTO—and informing the public—that [redacted] salts below 0.040 M have a "lower concentration[]" than the claimed range of "about *0.1M and 1.0M*." *See* Ex. D at 0112 (citing Holtz at cols. 26–27);

Spectrum, 164 F.3d at 1379.

To be sure, Amgen distinguished Holtz on multiple grounds (e.g., Holtz used different salts than what was being claimed), but this did not stop the Federal Circuit from invoking prosecution-history estoppel against Amgen in the *Coherus* case. As the Federal Circuit explained: "[W]here a patent applicant sets forth multiple bases to distinguish between its invention and the cited prior art, the separate arguments [can] create separate estoppels as long as the prior art was not distinguished based on the combination of these various grounds." *Coherus III*, 931 F.3d 1159 (quotation and citation omitted) (alterations in original). "Amgen did not rely on the combination of its asserted grounds to distinguish Holtz," *id.* at 1160-61, so Amgen surrendered subject matter with regard to all three arguments made in its July 14, 2008 office-action response. *See also* Ex. D at 0111 (emphasizing with italics that Holtz failed to teach three separate limitations).

Thus, while Amgen may not have needed to surrender lower concentrations of unclaimed [redacted] salts to overcome Holtz, "the scope of surrender is not limited to what is absolutely necessary to avoid a prior art reference; patentees may surrender more than necessary." *Tech. Props. Ltd. LLC v. Huawei Techs. Co.*, 849 F.3d 1349, 1359 (Fed. Cir. 2017); *see also* Ex. A *Coherus I*, slip op. at 9 n.7. As the Federal Circuit explained, "[w]hen this happens, we hold patentees to the actual arguments made, not the arguments that could have been made." *Tech Props.*, 849 F.3d

at 1359; *see also Coherus III*, 931 F.3d at 1161 (surrender attaches "whether or not actually required to secure allowance of the claim") (citation omitted).

B. Amgen's surrender of 0.040 M salt concentrations during prosecution of the parent application applies to the '707 patent-in-suit.

In its detailed statement, Amgen disputes Pfizer's contention "that prosecution history estoppel applies based on Amgen's statements during the parent '395 Patent prosecution." Ex. C at 20. While Amgen admits that "[p]rosecution history estoppel can extend from a parent application to subsequent patents in the same lineage," it asserts that "the 'arguments made in a related application do not automatically apply to different claims in a separate application.'" *Id.* (citation omitted). Amgen points to the fact that the '395 patent is directed to a single salt pair combination (citrate/phosphate), whereas the '707 patent claims "different salt pairs" (e.g., acetate/sulfate). *Id.* at 21. Amgen overlooks, however, that both the '395 and '707 patents contain the identical salt-concentration limitation at issue here.

"When multiple patents derive from the same initial application, the prosecution history regarding a claim limitation in any patent that has issued applies with equal force to subsequently issued patents that contain the same claim limitation." *Elkay Mfg.*, 192 F.3d at 980; *see also Microsoft Corp. v. Multi-Tech Sys. Inc.*, 357 F.3d 1340, 1349 (Fed. Cir. 2004) ("[P]rosecution history of one patent is relevant to an understanding of the scope of a common term in a second patent stemming from the same parent application."). Indeed, the prosecution history

regarding a particular limitation in one patent is "presume[d]" to inform the later use of that same limitation in related patents, "unless otherwise compelled." *See Omega Eng'g*, 334 F.3d at 1334; *see also id.* at 1333 ("As long as the same claim limitation is at issue, prosecution disclaimer made on the same limitation in an ancestor application will attach.").

This precedent is on point. The parent application, which issued as the '395 patent, recites the identical claim limitation "wherein the concentration of each of the first salt and the second salt in the mixture is between about 0.1 M and about 1.0." *Compare* Ex. D at 0109 *with* Ex. B at cl. 1.

Amgen's cases cited in its detailed statement, Ex. C at 20-21, largely concern "the prosecution of one claim term in a parent application," and "different claim language in a continuation application." *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1077-78 (Fed. Cir. 2005) (refusing to limit the meaning of the terms "no detectable [ ] activity" and "lacks [ ] activity" based on the prosecution of the term "substantially no [ ] activity" in a related application); *see also Biogen, Inc. v. Berlex Labs., Inc.*, 318 F.3d 1132, 1137 (Fed. Cir. 2003) (where the parent application limited nucleotide sequence claims to a "single construct," but the child claims "did not mention the single construct").

Amgen's remaining case, *Trading Techs. Int'l, Inc. v. Open E Cry, LLC*, 728 F.3d 1309 (Fed. Cir. 2013), is otherwise distinguishable. There, the Federal Circuit

explained that while "[p]rosecution history estoppel can extend from a parent application to subsequent patents in the same lineage, as can a prosecution disclaimer," this principal did not apply because the specification of the continuation-in-part "directly contradict[ed] the prosecution-based surrenders of claim scope" from the parent application. *Id.* at 1323. Moreover, during the prosecution of the later patent, the applicant "made clear" that the scope of the invention "was not limited" to the subject matter claimed in the parent. *Id.*

In contrast, nothing in the '707 patent's intrinsic record contradicts the prosecution-based surrender of 0.040 M salt concentrations (and lower) in the parent patent. In fact, the '707 patent specification distinguishes the claimed "intermediate concentration" salts from prior-art processes using "a low concentration" salt, including "a 0.024 M phosphate buffer"—[redacted]. Ex. B at 3:24–34, 3:37-41; *see also SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1345 (Fed. Cir. 2001) ("Having specifically identified, criticized, and disclaimed the [prior art] configuration, the patentee cannot now invoke the doctrine of equivalents to embrace a structure that was specifically excluded from the claims.") (quotation omitted). And, during the prosecution of the '707 patent, where Amgen sought to claim acetate salts before the same examiner, Amgen never rescinded any of its prior arguments to distinguish its invention over Holtz. *See generally* Ex. F.

"Although a disclaimer made during prosecution can be rescinded, permitting recapture of the disclaimed scope, the prosecution history must be sufficiently clear to inform the examiner that the previous disclaimer, and the prior art that it was made to avoid, may need to be re-visited." *Hakim v. Cannon Avent Grp., PLC*, 479 F.3d 1313, 1318 (Fed. Cir. 2007). Because Amgen never rescinded its prior statements, the same examiner had no reason to believe that Amgen's previous arguments regarding concentration needed "to be re-visited," and Amgen cannot be permitted to "recapture the disclaimed scope." *Id.* at 1318. Thus, unlike the unique facts in *Trading Techs.*, there is nothing to alter the presumption that "the prosecution history regarding a particular limitation in one patent . . . inform[s] the later use of that same limitation in related patents." 728 F.3d at 1322-23. And Amgen's "single action during prosecution can engender both a prosecution disclaimer and prosecution history estoppel" relevant to the '707 patent claims. *Id.*

III. Amgen has no plausible infringement claim because Pfizer [redacted].

Amgen contends that Pfizer uses [redacted], but it admits the concentration of [redacted]. Ex. C at 8 [redacted]. In view of the prosecution history, Amgen cannot plausibly allege infringement—either literally, or under the doctrine of equivalents.

Again, Amgen argued to the PTO that an acetate salt concentration as high as

0.040 M did "not teach or suggest" the use of salts at a concentration of "*about 0.1 to 1.0 M*." Ex. D at 0112. Such "clear assertions made during prosecution in support of patentability . . . create an estoppel" barring Amgen from making any argument—based on "about" or otherwise—that Pfizer's [redacted] salt meets the concentration limitation. *PODS*, 484 F.3d at 1368 (quotation omitted); *Spectrum*, 164 F.3d at 1379-80 (because the patentee "relinquished" subject matter during prosecution, the "term 'comprising' could not restore this excluded subject matter" through literal or equivalent infringement); *cf. Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd.*, 476 F.3d 1321, 1325, 1328–29 (Fed. Cir. 2007) ("[H]aving so distinctly claimed the 'about 1:5' ratio, Ortho cannot now argue that the parameter is broad enough to encompass, through the doctrine of equivalents, ratios outside of the confidence intervals . . . . [T]o do so would eviscerate the limitation.").

In short, Amgen surrendered salt concentrations of 0.040 M and below, and [redacted]—thus barring Amgen from alleging that Pfizer's undisputed [redacted] satisfies the concentration limitation. Therefore, Amgen cannot plausibly allege that Pfizer's process satisfies each and every element of any '707 patent claim. *See, e.g.*, *Coherus II*, 2018 WL 1517689 (granting motion to dismiss).

CONCLUSION

Pfizer respectfully requests dismissal of the complaint with prejudice.

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I hereby certify on this 4th day of March, 2020: This filing complies with the applicable type, font, and word limitations. This brief contains 4,866 words, which were counted by Microsoft Word.

/s/ Dominick T. Gattuso
Dominick T. Gattuso (#3630)