IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC. and AMGEN MANUFACTURING, LIMITED, Plaintiffs, v. HOSPIRA, INC. and PFIZER INC., Defendants.	Public Version Filed April 22, 2020 C.A. No. 20-cv-00201-CFC DEMAND FOR JURY TRIAL [redacted]

DEFENDANTS' REPLY BRIEF IN SUPPORT OF MOTION TO DISMISS

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SUMMARY OF ARGUMENT

Pfizer's motion to dismiss turns on a single legal issue: whether Amgen clearly and unmistakably surrendered salt concentrations below 0.040 M during prosecution. As Amgen concedes, it cannot prove infringement unless "[t]he [redacted] concentration in Pfizer's process" satisfies the claim limitation "about 0.1 M to 1.0 M." Br. 3, D.I. 24. Amgen further asserts that this dispute "rests entirely" on Pfizer's assertion that "Amgen surrendered [redacted] concentrations of 0.040 M or lower" during prosecution. *Id.* This is "a legal dispute that . . . turns on the clear and unambiguous prosecution history." *Amgen Inc. v. Coherus Biosciences Inc.*, 2018 WL 1517689, at *4 n.5 (D. Del. Mar. 26, 2018) (Stark, C.J.) ("*Coherus II*"), *aff'd* 931 F.3d 1154 (Fed. Cir. 2019) ("*Coherus III*"). The Court should dismiss Amgen's infringement claims based on Amgen's surrender of salt concentrations—particularly [redacted] concentrations—below 0.040 M.

When prosecuting the parent patent, Amgen argued that Holtz's disclosure of a 0.040 M [redacted] was "lower" than, and thus did not "teach or suggest," salt concentrations "between about *0.1M and 1.0M*." Ex. D at 0112, D.I. 20-4 (emphasis in original). This concession during prosecution of the parent patent "applies with equal force to subsequently issued patents," including the '707 patent-in-suit, "that contain the same claim limitation." *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 980 (Fed. Cir. 1999).

Amgen tries to delay resolution of this legal dispute by pointing to irrelevant claim construction and factual disputes. According to Amgen, "the parties' disagreement centers on the meaning of the term 'about 0.1M.'" Br. 9. Not so. Regardless of whether the term "about . . . avoids a strict numerical boundary," *id.*, Amgen's clear and unmistakable surrender of salt concentrations below 0.040 M during prosecution "narrows the ordinary meaning of the claim congruent with the scope of the surrender," *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1324 (Fed. Cir. 2003). And there are no material factual disputes, because Amgen concedes that "Pfizer's process" uses [redacted] concentration." Br. 3.

Amgen also argues that the Court should limit its surrender to the citrate/phosphate salt pairs claimed in the parent patent, because it "only needed to surrender concentrations pertaining to those salt pairs." Br. 13 (quoting *Amgen Inc. v. Mylan Inc.*, 2018 WL 6061213, at *24 (W.D. Pa. Nov. 20, 2018)). That is not the law. As the Federal Circuit has made clear, "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 Coherus III*, 931 F.3d at 1159-61 (same).

In sum, Amgen clearly and unmistakably surrendered salt concentrations below 0.040 M during prosecution, including Pfizer's undisputed [redacted] concentration. Amgen's complaint should be dismissed with prejudice.

ARGUMENT

The key issue before the Court is whether, as a matter of law, Amgen clearly and unmistakably surrendered during prosecution [redacted] concentrations below 0.040 M as to the claim limitation "about 0.1 M to 1.0 M." Amgen did so, and its infringement complaint should be dismissed with prejudice for this reason alone. Amgen's remaining arguments are all immaterial to this core, legal dispute.

I. Amgen surrendered salt concentrations below 0.040 M for the '707 patent.

During prosecution of the parent patent, Amgen clearly and unmistakably surrendered [redacted] concentrations below 0.040 M. Amgen argues that it distinguished Holtz on different grounds, and that its surrender does not extend to the '707 patent. Br. 13-20. Both arguments conflict with Federal Circuit precedent.

A. Amgen surrendered salt concentrations below 0.040 M during prosecution of the parent patent.

Amgen argues that it never "distinguished Holtz on the basis of salt concentrations," Br. 17, but Amgen's characterizations cannot change the actual words it used during prosecution. During prosecution of the parent patent, Amgen argued that the prior-art Holtz reference did not anticipate the pending claims for independent reasons, italicizing three distinct 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*." Ex. D at 0111, D.I. 20-4 (emphases in original). Amgen then clearly and unmistakably argued—with the same italics—that an example in Holtz failed to teach "the particular *combination of two salts, citrate and phosphate salts* at concentrations of between about *0.1M and 1.0M*." *Id.* at 0112 (emphases in original). That is, Amgen clearly and unmistakably argued that Holtz failed to teach using "[1] two salts only, [2] citrate and phosphate, [3] at concentrations of between about 0.1M and 1.0M." *Id.* at 0113.

Amgen distinguished Holtz on three different grounds, and Amgen's "separate arguments can create separate estoppels." *PODS Inc. v. Porta Stor Inc.*, 484 F.3d 1359, 1367-68 (Fed. Cir. 2007) (applying prosecution history estoppel where the patentee distinguished prior art for "three reasons" and "offered each argument as a separate basis for distinguishing [the prior art]"). In *Coherus III*, the Federal Circuit reached this same conclusion when analyzing the multiple arguments Amgen made in a different office-action response. 931 F.3d at 1160 ("[W]hile Amgen did assert multiple reasons for why Holtz is distinguishable, our precedent instructs that estoppel can attach to each argument.").[1] Here, Amgen clearly and unmistakably argued that Holtz failed to teach three distinct claim limitations, and

[1] Amgen claims that *Coherus III* is inapposite because the Federal Circuit did not hold that Amgen surrendered salt concentrations. Br. 20. To be sure, as Pfizer acknowledged in its opening brief, *Coherus III* addressed a different issue. But the holdings in that case confirm certain legal principles that apply equally here.

italicized each limitation to emphasize its separate arguments. "[R]egardless of the other two arguments Amgen made," estoppel applies to Amgen's arguments regarding the concentration limitation. *Id.* at 1161.

In arguing that Holtz failed to teach the concentration limitation, Amgen clearly and unmistakably surrendered salt concentrations below 0.040 M when arguing that Holtz did not "teach or suggest" salt concentrations "between about *0.1M and 1.0M*." Ex. D at 0112, D.I. 20-4 (emphasis in original). Amgen explained that Holtz used "40 mM [0.040 M] sodium acetate [and] 40mM [0.040 M] sodium phosphate" in its process, and clearly and unmistakably argued that these are "*lower* [salt] concentrations" than what was claimed—i.e., "about 0.1 M and 1.0 M." *Id.* (emphasis added). Amgen thus emphasized the claimed salt-concentration range ("about 0.1 M and 1.0 M"), and expressly argued that Holtz did not disclose this limitation because its 0.040 M [redacted] concentration was "lower" than that range. Amgen's surrender of "lower concentrations"—including [redacted] concentrations of 0.040 M and below—was both clear and unmistakable.

B. Amgen's claim-scope surrender applies to the '707 patent.

"As long as the same claim limitation is at issue, prosecution disclaimer made on the same limitation in an ancestor application will attach." *Omega Eng'g*, 334 F.3d at 1333-34. That is, "[w]hen 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 (emphasis added). This controlling legal principle applies here. Arguing otherwise, Amgen ignores that the parent patent and the '707 patent-in-suit "derive from the same initial application" and "contain the same limitation," *id.*—i.e., "about 0.1 M to 1.0." Thus, Amgen's clear and unmistakable surrender applies with "equal force" to both. *Id.*

The parent patent's recitation of different salt pairs (citrate/phosphate) than the '707 patent does not change this conclusion. Amgen's surrender of "lower concentrations" of [redacted] concerned the limitation "about 0.1 M to 1.0"—not the limitation concerning citrate and phosphate salt pairs. Indeed, if Amgen were distinguishing Holtz on the basis of the parent patent's *citrate/phosphate* salt pairs, Amgen would have had no reason to argue that Holtz's 0.040 M [redacted] concentration was a "lower concentration[]." Ex. D at 0112, D.I. 20-4.

Amgen's key case confirms Amgen "made an unmistakable representation that, at least for acetate and phosphate salt pairs, 0.04 M was *not* 'about 0.1 M.'" *Amgen Inc. v. Mylan Inc.*, 2018 WL 6061213, at *24 (W.D. Pa. Nov. 20, 2018). This "unmistakable representation" as to [redacted] is case-dispositive here. *Id.*

To be sure, the *Mylan* court found it "ambiguous" as to "whether the patentee intended that salt concentrations, *in a general sense*, less than 0.04 M are less than 'about 0.1 M,'" and refused to find such a broad disclaimer. *Id.* (emphasis added).

But this Court does not need to reach that issue because, unlike in *Mylan*, [redacted] below 0.040 M.

Regardless, the *Mylan* court's holding rests on legal error. It refused to apply any disclaimer broader than what was necessary to overcome Holtz: "To secure the issuance of that claim, the patentee would have only needed to surrender concentrations pertaining to those salt pairs [i.e., citrate and phosphate]. The Court will not extend the scope of the disavowal beyond what was surrendered in order to secure the patent." *Id.* According to that court, Amgen thus "only unequivocally disclaimed salt concentrations below 0.04 M for citrate and phosphate salt pairs," and did not generally surrender concentrations for all other salt pairs. *Id.*

Critically, the court's decision in *Mylan* fails to cite—and its holding contradicts—binding precedent. The Federal Circuit has repeatedly held that "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.*, 849 F.3d at 1359. Indeed, "there is no principle of patent law that the scope of a surrender of subject matter during prosecution is limited to what is absolutely necessary to avoid a prior art reference that was the basis for an examiner's rejection." *Norian Corp. v. Stryker Corp.*, 432 F.3d 1356, 1361-62 (Fed. Cir. 2005).

Under the proper standard, Amgen clearly and unmistakably surrendered more than "salt concentrations below 0.04 M for citrate and phosphate salt pairs."

Mylan, 2018 WL 6061213, at *24. As the *Mylan* court acknowledged, Amgen also unmistakably represented that its claims did not cover the lower concentration of [redacted] used in Holtz, even though Amgen was not claiming [redacted] and distinguished Holtz on multiple bases. *Id.* Even if Amgen "disclaimed more than was necessary," precedent requires that Amgen be held "to the actual arguments made, not the arguments that could have been made." *Tech. Props.*, 849 F.3d at 1359. "The question is what a person of ordinary skill would understand the patentee to have disclaimed during prosecution, not what a person of ordinary skill would think the patentee needed to disclaim during prosecution." *Id.* And Pfizer is the third party, after Coherus and Mylan, to read the prosecution history and understand Amgen as disclaiming concentrations below 0.040 M. *See Coherus III*, 931 F.3d at 1159-61 (holding that "separate arguments [can] create separate estoppels").

II. Pfizer's motion to dismiss does not turn on claim construction.

Amgen incorrectly argues that claim construction issues render Pfizer's motion premature. In support, Amgen argues that Pfizer improperly equates prosecution disclaimer with prosecution history estoppel, and the former doctrine requires claim construction. *See* Br. 9-10, 12. Once again, Amgen is wrong.

Amgen cannot dispute that courts address prosecution history estoppel on the pleadings—it lost that argument in *Coherus*. *See Coherus II*, 2018 WL 1517689, at *4. Both prosecution history estoppel and prosecution disclaimer turn on the same

legal question—whether a patentee's "disavowing actions or statements made during prosecution [are] both clear and unmistakable." *Omega Eng'g*, 334 F.3d at 1326 n.1 (explaining the doctrines apply "the same standard"). And both doctrines prevent a patentee from "recaptur[ing] subject matter surrendered from the literal scope of a claim during prosecution." *Coherus III*, 931 F.3d at 1159. Thus, regardless of the infringement theory, if a patentee "clearly relinquished" claim scope to preclude a literal infringement claim, "[t]hese actions [also] trigger application of prosecution history estoppel, precluding infringement under the doctrine of equivalents as a matter of law." *Spectrum Int'l Inc. v. Sterilite Corp.*, 164 F.3d 1372, 1379-80 (Fed. Cir. 1998); *Alpex Comput. Corp. v. Nintendo Co.*, 102 F.3d 1214, 1221 (Fed. Cir. 1996) ("[J]ust as prosecution history estoppel may act to estop an equivalence argument under the doctrine of equivalents, positions taken before the PTO may bar an inconsistent position on claim construction.").

No claim construction is required to address whether Amgen clearly and unmistakably surrendered an [redacted] concentration below 0.040 M. In fact, for purposes of this motion, Pfizer does not dispute that the "plain and ordinary meaning" of "about 0.1 M" is "approximately 0.1 M." *See* Br. 9. But "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." *Omega Eng'g*, 334 F.3d at 1324

(emphasis added). As a matter of law, Amgen disclaimed "about 0.1 M" from reaching Pfizer's [redacted] concentration when it clearly and unmistakably surrendered salt concentrations below 0.040 M. *Id.*

III. Amgen conceded the only pertinent fact at issue here.

Amgen cannot survive dismissal by relying on factual allegations from its pleadings and incorporated "3(C) Statement." Br. 3 n.1, 10-12. Amgen argues, for example, that the parties dispute whether "about 0.1 M" can be stretched to cover Pfizer's [redacted] concentration—even though [redacted] than 0.1 M. *See id.* Amgen's purported factual disputes are not only implausible, they are legally irrelevant.

If the Court agrees with Pfizer that Amgen surrendered [redacted] concentrations below 0.040 M, only one *undisputed* fact matters: "Pfizer's process" uses [redacted] *Id.* at 3. The Court should find, as a matter of law, that Amgen is barred from asserting infringement over an [redacted] concentration below 0.040 M—"the very embodiment that [Amgen] explicitly relinquished during prosecution." *Spectrum*, 164 F.3d at 1376-77 (barring patentee from asserting infringement either literally or under the doctrine of equivalents).

CONCLUSION

Pfizer respectfully requests dismissal of the complaint with prejudice.

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