Appeal No. 2018-1993

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

AMGEN INC.; AMGEN MANUFACTURING LIMITED,

Plaintiff-Appellants,

v.

COHERUS BIOSCIENCES INC.,

Defendant-Appellee.

Appeal from the United States District Court for the District of Delaware in Case No. 1:17-cv-00546-LPS, Chief Judge Leonard P. Stark

NON-CONFIDENTIAL RESPONSE BRIEF OF DEFENDANT-APPELLEE COHERUS BIOSCIENCES INC.

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CERTIFICATE OF INTEREST

Counsel for the appellee Coherus BioSciences Inc. certifies the following:

1. The full name of every party represented by me is:

   COHERUS BIOSCIENCES INC.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

   COHERUS BIOSCIENCES INC.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party represented by me are:

   None

4. The names of all law firms and the partners and associates that appeared for the party now represented by me in the trial court or are expected to appear in this Court (and who have not or will not enter an appearance in this case) are

   MORRIS JAMES LLP: Kenneth Dorsney, Richard Herrmann

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. See Fed. Cir. R. 47.4(a)(5) and 47.5(b).

   None

Date: October 31, 2018

/s/ Bradford P. Lyerla
Bradford. P. Lyerla

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CONFIDENTIAL MATERIAL OMITTED

Pursuant to Federal Circuit Rule 28(d)(2)(B), Defendant-Appellee prepared this public version of its brief which redacts certain information designated confidential pursuant to the district court's Protective Order entered on December 7, 2017. Specifically, the material omitted on pages 1, 10-12, 14, 15, 17-19, 21, 22, 36-38, and 40-43 contains references to Defendant-Appellee's accused process, and was designated confidential by Defendant-Appellee during discovery under the terms of the Protective Order.

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STATEMENT OF RELATED CASES

Coherus agrees with Amgen's Statement of Related Cases.

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JURISDICTIONAL STATEMENT

Coherus agrees with Amgen's jurisdictional statement.

STATEMENT OF THE ISSUES

1. During patent prosecution, Amgen argued that its patent overcame prior art because the prior art did not disclose the "*particular* combinations of salts"—emphasis in original—recited in the claims. Did the District Court err in holding that prosecution history estoppel barred Amgen from expanding the scope of the claim, via the doctrine of equivalents, beyond the particular combinations of salts recited in the claims?

2. The specification characterizes the "the present invention" as "combining two different salts having different lyotropic values," and expressly states that [redacted] and [redacted] have different lyotropic values. The claim, however, recites three particular combinations of salts with different lyotropic values, without reciting the [redacted]. Did the District Court err in holding that the disclosure-dedication doctrine bars Amgen from expanding the scope of the claim, via the doctrine of equivalents, to encompass the [redacted]?

STATEMENT OF THE CASE

In August 2016, Coherus filed an abbreviated Biologic License Application ("aBLA") with the FDA under the Biologics Price Competition and Innovation Act ("BPCIA"), seeking authorization to market a biosimilar of Amgen's pegfilgrastim

product, Neulasta. Appx12. Under the BPCIA, that filing was an artificial act of infringement. 35 U.S.C. § 271(e)(2)(C). Based on that filing, Amgen sued Coherus for infringement of U.S. Patent No. 8,273,707 (the "'707 patent"). The District Court dismissed Amgen's complaint, holding that Amgen's claim was barred by the doctrines of prosecution history estoppel and disclosure-dedication. Amgen now appeals that judgment.

A. The '707 Patent.

The '707 patent is directed to a method for purifying a protein using a technique known as hydrophobic interaction chromatography, or "HIC."

HIC is a technique for separating the components of a mixture. It is a well-known tool used to purify many types of proteins. Appx39 at 3:7-9. It is premised on the fact that different compounds within a mixture may move through a column of stationary particles at different rates, allowing the compounds within the mixture to be separated. In HIC, a column is first filled with solid particles having particular chemical properties, known as a "stationary phase" or "resin." Appx39 at 3:53-55. Next, a solution containing the protein is mixed with a buffer containing salts, and the mixture is poured onto the resin. Appx38-39 at 1:40-41, 3:16-19. This step is known as "loading" the column. Appx38-39 at 1:40-41, 2:2-3, 3:16-19. With an appropriate selection of resin and buffer containing salts, the desired protein's chemical properties cause it to bind to the solid resin, while the solution flows

through the column. Appx38-39 at 1:40-45, 3:53-61. More precisely, the salt in the buffer interacts with water molecules to reduce the protein's ability to dissolve in water. Appx38 at 1:41-43. This exposes regions of the proteins which are "hydrophobic" (*i.e.*, repelled by water), which in turn allows the proteins to be "absorbed by" (*i.e.*, bind to) hydrophobic groups on the resin. Appx38-39 at 1:41-46, 3:9-12, 3:53-64. "The more hydrophobic the [protein], the less salt is needed to promote binding." Appx38 at 1:44-45. The impurities remaining in the column are washed through the column by pouring more buffer solution through the column. Appx39-40 at 4:27-29, 6:64-67. Finally, molecules of the desired protein remaining on the matrix are detached (or "eluted") by pouring a final buffer solution through the column. Appx38 at 1:45-49, Appx40-41 at 6:67-7:12.

Only a finite amount of the protein of interest can bind to the resin during the loading procedure. If too much protein is loaded on to the column, "'breakthrough' or loss of protein to the solution phase before elution" will occur. Appx39 at 3:40-41. The column's "dynamic capacity" refers to the amount of protein in solution that can be loaded onto a column without significant breakthrough or loss of the protein into the solution phase prior to elution. Appx39 at 3:37-41, 4:10-16.

Amgen's '707 patent is directed to a technique for increasing the dynamic capacity of a column. According to the Abstract, the technique consists of "mixing a protein preparation with a solution having a first salt and a second salt, wherein

each salt has a different lyotropic value, and loading the mixture onto a hydrophobic interaction chromatography column." Appx32 (abstract). "The dynamic capacity of the column for a protein using the two salt combination will be increased compared with the dynamic capacity of the column for either single salt alone." *Id.* The specification explains that "the term 'lyotropic' refers to the influence of different salts on hydrophobic interactions." Appx39 at 4:33-34. The specification recites a list of anions in order of lyotropic value, the first four of which are phosphate (PO_4^{3-}), sulfate (SO_4^{2-}), acetate (CH_3COO^-), and chloride (Cl^-). Appx39 at 4:42-44. It explains that "[a]ccording to the present invention, combining two different salts having different lyotrophic (sic) values with a protein preparation allows more protein to be loaded onto a column with no or negligible breakthrough compared with higher salt concentrations of each single salt." Appx39 at 4:46-51.

The claims, however, are written more narrowly than the "present invention" as described in the specification. Whereas the specification refers generally to "combining two different salts having different lyotropic values," *id.*, all the claims recite three particular combinations: citrate/sulfate, citrate/acetate, and sulfate/acetate. Claim 1, which is representative, recites:

> 1. A process for purifying a protein on a hydrophobic interaction chromatography column such that the dynamic capacity of the column is increased for the protein comprising mixing a preparation containing the protein with a combination of a first salt and a second salt, loading the mixture onto a hydrophobic interaction chromatography column, and eluting the protein, wherein the first

> and second salts are selected from the group consisting of citrate and sulfate, citrate and acetate, and sulfate and acetate, respectively, and 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.

Appx45 15:8-18.

B. Prosecution history of the '395 patent.

The '707 patent is a divisional of an earlier application that issued as U.S. Patent No. 7,781,395 (the "'395 patent").

In the '395 patent application, Amgen originally sought patent protection for a broad genus of salt combinations. Amgen's independent claim, as originally drafted, encompassed any salt combinations "wherein the first and second salts have different lyotropic values." Appx635. Amgen also pursued dependent claims, one of which included the following limitation: "wherein the first salt and second salt are selected from the group consisting of citrate and sulfate; citrate and acetate; citrate and phosphate; acetate and sulfate; and sulfate and phosphate." *Id.*

In response, the Patent Office issued a "restriction" requirement under 37 C.F.R. § 1.146. That regulation provides: "In the first action on an application containing a generic claim to a generic invention (genus) and claims to more than one patentably distinct species embraced thereby, the examiner may require the applicant in the reply to that action to elect a species of his or her invention to which his or her claim will be restricted if no claim to the genus is found to be allowable." The Examiner stated: "Select **one** first and second salt from citrate & sulfate, citrate

& acetate, citrate & phosphate, acetate & sulfate, or sulfate & phosphate. All are patentably distinct due to the different actions of each. Each species would require a different search." Appx1115.

Thus, consistent with 37 C.F.R. § 1.146, the Examiner authorized Amgen to continue prosecuting its claim for a broad genus of salt combinations (*i.e.*, the claim with the limitation "wherein the first and second salts have different lyotropic values"). But it would have to elect a particular species of salt combination (*i.e.*, elect a particular first salt and a particular second salt).

On April 13, 2007, in response to this Office Amgen, Amgen "elect[ed] the combination of citrate and phosphate salts," while reiterating that it was still pursuing the "generic claim[]." Appx267.

On July 17, 2007, the Patent Office rejected the generic claim for lack of enablement. It stated that "the specification, while being enabling for the combination of citrate and phosphate salts for purifying a protein, does not reasonably provide enablement for a process for purifying a protein comprising mixing the protein with a first salt and a second salt having different lyotropic values." Appx1152. Further, the "breadth of the claims is excessive" because "Applicant has only provided guidance for the use of citrate, acetate, phosphate, and sulfate salts." Appx1153. It stated that "others skilled in the art would be unable to practice the invention as claimed without undue experimentation and with a

reasonable expectation of success, other than using" four particular combinations: citrate/phosphate, citrate/sulfate, citrate/acetate, and sulfate/acetate. Appx1153-1154.[1]

Amgen then amended its genus claim to add the limitation "wherein the first and second salts are citrate and phosphate salts"—*i.e.*, the species claim. Appx192. Amgen expressed disagreement with the enablement rejection, Appx194-195, but henceforth no longer prosecuted the genus claim.

The Examiner then rejected the species claim as obvious in view of U.S. Patent No. 5,231,178 to Holtz ("Holtz"). The Examiner stated that Holtz disclosed the claimed method using salts including "sodium sulfate, potassium sulfate, ammonium sulfate, potassium phosphate, sodium acetate, ammonium acetate, sodium chloride, sodium citrate and the like." Appx201. In response, Amgen argued that "Holtz et al. does not describe optimizing the purification process for commercial production of any protein by increasing the dynamic capacity of the HIC column(s) through the novel use of particular combinations of only two salts … there is no suggestion in Holtz et al. to use two salts, let alone the particular combination of salts of the claimed method." Appx212. The Examiner maintained the rejection of the claim. Appx1196-1199. In response, Amgen continued to argue that the "the use of a particular *combination* of salts … confers the advantageous properties

[1] The Examiner enumerated eight pairs, but each of the four pairs is listed twice.

described in the instant application. The unexpected and advantageous properties of the particular combination of salts recited in the instant claims are clearly shown in the application." Appx972.

Ultimately, Amgen added a claim limitation that "the dynamic capacity of the column is increased for" the protein at issue, while continuing to argue that "the pending claims recite a particular *combination* of salts. No combination of salts is taught or suggested in the Holtz et al. patent, nor is the *particular* combination of salts recited in the pending claims taught or suggested in this reference." Appx1238, 1240. The claims progressed to issuance.

C. Prosecution history of the '707 patent.

As mentioned above, the Examiner stated during prosecution that the specification enabled four particular salt combinations: citrate/phosphate, citrate/sulfate, citrate/acetate, and sulfate/acetate. Appx1153-1154. The claims of the '395 patent, however, recite only one of those combinations: citrate/phosphate.

The '707 patent is a divisional of the '395 patent. Its claims recite the other three combinations: citrate/sulfate, citrate/acetate, and sulfate/acetate. Aside from that difference, the claims of the '395 patent and the '707 patent are substantively identical.

As originally drafted, the claims of the '707 patent included the claim limitation that "the dynamic capacity of the column is increased for" the protein—

i.e., the claim limitation that was added to the '395 patent before issuance. Nonetheless, the claims were rejected in view of Holtz. The Examiner stated that Holtz discloses the claimed method with salts including "sodium sulfate, potassium sulfate, ammonium sulfate, potassium phosphate, sodium acetate, ammonium acetate, sodium chloride, sodium citrate and the like." Appx174.

In response, Amgen argued: "Applicants point out that the pending claims recite a particular *combination* of salts. No combinations of salts is taught nor suggested in the Holtz et al. patent, nor is the *particular* combinations of salts recited in the pending claims taught nor suggested in this reference." Appx182 (emphasis in original). Amgen also submitted a declaration by the inventor, Anna Senczuk. Dr. Senczuk's declaration gave specific efficiency, speed, and cost information with respect to the three particular combinations of salts disclosed in the claims: citrate/sulfate, citrate/acetate, and sulfate/acetate. Appx187-88. It then explained that "[u]se of this particular combination of salts greatly improves the cost-effectiveness of commercial manufacturing by reducing the number of cycles required for each harvest and reducing the processing time for each harvest." Appx188.

The Examiner rejected the claims again, stating that "Applicant contends that the instant claims recite a particular combination of salts. However, the examiner contends that the cited reference does disclose salts used in a method of

purification." Appx949. Amgen again objected to that rejection, citing the "lengthy development path" associated with determining "what combinations of salts would increase … dynamic capacity." Appx162. It pointed out that "merely adding a second salt to the traditional HIC process … will not produce applicants' claimed method." *Id.* The claims progressed to issuance. Appx31-45.

D. Procedural history.

In August 2016, Coherus filed an abbreviated Biologic License Application ("aBLA") with the FDA under the Biologics Price Competition and Innovation Act ("BPCIA"), seeking authorization to market a biosimilar of Amgen's pegfilgrastim product, Neulasta. Appx12. The Coherus manufacturing process contains [redacted] chromatography steps used to purify pegfilgrastim. As relevant here, the [redacted] step involves a column equilibrated with a buffer containing [redacted], and [redacted]. Appx6.

Based on that filing, Amgen sued Coherus for infringement of the '707 patent. The [redacted] in Coherus's manufacturing process and described in its aBLA did not match any of the three combinations in the claim-in-suit: citrate/sulfate, citrate/acetate, and sulfate/acetate. Thus, Amgen alleged infringement under the doctrine of equivalents.

Coherus filed a motion to dismiss. Magistrate Judge Burke issued a Report and Recommendation recommending that the motion be granted with prejudice on

the basis of argument-based prosecution history estoppel. The Magistrate Judge concluded that during prosecution, Amgen clearly and unmistakably surrendered claims using salt pairs other than the three salt pairs recited in the claims because Amgen "explicitly argued (at some length)…in order to overcome the rejected based on Holtz, that its claimed invention was distinguishable … because of the claims' use of specific salt pairs." Appx27.

The District Court agreed with the Magistrate Judge's Report and Recommendation, holding that the "prosecution history, namely, the patentee's correspondence in response to two office actions and a final rejection, shows a clear and unmistakable surrender of claim scope by [Amgen]." Appx6-7. The District Court separately concluded that there was an independent basis for dismissal: the disclosure-dedication doctrine. It explained that because the [redacted] being practiced by Coherus" was disclosed in the specification but not claimed, Amgen had dedicated it to the public. Appx9-10.

SUMMARY OF ARGUMENT

The District Court ruled that Amgen's suit must be dismissed for two independent reasons: argument-based prosecution history estoppel and disclosure dedication. Both holdings are correct.

The claims-in-suit are directed to a method of purifying proteins. They require a "combination of a first salt and a second salt … wherein the first and second

salts are selected from the group consisting of citrate and sulfate, citrate and acetate, and sulfate and acetate, respectively." Appx45. The accused process uses the [redacted] and [redacted]. It is undisputed that, under the literal terms of the claims, the accused process does not infringe. Amgen thus seeks to expand the scope of its patent claim to the [redacted] via the doctrine of equivalents.

Amgen's doctrine of equivalents theory is barred by argument-based prosecution history estoppel. During prosecution, the Examiner rejected the pending claims in light of the prior art Holtz reference. The Examiner explained that Holtz "beneficially discloses a method of purification" using various citrate, sulfate, and [redacted], as well as [redacted] and [redacted] Appx201. In response, Amgen did not dispute that Holtz "discloses the use of a number of salts," including [redacted] Appx182. But it pointed out: "No combinations of salts is taught nor suggested in the Holtz et al. patent, nor is the *particular* combinations of salts recited in the pending claims taught nor suggested in this reference." *Id.* (emphasis in original). By arguing that Holtz did not disclose the "*particular* combinations of salts recited in the pending claims," Amgen is estopped from expanding its claim, via the doctrine of equivalents, beyond the particular combinations of salts recited in the claims. *PODS, Inc. v. Porta Stor, Inc.*, 484 F.3d 1359, 1368 (Fed. Cir. 2007).

This case, moreover, is a particularly strong equitable candidate for applying argument-based prosecution history estoppel. The prosecution history record reveals that if Amgen had forthrightly prosecuted the claim it now pursues under the doctrine of equivalents, it would have risked rejection on the grounds of obviousness, lack of written description, and lack of enablement. Amgen now attempts to rewrite the prosecution history: Although Amgen *said* that Holtz did not disclose the "*particular* combinations of salts recited in the pending claims," Amgen claims it *meant* that Holtz did not disclose any combinations of salts at all. But the public notice function of the prosecution history precludes Amgen's efforts at revisionist history. Amgen secured its patent based on its unambiguous representation to the Examiner that its claim covered three particular salt combinations, and no others. Amgen must be held to its word.

Amgen offers an elaborate argument about why its statements in connection with the patent-in-suit's parent application should not give rise to prosecution history estoppel. This argument is irrelevant, because those statements are virtually identical to Amgen's statements in connection with the patent-in-suit itself. Moreover, Amgen did not present this argument below and has therefore waived it. Finally, the prosecution history of the parent application supports Coherus, not Amgen. During prosecution of the parent application, the Examiner concluded that claims involving salt combinations other than the ones identified in the claims were

not enabled. This is one reason that Amgen was so insistent that its claim was limited to the particular combinations recited in the patent-in-suit, and it further undermines Amgen's efforts to rewrite the prosecution history.

Amgen's claim is also barred by the disclosure-dedication doctrine. The specification characterizes the "present invention" as broad enough to encompass any combination of "two different salts having different lyotropic values." Appx39 at 4:47-48. The specification also explicitly states that [redacted] and [redacted] have different lyotropic values. Appx39 at 4:43-44. Thus, the specification discloses the [redacted]. But that combination is not recited in the claim. By disclosing subject matter in the specification without claiming it, Amgen dedicated that subject matter to the public. Its claim under the doctrine of equivalents therefore must fail.

ARGUMENT

I. The District Court Correctly Held That Amgen's Claim Is Barred By Prosecution History Estoppel.

The District Court correctly concluded that Amgen's claim under the doctrine of equivalents is barred by argument-based prosecution history estoppel.

This is the paradigmatic case for applying argument-based prosecution history estoppel. Amgen's claim, by its terms, requires a "protein with a combination of a first salt and a second salt … wherein the first and second salts are selected from the group consisting of citrate and sulfate, citrate and acetate, and sulfate and acetate,

respectively." Appx45 at 15:11-16. The accused method uses none of these combinations, instead using the [redacted] and [redacted]. Amgen seeks to expand its claim to encompass a [redacted] via the doctrine of equivalents. But during prosecution, in an effort to distinguish a prior art reference, Amgen told the Examiner that "the *particular* combination of salts recited in the pending claims"—emphasis in original—is not "taught nor suggested in this reference." Appx182. Amgen's claim is therefore limited to the particular combination of salts recited in the claims.

A. Amgen's Argument During Prosecution Triggers the Application of Prosecution History Estoppel.

It is well-settled that "arguments made to obtain allowance of the claims at issue" may "give rise to prosecution history estoppel." *Pharmacia & Upjohn Co. v. Mylan Pharms.*, 170 F.3d 1373, 1377 (Fed. Cir. 1999). "For an estoppel to apply, such assertions in favor of patentability must evince a clear and unmistakable surrender of subject matter." *Id.* (quotation marks and citations omitted). "To determine what subject matter has been relinquished, an objective test is applied, inquiring whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter." *Id.* (quotation marks and citations omitted).

This Court has held that arguments to the Examiner distinguishing prior art from the claim-in-suit may give rise to prosecution history estoppel. In *PODS, Inc. v. Porta Stor, Inc.*, 484 F.3d 1359 (Fed. Cir. 2007), during prosecution, the patentee

distinguished a prior art reference known as Dousset on three different grounds. One of those grounds was that Dousset "clearly lacks the teachings of the singular *rectangular-shaped frame*," and another was that Dousset "lacks combined elevating and positioning means as thought by the present invention which allows the carrier frame to be elevated and positioned as a *rectangular-shaped* frame with respect to the container, the vehicle and the ground." *Id.* at 1368 (quotation marks omitted; emphasis in original). The patentee then asserted an infringement claim under the doctrine of equivalents against a product lacking a rectangular-shaped frame. The court held that the infringement claim was barred by prosecution history estoppel: "The second basis PODS offered for distinguishing Dousset, along with the reference to a rectangular shape in the third basis, clearly and unmistakably shows that PODS limited its claims to a rectangular-based frame and surrendered any claim to a frame that was not rectangular or four-sided." *Id.*; *accord Am. Calcar, Inc. v. Am. Honda Motor Co., Inc.*, 651 F.3d 1318, 1340 (Fed. Cir. 2011) (statements by patentee during prosecution that distinguished prior art reference "clearly and unmistakably surrendered subject matter" and therefore triggered application of argument-based prosecution history estoppel).

These authorities require applying prosecution history estoppel here. The Examiner rejected the claims in light of the Holtz reference, explaining that Holtz "beneficially discloses a method of purification" using "salts which improve ... the

hydrophobic interaction chromatography matrix," including various citrate, sulfate, and acetate salts, as well as [redacted] and [redacted] Appx201. In response, Amgen did not dispute that Holtz "discloses the use of a number of salts," including [redacted] Appx182. But it pointed out that the pending claims recite "a particular *combination* of salts." *Id.* (emphasis in original). It then stated: "No combination of salts is taught nor suggested in the Holtz et al. patent, nor is the *particular* combinations of salts recited in the pending claims taught nor suggested in this reference." *Id.* (emphasis in original).

Thus, Amgen distinguished Holtz from the claim-in-suit on the ground that Holtz did not teach or suggest "the *particular* combinations of salts recited in the pending claims," going as far as to italicize the word "*particular*" so as to highlight that Holtz did not teach those particular combinations. Amgen is therefore estopped from expanding its claim beyond the particular combinations of salts recited therein.

Indeed, this case is indistinguishable from *PODS*. In *PODS*, the patentee's argument during prosecution that Dousset did not disclose a rectangular shape estopped the patentee from expanding its claim, via the doctrine of equivalents, to subject matter not disclosing a rectangular shape. Here, likewise, Amgen's argument during prosecution that Holtz did not disclose the "*particular* combinations of salts recited in the pending claims" estop Amgen from expanding

its claims, via the doctrine of equivalents, to subject matter not disclosing the particular combinations of salts recited in the pending claims.

At a minimum, Amgen is estopped from expanding its patent claim to encompass [redacted] and [redacted]. Amgen did not dispute that Holtz disclosed [redacted]. Appx182. Immediately thereafter, it stated that Holtz did not disclose the "*particular* combinations of salts recited in the pending claims." Appx182. These statements make clear that the claim does not encompass [redacted], thus foreclosing Amgen's infringement claim under the doctrine of equivalents.

B. Amgen Had Strategic Reasons For Making Its Argument to the Examiner, Making This A Particularly Strong Equitable Case For Applying Prosecution History Estoppel.

Amgen's argument to the Examiner results in prosecution history estoppel regardless of whether it was actually necessary to secure Amgen's patent. *PODS*, 484 F.3d at 1368 ("Clear assertions made during prosecution in support of patentability, whether or not actually required to secure allowance of the claim, may … create an estoppel." (quotation marks omitted)). It is clear from the surrounding context of the prosecution history, however, that Amgen likely had strategic reasons for insisting that its claim was limited to three particular combinations. If Amgen had forthrightly prosecuted a claim encompassing a broader array of salt combinations—the claim it now seeks to assert via the doctrine of equivalents—such

a claim would have risked rejection for several reasons. This fact makes this case a particularly strong equitable candidate for the application of prosecution history estoppel.

First, Amgen now apparently[2] seeks to expand its claim, via the doctrine of equivalents, to encompass *any* combination [redacted] salts that increase dynamic capacity. But if Amgen had told the Examiner it was prosecuting such a claim, the Examiner might have deemed such a claim to be a predictable variation of Holtz. Holtz itself disclosed a solution loaded onto a HIC column containing a combination of four salts: "16% saturated ammonium sulfate, 40 mM sodium acetate, 40 mM sodium phosphate, pH 4.5, and 0.4M NaCl [sodium chloride]," a fact Amgen recognized during prosecution of the parent patent. Appx21-22 n.8, Appx210. Given that Holtz disclosed a combination of four salts, the Examiner may well have deemed it obvious to claim a [redacted]. By contrast, emphasizing that Amgen had discovered three particular combinations of salts that improved

[2] Amgen has never explained its basis for asserting that the [redacted] is equivalent to the combinations recited in the claims. As the Magistrate Judge observed, "Amgen's Complaint does not actually allege any facts that would support the notion that there is equivalence between the [redacted] used in Coherus's process and one or more of the three recited salt pairs in the patent. It simply states the legal conclusion that there is such equivalence, nothing more … And so, the Complaint is clearly insufficiently pleaded in that respect." Appx18-19. Nevertheless, if Amgen's theory of equivalence would sweep in the [redacted], Amgen has identified no reason that it would not sweep in any other salt combination that increases dynamic capacity.

dynamic capacity supported Amgen's contention that its claim was non-obvious. *See, e.g.*, *AbbVie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr.*, 764 F.3d 1366, 1380 (Fed. Cir. 2014) ("A species contained in a previously patented genus may be patentable if the species manifests unexpected properties or produces unexpected results.").

Indeed, in later rebutting the Examiner's conclusion that the claims were obvious in light of Holtz, Amgen emphasized to the Examiner that the invention did not merely involve "routine optimization" but instead involved a "lengthy development path." Appx161-162. Amgen relied on the extensive testing that was necessary to determine "what combinations of salts would increase the dynamic capacity for the proteins on the HIC column." Appx162. This statement was intended to support Amgen's argument that the invention was non-obvious because of the challenge in determining the particular combinations of salts that increased dynamic capacity. Indeed, as the specification points out, some combinations do not. Appx44 at 13:64-14-5. Amgen's statements to the Examiner make no sense if the invention is directed to *any* combinations of salts that increased dynamic capacity—which is the scope of the invention that Amgen now apparently claims via the doctrine of equivalents.

Second, if Amgen had disclosed to the Examiner that it intended to expand its claim beyond the particular combinations of salts recited therein, it would have

risked a written-description rejection. As just noted, Amgen argued to the Examiner that identifying "what combinations of salts would increase the dynamic capacity for the proteins" required a "lengthy development path" that was not the product of "routine optimization." Appx161-162. If Amgen had then turned around and prosecuted a claim that encompassed additional, unspecified combinations of salts that increase dynamic capacity, the Examiner may have concluded that the specification did not sufficiently describe the combinations of salts covered by the claim, given that Amgen itself had acknowledged the extensive experimentation necessary to identify them. *See In re Jolley*, 308 F.3d 1317, 1323 (Fed. Cir. 2002) ("The question as to whether an application forms a proper support for a claim to a composition which is not specifically disclosed, but which falls among compositions suggested by general language in the application" turns on " whether the application would fairly suggest to the skilled worker in the art the particular composition claimed, or whether the desirability of that composition could be ascertained only by extensive experimentation") (quoting *Prutton v. Fuller*, 230 F.2d 459, 463 (CCPA 1956)).

Third, a claim encompassing combinations involving [redacted] would have been vulnerable to an enablement rejection. As originally drafted, Amgen's claim would have covered a broad genus of salt combinations: rather than enumerating three salt combinations, the claim would have encompassed any two

salts "wherein the first and second salts have different lyotropic values." Appx635.[3] The specification—both in the initial parent application, and in the final version of both the 395 and '707 patents—recites a list of anions in order of lyotropic value, including [redacted] and [redacted] Appx618-19; Appx39 at 4:42-44. Thus, the specification makes clear that [redacted] and [redacted] have different lyotropic values, which means that the originally-drafted claim would have encompassed the [redacted].

However, the Examiner rejected the originally-drafted claim on the ground that "[t]he breadth of the claims is excessive with regard to claiming a process for purifying a protein comprising mixing a preparation containing the protein with a solution containing a first salt and a second salt." Appx1153. The Examiner explicitly stated that *only* four combinations of salts were enabled by the specification: citrate/phosphate (the combination that appears in the otherwise identical claims of the '395 patent), and the three combinations that appear in the claims of the patent-in-suit. *Id.*; *see infra* at 6-7 (explaining prosecution history in more detail). Thus, Amgen had a powerful incentive for emphasizing that its claim was directed only to those combinations. If Amgen had forthrightly prosecuted a broader claim encompassing [redacted]—which Amgen now seeks

[3] "The term 'lyotropic' refers to the influence of different salts on hydrophobic interactions." Appx39 at 4:33-34.

to sweep in via the doctrine of equivalents—its claim would likely have been rejected on enablement grounds, given that the Examiner had already decided that such combinations were not enabled.

Thus, it is no surprise that Amgen was so emphatic that its claim was limited to the "*particular* combinations of salts recited in the pending claims." Appx182. Having made that representation to the Examiner, Amgen cannot expand its claim beyond the particular combinations of salts recited therein.

C. Amgen's Contrary Arguments Are Unpersuasive.

Amgen's efforts to avoid prosecution history estoppel lack merit.

i. The "invention" was not "increasing the dynamic capacity of the HIC column for a particular protein."

Amgen's lead argument is that the supposed "invention" is "increasing the dynamic capacity of the HIC column for a particular protein." Amgen Br. 27 (capitalization altered). In support of this contention, it points to statements in the specification showing that "salt pair combinations are selected for each … protein." Amgen Br. 28. It then includes an image of Table 1, which "identifies the increase in dynamic capacity" of the salt-pair recited in the '395 claims, one salt pair that did not raise the dynamic capacity, and the three salt-pairs recited in the '707 claims: citrate/sulfate, citrate/acetate, and sulfate/acetate. Amgen Br. 29. Based on this, Amgen asserts that its statements during prosecution served to "distinguish the

single salt used in the Holtz process as not increasing dynamic capacity, as opposed to the salt pair combinations recited in the claims each of which increases dynamic capacity." Amgen Br. 30-31. It goes as far as to accuse the District Court of "ignoring the requirement to increase dynamic capacity." Amgen Br. 31.

The District Court did not ignore anything. Contrary to Amgen's assertion, the "invention" is not "increasing the dynamic capacity … for a particular protein." Amgen Br. 27 (capitalization altered). Rather, as the specification states, the "present invention *provides combinations of salts useful for* increasing the dynamic capacity." Appx38 at 2:9-11 (emphasis added). The claims enumerate those combinations: "citrate and sulfate, citrate and acetate, and sulfate and acetate." Appx45. There is no basis for Amgen's theory that this limitation is somehow not part of the invention. In any event, Amgen's contention is irrelevant to the issue before the Court: whether Amgen's statement during prosecution limiting its claim to the "*particular* combinations of salts recited in the pending claims" triggers prosecution history estoppel. Appx182.

ii. Amgen was not merely distinguishing Holtz on the basis that Holtz did not disclose combinations in general.

Amgen next contends that what it was *really* trying to do is distinguish Holtz on the basis that Holtz did not disclose any combinations *at all*. Amgen Br. 33-36. It insists that its statement during prosecution "simply observes (correctly) as a

factual matter that Holtz does not disclose the particular combinations recited in the claims—because Holtz does not disclose using combinations of salts in the first instance." Amgen Br. 35.

This argument is irreconcilable with the prosecution history, which speaks for itself. Amgen told the Examiner: "No combinations of salts is taught nor suggested in the Holtz et al. patent, nor is the *particular* combinations of salts recited in the pending claims taught nor suggested in this reference." Appx182 (emphasis in original). The first part of that sentence distinguishes Holtz on the ground that it does not disclose any combinations. The second part of that sentence states that Holtz does not disclose the particular combinations of salts recited in the pending claims. Both parts of that sentence give rise to argument-based estoppel. *PODS*, 484 F.3d at 1368 ("Since PODS offered each argument as a separate basis for distinguishing Dousset, its rectangular-frame argument created a separate estoppel.").

Further, the immediately preceding sentence in Amgen's argument to the Examiner was: "Applicants point out that the pending claims recite a particular *combination* of salts." Appx182 (emphasis in original). Thus, Amgen made two statements using italics in two different ways. Its first statement emphasized the *combination* of salts. Its second statement emphasized the *particular* combinations of salts. Amgen now argues that despite making these two statements, it actually

meant to make only the first statement. This Court's case law does not allow Amgen to rewrite its unambiguous statements during prosecution in this manner. The "public notice function of a patent and its prosecution history requires that a patentee be held to what he declares during the prosecution of his patent." *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1344 (Fed. Cir. 2015) (quotation marks omitted).

Amgen also points out that "[n]owhere did the applicants say that combinations other than citrate/sulfate, citrate/acetate, and sulfate/acetate will not work." Amgen Br. 34. While true, this does not remotely support Amgen's position. One cannot obtain a patent on a combination merely by *not* saying it will *not* work. Rather, one must actually obtain a patent claim covering that other combination—and Amgen's remarks during prosecution make clear it did not do so.

iii. The Examiner's response to Amgen's remarks does not preclude the application of prosecution history estoppel.

Amgen's argument that Holtz did not disclose the "*particular* combinations of salts recited in the pending claims" was, at first, unsuccessful. The Examiner responded by rejecting the claims again, stating that "Applicant contends that the instant claims recite a particular combination of salts. However, the examiner contends that the cited reference does disclose salts used in a method of purification." Amgen Br. 36 (quoting Appx949). Amgen contends that this

statement by the Examiner serves to somehow undo the estoppel effect of its argument. Amgen Br. 35-36.

This argument is meritless. It is irrelevant whether the Examiner ultimately relied on Amgen's argument; the relevant point is that Amgen made the argument, and thus made clear to the public that the claim did not reach beyond the particular combinations recited therein. *PODS*, 484 F.3d at 1368 ("Clear assertions made during prosecution in support of patentability, whether or not actually required to secure allowance of the claim, may … create an estoppel" (quotation marks omitted)); *Fenner Investments, Ltd. v. Cellco P'ship*, 778 F.3d 1320, 1325 (Fed. Cir. 2015) ("[T]he interested public has the right to rely on the inventor's statements made during prosecution, without attempting to decipher whether the examiner relied on them, or how much weight they were given."); *Springs Window Fashions LP v. Novo Indus., L.P.*, 323 F.3d 989, 993-96 (Fed. Cir. 2003) ("[T]he examiner's remarks do not negate the effect of the applicant's disclaimer. … The public notice function of a patent and its prosecution history requires that a patentee be held to what he declares during the prosecution of his patent.").

In any event, even if an Examiner's statement could affect the prosecution history estoppel analysis, the Examiner's statement in this case would not. The Examiner's statement that "Applicant contends that the instant claims recite a

particular combination of salts" is perfectly consistent with Amgen's argument that the claims encompass only the particular combinations of salts recited therein.

iv. Amgen's response to the Examiner's subsequent rejection does not preclude the application of prosecution history estoppel.

Following the Examiner's rejection, Amgen renewed its argument that its claims were patentable. Appx159-163. Amgen suggests that its follow-up arguments to the Examiner somehow overrode the effect of its prior statements to the Examiner. Amgen Br. 37-40.

This argument also lacks merit. Amgen's follow-up arguments to the Examiner reinforce, rather than undermine, its prior statements in prosecution that its claim was limited to the particular combinations of salts disclosed therein. Amgen emphasized the "lengthy development path" associated with determining "what combinations of salts would increase … dynamic capacity." Appx162. It emphasized that "merely adding a second salt to the traditional HIC process … will not produce applicants' claimed method." *Id.* In other words, Amgen's invention was worthy of a patent because of its hard work in determining that *these particular* combinations of two salts—as opposed to any combination of two salts—would increase dynamic capacity. This argument is consistent with, and indeed reinforces, Amgen's prior statement during prosecution that Holtz did not disclose the particular combinations of salts in the recited claims.

Amgen also submitted the declaration of the inventor, Anna Senczuk, which it had also submitted alongside its previous response. Contrary to Amgen's contention (Amgen Br. 37-38), Dr. Senczuk's declaration also reinforces the argument for applying prosecution history estoppel. Dr. Senczuk's declaration gave specific efficiency, speed, and cost information with respect to the three particular combinations of salts disclosed in the claims: citrate/sulfate, citrate/acetate, and sulfate/acetate. Appx187-88. It then explained that "[u]se of this particular combination of salts greatly improves the cost-effectiveness of commercial manufacturing by reducing the number of cycles required for each harvest and reducing the processing time for each harvest." Appx188. By emphasizing the utility of the "particular combination of salts," and offering specific data directed to the particular combinations of salts recited in the claims, Dr. Senczuk further confirmed that Amgen's claim was limited to the particular combinations of salts recited in the claims. *See, e.g.*, *Pharmacia*, 170 F.3d at 1378 (inventor's statements in declaration supported application of argument-based prosecution history estoppel).

Certainly, neither Amgen nor Dr. Senczuk ever *walked back* Amgen's unambiguous argument that the claim was limited to the particular combinations recited therein. "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). Here, there is nothing approaching a clear disclaimer of Amgen's unambiguous statements during prosecution. Amgen is therefore bound by them.

v. Expert testimony and factual development is unnecessary

As a last resort, Amgen argues that it should be entitled to offer "evidence from one of ordinary skill in the art." Amgen Br. 42-43. But it overlooks that argument-based prosecution history estoppel is a question of law reviewed de novo, not a question that requires factual development. *Pharmacia & Upjohn Co. v. Mylan Pharms.*, 170 F.3d 1373, 1376 (Fed. Cir. 1999). Amgen's statement that "the question of infringement under the doctrine of equivalents 'rarely come[s] clear on a premature record,'" Amgen Br. 42-43, is misleading. Amgen cites *Mylan Institutional LLC v. Aurobindo Pharma Ltd.*, 857 F.3d 858, 866 (Fed. Cir. 2017) for that proposition. *Id.* at 43. But in that case, the court was saying that the question of *whether an accused product is equivalent to the claim-in-suit* requires factual development. This is because that is a question of fact. This case presents a question of prosecution history estoppel—a question of law.

* * *

Amgen should be held to its own unambiguous statements during prosecution. Amgen told the Examiner that Holtz did not disclose the particular combinations of salts recited in the pending claims. It never walked that statement back. That statement triggers prosecution history estoppel. Amgen's claim under the doctrine of equivalents is therefore barred.

II. Amgen's Arguments Concerning The Parent Application Are Irrelevant And Wrong.

During prosecution of the parent application of the patent-in-suit, Amgen told the Examiner that "Holtz et al. does not describe optimizing the purification process for commercial production of any protein by increasing the dynamic capacity of the HIC column(s) through the novel use of particular combinations of only two salts … there is no suggestion in Holtz et al. to use two salts, let alone the particular combination of salts of the claimed method." Appx212. Amgen contends that this statement should not give rise to prosecution history estoppel because it was made in connection with an earlier, superseded version of the claims. Amgen Br. 43-50.

This argument should be rejected. It is irrelevant, given that Amgen's statements in connection with the prosecution of the patent-in-suit suffice, standing alone, to establish prosecution history estoppel. Amgen also waived this argument by failing to present it to the district court. On the merits, Amgen's contention reflects an improper effort to rewrite the prosecution history of the parent patent. Amgen's argument is unavailing because the prosecution of the patent-in-suit alone

unambiguously supports application of argument-based prosecution history estoppel.

A. The Court Should Disregard Amgen's Arguments Because They Are Irrelevant, Waived, and An Improper Effort to Rewrite the Prosecution History.

As a threshold matter, if the Court agrees with Coherus's argument in Part I of this brief, Amgen's argument is irrelevant. The statement by Amgen that Coherus addresses in part I—that Holtz did not disclose the "*particular* combinations of salts recited in the pending claims"—was made in connection with the prosecution of the patent-in-suit, not the parent application. Thus, if that statement gave rise to an estoppel, the District Court's judgment should be affirmed. It is irrelevant whether *additional* statements made in connection with the parent application *also* give rise to an estoppel.

Moreover, Amgen's argument is waived. Amgen offers an elaborate explanation of why its amendments during prosecution show that its statement in connection with the parent application should not give rise to an estoppel. But Amgen did not make this argument in the District Court. While Amgen referred to the fact that one of its statements was made in connection with the parent application, Appx934, it never told the District Court *why* it should treat arguments in connection with the parent application differently from arguments in connection with the patent-

in-suit. The argument it advances in its appellate brief is absent from its district court briefing.

Even if Amgen's argument was not waived, it would be meritless. Amgen relies on the fact that it added the following claim limitation during prosecution: "such that the dynamic capacity of the column is increased for the protein." Amgen Br. 44. But there is no indication from the prosecution history that the addition of this limitation had any effect on its argument to the Examiner. Before adding this limitation, Amgen told the Examiner: that "there is no suggestion in Holtz et al. to use two salts, let alone the particular combination of salts of the claimed method." Appx212. In the very amendment where Amgen added the dynamic capacity limitation, it continued to argue that "[n]o combinations of salts is taught or suggested in the Holtz et al. patent, nor is the *particular* combination of salts recited in the pending claims taught or suggested in this reference. Appx1240. After adding this limitation, Amgen recited the same argument, almost verbatim, when it told the Examiner that "[n]o combinations of salts is taught nor suggested in the Holtz et al. patent, nor is the *particular* combinations of salts recited in the pending claims taught nor suggested in this reference." Appx182. These two statements are virtually identical. It is clear that the argument Amgen now advances did not occur to Amgen's patent prosecutor.

Nor does Amgen offer any theory as to *why* this amendment would have affected its argument to the Examiner. Even before Amgen's addition of its "dynamic capacity" claim limitation, the Abstract in Amgen's application recited that "[t]he dynamic capacity of the column for a protein using the two salt combination will be increased compared with the … dynamic capacity of the column for either single salt alone." Appx637. Amgen does not explain why adding "dynamic capacity" as a claim limitation would have affected its argument to the Examiner—and, indeed, as noted above, it did not.[4]

B. The Prosecution History of the Parent Application Supports Coherus, Not Amgen.

Amgen's account of the prosecution history of the parent application is incomplete—the complete account of that prosecution history actually bolsters the case for applying prosecution history estoppel. The Court is free to ignore this argument if it concludes that Amgen's arguments in connection with the prosecution of the patent-in-suit suffice to establish prosecution history estoppel. But if the Court considers the prosecution of the parent application, it should have a full

[4] Amgen also argues briefly that its statements in connection with the parent application did not "clearly and unmistakably" surrender claim scope. Amgen Br. 48-50. But for the reasons already explained, Amgen's statement that "there is no suggestion in Holtz et al. to use two salts, let alone the particular combination of salts of the claimed method," Appx212, is clear and unmistakable. *See supra* at 7-8. Amgen does not even address this statement. Instead it focuses exclusively on *other* portions of its argument to the Examiner and makes the irrelevant argument that *those* did not surrender claim scope. Amgen Br. 48-50.

understanding of what actually occurred. *See supra* at 5-8 (providing detailed account of prosecution history).

Amgen's original patent application was directed to a broad genus of salt combinations: any combination "wherein the first and second salts have different lyotropic values." Appx635. In response, the Patent Office issued a restriction requirement under 37 C.F.R. § 1.146. Under this regulation, when a patentee prosecutes a "generic claim to a generic invention (genus)," the Patent Office may require the applicant "to elect a species of his or her invention to which his or her claim will be restricted if no claim to the genus is found to be allowable." Thus, the Patent Office directed Amgen to elect a particular species of salt combination to prosecute alongside its genus claim.

On April 13, 2007, in response to this Office Action, Amgen told the Examiner that it "elect[ed] the combination of citrate and phosphate salts to be fully compliant." Appx267. It also made clear to the Examiner that it was still pursuing the "generic claim[]"—*i.e.*, the claim with the limitation "wherein the first and second salts have different lyotropic values." Appx267-68.

Next came an Office Action that goes unmentioned in Amgen's brief. In Amgen's telling, Amgen amended its claims on April 13, 2007, and then amended its claims again on November 16, 2007. Amgen Br. 10. Amgen makes no mention

of the fact that an Office Action was issued between those two amendments that was the basis for the second amendment.

That Office Action issued on July 17, 2007. The Patent Office rejected the genus claim on the ground that the specification, "does not reasonably provide enablement for a process for purifying a protein comprising mixing the protein with a first salt and a second salt having different lyotropic values." Appx1152. The Examiner concluded that the invention was enabled only with respect to four categories of salts: citrate/phosphate, citrate/sulfate, citrate/acetate, and sulfate/acetate. Appx1153-1154 (listing those four categories).[5]

Notably, [redacted] is not on that list, even though the generic claim would have encompassed that combination. The generic claim encompassed any salt combination "wherein the first and second salts have different lyotropic values," and the specification explicitly identified [redacted] and [redacted] as having different lyotropic values. Appx618-19.

Amgen then abandoned its genus claim, amending that claim to add the limitation "wherein the first and second salts are citrate and phosphate salts"—*i.e.*, the species claim. Appx192. While Amgen expressed disagreement with the enablement rejection, Appx194-195, it no longer prosecuted the generic claim. Amgen asserts in its brief that "such generic claims were included in the original

[5] The Examiner enumerated eight pairs, but each of the four pairs is listed twice.

application for the parent application and eventually issued in the '395 Patent," Amgen Br. 47, but that assertion is incorrect. The '395 Patent did *not* include generic claims; all claims of the '395 Patent recite the citrate/phosphate combination. *See* Amgen Br. 14 (quoting claim 1 of '395 Patent).

The patent-in-suit was filed as a divisional of the '395 patent application. It encompasses three additional species of salt combinations: citrate/sulfate, citrate/acetate, and sulfate/acetate. Thus, according to the Examiner, of the four salt combinations that are enabled by the specification, the '395 patent identifies one, and the patent-in-suit identifies the other three.

This more complete recitation of the prosecution history is relevant for two reasons. First, it undermines Amgen's effort to minimize its statements during prosecution of the parent application. Amgen claims that it limited the parent application to the citrate and phosphate salt pair "because of the Patent Office's restriction requirement in the parent application." Amgen Br. 46-47. Thus, Amgen theorizes, when Amgen prosecuted a divisional application encompassing additional salt combinations, this meant that the restriction requirement vanished, which meant that Amgen reserved the right to expand its claim to encompass [redacted] via the doctrine of equivalents. Amgen Br. 47-48. This convoluted argument ignores the Examiner's enablement rejection, which pointedly stated that "Applicant has only provided guidance for the use of citrate, acetate, phosphate, and

sulfate salts," and explicitly identifies the four salt combinations that are enabled by the specification. Appx1153. It is therefore not surprising that the '395 and '707 patents, collectively, specify those four salt combinations and no others. Nothing in this prosecution history could possibly suggest that Amgen would someday claim that [redacted] are infringing.[6]

Second, this portion of the prosecution history bolsters the fact that when Amgen emphasized that Holtz did not disclose the *particular* combinations of salts recited in the pending claims, Amgen meant what it said. The Examiner had previously determined that the patent would be enabled only with respect to four combinations: citrate/phosphate (the combination in the '395 patent), and the three combinations in the patent-in-suit. It thus makes sense that Amgen would have emphasized that its claim was directed to those particular combinations.

III. Amgen's Claim Under the Doctrine of Equivalents is Barred By The Disclosure-Dedication Doctrine.

The District Court held that Amgen's claim is not only barred by argument-based prosecution history estoppel, but is also barred by the disclosure-dedication doctrine. Appx9-10. That holding is correct, and is an independent basis for affirming the District Court's decision.

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[6] Moreover, this prosecution history would also support an amendment-based prosecution history estoppel argument. As originally drafted, the claim would have encompassed [redacted]; Amgen narrowed it to exclude that combination in light of the enablement rejection.

"[W]hen a patent drafter discloses but declines to claim subject matter … this action dedicates that unclaimed subject matter to the public. Application of the doctrine of equivalents to recapture subject matter deliberately left unclaimed would conflict with the primacy of the claims in defining the scope of the patentee's exclusive right." *Johnson & Johnson Assocs. Inc. v. R.E. Service Co.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002) (quotation marks omitted). For instance, in *Johnson & Johnson*, the claim-in-suit recited "a sheet of aluminum," but the specification read: "While aluminum is currently the preferred material for the substrate, other metals, such as stainless steel or nickel alloys may be used." *Id.* at 1055. The Court held that the disclosure-dedication doctrine applied: "Having disclosed without claiming the steel substrates, Johnston cannot now invoke the doctrine of equivalents to extend its aluminum limitation to encompass steel." *Id.*

PSC Computer Prods., Inc. v. Foxconn Int'l, Inc., 355 F.3d 1353 (Fed. Cir. 2004), elaborated upon the application of the disclosure-dedication doctrine. The court held that a "generic reference in a written specification" does not "necessarily dedicat[e] all members of that particular genus to the public"; rather, the "disclosure must be of such specificity that one of ordinary skill in the art could identify the subject matter that had been disclosed and not claimed." *Id.* at 1360. Applying that principle, the Court held that when a patent claim included a "resilient metal strap" limitation, and the specification stated that the strap "is made of a resilient metal

such as stainless steel although other resilient materials may be suitable for the strap," this "*generic* disclosure … did not dedicate all resilient materials other than stainless steel to the public." *Id.* at 1356, 1360. However, when the specification contained "the *specific* disclosure that '[o]ther prior art devices use molded plastic and/or metal parts that must be cast or forged which again are more expensive metal forming operations,'" this disclosure "dedicated the alternative use of plastic parts to the public." *Id.* at 1360.

Johnson & Johnson and *PSC* establish that Amgen dedicated the alleged equivalent to the public. The claim-in-suit covers three particular salt combinations: citrate/sulfate, citrate/acetate, and sulfate/acetate. Amgen seeks to expand its claim to encompass a [redacted]. That [redacted], however, was disclosed in the specification, but not claimed.

The specification states that "the term 'lyotropic' refers to the influence of different salts on hydrophobic interactions, more specifically the degree to which an anion increases the salting out effect on proteins, or for cations, increases the salting-in effect on proteins …" Appx39 at 4:33-37. It then discloses a series of nine "anions in order of decreasing salting-out effect," the first four of which were phosphate (PO_4^{3-}), sulfate (SO_4^{2-}), acetate (CH_3COO^-), and chloride (Cl^-). Appx39 at 4:42-44. It also discloses a series of "cations in order of increasing salting-in effect," one of which was [redacted]. Appx39 at 4:45-46. It explains that "[a]ccording

to the present invention, combining two different salts having different lyotrophic (sic) values with a protein preparation allows more protein to be loaded onto a column with no or negligible breakthrough compared with higher salt concentrations of each single salt." Appx39 at 4:46-51.

This portion of the specification triggers the application of the disclosure-dedication doctrine. The specification includes a list of anions stating that [redacted] has a greater lyotropic value than [redacted]—*i.e.*, that [redacted] and [redacted] have different lyotropic values. Appx39 at 4:43-44. It then characterizes the "present invention" as "combining two different salts having different lyotrophic (sic) values." Appx39 at 4:47-48. This characterization of the "present invention" is consistent with the patent claims as drafted in the parent application, which broadly encompassed any [redacted] "wherein the first and second salts have different lyotropic values." Appx635.

But the claim-in-suit, as ultimately issued by the Patent Office, does not encompass every combination of "different salts having different lyotropic values." Instead, it encompasses three particular combinations: citrate/sulfate, citrate/acetate, and sulfate/acetate. The specification states that [redacted] and [redacted] are different [redacted] having different lyotropic values, but that combination is not claimed. Amgen has therefore dedicated equivalents involving the [redacted] to the public, and its infringement claim under the doctrine of equivalents is barred.

Amgen's cursory arguments to avoid application of the disclosure-dedication doctrine lack merit. Amgen first states that the doctrine does not apply because the portion of the specification cited by the District Court did not "disclose any salt pairs." Amgen Br. 51-52. Effectively, however, it did. It characterized [redacted] and [redacted] as having different lyotropic values, and immediately thereafter, characterized the "present invention" as "combining two different salts having different lyotropic values." Appx39 at 4:41-48. This is more than sufficient for "one of ordinary skill" to "identify the subject matter that had been disclosed and not claimed"—*i.e.*, the [redacted]. *PSC*, 355 F.3d at 1360.

Next, Amgen asserts the doctrine does not apply because "the list does not identify a single salt" such as [redacted] and thus does not characterize the [redacted] as "an alternative to the claimed invention." Amgen Br. 52. This argument is wrong for two reasons. First, Amgen overlooks its own theory of infringement: that the equivalent in question is the [redacted], not [redacted] specifically involving [redacted]. Amgen's complaint and appellate brief make this clear. *See* Amgen Br. 36 ("Amgen alleged in its Complaint—which is taken as true here—that the salt combination used in Coherus's accused process [redacted] is equivalent to the claimed salt combinations … it is the use of the [redacted] and [redacted] to increase dynamic capacity that meets the claims under the doctrine of equivalents.")

The disclosure-dedication doctrine turns on whether the specification discloses *the claimed equivalent*. Because *the claimed equivalent* is [redacted], and the specification discloses *that* combination, Amgen's claim under the doctrine of equivalents must fail. Second, Amgen overlooks that the relevant portion of the specification discloses [redacted] the [redacted] and the [redacted]. Appx39 at 4:43, 4:45. One of skill in the art, and indeed any high-school student, is aware that [redacted] the [redacted] and [redacted] when dissolved. Thus, even if a disclosure of [redacted] were required for the disclosure-dedication doctrine to be satisfied, that requirement would be satisfied.

Amgen next emphasizes the applicable legal standard: that the "disclosure must be of such specificity that one of ordinary skill in the art could identify the subject matter that had been disclosed and not claimed." Amgen Br. 52. But as described above, that standard is amply satisfied in this case.

Finally, Amgen argues that the District Court should have heard expert testimony. Amgen Br. 53. But "the disclosure-dedication rule … presents a question of law, subject to de novo review." *Toro Co. v. White Consol. Indus., Inc.*, 383 F.3d 1326, 1331 (Fed. Cir. 2004). Thus, expert testimony is unhelpful for resolving that purely legal question. Moreover, Amgen offers no explanation of how expert testimony would have undermined the District Court's straightforward conclusion that the disclosure-dedication doctrine applies.

CONCLUSION

The judgment of the District Court should be affirmed.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 31, 2018, I caused the foregoing RESPONSE BRIEF OF DEFENDANT-APPELLEE COHERUS BIOSCIENCES INC. (CONFIDENTIAL and NON-CONFIDENTIAL versions) to be electronically filed with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the CM/ECF system, which caused a copy of the foregoing to be delivered by electronic means to counsel of record. I also caused a true and correct copy of the foregoing to be electronically served, pursuant to agreement of the parties, on Plaintiff-Appellant Amgen Inc. and Amgen Manufacturing, Limited's counsel of record as follows:

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CERTIFICATE OF COMPLIANCE

I hereby certify that:

1. This Brief complies with the type-volume limitation of Fed. Cir. R. 28.1(b) and Fed. Cir. R. 32(a) because this Brief contains 9867 words, excluding the parts of the Brief exempted by Fed. R. App. P. 32(f) and Federal Circuit Rule 32(b).

2. This Brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this Brief has been prepared in a proportionately spaced typeface using Microsoft Office Word 2013 in Times New Roman, Font Size 14.

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UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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Appellee
(State whether representing appellant, appellee, etc.)

October 31, 2018
(Date)