IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC. and AMGEN MANUFACTURING LIMITED,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil Action No. 17-546-LPS-CJB
	)	
COHERUS BIOSCIENCES INC.,	)	
	)	
Defendant.	)	

REPORT AND RECOMMENDATION

In this patent infringement action filed by Plaintiffs Amgen Inc. and Amgen Manufacturing Limited ("Plaintiffs" or "Amgen") against Defendant Coherus Biosciences Inc. ("Defendant" or "Coherus"), pending is Coherus's motion to dismiss the Complaint, filed pursuant to Federal Rule of Civil Procedure 12(b)(6) (the "Motion"). (D.I. 9) For the reasons that follow, the Court recommends that Coherus's Motion be GRANTED with prejudice.[1]

I. BACKGROUND

The Biologics Price Competition and Innovation Act ("BPCIA") was enacted by Congress to establish a regulatory process for an applicant to obtain approval by the United States Food and Drug Administration ("FDA") to market biological products that are "biosimilar" to biological reference products that have been FDA-approved. 42 U.S.C. § 262; (*see also* D.I. 1 at ¶ 8). In August 2016, Coherus filed an abbreviated Biologic License Application ("aBLA"), seeking FDA approval to market a biosimilar version of Amgen's pegfilgrastim product, Neulasta®. (D.I. 1 at ¶¶ 9-10) The parties then engaged in the exchange

[1] The Motion has been referred to the Court for resolution, (D.I. 6), and was fully briefed on June 22, 2017, (D.I. 22). Coherus's pending motion to seal its reply brief, (D.I. 21), is hereby GRANTED for the reasons articulated in that motion.

of information required by the BPCIA, and ultimately agreed in April 2017 that United States Patent No. 8,273,707 (the "'707 patent") should be included in an infringement action to be filed by Amgen pursuant to Section 262(*l*)(6)(A) of the BPCIA. (*Id.* at ¶¶ 12-13) Accordingly, on May 10, 2017, Amgen filed its Complaint, alleging that Coherus's process for manufacturing its biosimilar infringes the '707 patent. (*Id.* at ¶¶ 7, 18-20) Amgen seeks, *inter alia*, to enjoin Coherus from launching its pegfilgrastim biosimilar product. (*Id.* at ¶¶ 51, 56, 59, 65, 71)

The '707 patent is directed to a process for purifying proteins. Its specification explains that biologic drug products constitute therapeutic proteins that are manufactured inside living cells. (D.I. 1, ex. A, col. 1:19-25)[2] These proteins must then be separated from the source material. (*Id.*, col. 1:25-35) One such purification technique is known as hydrophobic interaction chromatography ("HIC"). (*Id.*, col. 1:36-51) With this process, a solution made up of the desired protein and associated impurities is poured onto a column filled with solid particles known as the "matrix." (*Id.*; *see also id.*, col. 3:53-61) The interaction between the matrix material and loading solution causes the proteins to adhere to the matrix as the solution flows through the matrix. (*Id.*, cols. 1:40-45, 3:53-61) This step in the HIC process is known as "loading" the mixture onto the column. (*Id.*, col. 1:40-41) More solution is then poured through the column to "wash" it. (*Id.*, col. 4:27-29) Finally, a different solution is then poured through the column to "elute" the desired proteins therefrom. (*Id.*, cols. 1:45-49, 4:29-30)

Amgen's claimed invention is a solution to a problem with HIC known as "breakthrough," in which significant amounts of protein are washed away with the impurities

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[2] The '707 patent is attached to the Complaint as Exhibit A. Hereafter, citation will be to the "'707 patent."

before the elution step begins. (*Id.*, cols. 3:37-41, 4:10-12) The specification explains that the claimed process increases the "'dynamic capacity'" of the column by "increas[ing] . . . the amount of protein that can be loaded onto a column without 'breakthrough[.]'" (*Id.*, col. 3:37-40) It does so by using "intermediate concentration[s]" of a combination of salts in the loading solution. (*Id.*, cols. 3:31-36, 4:24-27; *see also id.*, col. 2:39-42 ("The two salt buffers of the present invention result in an increase in dynamic capacity of an HIC column for a particular protein compared with the dynamic capacity achieved by single salts.")) As the patent summarizes: "The present invention is a process for purifying a protein comprising mixing a protein preparation with a buffered salt solution containing a first salt and a second salt, wherein each salt has a different lyotrophic value, and loading the protein salt mixture onto an HIC column." (*Id.*, col. 4:56-60)

The '707 patent contains two independent claims and 11 dependent claims. All 13 claims of the patent have at least two requirements. First, the combination of salts that is used in the loading solution must be one of three listed pairs of salts: "citrate and sulfate, citrate and acetate, [or] sulfate and acetate" (the "salt pairing limitation"). (*Id.*, cols. 15:15-16, 16:15-16) Second, the claims require 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." (*Id.*, cols. 15:16-18, 16:16-18)[3]

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[3] More specifically, independent claim 1 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*

II. STANDARD OF REVIEW

The sufficiency of pleadings for non-fraud cases is governed by Federal Rule of Civil Procedure 8, which requires "a short and plain statement of the claim showing that the pleader is entitled to relief[.]" Fed. R. Civ. P. 8(a)(2). When presented with a Rule 12(b)(6) motion to dismiss for failure to state a claim, a court conducts a two-part analysis. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009). First, the court separates the factual and legal elements of a claim, accepting "all of the complaint's well-pleaded facts as true, but [disregarding] any legal conclusions." *Id.* at 210-11. Second, the court determines "whether the facts alleged in the complaint are sufficient to show that the plaintiff has a 'plausible claim for relief.'" *Id.* at 211 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009)). A plausible claim does

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> *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.*

('707 patent, col. 15:8-18 (emphasis added))

Independent claim 10 recites:

> **10.** A method of increasing the dynamic capacity of a hydrophobic interaction chromatography column for a protein, comprising mixing a preparation containing the protein with a combination of a first salt and a second salt, and loading the mixture onto a hydrophobic interaction chromatography column, *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 and second salts in the mixture is between about 0.1 M and about 1.0 M.*

(*Id.*, col. 16:9-18 (emphasis added))

more than merely allege entitlement to relief; it must also demonstrate the basis for that "entitlement with its facts." *Id.* Thus, a claimant's "obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do[.]" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). In assessing the plausibility of a claim, the court must "'construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief.'" *Fowler*, 578 F.3d at 210 (quoting *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008)).[4]

III. DISCUSSION

Coherus asserts that it is entitled to dismissal of Amgen's Complaint for failure to state a claim because the accused manufacturing process described in Coherus's aBLA does not satisfy either of the two requirements of the '707 patent claims described above (i.e., that the combination of salts used must be either citrate/sulfate, citrate/acetate or sulfate/acetate, and that the concentration [redacted] must be between about 0.1 M and 1.0). (D.I. 10 at 2-3) Below, the Court need only evaluate the first of these requirements, as the Court agrees with Coherus that there is no plausible claim that its process satisfies the salt pairing limitation.[5]

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[4] In resolving a motion to dismiss, a court may consider not only the allegations in the Complaint, but also, *inter alia*, exhibits attached to the Complaint, documents integral to or explicitly relied upon in the Complaint, and matters of public record. *See, e.g.*, *In re Burlington Coat Factory Secs. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997); *Oshiver v. Levin, Fishbein, Sedran & Berman*, 38 F.3d 1380, 1384-85 & n.2 (3d Cir. 1994); *Quest Integrity USA, LLC v. Clean Harbors Indus. Servs., Inc.*, C.A. No. 14-1482-SLR, Civ. No. 14-1483-SLR, 2015 WL 4477700, at *2 (D. Del. July 22, 2015).

[5] At the outset, the Court notes that Amgen seems to suggest in its answering brief that patent infringement actions brought under the BPCIA are not subject to Federal Rule of Civil Procedure 12(b)(6). To that end, Amgen notes that infringement here turns on whether

The relevant accused step of the manufacturing process set forth in Coherus's aBLA[6] is [redacted] Hence, the combination of salts [redacted] is thus not "selected from the group consisting of citrate and sulfate,

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Coherus's intended manufacturing process is covered by Amgen's claims, and states that it may learn additional facts in discovery "to support its infringement claim." (D.I. 17 at 2, 19-20) Amgen's position thus seems to be that even if it cannot not now make out a plausible claim of infringement, that doesn't matter, because it might well learn additional facts in the future in the litigation that *would* allow it to make out such a claim (and so, in the meantime, it should get to proceed forward). That is not the way that the federal pleading requirements normally work, as if a plaintiff cannot make out a plausible claim in its complaint, then the complaint is to be dismissed pursuant to Rule 12(b)(6). If there is some reason why an infringement claim brought pursuant to the BPCIA is not required to pass muster under *Twombly* and *Iqbal*, Amgen has not sufficiently explained it. Or if there is some case law that says that is so, Amgen has not cited it.

[6] The Court's decision here takes into account the contents of Coherus's aBLA, as well as portions of the '707 patent's prosecution history that Coherus attached to its opening brief. (D.I. 10) Amgen asserts that Coherus's Motion, which similarly relies on such materials, "improperly relies on documents outside the Complaint[.]" (D.I. 17 at 2 (emphasis in original)) Amgen is incorrect. With respect to the aBLA, it is the document that formed the basis for Amgen's patent infringement claims, and as such, is referenced throughout the Complaint. (*See, e.g.*, D.I. 1 at ¶¶ 9-20, 46) Thus, it is clearly a document that is integral to the Complaint and one that the Court can rely upon at this stage. *See, e.g.*, *AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1378 n.5 (Fed. Cir. 2012) (finding that the district court did not err in considering defendant's submissions to the FDA in resolving a motion to dismiss, as the complaints at issue "referenced and relied on" those submissions); (D.I. 10 at 10; D.I. 22 at 3). As for the prosecution history, a court may take judicial notice of a patent's prosecution history in resolving a motion to dismiss, as the prosecution history is a public record. *See, e.g., Purdue Pharma L.P. v. Mylan Pharms. Inc.*, Civil Action No. 15-1155-RGA-SRF, 2017 WL 784989, at *4, *6 (D. Del. Mar. 1, 2017); *Genetic Techs. Ltd. v. Bristol-Myers Squibb Co.*, 72 F. Supp. 3d 521, 526, 532 (D. Del. 2014) (citing *Hockerson-Halberstadt, Inc. v. Avia Grp. Int'l, Inc.*, 222 F.3d 951, 957 (Fed. Cir. 2000)); *see also Anchor Sales & Mktg., Inc. v. Richloom Fabrics Grp., Inc.*, No. 15-CV-4442 (RA), 2016 WL 4224069, at *1 n.1 (S.D.N.Y. Aug. 9, 2016). The Court will further address Amgen's objection to considering the prosecution history later in this Report and Recommendation.

citrate and acetate, and sulfate and acetate," as required by the claims of the '707 patent. It is not disputed, then, that Coherus's manufacturing process cannot literally infringe this limitation of the patent. (D.I. 10 at 11; D.I. 17 at 7, 13-14) As a result, Amgen's Complaint instead alleges that Coherus's process infringes the salt pairing limitation only pursuant to the doctrine of equivalents. (D.I. 1 at ¶ 50)

A product that does not literally infringe a patent claim may still infringe under the doctrine of equivalents if the differences between the claimed invention and the accused product are insubstantial. *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21, 40 (1997); *Virnetx, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1322 (Fed. Cir. 2014); *see also Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 733 (2002) ("The doctrine of equivalents allows the patentee to claim those insubstantial alterations that were not captured in drafting the original patent claim but which could be created through trivial changes."). Under the doctrine of equivalents, the essential inquiry is whether there is equivalence between the elements of the accused process and the claimed elements of the patented invention. *Warner-Jenkinson Co.*, 520 U.S. at 21, 40; *MiiCs & Partners Am., Inc. v. Toshiba Corp.*, — F. Supp. 3d —, 2017 WL 4786426, at *3 (D. Del. Oct. 24, 2017).

Amgen's Complaint does not actually allege any facts that would support the notion that there is equivalence between [redacted] 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. (D.I. 1 at ¶ 50 ("With respect to the use of dual salts, in the Coherus process, a preparation containing protein is mixed with a combination of a first salt and a second salt, *which combination is the equivalent of one or more of the recited salt pairs*." (emphasis

added)) And so, the Complaint is clearly insufficiently pleaded in that respect.

But Coherus further argues that there is no reason to allow re-pleading here. This is because Coherus asserts that, in light of the doctrine of prosecution history estoppel, as a matter of law there *can be no* infringement of the '707 patent claims' salt pairing limitation under the doctrine of equivalents. (D.I. 10 at 12) As the United States Court of Appeals for the Federal Circuit has explained, "[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." *Trading Techs. Int'l, Inc. v. Open E Cry, LLC*, 728 F.3d 1309, 1322 (Fed. Cir. 2013). Whether prosecution history estoppel applies, and therefore whether a patentee may assert the doctrine of equivalents for a particular claim limitation, is a question of law. *Spectrum Pharms., Inc. v. Sandoz Inc.*, 802 F.3d 1326, 1337 (Fed. Cir. 2015); *Intellectual Ventures I LLC v. T-Mobile USA, Inc.*, C.A. No. 13-1632-LPS, 2017 WL 3723934, at *5 (D. Del. Aug. 29, 2017). Prosecution history estoppel can occur in two ways: (1) by making a narrowing amendment to a claim ("amendment-based estoppel"); or (2) by surrendering claim scope through argument to the patent examiner ("argument-based estoppel"). *Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349, 1363 (Fed. Cir. 2006).

Coherus relies on argument-based estoppel here as assertedly barring Amgen's infringement claim. (D.I. 10 at 11-12) To invoke argument-based estoppel, "the prosecution history must evince a clear and unmistakable surrender of subject matter." *Conoco, Inc.*, 460 F.3d at 1364 (internal quotation marks and citation omitted). The relevant inquiry is an objective test, which inquires "whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter." *Id.* (internal quotation marks and citation omitted); *see*

also AquaTex Indus., Inc. v. Techniche Sols., 419 F.3d 1374, 1382 (Fed. Cir. 2005). "[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." *PODS, Inc. v. Porta Stor, Inc.*, 484 F.3d 1359, 1367 (Fed. Cir. 2007) (internal quotation marks and citation omitted).[7]

Coherus contends that during prosecution of the '707 patent, Amgen distinguished a prior art reference ("Holtz") and overcame the patent examiner's ("Examiner") rejection, on the ground that Holtz did not teach or suggest the particular combinations of salts (citrate/sulfate, citrate/acetate and sulfate/acetate) claimed in the patent. As such, according to Coherus, Amgen is now estopped from asserting that a different salt combination [redacted] is infringing. (D.I. 10 at 12; D.I. 22 at 7-8)

To assess this issue, the Court turns to the prosecution history. In October 2010, the Examiner rejected the claims of the '707 patent as obvious over Holtz, a United States patent. (D.I. 10, ex. 2 at 4) Holtz was described by the Examiner as disclosing a method for purifying insulin-like growth hormone in which salts will be used to improve interaction between the protein and the matrix– [redacted] In rejecting the claims, the Examiner opined that:

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[7] Even where they are not necessary to secure allowance of the claim, statements that clearly and unmistakably surrender claim scope can preclude an assertion of equivalency. *See Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1252 (Fed. Cir. 2000) ("Unmistakable assertions made by the applicant to the . . . PTO . . . in support of patentability, whether or not required to secure allowance of the claim, . . . may operate to preclude the patentee from asserting equivalency[.]") (internal quotation marks and citation omitted).

> It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to purify a protein including an insulin-like growth hormone via the instantly claimed steps based upon the overall beneficial teachings provided by the cited reference. The adjustment of particular conventional working conditions (if not expressly taught) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

(*Id.* at 5)

In a January 26, 2011 Response to that Office Action, the patentee noted the Examiner's statement that Holtz "discloses the use of a number of salts . . . [redacted] The patentee then explained why it disagreed that its invention was obvious over Holtz: "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." (*Id.* (emphasis in original)) The patentee continued that "[t]he claimed subject matter is directed to use of combinations of salt that *increase the dynamic capacity* of the [HIC] columns." (*Id.* (emphasis in original)) In Holtz, meanwhile, "[t]here is no description or suggestion . . . for the use of any combination of salts to increase the dynamic capacity of a HIC[,]" (*id.*), nor any "suggestion in Holtz [] that any *particular* combinations of salts would have the result . . . of increasing dynamic capacity of a HIC[,]" (*id.* at 6 (emphasis added)).[8] The patentee also attached a Declaration of the patent's

[8] Coherus further points out that during prosecution of the parent patent, which claims recited a combination of "citrate and phosphate salts," (D.I. 10, ex. 7 at 3), the patentee explained that Holtz described an example containing a solution loaded onto a HIC column containing "16% saturated ammonium sulfate, 40 mM sodium acetate, 40 mM sodium

first-listed inventor, Anna Senczuk, to support its patentability position. (*Id.* at 5-7) In the Declaration, Ms. Senczuk explained that she performed experiments testing single salts and combination of salts, and that:

> [1] My co-inventor and I discovered that using *certain combinations* of salts will greatly improve the dynamic capacity of a . . . HIC[] column . . . . Previously, it was not known that *salt combinations* had anything to do with improving dynamic capacity of a HIC.
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> [2] Increasing the dynamic capacity of the HIC is very significant in a commercial manufacturing setting, since this allows more protein to be purified per purification cycle. . . . I performed calculations illustrating the benefits for commercial manufacturing of using *a specific dual salt combination* to load protein onto a HIC[.]

(*Id.*, ex. 4 at ¶¶ 2-3 (emphasis added)) Ms. Senczuk then sets out the "benefits that result from the use of dual salts in the HIC column[,]" noting that the claimed sulfate/citrate and sulfate/acetate combinations allowed for fewer cycles of purification, and that these combinations, as well as the claimed acetate/citrate combination, reduced processing time. (*Id.* at ¶ 4) Ms. Senczuk then concluded her Declaration by noting that:

> The improvement resulting from the use of dual salts in HIC goes beyond merely optimizing a column to best suit a particular protein. *Use 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.

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phosphate, pH 4.5, and 0.4M NaCl [sodium chloride][,]" (*id.* at 6). (D.I. 22 at 8) The patentee distinguished its invention by explaining that Holtz did not "teach or suggest combining the protein to be purified with the particular *combination of two salts, citrate and phosphate salts* . . . . [i]nstead, [disclosed in Holtz is] a protein solution containing lower concentrations of sodium acetate and sodium phosphate, together with [sodium chloride] and a high concentration of ammonium sulfate (four salts, not a combination of two salts as recited in the claimed method)[.]" (D.I. 10, ex. 7 at 6 (emphasis in original))

(*Id.* (emphasis added))

In an April 2011 Office Action, the Examiner maintained its rejection of the claims as obvious over Holtz for the same reasons as described above. (*Id.*, ex. 1 at 1, 4) In August 2011, the patentee traversed the rejection. The patentee explained that the Examiner's rejection over Holtz overlooked "the use of a *combination* of salts" in the invention's HIC process (and also overlooked the "*enhancement of the dynamic capacity of a HIC column*" caused by the invention). (*Id.* at 5 (emphasis in original)) Holtz, the patentee explained, "does not teach each and every element of the claimed invention[,]" "namely" because it "simply does not disclose, suggest or contemplate any steps involving a combination of two salts for any purpose whatsoever." (*Id.*) And later in its statement, the patentee further emphasized that "merely adding a second salt to the traditional HIC process, as the Patent Office appears to suggest, will not produce applicants' claimed method." (*Id.* at 7)

In view of this prosecution history, the Court finds that the patentee clearly and unmistakably—and indeed, repeatedly—indicated to competitors that it surrendered processes using combinations of salts different from the "*particular* combinations of salts recited in the [] claims[.]" (*Id.*, ex. 3 at 5 (emphasis in original)) The Court acknowledges that if all that was in the prosecution history was the patentee's general focus on the fact that its invention disclosed the use of a *combination* of salts (in contrast to Holtz's disclosure of the use of a single salt) then its conclusion would not be warranted. But in order to overcome the Examiner's rejection of the claims over Holtz, the patentee distinguished its invention not only on that ground, but also for

the independent reason that the invention recited the use of *particular* combinations of salts.[9] And the patentee supported its position with an inventor declaration providing test results for those *particular claimed combinations*—one that touted the benefits of use of those specific combinations—in order to show how their use resulted in a process that improved the dynamic capacity of a HIC column. In sum, the patentee's arguments distinguishing its invention from Holtz clearly and unmistakably demonstrate that it limited its claims to a process using one of the *particular*, recited combinations of salts; thus, Amgen surrendered any claim to a process that used other, unrecited salt combinations. *See PODS, Inc.*, 484 F.3d at 1367-68 (finding that statements made by the patentee during prosecution barred it from asserting that defendant's device infringed pursuant to the doctrine of equivalents where the patentee, "in support of its assertion of patentability over [prior art reference] Dousset, clearly stated that its claimed frame was rectangular in shape [and] [a] competitor would reasonably believe that [the patentee] had surrendered any claim to a frame that was not rectangular or four-sided in shape, such as [the defendant's] three-sided, u-shaped device"); *see also Ottah v. VeriFone Sys., Inc.*, 524 F. App'x 627, 629-30 (Fed. Cir. 2013) (affirming the district court's holding that the patentee's claim was barred by prosecution history estoppel where, in response to a prior art rejection, the patentee "emphasized that the patentability of the '840 patent's claim was based on the removable nature of the mount [and accordingly] [h]e cannot now, under the doctrine of equivalents, seek to broaden the scope of his claim to include mounts that are fixed as well as those that are

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[9] Indeed, as if to highlight this point even further, so that the Examiner would not miss it, the patentee actually placed the word "particular" in the phrase "particular combination of salts" in italics. (D.I. 10, ex. 3 at 5 ("No combinations of salts is taught nor suggested in the Holtz [] patent, nor is the *particular* combinations of salts recited in the pending claims taught nor suggested in this reference.") (emphasis in original))

removable"); *Anchor Sales & Mktg., Inc.*, 2016 WL 4224069, at *5 (concluding that argument-based prosecution history estoppel barred plaintiff from now arguing infringement under the doctrine of equivalents for methods of forming scalloped configuration in curtains that do not involve sliding a bead up and down, where the patentee had argued in prosecution that unlike the cord stops or toggles described in the prior art, the essence of his invention was sliding the sphere up and down).[10]

Amgen's arguments to the contrary are not persuasive. As an initial matter, it is telling that nowhere in Amgen's answering brief does it actually grapple with the substance of the prosecution history upon which Coherus's argument relies. Thus, it never attempts to explain with any specificity *why* those statements fail to trigger prosecution history estoppel. Instead, it

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[10] Other courts examining the type of language that can give rise to a finding of argument-based prosecution history estoppel have observed that in arguing to overcome a rejection, while a patentee may "surrender what the invention is being differentiated from, one does not necessarily surrender all other equivalents, especially when the applicant does not discuss or limit the contents of the claimed invention itself." *AstraZeneca UK Ltd. v. Dr. Reddy's Labs., Ltd.*, Civil Action No. 08-3237 (MLC), 2010 WL 4721384, at *7 (D.N.J. Nov. 15, 2010) (citing cases). Oftentimes, courts find argument-based estoppel where the applicant has specifically disclaimed a feature found in the prior art (a feature that a plaintiff is then trying to accuse of infringement pursuant to the doctrine of equivalents). *See id.* (citing cases); *see also, e.g., Texas Instruments Inc. v. U.S. Int'l Trade Comm'n*, 988 F.2d 1165, 1175 (Fed. Cir. 1993) ("By expressly stating that claim 12 was patentable because of the opposite-side gating limitation, particularly in light of their previous admission that same-sided gating was known in the art, the inventors unmistakably excluded the same-side gating as an equivalent."). However, patentees need not "stress the disadvantages of other equivalents to clearly and unmistakably surrender them[,]" for courts have found "clear and unmistakable surrender when the patentee asserted the singularity or uniqueness of the claimed invention in arguing for its patentability." *AstraZeneca UK Ltd.*, 2010 WL 4721384, at *8 (citing cases); *see also Anchor Sales & Mktg.*, 2016 WL 4224069, at *5. Here, as explained above, a competitor examining the prosecution history would reasonably believe that the patentee clearly and unmistakably surrendered combinations other than the particular combinations recited in the claims, in light of the way that the patentee emphasized that its claims were patentable on the separate basis that they included those particular combinations. *See, e.g., PODS, Inc.*, 484 F.3d at 1368.

makes three more peripheral arguments that the Court will take up below.

First, Amgen asserts in conclusory fashion that Coherus's argument regarding the salt-pairing limitation can be "raised after claim construction and discovery, and not before." (D.I. 17 at 15) Amgen makes no attempt to explain how claim construction or discovery would shed light on the objective inquiry regarding whether argument-based prosecution history estoppel applies here. Nor is that clear to the Court. And so in the absence of such an explanation, the Court finds it appropriate to resolve this question of law at the pleading stage. *See, e.g.*, *Jenny Yoo Collection, Inc. v. Watters Design Inc.*, 16-CV-2205 (VSB), 2017 WL 4997838, at *9 (S.D.N.Y. Oct. 20, 2017) ("Although examination of the prosecution history is typically handled during the summary judgment stage, whether prosecution history estoppel applies may be determined on a motion to dismiss."); *cf. In re Bendamustine Consolidated Cases*, Civil Action No. 13-2046-GMS, 2015 WL 1951399, at *1-3 (D. Del. Apr. 29, 2015) (in resolving a Rule 12(c) motion, considering ANDA filings and prosecution history over plaintiff's objection, where the plaintiff's theory of infringement was based on the doctrine of equivalents, and the only issue was whether plaintiff's doctrine-of-equivalents-arguments were barred by the disclosure-dedication rule).

Second, Amgen suggests that prosecution history estoppel does not apply to "clarifying amendments." (D.I. 17 at 15) Amgen is correct that clarifying statements made during prosecution do not amount to the clear and unmistakable surrender of subject matter that is required for prosecution history estoppel. *See, e.g.*, *Deering Precision Instruments, L.L.C. v. Vector Distribution Sys., Inc.*, 347 F.3d 1314, 1326 (Fed. Cir. 2003) (finding no prosecution history estoppel where the examiner had objected to original claim 9 but had stated that the claim would be allowed if rewritten in independent form, and where the applicants, in response, noted

that original claim 9 was already written in such form and also restated that a particular limitation in the claim was not disclosed in the references of record; the applicants' statement was deemed "merely a clarification of the Examiner's mistake"). But here again, Amgen makes no attempt to explain how the relevant statements actually amount to mere clarification, as opposed to the clear surrender of claim scope.

Finally, Amgen argues that Coherus has not met the stringent standard for applying argument-based estoppel. In doing so, it merely points to Coherus's statement (found in Coherus's opening brief) that "'[h]aving saved its claims by highlighting the use of *specific* salt pairs, Amgen cannot now expand its patent coverage by saying that its claims equivalently cover processes with *other* salt pairs.'" (D.I. 17 at 15-16 (quoting D.I. 10 at 12) (emphasis in original)) Amgen then focuses on Coherus's use of the word "highlighting" in that statement, arguing that "'*[h]ighlighting*' the use of specific salt pairs is not a clear and unmistakable surrender of other salt pairs that are not discussed in the prosecution history statements relied on by Coherus." (*Id.* at 16 (emphasis added)) But this bit of wordplay ignores the meat of Coherus's position. As detailed above, Coherus did not argue that the patentee had merely "highlighted" the use of specific salt pairs. Rather, as Coherus pointed out, the patentee explicitly argued (at some length) to the Examiner, in order to overcome the rejection based on Holtz, that its claimed invention was distinguishable from Holtz because of the claims' use of specific salt pairs. (D.I. 10 at 6, 12; D.I. 22 at 7-8) The Court thus agrees with Coherus that the patentee clearly and unmistakably surrendered to the public claims using salt pairings other than those recited in the claims of the '707 patent. *See Pharmacia & Upjohn Co. v. Mylan Pharms., Inc.*, 170 F.3d 1373, 1376-78 (Fed. Cir. 1999) (concluding that prosecution history estoppel precluded the patentee

from asserting the doctrine of equivalents against a composition that did not contain spray-dried lactose, explaining that a competitor of plaintiff's would reasonably interpret the applicant's prosecution statements to mean that spray-dried lactose was an indispensable component of the claimed formulations and noting that the plaintiff's arguments to the contrary "fail[ed] to address" or to "explain away" the key portions of the prosecution history).

For these reasons, the Court concludes that prosecution history estoppel bars Amgen from now attempting to reassert surrendered ground involving other combinations of salts, and thus recommends that Coherus's motion to dismiss be granted. *See Anchor Sales & Mktg, Inc.*, 2016 WL 4224069, at *6 (granting defendant's motion to dismiss where argument-based prosecution history estoppel barred plaintiff from arguing infringement under the doctrine of equivalents); *cf. Advantek Mktg., Inc. v. Shanghai Walk-Long Tools Co.*, Case No. CV 16-3061-R, 2016 WL 9178079, at *2 (C.D. Cal. Nov. 3, 2016) (granting motion for judgment on the pleadings where plaintiff's infringement allegations with respect to a design patent were barred by the doctrine of prosecution history estoppel); *Cumberland Pharms. Inc. v. InnoPharma, Inc.*, C.A. No. 12-618-LPS, 2013 WL 5945794, at *1-3 (D. Del. Nov. 1, 2013) (granting a motion to dismiss for failure to state a claim of infringement in ANDA litigation where all claims of the asserted patent required a formulation "free from a chelating agent" and the complaint alleged that defendant's accused product contained a "chelating agent").[11]

IV. CONCLUSION

For the foregoing reasons, the Court recommends that the Motion be GRANTED

[11] In light of the Court's conclusion, the Court need not consider Coherus's second argument that it cannot infringe because its manufacturing process [redacted] at the required concentration.

with prejudice.[12]

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the district court. *See Henderson v. Carlson*, 812 F.2d 874, 878–79 (3d Cir. 1987); *Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006). The parties are directed to the Court's Standing Order for Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the District Court's website, located at http://www.ded.uscourts.gov.

Because this Report and Recommendation may contain confidential information, it has been released under seal, pending review by the parties to allow them to submit a single, jointly proposed, redacted version (if necessary) of the Report and Recommendation. Any such redacted version shall be submitted no later than **December 12, 2017** for review by the Court, along with a motion for redaction that includes a clear, factually-detailed explanation as to why disclosure of any proposed redacted material would "work a clearly defined and serious injury to the party seeking closure." *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994) (internal quotation marks and citation omitted). The Court will subsequently issue a publicly-available version of its Report and Recommendation.

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[12] The Court recommends that the dismissal be with prejudice as Amgen did not make an argument that it should be granted leave to amend in the event of dismissal, (D.I. 17), and more importantly, because amendment would be futile in light of the Court's conclusion that Amgen's claim for relief fails as a matter of law, *see Anchor Sales & Mktg., Inc.*, 2016 WL 4224069, at *6 n.3.

Dated: December 7, 2017

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE