IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

AMGEN INC. and AMGEN MANUFACTURING LIMITED, Plaintiffs, v. MYLAN INC., MYLAN PHARMACEUTICALS INC., MYLAN GMBH and MYLAN N.V., Defendants.	Civil Action No. 17-cv-01235-MRH **REDACTED VERSION**

BRIEF IN SUPPORT OF MYLAN'S RENEWED MOTION FOR JUDGMENT ON THE PLEADINGS PURSUANT TO RULE 12(c) REGARDING U.S. PATENT NO. 8,273,707

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Defendants Mylan Inc., Mylan Pharmaceuticals Inc., Mylan GmbH and Mylan N.V. (collectively, "Defendants" or "Mylan") renew their Motion for Judgment on the Pleadings regarding the '707 patent. Specifically, Mylan moves for dismissal of Plaintiffs Amgen Inc.'s and Amgen Manufacturing Limited's (collectively, "Amgen") allegations of infringement of the '707 patent because, under the Court's claim construction, Mylan cannot infringe the '707 patent, either literally or under the doctrine of equivalents.

I. INTRODUCTION.

As Mylan established in its initial motion, there was no good faith basis for Amgen to assert infringement of the '707 patent from the get-go. There is even less reason now. The Court's recent Claim Construction Opinion confirms as much and warrants immediate dismissal. In short, the '707 patent is drawn to a narrow process for purifying proteins that requires the use of one of three *particular* "salt pairs" expressly recited in the claims. [redacted] Unburdened by the claims' plain language, the intrinsic evidence, and this Court's constructions, Amgen frivolously asserts infringement under the doctrine of equivalents—an allegation that necessarily stretches the '707 patent well beyond its limits and thus *cannot* succeed as a matter of law.[1]

More specifically, the process claimed in the '707 patent requires one of the following three salt pairs: (i) citrate and sulfate; (ii) citrate and acetate; or (iii) acetate and sulfate. The protein-of-interest (here, GCSF) is first mixed with the selected salt pair (i, ii, or iii) to form a

[1] Indeed, a Delaware Court has already dismissed litigation against a similarly-situated defendant—holding that the accused process *cannot* infringe the '707 patent as a matter of law (under the doctrine of equivalents) precisely because it does not use any of the *particular* salt pairs claimed. Judge Stark looked at the same evidence presented here and found that Amgen had clearly and unmistakably surrendered processes using combinations of salts different from the three specific pairs recited in the '707 patent claims and dismissed Amgen's infringement allegations. (*See* Section II.E below).

mixture. (11/20/2018 Claim Construction Op. at 43 ("[I]t is clear from a reading of the patent claim that 'the mixture' refers to the 'mixture' formed when 'a preparation containing the protein' is mixed with 'a combination of a first salt and a second salt.'") (ECF No. 171) ("CC Op.")). [redacted] Consequently, Amgen resorts solely to the doctrine of equivalents. But that, too, fails as a matter of law. To secure issuance of the '707 patent, Amgen unequivocally told the Patent Office (and the public) that its invention was "the *particular* combination of salts recited in the [] claims," (Ex. 1, '707 patent PH. 1/26/2011 Resp. to Office Action at 5 (emphasis in original)) and that "[u]se of *this particular combination of salts* greatly improves the cost-effectiveness of commercial manufacturing," (*id.*, 1/20/2011 Senczuk Decl. ¶ 4 (emphasis added)). Amgen is estopped from capturing other combinations of salts as alleged equivalents to the three *particular* salt pairs recited in the claims based upon its express surrender of all other processes during prosecution. *Trading Techs. Int'l, Inc. v. Open E Cry, LLC*, 728 F.3d 1309, 1322 (Fed. Cir. 2013) ("Prosecution 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.").

If that were not enough—it is, Amgen is further barred from relying on the doctrine of equivalents against Mylan under the dedication-disclosure rule. Here, the record is indisputable. The '707 patent specification expressly discloses [redacted]

[2] Amgen has taken the position that it needs discovery outside the information provided in Mylan's BLA and thus its claims should not be dismissed. That is nothing more than a legally baseless attempt to delay the inevitable. Indeed, Mylan's FDA-approved BLA governs the infringement inquiry here and provides all the information needed to confirm Mylan does not infringe the specific protein purification step narrowly claimed in the '707 patent. *See, e.g.*, *Amgen Inc. v. Apotex Inc.*, 712 F. App'x 985, 992 (Fed. Cir. 2017). There is no amount of other discovery Amgen may procure that is going to change what Mylan does in its accused process.

[redacted] Amgen consequently dedicated all such disclosed but unclaimed salt pairs to the public, and therefore, Amgen is barred, *as a matter of law*, from now trying to capture them as equivalents to the salt pairs expressly recited in the claims.

In sum, (1) literal infringement is not at issue here (indeed, Amgen does not even assert it), and (2) Amgen is both estopped and barred as a matter of law from alleging Mylan's accused process step is equivalent to the '707 patent claims. Consequently, Amgen has not stated—nor can it state—a claim for relief of infringement that is plausible on its face. The Court should dismiss Amgen's complaint with respect to the '707 patent entirely and enter judgment on the pleadings in favor of Mylan.

II. BACKGROUND.

On December 9, 2016, Mylan GmbH submitted its BLA to FDA pursuant to 42 U.S.C. § 262(k), seeking approval of Pegfilgrastim (MYL-1401H) Solution for Subcutaneous Injection, a proposed biosimilar to Neulasta® (pegfilgrastim) ("Mylan's BLA"). (ECF No. 27, Mylan Answer, Defenses and Countercls. ¶ 33 (Nov. 22, 2017)). On June 4, 2018, FDA approved Mylan's BLA. Amgen alleges that Mylan's process for manufacturing its pegfilgrastim biosimilar infringes the '707 patent under the doctrine of equivalents.[3] (ECF No. 1, Compl. ¶¶ 99-100 (Sept. 22, 2017)).

[3] Amgen does not even allege—nor can it—that Mylan literally infringes the '707 patent claims under this Court's claim constructions. (*See* ECF No. 183-1, Amgen's Second Amended Disclosure of Asserted Claims and Infringement Contentions ("Amgen's Second Amended Infringement Contentions"), Second Amended Appendix A at 6 [redacted].

A. Mylan's Renewed Rule 12(c) Motion for Judgment on the Pleadings.

On April 6, 2018, Mylan filed a Motion for Judgment on the Pleadings Pursuant to Rule 12(c) alleging Mylan cannot infringe the '707 patent as a matter of law ("Mylan's Rule 12(c) Motion"). Briefing of Mylan's Rule 12(c) Motion was completed on May 11, 2018.

On November 15, 2018, this Court issued an Order denying without prejudice Mylan's Rule 12(c) Motion, "subject to its reassertion (in whole or in part) following the issuance of the Court's Claim Construction Opinion and Order." (ECF No. 170, Order at 2). According to this Court, "Amgen's arguments in opposition to [Mylan's Rule 12(c)] Motion are premised on the Court adopting contrary constructions than the ones that Mylan proposes." (*Id.*) Thus, "[t]he resolution of these claim construction disputes could be, in the Court's estimation, dispositive of several considerations in that Motion." (CC Op. at 4 n.1).

B. The '707 Patent is Directed Toward an Allegedly Improved Protein-Purification Process Comprising "Particular" Salt Combinations.

As this Court observed, the '707 patent "generally discloses a protein purification process utilizing hydrophobic interaction chromatography (HIC)." (CC Op. at 36; *see also* Ex. 2, R&R[4] at 2 ("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. These proteins must then be separated from the source material. One such purification technique is known as hydrophobic interaction chromatography ('HIC')." (citations omitted))). Specifically, "[t]he '707 Patent teaches a process wherein a protein, first salt, and a second salt in solution are loaded onto a HIC column such that the dynamic capacity of the column is

[4] As explained in more detail below, Chief Judge Stark adopted Magistrate Judge Burke's Report and Recommendation, overruled Amgen's objections, and granted Coherus' Motion to Dismiss. *See Amgen Inc. v. Coherus Biosciences Inc.*, C.A. No. 17-546-LPS-CJB, 2018 WL 1517689, at *1 (D. Del. Mar. 26, 2018).

increased." (CC Op. at 36). Moreover, the '707 patent teaches that salt combinations other than the three particular citrate/sulfate/acetate combinations claimed "did ***not*** increase the dynamic capacity" of the HIC column and "did ***not*** prove to be an effective combination." (Ex. 3, '707 patent at col. 13, l. 64 – col. 14, l. 5 (emphasis added)).

Despite the focus of the '707 patent claims on three *particular* salt pairs, the specification discloses that "combining two different salts having different lyotrophic 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." (Ex. 3, '707 patent at col. 4, ll. 47-51). The '707 patent further discloses (<u>but does not claim</u>) a list of "different salts," [redacted]

[redacted]

(*Id.* at col. 4, ll. 33-46 (emphasis added)).[5]

[5] By disclosing but not claiming these salt pairs, Amgen dedicated to the public all other salt pairs but for the three "particular" salt pairs recited in the '707 patent claims. *Johnson & Johnston Assocs., Inc. v. R.E. Serv. Co.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002); *see also Coherus*, 2018 WL 1517689, at *3 (wherein Judge Stark "agree[d] with Coherus that another reason Amgen's claim for infringement of the '707 patent must be dismissed is that the patentee dedicated to the public" salts alleged to be equivalent by disclosing the same in the '707 patent and failing to claim such salts.).

C. November 20, 2018 Claim Construction Opinion.

This Court's November 20, 2018 Opinion construed the '707 patent term "mixing a preparation containing the protein with a combination of a first salt and a second salt" as "having its plain and ordinary meaning and that this step must be completed prior to the 'loading the mixture' step beginning." (CC Op. at 45). Specifically, this Court concluded "that the 'mixing a preparation' and 'loading the mixture' steps must be performed in the order written." (*Id.* at 43). Therefore,

> "the mixture" cannot be "load[ed] . . . onto a hydrophobic interaction chromatography column" until after its components are mixed and the mixture is formed. Had the patentee intended for that mixture to be formed within the column or on the separation matrix, the patentee could have listed the individual components of the mixture (the preparation of the protein and a combination of a first and second salt) as what is being "loaded."

(*Id.* at 44). Based upon this Court's construction, Amgen has withdrawn any claim that Mylan literally infringes the '707 patent. (*See* Amgen's Second Amended Infringement Contentions, Second Amended Appendix A at 6-7; [redacted]

D. Amgen Clearly and Unmistakably Surrendered Prior Art Salt Combinations During Prosecution of the '707 Patent.

During prosecution, Amgen clearly informed the Patent Office (and the public)[6] that at least two separate elements of its claimed invention were not found in the prior art: i) the use of the *particular* combinations of salts claimed, and ii) their purported ability to increase a column's dynamic capacity. Amgen argued each element throughout prosecution of the '707 patent.

[6] *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1344 (Fed. Cir. 2015) ("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." (citation omitted)).

1. '707 patent prosecution history.

Specifically, in October 2010, the Examiner rejected the pending claims as obvious over U.S. Patent No. 5,231,178 to Holtz ("Holtz"), which the Examiner found disclosed a method for purifying insulin-like growth hormone using salts that improve the hydrophobic interaction of the protein, "e.g., sodium sulfate, potassium sulfate, ammonium sulfate, potassium phosphate, sodium acetate, ammonium acetate, sodium chloride, sodium citrate and the like." (Ex. 1, '707 patent PH, 10/13/2010 Office Action at 4). The Examiner explained that:

> [i]t 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 response, Amgen argued that the prior art does not teach (i) any *combination* of salts, or (ii) "the *particular* combination of salts" claimed:

> Applicants submit that a *prima facie* case of obviousness has not been made. 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. Applicants point out that the patent to Holtz et al. is directed to "a

(*Id.*, 1/26/2011 Resp. to Office Action at 5 (italics in original, highlighting added)). In addition, Amgen presented a third argument to overcome Holtz: (iii) "[t]here is no description or suggestion in Holtz et al. for the use of any combination of salts to increase the dynamic capacity of a HIC." (*Id.*) In total, Amgen informed the Examiner (and the public) that its claimed invention was purportedly distinguishable from Holtz on at least three, separate grounds: (i)

Holtz does not disclose the ***particular*** combination of salts claimed, (ii) Holtz does not disclose any combination of just two salts, and (iii) Holtz does not disclose an increase in dynamic capacity.

Amgen also submitted an inventor declaration that discussed the supposed advantages of the three particular salt pairs recited in the claims: "sulfate/citrate," "sulfate/acetate," and "acetate/citrate." The declaration stated:

> 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.

(Ex. 1, '707 patent PH, 1/20/2011 Senczuk Decl. ¶ 4 (emphasis added)). Most importantly, Amgen left no doubt that its claimed invention was limited to processes using the *particular* salt pairs claimed and no others.

In an April 2011 Office Action, the Examiner maintained his rejection of the claims as obvious over Holtz for the same reasons as described above. (Ex. 1, '707 patent PH, 4/7/2011 Office Action (Final Rejection) at 2-4). The Examiner asserted that "Applicant contends that the instant claims recite a particular combination of salts" but found Amgen's argument unpersuasive. (*Id.* at 4). The Examiner also rejected Amgen's third argument regarding dynamic capacity, again stating that "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.*)

In its August 2011 Response, Amgen first resubmitted the Senczuk declaration: "***As a component of the instant Response***, applicants resubmit Declarant Senczuk's Declaration in its

entirety." (Ex. 1, '707 patent PH, 8/22/2011 Amendment After Final Rejection at 4 (emphasis added); *see also id.*, 1/20/2011 Senczuk Decl. ¶ 4 ("Use of this ***particular combination of salts*** greatly improves the cost-effectiveness of commercial manufacturing . . . .") (emphasis added)). Second, Amgen reiterated the same arguments from its January 2011 response (*id.*, 8/22/2011 Amendment After Final Rejection at 5 ("Applicants reiterate their position . . ."), including that Holtz did not teach "the use of a *combination* of salts" disclosed in the alleged invention. (*Id.*; *see also id.*, 1/26/2011 Resp. to Office Action at 5 ("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.") (emphasis in original)). Specifically, Amgen argued that "the Patent Office's argument again overlooks two elements of the claimed method—the use of a *combination* of salts in a HIC operation, and the *enhancement of dynamic capacity of a HIC column* imparted by applicants' method." (*Id.*, 8/22/2011 Amendment After Final Rejection at 5 (emphasis in original)). Amgen made clear that each was a separate basis for allegedly distinguishing its invention from the prior art, as it provided subsections of its arguments to the examiner, the first addressing the combination of salts claimed and the second addressing the alleged increase in dynamic capacity. (*Id.* at 5-6).

Further, Amgen again emphasized the particular salt combinations recited in the claims, not just any salts, as distinguishing the prior art, arguing that:

> merely adding a second salt to the traditional HIC process, as the Patent Office appears to suggest, will not produce applicants' claimed method. In fact, merely adding a second salt to the traditional HIC process will not even provide a working method; in this scenario the protein to be purified will precipitate out of solution and it will not be possible to load the protein onto the HIC column.

(Ex. 1, '707 patent PH, 8/22/2011 Amendment After Final Rejection at 7). Amgen also emphasized its work determining "what combinations of salts would increase . . . dynamic capacity." (*Id.*)

The Examiner subsequently issued a Notice of Allowance. The Examiner did not identify whether the Notice of Allowance was in response to a specific argument but rather stated only that "Claims 1-13 have been examined on the merits and found allowable." (Ex. 1, '707 patent PH, 7/16/2012 Notice of Allowance at 2). The patent-in-suit ultimately issued with thirteen (13) claims, of which claims 1 and 10 are the only independent claims, and each requires "a preparation containing the protein with a combination of a first salt and a second salt" and that the preparation or load solution contain *one of three combinations of salts*: [1] citrate and sulfate, [2] citrate and acetate, or [3] sulfate and acetate. All other claims depend from claims 1 and 10. Thus, every claim in the '707 patent requires the use of one of those specific, "particular" salt pairs in the loading solution.

2. '581 application prosecution history.

Amgen's arguments during prosecution of the '707 patent's parent application also emphasized the same combination arguments—namely, Holtz does not disclose any combination of just two salts *and* Holtz does not disclose the *particular* salt combinations claimed. The Examiner rejected the claims as anticipated by Holtz because Holtz includes an example containing a load solution of ammonium sulfate, sodium acetate, sodium phosphate and sodium chloride—a combination of four (4) salts. (Ex. 4, '581 parent application PH, 2/14/2008 Office Action at 2-3). In response, Amgen argued that:

> Holtz et al. . . . does not teach or suggest combining the protein to be purified ***with the particular combination of two salts*** . . . before loading the protein on the HIC column. Instead, a protein solution containing lower concentrations of sodium acetate and sodium phosphate, together with NaCl and a high concentration of

> ammonium sulfate (***four salts, not a combination of two salts as recited in the claimed method***), is loaded onto the HIC column.

(*Id.*, 7/14/2008 Resp. to Office Action at 6 (emphasis added); *see also id.* at 6-7 (arguing a different method in Holtz that described the preparation of the protein in a solution with three salts—sodium acetate, phosphate and ammonium sulfate—was a "three salt combination instead of two salts")). The parent claims issued with the same requirement for a two salt combination as claimed in the '707 patent. (*See* Ex. 5, '395 patent at col. 15, l. 17 – col. 16, l. 30). In fact, the claims of the '395 patent, which issued from the parent application of the '707 patent, are almost identical to the claims of the '707 patent, except they claim a different salt pair—phosphate and citrate.

E. The Related *Coherus* Litigation Confirms Amgen Surrendered Claim Scope During Prosecution.

On May 10, 2017, Amgen filed a complaint in the District of Delaware, alleging Coherus' Neulasta® biosimilar infringes the '707 patent. (*See* Complaint, *Amgen Inc. v. Coherus Biosciences, Inc*., No. 17-546-LPS-CJB (D. Del. May 10, 2017)). Coherus filed a Motion to Dismiss for Failure to State a Claim on June 1, 2017, in which Coherus argued, among other things, that (i) its process does not use any of the salt pairs required by the claims and, (ii) Amgen was estopped from alleging infringement under the doctrine of equivalents for processes using other salts.

On December 12, 2017, Magistrate Judge Burke issued a Report and Recommendation recommending granting Coherus' Motion, finding prosecution history estoppel barred Amgen from asserting combinations of salts other than those claimed. Citing Amgen's own arguments to the Patent Office, the court determined Amgen had "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[.]" (Ex. 2, R&R at

12). The court focused on Amgen's arguments distinguishing its invention from the prior art, specifically Holtz, and found "Amgen surrendered any claim to a process that used other, unrecited salt combinations." (*Id.* at 13-14; *id.* at 16 ("[T]he 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.")).

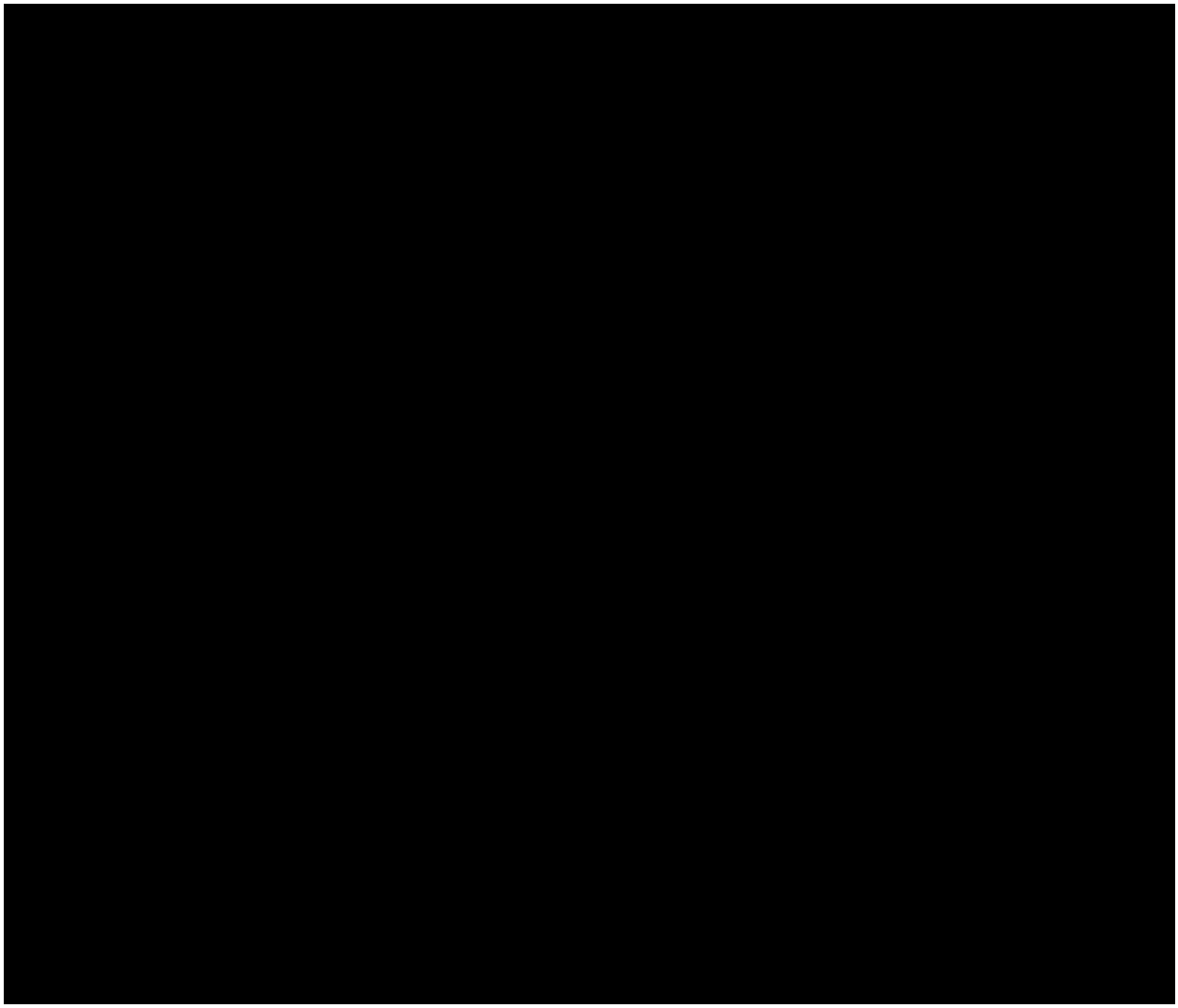
Chief Judge Stark then, on March 26, 2018, overruled Amgen's objections and adopted Judge Burke's Report and Recommendation, ordering dismissal of Amgen's Complaint against Coherus on the '707 patent. *Coherus*, 2018 WL 1517689, at *1. Additionally, Judge Stark "agree[d] with Coherus that another reason Amgen's claim for infringement of the '707 patent must be dismissed is that the patentee dedicated to the public" salts alleged to be equivalent by disclosing the same in the '707 patent and failing to claim such salts. *Id.* at *3.

F. Mylan's Manufacturing Process.

Mylan's BLA is for Pegfilgrastim (MYL-1401H) Solution for Subcutaneous Injection, a biosimilar to Neulasta® (pegfilgrastim). Pegfilgrastim is a PEGylated form[7] of the recombinant human granulocyte colony-stimulating factor (GCSF) analog known as "filgrastim." Mylan manufactures filgrastim [redacted]

[7] PEGylation is the process of binding a biodegradable polymer to a protein (here, filgrastim) that occurs *post*-purification and therefore is not relevant to the '707 patent. PEGylated filgrastim is retained longer in the bloodstream. [redacted]

[redacted]



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III. ARGUMENT.

A. Governing Law.

A motion for judgment on the pleadings under Federal Rule Civil Procedure 12(c) may be granted when the movant clearly establishes that no material issue of fact remains to be resolved and that it is entitled to judgment as a matter of law. *Wiseman Oil Co., Inc. v. TIG Ins. Co.*, 878 F. Supp. 2d 597, 600 (W.D. Pa. 2012) (citing *Rosenau v. Unifund Corp*., 539 F.3d 218, 221 (3d Cir. 2008)). When reviewing a motion for judgment on the pleadings, "a court must view the facts in the plaintiff's complaint as true and draw all reasonable inferences in the plaintiff's favor." *Snyder v. Daugherty*, 899 F. Supp. 2d 391, 400 (W.D. Pa. 2012); *see also Fowler v. UPMC Shadyside*, 578 F.3d 203, 210-11 (3d Cir. 2009). In other words, a court applies the same standard to a 12(c) motion as a motion to dismiss pursuant to Rule 12(b)(6), except a Rule 12(c) motion can be made after the pleadings are closed. *Snyder*, 899 F. Supp. 2d at 400; *Pa. Gen. Energy Co. v. Grant Twp.*, 139 F. Supp. 3d 706, 711 (W.D. Pa. 2015); *Drennen v. Cmty. Bank of N. Va.*, No. 05-1386, 2009 WL 440960, at *2 n.1 (W.D. Pa. Feb. 23, 2009) (citing *Turbe v. Gov't of the V.I.*, 938 F.2d 427, 428 (3d Cir. 1991)).

First, the court must separate the factual and legal elements of the claim, and "accept all of the complaint's well-pleaded facts as true, but may disregard any legal conclusions." *Fowler*, 578 F.3d at 210-11. Second, the court must determine "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 requires more than

merely alleging entitlement to relief, rather it must "'show' such an entitlement with its facts." *Id.* (citing *Phillips v. Cty. of Allegheny*, 515 F.3d 224, 234-35 (3d Cir. 2008)). Therefore, 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); *Iqbal*, 556 U.S. at 678.

In resolving a 12(c) motion, a court may consider, not only the pleadings, but also "undisputedly authentic documents attached to or submitted with the Complaint, as well as evidence outside the complaint/other items of record," including documents integral to or explicitly relied upon in the Complaint. *Wiseman*, 878 F. Supp. 2d at 601; *see also 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).

It is undisputed that Mylan's BLA forms the basis of Amgen's Complaint and is thus an authentic document "integral to the Complaint and one that the Court can rely upon at this stage." *See, e.g.*, *AstraZeneca Pharm. 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); (*see also* Ex. 2, R&R at 6 n.6). When infringement turns on the contents of an FDA application (such as an ANDA or a BLA) courts may grant Rule 12 motions if what is required in the FDA application would not infringe. *AstraZeneca*, 669 F.3d at 1378 n.5.

A court may also consider the prosecution history of the patent-in-suit. *See Genetic Techs. Ltd. v. Bristol-Myers Squibb Co.*, 72 F. Supp. 3d 521, 526 (D. Del. 2014) (finding motion "may also take judicial notice of the prosecution histories, which are 'public records'"); *Int'l Bus. Machs. Corp. v. Priceline Grp. Inc.*, No. 15-137-LPS-CJB, 2016 WL 626495, *20 n.18 (D.

Del. Feb. 16, 2016); *Quest Integrity USA, LLC v. Clean Harbors Indus. Servs., Inc.*, Nos. 14-1482-SLR, 14-1483-SLR, 2015 WL 4477700, *1 n.4 (D. Del. July 22, 2015) (prosecution history "is a public document that the court may rely upon in deciding this motion to dismiss").

Finally, a court may take notice of and rely on its claim construction opinion. *Intellectual Ventures I LLC v. AT & T Mobility LLC*, 235 F. Supp. 3d 577, 588 (D. Del. 2016), *reconsideration denied sub nom. Intellectual Ventures I LLC v. T-Mobile USA, Inc.*, No. CV 13-1632-LPS, 2017 WL 3706495 (D. Del. Aug. 23, 2017); *see also MAZ Encryption Techs. LLC v. Blackberry Corp.*, C.A. No. 13-304-LPS, 2016 WL 5661981, at *1 n.3 (D. Del. Sept. 29, 2016) (applying claim construction opinion, to the extent necessary, in deciding Rule 12(c) motion); *Maxell, Ltd. v. Fandango Media, LLC*, No. CV 17-07534 AG (SSX), 2018 WL 4502492, at *2 (C.D. Cal. Sept. 11, 2018) (ruling that "because claim[] construction is a question of law . . . a court 'may take notice of and rely on its claim construction opinion without converting Defendant's Motion into a motion for summary judgment'").

B. Amgen Cannot State A Claim For Infringement.

1. No literal infringement: [redacted]

As explained above, in view of the Court's claim construction (CC Op. at 43-45), Amgen has withdrawn—as it must—any prior allegation that Mylan literally infringes the '707 patent, and now relies the solely on the doctrine of equivalents. And for good reason, [redacted]—a limitation of both independent claims of the '707 patent. (Ex. 3, '707 patent at col. 15, ll. 14-16; *id*. at col. 16, ll. 14-16).

Under this Court's construction, each of the asserted claims of the '707 require forming a "mixture" before loading. (CC Op. at 43; *id.* at 44-45. And "the mixture" refers to the preparation or mixture formed when "'a preparation containing the protein' is mixed with 'a combination of a first salt and a second salt.'" (*Id*. at 43). Specifically, the mixture cannot be loaded "until after its components are mixed and the mixture is formed." (*Id.* at 44). Thus any salt used in any step other than the load cannot be considered part of the "mixture" under this Court's construction. [redacted]

For that reason alone, Mylan's process does not (and cannot) literally infringe any asserted claim. Amgen admits as much, having withdrawn any literal infringement claim.

2. Amgen is estopped from claiming Mylan infringes under the doctrine of equivalents.

As a matter of law, Amgen is estopped from making a doctrine of equivalents claim [redacted] That is because during prosecution of the '707 patent,

> Amgen distinguished a prior art reference ("Holtz") and overcame the patent examiner's [] 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, . . . Amgen is now estopped from asserting that a different salt combination . . . is infringing.

(Ex. 2, R&R at 9 (emphasis added)). "Indeed, as if to highlight this point even further, so that the Examiner would not miss it, [Amgen] actually placed the word 'particular' in the phrase 'particular combination of salts' in italics." (*Id.* at 13 n.9).

Although Amgen also separately argued the prior art also did not disclose *any* combination of just two salts, it unquestionably

> 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. 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.

(Ex. 2, R&R at 12-13 (footnote omitted)). Amgen did not dispute that Holtz disclosed the "use of a number of salts," [redacted] and in fact disclosed the use of three (3) or four (4) disclosed salts together. Instead, Amgen argued Holtz did not disclose "the *particular* combination of salts recited in the pending claims" and that the prior art did not teach or suggest those *particular* combinations claimed. (Ex. 1, '707 patent PH, 1/26/2011 Resp. to Office Action at 5 (emphasis in original)). Having secured issuance by arguing the claims required the use of *specific* salt pairs, Amgen cannot now expand the scope of those claims to cover purported equivalents [redacted]

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 Pharm., Inc. v. Sandoz Inc*., 802 F.3d 1326, 1337 (Fed. Cir. 2015). Prosecution history estoppel can occur in two ways: (1) by making a narrowing amendment to a claim ("amendment-based"); or (2) by surrendering claim scope through argument to the patent examiner ("argument-based"). *Conoco, Inc. v. Energy & Envtl. Int'l, L.C*., 460 F.3d 1349, 1363 (Fed. Cir. 2006); *see also Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 735, 739-40 (2002).

For argument-based estoppel to apply, "the prosecution history must evince a clear and unmistakable surrender of subject matter." *Conoco, Inc.*, 460 F.3d at 1364. 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.* (citation omitted); *see also AquaTex Indus., Inc. v. Techniche Sols.*, 419 F.3d 1374, 1382 (Fed. Cir. 2005). Even when "not necessary to secure allowance of the claim, statements that clearly and unmistakably surrender claim scope can preclude an assertion of equivalency." (Ex. 2, R&R at 9 n.7 (citing *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1252 (Fed. Cir. 2000))). Indeed, "[e]stoppel extends beyond the basis of patentability . . . . Clear assertions made during prosecution in support of patentability, whether or not actually required to secure allowance of the claim, may also create an estoppel." *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1583 (Fed. Cir. 1995); *see also PODS Inc. v. Porta Stor, Inc.*, 484 F.3d 1359, 1368 (Fed. Cir. 2007) (same).

Here, Amgen cannot escape argument-based estoppel as its statements to the Examiner "evince a clear and unmistakable surrender of subject matter." By arguing "repeatedly" that the *particular* combination of salts (citrate/sulfate, citrate/acetate and sulfate/acetate) claimed by the '707 patent distinguished the invention from the prior art, Amgen "clearly and unmistakably . . . indicated to competitors that it surrendered processes using combinations of salts different from the '*particular* combinations of salts recited in the [] claims[.]" (Ex. 2, R&R at 12).

In fact, this case is exactly the type of situation in which the Federal Circuit has found argument-based estoppel applies. For example, in *PODS*, the patentee offered numerous arguments during prosecution that the prior art did not disclose specific elements of the claimed invention. *PODS*, 484 F.3d at 1367-68. One of those grounds was that the prior art failed to disclose the specific rectangular shape of the claimed invention. *Id.* The patentee then asserted infringement under the doctrine of equivalents against a product that did not have rectangular shape. *Id.* The Federal Circuit found that the patentee's argument "in support of its assertion of

patentability over [the prior art], clearly stated that its claimed frame was rectangular in shape." *Id.*at 1368. Thus, "[a] competitor would reasonably believe that [the patentee] had surrendered any claim to a frame that was not rectangular . . . ."[8] *Id.*

The same is true here. Amgen asserted multiple grounds for distinguishing its invention from the prior art, one of them being that the prior art did not disclose the *particular* combinations of salts claimed. In fact, even after the Examiner rejected Amgen's reliance on the particular salts claimed, Amgen *again* submitted an inventor declaration relying on the "particular combination of salts" claimed. It was clearly an argument integral to Amgen's prosecution of the '707 patent, and thus a competitor would reasonably believe Amgen had surrendered its claim to salt combinations that were not expressly recited. *PODS*, 484 F.3d at 1367-68; *see also Southwall*, 54 F.3d at 1583.

Finally, Amgen relied on the same *particular* combination of salts argument during prosecution of the parent application and similarly did not dispute the prior art disclosed use of the salts claimed, [redacted] or the use of multiple salts together. (Ex. 4, '581 parent application PH, 2/14/2008 Office Action at 2-4; *id.*, 7/14/2008 Resp. to Office Action at 6-7). Instead, Amgen made clear that it sought to distinguish its invention based on the particular salts claimed. In fact, that is exactly what it did by separately patenting a different salt pair—phosphate and citrate—in the parent patent. (*See* Ex. 5, '395 patent at claims). Thus, the parent patent and its prosecution history also confirm that the alleged invention can only be directed to the *particular* salt pairs claimed in the '707 patent and cannot encompass any other unrecited salt combinations. *Biovail Corp. Int'l v. Andrx Pharm., Inc.*, 239 F.3d 1297, 1301

[8] The Federal Circuit also rejected PODS attempt to argue estoppel could not apply because its argument was not what was relied upon for a determination of patentability. *PODS*, 484 F.3d at 1368.

(Fed. Cir. 2001) ("When multiple patents derive from the same initial application, the prosecution history regarding a claim limitation in any patent that has issued applies with equal force to subsequently issued patents that contain the same claim limitation." (citation omitted)).

For these reasons alone, as another court has already held in *Coherus*, Amgen is estopped from claiming Mylan infringes under the doctrine of equivalents, and therefore, Amgen has not stated—nor can it state—a claim for relief of infringement that is plausible on its face. As such, Amgen's complaint should be dismissed with respect to the '707 patent entirely.

3. Amgen is barred from relying on the doctrine of equivalents under the dedication-disclosure rule.

As the court found in *Coherus*, Amgen's reliance on the doctrine of equivalents is further barred by the dedication-disclosure rule. *Coherus*, 2018 WL 1517689, at *3. Under that rule, when a patentee "discloses but declines to claim subject matter," it necessarily "dedicates that unclaimed subject matter to the public" and places it beyond the reach of the doctrine of equivalents. *Johnson & Johnston Assocs.*, 285 F.3d at 1054 . Here, [redacted] (*See* Ex. 3, '707 patent at col. 3, ll. 22-24). Additionally, during prosecution of the '707 patent parent application—which shares a common specification with the '707 patent—Amgen attempted to claim a process containing a first and second salt and argued that the specification disclosed a number of different "potential salts" for the invention, [redacted] (Ex. 4, '581 parent application PH, Original Claims; *id.*, 11/16/2007 Resp. to Office Action at 6 (identifying "potential salts")). After the Examiner rejected its claims and arguments in support thereof, Amgen was forced to narrow the parent application to a combination of citrate and phosphate [redacted]

For these reasons too, Amgen's equivalents-based infringement argument against Mylan is barred, rendering Amgen's claim for relief implausible on its face. Amgen's complaint can, and should, be dismissed with respect to the '707 patent entirely for this separate reason as well.

IV. CONCLUSION.

Mylan's BLA describes its manufacturing process in sufficient detail to establish, as a matter of law, that there can be no infringement. [redacted] and Amgen is both estopped and barred as a matter of law from relying on the doctrine of equivalents to satisfy that missing limitation. Moreover, Mylan's FDA-approved BLA controls the infringement inquiry; it defines Mylan's approved product as well as the process used to manufacture it, *see, e.g.*, 42 U.S.C. § 262(*l*)(3)(A)(i). Indeed, Mylan cannot market a pegfilgrastim product manufactured in a manner different from what the BLA describes. Consequently, Amgen's anticipated demands for more discovery outside the approved BLA should be disregarded as a transparent delay tactic. No amount of other discovery will (or even can) change the relevant evidence for the Court to conclude Mylan does not (and cannot) infringe the '707 patent.

Thus, for at least the reasons described above, Mylan's renewed motion for judgment on the pleadings should be granted.

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Respectfully submitted,

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