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 *Electronically Filed* **REDACTED VERSION**

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

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TABLE OF ABBREVIATIONS

Parties	
Mylan	Defendants Mylan Inc., Mylan Pharmaceuticals Inc., Mylan GmbH and Mylan N.V.
Amgen	Plaintiffs Amgen Inc. and Amgen Manufacturing Limited
Patents and References	
'395 patent	U.S. Patent No. 7,781,395 B2
'707 patent	U.S. Patent No. 8,273,707 B2
Holtz	U.S. Patent No. 5,231,178 A
'581 parent application	U.S. Application No. 10/895,581
Defined Terms	
aBLA	Mylan GmbH's Biologics License Application No. 761075
Coherus	*Amgen Inc. v. Coherus Biosciences, Inc.*, 17-CV-546 (LPS), 2018 WL 1517689 (D. Del. Mar. 26, 2018)
HIC	Hydrophobic interaction chromatography
Mylan Br.	Mylan's Brief in Support of its Motion for Judgment on the Pleadings Pursuant to Rule 12(c) Regarding U.S. Patent No. 8,273,707, dated April 6, 2018 (D.I. 81)
Opp'n	Amgen's Response in Opposition to Mylan's Motion for Judgment on the Pleadings Pursuant to Rule 12(c) Regarding U.S. Patent No. 8,273,707, dated April 27, 2018 (D.I. 87)
Patent Office	U.S. Patent and Trademark Office
PH	Prosecution history

TABLE OF AUTHORITIES

Federal Cases

I. INTRODUCTION.

Just as in *Coherus*, nothing about this motion is "premature." Dismissal based on prosecution history estoppel at this stage is entirely proper, as a matter of law. Nothing Amgen has said, or could say, or discover, or that the Court could rule on claim construction, would change either the analysis or outcome. Indeed, at the heart of Mylan's motion is the fundamental "public notice function of a patent and its prosecution history [that] requires [ ] a patentee be held to what he declares during the prosecution of his patent." *Hakim v. Cannon Avent Grp., PLC*, 479 F.3d 1313, 1318 (Fed. Cir. 2007) ("A patentee may not state during prosecution that the claims do not cover a particular device and then change position and later sue a party who makes that same device for infringement."). That is the fundamental purpose of prosecution history estoppel *and* prosecution disclaimer, and both are pure questions of law entirely appropriate to decide on a motion for judgment on the pleadings. *Mark I Mktg. Corp. v. R.R. Donnelley & Sons Co.*, 66 F.3d 285, 291 (Fed. Cir. 1995) ("The application of prosecution history estoppel is a question of law."); *Elkay Mfg. Co. v. EBCO Mfg. Co.*, 192 F.3d 973, 978 (Fed. Cir. 1999) (prosecution disclaimer is "a legal exercise which we are obligated to conduct independently").

As Mylan established in its opening brief, those legal principles require dismissal here on at least two independent grounds. [redacted] and thus cannot literally infringe—a fact that Amgen does not even contest. Amgen instead asserts a doctrine of equivalents theory expressly foreclosed by Amgen's own prosecution statements clearly and unmistakably surrendering all [redacted] ***Second***, because [redacted] Amgen resorts to concocting a literal

infringement theory [redacted] But Amgen cannot backtrack after clearly and unambiguously disclaiming HIC systems [redacted] i.e., anything other than the "two salt"/"dual salt system" Amgen claims is "key" to its alleged invention. And Amgen does not seriously press a doctrine of equivalents theory for the salt pair limitation, nor could it in view of the prosecution history and *Coherus* decision. Either of these two grounds is sufficient for the Court to grant Mylan's motion. The only necessary facts are locked in place, and not reasonably disputable, thus no more "fully developed record," or any discovery or claim construction, can change Amgen's past disclaimers and disavowals. The Court should hold Amgen to those statements, just as the *Coherus* court did, and dismiss Amgen's '707 patent allegations with prejudice.

II. ARGUMENT.

As an initial matter, Amgen suggests (Opp'n at 15, 20) without explanation that its allegations "*must* be credited as true." But Amgen misapprehends the law. The Court "need not [ ] accept as true allegations that contradict matters properly subject to judicial notice or by exhibit." *Anderson v. Kimberly-Clark Corp*., 570 F. App'x 927, 931 (Fed. Cir. 2014). Here, as Amgen admits, all "parties agree that the '707 Patent, the aBLA, and the '707 Patent prosecution history are part of the record." (*Id.* at 5). Amgen's infringement theories directly contradict that record, most notably Amgen's statements during prosecution. In view of the evidence properly before this Court, there can be no infringement as a matter of law.

A. Mylan Does Not Infringe the Salt Concentration Limitation: Amgen Is Estopped From Asserting Infringement Under the Doctrine of Equivalents.

Amgen concedes, as it must, that [redacted] literally infringe the claimed range of "about 0.1 M to about 1.0 M." Amgen's "equivalent" theory (Opp'n at 19) also fails as a matter of law. As

Mylan explained in its opening brief (Mylan Br. at 22-24), Amgen is estopped from asserting infringement of the salt concentration limitation under the doctrine of equivalents. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 733-34 (2002) ("*Festo V*"). In particular, to persuade the Patent Office to allow the claims that ultimately issued in the parent application, Amgen acknowledged unmistakably that salt concentrations [redacted] were not encompassed by "about 0.1 M." Amgen emphasized that prior art salt concentrations of 0.04 M (or 40 mM) were outside the claimed range of "about 0.1 M to about 1.0 M." The position Amgen took to get its claims allowed now prohibits Amgen from stretching its claims to cover [redacted] Amgen's arguments to the contrary have no merit.

1. Amgen's surrender of concentrations below 0.04 M in the parent application prosecution history applies equally to the '707 patent.

Amgen argues (Opp'n at 20-21) that its statements in the parent application do not give rise to estoppel because they were purportedly directed solely to concentrations of a salt pair (citrate and phosphate) not claimed in the '707 patent. This argument is misleading and wrong. Amgen used the salt concentration limitation as a distinct and separate basis for distinguishing its invention over the prior art. The Court here should hold Amgen to its past representations.

First, Amgen admits that the salt concentration limitation is identical in both the parent application and the '707 patent. (*See* Mylan Br. at 2, 9-10, 22-24; *see also* Opp'n at 1, 7, 14, 18-20). Indeed, Amgen refers to the "concentration limitation" throughout its briefing, highlighting it in green to separate and distinguish it from what Amgen defines as the "salt pair limitation"/"salt pair combination." (*See, e.g.*, Opp'n at 4-6, 9). And, the '707 patent and parent application (and the '395 patent that issued from the parent application), share the same specification. (*See generally* D.I. 81-2, 5, 6).

Thus, prosecution history statements relating to the same salt concentration limitation in the parent application apply "***with equal force*** to subsequently issued patents [including the '707 patent] that contain the ***same claim limitation***." *Biovail Corp. Int'l v. Andrx Pharm., Inc.*, 239 F.3d 1297, 1301 (Fed. Cir. 2001) (emphasis added) (quoting *Elkay*, 192 F.3d at 980).[1] Moreover, claim amendments and arguments that "restrict the scope of the claims" apply in each of the later issued patents containing the same limitation. *Augustine Med., Inc. v. Gaymar Indus., Inc.*, 181 F.3d 1291, 1300 (Fed. Cir. 1999).

Second, contrary to its argument here, Amgen previously unambiguously referred to the 40 mM salt concentrations disclosed in the prior art Holtz reference, which discloses salts other than citrate and phosphate, as "***lower concentrations***" than "about 0.1 M," required by the claims here. Specifically, Amgen explained that Holtz discloses a solution containing the protein and four salts, in which two of the four salts [redacted] are present at a concentration of only 40 mM:

> sulfate until IGF-1 protein precitates. The precipitated protein is then resuspended to a concentration of 425 mg/5 liters (85 mg/l), in a solution of 16% saturated ammonium sulfate, 40 mM sodium acetate, 40 mM sodium phosphate, pH 4.5, and 0.4M NaCl, and this solution is then loaded onto the HIC column (column 26, line 61 to column 27, line 10). Again Holtz et al. column 26 and 27 does not teach or suggest

(D.I. 81-5, '581 parent application PH, 7/14/2008 Resp. at 6 (emphasis added)). Amgen then distinguished the claimed concentration of "about 0.1M and 1.0M," from the concentration of each of the salts (not just the claimed salts) as being outside the claimed range:

[1] Amgen's case law is inapposite. In *Invitrogen*, the patentee argued that prosecution history relating to a claim limitation in the parent application could not be used to construe a *different* limitation in a continuing application, not an *identical* limitation as here. *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1078 (Fed. Cir. 2005). Further, unlike here, where Amgen remained silent regarding its previous statements with respect to concentrations below 0.04 M in the parent application, in *Biogen*, the patentee "***pointed out the erroneous understanding***" regarding the prior art in a parent application and explained why that aspect of the prior art was not relevant to the pending claims. *Biogen, Inc. v. Berlex Labs, Inc.*, 318 F.3d 1132, 1140-41 (Fed. Cir. 2003) (emphasis added).

> 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. Further, Holtz et al.,

(*Id.* (emphasis added)). A competitor reading the prosecution history of the parent application would clearly understand that [redacted] concentrations below 40 mM (0.04 M) is outside the claimed range of 0.1 M to 1.0 M.[2] Having clearly and unmistakably surrendered salt concentrations below 0.04 M (or 40 mM), Amgen cannot now [redacted][3]

Amgen also suggests (Opp'n at 21) that its amendment adding the salt concentration limitation in the parent application did not give rise to prosecution history estoppel because it was a "preliminary amendment that was not made in response to a prior art rejection." Nonsense. Any narrowing amendment made to comply with any provision of the Patent Act, including a voluntary one, may give rise to prosecution history estoppel. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359 (Fed. Cir. 2003) (en banc). Indeed, "[a] patentee's decision to narrow his claims through amendment may be presumed to be a general disclaimer of the territory between the original claim and the amended claim." *Festo V,* 535 U.S. at 740. Here, Amgen makes no attempt to explain how the amendment does not give rise to prosecution history estoppel. *Id.* at 740 ("patentee bears the burden of proving that an amendment was not made for a reason that would give rise to estoppel").

Amgen also misleads this Court by arguing that the pending claims in the parent application were limited to citrate and phosphate salts when it added the concentration limitation.

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[2] Amgen also argues its admissions while prosecuting a related European patent (Mylan Br. at 23 n.12) are "unique to foreign law," (Opp'n at 24), but its admissions address the "scope of the invention" not foreign law. *Apple Inc. v. Motorola, Inc.*, 757 F.3d 1286, 1312-13 (Fed. Cir. 2014).

[3] Amgen suggests the '707 patent is directed to "relatively low" concentrations, but that ignores the specification teaching the claimed range is an "intermediate concentration." (D.I. 81-2, '707 patent at col. 3, ll. 24-36).

(Opp'n at 21). That is not the case. Rather, at the time of the amendment, the claims were directed to *any* combination of salts having different lyotropic values or otherwise. (D.I. 81-5, '581 parent application PH, 4/13/2007 Resp. at 2-3).[4] Only later in prosecution did Amgen limit the claims to citrate and phosphate salts. (*Id.*, 11/16/2007 Resp. at 3). Therefore, Amgen's narrowing amendment gives rise to estoppel as to the concentration of *any* salt, including the combinations of salts claimed in the '707 patent.

2. Amgen's prosecution statements regarding salt concentration create a separate estoppel, regardless of other distinctions Amgen made over the prior art.

Amgen argues (Opp'n at 22) that it is not estopped by statements in the parent prosecution history regarding the concentration limitation because Amgen purportedly distinguished its alleged invention from the prior art on a "combination of various grounds." Amgen is not only wrong on the law but also confounds a combination of grounds with multiple, stand-alone grounds, for distinguishing the prior art.

The Federal Circuit has made clear that "any argument made regarding the need to distinguish the prior art . . . does create a separate estoppel, regardless of other distinctions made." *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1583 (Fed. Cir. 1995). "The fact that [the prior art] could have been distinguished, standing alone, on different grounds, is immaterial." *Desper Prods., Inc. v. QSound Labs., Inc.*, 157 F.3d 1325, 1340 (Fed. Cir. 1998).

Here, Amgen made express statements that its alleged invention was patentable over the Holtz reference based on its failure to meet three distinct, stand-alone claim elements: (1) a "combination of two salts only," (2) the particular salt combination of citrate and phosphate, and (3) salt concentrations of between "about 0.1 M and about 1.0 M." (D.I. 81-5, '581 parent

[4] Amgen suggests (Opp'n at 20-21) that estoppel should not apply because it added the concentration limitation in response to a restriction requirement. Again, not so. The restriction requirement was for an election of species of salt pairs, a separate and distinct claim element from salt concentration.

application PH, 7/14/2008 Resp. at 6). Amgen's representations about each of these stand-alone grounds can, and did, create a separate estoppel.

Amgen further incorrectly relies on the *PODS* decision. The patentee in *PODS* offered three different grounds for distinguishing its invention from the prior art, each directed to different elements of the pending claim. *PODS Inc. v. Porta Stor, Inc.*, 484 F.3d 1359, 1367-68 (Fed. Cir. 2007). The Federal Circuit found that "[t]he second basis PODS offered for distinguishing [the prior art] . . . clearly and unmistakably shows that PODS limited its claims." *Id.* at 1368. Likewise here, Amgen distinguished its alleged invention from the prior art on multiple grounds, each directed to distinct elements of the pending claims. In fact, Amgen *italicized* each separate element in the first page of its Response to highlight what it distinguished:

> Claim 1 of the instant application recites a process for purifying a protein on a hydrophobic interaction chromatography column 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 citrate and phosphate salts*, 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* (emphasis added).

(D.I. 81-5, '581 parent application PH, 7/14/2008 Resp. at 5 (emphasis added)). Then, throughout its Response, Amgen repeatedly *italicized* each distinct ground for distinguishing its alleged invention from the prior art:

> to column 27, line 10). Again Holtz et al. column 26 and 27 does not teach or suggest combining the protein to be purified with the particular *combination of two salts, citrate and phosphate salts* at concentrations of between about *0.1M and 1.0M* before loading the protein on the HIC column. Instead, a protein solution containing lower

(*Id.* at 6 (emphasis added)).

Because Amgen argued its alleged invention was distinguishable based on multiple, distinct stand-alone grounds, a competitor reading the prosecution history would reasonably

believe that any of those limitations alone could have provided the basis for patentability. *See Southwall*, 54 F.3d at 1583. Accordingly, Amgen's prosecution arguments are separate and distinct: the salt concentration limitation creates an independent estoppel that surrenders any equivalents containing salt concentrations below 0.1 M, and at the very least, below 0.04 M. *See id.* at 1582-83.

3. Amgen's silence regarding the concentration limitation in the '707 patent prosecution history does not rescind the surrender of claim scope made during prosecution of the parent application.

Amgen also contends (Opp'n at 23) estoppel should not apply because during prosecution of the '707 patent "Amgen did not challenge the Patent Office's position that Holtz discloses the use of a concentration that squarely overlaps with the '0.1 M and 1.0 [M]' concentration claimed." This argument is a red herring—silence does not rescind the previous surrender of claim scope, let alone inform the examiner that a previous surrender should be revisited. The Federal Circuit has expressly held that "an applicant cannot recapture claim scope that was surrendered" even when a continuing application is filed. *Hakim*, 479 F.3d at 1317; *see also Mark I*, 66 F.3d at 291-92 (holding that estoppel is not avoided by filing narrowed claims in a continuing application). To rescind a surrender of claim scope, the prosecution history must be sufficiently clear to inform a reasonable competitor that the previous surrender has been rescinded. *See Biogen*, 318 F.3d at 1141 (rescinding a prior surrender of claim scope only after patentee specifically "pointed out the erroneous understanding" of the prior art); *see also Hakim*, 479 F.3d at 1317 (emphasis added).

Here, Amgen never addressed the previous surrender of salt concentrations. The fact that Amgen "acknowledged" Holtz discloses concentrations between 0.1 M and 1.0 M during prosecution of the '707 patent does not rescind Amgen's previous surrender of salt concentrations below 0.04 M. Amgen simply chose not to pursue an argument, with the same

examiner for the same claim limitation, it knew would not succeed. The Federal Circuit has expressly recognized that an applicant's response to a rejection does not have to be successful to operate as an estoppel. *See Felix v. Am. Honda Motor Co.*, 562 F.3d 1167, 1182 (Fed. Cir. 2009) ("It is the patentee's response to a rejection—not the examiner's ultimate allowance of a claim—that gives rise to prosecution history estoppel."). Amgen's clear disavowal in the parent application's prosecution thus applies with equal force to the concentration limitation in the '707 patent. *See Elkay*, 192 F.3d at 980.

4. Dismissal of Amgen's claims based upon prosecution history estoppel is entirely appropriate at this stage.

Finally, Amgen suggests that somehow claim construction is required (Opp'n at 20) and further argues that "it is premature to resolve this question of infringement under the doctrine of equivalents at this early stage before completion of fact discovery and before expert discovery even begins," (*id.* at 24). But analysis of prosecution history estoppel needs no claim construction or discovery. It is solely a question of law based on the intrinsic record—the patent, the specification and the prosecution history, all of which, Amgen admits, is properly of record and should be considered. *Mark I Mktg.*, 66 F.3d at 291. No amount of discovery would change the facts. Indeed, Amgen does not identify any conflicting evidence undermining Mylan's statements of facts. In *Coherus*, the court granted a similar motion based on estoppel alone. *Amgen Inc. v. Coherus Biosciences Inc.*, 17-CV-546 (LPS), 2018 WL 1517689 at *4 (D. Del. Mar. 26, 2018). While Amgen may now dispute the interpretation of its own prior statements, as in *Coherus*, there is sufficient context based on the prosecution history to confirm that estoppel applies at this stage. *Id.*

B. Mylan Does Not Literally Infringe the Salt Combination Limitation: Amgen Disclaimed Combinations [redacted]

Amgen concedes, as it must, that [redacted]. That alone should be dispositive. (*See* Mylan Br. at 17-19). But Amgen has manufactured a literal infringement theory [redacted] Amgen disclaimed combinations of [redacted].

1. Amgen's prosecution statements in the parent application disavow a combination of [redacted]

As explained in Mylan's opening brief (Mylan Br. at 8-9), Amgen's clear and unmistakable statements during prosecution disclaimed HIC systems using [redacted]—i.e., anything other than the "dual salt system" which Amgen claims is "key" to its alleged invention, (Opp'n at 7).[5] Amgen also repeats its claim (Opp'n at 14) that "prosecution of the parent application is not germane" because the parent claims were purportedly directed to a different salt pair. Amgen is wrong on the law as explained above. And the facts for this limitation are akin to those discussed for the concentration limitation: (1) the salt combination limitation—"mixing a preparation containing the protein with a combination of a first salt and a second salt"—is distinct and separate from the *particular* salt pair limitation, *Southwall*, 54 F.3d at 1583, (2) the same claim limitation is in both the parent application and the '707 patent, (*see* Mylan Br. at 8), and (3) the '707 patent and parent application have the same specification.

[5] According to Amgen, "applicants selected the term 'dual salt system'" (or process), which is used repeatedly throughout the '707 patent specification and the prosecution histories, "to differentiate their disclosed method from the traditional ("Holtz") HIC process." (D.I. 81-4, '707 patent PH, 8/22/2011 Resp. at 6; *see also* D.I. 81-2, '707 patent at Abstract; *id.* at col. 2, ll. 39-42; *id.* at col. 6, ll. 41-51; *id.* at col. 6, l. 62; *id.* at col. 7, ll. 20-22; D.I. 81-5, '581 parent application PH, 7/14/2008 Resp. at 6-9).

Thus, the same analysis applies and Amgen's representations in the parent prosecution have equal force with respect to the '707 patent. *Elkay*, 192 F.3d at 980.

Amgen contends (Opp'n at 13-14, 16) it only disavowed "single salt" systems, and "interpreting those statements" requires "a fully developed record." Not so. ***First***, Amgen admits it distinguished Holtz for "not disclosing, suggesting, or contemplating any steps 'involving ***a combination of two salts*** for any purpose whatsoever.'" (Opp'n at 13 (emphasis added) (citing '707 patent PH, 8/22/2011 Resp. at 5); *see also* D.I. 81-4, '707 patent PH, 8/22/2011 Resp. at 5 (arguing the Patent Office "overlooks two elements of the claimed method—the use of a combination of salts in a HIC operation and the enhancement of the dynamic capacity of a HIC column"). Amgen further admits it relied upon the combination limitation to distinguish Holtz as disclosing a protein solution with "four salts, not a combination of two salts [**as recited in the claimed method**.]" (Opp'n at 14 (Amgen removed "as recited in the claimed method" from the original statement to the Patent Office)). [redacted]

Second, Amgen's prosecution history statements are not only clear and unmistakable, they are oft repeated by Amgen to confirm the limitation requires "a combination of two salts only":

> Therefore, because the reference to Holtz et al. does not describe all of the elements of the claimed process for purifying a protein comprising mixing the protein with a combination of two salts only, citrate and phosphate, at concentrations of between about 0.1M and 1.0M, and loading this mixture onto the column, Applicants submit that Holtz et al. does not anticipate the claimed subject matter. Reconsideration and withdrawal of the rejection on the basis of 35 U.S.C. § 102 (b) is respectfully requested.
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> * * *

> instant application, page 4). Holtz et al. merely describes in detail methods for purifying a single protein IGF-1 so that the protein is intact and correctly folded. 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. Further, there is no suggestion in Holtz et al. to use two salts, let alone the particular combination of salts of the claimed method, since, as described above, more than two salts are used in the protein solutions for every HIC column described in Holtz et al.

(D.I. 81-5, '581 parent application PH, 7/14/2008 Resp. at 7-8 (emphasis added); *id.* at 9 ("the claimed two salt processes")).

Third, Amgen admits that, under its infringement theory, [redacted]

> recited in the claimed method), is loaded onto the HIC column. Further, Holtz et al., column 27, lines 17 to 31, describes a second method of preparing IGF-1 for a HIC column, comprising collecting the IGF-1 eluant from the cation exchange column, diluting into sodium acetate/phosphate buffer in addition to adding ammonium sulfate to 15% of saturation levels (three salt combination instead of two salts). Again Holtz

(D.I. 81-5, '581 parent application PH, 7/14/2008 Resp. at 7-8 (emphasis added)).

Fourth, this Court should reject Amgen's attempts to escape the scope of its disavowal by conspicuously misquoting the prosecution history to focus solely on its disavowal of single-salt systems. (Opp'n at 16). While Amgen certainly disavowed single-salt systems too, Amgen's lengthy focus on single salts ignores its other clear and unmistakable statements limiting its invention to "***a combination of two salts only***." (D.I. 81-5, '581 parent application PH, 7/14/2008 Resp. at 7 (emphasis added)). In fact, Amgen omits portions of its prosecution history statements tying the alleged invention to only two salts. Amgen acknowledges it argued Holtz disclosed "four salts, not a combination of two salts" but removes "as recited in the claimed method" from the remainder of the quote in its brief. (*See* Opp'n at 14). Amgen also

fails to include the final sentence in a quote from the '707 patent prosecution history explaining that "applicants selected the term 'dual salt system' to ***differentiate their disclosed method*** from the traditional (Holtz) HIC process," which Amgen refers to as disclosing single-salt systems, or a high concentration of a single salt with a buffer, which can contain additional salts (i.e., three-salt and four-salt combinations). (D.I. 81-4, '707 patent PH, 8/22/2011 Resp. at 5-6; *see also* D.I. 81-5, '581 parent application PH, 7/14/2008 Resp. at 8 (referring to the "typical methods" disclosed in Holtz including three-salt and four-salt combinations)).

Last, [redacted] is not only irrelevant, but also legally baseless and contradicted by Amgen's own prosecution statements. (*See, e.g.*, Mylan Br. at 20). As even Amgen now admits, it attempted to distinguish Holtz on the basis that the mixture is not formed *before loading*, and even quotes in its Opposition Amgen's prior statement alleging Holtz does not teach a combination of two salts "***before loading the protein on the HIC column***." (Opp'n at 14 (emphasis added)). Such statements are just as clear and unmistakable as Amgen's statements above limiting the claims to a combination of only two salts, nor are they isolated—Amgen repeated its argument that the mixture must be formed *before* loading three times in one single amendment in the parent application. (D.I. 81-5, '581 parent application PH, 7/14/2008 Resp. at 6-8).

2. Dismissal of Amgen's infringement claims based on its clear and unmistakable disclaimer is entirely appropriate at this stage.

Finally, Amgen argues (Opp'n at 13) that disclaimer should not be addressed at the pleading stage, but Amgen presents no factual disputes concerning the "scope of the claims," or which require a "fully developed record to solve." *Atlas IP, LLC v. Exelon Corp.*, 189 F. Supp. 3d 768, 778 (N.D. Ill. 2016), *aff'd sub nom. Atlas IP, LLC v. Commonwealth Edison Co.*, 686 F.

App'x 921 (Fed. Cir. 2017) (granting motion to dismiss where patentee's "action thus depends on a claim construction that is wrong as a matter of law. Hence any amendment would be futile."); *Scripps Res. Inst. v. Illumina, Inc.*, No. 16-cv-661-JLS (BGS), 2017 WL 1361623, at *4 (S.D. Cal. Apr. 14, 2017) (recognizing courts may construe claim terms, when based on the intrinsic record, which are questions of law, at the pleading stage). Thus, Amgen is "entirely incorrect in stating that claim construction cannot be engaged in at all at the motion to dismiss stage, at least when it is based on facts alleged in or reasonably inferable from the complaint." *Atlas*, 189 F. Supp. 3d at 774. Amgen's argument is an attempt to delay the inevitable.

Amgen's reliance (Opp'n at 13) on *Nalco* is also misplaced. There, the defendants argued a patentee's statement during an *inter partes* reexamination regarding the general understanding of a claim term, but not tied to the alleged invention, estopped the patentee from claiming infringement. *Nalco Co. v. Chem-Mod LLC*, 883 F.3d 1337, 1349 (Fed. Cir. 2018). That is not the circumstance here. Amgen's clear and unambiguous statements are its own characterizations of the scope of the claim limitations at issue. Amgen's dispute regarding application of its prosecution disavowals is legal (not factual), just as in *Coherus*, and thus resolution is entirely appropriate at this stage. *Coherus*, 2018 WL 1517689, at *4 n. 5 (finding Amgen's citation to *Nalco* unavailing as no factual disputes have been identified by Amgen, "only a legal dispute that, in the Court's view, turns on the clear and unambiguous prosecution history").

C. Mylan Does Not Infringe the Salt Pair Limitation Under the Doctrine of Equivalents Either.

Amgen barely tries (Opp'n at 15) to rebut Mylan's showing that prosecution history estoppel bars any claim of infringement of the salt pair limitation under the doctrine of equivalents. And for good reason. The prosecution statements identified by Mylan as

supporting estoppel are undeniable, and therefore not seriously disputed by Amgen. (*See* Mylan Br. at 17-19). Additionally, *Coherus* already confirmed the statements "clearly and unmistakably surrendered claim scope beyond the salt combinations listed in the claims of the '707 patent." *Coherus*, 2018 WL 1517689, at *2. As recognized in *Coherus*, "Amgen acknowledges each of the statements to which [Mylan] points and does not identify any conflicting evidence," thus this Court "has sufficient context in this case to make a decision of law that prosecution history estoppel applies." *Id.* at *4.

Amgen also disputes (Opp'n at 17) that [redacted] Again, Amgen ignores the *Coherus* finding that Amgen "dedicated to the public" salts not claimed based on the *exact same* "list of lyotropic" salts in the specification. *Coherus*, 2018 WL 1517689, at *3. Amgen's doctrine of equivalents argument as to the salt combination is meritless for this additional reason as well.

III. CONCLUSION.

For the foregoing reasons, Mylan's motion to dismiss Amgen's allegations in the complaint regarding the '707 patent with prejudice should be granted.

Dated: May 11, 2018

Respectfully submitted,

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