

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

AMGEN INC. and AMGEN	:	
MANUFACTURING LIMITED,	:	
	:	
Plaintiffs,	:	
	:	
v.	:	C.A. No. 17-546-LPS-CJB
	:	[REDACTED]
COHERUS BIOSCIENCES INC.,	:	
	:	
Defendant.	:	

MEMORANDUM ORDER

WHEREAS, Magistrate Judge Burke issued a 19-page Report and Recommendation (the “Report”) (D.I. 50), dated December 7, 2017, recommending that the Court grant Defendant Coherus Biosciences Inc.’s (“Defendant” or “Coherus”) motion to dismiss (D.I. 9) Plaintiffs Amgen, Inc. and Amgen Manufacturing, Limited’s (“Plaintiffs” or “Amgen”) Complaint for failure to state a claim upon which relief may be granted;

WHEREAS, on December 21, 2017, Amgen objected to the Report (“Objections”) (D.I. 53), specifically objecting to the Report’s interpretation of the prosecution history in finding that Amgen “clearly and unmistakably” surrendered claim scope regarding particular combinations of salts that were not specifically listed in the claims of U.S. Patent No. 8,273,707;

WHEREAS, on January 9, 2018, Coherus responded to Amgen’s Objections (“Response”) (D.I. 57), asserting that the Report properly interpreted the prosecution history, and further, that two additional grounds support granting its motion to dismiss: (1) Amgen dedicated the surrendered claim scope to the public by disclosing alternative salt combinations in the ’707

patent specification but not claiming them; and (2) Amgen surrendered salt combinations in concentrations greater than the amount Coherus uses;

WHEREAS, the Court has considered the parties' objections and responses *de novo*, see *St. Clair Intellectual Prop. Consultants, Inc. v. Matsushita Elec. Indus. Co., Ltd.*, 691 F. Supp. 2d 538, 541-42 (D. Del. 2010); 28 U.S.C. § 636(b)(1); Fed. R. Civ. P. 72(b)(3);

NOW THEREFORE, IT IS HEREBY ORDERED that:

1. Amgen's Objections (D.I. 53) are OVERRULED, Judge Burke's Report (D.I. 50) is ADOPTED, and Coherus's Motion to Dismiss (D.I. 9) is GRANTED.

2. The '707 patent is directed to a process for purifying proteins during which the dynamic capacity – “the amount of protein that can be loaded onto a column without ‘breakthrough’ or loss of protein to the solution phase before elution” – of a hydrophobic interaction chromatography (“HIC”) column is increased by using a combination of two salts in the loading solution. '707 patent at 2:39-42, 3:38-41. Independent claim 1 of the patent reads:

A process for purifying a protein on a hydrophobic interaction chromatography column such that the dynamic capacity of the column is increased for the protein comprising mixing a preparation containing the protein with a combination of a first salt and a second salt, loading the mixture onto a hydrophobic interaction chromatography column, and eluting the protein, ***wherein the first and second salts are selected from the group consisting of citrate and sulfate, citrate and acetate, and sulfate and acetate, respectively, and wherein the concentration of each of the first salt and the second salt in the mixture is between about 0.1 M and about 1.0.***

'707 patent at claim 1 (emphasis added).

3. Amgen alleges that Coherus's abbreviated Biologic License Application (“aBLA”) infringes the '707 patent [REDACTED]. (D.I. 1 at

¶¶ 48-50; D.I. 17 at 13-15) In describing the equilibrium buffer used in this step, Coherus's aBLA explains: [REDACTED]

[REDACTED] (D.I.10 Ex. 9 at 1701-CHS-00343268) Thus, Coherus contends there cannot be infringement because [REDACTED]

[REDACTED] (See D.I.10 at 8-9) Amgen counters that the aBLA infringes the '707 patent under the doctrine of equivalents because "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." (D.I. 1 at ¶ 50) The Report found argument-based prosecution history estoppel prevented Amgen from being able to prevail on this theory of infringement under the doctrine of equivalents. (Report at 17)

4. The Report found that the patent applicants clearly and unmistakably surrendered claim scope beyond the salt combinations listed in the claims of the '707 patent – i.e., citrate and sulfate, citrate and acetate, and sulfate and acetate. (Report at 12-13) In doing so, according to Amgen, the Report "misinterpret[s] the arguments Amgen made to the Patent Office during the prosecution of the '707 patent" and "ignores context." (Objections at 5-6) The Court agrees with the Report and disagrees with the Objections.¹

5. The prosecution history, namely, the patentee's correspondence in response to two

¹The Court also disagrees with Coherus' contention that Amgen waived the arguments it is making in its Objections because they were not presented to the Magistrate Judge. (See Response at 6) Amgen has always contested the application of prosecution history estoppel, and in its motion briefing contended that "'highlighting' 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." (D.I. 17 at 16) While this statement is not as detailed as Amgen's Objections, the Court finds Amgen has not waived it.

office actions and a final rejection, shows a clear and unmistakable surrender of claim scope by the patentee. See *Intendis GmbH v. Glenmark Pharms. Inc., USA*, 822 F3d 1355, 1365 (Fed. Cir. 2016) (stating that argument-based prosecution history estoppel applies when prosecution history “evinces a clear and unmistakable surrender of subject matter”).

6. First, in a February 2008 Office Action, the Patent Office rejected the parent patent of the '707 patent as obvious over Holtz, a United States patent that disclosed “a method for purification of insulin-like growth hormone,” in which salts are used to “improve the hydrophobic interaction” between the protein and the HIC matrix. (D.I. 10 Ex. 6 at 4) Holtz specifically listed salts such as “sodium sulfate, potassium sulfate, ammonium sulfate, potassium phosphate, sodium acetate, ammonium acetate, sodium chloride, sodium citrate and the like.” (*Id.*) In July 2008, the patentee responded that “Holtz et al. does not describe optimizing the purification process for commercial production of any protein by increasing the dynamic capacity of the HIC column(s) through the novel use of *particular combinations* of only two salts.” (*Id.* Ex. 7 at 8) (emphasis added) The patentee continued, “there is no suggestion in Holtz et al. to use two salts, *let alone the particular combination of salts of the claimed method . . .*” (*Id.*) (emphasis added) The patentee made this statement – referencing the “particular combinations of salts of the claimed method” – even though the Patent Office had specifically pointed out that Holtz disclosed [REDACTED] which Amgen now alleges is equivalent to salts claimed in its patent.²

²The parent patent’s claim 1 recited a combination “wherein the first and second salts are citrate and phosphate salts,” while the larger group of three combinations of salts – “citrate and sulfate, citrate and acetate, and sulfate and acetate” – is claimed in the '707 patent as issued. (D.I. 10 Ex. 7 at 3)

7. Later, in an October 2010 Office Action, the Patent Office once more rejected the '707 patent claims as obvious over Holtz, again listing the various salts disclosed by Holtz, [REDACTED] (D.I. 10 Ex. 2 at 4) On January 26, 2011, the patentee argued in its response that the pending claims were different from Holtz because they “recite a particular *combination* of salts [and n]o combination of salts is taught nor suggested in the Holtz et al. patent, nor is the *particular* combinations of salts recited in the pending claims taught nor suggested in this reference.” (D.I. 10 Ex. 3 at 5) Thus, the patentee once more distinguished its application by (1) the use of dual salts and (2) “the particular combinations of salts” recited in the application that became the '707 patent.

8. In April 2011, the Examiner issued a Final Rejection, maintaining its rejection of the claims as obvious over Holtz. (D.I. 10 Ex. 1 at 1, 4) The patentee responded in August 2011, arguing 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 the dynamic capacity of a HIC column* imparted by the applicants’ method.” (*Id.* at 5) The patentee further stated 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) The patentee, therefore, was again telling the Patent Office that merely using two salts, while different from Holtz, was not within the scope of its claims.

9. Amgen’s correspondence with the Patent Office shows “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.” (Report at 12; *see also* *PODS, Inc. v. Porta Stor, Inc.*, 484 F.3d 1359, 1368 (Fed.

Cir. 2007) (describing prosecution history estoppel inquiry depends on “whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter”)) As the Report correctly stated, “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 [recommending granting Coherus’s motion to dismiss] 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.” (*Id.* at 12-13) Accordingly, argument-based prosecution history estoppel bars Amgen from succeeding on its claim of infringement under the doctrine of equivalents.³

10. While the Report understandably and appropriately did not reach Coherus’ other arguments, the Court agrees 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 the [REDACTED]

[REDACTED] (See ’707 patent at 4:42-51) [REDACTED]

[REDACTED]

“combining two different salts having different lyotropic 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”) But [REDACTED] was not claimed – and,

³While the Court agrees with the Report’s ultimate conclusion about prosecution history estoppel, the Court does not find inventor Senczuk’s Declaration (D.I. 10 Ex. 4 at 1) to provide the strong support for this conclusion that the Report found (*see* Report at 13) (noting, correctly, that “patentee supported its position with an inventor declaration providing test results for those *particular claimed combinations*”). The Court understands the Declaration to be principally concerned with comparing combinations of salts to use of a single salt and improving dynamic capacity of a HIC column.

thus, has been dedicated to the public. *See Johnson & Johnston Assocs., Inc. v. R.E. Serv. Co.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002) (“[W]hen a patent drafter discloses but declines to claim subject matter, as in this case, this action dedicates that unclaimed subject matter to the public. Application of the doctrine of equivalents to recapture subject matter deliberately left unclaimed would conflict with the primacy of the claims in defining the scope of the patentee's exclusive right.”) (internal quotation marks omitted).⁴

11. Amgen argues that dismissal is premature because the Court has not had the benefit of a developed record and because there are factual disputes. (Objections at 8-9; D.I. 68 at 1) The Court disagrees. Unlike in *Amgen Inc. v. Alkem Labs. Ltd.*, 2017 WL 6493150, at *2 n.2 (D. Del. Dec. 19, 2017), the facts in the prosecution history here are undisputed. Amgen acknowledges each of the statements to which Coherus points and does not identify any conflicting evidence. (*See generally* Report 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.”) Amgen merely disputes the interpretation of those facts, contending that, in context, they do not support a finding of estoppel. But the Court has sufficient context in this case to make a decision of law that prosecution history estoppel applies. *See EMD Millipore Corp. v. AllPure Techs., Inc.*, 768 F.3d 1196, 1201 (Fed. Cir. 2014).⁵

⁴The Court has chosen not to address Coherus’ third argument for dismissal, based on the amount of ██████████ Coherus uses. (*See* D.I. 10 at 13-15)

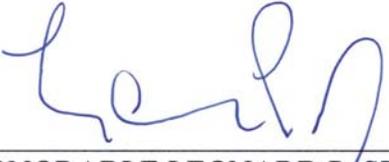
⁵Amgen’s citation to the Federal Circuit’s very recent decision in *Nalco Co. v. Chem-Mod, LLC*, 883 F.3d 1337 (Fed. Cir. 2018), is equally unavailing. In *Nalco* the parties had disputes over the proper construction of claim terms that were inappropriate to resolve on a motion to dismiss. Here no such disputes have been identified – only a legal dispute that, in the

12. Given the Court's conclusions about the clear and unmistakable disclaimer in the prosecution history, necessitating dismissal of Amgen's claim for infringement under the doctrine of equivalents, and given Amgen's acknowledgment that Coherus does not literally infringe, amendment of the complaint would be futile. Therefore, the Court denies Amgen's request for leave to amend.

As the Court has issued this Memorandum Order under seal, IT IS FURTHER ORDERED that the parties shall meet and confer and, no later than March 28, submit a proposed redacted version of it.

IT IS FURTHER ORDERED that, no later than March 28, the parties shall submit a joint status report advising the Court as to their position(s) as to how this case should now proceed.

March 26, 2018
Wilmington, Delaware



HONORABLE LEONARD P. STARK
UNITED STATES DISTRICT JUDGE

Court's view, turns on the clear and unambiguous prosecution history.