Appeal No. 2018-1993

United States Court of Appeals for the Federal Circuit

AMGEN INC., AMGEN MANUFACTURING LIMITED,

Plaintiffs-Appellants,

– v. –

COHERUS BIOSCIENCES INC.,

Defendant-Appellee.

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

NON-CONFIDENTIAL REPLY BRIEF FOR PLAINTIFFS-APPELLANTS AMGEN INC. AND AMGEN MANUFACTURING, LIMITED

WENDY A. WHITEFORD
LOIS M. KWASIGROCH
KIMBERLIN L. MORLEY
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, California 91320
(805) 447-1000

NICHOLAS GROOMBRIDGE
JENNIFER H. WU
JENNIFER GORDON
PETER SANDEL
STEPHEN A. MANISCALCO
JACOB T. WHITT
GOLDA LAI
PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
1285 Avenue of the Americas
New York, New York 10019
(212) 373-3000

Attorneys for Plaintiffs-Appellants Amgen Inc. and Amgen Manufacturing, Limited

December 12, 2018

CERTIFICATE OF INTEREST

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

   AMGEN INC. and AMGEN MANUFACTURING, LIMITED

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

   AMGEN INC. and AMGEN MANUFACTURING, LIMITED

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

   AMGEN INC.

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

   MORRIS, NICHOLS, ARSHT & TUNNELL LLP: Jack B. Blumenfeld, and Maryellen Noreika (who is no longer with the firm)

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

   Amgen Inc., et al. v. Mylan Inc., et al., No. 2:17-cv-01235-MRH (W.D. Pa.).

Date: December 12, 2018

/s/ *Nicholas Groombridge*
Nicholas Groombridge

TABLE OF CONTENTS

Page

CONFIDENTIAL MATERIAL OMITTED

Pursuant to Federal Circuit Rule 28(d)(2)(B), Plaintiffs-Appellants prepared this public version of their brief which redacts certain information designated confidential pursuant to the district court's Protective Order entered on December 7, 2017. Specifically, the material omitted on pages i, 4, 9, 10, 19, 22, 25, and 27-29 contains references to Defendant-Appellee's accused process, and was designated confidential by Defendant-Appellee during discovery under the terms of the Protective Order.

TABLE OF AUTHORITIES

Page(s)

CASES

TABLE OF AUTHORITIES (CONTINUED)

Page(s)

STATUTES

INTRODUCTION

The district court erred in holding that argument-based prosecution history estoppel ("PHE") and the dedication-disclosure doctrine apply to bar Amgen from asserting infringement under the doctrine of equivalents in this case.

First, argument-based PHE does not apply because the single Amgen statement in the '707 Patent prosecution on which the district court relied is not a clear and unmistakable surrender of subject matter. (Blue Br. at 20-23, 25-50.) "The relevant inquiry is whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter." *Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349, 1364 (Fed. Cir. 2006). Here, the single Amgen statement-at-issue as to "particular" salt pair combinations was made in a response that the Examiner did not accept as a basis to overcome the prior art and allow the claims. (Appx177-184 at Appx182-183; Appx944-950 at Appx947-949; Blue Br. at 14-18, 30-41.) Indeed, the '707 Patent claims were allowed only after Amgen argued in a later response, without referring to particular salt pairs, that the claimed method uses "a *combination* of salts in a HIC operation, and the *enhancement of the dynamic capacity of a HIC column* imparted by applicants' method." (Appx157-168 at Appx160-161; *see* Blue Br. at 18, 20-21, 34-41.)

In these circumstances, a competitor would not be reasonably justified in concluding that Amgen gave up coverage of all salt pair combinations other than

those claimed. (Blue Br. at 14, 18, 30-41.) Taking the prosecution history as a whole, as the law requires, a reasonable competitor would necessarily conclude that the key to the invention was the use of a pair of salts to increase dynamic capacity beyond what could be achieved with a single salt. (*Id.*) The reasonable competitor would see that Amgen's arguments based on the "particular" salt combinations alone had been unsuccessful and that the fundamental issue was the comparison between the effect on dynamic capacity with the use of a pair of salts versus a single salt. (*Id.*) Thus, the district court erred in holding that Amgen's statement is a clear and unmistakable surrender of subject matter.

Coherus argues that "[i]t is irrelevant whether the Examiner ultimately relied on Amgen's argument; the relevant point is that Amgen made the argument, and thus made clear to the public that the claim did not reach beyond the particular combinations recited therein." (Red Br. at 26-30.) This is incorrect because the Examiner's reliance must be considered in determining whether there is argument-based PHE. While "[c]lear assertions made during prosecution in support of patentability, whether or not actually required to secure allowance of the claim, may also create an estoppel," a court "must examine the character of assertions made in the prosecution history in addition to the result of those assertions, i.e., whether they result in allowance, when determining whether they create an estoppel." *Southwall Techs. v. Cardinal IG Co.*, 54 F.3d 1570, 1583 (Fed. Cir.

1995). Further, "[a]lthough actual reliance by the examiner need not be shown, if an estoppel is to rest upon argument made during the examination process, the circumstances must be such as to permit the inference that such reliance in fact occurred. A showing that the conduct in question played a material role in the issuance of the patent usually suffices." *Zenith Labs., Inc. v. Bristol-Myers Squibb Co.*, 19 F.3d 1418, 1425 n.8 (Fed. Cir. 1994) (citing *Mannesmann Demag Corp. v. Eng'g Metal Prods. Co.*, 793 F.2d 1279, 1285 (Fed. Cir. 1986)).

In addition, the district court erred in relying on Amgen's statement in the prosecution of the '395 Patent application (the parent to the '707 Patent) because the statement relates to claims that are materially different from the issued '707 Patent claims. (Blue Br. at 43-48.) In apparent recognition of the district court's error on this point, Coherus asks this Court to ignore Amgen's statement in the parent application because Amgen's correspondence "in connection with the prosecution of the patent-in-suit suffice[s], standing alone, to establish prosecution history estoppel." (Red Br. at 31-38.) As discussed above, however, Amgen's statement in the '707 Patent prosecution correspondence is not a clear and unmistakable surrender of claim scope as to all salt combinations other than those claimed.

Second, the district court erred in limiting the scope of equivalents for the recited salt pairs under the dedication-disclosure doctrine. (Appx4-11 at Appx9-

10.) In its Reply, Coherus commits the same error by failing to analyze whether the "unclaimed subject matter [was] identified by the patentee as an alternative to a claim limitation." *SanDisk Corp. v. Kingston Tech. Co., Inc.*, 695 F.3d 1348, 1364 (Fed. Cir. 2012) (quoting *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364, 1379 (Fed. Cir. 2005)); Red Br. at 38-43. Coherus argues instead that a person of ordinary skill would find that the specification "[e]ffectively" discloses [redacted] and [redacted] in combination. (Red Br. at 40-42.) Putting aside that no record evidence supports this assertion, "effective disclosure" is not the correct test.

When read properly, neither the specification of the '707 Patent nor its prosecution history identifies a [redacted] with the requisite specificity, let alone as an alternative to the recited salt pairs to support application of the dedication-disclosure doctrine. And none of the specific salt pairs disclosed in the specification includes [redacted]. Accordingly, the [redacted] was not "identified by the patentee as an alternative to a claim limitation," and the dedication-disclosure doctrine does not bar Amgen from asserting equivalence. *See SanDisk Corp.*, 695 F.3d at 1364.

ARGUMENT

I. The District Court Erred in Applying Argument-Based Prosecution History Estoppel to Bar Amgen From Asserting Infringement Under the Doctrine of Equivalents

The district court held that argument-based PHE applies here based on Amgen's correspondence in response "to two office actions and a final rejection" from the parent '395 Patent application (July 14, 2008 Response to Office Action (Appx204-213)) and the '707 Patent application (January 26, 2011 and August 22, 2011 Responses to Office Action (Appx177-184 and Appx157-168, respectively). (Appx6-7.) This is error. Taken as a whole, a reasonable competitor would not reasonably believe that Amgen had surrendered salt pairs other than the ones claimed in the '707 Patent. (Blue Br. at 20-23, 25-50.)

A. The Prosecution of the '707 Patent Claims Does Not Evince a Clear and Unmistakable Disavowal as to Those Claims

As discussed above, the "relevant inquiry is whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter." *Conoco*, 460 F.3d at 1364. This is an objective standard. *Pharmacia & Upjohn Co. v. Mylan Pharms. Inc.*, 170 F.3d 1373, 1377 (Fed. Cir. 1999); Blue Br. at 42-43. *Conoco* held that the patentee's statements to "demonstrate to the examiner that a fatty acid wax was not the same as a metal stearate to alleviate the examiner's obviousness concerns" was a "clear surrender of metal stearates" but not "a clear surrender of other possible equivalents." *Conoco*, 460 F.3d at 1364.

Similarly, Amgen's statement-at-issue in the '707 Patent prosecution about Holtz is not a clear surrender of other possible equivalents to the '707 Patent claimed salt pair combinations. (Blue Br. at 14-18, 27-43.) Indeed, none of the arguments that Amgen made in its last submission before allowance—which presumably must be the focus of any argument-based PHE analysis—addressed, let alone limited the invention to the "particular" salts recited in the claims. (*Id.* at 18, 20-22, 40.) A reasonable competitor viewing the prosecution history as a whole would recognize that Amgen's arguments based on "particular" salt combinations alone had not overcome the prior art, and a reasonable competitor would appreciate that the claims were allowed because they recite the use of a pair of salts to increase dynamic capacity beyond what could be achieved with a single salt. (*Id.* at 20-22, 27-43.) Thus, the district court erred in holding that Amgen's statement is a clear and unmistakable surrender of subject matter.

The district court stated in paragraph 9 of its decision that, "in order to overcome the Examiner's rejection of the claims over Holtz, the patentee distinguished its invention not only on that ground [the use of a combination of salts], but also for the independent reason that the invention recited the use of ***particular*** combinations of salts." (Appx8-9.) This is error because the '707 Patent claims issued only after Amgen argued—without reference to ***particular*** combinations of salts—that the claimed method uses "a *combination* of salts in a

HIC operation, and the *enhancement of the dynamic capacity of a HIC column* imparted by applicants' method." (Appx160-161; *see* Blue Br. at 14-18, 20-21, 30-41.) Specifically, the Examiner maintained his rejections of the pending claims of the '707 Patent application as obvious over Holtz (Appx169-176 at Appx173-175) and did not accept Amgen's arguments that "[n]o combinations of salts is taught nor suggested in the Holtz et al. patent, nor is the particular combinations of salts recited in the pending claims taught nor suggested in this reference." (Appx182-184; Appx949; Blue Br. at 14-18, 20-21, 30-41.)

Coherus argues that "[i]t is irrelevant whether the Examiner ultimately relied on Amgen's argument; the relevant point is that Amgen made the argument, and thus made clear to the public that the claim did not reach beyond the particular combinations recited therein." (Red Br. at 27-30.) This is incorrect. The Examiner's reliance must be considered in determining whether there is argument-based PHE. *See Southwall Techs.*, 54 F.3d at 1583; *Zenith Labs.*, 19 F.3d at 1425. In *Zenith*, this Court held that argument-based PHE does not apply where "[t]here is no indication that the examiner ever relied on the statements regarding manufacturing-related characteristics in allowing the patent to issue." *Id.* at 1425. The same reasoning applies here. Contrary to Coherus's assertions (Red Br. at 26-30), the Examiner maintained the rejection of the claims reciting particular salt combinations after having considered Amgen's argument that the "particular

combination of salts recited in the pending claims" distinguished the invention over the prior art. (Blue Br. at 18, 20-21, 30-41.) It was not until Amgen amended the claims to require an increase in dynamic capacity, and distinguished the prior art on the grounds that it disclosed neither a combination of salts nor an increase in dynamic capacity, that the claims were allowed. (*Id.* at 40; Appx1237-1245 at Appx1238; Appx1249-1251.) In these circumstances, a competitor would not have been "reasonably justified in concluding that [Amgen], through the statements in question, gave up coverage of [salt combinations] other than [the specific combinations claimed]." *Zenith Labs.*, 19 F.3d at 1424. Thus, the district court erred in holding that Amgen's statement is a clear and unmistakable surrender of subject matter. (Blue Br. at 20-22, 27-41.)

Coherus asserts that Amgen's argument in its January 26, 2011 Response gives rise to argument-based PHE. (Red Br. at 24-30; Appx182-184.) But, as in *Zenith*, Amgen's argument in its January 26, 2011 Response does not give rise to argument-based PHE where "[t]here is nothing in the record" to suggest that it "played any role in the procurement" of the '707 Patent, and "[t]here is no indication the examiner ever relied on the statements . . . in allowing the patent to issue." *Id.* at 1424-1425; *see also Lifestream Diagnostics, Inc. v. Polymer Tech. Sys., Inc.*, 109 Fed. App'x 411, 414 (Fed. Cir. 2004) (non-precedential) ("[O]ur statement in *Zenith* requiring reliance was in regard to [argument-based]

prosecution history estoppel, not argument-based estoppel [in the context of claim construction].") (Appx1300-1305 at Appx1301).[1]

Coherus's other arguments fail. ***First,*** Coherus argues that Amgen told the Examiner that Amgen "was worthy of a patent because of its hard work in determining that *these particular* combinations of two salts—as opposed to any combination of two salts—would increase dynamic capacity." (Red Br. at 28.) This is incorrect. Amgen never used the phrase "particular combinations" in its Remarks in the August 22, 2011 Amendment After Final Rejection, which was what led to allowance of the claims. (Appx159-163.) That Amgen used the phrase "particular combinations" in earlier statements to the Examiner that were unsuccessful in obtaining allowance of the claims does not mean that the invention is now limited to particular salt combinations. (Blue Br. at 20-22, 30-43.)

Second, Coherus argues that "[a]t a minimum" Amgen's statements regarding Holtz should estop Amgen from asserting infringement with respect to "combinations of [redacted] and [redacted]" because Amgen did not dispute that Holtz disclosed [redacted] salts. (Red Br. at 18.) Again, Coherus is relying on Amgen's

[1] *Zenith* held that the district court's error in applying argument-based PHE was harmless because the plaintiff had not proven doctrine of equivalents based on the bench trial record. 19 F.3d at 1425. No such record exists here, where the district court dismissed Amgen's Complaint without discovery, much less trial evidence. (Blue Br. at 42-43.)

statements that the Examiner rejected. In the August 22, 2011 Amendment After Final Rejection that led to the allowance of the '707 Patent claims, Amgen did not say anything about combinations that specifically include [redacted], but rather distinguished Holtz on the basis that it did not "disclose, suggest or contemplate any steps involving a combination of two salts for any purpose whatsoever." (Appx159-163.)

Third, Coherus points to the declaration of co-inventor Dr. Anna Senczuk that Amgen submitted with the August 22, 2011 Amendment After Final Rejection to support its argument that "Amgen's follow-up arguments to the Examiner reinforce, rather than undermine, its prior statements" from the January 26, 2011 Response. (Red Br. at 28-29.) This misses the point. The district court did not rely on Dr. Senczuk's declaration to support application of argument-based PHE here. (Appx9 n.3.) Specifically, the district court stated: "While the Court agrees with the Report's ultimate conclusion about prosecution history estoppel, the Court does not find inventor Senczuk's Declaration to provide the strong support for this conclusion that the Report found." *Id.* (citations omitted). Nothing in Amgen's characterization of Dr. Senczuk's declaration, nor in the declaration itself, indicates that Amgen surrendered any salt combination. (Blue Br. at 15-18, 39-40.) As the district court correctly recognized, Dr. Senczuk's declaration was concerned with "comparing combinations of salts to use of a single salt and improving dynamic

capacity of a HIC column" (Appx9), and Amgen submitted Dr. Senczuk's declaration as secondary evidence of non-obviousness to demonstrate the unexpected beneficial effects of salt combinations for increasing dynamic capacity. (Appx162-167; *see* '707 Patent, 1:66–2:24, 7:55–11:35.)

Fourth, Coherus argues that *PODS, Inc. v. Porta Stor, Inc.*, 484 F.3d 1359 (Fed. Cir. 2007) "require[s] applying prosecution history estoppel here" and that "this case is indistinguishable from *PODS*." (Red Br. at 15-18.) This is incorrect. In *PODS*, this Court *sua sponte* considered estoppel in the context of a claim construction appeal. Brief of Defendant, Appellant, *PODS, Inc. v. Porta Stor, Inc.*, 484 F.3d 1359 (Fed. Cir. 2007) (No. 2006-1504), 2006 WL 3265354, at Issue 2 (Appx1306-1328 at 1315-1317); *see* 484 F.3d at 1367-68. *PODS* held that there was a clear and unmistakable surrender of subject matter where the applicant overcame the prior art by distinguishing the rectangular-frame feature as not disclosed in the prior art (among other arguments) and amending the claims to require that feature ("around the container"). Brief of Defendant, Appellant, *PODS, Inc. v. Porta Stor, Inc.*, 484 F.3d 1359 (Fed. Cir. 2007) (No. 2006-1504), 2006 WL 3265354, (Appx1315-1317); *see PODS*, 484 F.3d at 1367-68. After the language "around the container"—which Appellants said "referred to a single rectangular frame that went 'around the container'"—was added to claim 1, it was then "allowed by the examiner." Brief of Defendant, Appellant, *PODS, Inc. v.*

Porta Stor, Inc., 484 F.3d 1359 (Fed. Cir. 2007) (No. 2006-1504), 2006 WL 3265354, at Issue 2 (Appx1315-1317); *see PODS*, 484 F.3d at 1367-68. That is not the case here, where the Examiner continued to reject (and did not allow) the pending claims following Amgen's January 26, 2011 Response.

Fifth, Coherus cites two cases to argue that because "the interested public has the right to rely on inventor's statements made during prosecution, without attempting to decipher whether the examiner relied on them, or how much weight they were given," any subsequent clarifications of Amgen's arguments in the August 22, 2011 Amendment After Final Rejection are irrelevant. (*See* Red Br. at 27 (citing *Fenner Invs., Ltd. v. Cellco P'ship*, 778 F.3d 1320, 1325 (Fed. Cir. 2015) and *Springs Window Fashions LP v. Novo Indus., L.P.*, 323 F.3d 989, 993-96 (Fed. Cir. 2003)).) But neither of those cases involved the application of argument-based PHE where, as here, the applicant's statements during prosecution are ambiguous rather than a clear and unmistakable surrender of subject matter. *Fenner* and *Springs Windows* both address prosecution disclaimer in the context of claim construction, which is a wholly separate doctrine from PHE which bars the assertion of the doctrine of equivalents. *See Southwall Techs.*, 54 F.3d at 1578. The issue here is not whether the prosecution history includes statements supporting a particular claim construction that is also supported by the specification. And the prosecution disclaimer cases cited by Coherus do not

address whether there is clear and unmistakable surrender so as to warrant application of argument-based PHE.

B. The Prosecution of the '395 Patent Does Not Evince a Clear and Unmistakable Disavowal as to the '707 Patent Claims

The district court erred in relying on Amgen's statements in the parent application because the claims that issued in the '395 Patent[2] address different salt pairs than the ones claimed in the '707 Patent and thus Amgen's statements in that application do not create argument-based PHE for the '707 Patent claims. *See Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1078 (Fed. Cir. 2005); Blue Br. at 9-14, 22-23, 43-48. Coherus apparently agrees: even though the district court relied on the parent application to find argument-based PHE, Coherus asks this Court to ignore Amgen's statements in the parent application because "Amgen's statements in connection with the prosecution of the patent-in-suit suffice, standing alone, to establish prosecution history estoppel." (Red Br. at 31-38.)

At the same time, Coherus criticizes Amgen for not discussing portions of the prosecution history of the '395 Patent, for example "mak[ing] no mention" of

[2] Amgen's Blue Brief correctly states in two places that the only claims issued in the '395 Patent are specific claims requiring citrate and phosphate salt pairs (and thus, not generic claims). (*See, e.g.*, Blue Br. at 14, 46.) Amgen then stated inadvertently that "generic claims were included in the original application and eventually issued in the '395 Patent." (*Id.* at 47.) The latter half of this last statement is not correct, as is clear from the earlier statements. (Red Br. at 36-37.)

the July 17, 2007 Office Action. (Red Br. at 35-36.) But Coherus fails to note that this office action is not in the record below and that Coherus unilaterally included it in the Red Brief. (Red Br. at 34-35.) Amgen cannot be faulted for discussing only those materials which were before the district court and thus in the appeal record here.

Nonetheless, the portions of the parent application prosecution history that are not part of the appeal record do not help Coherus. (Appx1063-1299.) Even if the Court were to consider the parent application, Amgen's statements in the '395 Patent prosecution history do not create argument-based PHE as to the '707 Patent claims. As is the case with the '707 Patent prosecution history, in the '395 Patent prosecution history, the Examiner did not accept Amgen's argument that the claimed invention is distinguishable over Holtz based solely on the "particular" combinations of salts. (Blue Br. at 9-14, 22-23, 43-48.) Rather, the Examiner allowed the pending '395 Patent claims only after Amgen amended the claims to require an increase in dynamic capacity due to the combination of salts and distinguished the prior art on that ground. (*Id.*) Accordingly, a competitor would not reasonably rely on such statements as to the claimed salts to be a clear and unmistakable disavowal of claim scope as to other salts. *See Zenith Labs.*, 19 F.3d at 1424-25; *Southwall Techs.*, 54 F.3d at 1583.

Specifically, the original claims in the application for the '395 Patent required salt pair combinations, including dependent claims that required specific salt pair combinations. (Appx1063-1094 at Appx1087-1088.) But none of the original claims required an increase in dynamic capacity resulting from the use of those specific salt pair combinations. (*Id.*; Blue Br. at 9-14, 22-23, 43-48.) In its February 14, 2008 Office Action, after the claims had been amended to recite citrate and phosphate, the Examiner rejected the pending claims as anticipated and obvious over the Holtz reference. (Blue Br. at 11-12, 48-50; Appx196-203 at Appx199-202.) In its July 14, 2008 Response, Amgen distinguished Holtz from the then-claimed invention on the basis that Holtz "does not describe or suggest combining the protein to be purified with the particular *combination* of two salts, ***citrate and phosphate*** salts, as recited in the claimed process." (Appx210 (second emphasis added); *see* Appx209-211; Blue Br. at 12, 43-49.)

However, the Examiner did not allow the claims based on this argument. In an October 24, 2008 Office Action, the Examiner withdrew the anticipation rejection but maintained the obviousness objection over Holtz. (Appx1194-1199 at Appx1196-1198.) Amgen disagreed with the Examiner again in its April 23, 2009 Request for Continued Examination: "Applicants point out again that it is the use of a particular *combination* of salts that confers the advantageous properties

described in the instant application." (Blue Br. at 13; Appx968-974 at Appx972.)[3] But the Examiner rejected Amgen's arguments in a May 19, 2009 Office Action. (Blue Br. at 13-14; Appx1218-1223 at Appx1220-1222.)

In its November 19, 2009 Response, Amgen amended claim 1 to add language requiring "that the dynamic capacity of the column is increased for that protein". (Appx1238; *see* Blue Br. at 43-44.) Amgen again argued that the pending claims recite a particular combination of salts and also argued that "[t]he claimed subject matter is directed to use of combinations of salts that *increase the dynamic capacity* of the [HIC] columns." (Appx1240-1241.) Only after Amgen added this claim language so that all claims required an increase in dynamic capacity did the Examiner then issue a Notice of Allowance on March 19, 2010. (Appx1249; *see* Blue Br. at 43-44.) Thus, Amgen's earlier correspondence does not evince a clear and unmistakable surrender of claim scope to a competitor. And Coherus's argument otherwise—that the amendment of the claims to add the increasing dynamic capacity language did not have any effect on Amgen's arguments to the Examiner (Red Br. at 33-34)—is incorrect.

[3] Amgen made arguments in the '395 Patent prosecution related to dynamic capacity as to citrate and phosphate prior to the amendment of the claims to include such dynamic capacity language. (Appx972.) The same is not true for the '707 Patent claims at issue in this appeal. (Appx179-184.)

C. Expert Testimony and Factual Development are Relevant to Determining Whether Prosecution History Estoppel Applies

Coherus argues that because argument-based PHE is a question of law, it requires no factual development. (Red Br. at 30.) This is incorrect. The test for PHE is "an objective test . . . inquiring 'whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter,'" but this test does not foreclose factual inquiry. *See Pharmacia*, 170 F.3d at 1377. Under the reasonable competitor standard, "the point is the knowledge of one reasonably skilled in the art who views the question from the perspective of a competitor in the marketplace." *Id.* at 1377 n.2 (quoting *Hoganas AB v. Dresser Indus., Inc.*, 9 F.3d 948, 952 n.15 (Fed. Cir. 1993). And, as may be the case with claim construction, evidence of how one of ordinary skill in the art, or of how a reasonable competitor, would understand the technical language used in the claims and in the prosecution history would be useful in resolving this dispute: "It is, after all, a competitor who is desirous of ascertaining the scope of the claims, but it is one skilled in the art who is best able to understand them. Nonetheless, the standard is the reasonable competitor standard." *Id.*; *see* Blue Br. at 42-43.

Accordingly, in evaluating whether PHE applies, "all aspects of the prosecution must be viewed as they would be viewed by persons of skill in the field of the invention." *Hebert v. Lisle Corp.*, 99 F.3d 1109, 1118 (Fed. Cir. 1996). Moreover, the estoppel inquiry must analyze the prosecution history as a whole,

Pharmacia, 170 F.3d at 1376-77, and ensure that prosecution arguments or amendments are "taken in context," *Intendis GMBH v. Glenmark Pharms. Inc., USA*, 822 F.3d 1355, 1365 (Fed. Cir. 2016). Thus, to the extent the prosecution history requires interpretation, or the claims require construction, it was error for the district court to dismiss Amgen's Complaint without considering evidence from a reasonable competitor or one of ordinary skill in the art.

D. Coherus's New Arguments Fail

1. Coherus Cannot Read Out the Claim Language Requiring an Increase in Dynamic Capacity

Coherus asserts that "the 'invention' is not 'increasing the dynamic capacity . . . for a particular protein.'" (Red Br. at 23-24.) Under Coherus's interpretation, the specific salt combinations recited in the claims are the invention. (*Id.* at 24.) It appears that Coherus is asking this Court to construe the claims to read out the language requiring an increase in dynamic capacity, which is an issue that the district court did not consider or decide before dismissing Amgen's Complaint. Amgen respectfully submits that this Court should not construe the claims for the first time on appeal where, as here, the district court did not engage in claim construction before granting Coherus's Motion to Dismiss. In any event, Coherus's interpretation of the claims is contrary to the intrinsic evidence, which repeatedly says that an increase in dynamic capacity is the result of the invention. *See, e.g.*, '707 Patent, Abstract, 2:9-12, 2:39-42; Appx161; Appx182-183. For

example, the claims require an increase in dynamic capacity. '707 Patent, 15:9-10. The specification says "[t]he present invention provides combinations of salts useful for increasing dynamic capacity" and "[t]he two salt buffers of the present invention result in an increase in dynamic capacity of an HIC column for a particular protein . . . ." *Id.*, 2:9-12, 39-42. And, as discussed above, Amgen relied on the claim language requiring the increase in dynamic capacity to distinguish prior art, after which the claims were allowed. (Appx1240-1241; Appx1249.)

2. Amgen Did Not Waive Its Arguments Regarding the Prosecution of the Parent '395 Patent

Coherus incorrectly argues that Amgen waived its arguments that the parent application statements do not give rise to argument-based PHE. (Red Br. 32.) The first time that the parent application statements were relied on to find PHE was in the district court decision on appeal. (Appx7.) Thus, Amgen properly addressed this issue in its Blue Brief. To be clear, Coherus itself did not rely on the parent application statements in its Motion to Dismiss before the district court. (Appx134-156 at Appx143, Appx148-150; *but see* Appx143-144; Appx150-152.)[4]

[4] Coherus referenced the parent application in its district court Reply but without analysis as to how the parent application allegedly supported a finding of argument-based PHE for the '707 Patent claims. (Appx606 (arguing that, "in the parent application, Amgen admitted that the prior art included examples containing" other salts, including [redacted]).)

Nevertheless, Amgen argued against "extending prosecution history estoppel from [a] parent application to subsequent patents" in opposing that Motion as Coherus acknowledged. (Appx320-346 at Appx340; *see* Appx595-609 at Appx606.) Further, the magistrate judge's Report and Recommendation on Coherus's Motion to Dismiss included a footnote identifying the July 14, 2008 Response from the prosecution history of the '395 Patent, but without relying on it to find argument-based PHE. (Appx12-Appx30 at Appx21-22; *see also* Appx210.) Amgen addressed the magistrate judge's footnote in its objections to that Report: the "statement, about the pending claims in the '395 Patent, certainly does not render Amgen's statements during the prosecution of the '707 Patent a clear and unmistakable surrender of claim scope under the doctrine of equivalents." (Appx923-939 at Appx934.) Accordingly, there is no waiver.

3. Coherus's Arguments That the Examiner Would Have Rejected the Claims, as Construed by Amgen to Assert Infringement Here, Are Speculation

Coherus argues for the first time on appeal that, had the Examiner realized that the claims could "encompass *any* combination of two salts that increase dynamic capacity" under the doctrine of equivalents, then "the Examiner ***might have*** deemed such a claim to be a predictable variation on Holtz." (Red Br. at 19-20 (second emphasis added).) Coherus further argues that the claims may have been susceptible to written-description and enablement rejections given their full

scope under the doctrine of equivalents. (*Id.* at 20-23.) Coherus did not make these arguments to the district court and thus Amgen respectfully submits that this Court should not consider them here. Even if the Court does consider them, Coherus's arguments fail because they are speculation and unsupported by anything in the record. This Court has rejected similar arguments that PHE should be applied when a statement allegedly giving rise to the estoppel "forestalled an obviousness rejection" that the examiner never made. *See Zenith Labs.*, 19 F.3d at 1425-26.

First, Coherus argues that the Examiner might have found the claims obvious had the Examiner known that the scope of the claims could extend to equivalent salt combinations to those recited in the claims. (Red Br. at 19-20.) According to Coherus, because Holtz "disclosed a combination of four salts, the Examiner may well have deemed it obvious to claim a combination of two salts." (*Id.*) This is speculative and incorrect because it ascribes no meaning to (or ignores) the "dynamic capacity" limitation of the claim and it ignores what actually happened during prosecution of the '707 Patent. The Examiner did not allow the claims over Holtz based on the particular claimed salt combinations. Rather, the '707 Patent claims were allowed based on the argument that a combination of salts increased dynamic capacity. (Appx159-163; Appx940-943.)

Indeed, in the prosecution history section cited by Coherus, Amgen does not identify the claimed salt combinations in order to distinguish the prior art. (Red Br. at 19-20; Appx161-162.) Rather, Amgen cited to examples from the specification to illustrate that choosing salts and salt concentrations that increase dynamic capacity was not merely a matter of judicious selection and routine optimization. (Appx161-162; *see* '707 Patent, 5:25-58.) Thus, the patentability of the claimed invention is not simply adding two salts together, but rather increasing the dynamic capacity of a HIC column for a protein of interest through the use of salt combinations: "merely adding a second salt to the traditional HIC process, as the Patent Office appears to suggest, will not produce applicants' claimed method[,] . . . [or even] a working method." (Appx162.)

Second, Coherus argues that "a claim encompassing combinations involving [redacted] salts would have been vulnerable to an enablement rejection" (Red. Br. at 21-23) or "risked a written-description rejection" had Amgen "prosecuted a claim that encompassed additional, unspecified combinations of salts that increase dynamic capacity." (*Id.* at 20-21.) These assertions too were not raised by Coherus in the district court, are speculative, and ignore the prosecution history. Moreover, Coherus fails to cite any legal authority for the relevance of these arguments to the issue now on appeal. (*Id.* at 20-23.) Coherus appears to argue that general principles of equity somehow make its speculation relevant, but even

if that made these arguments legally relevant—and it does not—the record shows no inequity here. Rather, the record shows that Amgen was nothing less than forthright. (*Id.*)

The Examiner issued an enablement rejection in the parent application with respect to the original claims that did not include the language requiring an increase in dynamic capacity. (Appx1119-1124; Appx1149-1155 at Appx1152-54.) Specifically, the Examiner issued a restriction requirement and rejected the claims under 35 U.S.C. § 112 on the ground that "the specification, while being enabling for the combination of citrate and phosphate salts for purifying a protein, does not reasonably provide enablement for a process [using] a first salt and a second salt having different lyotropic values." (Appx1113-1117 at Appx1115-1117; Appx1151-1154.) Amgen responded to that rejection by electing "the combination of citrate and phosphate salts" in compliance with the restriction requirement. (Appx189-195 at Appx194-195.) Amgen also argued that the patent specification provides ample guidance for practicing the full scope of the claims as originally written. (*Id.*; *see* '707 Patent, 5:25–6:17, 11:51–15:6.) The Examiner then withdrew the enablement rejection. (Appx1167-1172 at Appx1169.)

Notably, the Examiner never rejected the claims for lack of written description. Coherus's suggestion that the inventors engaged in "extensive experimentation" to develop the invention proves only that the invention was not a

simple exercise in "routine optimization." (Red Br. at 20-21; Appx161-162.) Regardless, written description is evaluated from the perspective of one of ordinary skill based on the four corners of the specification, and not based on what experimentation was actually done to develop the invention. *See Streck, Inc. v. Research & Diagnostics Sys., Inc.*, 665 F.3d 1269, 1285 (Fed. Cir. 2012) ("This test requires an 'objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art.'" (quoting *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010)). Coherus cites *In re Jolley*, 308 F.3d 1317, 1323 (Fed. Cir. 2002), but that case is inapposite because it does not address the written description requirement under 35 U.S.C. § 112. No legal or equitable principle justifies the application of PHE based on Coherus's speculative assertion that broader claims would have drawn an enablement or written description rejection from the Examiner.

As explained above, the specification sufficiently enables and describes the invention of increasing dynamic capacity using a combination of salts "selected for each particular protein through a process of establishing precipitation curves for each salt individually, and precipitation curves for the combination of salts" as taught by the specification of the patent. *See* '707 Patent, 2:15-20, 5:25-58 (explaining the general principal of selecting salts for a particular protein); *see also*

id., 11:51–14:5, 14:6–15:6 (demonstrating the process for a series of specific salts for specific proteins).

4. Amgen Did Not Surrender [redacted] From the Scope of the '707 Patent Claims in the Parent '395 Patent Application

Coherus argues for the first time on appeal that Amgen has surrendered all [redacted] from the '707 Patent based on two events in the '395 Patent parent application prosecution: Amgen's election of citrate and phosphate in accordance with the Examiner's restriction requirement and the Examiner's enablement rejection of genus claims that did not recite specific salt combinations. (Red Br. at 34-38.) According to Coherus, because the Examiner issued an enablement rejection as to the original claims in the '395 Patent application "[n]othing in this prosecution history could possibly suggest that Amgen would someday claim that [redacted] are infringing" in the '707 Patent claims that later issued. (*Id.* at 37-38.) This Court should not consider this new argument for the first time on appeal. And, an enablement rejection against the original claims of the '395 Patent has no bearing on whether argument-based PHE applies to the '707 Patent claims here.

Nonetheless, the restriction argument fails because Amgen made clear that the narrowing of the genus claims was "in response to the previously issued restriction requirement" and that it disagreed with the Examiner's enablement

rejection. (Appx194-195.) Further, the '395 Patent prosecution history is directed to pending claims that are materially different from those that issued in the '707 Patent. The enablement argument also fails because, rather than narrowing the claims, Amgen argued that the genus claims were enabled and expressly cited those arguments (as well as the narrowing amendments) as a basis for reconsideration or withdrawal of the rejection. (*Id.*) In its November 16, 2007 Response, Amgen asserted that the invention is "directed to the use of the combination of an intermediate concentration of a buffering salt in combination with an intermediate concentration of a second buffering or non-buffering salt for purifying proteins on a HIC column." (*Id.*) Amgen also noted that "[t]his combination of salts [*i.e.*, a first buffering salt and a second buffering or non-buffering salt] offers advantages . . . by increasing the dynamic capacity of the column." (*Id.*) Thus, Amgen clearly informed the public that it considered the full scope of the genus claims enabled by the specification.

II. The Dedication-Disclosure Doctrine Does Not Bar Amgen From Asserting Infringement Under the Doctrine of Equivalents

The district court's application of the dedication-disclosure doctrine to limit the scope of equivalents is error. (Blue Br. at 53.) Coherus acknowledges that a "generic reference in a written specification" does not "necessarily dedicate[] all members of that particular genus to the public" and that for the doctrine to apply the "disclosure must be of such specificity that one of ordinary skill in the art could

identify the subject matter that had been disclosed and not claimed." *PSC Comput. Prods., Inc. v. Foxconn Int'l, Inc.*, 355 F.3d 1353, 1360 (Fed. Cir. 2004); Red Br. at 39. Coherus, however, fails to address, or indeed even mention, that this Court later "clarified" its earlier precedent on the dedication-disclosure doctrine to add that "before unclaimed subject matter is deemed to have been dedicated to the public, that unclaimed subject matter must have been identified by the patentee as an alternative to a claim limitation." *SanDisk Corp. v. Kingston Tech. Co., Inc.*, 695 F.3d 1348, 1364 (Fed. Cir. 2012) (quoting *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364, 1379 (Fed. Cir. 2005). Neither the district court nor Coherus identified a specific disclosure in the specification of the '707 Patent of a combination of [redacted] and [redacted], or indeed any ***combination*** including [redacted], as an alternative to the "citrate and sulfate, citrate and acetate, and sulfate and acetate" claim limitation.

Coherus offers a complicated argument for how a person of ordinary skill in the art might infer that a [redacted] could be an alternative to the claim limitation based on the teachings of the specification or prosecution history. (Red Br. at 40-43.) Coherus begins with the specification's disclosures of [redacted], [redacted], and [redacted], among multiple other ions, in the lyotropic series and the specification's teaching that "[a]ccording to the present invention, 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." (Red Br. at 40-41; '707 Patent, 4:46-51.) Coherus then argues—directly contrary to its written description argument discussed above—that because the specification "characterized [redacted] and [redacted] as having different lyotropic values," one of ordinary skill could "identify the subject matter had been disclosed and not claimed." (Red Br. at 42.) According to Coherus, the specification "[e]ffectively" discloses a [redacted].

This is a new theory that was not raised to the district court, which did not consider or rely on this theory to reach its decision. (Appx9-10; Appx149-150; Appx606-607; Appx955-967 at Appx965-966.) Amgen respectfully submits that the Court should not consider it now for the first time on appeal. Further, Coherus's new theory fails to prove that application of dedication-disclosure is warranted. "Whether a person of ordinary skill ultimately could employ the disclosures of the patent to implement a purported equivalent does not amount to actually disclosing to one of ordinary skill that equivalent 'as an alternative to a claim limitation.'" *SanDisk*, 695 F.3d at 1364 (quoting *Pfizer*, 429 F.3d at 1379). "Effectively" disclosing a potential alternative to a claim limitation is not "actually disclosing" an alternative to a claim limitation. Here, the specification of the '707 Patent describes the preferred composition of salt combinations that may be useful.

'707 Patent, 5:63-64; *see id.*, 5:65–6:1, 6:5-7. But the specification does not actually disclose a [redacted], let alone a [redacted] and [redacted] combination for filgrastim protein purification by HIC with the requisite specificity and relation to the salt combinations recited in the claims to apply the dedication-disclosure doctrine here. Accordingly, the district court erred in finding that Amgen dedicated to the public a salt pair combination for purifying filgrastim protein.

Finally, as it does for argument-based PHE, Coherus argues that the disclosure-dedication doctrine is a question of law and thus expert testimony is "unhelpful for resolving" this dispute. (Red. Br. at 43.) But Coherus's own arguments prove this wrong. Coherus itself relies on attorney argument for what a person of ordinary skill in the art would understand from the specification, namely that it "[e]ffectively" discloses a [redacted] with requisite specificity based on its discussion of the lyotropic series. (Red Br. at 41-42.) Thus, the district court erred in applying the disclosure-dedication doctrine on the pleadings without the benefit of a fully developed record.

CONCLUSION

For the foregoing reasons, Amgen respectfully requests that this Court reverse, vacate, and/or remand the district court judgment dismissing Amgen's Complaint.

Dated: December 12, 2018

Respectfully submitted,

/s/ *Nicholas Groombridge*
Nicholas Groombridge
Jennifer H. Wu
Jennifer Gordon
Peter Sandel
Stephen A. Maniscalco
Jacob T. Whitt
Golda Lai
PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019
(212) 373-3000

Wendy A. Whiteford
Lois M. Kwasigroch
Kimberlin L. Morley
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320
(805) 447-1000

Attorneys for Plaintiffs-Appellants

CERTIFICATE OF SERVICE

I hereby certify that on this 12th of December, 2018, I caused the REPLY BRIEF FOR PLAINTIFFS-APPELLANTS AMGEN INC. AND AMGEN MANUFACTURING, LIMITED (CONFIDENTIAL AND NON-CONFIDENTIAL) to be filed with the Clerk of the Court through CM/ECF. I also caused a true and correct copy of the REPLY BRIEF FOR PLAINTIFFS-APPELLANTS AMGEN INC. AND AMGEN MANUFACTURING, LIMITED (CONFIDENTIAL AND NON-CONFIDENTIAL) to be electronically served, pursuant to agreement of the parties, on Defendant-Appellee Coherus Biosciences Inc.'s counsel of record as follows:

JENNER & BLOCK LLP
Bradford P. Lyerla (blyerla@jenner.com)
Louis E. Fogel (lfogel@jenner.com)
Adam G. Unikowsky (aunikowsky@jenner.com)
Aaron A. Barlow (abarlow@jenner.com)
Susan O'Brien (so'brien@jenner.com

/s/ *Nicholas Groombridge*
Nicholas Groombridge

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Circuit Rule 32(a). The brief contains 6,808 words, excluding parts of the brief exempted by Fed. R. App. P. 32(f) and Federal Circuit Rule 32(b). The word count includes the words counted by the Microsoft Word 2016 function. This brief also complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6). The brief has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point font of Times New Roman.

Dated: December 12, 2018

/s/ *Nicholas Groombridge*
Nicholas Groombridge

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CERTIFICATE OF COMPLIANCE MOTIONS OR BRIEFS CONTAINING MATERIAL SUBJECT TO A PROTECTIVE ORDER

Motion / Response / Reply Containing Material Subject to a Protective Order

☐ This motion, response, reply complies with the limitations set forth in Fed. Cir. R. 27(m) and contains [*state the number of*] _____ words (including numbers) marked as confidential, or

☐ This motion, response, reply does not comply with the word count limitations set forth in Fed. Cir. R. 27(m) and a motion requesting permission to exceed the maximum word count limitation is being filed contemporaneously with the filing of this motion, response, or reply.

Briefs Containing Material Subject to a Protective Order

☑ This brief complies with the limitations set forth in Fed. Cir. R. 28(d) and contains [*state the number of*] 5 words (including numbers) marked as confidential, or

☐ This brief does not comply with the word count limitations set forth in Fed. Cir. R. 28(d) and a motion is requesting permission to exceed the maximum word count limitation is being filed contemporaneously with the filing of this brief.

/s/ Nicholas Groombridge
(Signature of Attorney)

Nicholas Groombridge
(Name of Attorney)

Plaintiffs-Appellants
(State whether representing appellant, appellee, etc.)

12/12/2018
(Date)