Nos. 2019-1650, 2019-1770

In the United States Court of Appeals for the Federal Circuit

AMGEN INC.
Plaintiff-Appellant

v.

WATSON LABORATORIES, INC., ACTAVIS PHARMA, INC.,
Defendants-Appellees,

CIPLA LIMITED, CIPLA USA INC.,
Defendants-Amici Curiae,

AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS OF NEW YORK LLC, CADILA HEALTHCARE LTD., DBA ZYDUS CADILA, PIRAMAL HEALTHCARE UK LIMITED, SUN PHARMA GLOBAL FZE, SUN PHARMACEUTICAL INDUSTRIES, INC., SUN PHARMACEUTICAL INDUSTRIES, LTD., ZYDUS PHARMACEUTICALS (USA) INC.,
Defendants.

On appeal from the United States District Court for the District of Delaware, Case No. 1:16-cv-00953-MSG

BRIEFS FOR DEFENDANTS-APPELLEES WATSON LABORATORIES, INC. and ACTAVIS PHARMA, INC.

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CERTIFICATE OF INTEREST
[Watson Laboratories, Inc. and Actavis Pharma, Inc.]

1. Full name of party represented by us: Watson Laboratories, Inc. and Actavis Pharma, Inc.

2. Name of any real party in interest not identified in response to question 3: Watson Laboratories, Inc. and Actavis Pharma, Inc.

3. Parent corporations and publicly held companies that own 10% or more of the stock in the party:

Watson Laboratories is an indirect wholly owned subsidiary of Teva Pharmaceuticals USA, Inc., which is an indirect wholly owned subsidiary of Teva Pharmaceutical Industries Ltd., which is a publicly traded company. Teva Pharmaceutical Industries Ltd. is the only publicly traded company that owns 10% or more of the stock of Teva Pharmaceuticals USA, Inc. and Watson Laboratories.

Actavis Pharma is an indirect wholly owned subsidiary of Teva Pharmaceuticals USA, Inc., which is an indirect wholly owned subsidiary of Teva Pharmaceutical Industries Ltd., which is a publicly traded company. Teva Pharmaceutical Industries Ltd. is the only publicly traded company that owns 10% or more of the stock of Teva Pharmaceuticals USA, Inc. and Actavis Pharma.

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

From Shaw Keller LLP: John W. Shaw, David, M. Fry, Karen E. Keller; from Haynes & Boone LLP: Elizabeth M. Crompton, John W. Bateman, and C. Kyle Musgrove; from Winston & Strawn LLP: Elizabeth E. Grden

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 appeals.

Watson is aware of the following pending cases that may be directly affected by the decision here:

1) *Amgen Inc. v. Amneal Pharmaceuticals LLC*, Nos. 18-2414 (docketed Sept. 25, 2018) and 19-1086 (docketed Oct. 16, 2018) (Fed. Cir.). These consolidated cases concern the same district court case and relate to the same patent (U.S. Patent No. 9,375,405). These cases have been fully briefed and were argued on October 1, 2019 before Judges Newman, Lourie, and Taranto.
2) *Cipla Ltd. v. Amgen Inc.*, No. 19-cv-44 (filed Jan. 8, 2019) (D. Del). This case involves a settlement agreement between Amgen and Cipla relating to U.S. Patent No. 9,375,405.
3) *Amgen Inc. v. Accord Healthcare, Inc.*, No. 18-cv-956 (filed June 28, 2018) (D. Del.). Amgen has asserted U.S. Patent No. 9,375,405 against the defendants in that case.

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STATEMENT OF RELATED CASES

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3) *Amgen Inc. v. Accord Healthcare, Inc.*, No. 18-cv-956 (filed June 28, 2018) (D. Del.). Amgen has asserted U.S. Patent No. 9,375,405 against the defendants in that case.

COUNTERSTATEMENT OF THE ISSUES

I. Whether the Court should direct entry of the consent judgment necessary to effectuate the parties' settlement agreement. Watson has not appealed the district court's refusal to issue an indicative ruling that it would vacate the judgment of noninfringement and does not substantively address it here, except to clarify that Watson has not admitted infringement.

II. If the Court reaches the merits of Amgen's appeal of the judgment of noninfringement, whether that judgment should be affirmed, where:

A. The district court properly applied the legal standard for the doctrine of equivalents, and there is no clear error in its findings of fact that Amgen failed to meet its burden of proof that Watson's ANDA Products will not infringe under the doctrine of equivalents.

B. In the alternative, Amgen's equivalents arguments are barred by prosecution history estoppel because Amgen agreed to narrow the disintegrant limitation in order to overcome an obviousness rejection, thus surrendering the right to use the doctrine of equivalents to claim unlisted disintegrants.

C. In the event of a reversal of the district court's claim construction, a new trial is not warranted because Amgen has suffered no

prejudice from this allegedly erroneous ruling—it is, at most, harmless error.

INTRODUCTION

If the Court declines to reverse the district court's decision denying vacatur of the judgment of noninfringement (which Watson has not appealed, *see* Argument Part I, *infra*), and reaches the merits of the noninfringement judgment, it should affirm.

Watson has not admitted that the generic cinacalcet hydrochloride tablets described in Watson's Abbreviated New Drug Application No. 204377 (the "ANDA Products") infringe the patent-in-suit. It would have been willing to stipulate to infringement solely for purposes of settling the case via the consent judgment that the district court has refused to enter. Watson maintains that the district court made no errors in its findings of fact and correctly determined that Watson would not infringe the asserted claims of the '405 patent. In the event that the Court reaches the merits, it should find no clear error in the district court's conclusion that there is no infringement under the doctrine of equivalents. In the alternative, this Court may also affirm on the ground that Amgen's equivalents arguments should have been barred by prosecution history estoppel.

On the doctrine of equivalents, the district court's ruling was based on Amgen's complete failure to meet its burden of proof. By providing only brief and conclusory testimony regarding his opinions under the function-way-result test, Amgen's expert failed to provide the court with the particularized testimony required

to prove equivalent infringement. The documents cited by Amgen's expert directly contradicted his conclusions. By contrast, the court credited the testimony of Watson's expert, which was thoroughly supported by peer-reviewed scientific literature. Accordingly, the court found that, even beyond Amgen's failure under the function-way-result test, Watson had showed substantial differences between the claims and the accused equivalent.

Amgen's attempts to recast the district court's findings of fact as legal error are misplaced. The district court properly applied this Court's precedent to its comprehensive factual findings and reached well-founded conclusions. Amgen argues that the district court was overly strict in its approach, but the record shows the opposite: the district court gave Amgen the benefit of the doubt wherever possible, even considering theories of infringement that Amgen did not properly present at trial.

At bottom, this case turned on the district court's evaluation of the testimony from competing experts. The district court found Watson's expert to be credible while Amgen's expert was not. Such determinations are entitled to great deference from this Court and should not be overturned.

In the alternative, this Court can also affirm the noninfringement judgment on the basis of prosecution history estoppel. The district court declined to decide this issue as to Watson, instead finding that its conclusions on the doctrine of equivalents

were sufficient to enter judgment in Watson's favor. The district court did reach the issue as to Watson's co-defendant, Piramal, however, and found that Amgen had surrendered its right to reclaim excipients that it surrendered during prosecution. That finding was correct. In response to an obviousness rejection, Amgen offered to narrow its claims by restricting the amount of the active ingredient (cinacalcet HCl). The Examiner did not directly allow those claims; instead, he initiated a phone call with Amgen's counsel to further amend the claims. In this amendment, Amgen agreed to narrow the disintegrant limitation so that, instead of broadly claiming *any* disintegrant, it only claimed three specific disintegrants recited in a closed Markush group. With this narrowing amendment (which similarly limited the binder limitation), the Examiner found a sufficiently narrow combination of components to overcome the prior art and allowed the claims now asserted against Watson. Accordingly, Amgen should be estopped from reclaiming the ground it surrendered.

Although Amgen did not address prosecution history estoppel in its opening brief, it briefed and argued this issue in its related appeal against Amneal and Piramal (No. 18-2414) ("the *Amneal* appeal"). There, Amgen argued that—despite the Examiner's express statements—it had not agreed to the Examiner's Amendment for reasons substantially related to patentability. Instead, Amgen would have this Court look to the remarks it made eight months later, in a completely separate amendment, as probative of its intentions when agreeing to the Examiner's Amendment. But the

district court found that these subsequent, self-serving statements did not undermine the logical conclusion to be drawn from the events leading up to Amgen's surrender. The district court also correctly found that, by agreeing to narrow the combination of components claimed by the binder and disintegrant limitations, Amgen could not fairly expand the number of combinations under the doctrine of equivalents under the tangential relation exception to prosecution history estoppel.

Finally, Amgen incorrectly asserts that the district court's claim construction ruling (finding the Markush groups were, in fact, closed) was wrong, necessitating a new trial. Even if the district court were wrong—and it is not—Amgen has failed to show (or even assert) that the purported error caused it any prejudice with respect to Watson. At trial, Amgen presented the same exact arguments it had intended to; it could not have been prejudiced by the claim construction ruling. And the district court correctly pointed out that the noninfringement determination as to Watson did not depend in any way on the alleged claim-construction error. Because any such error would be harmless, this Court should affirm the judgment of noninfringement.

COUNTERSTATEMENT OF THE CASE

I. The patent-in-suit claims a finite number of combinations of excipients that can be used to make a tablet.

U.S. Patent No. 9,375,405 ("the '405 patent") is one of several patents listed in the FDA's "Orange Book" in connection with Amgen's product, Sensipar®. The four patents claiming the invention of the active ingredient, cinacalcet, and methods

of treatment have all expired, leaving the '405 patent as the last remaining barrier to generic entry (the sixth patent has never been asserted against Watson). The asserted claims of the '405 patent are directed to pharmaceutical compositions containing cinacalcet hydrochloride. Claim 1 is representative, and provides:

> A pharmaceutical composition comprising:
>
> (a) from about 10% to about 40% by weight of cinacalcet HCl in an amount of from about 20 mg to about 100 mg;
>
> (b) from about 45% to about 85% by weight of a diluent selected from the group consisting of microcrystalline cellulose, starch, dicalcium phosphate, lactose, sorbitol, mannitol, sucrose, methyl dextrins, and mixtures thereof,
>
> (c) from about 1% to about 5% by weight of at least one binder selected from the group consisting of povidone, hydroxypropyl methylcellulose, hydroxypropyl cellulose, sodium carboxymethylcellulose, and mixtures thereof; and
>
> (d) from about 1% to 10% by weight of at least one disintegrant selected from the group consisting of crospovidine, sodium starch glycolate, croscarmellose sodium, and mixtures thereof,
>
> wherein the percentage by weight is relative to the total weight of the composition, and wherein the composition is for the treatment of at least one of hyperparathyroidism, hyperphosphonia, hypercalcemia, and elevated calcium phosphorus product.

Appx8065.

In addition to the limitation regarding the amount of cinacalcet, claim 1 requires the composition to have certain non-active ingredients, "excipients," which are commonly used in the preparation of pharmaceutical compositions, particularly in tablet formulations. Claim limitation 1(b) is limited to eight specific "diluents,"

excipients that increase the tablet size and weight. Appx3330-3331 (185:20-186:7). Claim limitation 1(c) is limited to four specific "binders," excipients that hold the composition together. Appx3331 (186:8-20). Claim limitation 1(d) is limited to three specific "disintegrants," or excipients that "rapidly break up [a tablet] when in contact with the gastric fluid." Appx3331 (186:21-187:7).

The excipient limitations in (b), (c), and (d) are written in "Markush" form, a special type of limitation that allows the patentee to recite the specific excipients within the scope of the claim. A Markush claim is typically expressed by the inclusion of the phrase "a member selected from the group...," which is then commonly modified by including the terms of art, "comprising" to signal that the group is presumed be open to unrecited alternatives, or "consisting of" to signal that it is not. The Markush groups in claim 1(c) and 1(d) use the phrase "consisting of, thus the district court construed these limitations to mean that the groups are closed to unlisted binders and disintegrants. Appx46; Appx52-53.

II. The district court found that Watson does not infringe under the doctrine of equivalents.

Amgen sued Watson and several other manufacturers, claiming that their generic products would infringe the '405 patent if they were to enter the market. Appx81-99; Appx5803-5804. After a four-day trial on infringement that focused on claim 1 in light of a stipulation between the parties, the district court entered a judgment that Watson did not infringe claims 1-6 and 8-20. Appx7-8.

Amgen never asserted that Watson literally infringed the asserted claims, because Watson's ANDA Products do not contain any of the disintegrants recited in the Markush group of claim 1(d). *See* Appx28. Instead, Amgen argued that the disintegrant used in Watson's ANDA Products, low-substituted hydroxypropyl cellulose ("L-HPC"), satisfied claim 1(d) under the doctrine of equivalents. Because the district court determined that its conclusion that Watson did not infringe the disintegrant limitation was sufficient to enter a judgment in Watson's favor, it did not decide whether Watson's ANDA Products would infringe the binder limitation of claim 1(c) (Watson maintains that they would not). Appx28. For the same reason, the district court did not rule on Watson's argument that Amgen's equivalence arguments should be barred by prosecution history estoppel, explaining, "I do not decide... that the estoppel defense was not available to [Watson]. Rather, I conclude that even if it was not available, Amgen still could not prove infringement for the reasons stated." Appx44.

The district court's ruling was thus based on its conclusion that Amgen had failed to prove infringement under the doctrine of equivalents. Appx36. The court considered and rejected the arguments Amgen presented at trial, as well as arguments that Amgen improperly raised for the first time in its post-trial briefs. Appx29 ("Watson correctly points out that Amgen did not fairly present these positions in

expert discovery or at trial. For that reason alone, Amgen's new infringement theories should be disregarded as an unfair surprise."). The district court found that Amgen had failed to satisfy its burden of proof under *any* of its theories of equivalence. *Id*. ("[I]n explaining why Amgen's new theories under the function-way-result test are not persuasive, I will necessarily explain why Amgen's original theory also would have failed.").

A. The district court rejected Amgen's theories under the function-way-result test.

At trial, Amgen presented only one theory of equivalence: "L-HPC is equivalent only to crospovidone and only under the function-way-result test." Appx29; Appx3753 (552:3-10 (admitting that Amgen's expert only applied the function-way-result test in his analysis)). The new theories first raised in Amgen's post-trial brief asserted that Watson's L-HPC is also equivalent to the other two disintegrants recited in claim 1, sodium starch glycolate and croscarmellose sodium. Appx29. These new theories did not save Amgen, however, as the district court found that Amgen failed to meet its burden under the function-way-result test in either case. *Id.*

The court held that Amgen had failed to present ***particularized*** testimony of an expert or a person skilled in the art regarding the function, way, and result for the disintegrants to be compared. Appx30. It found that Amgen's evidence amounted

to nothing more than a "brief assertion" by its expert, Dr. Davies, that the disintegrants in claim 1 and L-HPC are equivalent in that they are all "superdisintegrants" with "similar disintegrant capability." *Id.* The court found this testimony insufficient to carry Amgen's burden. *Id*. Even though the district court could have ended its analysis there, it did not hold Amgen to its thin trial record, instead probing beyond Amgen's failure of proof to evaluate the scientific evidence presented to the court on each prong of the function-way-result test.

Function. Amgen argued that Watson's L-HPC had the same function as the three disintegrants in claim 1, i.e., to "act as 'superdisintegrants.'" Appx30. But the district court rejected this argument based on its review of the scientific literature, noting that the very same literature Dr. Davies relied on to argue that the disintegrants recited in claim 1 are superdisintegrants *also* explained that L-HPC was *not* a superdisintegrant. Appx30-31. Indeed, this document explained that L-HPC, an older disintegrant, was not a member of the "new" and "improved" "generation of disintegrants" to which the Markush group disintegrants belonged. Appx31.

Way. Next, the court found that Amgen failed to carry its burden of showing that L-HPC functions in substantially the same way as the Markush group disintegrants. As to crospovidone, the court found that the evidence at trial actually proved the opposite. Appx31-32.

The "way" disintegrants dissolve tablets is referred to as a "mechanism of action," and there are several known mechanisms; some excipients, like crospovidone (one of the three disintegrants claimed), use more than one. Appx3859-3861 (658:8-660:14). Dr. Davies testified that all three of the claimed disintegrants swell to some extent, but the district court found that his testimony lacked credibility. Appx31. The court noted that Dr. Davies' testimony regarding crospovidone was unclear, and that "Amgen presented no evidence to corroborate [his] testimony" regarding the other two disintegrants recited in claim 1. *Id.* By contrast, the court found that Watson's expert, Dr. Leah Appel, "gave persuasive testimony, corroborated by scientific literature" showing the different mechanisms of action used by the disintegrants being compared. Appx31-32.

Result. Finally, the court found that Amgen failed to prove "that L-HPC achieves substantially the same result as all three listed disintegrants." Appx34. It observed that Amgen's argument was again unsupported by scientific literature and instead "rests on a single sentence in a marketing brochure from [the manufacturer of L-HPC]." Appx32. But, even the brochure itself "calls into doubt Amgen's assertion": while the brochure suggested that L-HPC "has similar disintegration capability to the other superdisintegrants," the data it presented showed that the rate of disintegration actually depended heavily on the specific disintegrant and active ingredient tested. Appx32-33. Thus, the court concluded that "it cannot be shown that

L-HPC provides disintegration rates substantially similar to the superdisintegrants without testing involving the active ingredient at issue here"—evidence that Amgen did not present. Appx33-34. Rather, the only evidence Amgen presented was an inadequate comparison of two distinctly different formulations in Watson's lab notebook. Appx34 n.10 (crediting Dr. Appel's testimony that formulations were too different to provide a meaningful comparison).

B. The district court found that L-HPC is substantially different from crospovidone and the other disintegrants in claim 1.

Although Amgen presented no evidence or argument at trial on the insubstantial differences test, the district court still considered the new arguments Amgen raised for the first time in its post-trial briefing. Appx29. Not only did the court find that Amgen failed to meet its burden under this test, but it further held that Watson's expert, Dr. Appel, provided credible testimony—corroborated by scientific literature—fully applying the insubstantial differences test and showing that L-HPC is substantially different from crospovidone.[1]

The district court was persuaded by Dr. Appel's testimony regarding the differences between L-HPC and crospovidone that would be relevant to a person of ordinary skill in the art ("POSA"). Appx34-36. The court found that differences in

[1] The district court did not evaluate Amgen's argument that L-HPC is insubstantially different from *all* of the disintegrants recited in claim 1, as "Amgen provided no argument" beyond a single conclusory sentence. Appx29 n.6.

physical shape, chemical structure, multi-functionality, and potency levels would be relevant to each disintegrant's performance in a particular formulation. *Id*. Based on this evidence, the court held that Amgen failed to "carr[y] its burden of showing that L-HPC is equivalent to crospovidone under the insubstantial differences test." Appx36.

III. The parties' frustrated attempts to effectuate their settlement complicate this appeal.

Amgen appealed the infringement judgment as to Watson, as well as three other codefendants (Amneal, Piramal, and Zydus) with whom the case had been consolidated for trial. Appx135-136. On December 28, 2018—after Amgen had filed its opening brief but before the defendants responded—Watson launched its cinacalcet product at risk. On January 2, Watson and Amgen agreed to settle. Appx5078. Under the terms of the settlement agreement, Watson would, among other things, agree to the entry of a consent judgment stipulating that a future launch of its ANDA Products would (subject to certain exceptions) infringe the '405 patent. ADD-6, ADD-30.

Because the proposed consent judgment contained a stipulation of infringement, the parties needed to move the district court to vacate the existing judgment of non-infringement as to Watson so the consent judgment could be entered. Appx5078-5079. With the appeal still pending, the parties used the procedure provided for in Civil Rule 62.1 and Appellate Rule 12.1 to request an indicative ruling

that the district court would, if the case were remanded, vacate the judgment and enter the consent judgment. Appx5080. This Court stayed the appeal pending the outcome of the indicative-ruling request. Order Granting Stay, *Amgen Inc. v. Amneal Pharm. LLC*, No. 18-2414 (Fed. Cir. Jan. 11, 2019), ECF No. 61.

The district court, however, declined to issue an indicative ruling that it would vacate the judgment. Appx6. Amgen appealed the district court's decision, but Watson elected not to. Appx140-141. The indicative-ruling appeal was consolidated with Amgen's merits appeal of the non-infringement judgment as to Watson, which had been severed from the other codefendants' consolidated appeal while the motion for indicative ruling was pending.[2] Consolidation Order, *Amgen Inc. v. Amneal Pharm. LLC*, No. 19-1770 (Fed. Cir. Apr. 29, 2019), ECF No. 2; Deconsolidation Order, *Amgen Inc. v. Amneal Pharm. LLC*, No. 18-2414 (Fed. Cir. Feb. 1, 2019), ECF No. 64. At the same time, this Court also lifted the stay that had been in place since the parties filed that motion in January. *Amgen Inc. v. Watson Labs., Inc.*, No. 19-1650 (Fed. Cir. Apr. 29, 2019), ECF No. 26. This appeal resumed.

[2] That appeal has been fully briefed and argued. Oral Argument, *Amgen Inc. v. Amneal Pharm. LLC*, No. 18-2414 (Fed. Cir. Oct. 1, 2019), ECF No. 114.

SUMMARY OF ARGUMENT

I. Watson has not appealed the district court's decision not to issue an indicative ruling, and thus takes no position on that issue except to note that Amgen has incorrectly stated that Watson has admitted to infringement.

II. If the Court does reach the merits of the district court's noninfringement judgment, it should affirm.

A. Amgen has failed to raise any issue of law with regard to the district court's application of the standard under the doctrine of equivalents. Instead, the district court properly applied this Court's decision in *AquaTex Industries, Inc. v. Techniche Solutions*, 479 F.3d 1320 (Fed. Cir. 2007), which requires an expert to provide particularized testimony on the function, way, and result prongs of the test for equivalent infringement. Moreover, Amgen has not shown clear error in the district court's finding of fact. *UCB, Inc. v. Watson Labs., Inc.*, 927 F.3d 1272, 1284 (Fed. Cir. 2019). The record below makes clear that the district court found the testimony of Watson's expert to be more credible than the conclusory assertions proffered by Amgen's expert. Accordingly, it concluded that Amgen failed to meet its burden to show equivalent infringement under the function-way-result test, while Watson's expert had persuasively shown substantial differences between the disintegrant used in Watson's ANDA Products and the three disintegrants recited in the closed Markush group of claim 1(d).

B. In the alternative, this Court may affirm the finding of noninfringement on the grounds of prosecution history estoppel. In Amgen's related case against Piramal, the district court correctly analyzed the file history of the '405 patent and concluded that Amgen was forced to narrow the binder and disintegrant limitations to closed Markush groups in order to overcome the prior art. While Amgen argues that its claims are still obvious, even with this narrowing amendment, the key issue is whether or not the amendment was made for *purposes substantially related to patentability*, not whether the Examiner's analysis was correct. Thus, Amgen's attempt to relitigate the prosecution history must fail.

C. In the event that this Court overturns the claim construction ruling in the *Amneal* appeal, it should have no impact on these proceedings. Amgen has made no attempt to show why a reversal of that claim construction ruling would change the result in its case against Watson—likely because it would not. Because any error in the claim construction was harmless, there is no basis to reverse and/or remand this case.

STANDARD OF REVIEW

While issues such as claim construction and the application of prosecution history estoppel are reviewed *de novo*, "[i]nfringement is a question of fact" that this Court reviews "for clear error." *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 845 F.3d 1357, 1364 (Fed. Cir. 2017) (quotation omitted); *see also Allergan, Inc. v.*

Sandoz Inc., 796 F.3d 1293, 1311 (Fed. Cir. 2015). Under this standard, reversal is only appropriate when this Court "is left with a definite and firm conviction that the district court was in error." *Eli Lilly*, 845 F.3d at 1364.

"A district court has broad discretion in determining witness credibility, and [this Court gives] great deference to those determinations." *SynQor, Inc. v. Artesyn Techs., Inc.*, 635 F. App'x 891, 894 (Fed. Cir. 2015). "Credibility determinations by the trial judge can virtually never be clear error." *Agfa Corp. v. Creo Prods., Inc.*, 451 F.3d 1366, 1379 (Fed. Cir. 2006) (quotation omitted).

ARGUMENT

I. Watson does not challenge the order denying vacatur, but clarifies that it has not admitted infringement.

Watson elected not to appeal the order denying the parties' joint motion to vacate the noninfringement judgment, and therefore takes no position on that issue. *See* Appx5239. However, a clarification is in order. To the extent that Amgen's arguments in favor of vacatur use language in the parties' pending settlement agreement as substantive evidence of infringement (*see, e.g.*, Amgen's Confidential Opening Brief ("Br.") 1, 3, 5, 11, 16, 21-24, 26, 30), Watson emphasizes that it was willing to stipulate to that language *solely* for the limited purpose of settling this case.[3]

[3] Amgen points to language in the parties' proposed consent judgment as the source of the purported "admission," but the consent judgment has not yet been entered.

Stated simply, Watson has not admitted infringement. Notably, Amgen never argues that Watson's purported admission is relevant to this Court's review of the merits. *See* Br. at 37-53 (arguing the merits of the noninfringement judgment without reference to the purported admission). Nor could it, as Watson's statements about infringement were made in furtherance of a proposed settlement that has not gone into effect, and Amgen thus cannot use it "to prove or disprove the validity" of its infringement claim. *See* Fed. R. Evid. 408(a)(1); *Park v. Ahn*, 778 F. App'x 129, 133 (3d Cir. 2019) ("Rule 408 … now prohibits the use of *all* statements made during settlement negotiations to prove the validity of a claim." (citation omitted)); *Affiliated Mfrs., Inc. v. Aluminum Co. of Am.*, 56 F.3d 521, 530 (3d Cir. 1995).

Prism Techs. LLC v. Sprint Spectrum L.P., 849 F.3d 1360 (Fed. Cir. 2017), which Amgen cites to suggest that it is "appropriate to take Watson at its word" about its infringement statements (Br. at 23), does not prove otherwise. That case merely affirmed the admissibility of the patentee's settlement agreement with AT&T for the purpose of setting reasonable royalty damages in a trial against Sprint (*id.* at

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See Appx2. Amgen maintains that, "until th[e] 'Effective Date'" of the agreement, which is tied to the entry of the consent judgment, "[c]ertain elements of the parties' dispute, such as [its] agreement to release its claims for damages … and [Watson]'s agreement to pay Amgen … will not be resolved." Doc. 53 at 3-4. Accordingly, "the parties' [settlement] agreement does not become fully effective until entry of [the] consent judgment." Br. 24. So under Amgen's own reading, an admission that future sales "would infringe," offered in consideration for a release of liability, could not yet have taken effect. *See* Appx2.

1368), which has no bearing on whether a party's own statements made in a settlement agreement that never went into effect may be used to prove its liability.

II. If the district court's ruling is not vacated pursuant to the settlement agreement, it should be affirmed on the merits.

If the Court declines to reverse the district court's ruling on the motion to vacate and decides this appeal on the merits, the district court's ruling should be affirmed for several independent reasons.[4]

First, the district court's finding of noninfringement correctly applied the applicable legal standards and found that Amgen failed to meet its burden of proof. Rather than providing particularized testimony, Amgen's expert provided only conclusory assertions that were flatly contradicted by the only document he presented to support them. By contrast, the district court found that Watson's expert provided comprehensive rebuttal testimony that was supported by peer-reviewed literature. The district court's credibility determinations led to findings of fact that are strongly supported by the record and are entitled to great deference.

Second, and alternatively, the district court's finding of noninfringement can be affirmed on the basis of prosecution history estoppel. Although the district court did not need to reach this issue in order to find in Watson's favor, an examination of

[4] As noted, Amgen does not argue that Watson's purported "admission" in the settlement agreement is a basis for reversal, and such an argument would be meritless in any event. *See supra* at 17.

the record shows that, in order to overcome the prior art, the Examiner and Amgen agreed to an amendment that narrowed the disintegrant limitation in claim 1 from "any disintegrant" to a Markush group naming only three individual disintegrants. This was not a mere clarifying amendment that falls within the exceptions to the doctrine of prosecution history estoppel—it was an unequivocal surrender of the right to claim that the use of L-HPC infringes claim 1 under the doctrine of equivalents.

Finally, the district court's finding of noninfringement should not be overturned even if the claim construction ruling is reversed. Amgen asks for a mulligan based on its alleged "confusion" at trial but it is not entitled to one. The claim construction would have pertained to the issue of *literal* infringement, but Amgen has never contended that Watson's ANDA Products literally infringe the disintegrant limitation of claim 1. Amgen does not (and cannot) argue that the district court's ruling had any effect on the arguments it presented at trial as they relate to Watson. Accordingly, any error in the claim construction would be harmless.

A. The district court properly found no infringement under the doctrine of equivalents.

The district court properly found that Amgen failed to satisfy its burden to prove infringement under the doctrine of equivalents. The district court found that the testimony of Amgen's expert failed to meet this Court's requirement that "*a pa-*

tentee must ... provide particularized testimony and linking argument as to the 'insubstantiality of the differences' between the claimed invention and the accused device or process, or with respect to the function, way, result test." *AquaTex*, 479 F.3d at 1328 (emphasis in original) (quoting *Tex. Instruments, Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1567 (Fed. Cir. 1996)). "Generalized testimony as to the overall similarity between the claims and the accused infringer's product or process will not suffice." *Id*.

Amgen argues that the district court's analysis "was wrong as a matter of law" because it applied an "overly stringent" standard, but this argument fails on its face. Br. 42. The testimony proffered by Amgen's expert was undeniably conclusory and failed to meet this Court's standard for proving infringement under the doctrine of equivalents. Moreover, contrary to Amgen's arguments on appeal, the district court was remarkably flexible in its approach, fully considering arguments that Amgen introduced for the first time in its post-trial briefs rather than properly presenting them at trial. Appx29.

Amgen also ignores the fact that the district court did not stop its analysis (even though it could have) after concluding that Amgen's expert testimony was technically deficient as a matter of law. Rather, the district court considered and rejected Dr. Davies' opinions and Amgen's attorney arguments on their merits as well; it found that Amgen's positions were not supported by scientific literature, and

credited the well-supported opinions of Watson's expert instead. Appx29-36. These credibility determinations and findings of fact are entitled to great deference here. *UCB*, 927 F.3d at 1284 (infringement under the doctrine of equivalents is a factual question that can only be overturned for clear error); *Agfa Corp.*, 451 F.3d at 1379.

1. The district court properly applied the standard for analyzing the doctrine of equivalents, which required more than conclusory testimony.

The district court properly held that Amgen failed to meet the *AquaTex* requirement that an expert must provide *particularized* (not *generalized*) testimony to satisfy the patentee's burden of proof on infringement. Appx30. At trial, Dr. Davies disregarded this Court's instruction that "the substantial differences test may be more suitable ... for determining equivalence in the chemical arts," *UCB*, 927 F.3d at 1284 (alteration in original) (quoting *Mylan Institutional LLC v. Aurobindo Pharma Ltd.*, 857 F.3d 858, 869 (Fed. Cir. 2017)), and instead only provided testimony under the "function-way-result" test. Appx29; Appx3753 (552:3-10). While this deficiency was not fatal in itself, Dr. Davies compounded the flaws in his testimony by offering only generalized and conclusory explanations as to his theory of equivalence.

Dr. Davies opined that the disintegrant used in Watson's ANDA Products (L-HPC) infringed claim 1 under the doctrine of equivalents because claim 1(d) recites

a Markush group of three "superdisintegrants," and L-HPC is also a "superdisintegrant" with "similar disintegrant capability to other superdisintegrants." Appx30 (citing Appx3469 (295:4-15)). Dr. Davies also opined that: (1) L-HPC swells like other superdisintegrants; (2) L-HPC rapidly breaks up the formulation like a superdisintegrant; and (3) Watson "designed the formulation to match the Sensipar formulation." Appx3469 (295:12-19); Appx3479 (305:4-16).

His testimony, however, did not go any deeper than these generalized conclusions. Dr. Davies provided no explanation of the basis for his opinions beyond his *ipse dixit*. For example, Dr. Davies' testimony referred to two documents that supposedly supported his positions. However, the district court found that the first document, a treatise describing various disintegrants, actually *contradicted* Dr. Davies' conclusion that L-HPC was a superdisintegrant, as the treatise clearly distinguished L-HPC from the three superdisintegrants in claim 1. Appx30-31 (citing Appx11439; Appx11449; Appx7749). Nor did the second document, a marketing brochure created by the manufacturers of L-HPC, credibly support Dr. Davies' assertion that L-HPC was similar to the three superdisintegrants. Appx32-33 (citing Appx12464). To the contrary, the district court found that the data presented in the brochure showed significant differences between L-HPC and each of the three superdisintegrants based on the amount of disintegrant used and the specific formulation at issue. Because Dr. Davies had utterly failed to explain and support his opinions—and even,

at times, undermined them—the district court had no choice but to find that Amgen failed to meet its burden to provide particularized expert testimony on its theory of equivalents. Appx30 (citing *AquaTex*, 479 F.3d at 1329).

Amgen attempts to defend its trial presentation by arguing that *AquaTex* merely requires that testimony on the doctrine of equivalents be applied on a limitation-by-limitation basis. Br. 44. But *AquaTex* makes clear that the patentee must provide ***more*** than "lawyer argument and generalized testimony about the accused product." 479 F.3d at 1329 (affirming summary judgment of noninfringement). The particularized-testimony requirement is intended to "assure that the fact-finder does not, under the guise of applying the doctrine of equivalents, erase a plethora of meaningful structural and function limitations of the claim on which the public is entitled to rely in avoiding infringement." *Gemalto S.A. v. HTC Corp.*, 754 F.3d 1364, 1374 (Fed. Cir. 2014) (internal quotation omitted). Limitation-by-limitation analysis that is wholly conclusory would not satisfy *AquaTex*, either.

Similarly, Amgen incorrectly accuses the district court of imposing a "magic words" requirement.[5] Br. 45. Amgen cites *Malta v. Schulmerich Carillons, Inc.*, 952 F.2d 1320, 1327 n.5 (Fed. Cir. 1991), which does eschew such a requirement—

[5] Amgen also complains that the district court "chided Amgen's expert for failing to use the words 'function,' 'way,' and 'result'" (Br. 44), but that criticism was made in the district court's analysis of another defendant's products, not Watson's.

but the same sentence goes on to explain that "it at least requires the *evidence* to establish *what* the function, way, and result of *both* the claimed device and accused device are, and *why* those functions, ways, and results are substantially the same." *Id*. (emphasis in original). This is precisely what Amgen's expert failed to do, and this Court has long rejected conclusory expert testimony. *See, e.g.*, *Akzo Nobel Coatings, Inc. v. Dow Chem. Co.*, 811 F.3d 1334, 1343 (Fed. Cir. 2016) (criticizing patentee's reliance on statement that failed "to articulate how Dow's accused process operates in substantially the same way"); *Eastcott v. Hasselblad USA, Inc.*, 564 F. App'x 590, 596 (Fed. Cir. 2014) (rejecting expert's affidavit as conclusory because "it simply does not provide a sufficient explanation of which specific structures ... are equivalent to the limitations"); *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1329 (Fed. Cir. 2001) ("Broad conclusory statements offered by Telemac's expert are not evidence and are not sufficient to establish a genuine issue of material fact."); *Tex. Instruments*, 90 F.3d at 1567-68 (rejecting generalized testimony that accused and claimed processes "were the same and performed the same function"). The requirement that expert testimony be non-conclusory is hardly "formalistic." *Contra* Br. 44. It is precedent, and the district court applied it correctly.

Amgen's argument that the district court's standard was "too rigid" cannot be squared with the scope and content of the court's findings. At trial, Amgen's sole

theory as to the doctrine of equivalents was that, under (only) the function-way-result test, L-HPC was equivalent to crospovidone. *See* Appx29 (citing Appx3753 (552:3-10); Appx4327 (1089:5-7)). In its post-trial briefs, however, Amgen advanced three new arguments it had never made before: (1) L-HPC is equivalent to all three disintegrants in claim 1(d) under the function-way-result test; (2) L-HPC is equivalent to crospovidone under the insubstantial differences test; and (3) L-HPC is equivalent to all three disintegrants in claim 1(d) under the insubstantial differences test. Appx29. While the district court rejected Amgen's third theory, which was merely mentioned in a single sentence without supporting argument, the court did fully consider and evaluate the first two theories, even though they were not fairly presented at trial (let alone supported by expert testimony). *Id.* Amgen's lack of success on this issue was not the result of an overly formalistic district court, but rather its own failure to satisfy its burden of proof.

2. There is no clear error in the findings of fact supporting the district court's finding of non-infringement.

Even though the district court could have rested on its finding that Amgen's expert failed to provide particularized testimony, it proceeded to evaluate Amgen's arguments on their merits, concluding that Amgen failed to establish equivalence under either the function-way-result test or the insubstantial differences test. Appx29-36. These findings of fact are thoroughly supported by the evidence presented, and thus do not contain any clear error that would warrant reversal.

Amgen suggests that the district court's careful findings of fact should be reviewed *de novo* in connection with "its reliance on a faulty legal standard," but this is simply incorrect. Br. 44-45. The district court's findings are based on the testimony of expert witnesses and review of the evidence presented. Thus, they are findings of fact that are reviewed for clear error. *UCB*, 927 F.3d at 1284; *Anchor Wall Sys., Inc. v. Rockwood Retaining Walls, Inc.*, 340 F.3d 1298, 1313 (Fed. Cir. 2003) ("Infringement under the doctrine of equivalents frequently turns on questions of fact, such as whether the allegedly infringing device performs substantially the same function in substantially the same way to achieve substantially the same result as the claimed invention."). Under either standard, Amgen's criticisms of the district court's findings of fact lack merit.

a. There is no error in the district court's findings of fact on the function-way-result test.

Function. On the function prong, Amgen argues that the district court improperly overlooked Watson's FDA submissions in concluding that Watson's disintegrant did not have the same function as the disintegrants recited in claim 1(d). Br. 46. But in making this argument, Amgen either reframes or ignores the arguments that it made below.

At trial, Amgen argued that the disintegrants in claim 1(d) "are understood by a POSA to function as superdisintegrants." Appx4506; *see also* Appx4529 ("L-HPC functions as a superdisintegrant in pharmaceutical formulations, like crospovidone

and the other excipients listed in element (d).”). In evaluating the argument *as Amgen framed it*, the district court found that Amgen failed to prove that L-HPC functions “as a superdisintegrant.” Appx30. This finding of fact was based on the scientific literature that Dr. Davies himself relied on, which specifically and unequivocally distinguished the three superdisintegrants in claim 1(d) from other disintegrants like L-HPC. Appx30-31 (citing Appx7749; Appx11439; Appx11449).

Now, Amgen attempts to pivot away from the position it took at trial by stating that the actual function of element 1(d) was just to disintegrate the tablet, not to function as a “superdisintegrant.” Br. 46. But Amgen’s opportunistic shift does not change the record below, let alone create any clear error.

Way. Next, the district court found that Amgen failed to prove that L-HPC functions in substantially the same way based on the literature presented. Appx31-32. Both experts agreed that the “way” prong of the test should be evaluated by comparing the mechanism of action of the disintegrants, i.e., the way the disintegrant breaks up the tablet. Appx3470 (305:4-16 [Davies]); Appx3859-3861 (658:8-660:14 [Appel]). Both experts also agreed that the primary mechanism of action for L-HPC is swelling. Appx3479 (305:9-13 [Davies]); Appx3860 (659:14-17 [Appel]). Contrary to Amgen’s assertion, the district court did not find it “undisputed” that “L-HPC and two of the three listed disintegrants act in ‘substantially the same

way'—through swelling." Br. 47. Just the opposite: for two of the three listed disintegrants, it found that "Amgen presented no evidence to corroborate Dr. Davies' testimony that the primary mechanism of action is swelling." Appx31.

As to the third disintegrant, crospovidone, there was a dispute of fact—which the district court resolved in Watson's favor. Dr. Davies argued that crospovidone also disintegrated tablets by swelling, but the district court found his testimony "unclear," pointing specifically to a passage in which he stated that superdisintegrants "also encourage the wicking of water and there are a number of different mechanisms by which they work." Appx31 (citing Appx3718-3719 (517:20-518:1)). By contrast, the district court had no problem understanding the testimony of Watson's expert, Dr. Appel, who supported her opinions with clear scientific literature explaining that the primary mechanism of action for crospovidone is the recovery of elastic energy of deformation, and that any swelling with crospovidone would only play a minor role. Appx31-32 (citing Appx3859-3860 (658:5-659:4); Appx3869 (668:3-20); Appx3926-3927 (725:20-726:12)). Based on its assessment of the competing expert opinions, the district court determined that Watson's expert was more credible and held that Amgen had failed to meet its burden of proof on the way prong. Appx32.

On appeal, Amgen argues that the district court erred because it evaluated the way prong by looking at the primary mechanism of action of the disintegrants, i.e.,

the *way* in which the disintegrants disintegrate tablets. Instead, Amgen argues that "equivalence is *determined* by answering the question of whether the relevant feature of the accused product possesses the property embodied by the Markush group"—that is, the *ability* to disintegrate. Br. 47 n.7 (emphasis in original). Thus, Amgen urges this Court to ignore the differences in these excipients and rule that the doctrine of equivalents should apply to *any disintegrant*, the only established commonality in the Markush group. This argument must fail.

During the prosecution of the '405 patent, Amgen originally claimed "from about 1% to 10% by weight of at least one disintegrant." Appx9948. The Examiner found that these original claims were obvious in view of the prior art, and required Amgen to narrow the disintegrant limitation to this Markush group naming these three specific disintegrants. Appx10023-10024; Appx10028 (citing the narrowed combination of components as the reason for allowing the claims). Amgen's argument that any disintegrant should be deemed equivalent to its Markush group would artificially (and impermissibly) broaden the narrow claims that Amgen specifically agreed to in order to obtain the patent.

It is no surprise, therefore, that Amgen does not cite to any authority suggesting that this analysis would be proper under the doctrine of equivalents. It cannot, because no court has ever so held. Instead, Amgen cites *Ecolochem, Inc. v. Southern*

California Edison Co., which holds that "for the purpose of ***claim validity***, the members of the claimed group are functionally equivalent. Thus, if utilizing one element of the group is anticipated or obvious, the patentee is precluded from arguing that the claim is valid." 91 F.3d 169, at *2 (Fed. Cir. 1996) (unpublished) (emphasis added). Neither *Ecolochem* nor the MPEP opines on how the doctrine of equivalents applies to Markush groups.

This Court's discussion of the doctrine of narrow claiming in *UCB*, however, *is* relevant. There, this Court explained that an earlier decision had correctly concluded that the doctrine of equivalents should not apply to narrowly drawn claims where the alleged equivalent (i) did not have the same advantageous characteristics as the subset of compounds that was actually claimed, and (ii) the inventors were aware of the alleged equivalent at the time of drafting. *UCB*, 927 F.3d at 1281 (citing *Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, 683 F.3d 1356, 1366 (Fed. Cir. 2012)). Both of the facts the *UCB* and *Wrigley* Courts identified are present here. First, according to Amgen, L-HPC is "a *worse* disintegrant than those listed in claim element (d)." Br. 41 (citing Appx30-34). And, second, there is no question that the inventors in this case were aware of L-HPC and knew how to claim it if so desired. The record shows that Hung-Ren (Homer) Lin, one of the inventors of the '405 patent, is also a named inventor of U.S. Patent No. 6,514,529, which specifically discloses and claims the use of L-HPC as a disintegrant; it follows that that the inventors

of the '405 patent were necessarily aware of L-HPC at the time and had added it to a Markush group with the specific disintegrants at issue now. *See* Appx7764, Appx7767 (6:55-58); Appx7770 (cl. 9). Because both of these conditions are satisfied, the doctrine of narrow claiming should prevent Amgen from asserting equivalence.

Even beyond that, Amgen's equivalence arguments would vitiate the Markush group limitation, transforming a closed claim into an open one. This Court has explained that "if a patent claim recites 'a member selected from the group consisting of A, B, and C,' the 'member' is presumed to be closed to alternative ingredients D, E, and F." *Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp.*, 831 F.3d 1350, 1358 (Fed. Cir. 2016) (quoting *Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l, Inc.*, 246 F.3d 1336, 1348 (Fed. Cir. 2001)). Accordingly, the Markush group in claim 1(d), which provides that "at least one disintegrant" must be selected "from the group consisting of crospovid[one], sodium starch glycolate, croscarmellose sodium, and mixtures thereof," is presumed to be closed to unrecited alternatives like L-HPC. The doctrine of equivalents cannot be used to open this Markush group up to L-HPC. *Carnegie Mellon Univ. v. Hoffmann-La Roche, Inc.*, 541 F.3d 1115, 1129 (Fed. Cir. 2008) ("[A] finding that *Taq* is an equivalent of *E. coli* would essentially render the 'bacterial source [is] *E. coli*' claim limitation meaningless, and would thus vitiate that limitation of the claims." (second

alteration in original)). In other words, Amgen's theory of equivalence effectively changes claim 1(d) into a "comprising" claim.

Result. Amgen's assertions of error on the result prong rest on the erroneous premise that any generic product should be found to infringe claim 1 under the doctrine of equivalents by virtue of its bioequivalence to Amgen's brand product, Sensipar®. *See* Br. 46 (citing Watson's ANDA submission "promising that its product will in fact function as Sensipar® does"); *id.* at 47-48 (claiming Watson's intention "was to make a drug that performed the same way as Amgen's"). But while "bioequivalency may be relevant to the function prong of the function-way-result test, bioequivalency and equivalent infringement are different inquiries." *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1298 (Fed. Cir. 2009).

Amgen also ignores this Court's precedent when it argues that the result prong should have been satisfied by reference to the disintegration tests in Watson's ANDA.[6] Br. 48-49. The district court, however, found these tests irrelevant in view of the testimony of Watson's expert, who had explained that the tests involved distinctly different formulations. Appx34 n.10 (citing Appx3941-3942 (740:3-741:14)). According to Dr. Appel, the varying amounts of certain excipients in these

[6] These allegedly dispositive disintegration tests were not considered at all by Amgen's expert as part of its *prima facie* case. Watson's testing was only discussed during the cross-examination of Watson's expert, Dr. Appel. Appx3935-3943 (734:23-742:21).

formulations could have a material impact on the disintegration time, thus rendering a comparison of the test results irrelevant for purposes of evaluating equivalence. *Id*.

Instead of relying on these disintegration tests, the district court credited the only piece of evidence that made an apples-to-apples comparison of different disintegrants, a "marketing brochure from the chemical company Shin Etsu." Appx32-33 (citing Appx12464). Amgen had argued that L-HPC achieved substantially the same results as the other disintegrants based on a representation in the brochure that L-HPC had similar disintegration capability to the superdisintegrants recited in claim 1(d). But the district court correctly observed that this puffery was not part of a credible, peer-reviewed scientific publication. Appx32.

More important, however, the district court noted that the data presented in the brochure did not prove substantial similarity. Appx33. Instead, it showed disintegration rates for three different formulations where the only difference was the disintegrant used. In this direct comparison, the data in the brochure clearly demonstrated that the disintegration time varied substantially based on the active ingredient and the amount of disintegrant. *Id*. The district court agreed with Watson that this variability in results demonstrated that the only way to prove that the results are

substantially similar is via an apples-to-apples comparison of disintegrants in a formulation using cinacalcet. The court found that, by failing to conduct any such testing, Amgen had again failed to meet its burden. Appx33-34.

Amgen points to the district court's statement that the "dissolution profile has not been relevant in this litigation" as evidence of "the improper lens through which the district court analyzed equivalents" (Br. 49), but this is not so. In fact, the district court's statement related to the original claim in the application that ultimately issued as the '405 patent, which included a claim to a particular dissolution profile—not the claim at issue here, which does not.

Ultimately, Amgen cannot avoid the fatal flaw in its arguments on appeal: the district court found that Amgen failed to meet its burden of proof on all three prongs of the function-way-result test. While these findings were strongly supported by the record at trial, the district court only needed to find that Amgen failed one of these prongs in order to enter a judgment of noninfringement. By finding that Amgen failed on *all three* prongs, the district court made clear that it found Amgen's proof to be deficient in all relevant respects.

b. There is no error in the district court's findings of fact on the insubstantial differences test.

Although Amgen did not offer any expert testimony whatsoever on the insubstantial differences test, the district court still considered its arguments that L-HPC is insubstantially different from crospovidone. Appx34. As such, the district court

could have ruled in Watson's favor based on Amgen's lack of expert evidence alone; however, it instead credited the particularized testimony of Watson's expert, who "identified several differences between L-HPC and crospovidone, which were corroborated by scientific literature." *Id.*

In deriding this as a "back-of-the-hand analysis" that "indulged Watson's comparison of insignificant physical and chemical differences" (Br. 49), Amgen ignores the actual findings of fact made by the district court that Watson's Dr. Appel had credibly testified that: (1) the difference in physical shape between L-HPC and crospovidone plays a crucial role in the manufacturing process; (2) the difference in the chemical structures of these excipients means that a POSA would not consider them to be equivalents; (3) a POSA would also consider L-HPC's capacity to function as a binder *or* disintegrant, whereas crospovidone is only a disintegrant; and (4) L-HPC is a less potent disintegrant than crospovidone. Appx35-36.

Amgen disregards this corroborated testimony on how a POSA would view the differences between disintegrants. Instead, it claims those differences are irrelevant to the performance of L-HPC as a disintegrant in Watson's formulation. But Amgen's argument lacks an evidentiary basis, and its own expert never offered any such opinions at trial. Amgen had notice of Watson's counterarguments during expert discovery, but did nothing to rebut these points. *See, e.g.*, Appx29 n.6 (observing that Amgen's argument that L-HPC is insubstantially different from the recited

disintegrants consisted of a single conclusory sentence); Appx3753 (552:3-10). Conclusory denials made only via attorney argument, however, are no substitute for credible expert testimony. With no evidence to support its position, Amgen failed to carry its burden of proving insubstantial differences.

In arguing that the district court should have recognized that the similarities mean more than the differences (Br. 50-51), Amgen overreads *UCB*. Nothing in *UCB* establishes a blanket rule requiring district courts to ignore testimony on substantial differences; all the Court did was simply affirm the district court's conclusion that the differences did not matter for how the claimed invention worked in that particular case. 927 F.3d at 1284-85. In this case, however, the district court found that those differences *do* matter. And, because those differences are well-supported by testimony and scientific literature, they should be affirmed. The burden of proof on infringement was on Amgen, and its criticisms of the court's findings do not create reversible error.

In sum, the district court was correct to find no infringement under the doctrine of equivalents, and this Court can and should affirm on this ground.

B. The finding of noninfringement can also be affirmed under the doctrine of prosecution history estoppel.

This Court may also affirm the judgment on the alternative ground that prosecution history estoppel bars Amgen's doctrine of equivalents arguments. At trial,

Watson argued that Amgen's equivalents arguments should have been barred altogether in view of the Examiner's Amendment, which narrowed the scope of the disintegrant limitation from "any disintegrant" to a Markush group ***consisting of*** only three specific disintegrants. Because this amendment was made for reasons substantially related to patentability, Amgen should be estopped from recapturing the claim scope it surrendered in order to obtain the '405 patent.

While the district court found that the Examiner's Amendment was a narrowing amendment made for reasons substantially related to patentability, it did not need to consider the full extent of Amgen's surrender as it pertained to Watson, as it had already found that Watson did not infringe for the reasons explained above. "[F]or the sake of expediency," the district court only addressed estoppel as to defendant Piramal, and concluded that Amgen was estopped from asserting the doctrine of equivalents against it. Appx43-44. For the same reasons, this Court may affirm the district court's finding of noninfringement as to Watson. *See Rexnord Indus., LLC v. Kappos*, 705 F.3d 1347, 1356 (Fed. Cir. 2013) ("On judicial review, the correctness of the decision appealed from can be defended by the appellee on any ground that is supported by the record...").

This Court uses the framework it announced in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co*., 344 F.3d 1359 (Fed. Cir. 2003) (en banc), to determine whether prosecution history estoppel applies. It first determines whether the

amendment in question "narrowed the literal scope of a claim." *Id.* at 1366. On this issue there is no dispute; Amgen conceded at trial that the Examiner's Amendment was narrowing. Appx4850; Appx4293 (1055:14-16 [Murnane, Amgen's lead counsel]) ("when your Honor was asking me, I didn't contest narrowing and I'm not"); Appx3576 (402:19-22 [Davies]).

The second prong of the *Festo* test asks whether the narrowing of the binder and disintegrant limitations in the Examiner's Amendment was substantially related to patentability. 344 F.3d at 1367. This determination is based on what "a person of skill in the field of the invention ... would conclude from the prosecution record." *Merck & Co. v. Mylan Pharm., Inc.*, 190 F.3d 1335, 1340 (Fed. Cir. 1999). After considering the file history and the testimony of expert witnesses from both sides, the district court concluded that the narrowing achieved by the Examiner's Amendment was indeed made for reasons substantially related to patentability, rejecting Amgen's arguments to the contrary. Appx38-42.

The district court was correct that Amgen was forced to narrow the binder and disintegrant limitation to closed Markush groups reciting four binders and three disintegrants—and thus surrendered its right to recapture this surrendered claim scope through the equitable principles of the doctrine of equivalents. *See Festo*, 344 F.3d at 1367.

Although Amgen did not discuss this issue in its Opening Brief, its arguments against prosecution history estoppel are fully presented in the *Amneal* appeal, which has already been briefed and argued. Watson anticipates that it will raise the same arguments here, on reply. Assuming it does, the following analysis will explain why (1) the district court was correct to conclude that the only logical inference was that the Examiner required the narrowing of these limitations for the purpose of overcoming the prior art references; (2) Amgen's arguments to the contrary are wrong, and the district court was correct to reject them; and (3) as the district court (again) found with respect to defendant Piramal, Amgen's underdeveloped argument that the "tangential relation" exception applies to L-HPC is incorrect. This Court should resist Amgen's attempts to distort the record in its favor, and should instead affirm the district court's finding of noninfringement on this ground.

1. The district court correctly determined that the Examiner's Amendment was made for reasons related to patentability.

The district court concluded that the Examiner's amendment was made for reasons substantially related to patentability because "[i]t was only after Amgen agreed to the entry of the Examiner's Amendment that the Examiner allowed the claim over the prior art. There would have been no need for the Examiner to propose an amendment if Amgen's 2014 Amendment was sufficient." Appx38 (citation omitted). Reading the prosecution record as a whole, Occam's razor holds true, and the simplest explanation for the Examiner's Amendment is indeed the correct one:

Amgen agreed to narrow the claims by adding the Markush groups in order to overcome the obviousness rejection and obtain the patent. It follows that "the reason for that amendment was a substantial one relating to patentability," *see Festo*, 344 F.3d at 1366. The district court thus reached the right result for the right reasons. Appx38-44.

The prosecution history shows that, in the first formal action regarding the application leading to the '405 patent, Amgen's claims were rejected as obvious in view of the prior art. Appx9983-9987. These claims contained one independent claim,[7] which read:

> 2. A pharmaceutical composition comprising:
>
> (a) from about 10% to about 40% by weight of cinacalcet HCl;
>
> (b) from about 45% to about 85% by weight of a diluent selected from the group consisting of microcrystalline cellulose, starch, dicalcium phosphate, lactose, sorbitol, mannitol, sucrose, methyl dextrins, and mixtures thereof,
>
> (c) from about 1% to about 5% by weight of at least one binder; and
>
> (d) from about 1% to 10% by weight of at least one disintegrant,
>
> wherein the percentage by weight is relative to the total weight of the composition.

[7] Because the application originally consisted of one claim that was withdrawn before it was considered by the PTO, the claims considered by the PTO begin with independent claim 2. Appx9737; Appx3822-3823 (621:23-622:14).

Appx9948.[8]

The Examiner found that cinacalcet combined with 1%-5% of any binder and 1%-10% of any disintegrant was a conventional idea and could not be patented in view of a prior art patent teaching the use of calcimimetic compounds like cinacalcet (the Van Wagenen patent) and two patents teaching the preparation of pharmaceutical compounds utilizing diluents, binders, and disintegrants (the Creekmore and Hsu patents). Appx9983-9987.

In response to the obviousness rejection, Amgen filed an Amendment on December 15, 2014. The only change Amgen made in this Amendment was to narrow independent claim 2 by adding "in an amount of from about 20 mg to about 100 mg" to the cinacalcet HCl limitation in claim 2(a). Appx9999 (underlining in original).

The next entry in the prosecution history indicates that the Examiner initiated a phone call with Amgen's counsel on March 12, 2015. During this call, the Examiner and Amgen agreed to an Examiner's Amendment further narrowing the claims in two significant ways: first, claim 2(c) was narrowed by replacing the broad language covering use of *any* binder to a closed Markush group reciting four specific binders; and second, claim 2(d) was narrowed by replacing the broad language covering the use of *any* disintegrant to a closed Markush group reciting three specific

[8] Claims 3-23 depended from claim 2. Claim 24 is an independent claim but is identical to claim 2 in relevant part. Appx9948-9952.

disintegrants. Appx10030. As amended by the Examiner, claim 2 now read as follows:

> A pharmaceutical composition comprising:
>
> (a) from about 10% to about 40% by weight of cinacalcet HCl in an amount of from about 20 mg to about 100 mg;
>
> (b) from about 45% to about 85% by weight of a diluent selected from the group consisting of microcrystalline cellulose, starch, dicalcium phosphate, lactose, sorbitol, mannitol, sucrose, methyl dextrins, and mixtures thereof,
>
> (c) from about 1% to about 5% by weight of at least one binder selected from the group consisting of povidone, hydroxypropyl methylcellulose, hydroxypropyl cellulose, sodium carboxymethylcellulose, and mixtures thereof; and
>
> (d) from about 1% to 10% by weight of at least one disintegrant selected from the group consisting of crospovidone [sic], sodium starch glycolate, croscarmellose sodium, and mixtures thereof,
>
> wherein the percentage by weight is relative to the total weight of the composition, and wherein the composition is for the treatment of at least one of hyperparathyroidism, hyperphosphonia, hypercalcemia, and elevated calcium phosphorus product.

Appx10023-24 (underlining added to show Examiner's amendments). After the Examiner allowed Amgen's claims, they remained unchanged until the '405 patent issued, even though Amgen filed a series of Requests for Continued Examination. Indeed, even though Amgen submitted a "Preliminary Amendment" on December 1, 2015, it did not change the claims. Appx11267-11283.

As the district court correctly recognized, the most logical interpretation of this file history is that Amgen's December 15, 2014 amendment narrowing the

amount of cinacalcet HCl was not enough to convince the Examiner to issue the patent over the prior obviousness rejection. Appx40; *compare* Appx9999 (Dec. 15, 2014 Amendment), *with* Appx10023 (initiating Mar. 12, 2015 interview with Amgen). While the precise words exchanged during the Examiner-Initiated Interview are not known, the district court incisively observed that it was not until Amgen agreed to the Examiner's Amendment "add[ing] the Markush groups to the binder and disintegrant limitations" that the Examiner allowed the claims. Appx38.

The district court saw through Amgen's argument that only the active ingredient element had been narrowed for the purpose of patentability. *Id*. It recognized that Amgen had "tried and failed" in its December 15, 2014 amendment to narrow only the amount of cinacalcet HCl—had that amendment been sufficient, "[t]here would have been no need" for the Examiner's Amendment narrowing the binder and disintegrant limitations as well. *Id.* Indeed, citing the Examiner's stated reasons for allowing the claims, the district court concluded that the claims were allowed because "the closest prior art 'fails to specifically disclose or render obvious the *combination of components* and in the amounts thereof.'" *Id.* (emphasis in original) (quoting Appx10028).

Further supporting its conclusion that the amendments adding the Markush groups were the key to overcoming the prior art, the district court recognized that

the way that the claims were narrowed tracked two "recognized methods for overcoming an obviousness rejection." Appx39. *First*, importing limitations, like those containing the binder and disintegrant Markush groups from dependent claims 6 and 8, into the independent claims is a common way to narrow claims in order to secure a patent. *Id.* (citing *Ranbaxy Pharm., Inc. v. Apotex, Inc.*, 350 F.3d 1235, 1240 (Fed. Cir. 2003) (amendment made for substantial reason related to patentability where dependent claims were rewritten as independent claim), and *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 261 F.3d 1345, 1350 (Fed. Cir. 2001) (prosecution history estoppel applied where "the limitations at issue ... were included in dependent application claims and were later incorporated into the independent claims that were allowed and issued")).

Second, "an obviousness rejection can be overcome by narrowing a claim to a smaller set of members within a group." *Id.* (citing *Ranbaxy Pharm.*, 350 F.3d at 1240-41 (obviousness rejection overcome by narrowing "'highly polar solvent' to a defined group of solvents"), and *Merck*, 190 F.3d at 1340-41 (narrowing from broad claims to a certain subset was done "primarily in consideration of the patentability rejection")). Here, the district court found that, as amended by the Examiner, claim 2 allowed 12 possible combinations of binders and disintegrants while the prior art disclosed far more (19 binders, 8 disintegrants, and 152 combinations for Creekmore (Appx11479 (2:32-4); Appx3843 (633:10-21)); and 10 binders, 12 disintegrants, and

120 combinations for Hsu (Appx11496; Appx11498; Appx3843-3844 (633:22-634:11))).

Having decided that the Examiner's Amendment narrowed Amgen's claims for reasons related to patentability, the court next considered the scope of equivalents Amgen surrendered. The court flatly rejected Amgen's argument that no equivalents were surrendered because the amendments to the binder and disintegrant limitation were merely tangential to the purpose behind the Examiner's amendment. Appx43 ("Amgen has failed to show that the Examiner's Amendment bore no more than a tangential relation to the equivalent in question").

While the district court went on to hold that Amgen had surrendered its right to claim PGS as a binder under the doctrine of equivalents, *id.*, it did not decide whether L-HPC was within the scope of estoppel because Amgen had failed to prove that Watson infringed anyway. Appx44. Nevertheless, its reasoning as to the binder limitation of claim 1(c) applies with equal force to the disintegrant limitation of claim 1(d). Appx43 (finding that the Examiner's Amendment was not tangential).

2. No meritorious counterarguments are available to Amgen.

Amgen's briefing in the *Amneal* appeal offers four principal arguments why the foregoing analysis is wrong and that the Examiner's Amendment was actually made for reasons unrelated to patentability: (1) that it misinterpreted key parts of the file history, (2) that it failed to consider the entire file history, (3) that Amgen's

vague, later-in-time remarks explain what the Examiner did, or (4) that its remarks merely clarified what was already inherent in the claims. Each is incorrect.

a. The district court did not misinterpret the prosecution history.

Amgen's opening brief in the *Amneal* appeal criticizes the district court's reading of the key part of the file history, specifically its interpretation of the First Notice of Allowance. Amgen's Corrected Opening Br. at 51-53, *Amgen Inc. v. Amneal Pharm. LLC*, No. 18-2414 (Fed. Cir. Dec. 11, 2018), ECF No. 54 ("Amgen/Amneal Br."). According to Amgen, the addition of the binder and disintegrant Markush groups in the Examiner's Amendment was not made for reasons related to patentability, as "those amendments could not distinguish the cited art (Creekmore and Hsu) because that art already disclosed all of the same excipient species." *Id.* at 51. In essence, Amgen argues that the Examiner's Amendment could not have been made for reasons related to patentability because the proposed changes did not render the claims patentable. This argument is fundamentally flawed.

"[W]here a change is made to overcome an objection based on the prior art," courts are ***not*** "free to review the correctness of that objection when deciding whether to apply prosecution history estoppel." *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 33 n.7 (1997). Rather, "[w]hat *is* permissible for a court to explore is the reason (right or wrong) for the objection and the manner in

which the amendment addressed and avoided the objection." *Id.* (emphasis in original). Here, the district court properly inferred that the Examiner declined to allow the claims based solely on Amgen's narrowing of the amount of cinacalcet; instead, he *also* required Amgen to add the binder and disintegrant Markush groups before he would agree to find a patentable combination of components. Amgen "may not both make the amendment and then challenge its necessity in a subsequent infringement action on the allowed claim." *Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1356 (Fed. Cir. 1998); *see also Tech. Props. Ltd. LLC v. Huawei Techs. Co.*, 849 F.3d 1349, 1359 (Fed. Cir. 2017) ("The question is what a person of ordinary skill would understand the patentee to have disclaimed during prosecution, not what a person of ordinary skill would think the patentee needed to disclaim during prosecution."); *Norian Corp. v. Stryker Corp.*, 432 F.3d 1356, 1361-62 (Fed. Cir. 2005) (even where patentee surrenders more than "absolutely necessary" to avoid prior art, "we have held the patentees to the scope of what they ultimately claim").

The Examiner's actions with respect to claims 6 and 8 reinforce this conclusion. On reply in the *Amneal* appeal, Amgen speculated that, in view of the Examiner's rejection of dependent claims 6 and 8, the narrowed combination of components claimed by the Markush groups could not have been the basis for allowing the claims. Amgen's Reply Br. at 21, No. 18-2414 (Fed. Cir. Mar. 20, 2019), ECF No. 75 ("Amgen/Amneal Reply"). Not only is this an improper attempt to litigate the

merits of the Examiner's decision, it is also substantively wrong. Claim 6 contained a single limitation that would have narrowed the binders to a Markush group, but allowed any disintegrant. Similarly, claim 8 contained a single limitation that would have narrowed the disintegrants to a Markush group, but allowed any binder. Appx10000. The Examiner rejected both of these dependent claims—supporting the district court's conclusion that only by narrowing ***both*** the binder and disintegrant limitations did Amgen create a sufficiently narrow combination of components. Appx39.

Amgen's next argument in its opening brief in the Amneal appeal was that the district court erroneously focused on the First Notice of Allowability to the exclusion of the subsequent notices of allowance. Amgen/Amneal Br. 50-51, 53-54. According to Amgen, the district court improperly credited the statement the Examiner made at the time he found the claims patentable over the prior art (thus overcoming the rejection), and instead should have given more credence to the Examiner's subsequent statements, which were made in response to Amgen's Requests for Continued Examination, claiming that they "add[] to the overall picture." Amgen/Amneal Br. 53-54. But this ignores the context in which these Notices were issued. For example, in the Second Notice of Allowance, the Examiner only considered the information Amgen presented in an Information Disclosure Statement containing documents related to the prosecution of a European patent. Appx10759. And the Third

and Fourth Notices of Allowance were issued after consideration of documents that were "not deemed to be pertinent to the claimed invention." Appx11283; Appx11339. It is no surprise that Amgen offers no explanation of how these Notices of Allowance should or would change the conclusions reached by the district court. Amgen/Amneal Br. 54.

Even beyond that, Amgen does not provide any legitimate explanation as to how the language used in these Notices is meaningfully different. In the Notices of Allowance, the Examiner states:

Notice	**Reason for Allowance**
First Notice (Appx10028)	"the combination of components and in the amounts thereof"
Second Notice (Appx10759)	"the nature of the excipients and their respective amounts"
Third Notice (Appx11283)	"the nature of the excipients and their respective combinations"
Fourth Notice (Appx11339)	"the nature of the excipients and their respective combinations"

Amgen attempts to inflate the significance of these minor phrasing differences, but nothing in the record suggests that the Examiner intended to express different reasons for allowing the claims. Rather, in three of the four notices of allowance, the Examiner cited the combinations of the excipients as the basis for distinguishing the claimed subject matter from the prior art. *See* Appx10028 (First Notice); Appx11283 (Third Notice); Appx11339 (Fourth Notice). Thus, Amgen is simply

wrong that "the categories of excipients mattered [to the Examiner] but the particular ones in the Markush groups did not." Amgen/Amneal Br. 54. The record shows that they did.

Finally, Amgen complains that the district court improperly disregarded the statement it made in a 2015 Preliminary Amendment that "[t]hese amendments have not been made in response to a prior art rejection but rather to place the claims in proper format and to better define the claimed subject matter, including equivalents." Amgen/Amneal Br. 48-49 (quoting Appx11273); Amgen/Amneal Reply 19. According to Amgen, these statements did not offer an explanation of the basis for that 2015 Preliminary Amendment, but rather were explaining the Examiner's Amendment, which had been entered eight months prior. Amgen/Amneal Br. 49. This argument strains credulity and should be rejected.

Fundamentally, Amgen asks this Court to credit its own post-hoc statement that the amendments were not made in response to a prior art rejection over the Examiner's apparent reliance on the combinations of components to overcome the previously asserted prior art. But the court is under no obligation to consider Amgen's self-serving remarks here. *Bai*, 160 F.3d at 1355 (patentee's "boilerplate remark to the examiner that he amended his claims to 'specifically and expressly recite the structural details' of his invention" rather than to overcome the prior art "does not affect our conclusion").

Amgen attempts to bolster its self-serving interpretation of the file history by arguing that the "Examiner never disputed or took any issue with that statement." Amgen/Amneal Br. 49. But the law does not permit Amgen to put words in the Examiner's mouth, let alone conflate silence with acquiescence. To the contrary, a "[f]ailure by the examiner to respond to any statement commenting on reasons for allowance does not give rise to any implication." 37 C.F.R. § 1.104(e); *see also* MPEP § 1302.14 (application file history should speak for itself).

Amgen went even further on reply, claiming that the Examiner's silence should count here because "the Examiner *invited* Amgen's statement—and then never disputed it." Amgen/Amneal Reply 20 (emphasis in original). This cannot be squared with the facts. The remarks in question were not submitted until eight months later, in connection with an amendment that made no substantive changes to the pending claims. Placed in proper context, the Examiner's silence can hardly be viewed as an endorsement. Rather, the more logical explanation is that Amgen's litigation counsel hoped to reframe the prosecution history in a way that supported its case. In any event, if Amgen's position were correct (and it is not), it would completely subvert the doctrine of prosecution history estoppel—any patentee could paper over its earlier admissions simply by filing a self-serving amendment.

b. The Examiner's Amendment was not a "clarifying" amendment.

Amgen further attempts to avoid estoppel by arguing that the addition of Markush groups to claim 1 simply "clarified" and "made more explicit" what was already present in the claims: that claims (c) and (d) cover "hardening binders" and "superdisintegrants." Amgen/Amneal Br. 49-50; Amgen/Amneal Reply 21-22. While estoppel does not apply to "clarifying" or "cosmetic" amendments, this exception only applies to amendments that ***do not*** narrow the claims. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.* ("*Festo VIII*"), 535 U.S. 722, 724 (2002) (where an "amendment is truly cosmetic, it would not narrow the patent's scope"); *Intendis GmbH v. Glenmark Pharm. Inc., USA*, 822 F.3d 1355, 1365-66 (Fed. Cir. 2016) ("Amendment-based estoppel does not apply because the amendment was not a narrowing amendment made to obtain the patent," but rather "a clarifying amendment."). Amgen's argument is thus precluded by the record and the claims themselves.

At trial, Amgen *conceded* that the addition of the Markush groups *narrowed* the claims. Appx3574-3576 (400:8-402:22); Appx4293 (1055:14-16). As the district court properly noted, this admission alone is dispositive. Appx42 ("[T]he Examiner's Amendment admittedly narrowed the claims, so it is not a clarifying amendment."). Amgen now attempts to walk this concession back arguing that the addition of the Markush groups to claims that previously allowed the use of *any*

binder or *any* disintegrant "made more explicit what was already claimed." Amgen/Amneal Br. 50. Though Amgen hypothesizes that this is so because the binder and disintegrant limitations were previously "disclosed in the specification" (*id.*), at best, all this would establish is (as Amgen argued at trial) that the Markush groups were added to comply with the written description requirement (Appx3240 (95:1-13))—still a narrowing amendment made for reasons of patentability. *See, e.g.*, *Festo*, 535 U.S. at 724 ("[I]f a § 112 amendment is necessary and narrows the patent's scope—even if only for better description—estoppel may apply.").

Amgen also argues that a procedural nuance in the file history shows that the addition of the Markush groups was non-substantive, and thus clarifying. It argues that, according to Section 714(E) of the Manual of Patent Examining Procedure ("MPEP"), a three-month extension and additional fees would be required if the amendment were substantive; because no extension was required and no fees were paid here, it follows that "the Examiner's Amendment was not substantive." Amgen/Amneal Reply 22. This argument, which finds no support in the case law, relies on parts of Section 714(E) that relate to Examiner's Amendments to *non-compliant amendments submitted by the applicant*, and do not apply here. *See* MPEP § 714(E) ("The examiner's amendment should include the reason why the amendment is non-compliant and indicate how it was corrected.").

Amgen skips over another provision of Section 714(E) that does not help its cause. "Authorization from the applicant or attorney/agent of record" is not required when an amendment is non-substantive—and yet the Examiner sought and obtained authorization from Amgen's counsel before entering the amendment under discussion here. *Id.* This supports the position that the amendment *was*, in fact, substantive.

3. The scope of surrender bars Amgen from claiming L-HPC as a disintegrant.

Once this Court determines that the amendment was made for reasons related to patentability, the only question remaining is "the scope of the subject matter surrendered by the narrowing amendment." *Festo*, 344 F.3d at 1367. Under *Festo VIII*, a patentee is presumed to have surrendered all territory between the original claim limitation and the claim limitation as narrowed by an amendment. *Festo*, 344 F.3d at 1367 (citing 535 U.S. at 740). While the district court did not reach the issue of whether L-HPC is within the scope of surrender (Appx43-44), this Court reviews the issue *de novo*. *See Schwarz Pharma, Inc. v. Paddock Labs., Inc.*, 504 F.3d 1371, 1375 (Fed. Cir. 2007). This Court can and should conclude that Amgen surrendered L-HPC as an equivalent.

A patentee is "presumed to have surrendered the equivalents that may have been encompassed by" the original claim language. *Ranbaxy Pharm.*, 350 F.3d at 1241. Here, the claims originally recited "from about 1% to 10% by weight of at

least one disintegrant" (Appx9999)—*any* disintegrant—and were narrowed by the Examiner's Amendment to "from about 1% to 10% by weight of at least one disintegrant selected from the group consisting of crospovid[o]ne, sodium starch glycolate, croscarmellose sodium, and mixtures thereof" (Appx10023-10024). L-HPC, which was known in the art (and to at least one of the named inventors of the '405 patent[9]) to be a disintegrant for use in oral pharmaceutical tablet formulations at the time of the '405 patent's invention, was encompassed by the original claim language but excluded by the amended language from the disintegrant Markush group.

It is thus incumbent on Amgen to rebut the presumption that L-HPC is within the scope of surrender by fitting it into one of the three *Festo VIII* exceptions: "that the alleged equivalent would have been unforeseeable at the time of the narrowing amendment, that the rationale underlying the narrowing amendment bore no more than a tangential relation to the equivalent in question, or that there was 'some other reason' suggesting that the patentee could not reasonably have been expected to have described the alleged equivalent." *Festo*, 344 F.3d at 1368 (quoting 535 U.S. at 740-41). It raised only one—that the reason for the narrowing amendment bears "only a tangential relation" to the equivalent. Amgen/Amneal Br. 52 (citing *Insituform*

[9] U.S. Patent No. 6,514,529, which names one of the inventors of the '405 patent, Hung-Ren (Homer) Lin, as an inventor, specifically discloses and claims the use of L-HPC as a disintegrant. *See* Appx7767 (6:55-58); Appx7770 (cl. 9). The inescapable conclusion is that Lin would have known of L-HPC. *See supra* Part II.A.2.a.

Techs., Inc. v. CAT Contracting, Inc., 385 F.3d 1360, 1370 (Fed. Cir. 2004)). This exception focuses on "the patentee's objectively apparent reason for the narrowing amendment, which must be discernible from the prosecution history record." *Felix v. Am. Honda Motor Co.*, 562 F.3d 1167, 1184 (Fed. Cir. 2009) (quoting *Festo*, 344 F.3d at 1369).

Amgen's reliance on the "very narrow" tangential exception to prosecution history estoppel is futile. *See Integrated Tech. Corp. v. Rudolph Techs., Inc.*, 734 F.3d 1352, 1358 (Fed. Cir. 2013) (internal quotation marks omitted). Substantively, Amgen cannot show that the relationship between the amendment and the equivalent (L-HPC) was "tangential." According to Amgen, "the number of excipient combinations has nothing to do with the shared properties of the Markush groups—namely, as hardening binders and superdisintegrants." Amgen/Amneal Br. 52. But it is objectively apparent from the prosecution history that, for the purpose of securing the patent, Amgen needed to narrow the combination of components claimed, and thus agreed to narrow its claims from "any disintegrant" to a narrow set of three specifically named disintegrants using a closed Markush group. *See Felix*, 562 F.3d at 1184. Since the reason for the narrowing amendment was to limit the combination of components, Amgen cannot use the doctrine of equivalents to expand the number of combinations by including L-HPC. Thus, L-HPC has a direct, not tangential,

relation to the rationale for the Examiner's Amendment. Amgen has the burden on this issue, and it has offered no convincing explanation otherwise.

The most logical interpretation of the file history is that the Markush groups were added to cure the obviousness problem identified by the Examiner. But even if this Court were to accept Amgen's contrary arguments, they would establish at most that the Markush groups were added to cure a written description problem. *See supra* at 53. The Markush form of claiming shows that the identity of the disintegrants chosen mattered for patentability, and L-HPC would still not bear a tangential relation to the amendment's rationale.

Accordingly, this Court may dispose of this case on the ground that prosecution history estoppel bars Amgen's doctrine of equivalents arguments.

C. The finding of noninfringement can be affirmed regardless of the district court's claim construction.

As an afterthought, Amgen argues that the district court's finding of noninfringement as to Watson should be vacated because of the district court's claim construction ruling. Br. 51. But Amgen provides no explanation as to how this claim construction ruling impacted the outcome for Watson at trial, instead presuming that the district court's judgment should be vacated whether or not the claim construction affected the outcome. Br. 52.

That is not the correct legal standard. "When [this Court] determine[s] on appeal, as a matter of law, that a trial judge has misinterpreted a patent claim, [it]

independently construe[s] the claim to determine its correct meaning, and then determine[s] if the facts presented at trial can support the appealed judgment." *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1328 (Fed. Cir. 2002) (quotation omitted). In other words, Amgen must show that the alleged error in claim construction was not harmless.

Here, Amgen does not and cannot allege that the district court's claim construction ruling had a material impact on the district court's findings in favor of Watson. Indeed, it essentially concedes that there is no impact, acknowledging that "the district court's noninfringement decision as to Watson … did not involve any unlisted disintegrant." Br. 52. Because the claim construction was not relevant to Amgen's theory of infringement, at trial Amgen presented the exact same theories and evidence it had presented before the construction was issued. Amgen's theories did not change until its counsel raised new ones in its post-trial briefing—which could have had no bearing on the claim construction ruling.

Amgen's only alleged prejudice is that "the claim construction issue had 'caus[ed] some confusion.'"[10] Br. 52 (citing Appx4261). But "some confusion" (if indeed there was any) is not prejudice, and certainly does not warrant a new trial.

[10] Amgen also asserts that Watson's arguments regarding the binder limitation would somehow warrant a remand of this case on its merits. Br. 53. As these arguments did not serve as the basis for the district court's finding of infringement and are not asserted in this appeal, Amgen's argument is disingenuous, at best.

Walker Digital, LLC v. Microsoft Corp., 590 F. App'x 956, 961 (Fed. Cir. 2014) (finding district court's claim construction to be harmless error where defendant's products did not infringe under modified claim construction); *Finjan, Inc. v. Secure Computing Corp.*, 626 F.3d 1197, 1207 (Fed. Cir. 2010) (refusing to order new trial when appellant did not explain how different construction would change outcome of infringement analysis); *Innovad Inc. v. Microsoft Corp.*, 260 F.3d 1326, 1334-35 (Fed. Cir. 2001) ("the movant remains entitled to judgment as a matter of law despite an error in claim construction").

CONCLUSION

For all these reasons, the judgment in favor of Watson should be affirmed.

Respectfully submitted,

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NOVEMBER 4, 2019

CERTIFICATE OF SERVICE

I certify that, on November 4, 2019, I caused the foregoing Brief for Defendants-Appellees Watson Laboratories, Inc. and Actavis Pharma, Inc. to be electronically filed with the Clerk of Court using the CM/ECF system, and thereby served via CM/ECF on counsel for all parties.

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION, TYPEFACE REQUIREMENTS, AND TYPE-STYLE REQUIREMENTS

1. This brief complies with the type-volume limitation of Federal Circuit Rule 28.1(b)(2)(A) because it contains 13,919 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii) and Federal Circuit Rule 32(b).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in 14-point Times New Roman, a proportionally spaced typeface, using Microsoft Word 2010.

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