Nos. 2019-1650, 2019-1770

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-00853-MSG

NON-CONFIDENTIAL REPLY BRIEF FOR PLAINTIFF-APPELLANT AMGEN INC.

Wendy A. Whiteford
Lois M. Kwasigroch
Eric M. Agovino
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320
Telephone: (805) 447-0464

John D. Murnane
Joshua I. Rothman
Alicia A. Russo
VENABLE LLP
1290 Avenue of the Americas
New York, NY 10104-3800
Telephone: (212) 218-2100

Bradford J. Badke
Sona De
SIDLEY AUSTIN LLP
787 Seventh Avenue
New York, NY 10019
Telephone: (212) 839-5300

Ryan C. Morris
Joshua J. Fougere
Lauren Cranford Katzeff
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
Telephone: (202) 736-8000

Counsel for Plaintiff-Appellant Amgen Inc.

CERTIFICATE OF INTEREST

Counsel for Plaintiff-Appellant Amgen Inc. certifies the following:

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

Amgen Inc.

2. The names of the real parties in interest represented by me are:

See response to number 1.

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

None.

4. The names of all law firms, and the partners or associates, that appeared for the party represented by me in the trial court or are expected to appear in this Court and who are not already listed on the docket for the current case are:

Venable LLP (formerly, Fitzpatrick, Cella, Harper & Scinto)
Frederick C. Millett, Erica L. Norey, Gabrielle Markeson, James R. Tyminski, Robert S. Pickens, Rosanna W. Gan, Kathryn E. Easterling, Una Fan, Katherine Y. Kim

Morris, Nichols, Arsht & Tunnell LLP
Jack B. Blumenfeld, Maryellen Noreika

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal is:

Counsel for Amgen is aware of two pending consolidated cases before this Court that may be directly affected by the decision here: *Amgen Inc. v. Amneal Pharmaceuticals LLC,* No. 18-2414, docketed September 25, 2018, and No. 19-1086, docketed October 16, 2018. Those appeals concern the same district court case and the same patent, U.S. Patent No. 9,375,405 (the ’405 patent) at issue here.

Counsel for Amgen is also aware of a case before the U.S. District Court for the District of Delaware that may be directly affected by the Court’s decision here: *Cipla Ltd. v. Amgen Inc.*, C.A. No. 19-cv-44, filed January 8, 2019. That dispute concerns settlement agreements regarding the ’405 patent.

/s/ Bradford J. Badke
Bradford J. Badke

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CONFIDENTIAL MATERIAL OMITTED

The material omitted on pages 1, 3, 5, 6, 8, 9, 11, 15, 17, 20, 21, 25, 26, 27, and 29 of this brief contains information filed under seal or subject to a protective order.

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INTRODUCTION

The Amgen-Watson agreement should resolve this case through vacatur and remand because Watson agreed that the existing non-infringement judgment is wrong, because the parties mutually wanted and sought vacatur based on that agreement, and because such a result advances the public's interest in enforcing settlements and in the "orderly operation" of Hatch-Waxman litigation.

Watson—the only other party to this appeal—does not dispute that outcome. Instead, Watson "takes no position" on whether vacatur is proper, while simultaneously trying to walk away from its clear-cut infringement admission because it appears in a settlement agreement. But Watson's admission was just that, an admission freely and knowingly made to gain a benefit—"fully resolv[ing] the[] respective infringement claims and invalidity counterclaims," APPX5082—through negotiated terms, rather than through the cost and uncertainty of litigation. The agreement itself says that Watson infringes in several places. [redacted] Watson then joined a motion characterizing the agreement as one in which it "admitted" infringement. APPX5082-5083. And two other courts that have considered the agreement have found that Watson "agreed that it had infringed the '405 patent." *Cipla Ltd. v. Amgen Inc.*, 778 F. App'x 135, 137 (3d Cir. 2019); *see also Cipla Ltd. v. Amgen Inc.*, 386 F. Supp. 3d 386, 391 (D. Del. 2019) (same).

The mere fact that Watson's infringement admission appears in a settlement agreement does not diminish its impact on the vacatur question. The whole vacatur issue is premised on the parties' desire to end litigation (*i.e.*, settle), followed by an analysis of what factors support altering the underlying judgment to do so. Here, Amgen and Watson agreed to end their dispute, with Watson admitting infringement and jointly pursuing entry of an infringement consent judgment—a circumstance in which Watson's admission plainly undermines the existing and contrary district court judgment. Watson should be held to the full legal effect of its admission, and the district court's judgment should be vacated with instructions to enter the consent judgment.

Contrary to competitor *amici* Cipla's assertion, as the continuation of this appeal makes plain, the Amgen-Watson litigation is not moot while the district court's non-infringement judgment remains in place. Amgen *wants* the agreement to moot its litigation with Watson, but doing so requires vacatur and entry of the infringement consent judgment. That has not yet happened, allowing Watson a platform to contest infringement on the merits in this appeal. And, although Cipla has launched its generic product at-risk and hopes to protect that gamble here, Cipla's self-interested antitrust agenda has no place in this patent case. Its transparent efforts to use this appeal as a dress rehearsal for antitrust claims being litigated elsewhere should not be entertained.

If the Court does not vacate based on the parties' agreement, it should do so based on the district court's errors under the doctrine of equivalents. Watson's protracted defense of the very non-infringement decision that it previously moved to vacate further ignores its own representations to the FDA. As a comparison of the claimed Sensipar® formulation to Watson's ANDA formulation shows, *infra* at 15, they are virtually identical except for Watson's decision to substitute an equivalent disintegrant (L-HPC) for Sensipar®'s crospovidone. [redacted] Such an inconsequential change is exactly why the doctrine of equivalents exists. Watson's products infringe—just as Watson admitted they do.

ARGUMENT

I. THIS COURT SHOULD VACATE THE DISTRICT COURT'S NON-INFRINGEMENT JUDGMENT IN LIGHT OF THE PARTIES' AGREEMENT TO SETTLE.

There are two independent bases for vacating the non-infringement judgment in light of the parties' agreement: (A) directly under 28 U.S.C. § 2106 and (B) on appeal from the indicative ruling decision.

A. The Court Should Vacate the Non-Infringement Judgment Under Its § 2106 Authority.

This Court "may affirm, modify, vacate, set aside or reverse any judgment, decree, or order of a court lawfully brought before it for review, and may remand

the cause and direct the entry of such appropriate judgment, decree, or order, or require such further proceedings to be had as may be just under the circumstances."[1] 28 U.S.C. § 2106.

Under that authority, Amgen detailed three reasons why the Court should vacate the non-infringement judgment and remand for entry of the consent judgment: (1) Watson admitted infringement, *see Aqua Marine Supply v. AIM Machining, Inc.*, 247 F.3d 1216, 1221 n.1 (Fed. Cir. 2001); (2) the deal benefitted both parties, *see Major League Baseball Props., Inc. v. Pac. Trading Cards, Inc.*, 150 F.3d 149, 152 (2d Cir. 1998); and (3) the particulars of Hatch-Waxman litigation amplify the need for orderly and effective settlements. Amgen Br. 19-33. Watson "takes no position" on vacatur, but does take a passing swipe at the first reason for vacatur by claiming its admission should not count.

1. Watson Admitted Infringement.

The first reason for vacatur is that Watson's admission of infringement undermines confidence in the non-infringement judgment currently in place. Amgen Br. 21-24; *Aqua Marine*, 247 F.3d at 1221 n.1; *see also Lawrence ex rel. Lawrence v. Chater*, 516 U.S. 163, 171 (1996) (per curiam) (noting the Supreme

[1] The statute's plain language contradicts Cipla's suggestion that § 2106 is limited to "vacatur." Cipla Br. 19-20. The Court has authority to alter the judgment however it sees fit, *and* to remand with instructions to enter an "appropriate judgment."

Court's practice of vacating judgments "in light of plausible confessions of error"). That is perfectly logical, and the fact that Watson's agreement on infringement was unequivocal and occurred late in litigation, after Amgen's opening brief on appeal, reflects an "especially probative" "assessment by [an] interested and adversarial part[y] o[n] the range of plausible litigation outcomes." *Prism Techs. LLC v. Sprint Spectrum L.P.*, 849 F.3d 1360, 1369 (Fed. Cir. 2017).

Watson does not challenge the consequences of its admission for purposes of deciding vacatur, *and that should be all that matters*. When a winning party like Watson signs an agreement that says, in effect, the judgment was in error, that supports vacating the existing judgment and entering one consistent with the post-judgment admission. Amgen Br. 21-24. Watson's supposed "clarification" that it stipulated to infringement "solely for the limited purpose of settling this case," Watson Br. 16 (emphasis omitted), is *not* a limitation that appears anywhere in the actual agreement. *See* [redacted] But even Watson's alleged "limited purpose" is entirely consistent with the result Amgen urges: fully effectuating the parties' settlement agreement through vacatur is precisely the "purpose" that Watson's admission serves here.

Watson's remaining attempts to backtrack and contend that it actually "has not admitted infringement" defy reality. Watson Br. 17-18 & n.3. Watson's infringement admission was effective upon the agreement's execution. Although

some parts of the settlement agreement (including Watson's agreement to pay Amgen damages) are explicitly tied to the "Effective Date," which has not yet occurred, the infringement admission is not among them. [redacted] *Id.*; *see, e.g.*, *AgroFresh Inc. v. Essentiv LLC*, No. 16-cv-662, 2018 WL 6919514, at *3 (D. Del. Dec. 11, 2018) ("The Settlement Agreement does not condition [the plaintiff's] obligation to file a motion dismissing [certain] defendants from the litigation on the fulfillment of all obligations under the terms of the Settlement Agreement.").

The proposed consent judgment, which was jointly signed and submitted to the district court consistently states in the past tense that "Defendants *have admitted* … infringe[ment]," [redacted] (emphasis added), confirming that Watson already made that admission in the agreement itself. The Third Circuit agreed. *Cipla*, 778 F. App'x at 137 (stating that Watson "agreed that it had infringed" in appeal from preliminary injunction decision in the antitrust case); *see also Cipla*,

386 F. Supp. 3d at 391 (Watson "stipulated that the [Watson] Product *does infringe* the '405 patent").

Neither Rule 408 nor the settlement context more generally negates Watson's admission. Because Watson relied on and cited to its own admission in a joint district court filing, APPX5078, APPX5083, APPX5097, it cannot invoke Rule 408 for the first time on appeal to avoid those admissions now. *See, e.g.*, *Eisenberg v. Univ. of N.M.*, 936 F.2d 1131, 1134 (10th Cir. 1991) (party "waived any claim to Rule 408 protection by her own submission of the affidavit to the court"). Indeed, in *Prism*, this Court rejected a Rule 408 objection after the party failed to raise it in district court. 849 F.3d at 1373-75. This case should follow *a fortiori*, as Watson not only failed to object, but affirmatively opened the door to the agreement by using it to seek a consent judgment of infringement from the district court. Having so relied on the agreement, Watson waived any purported Rule 408 claim. It cannot now complain that Amgen is using the same agreement as a basis to achieve the same result—namely, vacatur and entry of a final judgment of infringement.

2. Vacatur Is Warranted Because the Deal Benefitted Both Parties.

The second reason for vacatur is that the "victor in the district court wanted a settlement as much as, or more than, the loser did." *Major League Baseball*, 150 F.3d at 152. This was not a case in which Amgen unilaterally tried to end the

litigation; Watson joined that effort. Amgen Br. 24-27. Watson does not dispute this. Nor could it, given the potential damages Watson faces for its acknowledged "at-risk" launch.[2]

3. Vacatur Is Warranted Because It Will Promote The Public Interest in Efficient Hatch-Waxman Litigation.

The third reason for vacatur is that it promotes "the orderly operation of the federal judicial system." *U.S. Bancorp Mortg. Co. v. Bonner Mall P'ship*, 513 U.S. 18, 27 (1994). Settlements do that as a general matter, and especially so in the Hatch-Waxman context, where overlapping lawsuits often require that brand-generic settlements be effectuated through vacatur and entry of consent judgments to protect against any unintended collateral impact on earlier litigants and settlements (like Cipla's). Amgen Br. 27-33. Again, Watson does not dispute this.

Cipla offers no serious rejoinder to this important point in favor of vacatur either, having already launched its competing product. Instead, Cipla tries to detract from the pro-competitive nature of the agreement by misrepresenting the facts. Cipla ignores that the agreement benefits the public by giving up [redacted]

[2] Cipla's efforts to distinguish *Major League Baseball*, Cipla Br. 21, are unavailing. In that case, the appellee's inability to pay signaled the appellee's underlying interest in avoiding "severe financial risk" by continuing the appeal, *Aqua Marine*, 247 F.3d at 1221—an interest that Watson clearly had too. And like the agreement in *Major League Baseball*, which "was contingent on vacatur," Cipla Br. 21, parts of the Amgen-Watson agreement are also contingent on entry of the consent judgment that sets the "Effective Date." *See, e.g.*, [redacted]

[redacted] of patent protection to earlier generic entry. Amgen Br. 29 (citing [redacted]). Cipla asserts that the "Amgen-[Watson] Agreement did not … call for the submission of evidence of pro-competitive effects to the district court." Cipla Br. 12. But antitrust claims are not a part of this case, and so there was no reason to present evidence on such issues in the district court. In any event, Amgen and Watson *were* required to and did [redacted]. Cipla also misleadingly clip-quotes the district court's preliminary injunction opinion in its antitrust case to contend that Amgen and Watson sought to "deter … competition." Cipla Br. 20-21. But the omitted language shows this statement merely described *Cipla's allegations* and, in the same paragraph, the court stated that "it also seems plausible that Amgen and [Watson] may have reasonably assessed the risks each faced on appeal (and otherwise) and reached a rational compromise of their patent disputes." *Cipla*, 386 F. Supp. 3d at 409. Exactly.[3]

[3] Amgen already refuted Cipla's related contention (Cipla Br. 20) that the non-infringement judgment should stand because court decisions are valuable to the legal community. *See* Amgen Br. 27-33.

B. The Court Should Vacate the Non-Infringement Judgment Because the District Court's Analysis Was Critically Flawed.

Separate and apart from the Court's authority to vacate under section 2106, the same result is appropriate on direct review of the district court's indicative ruling decision. Amgen Br. 33-37. To reiterate briefly, the district court: (1) used the wrong legal standard, (2) incorrectly applied Federal Rule of Civil Procedure 60(b), (3) was wrong to treat the litigation as "moot," and (4) incorrectly characterized the bilateral agreement as one in which Amgen unilaterally "voluntarily terminate[d] the controversy." *Id.* Watson is again silent on these issues.

Cipla's brief takes issue only with this Court's jurisdiction,[4] not the underlying substantive arguments. More specifically, Cipla argues that the Amgen-Watson dispute is moot. Cipla Br. 6, 13-18. It is not, and the district court's indicative ruling decision was wrong to presuppose that it is. Cipla relies heavily on two cases—*Aqua Marine* and *United States v. Johnson*—but neither supports mootness. In *Aqua Marine,* the mootness conclusion was a direct result of the fact that, "in light of the settlement, the [appellees] no longer ha[d] any

[4] Cipla's passing contention that there is "no … basis for appellate review" of the indicative ruling (Cipla Br. 5, 17-18) is incorrect. Appellate courts across the country, including the Third Circuit, routinely hear such appeals. *See, e.g.*, *Ray v. Pinnacle Health Hosps., Inc.*, 416 F. App'x 157, 161 n.3, 166 (3d Cir. 2010); Amgen Br. 4 (citing additional cases).

interest in the outcome of the validity issue on appeal" and were not litigating it. 247 F.3d at 1219-20. *United States v. Johnson* stands for, at most, the unremarkable proposition that opposing parties need adversarial interests for a federal court to maintain jurisdiction. 319 U.S. 302, 303-05 (1943). Here, however, Amgen's damages claim remains unresolved, and there can be no clearer evidence that this appeal is not moot than Watson's 59-page adversarial brief purporting to defend the district court's non-infringement decision.

In the end, Cipla's all-or-nothing mootness argument reflects a fundamental misunderstanding of the vacatur issue. *If* this Court vacates the judgment of non-infringement and orders entry of the infringement consent judgment, *then* the Amgen-Watson agreement would be fully effectuated and *then* the parties' dispute would be moot, as the parties intended. For now, critical portions of the agreement remain contingent on the consent judgment's entry, and the dispute is very much alive. *See, e.g.*, [redacted].[5]

Indeed, when and whether to vacate in light of a settlement agreement is the entire point of *Bancorp* and its progeny. If the mere fact of such an agreement

[5] Cipla's assertions that Amgen "persuaded" the district court in the antitrust case to find the agreement binding (Cipla Br. 11) are incomplete—those assertions pertained to only some provisions, not those tied to the "Effective Date."

meant that this Court *had to* dismiss the appeal for mootness, as Cipla urges, then the vacatur decisions in this body of law would have never been possible. Article III does not hamstring courts so categorically. *See, e.g.*, *Bancorp*, 513 U.S. at 20-22 (rejecting such an argument and recognizing that courts "may make such disposition of the whole case as justice may require"); *Aqua Marine*, 247 F.3d at 1218-21 (applying *Bancorp* and considering vacatur after concluding case was moot).

C. Cipla's Additional Miscellaneous Arguments Are Meritless.

Cipla's brief is full of distractions, but Amgen responds briefly to the three most egregious ones.

First, Cipla continues to hurl irrelevant and baseless allegations of "collusion" and purportedly "collusive" judgments. Cipla trumpeted the same refrain in two previous motions, ECF Nos. 49, 58, and the Court should ignore them again here. Cipla has a forum where its antitrust allegations are being aired, and it is in a separate Delaware case—not in this lawsuit or this appeal. Not only is there a "general principle" against "duplicative litigation," *Colo. River Water Conservation Dist. v. United States*, 424 U.S. 800, 817 (1976), but this is a Court

of review, not a forum where an *amicus* like Cipla can test out irrelevant and unsupported allegations that *no* court has yet decided.[6]

Second, there is no evidentiary barrier to this Court's full consideration of the vacatur issue. Cipla's suggestions that the Amgen-Watson agreement cannot be considered here because it was not introduced below is meritless. Cipla Br. 18 & n.2, 20-21. The Amgen-Watson agreement was executed after the district court record was closed and while this case was on appeal—a circumstance in which appellate courts can and often do consider such agreements under § 2106. *See, e.g.*, *Bancorp*, 513 U.S. at 20-21; *Major League Baseball*, 150 F.3d at 151.

Finally, there is no merit to Cipla's assertion that the Amgen-Watson agreement was nefariously "withheld" from the district court. Cipla Br. 21. On the contrary, the parties represented the substance of the agreement to the district court, *see* APPX5077-5094, and followed the common practice (including for other settlements in this case) of retaining confidential settlement agreements. The parties explicitly told the district court that the "specific terms of the agreement are confidential," and then described some of its key features. APPX5082. The district court gave no indication that its decision was impacted by the adequacy of

[6] Indeed, Cipla's claims of "collusion" are so far-fetched that the Delaware court declined to give them any meaningful consideration in its preliminary injunction analysis, describing them as "extravagant" and "far from proven." *Cipla*, 386 F. Supp. 3d at 410 n.26; *see also* ECF No. 53, at 19 (further refuting these allegations).

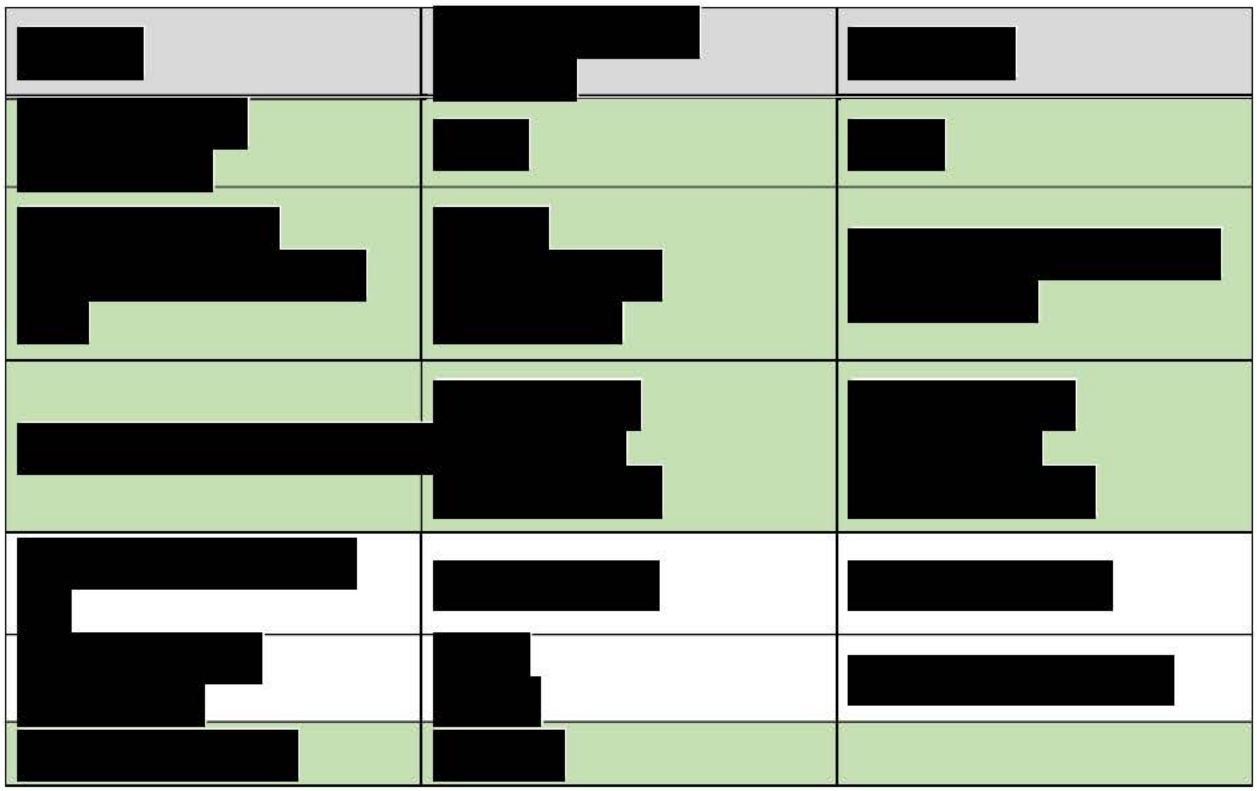
the record, and other parties in analogous situations have taken the same sensible approach. *See, e.g., Braintree Labs Inc. v. Lupin Atlantis Holdings SA*, No. 3:11-cv-01341, 2016 WL 8814360 (D.N.J. Sept. 20, 2016) (no apparent provision of confidential settlement agreement to the district court vacating judgment). The Court can consider the Amgen-Watson agreement here.

II. IN THE ALTERNATIVE, THE COURT SHOULD VACATE THE DISTRICT COURT'S ERRONEOUS NON-INFRINGEMENT JUDGMENT ON THE MERITS.

Watson's contentions for affirmance "[i]f the Court declines" to vacate in light of the agreement are undermined by its admitted infringement and contrary to its agreement not to challenge infringement going forward. *Supra* § I.A.1. That alone is reason to reject Watson's attempt to defend a district court decision reaching the opposite result.

Should the Court nevertheless consider the merits, Watson's brief does not erase the legal errors the district court made or justify its failure to use the proper evidence in its infringement analysis.

Watson does not dispute that its ANDA formulation is effectively a spot-on copy of the patented Sensipar® product with one exception, swapping L-HPC for crospovidone as a disintegrant:



APPX4499. Notably,

APPX11930. Watson cannot run from this record. Admissions in ANDA filings can be "[f]atal" to an equivalents defense, *Intendis GmbH v. Glenmark Pharm. Inc., USA*, 822 F.3d 1355, 1362 (Fed. Cir. 2016), yet the district court neglected to consider or misinterpreted both law and key evidence, including the ANDA, in reaching untenable conclusions.

Tellingly, despite near identity between the formulations, the district court reached the highly unusual conclusion that *none* of the function, way, or result prongs were satisfied, and neither was the insubstantial differences test. In other

words, according to the district court, an admitted disintegrant in a generic formulation designed to copy Sensipar® had *nothing* in common with that limitation in the patent covering Sensipar®. Watson points to this clean sweep as if it is a good thing, Watson Br. 34, but it actually lays bare the district court's flawed view of equivalents, which includes failing to hold Watson to its sworn statements to the FDA. The district court's determination was based on several clear legal errors and should be reversed.

A. The Court Should Vacate Because The District Court's Equivalents Analysis Was Erroneous.

As Amgen showed, the district court applied an improperly rigid legal standard for equivalents in at least two respects: (1) insisting on "particularized testimony" in a manner inconsistent with this Court's precedent, and (2) misapplying the function-way-result and insubstantial differences tests to credit irrelevant distinctions and ignore Watson's ANDA admissions bearing on equivalents. Amgen Br. 42-53. Watson seeks to bury these mistakes with the familiar theme about deference to the fact-finder while obfuscating an already-confused record, but that does not withstand scrutiny. A misapplication of law is a legal error, warranting reversal.

1. The District Court Misapplied This Court's Requirement For "Particularized Testimony."

The district court erred by misreading the law on "particularized" testimony in *AquaTex* to require Amgen's expert, Dr. Davies, to have testified differently. But *AquaTex* holds only that equivalents comparisons must be done limitation-by-limitation—*i.e.*, "particularized" by limitation—rather than as an overall comparison between the accused products and the claims as a whole—and Dr. Davies consistently focused on the disintegrant limitation in his testimony. Amgen Br. 44-45. Watson seems to agree, but then adds that "wholly conclusory" expert testimony is improper and accuses Amgen of "fail[ing]" to provide testimony on "*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." Watson Br. 23-24. But Dr. Davies did exactly what Watson said he did not:

- *Function.* Dr. Davies testified that like "the other super disintegrants" in the claim, L-HPC "break[s] up the formulation, releasing the small particles and granules [therein]. [redacted]" APPX3479. That says both "what" the function is and "why" the claimed disintegrants and L-HPC have substantially the same function.

- *Way.* Dr. Davies testified that L-HPC "has the same swelling characteristics as the other super disintegrants [claimed]. [L-HPC] rapidly swells." APPX3479. Dr. Davies further testified more generally that the claimed disintegrants "swell[] rapidly thereby promoting the wicking of the solution fluid into the product," APPX3445, and that L-HPC also "rapidly swell[s] and disrupt[s] the product." APPX3480. That says "what" the way is and "why" the claimed disintegrants and L-HPC work in substantially the same way.

- *Result.* Dr. Davies explained that the claimed disintegrants and L-HPC lead to rapid tablet disintegration and dissolution. APPX3606 ("L-HPC has similar disintegration capability to the other super disintegrants"). When asked whether L-HPC has slightly different disintegration results than the claimed disintegrants, moreover, Dr. Davies stated that "all [were] rapidly disintegrating," and that "collectively these super[] disintegrants, including L-HPC, disintegrate the tablet quickly, like a super disintegrant does." APPX3609-3611. That says "what" the result is and "why" the claimed disintegrants and L-HPC achieve substantially the same result.

As this shows, Dr. Davies' testimony on each prong of the function-way-result test is hardly "conclusory." The district court's demand for more was error. This *is* "particularized" testimony under *AquaTex*.

None of Watson's string-cited cases (Watson Br. 24) supports a different result. *Malta v. Schulmerich Carillons, Inc.*, involved a patent on handbell designs using "buttons" of differing hardness as striking surfaces to adjust the bell's volume. 952 F.2d 1320, 1321-22 (Fed. Cir. 1991). Expert testimony that the accused product's features simply "function[ed] like buttons" was too "offhand and conclusory." *Id.* at 1326-27. The problem in *Akzo Nobel Coatings, Inc. v. Dow Chemical Co.*, 811 F.3d 1334, 1343 (Fed. Cir. 2016) was that the expert "fail[ed] to articulate" which claim construction he used and described at a "broad [and] conclusory" level the similarity between the claimed and accused processes, rather than addressing whether or why the difference between the two—one process used accumulation and one did not—mattered. The expert testimony in Watson's two other cases was equally deficient. *See, e.g., Eastcott v. Hasselblad*

USA, Inc., 564 F. App'x 590, 595-96 (Fed. Cir. 2014) (expert "lists paragraphs that primarily recite the limitations … and then broadly states that the [accused] adapter contains these limitations"); *Tex. Instruments Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1567-68 (Fed. Cir. 1996) ("[T]estimony that the 'conductors' in the accused processes and the claimed processes were the 'same' and performed the 'same function' was merely generalized testimony as to overall similarity."). If anything, the contrast between the testimony in Watson's cited cases and Dr. Davies only underscores that his testimony was more than sufficient.

2. The District Court Did Not Apply The Correct Legal Standards For Equivalents.

The district court's equivalents analysis was also legally flawed when it came to articulating and applying the function-way-result[7] and insubstantial differences tests. Amgen Br. 46-51.[8] This Court has repeatedly held that equivalents "should not be the prisoner of a rigid formula," and that, when an accused product "chang[es] one ingredient of a claimed composition, it is appropriate for a court to consider … whether the changed ingredient has the same

[7] Watson's continued suggestion that there was something wrong with Amgen's invocation of the function-way-result test in chemical cases, Watson Br. 21, is incorrect. *See, e.g.*, *Intendis*, 822 F.3d at 1360-64.

[8] Watson alleges that Amgen added "new" theories related to these tests in post-trial briefing. Watson Br. 25. Because Watson (correctly) never actually argues that Amgen waived any equivalents arguments and admits that the district court considered these arguments, the Court can disregard these editorials.

purpose, quality, and function as the claimed ingredient." *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1579-80 (Fed. Cir. 1984). The purpose, quality, and function of Watson's disintegrant is the same as in the patent. The district court's contrary decision reflected an improperly "rigid formula" and turned on alleged points of distinction that missed the proverbial forest for the trees.

Function (tablet disintegration). The function of the claimed disintegrants is tablet disintegration. The question here is whether L-HPC as a disintegrant "performs substantially the same function." It does, by Watson's own representation to the FDA. [redacted] and Watson's expert admitted that "you can achieve disintegration with L-HPC just like you can with those [claimed] disintegrants." Amgen Br. 46 & n.6 (quoting APPX3894). That should have been the end of it. Watson's failure to acknowledge its own ANDA admissions and expert testimony in its response brief is telling.

Instead, Watson defends the district court's "function" analysis based on a supposed distinction between "superdisintegrants" and "disintegrants." Watson Br. 26-27. Even under the district court's differentiation between claimed "superdisintegrants" and L-HPC as a "disintegrant," however, they share substantially the same disintegrant function. Indeed, even Watson's cited literature

does not "distinguish[]" between superdisintegrants and disintegrants *as to their function*. *Id.* They all break up the tablet when it reaches the gut: "Disintegrants bring about tablet matrix break-up in an aqueous medium"—that is the function—"and are commonly classified further in literature as disintegrants and superdisintegrants." APPX11439 (cited at Watson Br. 27). This literature confirms that both share the same function.

To the extent that other disintegrants work faster than L-HPC does not change their substantial functional similarity with L-HPC. [redacted] underscores that there is no substantial difference between these disintegrants as to function. Otherwise, Watson would have had to significantly raise the amount of L-HPC to compensate. It did not. The district court's analysis simply does not hold together.[9]

Way (water uptake/swelling). The way the claimed disintegrants work is by water uptake and resulting swelling. The district court again focused on the wrong point of comparison and therefore failed to recognize that there was no genuine

[9] Watson's efforts to deflect the problem with the district court's analysis onto how Amgen "framed" the issue, and to accuse Amgen of "pivot[ing]" in its position are also baseless. Watson Br. 26-27. Amgen's arguments did not turn on the labels of "superdisintegrant" or "disintegrant," as Watson suggests, but on the actual function performed by the disintegrants.

dispute that L-HPC and the claimed disintegrants work "in 'substantially the same way.'" Amgen Br. 47-48. Namely, both parties' experts agreed that L-HPC and two listed disintegrants act through "swelling," and that alone should have been dispositive. *Id.*

Watson asserts incorrectly that the district court held "the opposite" because Amgen had not presented additional evidence "to corroborate Dr. Davies' testimony that the primary mechanism of action is swelling." Watson Br. 27-28. This is just another legal error. Nothing more was needed from Amgen, because equivalents can be proven through, among other things, "testimony of experts or others versed in the technology." *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 609 (1950). That is precisely what Amgen provided.

Moreover, Watson's own litigation statements make the parties' agreement on this point crystal clear. When discussing the claimed disintegrants sodium starch glycolate and croscarmellose sodium alongside L-HPC, for example, Watson's post-trial brief admitted that "all three excipients can work to disintegrate a tablet via swelling." APPX4636; *see also* APPX3879 (Watson expert testifying about claimed disintegrants and L-HPC all swelling). Thus, the district court erred in refusing to find that the claimed disintegrants and L-HPC work in "substantially the same way."

Watson next seeks to defend the district court's comparison of L-HPC and crospovidone as simply "resolv[ing]" a "dispute of fact," Watson Br. 28, but that is incorrect. As a legal matter, there is no support in this Court's case law for resting the "way" comparison on an excipient's "*primary* mechanism," as the district court did, especially where both sides agree that L-HPC and crospovidone both perform their disintegrant function in substantially the same way by involving swelling. Amgen Br. 47.

More fundamentally, however, and consistent with the legal errors that pervaded the equivalents analysis, the district court and Watson have too narrowly parsed mechanisms of action that are all synonymous with swelling—in other words, that all work in "substantially the same way." There is no dispute that L-HPC swells. APPX31. For its part, Watson highlights the district court's statement about a supposed lack of clarity in Dr. Davies' testimony about "wicking" by the claimed disintegrants, but the court's comment only shows it was confused. The fact that the claimed disintegrants "also encourage the wicking of water," Watson Br. 28, supports the opposite finding, *i.e.*, that the "way" prong has been satisfied because the wicking of water results in swelling. *See, e.g.*, APPX3445 (Dr. Davies); APPX32 n.9 (describing wicking as a process of liquid uptake). By the same token, the district court purported to differentiate the claimed crospovidone from L-HPC because crospovidone's "primary mechanism of action

is … the recovery of elastic energy of deformation." APPX31-32. But even Watson's expert agreed that this just means that the excipient is compressed during manufacture and then, upon reaching the liquid environment of the stomach, it regains or "recover[s]" its shape and expands to disintegrate. APPX3860. That expansion describes swelling by liquid uptake.

Watson closes its "way" discussion by invoking the narrow claiming and vitiation doctrines, Watson Br. 29-32, but the district court invoked neither in its decision as to Watson. APPX27-36. There are simply no findings from the district court to support Watson's assertions. This Court should not entertain them for the first time.

Moreover, Watson's arguments on both prongs of the narrow claiming doctrine are unsupported by the record. On the first prong, which asks whether the alleged equivalent had the same advantageous characteristics as the claimed compounds, Watson declares that "according to Amgen, L-HPC is 'a *worse* disintegrant than those listed in claim element (d).'" Watson Br. 30. False: Amgen's brief said that this was the counterintuitive position *of Watson's expert*. Amgen Br. 41. On the second prong, which asks about the inventors' knowledge of the alleged equivalent, Watson advances its own spin on the record, but none of this was even addressed in the district court decision.

Watson's claim vitiation argument is no better. According to Watson, applying the doctrine of equivalents would "vitiate" the Markush group limitation and "effectively change[] claim 1(d) into a 'comprising' claim." Watson Br. 31-32. After erroneously finding the Markush groups "closed" to unlisted binders or disintegrants, however, even the district court held that Amgen could "still rely on the doctrine of equivalents to prove infringement of an element containing a closed Markush group." APPX60-61. Watson's argument cannot be squared with that.

Result (Rapid release of active to treat disease). The result of using the claimed disintegrants is rapid release of the cinacalcet HCl active ingredient to treat disease. Again, [redacted]. Amgen Br. 48-49. The court erred in not crediting this evidence, and Watson's responses cannot run from that record.

Equivalents must be determined by comparing Watsons' disintegrant to what is claimed. *See, e.g.*, *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 812 (Fed. Cir. 2002). Yet Watson leans on the district court's decision to focus on a manufacturer's brochure, arguing that it was the only document whose formulations "made an apples-to-apples comparison of different disintegrants." Watson Br. 32-34. Wrong. That brochure described tablets *without* cinacalcet HCl—hardly an "apples-to-apples comparison" to the claimed invention. Amgen

Br. 48.[10] The brochure was not the "only piece of evidence" on this point, Watson Br. 33, and the district court was wrong to treat it as if it were.

The proper comparison of [redacted] to verify equivalents is found in Watson's own tests, but the district court ignored them on the theory that the tests involved "different formulations." Watson Br. 32-33 (citing APPX34 n.10). Watson [redacted] that literally met the claim (used each claimed excipient within the claimed amounts) [redacted] and showed the result was substantially the same. *That* is what mattered for equivalents.

[redacted]

[10] There was also expert testimony that this brochure showed substantially similar disintegration times for L-HPC and claimed disintegrants when analyzed correctly. APPX3606; APPX4867.

[redacted]

Watson argues that this all relates to "bioequivalence," and is therefore irrelevant to the doctrine of equivalents. Watson Br. 32. Nonsense. Amgen is not relying on bioequivalence in and of itself to prove equivalents. It is the underlying facts that are informative: [redacted]. APPX3430-3431 (Dr. Davies); *see also Intendis GmbH v. Glenmark Pharm. Ltd.*, 117 F. Supp. 3d 549, 576-77 (D. Del. 2015) (ANDA filer's "bioequivalence" representation to the FDA was evidence that substituted excipient achieved same active ingredient delivery "result" as claimed excipient under doctrine of equivalents).

Insubstantial Differences. Watson's defense of the district court's insubstantial differences analysis is about as conclusory as the district court's analysis itself. Watson Br. 34-36. Watson nowhere confronts the need for the differences that the district court focused on to "actually affect[] a[] property of the [composition] relevant to the claim at hand." *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1352 (Fed. Cir. 2003). Here, once again, the district court simply did not conduct a proper equivalents analysis or apply the correct legal standards because it made no such finding. Amgen Br. 49-51 (explaining why none of the cited differences was relevant to disintegrant properties). That is legal error.

Watson is similarly wrong to accuse Amgen of "overread[ing]" this Court's on-point decision in *UCB, Inc. v. Watson Laboratories Inc.*, 927 F.3d 1272 (Fed. Cir. 2019). Watson Br. 36. The Court there rested its decision on a point of law: the asserted differences need to "matter for how the claimed invention works." 927 F.3d at 1284. Watson declares that four structural "differences" between L-HPC and crospovidone "*do* matter." Watson Br. 36. But even that conclusory statement misses the point: the identified differences do not "matter" because they do not change "how the claimed invention works," do not "affect a property

relevant to the claim at hand," and are therefore legally irrelevant to the disintegrant limitation.[11]

With little to say on substance, Watson argues that Amgen "lacks an evidentiary basis" to show error in the district court's analysis because Dr. Davies focused on the function-way-result test. Watson Br. 34-36. Watson is mistaken. Watson's expert made the insubstantial differences test her lead argument on equivalents. Amgen thus explained, based on Watson's expert's concessions and Amgen's own expert testimony, that the alleged differences were *not* substantial. *See, e.g.*, APPX4867-4868. As discussed above, the district court failed to apply the relevant legal inquiry, and additional testimony demonstrated that there were no "substantial differences" on relevant properties. *See, e.g.*, APPX3479; APPX3609-3611; APPX3856-3857 (Watson expert testifying that shape affects manufacturing). Thus, there is an "evidentiary basis" for Amgen to attack that erroneous conclusion on appeal.

[11] To repeat briefly, disintegration necessarily occurs *after* the tablet is swallowed, and yet two of the four recited differences (physical shape and multi-functionality) allegedly impact manufacturing and binding properties, APPX35, which are relevant only *before* the tablet is taken and therefore irrelevant to disintegration. A third, about chemical structures, is meaningless, because even each of the claimed disintegrants have different "chemical structures," which is why they have different chemical names. The final one, related to potency differences, is negated by Watson's ability to substitute [redacted] L-HPC for cropovidone.

B. The Court Should Reject Watson's Alternative Prosecution History Estoppel Argument.

Facing numerous errors in the district court's equivalents analysis, Watson argues for affirmance on the alternative ground of prosecution history estoppel. Watson Br. 36-57. But, as Watson recognizes, the issue of prosecution history estoppel was not a basis for the district court's decision as to Watson; rather, it was briefed and argued in the related appeal, *Amgen Inc. v. Amneal Pharmaceuticals LLC,* Nos. 18-2414, 19-1086, with respect to a different defendant (Piramal) and a different equivalent (PGS) for a different limitation (binder). As Amgen explained there, the prosecution record taken as a whole shows the district court's estoppel finding was wrong. Whether or not that case is decided before this one, moreover, the Court need not and should not give creed to Watson's argument of the issue on appeal, especially where Watson admits that its arguments duplicate Piramal's.

In addition, Watson's argument appears to be that Amgen cannot assert equivalents as to L-HPC, but that is not a position the district court ever adopted. On the contrary, as the district court stated explicitly, "I have not decided the full scope of what Amgen surrendered through prosecution history estoppel, only that it surrendered as an equivalent the use of pregelatinized starch, in whole or in part, as a binder." APPX44. As the prosecution record shows, Amgen did not surrender any equivalents. But whatever the outcome in Appeal No. 18-2414, there is no reason to leap to a conclusion broader than the one the district court reached.

C. The Court Should Vacate Based On The District Court's Erroneous Claim Construction.

Amgen argued that the district court's claim construction errors provide an independent basis to vacate and remand for a reset. Amgen Br. 51-53. These points were also briefed and argued in Appeal No. 18-2414.

Watson argues that any claim construction error can be disregarded as "harmless" because the claim construction did not impact Watson. Watson Br. 57-59. Watson's brief, however, demonstrates why the last-minute claim construction infected Watson's case as much as any other defendant's. More specifically, Watson asserts that L-HPC is not equivalent to the listed disintegrants by arguing *about the scope of the claims* through discussions of the Markush groups, claim vitiation, and narrow claiming. *Id.* at 28-32. In short, Watson's own arguments show that a reversal on claim construction warrants a remand to revisit the infringement analysis as to Watson.

CONCLUSION

For the foregoing reasons, and those provided in Amgen's opening brief, the Court should vacate the district court's non-infringement judgment and direct it to enter the parties' consent judgment of infringement.

Date: November 25, 2019

Respectfully submitted,

By: /s/ Bradford J. Badke

Wendy A. Whiteford
Lois M. Kwasigroch
Eric M. Agovino
AMGEN, INC.
One Amgen Center Drive
Thousand Oaks, CA 91320
Telephone: (805) 447-0464

John D. Murnane
Joshua I. Rothman
Alicia A. Russo
VENABLE LLP
1290 Avenue of the Americas
New York, NY 10104-3800
Telephone: (212) 218-2100

Bradford J. Badke
Sona De
SIDLEY AUSTIN LLP
787 Seventh Avenue
New York, NY 10019
Telephone: (212) 839-5300

Ryan C. Morris
Joshua J. Fougere
Lauren Cranford Katzeff
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
Telephone: (202) 736-8000

Counsel for Plaintiff-Appellant Amgen, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on November 25, 2019, a true and correct copy of the foregoing was timely filed with the Clerk of the Court using the appellate CM/ECF system. I further certify that I caused a copy of the confidential version to be served on all parties by email at the email addresses listed below.

George C. Lombardi
Winston & Strawn LLP
35 West Wacker Drive
Chicago, IL 60601
GLombard@winston.com

/s/ Bradford J. Badke
Bradford J. Badke

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitations of Federal Rule of Appellate Procedure 32(a)(7)(B) and the Rules of this Court, because it contains 6,981 words (as determined by the Microsoft Word word-processing system used to prepare the brief), excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

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/s/ Bradford J. Badke

Bradford J. Badke
SIDLEY AUSTIN LLP
787 Seventh Avenue
New York, NY 10019
(212) 839-5300

Counsel for Appellant
Amgen, Inc.

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/s/ Bradford J. Badke
(Signature of Attorney)

Bradford J. Badke
(Name of Attorney)

Plaintiff-Appellant
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(Date)