Nos. 18-1551, 18-1552

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

AMGEN INC., AMGEN MANUFACTURING, LIMITED,
Plaintiffs-Appellants,
v.
SANDOZ INC., SANDOZ INTERNATIONAL GMBH, SANDOZ GMBH,
Defendants-Appellees.

AMGEN INC., AMGEN MANUFACTURING, LIMITED,
Plaintiffs-Appellants,
v.
SANDOZ INC., SANDOZ INTERNATIONAL GMBH, SANDOZ GMBH, LEK PHARMACEUTICALS, D.D.,
Defendants-Appellees.

Appeals from the United States District Court for the Northern District of California, case nos. 3:14-cv-04741-RS, 3:16-cv-02581-RS, Hon. Richard Seeborg

---

APPELLEES' RESPONSE TO PETITION FOR REHEARING EN BANC

ERIK J. OLSON
ERIC C. PAI
MORRISON & FOERSTER LLP
755 Page Mill Road
Palo Alto, CA 94304
Telephone: (650) 813-5600

DEANNE E. MAYNARD
BRIAN R. MATSUI
BRYAN J. LEITCH
MORRISON & FOERSTER LLP
2000 Pennsylvania Avenue, N.W.
Washington, D.C. 20006
Telephone: (202) 887-8740
DMaynard@mofo.com

Counsel for Appellees

JULY 29, 2019

CERTIFICATE OF INTEREST

Counsel for defendants-appellees Sandoz Inc., Sandoz International GmbH, Sandoz GmbH, Lek Pharmaceuticals d.d. certifies the following:

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

Sandoz Inc., Sandoz International GmbH, Sandoz GmbH, Lek Pharmaceuticals d.d.

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

N/A

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

Sandoz Inc., Sandoz International GmbH, Sandoz GmbH, and Lek Pharmaceuticals d.d. are indirect subsidiaries of Novartis AG, which trades on the SIX Swiss Exchange under the ticker symbol NOVN and whose American Depository Shares are publicly traded on the New York Stock Exchange under the ticker symbol NVS.

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

MORRISON & FOERSTER LLP (including lawyers no longer with the firm): Rachel Krevans, David C. Doyle, Grant J. Esposito, Anders T. Aannestad, Marc A. Hearron, Stephen D. Keane, Joseph R. Palmore, Julie Y. Park, Lena H. Hughes, Brian M. Kramer, Jessica A. Roberts, James R. Hancock, Nicholas E. Ham, Teresa A. MacLean.

KIRKLAND & ELLIS LLP: James F. Hurst, Michael D. Shumsky, John K. Crisham, Reid P. Huefner, James W. Beard, Jeanna M. Wacker, Cristina Q. Almendarez.

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:

None.

Dated: July 29, 2019 /s/ Deanne E. Maynard

TABLE OF CONTENTS

CERTIFICATE OF INTEREST i

TABLE OF AUTHORITIES iv

INTRODUCTION 1

BACKGROUND 2

A. This Court's (Unchallenged) Affirmance Of The District Court's Claim Construction Of Claim 7 Of The '878 Patent 3

B. This Court's Affirmance Of The District Court's Noninfringement Ruling 5

REASONS THE PETITION SHOULD BE DENIED 8

A. The Court Correctly Rejected Amgen's Equivalents Argument Applying Well-Settled Law, Not Any New "Exceptional Case" Standard 8

B. Amgen's Fact-Specific Arguments Cannot Justify En Banc Relitigation Of The Court's Correct Ruling 12

CONCLUSION 16

TABLE OF AUTHORITIES

Cases

Advanced Steel Recovery, LLC v. X-Body Equipment, Inc.,
808 F.3d 1313 (Fed. Cir. 2015) 9, 11

Akzo Nobel Coatings, Inc. v. Dow Chemical Co.,
811 F.3d 1334 (Fed. Cir. 2016) 14

Apple Inc. v. Samsung Electronics Co., Ltd.,
809 F.3d 633 (Fed. Cir. 2015) 12

AquaTex Indus., Inc. v. Techniche Sols.,
479 F.3d 1320 (Fed. Cir. 2007) 11

Augme Technologies, Inc. v. Yahoo! Inc.,
755 F.3d 1326 (Fed. Cir. 2014) 14

Cambrian Science Corp. v. Cox Communications, Inc.,
617 F. App'x 989 (Fed. Cir. 2015) 14

Continental Paper Bag v. Eastern Paper Bag Co.,
210 U.S. 405 (1908).....15

Duncan Parking Techs., Inc. v. IPS Grp., Inc.,
914 F.3d 1347 (Fed. Cir. 2019) 7, 9

Gemalto S.A. v. HTC Corp.,
754 F.3d 1364 (Fed. Cir. 2014) 14

Graver Tank & Mfg. Co. v. Linde Air Prods. Co.,
339 U.S. 605 (1950).....9

Mformation Technologies, Inc. v. Research in Motion Ltd.,
764 F.3d 1392 (Fed. Cir. 2014) 4

Michelotti v. United States,
557 F. App'x 956 (Fed. Cir. 2014) 12

Perkin–Elmer Corp. v. Westinghouse Elec. Corp.,
822 F.2d 1528 (Fed. Cir. 1987) 10

Rembrandt Patent Innovations, LLC v. Apple, Inc.,
716 F. App'x 965 (Fed. Cir. 2017) 14

SmithKline Beecham Corp. v. Apotex Corp.,
439 F.3d 1312 (Fed. Cir. 2006) 15

Warner-Jenkinson Co. v. Hilton Davis Chem. Co.,
520 U.S. 17 (1997) 9, 11, 15, 16

INTRODUCTION

Amgen's petition for rehearing en banc depends on a misreading of this Court's decision. Taking six words out of context, Amgen argues that this Court adopted a new "exceptional case" standard for the doctrine of equivalents. Amgen speculates that this supposed new standard might be like the "exceptional case" requirement in Section 285 and that, if so, it is inconsistent with binding precedent.

But the Court neither adopted nor applied an "exceptional case" standard. Its doctrine of equivalents ruling broke no new ground. Applying settled law to the undisputed facts of this case, it correctly held that Amgen's equivalents argument fails because Sandoz's accused "purification process works in a substantially different way" from the asserted claim. Op. 11. For that reason, Amgen can only speculate about what an "exceptional case" standard might require or how one might be applied in future cases. This Court said nothing about that because it adopted no such standard. Without the six words Amgen highlights, the reasoning and outcome of the Court's decision would remain the same; the only change would be in this observation: "The doctrine of equivalents ~~applies only in exceptional cases and~~ is not 'simply the second prong of every infringement charge, regularly available to extend protection beyond the scope of the claims.'" Op. 11 (strikeouts added).

The remaining few pages of Amgen's petition merely reargue the merits. Such fact-specific arguments cannot justify en banc rehearing. In any event,

Amgen's petition cannot overcome the problems that doomed its equivalents argument in both this Court and the district court. As Sandoz explained, "Amgen failed to provide any factual support for its equivalency argument before the district court." Op. 11. This Court "agree[d] with Sandoz and concluded that the district court correctly held" Sandoz entitled to summary judgment. Op. 11. That conclusion is correct: Amgen put forth nothing but a conclusory statement from its expert that Sandoz's accused process, if not literally the same, was at least equivalent to the claimed method. Amgen's expert backtracked even from that bald statement, saying at his deposition only that Sandoz's process "might" be equivalent. Appx3943.

BACKGROUND

In this Biologics Price Competition and Innovation Act action, Amgen asserted, as relevant here, U.S. Patent No. 8,940,878 ("'878 patent"), accusing of infringement a part of Sandoz's protein purification process used in the manufacture of the biosimilars filgrastim and pegfilgrastim. Filgrastim and pegfilgrastim are recombinant proteins that are genetically engineered using techniques that have been around since the 1980s. Appx34. Once a protein has been genetically produced, it must be purified to remove contaminants from manufacturing. Appx34-35.

A. This Court's (Unchallenged) Affirmance Of The District Court's Claim Construction Of Claim 7 Of The '878 Patent

The '878 patent claims methods of protein purification by adsorbent chromatography, a well-known method that involves separating the components of a solution using a stationary separation matrix, typically small beads that bind to some but not other substances. Op. 4; Appx2728. The claimed methods cover capturing the protein, washing away contaminants, and then releasing the protein—in three separate steps, using three separate solutions. Op. 10-11.

Amgen raised only claim 7 on appeal. The last three steps (e) through (g) are relevant here:

> 7. A method of purifying a protein expressed in a non-native limited solubility form in a non-mammalian expression system comprising:
>
> (a) expressing a protein in a non-native limited solubility form in a non-mammalian cell;
>
> (b) lysing a non-mammalian cell;
>
> (c) solubilizing the expressed protein in a solubilization solution comprising one or more of the following:
>
> (i) a denaturant;
>
> (ii) a reductant; and
>
> (iii) a surfactant;
>
> (d) forming a refold solution comprising the solubilization solution and a refold buffer, the refold buffer comprising one or more of the following:

> (i) a denaturant;
>
> (ii) an aggregation suppressor;
>
> (iii) a protein stabilizer; and
>
> (iv) a redox component;
>
> (e) directly applying the refold solution to a separation matrix under conditions suitable for the protein to associate with the matrix;
>
> (f) washing the separation matrix; and
>
> (g) eluting the protein from the separation matrix, wherein the separation matrix is a non-affinity resin selected from the group consisting of ion exchange, mixed mode, and a hydrophobic interaction resin.

Appx77 (col.22:3-28).

In a holding not challenged by Amgen's en banc petition, this Court "conclude[d] that the district court correctly construed the washing and eluting limitations as separate process steps performed by adding discrete solutions to the separation matrix in sequence." Op. 10. The Court reasoned that "the claim language logically requires that the process steps, lettered (a) through (g), be performed in sequence." Op. 9 (citing *Mformation Technologies, Inc. v. Research in Motion Ltd.*, 764 F.3d 1392, 1398–1400 (Fed. Cir. 2014)). "For example, expressing the protein in a non-mammalian cell (limitation (a)) obviously must occur before the step of lysing that cell (limitation (b))." Op. 9. "There is no indication on the face of claim 7 that the washing and eluting steps are any different."

Op. 9. In addition, "washing and eluting are consistently described in the specification as separate steps performed by different solutions." Op. 9 (citing '878 patent at Appx71, Appx75 (col.10:44-46, col.10:33-34, col.17:46-21:42)). The Court thus rejected Amgen's argument that "the 'washing' and 'eluting' limitations describe functions, rather than actual process steps." Op. 9.

B. This Court's Affirmance Of The District Court's Noninfringement Ruling

Sandoz's process. When manufacturing filgrastim and pegfilgrastim, Sandoz uses several separate purification processes. Amgen accused only one of those processes. The undisputed record shows that, unlike Amgen's three-step and three-solution method, the accused process involves one continuous step, with no separate washing or eluting steps or solutions. Op. 10-11.

In the accused process, Sandoz removes a particular contaminant that interferes with Sandoz's later purification processes from the refold solution containing filgrastim. The contaminant binds to the separation matrix. Appx3975-3976. The rest of the refold solution, including the filgrastim and other contaminants, are "not retained on the column" holding the separation matrix. Appx3975-3976. Rather, the remaining solution exits the column and is collected. Appx3975-3976. At the end of this step, the separation matrix containing the bound contaminant is discarded. Appx3975-3976; Appx3803-3804.

Literal infringement. The district court held that Sandoz's process did not literally infringe claim 7. On appeal, Amgen challenged only the district court's claim construction; it did not challenge literal infringement under the district court's (and now this Court's) construction. Nor could it. Claim 7 requires three steps and three distinct solutions—the refold, washing, and eluting solutions. "Since there is no dispute that Sandoz's current process only uses one step and one solution, it cannot literally infringe claim 7." Op 10.

Doctrine of equivalents. As to equivalents, Amgen admitted in the district court that it had presented only two paragraphs of expert testimony on its doctrine-of-equivalents theory. Appx4863-4864. Amgen's expert conclusorily asserted that Sandoz's continuous application of refold solution could perform the same function as the separate refold, washing, and eluting solutions "in the same way" to achieve the same result. Appx5271-5272; Appx5265-5266. When pressed at his deposition about this testimony, Amgen's expert backtracked: "I think it infringes literally and *might* also infringe equivalently." Appx3943 (emphasis added). In district court, Amgen asserted that its lack of equivalents evidence did not matter because the focus of its case was literal infringement. Appx4863-4864. The district court granted summary judgment against Amgen. Appx12-13.

This Court unanimously affirmed. Contrary to Amgen's assertion in its en banc petition, the Court did not "recognize[]" that "Amgen presented *evidence*" of

equivalents. Pet. 11 (emphasis added). The Court noted only that "Amgen *argue[d]* that Sandoz's one-step, one-solution process is insubstantially different." Op. 10 (emphasis added). And the Court "agree[d] with Sandoz" "that Amgen failed to provide any factual support for its equivalency argument before the district court." Op. 11. It "conclude[d] that the district court correctly held that Sandoz's one-step, one-solution process does not function in the same way as the claimed process." Op. 11.

The Court held that Amgen's equivalents argument "seeks to cover, one way or another, any method of using a salt concentration gradient in an adsorbent matrix to separate a protein of interest from other solutes." Op. 11. The Court explained that "claim 7 is not that broad." Op. 11. "[T]he claim recites a sequence of steps requiring application of 'refolding,' 'washing,' and 'eluting' solutions, and our precedent prohibits us from overriding the natural language of claim 7 to extend these limitations to cover nearly any type of adsorbent chromatographic separation." Op. 11. The Court went on to observe that the doctrine of equivalents cannot be used to eliminate limitations and expand the scope of the claims:

> The doctrine of equivalents applies only in exceptional cases and is not "simply the second prong of every infringement charge, regularly available to extend protection beyond the scope of the claims." *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538 (Fed. Cir. 1991); *see also Duncan Parking Techs., Inc. v. IPS Grp., Inc.*, 914 F.3d 1347, 1362 (Fed. Cir. 2019) ("[T]he doctrine of equivalents cannot be used to effectively read

> out a claim limitation . . . because the public has a right to rely on the language of patent claims." (citing *Primos, Inc. v. Hunter's Specialties, Inc.*, 451 F.3d 841, 850 (Fed. Cir. 2006))).

Op. 11. The Court concluded "that Sandoz does not infringe claim 7 under the doctrine of equivalents because its one-step, one-solution purification process works in a substantially different way from the claimed three-step, three-solution process." Op. 11.

REASONS THE PETITION SHOULD BE DENIED

A. The Court Correctly Rejected Amgen's Equivalents Argument Applying Well-Settled Law, Not Any New "Exceptional Case" Standard

Amgen bases its en banc petition on a false premise—that the Court imposed a new "exceptional case" standard. Seizing on just six words, Amgen argues that this supposed "new rule" "represents a profound change in the law that appears to impose an equitable standard explicitly rejected by the Supreme Court." Pet. 3.

The fatal flaw in Amgen's argument is that the Court neither created nor applied an "exceptional case" standard. Applying the familiar function-way-result test, the Court held that "Sandoz's one-step, one-solution purification process works in a substantially different way from the claimed three-step, three-solution process." Op. 11. As Amgen no longer contests, claim 7 requires the application of three separate solutions—the refold, washing, and eluting solutions—in three distinct steps. Op. 9; *supra* pp. 4-5. But Sandoz's accused process works an entirely

different way; it uses only one step and one solution. Op. 11. Based on these differences, the Court "agree[d] with Sandoz" that the undisputed evidence showed that the single step and single solution in Sandoz's accused process "accomplishes purification in a different way" from the three distinct steps and three discrete solutions in claim 7. Op. 11.

This conclusion reflects a straightforward, fact-specific application of the Supreme Court's and this Court's settled law to the undisputed facts. "Under the doctrine of equivalents, a product or process that does not literally infringe a patent claim may nevertheless be held to infringe 'if it performs substantially the same function in substantially the same way to obtain the same result.'" *Duncan*, 914 F.3d at 1362 (quoting *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1950)). But an equivalents case fails if the function, way, or result is not substantially the same. When a patentee fails to meet any one of these three requirements, "'district courts are obliged to grant partial or complete summary judgment.'" *Advanced Steel Recovery, LLC v. X-Body Equipment, Inc.*, 808 F.3d 1313, 1319 (Fed. Cir. 2015) (quoting *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39 n.8 (1997)). "That a claimed invention and an accused device may perform substantially the same function and may achieve the same result will not make the latter an infringement under the doctrine of equivalents where it performs the function and achieves the result in a substantially different way." *Id.*

at 1320 (quoting *Perkin–Elmer Corp. v. Westinghouse Elec. Corp.*, 822 F.2d 1528, 1532 n.6 (Fed. Cir. 1987)). Thus, the substantial differences in the way Sandoz's process works defeats equivalents here. That is what the Court held. Op. 10-11.

Nothing about the Court's decision broke the new ground imagined by Amgen's petition—as Amgen essentially acknowledges by providing only speculation as to how an "exceptional case" standard might be inconsistent with precedent "*if*" the Court meant this or "*if*" the Court meant that. Pet. 4, 7, 9 (emphasis added). Contrary to Amgen's hypothetical, the Court engaged in no "consideration of the equities." Pet. 4. It never suggested that Amgen's equivalents case had to "stand[] out from the others in terms of its substantive strength" (Pet. 7) nor that Amgen's patent claim had to be "especially inventive" (Pet. 9). Rather, the Court rejected Amgen's equivalents argument because Amgen failed to show that Sandoz's accused process works in substantially the same way as the claimed method. Op. 10-11.

Amgen complains that the decisions cited by the Court—*London*, *Duncan*, and *Primos*—"do not provide the necessary support for" an "exceptional case" standard. Pet. 9-10. That too confirms the Court adopted no such rule. Amgen also notes that the decision in *London* stated that the doctrine of equivalents is an "equitable doctrine," which the Supreme Court rejected in *Warner-Jenkinson*. Pet. 10-11. But the Court here never cited *London* for that proposition. And the

Court's accompanying reliance (Op. 11) on *Duncan* and *Primos*, both subsequent to *Warner-Jenkinson*, debunks Amgen's suggestion that the Court relied on overruled law.

Instead, the Court relied on *London*, *Duncan*, and *Primos* for the proposition that the doctrine of equivalents cannot be used to eliminate a claim limitation and expand the scope of the claims. Op. 11. Amgen rightly never suggests that proposition misstates the law. As the Supreme Court reiterated in *Warner-Jenkinson*, "[i]t is important to ensure that the application of the doctrine, even as to an individual element, is not allowed such broad play as to effectively eliminate that element in its entirety." 520 U.S. at 29. A patentee thus must "provide particularized testimony and linking argument" on a limitation-by-limitation basis to prove infringement by equivalents. *Advanced Steel*, 808 F.3d at 1319 (quoting *AquaTex Indus., Inc. v. Techniche Sols.*, 479 F.3d 1320, 1328 (Fed. Cir. 2007)).

At bottom, Amgen hypothesizes a new "exceptional case" rule based on misreading six words in the Court's decision and then imagines "significant harm" from that fiction. Pet. 14-16. But the decision creates no "inflexible," "new rule" (Pet. 14) nor raises any issue as to "who decides infringement under the doctrine of equivalents" (Pet. 16). If others in future cases attempt to take those six words out of context, the Court can address it at that time.

In the alternative, the Court could amend its opinion while leaving the judgment the same and deny rehearing, as it has done in other cases. *See* Order Pet. Rehearing, *Apple Inc. v. Samsung Electronics Co., Ltd.*, 809 F.3d 633 (Fed. Cir. Dec. 16, 2015) (No. 14-1802) ECF No. 152; Order Pet. Rehearing, *Michelotti v. United States*, 557 F. App'x 956 (Fed. Cir. March 3, 2014), (No. 13-5131) ECF No. 21. Amgen's alleged concerns could be negated by striking six words from the following sentence: "The doctrine of equivalents ~~applies only in exceptional cases and~~ is not 'simply the second prong of every infringement charge, regularly available to extend protection beyond the scope of the claims.'" Op. 11 (strikeouts added). With such an amendment, the rationale of the decision would equally support the Court's noninfringement judgment.

B. Amgen's Fact-Specific Arguments Cannot Justify En Banc Relitigation Of The Court's Correct Ruling

In the petition's remaining several pages, Amgen reargues the merits of its equivalents theory. Pet. 11-14. Such fact-specific arguments cannot justify en banc review. In any event, Amgen again bases its arguments on a fallacy. Amgen criticizes the Court for supposedly "recogniz[ing]" that "Amgen presented *evidence* that 'Sandoz's one-step, one-solution process is insubstantially different'" but then "did not address this evidence." Pet. 11-12; Pet. 11 (faulting the Court for not "considering the evidence Amgen presented"). But the Court never "recognized" any such evidence. It stated only that "Amgen *argues* that Sandoz's one-step, one-

solution process is insubstantially different" from claim 7's process. Op. 10 (emphasis added).

Amgen presented no such evidence for the Court to "recognize." This Court "agree[d] with Sandoz" that "Amgen failed to provide any factual support for its equivalency argument before the district court." Op. 11. For good reason: the sum total of Amgen's "evidence" was its expert's conclusory statement that even if "the solution applied to the separation matrix must be something other than the refold solution itself, I nevertheless am of the opinion that 'washing the separation matrix'" and "'eluting protein from the separation matrix'" are "met equivalently." Appx5265-5266; Appx5271. He offered no justification for this "opinion." He provided a three-sentence paragraph merely parroting the legal standard: the refold solution could perform "substantially the same function" as separate washing and eluting solutions "in the same way" to "achieve substantially the same, if not the same, result." Appx5271-5272; Appx5265-5266. That was it; nothing more.[1]

Indeed, in his deposition, Amgen's expert could not explain why the differences are insubstantial. Appx3942-3946. He instead retreated to his literal infringement theories: "I don't see any elements of the claim as constructed that are not present in the Sandoz process." Appx3942. When pressed, he said, "I think it

[1] Amgen's brief in this Court (at 52) cited both its expert's report and his summary judgment declaration, but those were word-for-word identical. *Compare* Appx5265-5266, *and* Appx5271-5272, *with* Appx4943-4944, *and* Appx4948-4949.

infringes literally and *might* also infringe equivalently." Appx3943 (emphasis added).

Consistent with precedent, the panel correctly rejected this as insufficient. This Court repeatedly has held that "[g]eneralized testimony as to the overall similarity between the claims and the accused infringer's product or process will not suffice." *Gemalto S.A. v. HTC Corp.,* 754 F.3d 1364, 1374 (Fed. Cir. 2014). Amgen needed more than "conclusory" expert testimony "stating only that the product would 'operate the same,' 'perform [the functions described in the patent] in essentially the same way,' and 'would [produce] the same result.'" *Augme Technologies, Inc. v. Yahoo! Inc.*, 755 F.3d 1326, 1336 (Fed. Cir. 2014); *see Akzo Nobel Coatings, Inc. v. Dow Chemical Co.*, 811 F.3d 1334, 1343 (Fed. Cir. 2016) (rejecting expert's equivalents testimony as "broad and scant" and fails "to articulate how [the] accused process operates in substantially the same way"); *Rembrandt Patent Innovations, LLC v. Apple, Inc*., 716 F. App'x 965, 977 (Fed. Cir. 2017) (holding that "conclusory [expert] testimony … on the 'way' prong is insufficient to create a genuine issue of material fact for trial regarding infringement by equivalents"); *Cambrian Science Corp. v. Cox Communications, Inc.*, 617 F. App'x 989, 994 (Fed. Cir. 2015) (rejecting equivalents testimony that merely states that "if literal infringement is not met," then "limitation is met under the doctrine of

equivalents because any differences between the structure and the claim limitations are insubstantial").

For the first time, Amgen's petition argues that equivalents only needs to be proven as to the claimed "point of novelty" or "essence of the invention"—not to other, less important elements. Pet. 12-13 (quoting *Continental Paper Bag v. Eastern Paper Bag Co.*, 210 U.S. 405, 421 (1908)). Amgen forfeited that argument by not raising it previously. *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1319 (Fed. Cir. 2006) ("[A]rguments not raised in the opening brief are waived."). Such a newfound argument could not justify rehearing in any event because the Court's decision says nothing about the "point of novelty" or "essence of the invention"—no doubt because Amgen never raised it.

Regardless, Amgen's argument that there is a lower burden to show equivalents for purportedly less important limitations fails for two additional reasons. First, Amgen bases that argument solely on *Continental Paper Bag*. Pet. 13. But nothing in that decision limits equivalents to the "essence of the invention" or holds that other elements matter less. Rather, the Supreme Court merely held that the scope of that claim, and thus its equivalents, did not exclude "the very essence of the invention." *Continental Paper Bag*, 210 U.S. at 422. Second, Amgen's theory that purportedly less important elements do not matter is contradicted by *Warner-Jenkinson*, which holds that "[e]ach element contained in a

patent claim is deemed material to defining the scope of the patented invention, and thus the doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole." 520 U.S. at 29.

CONCLUSION

Rehearing should be denied or, in the alternative, denied with an amendment to the Court's opinion to strike the words "applies only in exceptional cases and", with the Court's opinion and judgment otherwise remaining the same.

Dated: July 29, 2019

Respectfully submitted,

/s/ Deanne E. Maynard

DEANNE E. MAYNARD
BRIAN R. MATSUI
BRYAN J. LEITCH
MORRISON & FOERSTER LLP
2000 Pennsylvania Avenue N.W.
Washington, D.C. 20006
Telephone: (202) 887-8740
DMaynard@mofo.com

ERIK J. OLSON
ERIC C. PAI
MORRISON & FOERSTER LLP
755 Page Mill Road
Palo Alto, CA 94304
Telephone: (650) 813-5600

Counsel for Appellees

CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the type-volume limitation of Fed. Cir. R. 35(e)(4) and Fed. Cir. R. 40(d) because it contains 3,450 words excluding the parts of the response exempted by Fed. Cir. R. 35(c)(2).

This response complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this response has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point Times New Roman font.

Dated: July 29, 2019

/s/ Deanne E. Maynard
Deanne E. Maynard

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the CM/ECF system on July 29, 2019.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

Dated: July 29, 2019

/s/ Deanne E. Maynard
Deanne E. Maynard

dc-1104482