Appeal Nos. 2018-1551, 2018-1552

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.

Appeal from the United States District Court for the Northern District of California in No. 3:14-cv-04741-RS, Judge Richard Seeborg

AMGEN INC., AMGEN MANUFACTURING, LIMITED,

Plaintiffs-Appellants,

– v. –

SANDOZ INC., SANDOZ INTERNATIONAL GMBH, SANDOZ GMBH, LEK PHARMACEUTICALS, D.D.,

Defendants-Appellees.

Appeal from the United States District Court for the Northern District of California in No. 3:16-cv-02581-RS, Judge Richard Seeborg

AMGEN'S PETITION FOR REHEARING *EN BANC*

(For Appearances See Inside Cover)

June 7, 2019

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CERTIFICATE OF INTEREST

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

   AMGEN INC. and AMGEN MANUFACTURING, LIMITED

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

   AMGEN INC. and AMGEN MANUFACTURING, LIMITED

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

   AMGEN INC.

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

   SIDLEY AUSTIN LLP: Vernon M. Winters and Sue Wang, and Alexander David Baxter who is no longer with the firm; PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP: Stephen Maniscalco, Arielle Linsey, Michael T. Wu, and Ana J. Friedman who are each no longer with the firm.

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

   Amgen Inc., et al. v. Mylan Inc., et al., No. 2:17-cv-01235-MRH (W.D. Pa.). In an abundance of caution, Appellants also identify *Amgen Inc., et al. v. Hospira, Inc., et al.*, No. 1:18-cv-01064-CFC (D. Del.). The parties in that case have disputed the meaning of "washing" and "eluting" in U.S. Patent No. 9,643,997. The '997 Patent is related to U.S. Patent No. 8,940,878, which is at issue in this appeal.

Dated: June 7, 2019

Nicholas Groombridge

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RULE 35(b) STATEMENT

Based on my professional judgment, I believe the panel decision is contrary to the following decisions of the Supreme Court of the United States: *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002); *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17 (1997); and *Graver Tank & Manufacturing Co. v. Linde Air Products Co.*, 339 U.S. 605 (1950).

This appeal also requires an answer to the following precedent-setting question of exceptional importance: Whether infringement under the doctrine of equivalents applies "only in exceptional cases."

Nicholas Groombridge
Principal Attorney for Plaintiffs-Appellants

INTRODUCTION

Amgen respectfully submits that *en banc* review is warranted because a panel of this Court has established a bright-line rule that "[t]he doctrine of equivalents applies only in exceptional cases," which it then applied to "[a]ccordingly" find that the district court was correct to grant summary judgment of no infringement under the doctrine of equivalents. Slip op. at 11. Under the panel's rule, where there is no literal infringement, there can be no infringement under the doctrine of equivalents unless the case is "exceptional," a term that the panel did not define. Such a rule is contrary to Supreme Court precedent and this Court's precedent. Under the correct standard for proving infringement under the doctrine of equivalents, the district court's grant of summary judgment should be reversed.

The panel decision effects a profound change in the law, as commentators were swift to observe after the decision issued. *See, e.g.*, Dennis Crouch, *Federal Circuit: "The Doctrine of Equivalents Applies ONLY in Exceptional Cases"*, PATENTLYO (May 8, 2019) (panel decision "seems to be a major step without precedential backing"); Stephen Rabinowitz and Robert Rhoad, *Federal Circuit Panel Describes the Doctrine of Equivalents as Applying "Only in Exceptional Cases"*, JD SUPRA (May 21, 2019) ("[T]he panel's narrow application of the

doctrine of equivalents illustrates the unsettled nature of this doctrine in Federal Circuit precedent.").

In addition, the panel's retroactive application of this new rigid standard requiring proof of "exceptionality" diminishes and in many cases may destroy the value of existing patent claims. The panel's holding thus inflicts significant harm on industries that depend heavily on their investments in patented inventions based on a stable interpretation of the patent laws.

ARGUMENT FOR REHEARING *EN BANC*

I. The Panel's Holding That the Doctrine of Equivalents Applies "Only in Exceptional Cases" is Contrary to Supreme Court Precedent and this Court's Precedent

The panel's new rule—requiring that the doctrine of equivalents apply "only in exceptional cases"—represents a profound change in the law that appears to impose an equitable standard explicitly rejected by the Supreme Court.

The panel decision raises the question: what is an exceptional case that warrants application of the doctrine of equivalents to reach a finding of infringement? The concept of "exceptional cases" does not exist in a vacuum; it has meaning in the law. *See, e.g.*, *Kaw Nation v. Norton,* 405 F.3d 1317, 1323-24 (Fed. Cir. 2005); *Bayer CropScience AG v. Dow AgroSciences LLC*, 851 F.3d 1302, 1306 (Fed. Cir. 2017) (courts use a "holistic and equitable approach" to determine whether a case is "exceptional" under section 285); *Mathis v. Spears,*

857 F.2d 749, 754 (Fed. Cir. 1988) (courts use their "inherent equitable power . . . in determining the level of exceptionality" under section 285); *see also Octane Fitness, LLC v. Icon Health & Fitness, Inc.*, 572 U.S. 545, 554 (2014) (exceptionality means a case that "stand[s] out from the others with respect to the substantive strength of a party's litigating position (considering both the governing law and the facts of the case)").

First, if the "exceptional case" standard called for by the panel decision is to be determined from a consideration of the equities, this is contrary to Supreme Court precedent. Following this Court's decision in *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538 (Fed. Cir. 1991)—a case the panel cited here, slip op. at 11—courts considered the equities in assessing infringement under the doctrine of equivalents. *See, e.g.*, *Beraha v. C.R. Bard, Inc*., 870 F. Supp. 1085, 1091 (N.D. Ga. 1994) (considering whether there are "exceptional circumstances which justify imposing an equitable remedy"), *aff'd* 64 F.3d 678 (Fed. Cir. 1995) (Rule 36). Since then, however, the Supreme Court rejected the notion that infringement under the doctrine of equivalents requires consideration of the equities:

> Relying on *Graver Tank*'s references to the problem of an "unscrupulous copyist" and "piracy," 339 U.S., at 607, 70 S.Ct., at 855–856, petitioner would require judicial exploration of the equities of a case before allowing application of the doctrine of equivalents. To be sure, *Graver Tank* refers to the prevention of copying and piracy when describing the benefits of the doctrine of equivalents. That the doctrine produces such benefits, however, does not mean that

> its application is limited only to cases where those particular benefits are obtained.

Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 34 (1997).

That the doctrine of equivalents is available in all cases and assessed without regard to the equities is consistent with the past 150 years of Supreme Court precedent. The Supreme Court first adopted the doctrine of equivalents in *Winans v. Denmead*, 56 U.S. (15 How.) 330 (1854), stating that "[t]he exclusive right to the thing patented is not secured, if the public are at liberty to make substantial copies of it, varying its form or proportions." *Id.* at 343. In subsequent cases, the Supreme Court set forth a test for determining infringement under the doctrine of equivalents that does not involve consideration of the equities. For example, in *Seymour v. Osborne*, the Supreme Court held that "*[b]onâ fide* inventors of a combination are as much entitled to suppress every other combination of the same ingredients to produce the same result, not substantially different from what they have invented and caused to be patented, as any other class of inventors." 78 U.S. 516, 556 (1870). The Supreme Court noted that, "[p]atentees, therefore, are entitled in all cases to invoke to some extent the doctrine of equivalents." *Id.* at 555.

More recently, the Supreme Court has reaffirmed the continued vitality of the doctrine of equivalents, and articulated a flexible test for assessing infringement under the doctrine of equivalents without requiring consideration of

the equities. The Supreme Court stated in *Graver Tank* & *Manufacturing Co. v. Linde Air Products Co.*:

> Outright and forthright duplication is a dull and very rare type of infringement. . . . Originating almost a century ago in the case of *Winans v. Denmead*, 15 How. 330, 14 L.Ed. 717, [the doctrine of equivalents] has been consistently applied by this Court and the lower federal courts, and continues today ready and available for utilization when the proper circumstances for its application arise. . . .
>
> What constitutes equivalency must be determined against the context of the patent, the prior art, and the particular circumstances of the case. Equivalence, in the patent law, is not the prisoner of a formula and is not an absolute to be considered in a vacuum. It does not require complete identity for every purpose and in every respect.

339 U.S. 605, 607-09 (1950). The Supreme Court thus reaffirmed the doctrine in that case, even over a dissent that the doctrine of equivalents produces the result that a competitor "cannot rely on what the language of a patent claims." *Id.* at 607, 617 (Black, J. dissenting).

The Supreme Court has explicitly stated that, under its decision in *Warner-Jenkinson,* "equivalents remains a firmly entrenched part of the settled rights protected by the patent." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 733 (2002). Notably, the Court has never stated that equivalents form a part of the rights protected by only some patents or only in exceptional circumstances. On the contrary, the Court has held that "[t]he scope of a patent is not limited to its literal terms but instead embraces all equivalents to the claims described." *Id.* at 732.

In *Warner-Jenkinson*, the Supreme Court also made clear that if the doctrine is to be discarded, it is Congress and not the Court that should do so:

> [T]he lengthy history of the doctrine of equivalents strongly supports adherence to our refusal in *Graver Tank* to find that the Patent Act conflicts with that doctrine. Congress can legislate the doctrine of equivalents out of existence any time it chooses. The various policy arguments now made by both sides are thus best addressed to Congress, not this Court.

520 U.S. at 28. And the Court held that determination of infringement under the doctrine of equivalents does not "require judicial exploration of the equities." *Id.* at 34-35.

Further, in *Festo*, the Supreme Court rejected the argument that the doctrine of equivalents undermines innovation:

> [T]he clearest rule of patent interpretation, literalism, may conserve judicial resources but is not necessarily the most efficient rule. The scope of a patent is not limited to its literal terms but instead embraces all equivalents to the claims described.
>
> It is true that the doctrine of equivalents renders the scope of patents less certain. . . . These concerns with the doctrine of equivalents, however, are not new. Each time the Court has considered the doctrine, it has acknowledged this uncertainty as the price of ensuring the appropriate incentives for innovation, and it has affirmed the doctrine over dissents that urged a more certain rule.

535 U.S. at 732 (citing *Winans*, 56 U.S. at 343, 347).

Second, if the panel's requirement of an "exceptional case" means that the doctrine of equivalents is available only for a case that stands out from the others in terms of its substantive strength on the merits, this is also contrary to Supreme

Court precedent. Like literal infringement, the test for infringement under the doctrine of equivalents requires only a comparison of the properly construed claims to the accused instrumentality. *See Warner-Jenkinson*, 520 U.S. at 26 & n.4 ("[T]here is no basis for treating an infringing equivalent any differently from a device that infringes the express terms of a patent."). To the extent that the panel required additional facts to be shown to prove infringement under the doctrine of equivalents, this is contrary to Supreme Court and this Court's precedent. Indeed, this Court held *en banc* in *Hilton Davis Chemical Co. v. Warner-Jenkinson Co.* that to prove infringement under the doctrine of equivalents, nothing more than "proof of insubstantial differences between the claimed and accused products or processes" is required. 62 F.3d 1512, 1521-22 (Fed. Cir. 1995) (en banc).

For example, in *Union Paper-Bag Machine Co. v. Murphy*, the Supreme Court held that there is infringement under the doctrine of equivalents "if it performs substantially the same function in substantially the same way to obtain the same result." 97 U.S. 120, 125 (1877); *see Sanitary Refrigerator Co. v. Winters*, 280 U.S. 30, 42 (1929) ("[I]f two devices do the same work in substantially the same way, and accomplish substantially the same result, they are the same, even though they differ in name, form or shape."); *Siemens Med. Solutions USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc.*, 637 F.3d 1269, 1279 (Fed. Cir. 2011). The Supreme Court applied this function-way-result test in

Hobbs v. Beach to find infringement under the doctrine of equivalents because "the two machines are alike in their functions, combination, and elements." 180 U.S. 383, 401 (1901); *see Morley Sewing Mach. Co. v. Lancaster*, 129 U.S. 263, 273 (1889) ("[A]ll subsequent machines [of the invention] which employ substantially the same means to accomplish the same result are infringements . . . .").

Third, if the panel's requirement of an "exceptional case" to prove infringement under the doctrine of equivalents means that the patent claims must be especially inventive in some way, this too is contrary to Supreme Court precedent. The Supreme Court has long rejected the argument that infringement under the doctrine of equivalents is limited to so-called pioneer patents. For example, in *Continental Paper Bag Co. v. Eastern Paper Bag Co.*, the Supreme Court affirmed the holding that the accused machine was "within the doctrine of equivalents," noting that it is not the case "that only pioneer patents are entitled to invoke" the doctrine of equivalents. 210 U.S. 405, 415, 421-22 (1908); *see Graver Tank*, 339 U.S. at 608 ("The doctrine operates not only in favor of the patentee of a pioneer or primary invention, but also for the patentee of a secondary invention.").

Finally, the cases cited by the panel do not provide the necessary support for its statement that the "doctrine of equivalents applies only in exceptional cases." Slip op. at 11. The primary case on which the panel relies is *London*, 946 F.2d at 1538, which was followed by this Court and at least three district courts for the

proposition that determining infringement under the doctrine of equivalents requires consideration of the equities. *Id.*[1] But *London*'s articulation of the doctrine of equivalents as an equitable doctrine was rejected by this Court and the Supreme Court. As discussed above, the Supreme Court held in *Warner-Jenkinson* that the doctrine of equivalents does not require any "judicial exploration of the equities." 520 U.S. at 34-35. The panel also cited *Duncan Parking Technologies, Inc. v. IPS Group, Inc.*, 914 F.3d 1347 (Fed. Cir. 2019) and *Primos, Inc. v. Hunter's Specialties, Inc.*, 451 F.3d 841, 850 (Fed. Cir. 2006). Slip op. at 11. Neither case, however, addresses whether exceptionality is required to prove infringement under the doctrine of equivalents.

[1] *See, e.g.*, *Am. Home Prods. Corp. v. Johnson & Johnson*, 979 F.2d 216, at *3 (Fed. Cir. 1992) (The doctrine of equivalents "is an equitable remedy available only upon a suitable showing. AHP must put forth proof of the equities.") (non-precedential); *Extrel FTMS, Inc. v. Bruker Instruments, Inc.*, 954 F.2d 734, at *2 (Fed. Cir. 1992) (non-precedential); *see also Beraha*, 870 F. Supp. at 1091, *aff'd* 64 F.3d 678 ("Having carefully considered the application of the doctrine of equivalents to the facts presented, the Court concludes that there are no exceptional circumstances which justify imposing an equitable remedy in this case."); *Larami Corp. v. Amron*, No. 91-cv-6145, 1993 WL 69581 (E.D. Pa. Mar. 11, 1993), *aff'd* 91 F.3d 166 (Fed. Cir. 1996) (non-precedential) ("[T]he doctrine [of equivalents] is reserved for the exceptional case."); *Talk To Me Prods., Inc. v. Lanard Toys, Inc.*, 811 F. Supp. 93, 95 (E.D.N.Y. 1992), *aff'd 26* F.3d 138 (Fed. Cir. 1994) (non-precedential) ("Application of the doctrine [of equivalents] is limited to exceptional situations in order to discourage careless claim drafting.").

II. Under the Correct Standard for Assessing Infringement Under the Doctrine of Equivalents, the Panel Erred in Affirming the District Court's Grant of Summary Judgment as to the '878 Patent

The panel held that there is no infringement under the doctrine of equivalents for the same reasons that it held that there is no literal infringement. The panel reached this conclusion based on its erroneous application of an "exceptional case" standard. Specifically, the panel held that there is no literal infringement because "the washing and eluting steps of claim 7 [of the '878 Patent] require discrete solutions." Slip op. at 9-10. The panel next held that "Sandoz's one-step, one-solution process does not function in the same way as the claimed process" because "our precedent prohibits us from overriding the natural language of claim 7 to extend these limitations [washing and eluting] to cover nearly any type of adsorbent chromatographic separation." *Id.* at 11. The panel then relied on the "exceptional case" standard to "accordingly" affirm the district court's grant of summary judgment of non-infringement under the doctrine of equivalents. *Id.*

Thus, the panel relied on the "natural" or literal language of claim 7 to reject Amgen's theory of infringement under the doctrine of equivalents, without considering the evidence Amgen presented to demonstrate infringement under the doctrine of equivalents. As the panel recognized, Amgen presented evidence that "Sandoz's one-step, one-solution process is insubstantially different from the claimed three-step, three-solution process because it 'achieves the same functions

(washing and eluting), in substantially the same way (binding protein preferentially compared to contaminants, and then raising salt concentration to reverse protein binding) to achieve the same result (protein purification).'" *Id.* at 10. Specifically, in Sandoz's process when the one solution is continuously applied directly to the top of the column, its composition changes as it flows through the column. And, as the conditions in the column change, protein binds, then the solution passes down the column to carry away unbound contaminants that are discarded (washing), and, lastly, the protein to be purified unbinds from the separation matrix to flow out of the bottom of the column (elution).

The panel did not address this evidence, effectively holding that there is no infringement under the doctrine of equivalents because there is no literal infringement. This is contrary to Supreme Court and this Court's precedents, as discussed above. Applying the correct standard for assessing infringement under the doctrine of equivalents, there is a genuine dispute of material fact as to whether Sandoz's process infringes the '878 Patent under the doctrine of equivalents under the panel's claim construction. Slip op. at 9-10. The only basis on which the district court determined that there was no infringement of the '878 Patent was that Sandoz's accused process did not meet the "washing" and "eluting" terms of claim 7, which are not the point of novelty of the claim. The point of novelty lies in the "directly applying" language of the claim, which Sandoz practices literally.

See, e.g., '878 Patent, col.15:25-42. This matters because the Supreme Court has considered, in applying the doctrine of equivalents, whether the accused infringer practices the "peculiar feature of novelty, which clearly distinguished it from all that went before it." *Cont'l Paper Bag*, 210 U.S. at 421. Where, as here, the accused infringer literally practices "the very essence of the invention," *id.* at 422, infringement under the doctrine of equivalents should not be defeated because other aspects of the claim are not met literally.

Under the correct standard for assessing infringement under the doctrine of equivalents, the washing and eluting elements of the claim are met equivalently by the Sandoz washing and eluting solutions that are formed *in situ* in the column. As the Supreme Court recognized in *Graver Tank*, there can be "equivalence between chemical ingredients" and "[c]onsideration must be given to the purpose for which an ingredient is used in a patent [and] the qualities it has when combined with the other ingredients." 339 U.S. at 609. Here, the '878 Patent claims are agnostic as to whether the washing and eluting solutions are formed *ex situ* and added seriatim (as claimed literally under the panel's construction) or formed *in situ* (as covered equivalently). And the compositional changes that take place after Sandoz's direct application of one solution to the column inexorably achieve the same washing and eluting functions as in the claimed process because, as a matter of chemistry, that single solution changes over time into a washing solution and, subsequently, into

an eluting solution. Thus, the panel improperly foreclosed a finding of infringement under the doctrine of equivalents by limiting the claims to their literal scope (as construed).

The impact of the panel decision is that, in the vast majority of cases, infringement under the doctrine of equivalents will be foreclosed where there is no literal infringement. This flies in the face of Supreme Court precedent which makes clear that the availability of a theory of infringement under the doctrine of equivalents does not turn on the strength of the patentee's literal infringement case. *Warner-Jenkinson*, 520 U.S. at 26 & n.4.

III. The Panel's New Rule Will Cause Significant Harm

A. The Supreme Court has Criticized Such Bright-Line Rules

The panel's new rule requiring exceptionality to find infringement under the doctrine of equivalents is exactly the kind of inflexible rule the Supreme Court has consistently rejected. *See Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 136 S.Ct. 1923, 1935 (2016); *Octane Fitness*, 572 U.S. at 553; *Bilski v. Kappos*, 561 U.S. 593, 604 (2010); *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 419 (2007); *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 394 (2006); *Festo*, 535 U.S. at 737. Indeed, the panel's new rule violates the Supreme Court's admonition against the retroactive adoption of such bright-line rules. It is also contrary to the Supreme Court's guidance in *Festo* that "courts must be cautious before adopting changes

that disrupt the settled expectations of the inventing community. . . . The doctrine of equivalents [is] settled law. . . . Fundamental alterations in these rules risk destroying the legitimate expectations of inventors in their property." 535 U.S. at 739.

Shortly after the panel decision, commentators observed that this "seems to be a major step without precedential backing." *See* Dennis Crouch, *Federal Circuit: The Doctrine of Equivalents Applies ONLY in Exceptional Cases*, PATENTLYO (May 8, 2019); Kevin E. Noonan, *Amgen Inc. v. Sandoz Inc. (Fed. Cir. 2019)*, PATENTDOCS (May 12, 2019); Devin Cummins, *Federal Circuit Suggests Infringement May Be Found Under the Doctrine of Equivalents Only in Exceptional Cases*, DORITY & MANNING (May 31, 2019) (panel opinion "may represent a restriction or narrowing of the doctrine"); Stephen Rabinowitz and Robert Rhoad, *Federal Circuit Panel Describes the Doctrine of Equivalents as Applying "Only in Exceptional Cases"*, JD SUPRA (May 2019) ("[T]he panel's narrow application of the doctrine of equivalents illustrates the unsettled nature of this doctrine in Federal Circuit precedent.").

B. There is No Meaningful Remedy to Mitigate the Harm Created by the New Rule

The panel's rule restricting the doctrine of equivalents to "exceptional cases" can be expected to discourage innovation. *Festo*, 535 U.S. at 731 ("If patents were always interpreted by their literal terms, their value would be greatly

diminished."). The panel decision also leaves patentees with no meaningful remedy to mitigate the harm created by this new rule. If the answer is that such patentees should return to the PTO to obtain protection for the specific equivalent at issue, that answer is contrary to the entire purpose of the doctrine of equivalents. *Id.* at 731-32 (a patent "embraces all equivalents to the claims described" given that "the nature of language makes it impossible to capture the essence of a thing in a patent application").

Lastly, the panel decision raises an important question of who decides infringement under the doctrine of equivalents. Whether an accused process infringes under the doctrine of equivalents in jury cases is a question for the jury. *See Warner-Jenkinson*, 520 U.S. at 23; *Siemens*, 637 F.3d at 1278-79. But if infringement under the doctrine of equivalents requires a threshold determination as to whether a case is "exceptional," is that question for the judge to decide even in jury cases? *See In re Rembrandt Techs. LP Patent Litig.*, 899 F.3d 1254, 1277 (Fed. Cir. 2018) ("*Octane Fitness* gives district courts broad discretion in the exceptional-case determination.").

CONCLUSION

Amgen respectfully submits that the panel decision should be reconsidered by the *en banc* Court, and that the Court should provide definitive guidance as to the proper test for infringement under the doctrine of equivalents.

Respectfully submitted,

Dated: June 7, 2019

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ADDENDUM

United States Court of Appeals for the Federal Circuit

AMGEN INC., AMGEN MANUFACTURING, LIMITED,
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v.

SANDOZ INC., SANDOZ INTERNATIONAL GMBH, SANDOZ GMBH,
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2018-1551

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2018-1552

Appeal from the United States District Court for the Northern District of California in No. 3:16-cv-02581-RS, Judge Richard Seeborg.

Decided: May 8, 2019

NICHOLAS P. GROOMBRIDGE, Paul, Weiss, Rifkind, Wharton & Garrison LLP, New York, NY, argued for plaintiffs-appellants. Also represented by JENNIFER GORDON, GOLDA LAI, STEPHEN ACCURSIO MANISCALCO, PETER SANDEL, ERIC ALAN STONE, JACOB WHITT, JENNIFER H. WU; LOIS M. KWASIGROCH, KIMBERLIN L. MORLEY, WENDY A. WHITEFORD, Amgen Inc., Thousand Oaks, CA.

DEANNE MAYNARD, Morrison & Foerster LLP, Washington, DC, argued for defendants-appellees. Also represented by BRYAN LEITCH, BRIAN ROBERT MATSUI; ERIK JEFFREY OLSON, ERIC C. PAI, Palo Alto, CA.

Before LOURIE, O'MALLEY, and REYNA, *Circuit Judges*.

LOURIE, *Circuit Judge*.

Amgen Inc. and Amgen Manufacturing Ltd. (collectively, "Amgen") appeal from two decisions of the United States District Court for the Northern District of California in two patent infringement actions brought by Amgen under the Biologics Price Competition and Innovation Act ("BPCIA"), 42 U.S.C. § 262 (2012). The court construed claims of U.S. Patents 6,162,427 (the "'427 patent") and 8,940,878 (the "'878 patent"), *Amgen Inc. v. Sandoz Inc.*, No. 14-CV-04741-RS, 2016 WL 4137563 (N.D. Cal. Aug. 4, 2016) ("*Claim Construction Order*"), and granted summary judgment of noninfringement of claim 7 of the '878 patent

by Sandoz's filgrastim biosimilar and its proposed pegfilgrastim biosimilar, *Amgen Inc. v. Sandoz Inc.*, 295 F. Supp. 3d 1062, 1064 (N.D. Cal. 2017) ("*Decision*"). We conclude that the district court correctly construed the claims and granted summary judgment of noninfringement of claim 7. The judgment of the district court is therefore affirmed.

BACKGROUND

Amgen created and commercialized two related biologic products, filgrastim (marketed as Neupogen®) and pegfilgrastim (marketed as Neulasta®), indicated for treating neutropenia, a deficiency of white blood cells. Neutropenia often results from exposure to certain chemotherapeutic regimens or radiation therapy during cancer treatment. Filgrastim is a recombinant analog of granulocyte-colony stimulating factor ("G-CSF"), a naturally-occurring human glycoprotein that stimulates the production of neutrophils and stem cells and their release into the bloodstream. Pegfilgrastim is materially identical but much larger because it is conjugated to a polyethylene glycol molecule, which enables long-acting administration. Both of Amgen's products are generally indicated to stimulate neutrophil production, and Neupogen® is further indicated to mobilize stem cells from the bone marrow into the bloodstream for collection for autologous stem cell transplantation.

In 2014, Sandoz submitted to the Food and Drug Administration ("FDA") an abbreviated Biologics License Application ("aBLA") to market a biosimilar filgrastim product. While Sandoz's aBLA referenced Neupogen®, Sandoz elected not to provide Amgen with its aBLA or manufacturing information. In October 2014, Amgen filed a complaint for, *inter alia*, a declaratory judgment that Sandoz's proposed biosimilar would infringe the '427 patent. *See* 35 U.S.C. § 271(e)(2)(C) (defining submission of an aBLA as an act of patent infringement); 42 U.S.C. § 262(l)(9)(C) (allowing a reference product sponsor to

bring a declaratory judgment action regarding "any patent that claims the biological product or a use of the biological product" when the biosimilar applicant does not provide its aBLA and manufacturing information).[1] In 2015, Sandoz received FDA approval for its filgrastim biosimilar, Zarxio®. After Sandoz launched Zarxio®, Amgen amended its complaint to plead infringement of the '878 patent under 35 U.S.C. §§ 271(e)(2)(C)(ii), (g).

In 2015, Sandoz submitted an aBLA to market a biosimilar pegfilgrastim product referencing Neulasta®. In May 2016, Amgen filed a complaint for infringement of the '878 patent under 35 U.S.C. § 271(e)(2)(C)(i) and 42 U.S.C. § 262(l)(6)(A). Sandoz has not yet received approval for its proposed pegfilgrastim biosimilar.

The '878 patent discloses methods of protein purification by adsorbent chromatography, a well-known method that involves separating the components of a solution ("the mobile phase") based upon their chemical attraction to the molecules or ions that comprise a stationary separation matrix ("the stationary phase"). The '878 patent refers to several methods of chromatography, including protein affinity and non-protein affinity methods like ion exchange. '878 patent col. 15 ll. 17–24. The '878 patent further discloses use of a salt or pH gradient to control the elution of the protein of interest, as well as the preceding elution (or "washing") from the matrix of unwanted components of a refold solution containing the protein of interest. *Id.* col.

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[1] These cases have an extensive procedural history concerning issues not relevant to this appeal. *See Amgen Inc. v. Sandoz Inc.*, 877 F.3d 1315 (Fed. Cir. 2017); *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347 (Fed. Cir. 2015), *rev'd in part, vacated in part*, 137 S. Ct. 1664 (2017).

16 ll. 2–22. Claim 7, recited below, is directed to the use of a non-affinity separation matrix.

> 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.

The '427 patent discloses methods of treating "diseases requiring peripheral stem cell transplantation." '427 patent col. 1 ll. 9–10. Certain cancer treatments, like chemotherapy and radiation, can destroy stem cells, so stem cells are often collected from a person's bloodstream in a process called leukapheresis and re-infused after such treatment. The claimed invention lies in administering G-CSF *before* chemotherapy to "achiev[e] a superior yield of stem cells," so that fewer leukaphereses are required to achieve the stem cell transplant. *Id.* col. 1 ll. 58–61. Representative claim 1 reads:

> 1. A method of treating a disease requiring peripheral stem cell transplantation in a patient in need of such treatment, comprising
>
> > administering to the patient a hematopoietic stem cell mobilizing-effective amount of G-CSF; and
> >
> > thereafter administering to the patient a disease treating-effective amount of at least one chemotherapeutic agent.

No other claim from either the '427 patent or the '878 patent is before us in this appeal.

The district court construed "disease treating-effective amount of at least one chemotherapeutic agent" in claim 1 of the '427 patent as limited to "[a]n amount sufficient to treat a disease for which at least one chemotherapeutic agent is prescribed." *Claim Construction Order*, 2016 WL 4137563, at *18. The court thereby rejected Amgen's argument that the amount must be "sufficient to enhance the mobilization of stem cells," *id.* at *6–7, regardless of its effect on the underlying disease. Amgen thereafter stipulated to noninfringement of the '427 patent contingent upon its right to appeal from the district court's claim construction order. J.A. 49–53.

With respect to the '878 patent, the district court treated the Neupogen® and Neulasta® cases together. It construed limitations (f) and (g) of claim 7 (the "washing" and "eluting" steps) as separate steps and further clarified that the eluting step "must occur after the step of 'washing the separation matrix.'" *Claim Construction Order*, 2016 WL 4137563, at *18. As construed, performing limitations (e)–(g) of the process of claim 7 requires:

> (e) applying the refold solution to a separation matrix . . . ,
>
> (f) applying a solution to remove . . . unwanted components of the refold solution . . . while preserving [protein] binding . . .; and
>
> (g) applying a solution that reverses the binding of the purified protein . . . .

Id.

Since it is undisputed that Sandoz's process only involves one step—applying the refold solution to the matrix, with no separate washing or eluting steps—the district court granted summary judgment that neither Zarxio® nor Sandoz's proposed pegfilgrastim biosimilar infringes claim 7 of the '878 patent. *Decision*, 295 F. Supp. 3d at 1071.

Amgen appeals. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

We review a district court's grant of summary judgment according to the law of the regional circuit. *Kaneka Corp. v. Xiamen Kingdomway Grp. Co.*, 790 F.3d 1298, 1303 (Fed. Cir. 2015) (citing *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 769 F.3d 1371, 1377 (Fed. Cir. 2014)). In the Ninth Circuit, summary judgment is reviewed *de novo*, *Brunozzi v. Cable Commc'ns, Inc.*, 851 F.3d 990, 995 (9th Cir. 2017) (citing *Ctr. for Bio-Ethical Reform, Inc. v. L.A. Cty. Sheriff Dep't*, 533 F.3d 780, 786 (9th Cir. 2008)), and

is appropriate when, viewing the evidence in favor of the non-movant, there is no genuine dispute of material fact, *Zetwick v. Cty. of Yolo*, 850 F.3d 436, 440 (9th Cir. 2017) (citing *United States v. JP Morgan Chase Bank Account No. Ending 8215*, 835 F.3d 1159, 1162 (9th Cir. 2016)).

Claim construction is ultimately an issue of law, which we review *de novo*. *Shire Dev., LLC v. Watson Pharm., Inc.*, 787 F.3d 1359, 1364 (Fed. Cir. 2015). We review *de novo* the district court's findings of fact on evidence "intrinsic to the patent (the patent claims and specification[], along with the patent's prosecution history)," and review for clear error all other subsidiary findings of fact. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015). While infringement is a question of fact, *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1309 (Fed. Cir. 2009), we review *de novo* the district court's grant of summary judgment of noninfringement, *Unwired Planet, LLC v. Apple Inc.*, 829 F.3d 1353, 1356 (Fed. Cir. 2016). The patentee has the burden of proving infringement by a preponderance of the evidence. *SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988).

I. '878 Patent

Amgen contends that the district court misconstrued the "washing" and "eluting" claim limitations in both its claim construction and summary judgment decisions as requiring distinct solutions added to the matrix at different times. Instead, Amgen argues, the claims cover any number of solutions or steps as long as the functions of washing and eluting happen in sequence, and it cites as support the specification's teaching that a wide variety of solutions will work to perform the washing and eluting steps. Amgen claims that, in Sandoz's process, washing precedes elution at any given point in the separation matrix; that is, washing may occur toward the bottom of the matrix at the same time that elution occurs toward the top. Thus, Amgen argues that Sandoz's process infringes because the claim

construction only generally requires that washing precede elution.

Sandoz responds that the claim logically requires a series of steps and cites *Mformation Technologies, Inc. v. Research in Motion Ltd.*, 764 F.3d 1392, 1398–1400 (Fed. Cir. 2014), as holding that a process claim is properly limited to a certain order of steps "'when the claim language, as a matter of logic or grammar, requires that the steps be performed in the order written, or the specification directly or implicitly requires' an order of steps." *Id.* at 1398 (quoting *TALtech Ltd. v. Esquel Apparel, Inc.*, 279 F. App'x 974, 978 (Fed. Cir. 2008)). Sandoz argues that the district court correctly concluded, in light of the specification, that the step of applying the washing solution to the matrix must precede the step of applying the elution solution, which it claims does not occur in its process.

We agree with Sandoz that the washing and eluting steps of claim 7 require discrete solutions. Amgen's argument to the contrary is, at its core, that the "washing" and "eluting" limitations describe functions, rather than actual process steps. *See* Reply Br. 14 ("[T]he claims and specification . . . define washing and eluting as functional steps."). We reject this argument for two reasons. First, as in *Mformation*, the claim language logically requires that the process steps, lettered (a) through (g), be performed in sequence. For example, expressing the protein in a non-mammalian cell (limitation (a)) obviously must occur before the step of lysing that cell (limitation (b)). There is no indication on the face of claim 7 that the washing and eluting steps are any different. Second, washing and eluting are consistently described in the specification as separate steps performed by different solutions. *See* '878 patent col. 10 ll. 44–46 ("After the separation matrix with which the protein has associated has been washed, the protein of interest is eluted from the matrix using an appropriate solution."), col. 10 ll. 31–34 ("The wash buffer can be of any composition, as long as [it] . . . maintains the interaction

between the protein and matrix."), col. 17 l. 46–col. 21 l. 42 (disclosing four exemplary purification methods using separate washing and eluting steps and discrete solutions).

Critically, the same conclusion would follow even if the district court had accepted Amgen's proposed constructions of these limitations. Amgen requested that the washing and eluting limitations be construed as separate process steps, such that limitations (e)–(g) would read:

> (e) applying the refold solution to a column that contains the separation matrix . . . ,
>
> (f) adding a solution into the column . . . to remove materials in the refold solution that do not interact with the separation matrix . . . ; and
>
> (g) adding a solution into the column . . . which [h]as the effect of reversing the interactions between the protein and the separation matrix . . . .

See Claim Construction Order, 2016 WL 4137563, at *12, *17. Since there is no dispute that Sandoz's current process only uses one step and one solution, Reply Br. 9, it cannot literally infringe claim 7. We therefore need not further address Amgen's argument for literal infringement. We conclude 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.

Amgen next argues that the district court erred by rejecting its argument that Sandoz's process infringes claim 7 through the doctrine of equivalents. Amgen argues that Sandoz's one-step, one-solution process is insubstantially different from the claimed three-step, three-solution process because it "achieves the same functions (washing and eluting), in substantially the same way (binding protein preferentially compared to contaminants, and then raising salt concentration to reverse protein binding) to achieve the same result (protein purification)." Appellant Br. 52.

Sandoz responds that the district court properly analyzed Amgen's argument and found that Sandoz's one-step, one-solution process accomplishes purification in a different way from the claimed method and, as a result, is not equivalent. Sandoz further argues that Amgen failed to provide any factual support for its equivalency argument before the district court.

We agree with Sandoz and conclude 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. In essence, Amgen 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. But claim 7 is not that broad. As the district court held, the 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. 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))). Accordingly, the district court was correct to grant summary judgment 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.

Amgen also maintains that the district court abused its discretion by denying Amgen's motion for a continuance

under Federal Rule of Civil Procedure 56(d), which allows a district court to deny or postpone summary judgment if the nonmovant shows that "it cannot present facts essential to justify its opposition." *Decision*, 295 F. Supp. 3d at 1070 (quoting Fed. R. Civ. P. 56(d)). It is undisputed that Sandoz intends, at some point in the future, to modify its purification processes for both Zarxio® and its proposed pegfilgrastim biosimilar to accommodate the use of a different resin in its separation matrix, but Amgen contends that Sandoz has neither submitted to the FDA a corresponding amendment to its aBLA nor provided Amgen with the details of that modification. Amgen argues that judgment cannot be rendered on a technical act of infringement of a process patent under 35 U.S.C. § 271(e)(2) if a biosimilar applicant plans to submit a modification of a relevant process to the FDA but has not yet done so. Otherwise, Amgen warns, it will be "effectively deprive[d] [of] the ability to allege infringement in the future," and Sandoz will be free "to make any changes it wishes to the modified process because it has been declared non-infringing in advance." Appellant Br. 57.

Sandoz argues in response that it provided Amgen with ample details regarding the modification well in advance of summary judgment, and Amgen's failure to diligently pursue discovery bars it from using Rule 56(d) to stave off summary judgment. *See Mackey v. Pioneer Nat'l Bank*, 867 F.2d 520, 524 (9th Cir. 1989). Sandoz also maintains that the details Amgen seeks are immaterial to infringement because it will continue to use the one-step, one-solution process that has already been held noninfringing.

We agree with Sandoz that, regarding its proposed pegfilgrastim biosimilar, the district court did not abuse its discretion. In *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997), we held that a proper analysis of a technical act of infringement under § 271(e)(2) requires a determination of whether "[w]hat is likely to be sold" will infringe "in the conventional sense" of patent infringement.

Id. at 1569–70. This "hypothetical inquiry," *id.* at 1569, may be complex, given that ANDA and biosimilar applicants often make changes to their applications while they are pending, *see, e.g.*, *Ferring B.V. v. Watson Labs., Inc.-Fla.*, 764 F.3d 1382, 1390 n.6 (Fed. Cir. 2014). We have thus recognized that, while a district court cannot ignore amendments to an ANDA or aBLA, *Sunovion Pharm., Inc. v. Teva Pharm. USA, Inc.*, 731 F.3d 1271, 1279–80 (Fed. Cir. 2013), it also has a broad mandate to render a "just, speedy, and inexpensive" decision, *In re Micron Tech., Inc.*, 875 F.3d 1091, 1100 (Fed. Cir. 2017) (quoting *Dietz v. Bouldin*, 136 S. Ct. 1885, 1891 (2016)), based upon the evidence of record, *see Ferring*, 764 F.3d at 1391 (holding that a district court has discretion to consider an amended ANDA after issuing a decision but before final judgment). We therefore conclude that the district court was not obligated to postpone summary judgment until Sandoz submitted its amended pegfilgrastim aBLA.

In contrast with certain of our previous cases, the question here is of little consequence to infringement because Amgen has conceded that, under the claim construction we have affirmed, there is no genuine dispute that the process Sandoz will likely use to manufacture its proposed pegfilgrastim biosimilar—whether it uses the current resin or the new resin—will not infringe claim 7. J.A. 7056–57; Reply Br. 23. Claim 7 does not distinguish between types of resins. Thus, the district court did not abuse its discretion in denying Amgen's Rule 56(d) motion or err in granting summary judgment of noninfringement regarding the proposed pegfilgrastim biosimilar.

We further agree with Sandoz that its current process, which it uses to manufacture Zarxio®, does not infringe claim 7. Because Zarxio® is currently marketed, it is unnecessary to determine "what is likely to be sold," as is required for a technical act of infringement. *Glaxo*, 110 F.3d at 1569–70. Instead, infringement turns on whether Sandoz's current process for manufacturing Zarxio®

infringes claim 7 according to conventional principles of patent infringement. *See Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1365–66 (Fed. Cir. 2003) ("[T]he substantive determination [of] actual infringement [under § 271(e)(2)] . . . is determined by traditional patent infringement analysis . . . ."). Applying those principles, the district court granted summary judgment of noninfringement, *Decision*, 295 F. Supp. 3d at 1067–69, and as we concluded above, the district court did not err either in construing claim 7 or in granting summary judgment.

We also note that Amgen is not, as it alleges, left without a remedy for possible future infringement if the facts change. It may in a future action plead infringement of claim 7 by Zarxio® or, if approved, Sandoz's pegfilgrastim biosimilar to the extent permitted by the Patent Act and the principles of *res judicata* and collateral estoppel. *See, e.g.*, *Bayer AG v. Biovail Corp.*, 279 F.3d 1340, 1349–50 (Fed. Cir. 2002) (declining to apply collateral estoppel from previous Hatch-Waxman case when defendant's marketed product differed from that of the hypothetical inquiry). We conclude that the district court did not abuse its discretion in denying Amgen's Rule 56(d) motion or err in granting summary judgment of noninfringement.

II. '427 Patent

Finally, Amgen argues that the district court misconstrued the limitation of "disease treating-effective amount" of a chemotherapeutic agent in claim 1 of the '427 patent as "an amount sufficient to treat a disease for which at least one chemotherapeutic agent is prescribed." *Claim Construction Order*, 2016 WL 4137563, at *6–7. Specifically, Amgen asserts that the phrase only limits the amount of the chemotherapeutic agent administered and that the method of claim 1 encompasses "situations where the chemotherapeutic agent is prescribed only for stem cell mobilization rather than treatment of an underlying disease." Appellant Br. 63; *see also* Reply Br. 24.

Sandoz responds that Amgen's construction would read disease treatment out of the claim and collapse the claim's textual distinction between a "stem cell mobilizing-effective amount" of G-CSF and a "disease treating-effective amount" of the chemotherapeutic agent.

We agree with Sandoz that "disease treating" requires that the chemotherapeutic agent be administered to treat an underlying disease. As an initial matter, the preamble of claim 1, as construed, arguably precludes Amgen's construction. The district court construed the preamble, "[a] method of treating a disease requiring peripheral stem cell transplantation," as requiring that the stem cell transplant be incorporated as a component of a method of treating an underlying disease, such as cancer, *Claim Construction Order*, 2016 WL 4137563, at *5–6, and Amgen does not dispute that construction on appeal. The claimed method therefore must be performed to treat an underlying disease. As the claim itself states, the "disease treating-effective amount" of a chemotherapeutic agent does precisely that.

Moreover, neither the claim nor the specification lends support to Amgen's interpretation of "disease treating-effective amount." Amgen's construction would broaden claim 1 to cover administration of G-CSF and a chemotherapeutic agent solely for the purpose of mobilizing stem cells. Such a conclusion would require interpreting "disease treating" as "stem cell mobilizing," but "[o]ur precedent instructs that different claim terms are presumed to have different meanings." *Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1382 (Fed. Cir. 2008) (citing *Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 448 F.3d 1324, 1333 n.3 (Fed. Cir. 2006)). Had Amgen simply wanted to claim a method of mobilizing stem cells, in any context, it could have done so. *See Merck & Co., Inc. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005) ("A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so." (citing

Elekta Instrument S.A. v. O.U.R. Sci. Int'l, Inc., 214 F.3d 1302, 1307 (Fed. Cir. 2000))).

Amgen's argument to the contrary—that not all chemotherapeutic agents can mobilize stem cells on their own—cannot be maintained in view of its simultaneous contention that "disease treating" should be construed as "stem cell mobilizing." And while the specification is relatively sparse, it does indicate that disease treatment refers to an overall regimen for treating an underlying disease, which includes, but is not limited to, a stem cell transplant. *See, e.g.*, '427 patent col. 1 ll. 9–11 ("treatment of diseases . . . e.g., in high-dosage chemotherapy or bone marrow ablation by irradiation"), col. 1 ll. 28–29 ("the success of treatment crucially *depends on* [stem cell mobilization]" (emphasis added)), col. 1 ll. 56–58 ("the run-up to the treatment of particular diseases, e.g., in preparing a myeloablative or myelotoxic therapy"). In summary, we conclude that the district court did not err in construing claim 1 of the '427 patent.

CONCLUSION

We have considered the rest of the parties' arguments but find them unpersuasive. The judgment of the district court is

AFFIRMED

CERTIFICATE OF SERVICE

I hereby certify that on this 7th of June, 2019, I caused the foregoing Petition of Plaintiffs-Appellants Amgen Inc. and Amgen Manufacturing Limited for Rehearing *En Banc* Pursuant to Fed. R. App. P. 35(b) to be filed with the Clerk of the Court using the CM/ECF system. I also caused a true and correct copy of Petition of Plaintiffs-Appellants Amgen Inc. and Amgen Manufacturing Limited for Rehearing *En Banc* Pursuant to Fed. R. App. P. 35(b) to be electronically served on Defendant-Appellee Sandoz Inc.'s counsel of record, pursuant to agreement of the parties, as follows:

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Circuit Rule 32(a). The brief contains 3,850 words, excluding parts of the brief exempted by Fed. R. App. P. 32(f) and Federal Circuit Rule 32(b). The word count includes the words counted by the Microsoft Word 2016 function. This brief also complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6). The brief has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point font of Times New Roman.

Dated: June 7, 2019

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