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

2018-1551

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

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.

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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