United States Court of Appeals for the Federal Circuit

BRAINTREE LABORATORIES, INC.,
Plaintiff-Appellee,

v.

NOVEL LABORATORIES, INC.,
Defendant-Appellant.

2013-1438

Appeal from the United States District Court for the District of New Jersey in No. 11-CV-1341, Judge Peter G. Sheridan.

Decided: April 22, 2014

JOHN J. REGAN, Wilmer Cutler Pickering Hale and Dorr LLP, of Boston, Massachusetts, argued for plaintiff-appellee. With him on the brief were MARK C. FLEMING, NISHAT A. SHAIKH, JENNIFER C. BROWN, and MICHAEL A. GREENE; and CHRISTOPHER R. NOYES, of New York, New York.

RONALD M. DAIGNAULT, Robins, Kaplan, Miller & Ciresi L.L.P., of New York, New York, argued for defendant-appellant. With him on the brief were DAVID LEICHTMAN, MATTHEW B. MCFARLANE and OREN D. LANGER.

Before DYK, PROST, and MOORE, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* PROST.

Opinion concurring in part, dissenting in part, and concurring in the result filed by *Circuit Judge* DYK.

Dissenting opinion filed by *Circuit Judge* MOORE.

PROST, *Circuit Judge*.

This is a patent infringement case under the Hatch-Waxman Act. *See* 35 U.S.C. § 271(e)(2)(A). Defendant-Appellant Novel Laboratories, Inc. ("Novel") appeals the grant of summary judgment by the United States District Court for the District of New Jersey that U.S. Patent No. 6,946,149 ("'149 patent") held by Braintree Laboratories, Inc. ("Braintree") is infringed by the composition covered by Novel's abbreviated new drug application ("ANDA"). *See Braintree Labs., Inc. v. Novel Labs., Inc.*, No. 11-CV-1341, 2013 WL 211252 (D.N.J. Jan. 18, 2013) ("*Infringement Opinion*"). The district court entered summary judgment of infringement based on its construction of four disputed claim terms. *See Braintree Labs., Inc. v. Novel Labs., Inc.*, No. 11-CV-1341, 2012 WL 4120907 (D.N.J. Sept. 19, 2012) ("*Claim Construction Order*"). Novel challenges the district court's claim construction for two of those terms. Following a six-day bench trial on Novel's invalidity defenses, the district found that Novel failed to prove that the asserted claims were invalid. *See Braintree Labs., Inc. v. Novel Labs.*, No. 11-CV-1341, 2013 WL 2970739 (D.N.J. June 4, 2013) ("*Validity Opinion*"). Novel also appeals those findings.

Because we agree with Novel that the district court erred in its construction of the claim term "clinically significant electrolyte shifts," we reverse the district court's claim construction of that term, vacate the district court's grant of summary judgment of infringement, and

remand for further factual findings to determine whether the composition covered by Novel's ANDA product infringes under the new claim construction articulated herein. Further, we affirm the district court's findings that the asserted claims of the '149 patent are not invalid.

I. BACKGROUND

Braintree is a pharmaceutical company that manufactures the SUPREP® Bowel Prep Kit ("SUPREP"), which helps to prepare patients for colonoscopies. The colon needs to be visually clear in order to successfully perform a colonoscopy, so prior to the examination patients typically drink several liters of a solution to induce diarrhea.

By the late 1990s, two colon cleansing options existed, both of which had some disadvantages. The first option was considered the safest but required patients to drink large volumes of unappetizing isotonic prep formulas, resulting in low patient compliance. The second option was to administer a low-volume, hypertonic prep. However, this option caused severe electrolyte shifts, leading to heart failure, kidney failure, neurological impairment, and even death.

Braintree's '149 patent discloses a combination of magnesium sulfate, potassium sulfate, and sodium sulfate, which can be digested in small volumes to safely and effectively induce colonic purging without causing clinically significant electrolyte shifts. *See, e.g.*, '149 patent abstract.

Claim 15, which the parties agree is representative, recites:

> A composition for inducing *purgation* of the colon of *a patient*, the composition comprising from about 100 mL to about 500 mL of an aqueous hypertonic solution comprising an effective amount of Na_2SO_4, an effective amount of $MgSO_4$, and an effective amount of K_2SO_4, wherein the composi-

> tion does not produce any *clinically significant electrolyte shifts* and does not include phosphate.

Ex Parte Reexamination Certificate, '149 patent col. 2 ll. 23-30 (emphases added).

Braintree alleges that SUPREP is a commercial embodiment of the '149 patent. Novel is a generic drug manufacturer.

II. PROCEDURAL HISTORY

On November 8, 2010, Novel filed an ANDA for a proposed generic copy of SUPREP. A few months later, Novel sent Braintree a Paragraph IV certification of invalidity/noninfringement letter asserting that "each of the claims of the '149 patent is either invalid or is not infringed" by Novel's product. On March 9, 2011, Braintree filed this action seeking a declaration that Novel's ANDA product infringes the '149 patent. Novel asserted counterclaims of noninfringement and invalidity.

After construing claim terms, the district court granted summary judgment of infringement in Braintree's favor and denied Novel's motion for reconsideration, ruling that SUPREP meets all limitations of the asserted claims. *See Infringement Opinion* at *10. Following a bench trial regarding validity, the district court found that Novel "did not show proof that met the clear and convincing standard" that the asserted claims were anticipated, nor were they obvious or indefinite. *Validity Opinion* at *25-26.

III. DISCUSSION

This appeal concerns challenges to the district court's claim constructions, its grant of summary judgment regarding infringement, and its findings following a bench trial regarding validity. Regarding claim construction, Novel argues that the district court misconstrued the claim terms "purgation" and "clinically significant electro-

lyte shifts." Based on these erroneous claim constructions, Novel argues that the district court improperly granted Braintree's motion for summary judgment on infringement. Regarding validity, Novel argues that the district court erred when it failed to find that (1) U.S. Patent No. 4,975,286 ("Hechter") anticipates the asserted claims of the '149 patent; (2) the prior art, as understood by a person of skill in the art, renders the asserted claims obvious; and (3) the asserted claims are invalid because the term "purgation" is indefinite under 35 U.S.C. § 112, ¶ 2. We address each of Novel's challenges in turn.

A. Claim Construction

Claim construction is a question of law, *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976-79 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996), that we review de novo without deference. *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454-55 (Fed. Cir. 1998) (en banc).

1. Purgation

The district court construed "purgation" to mean "an evacuation of a copious amount of stool from the bowels after oral administration of the solution." *Claim Construction Order* at *6. In adopting this construction, the district court rejected Novel's argument that "purgation means cleansing," concluding that "[a]lthough cleansing is a term in the specification of the '149 [p]atent, [the asserted claims] clearly adopt purgation as the methodology to improve visualization of the colon." *Id.* at *3.

On appeal, the parties dispute the construction of the claim term "purgation" because the asserted claims cover compositions "comprising from about 100 mL to about 500 mL of an aqueous hypertonic solution." Ex Parte Reexamination Certificate, '149 patent col. 2 ll. 24-26. Braintree sells SUPREP in a kit containing two six-ounce bottles of concentrated solution, along with a dilution cup. A patient must dilute each of the two six-ounce bottles

with ten ounces of water to form two sixteen-ounce solutions. Each of those half-dose sixteen ounce solutions has a total volume of 473 mL, which is within the range found in the asserted claims of the '149 patent, but Braintree concedes that neither dose accomplishes a full cleansing. Thus, Braintree's "one bottle" infringement theory asserts that one (half-dose) bottle of SUPREP, diluted with water to become a sixteen ounce solution, falls within the asserted claims. This infringement theory can prevail if purgation means the "evacuation of a copious amount of stool from the bowels after oral administration of the solution," which is something less than a full cleansing.

Novel argues that SUPREP does not infringe the asserted claims if "purgation" means cleansing, because a full cleansing only occurs after ingesting 946 mL of solution (i.e., two doses). Pointing to the specification, Novel alleges that the physiological event that the inventor contemplated was cleansing the colon for a colonoscopy. *See, e.g.*, '149 patent title, abstract. Novel also relies on a passage in the specification which indicates that a dosage amount is "effective" only if it produces a clean colon in preparation for a colonoscopy or other surgical procedures. *Id.* at col. 5 ll. 19-24 ("Optimally, the effective dose may be divided and administered, to the patient in two, or more administrations over an appropriate time period. Generally, 2 doses administered of equal portions of the effective dose, separated by 6 to 24 hours produce satisfactory purgation."). Thus, Novel argues that an effective amount of solution must cleanse the colon.

Novel also points to Braintree's 2010 patent term extension request, where Braintree represented to the U.S. Patent and Trademark Office ("PTO") that "[t]he SUPREP product is an osmotic laxative for cleansing *(i.e., purging)* of the colon . . . ." J.A. 22172 (emphasis added). Therefore, Novel argues that Braintree's representation that purgation is equivalent to cleansing reflects the proper construction of "purgation."

While we have considered all of Novel's arguments supporting its proposed construction of "purgation," we find them unpersuasive. "In construing claims, the analytical focus must begin and remain centered on the language of the claims themselves, for it is that language that the patentee chose to use to 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.'" *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001) (quoting 35 U.S.C. § 112, ¶ 2 (1975), *amended by* 35 U.S.C. § 112(b)). The asserted claims here only require that the compositions "induce" (i.e., bring about or start) diarrhea. The claims do not contain language that requires achieving a fully cleansed colon for a colonoscopy. Thus, while cleansing is the goal specifically articulated in the specification, it is not a claim requirement. *See Comaper Corp. v. Antec, Inc.*, 596 F.3d 1343, 1348 (Fed. Cir. 2010) (citation omitted) ("There is an inference . . . that two different terms used in a patent have different meanings.").

Novel's reliance on the claim term "effective amount" is also misplaced. The district court construed "effective amount" as an amount of solution "necessary to produce a colonic purgation, while not producing clinically significant electrolyte shifts," and Novel has not challenged this construction. *Claim Construction Order* at *5. Since an "effective amount" only requires purgation and not a full cleansing, it is consistent to construe purgation as an evacuation of a copious amount of stool. Although the specification contemplates a scenario in which an effective amount could produce a full cleansing, it does so only in terms of a preferred embodiment. *See Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1342 (Fed. Cir. 2010) (citation omitted) ("'[I]t is improper to read limitations from a preferred embodiment described in the specification—even if it is the only embodiment—into the claims

absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited.'").

Finally, we conclude that Braintree's statement that SUPREP is a product for "cleansing (i.e., purging)" in its patent term extension request does redefine "purgation" as "cleansing." Whether a statement to the PTO that includes "i.e." constitutes a clear and unmistakable disavowal of claim scope depends on the context. *See, e.g.*, *Toshiba Corp. v. Imation Corp.*, 681 F.3d 1358, 1370-71 (Fed. Cir. 2012). In this case, the post-issuance statement of the patentee does not modify the plain meaning of the word "purgation." Thus, we hold that Braintree's statement was not a clear and unmistakable disavowal. *See SkinMedica, Inc. v. Histogen Inc.*, 727 F.3d 1187, 1199-1201 (Fed. Cir. 2013); *Elbex Video, Ltd. v. Sensormatic Elecs. Corp.*, 508 F.3d 1366, 1371 (Fed. Cir. 2007).

For the aforementioned reasons, we affirm the district court's construction of the claim term "purgation."

2. Clinically Significant Electrolyte Shifts

The district court originally construed "clinically significant electrolyte shifts" to require "alterations in blood chemistry that are outside the normal upper or lower limits of their normal range *or* other untoward effects." *Claim Construction Order* at *6. Later, in considering the parties' summary-judgment motions, the district court amended its construction and re-defined "clinically significant electrolyte shifts" to be "alterations in blood chemistry that are *both* outside the normal upper or lower limits of their range *and* accompanied by or manifested as other untoward effects." *Infringement Opinion* at *7 (emphases added). The district court explained that it modified its original construction to make it conjunctive because the specification refers to "electrolyte shifts leading to serious health problems for the patient." *Id.* It further explained that the phrase "untoward effects" may refer to "those fatal side effects of the [prior art] solution because such

side effects are referred to in the specification" and "is meant to show that electrolyte abnormalities are not clinically significant unless they lead to serious adverse health effects, like those caused by [the prior art]." *Id.*

On appeal, Novel argues that in requiring both alterations in blood chemistry and other untoward effects, the district court ignored the inventor's clear definition of the term "clinically significant electrolyte shifts" in the specification. *See* '149 patent col. 2 ll. 47-51 ("The terms 'clinically significant' as used herein are meant to convey alterations in blood chemistry that are outside the normal upper or lower limits of their normal range or other untoward effects.").

In defending the district court's final construction, Braintree argues that the preferred embodiment—referred to as Solution D in the '149 patent—caused alterations in some patients' blood chemistry, but those alterations were found to be "clinically insignificant." '149 patent col. 10 ll. 32-33. Thus, according to Braintree, the definition found in the specification would exclude Solution D, which is the preferred embodiment in the '149 patent. And "[a] claim construction that excludes the preferred embodiment 'is rarely, if ever, correct and would require highly persuasive evidentiary support.'" *Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*, 616 F.3d 1283, 1290 (Fed. Cir. 2010) (citation omitted).

Under our precedent, the patentee's lexicography must govern the claim construction analysis. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005) (en banc). Therefore, we disagree with the district court's modification of the clear language found in the specification. We reverse the district court's claim construction and construe "clinically significant electrolyte shifts" to be "alterations in blood chemistry that are outside the normal upper or lower limits of their normal range or other untoward effects."

B. Infringement

We review the grant of summary judgment under the law of the regional circuit. *Lexion Med., LLC v. Northgate Techs., Inc.*, 641 F.3d 1352, 1358 (Fed. Cir. 2011). The Third Circuit reviews the grant of summary judgment de novo. *Nicini v. Morra*, 212 F.3d 798, 805 (3d Cir. 2000) (en banc). Summary judgment is appropriate if the movant "shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a).

Based on its construction of "purgation," which does not require a full cleanse, the district court found that one bottle of SUPREP meets the "purgation" claim limitation, as it will induce an evacuation of a copious amount of stool from the bowels and is a composition comprising 473 mL of an aqueous hypertonic solution. *Infringement Opinion* at *9-10. We affirm the district court's construction of this term, and we likewise affirm the district court's finding that one (half-dose) bottle of SUPREP practices this claim limitation.

The district court also found that SUPREP practices the "wherein the composition does not produce any clinically significant electrolyte shifts" limitation. *Id.* at *6-8. It based its conclusion not only on its erroneous construction of the term "clinically significant electrolyte shifts" but also on its importation of the claim terms "a patient" into this limitation. *Id.* at *8. The words "a patient" are found in the preamble. *See* Ex Parte Reexamination Certificate, '149 patent col. 2 ll. 23-24. The district court explained that, based on its review of the record, "it appears that the administration of the composition and evaluation of the electrolyte levels in [the asserted claims] were meant to be done on a per patient basis." *Infringement Opinion* at *8. It defined "a patient" to mean "one or more patients." *Id.* It then found that "at least one patient to whom SUPREP is administered will experi-

ence, or has experienced, no clinically significant electrolyte shifts." *Id.*

"[I]f the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999) (citations omitted). Conversely, a preamble is not limiting "where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention." *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997).

Neither party has argued on appeal that the district court erred in importing "a patient" into this limitation. However, the parties are at odds over whether the district court's definition of "a patient" is correct. Novel argues that the district court's definition limits the utility of the claimed compositions to administration in a single patient. Indeed, such an interpretation would allow a composition to meet the claims even if 99 patients out of 100 experienced clinically significant electrolyte shifts, as long as one patient did not.

In support of the district court's definition of "a patient," Braintree argues that "a patient" must mean one or more patients, as it cannot be the case that no infringement can occur if SUPREP causes a clinically significant electrolyte shift in a single patient.

We agree with Novel and conclude that, in this case, the district court's definition of "a patient" is incorrect. In view of the proper claim construction of "clinically significant electrolyte shifts," the district court's application of the claim terms "a patient" leads to the absurd result of infringement even if a composition causes clinically significant electrolyte shifts in a large percentage of patients. Therefore, we instead interpret "a patient" to mean the general class of persons to whom the patented

compositions are directed, i.e., a patient population. This definition of a patient is consistent with the "invention the patentee intended to define and protect." *Rowe*, 112 F.3d at 478. Indeed, in the specification, the inventor states that his "objective was to find a well tolerated orally administered colonic purgative that . . . avoided the risks of upset or electrolyte balance *in patients*." '149 patent col. 4 ll. 45-48 (emphasis added). In addition, the inventor states that a preferred embodiment has been "well tolerated by *normal* people." *Id.* at col. 11 ll. 43-44 (emphasis added). And in the '149 patent's abstract, the inventor described his invention as "[a] compromise between convenient, distasteful, solid or low volume, hyperosmotic solutions which cause considerable fluid and electrolyte imbalances *in patients* and large volume, difficult to consume, iso-osmotic solutions . . . ." *Id.* at abstract (emphasis added).

We note that there is evidence in the record that at least some patients experienced alterations in blood chemistry that are outside the normal upper or lower limits of their normal range. *See, e.g.*, J.A. 924, 5059-71, 6683, 6694, 6759, 6831, 6833, 6849, 6857. Therefore, we conclude that there remains a genuine dispute as to whether SUPREP avoids producing any clinically significant electrolyte shifts in a patient population. We vacate the district court's grant of summary judgment of infringement, and we remand this matter to the district court for further factual findings concerning whether such alterations qualify as "clinically significant electrolyte shifts" in accordance with the proper claim construction articulated here within.

C. Invalidity

Invalidity must be proven by clear and convincing evidence. *WMS Gaming Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1355 (Fed. Cir. 1999). On appeal from a bench trial, we review the district court's conclusions of law de novo

and findings of fact for clear error. *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1123 (Fed. Cir. 2000).

1. Anticipation by Hechter

Anticipation is a question of fact, and a district court's findings on this issue are reviewed for clear error. *See Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1082 (Fed. Cir. 2008). Below, the district court found that Novel "did not show proof that met the clear and convincing standard" that the asserted claims were anticipated by Hechter. *Validity Opinion* at *25. The district court credited Braintree's expert witness's opinion that Hechter does not disclose several limitations of the asserted claims. *Id.* at *24. On appeal Novel argues again that Hechter anticipates the asserted claims of the '149 patent.

Hechter teaches first mixing 60 grams of a dry powder composition with one-liter of water and then later adding three additional liters of water prior to administration. Hechter col. 3 ll. 52-62. Novel argues that Hechter expressly discloses the preparation of a one-liter hypertonic solution because during the first step, the composition in Hechter is mixed with one-liter of water. *See id.* at col. 3 ll. 55-59. It alleges that Hechter further discloses that 1.6 liters, or 40% of its four-liter solution, is capable of cleansing the colon (*Id.* at col. 4 ll. 13-16); 40% of one-liter is 400 mL. Novel also claims that the initial solution in Hechter is inherently hypertonic.

We note that during prosecution, the examiner initially rejected the claims over Hechter. *See* J.A. 21889. Braintree then added the word "hypertonic" to its claims, explaining that Hechter taught administering 3 to 4 liters of an isotonic solution, while the claims were directed to hypertonic solutions. J.A. 21906, 21913-14. In response, the examiner withdrew the rejections. J.A. 21922.

After reviewing Hechter and the '149 patent's prosecution history, we conclude that Novel's argument is flawed for at least three reasons. First, Hechter does not disclose administering this initial one-liter solution to a patient. And we find no clear error in the district court's finding that skilled artisans would not have administered Hechter's initial mixing solution because, as the '149 patent explains, "concentrating the large volume, [isotonic preparations] into smaller volumes does not achieve the same effectiveness, and is not as safe." '149 patent col. 3 ll. 26-28. Second, although theoretically the initial one-liter solution described in Hechter could be hypertonic in a patient, both parties' experts agreed that the only way to know whether Hechter's initial mixing solution was hypertonic would be to test it. *See* J.A. 21251-52, 21422, 21622. But Novel has no evidence to suggest that the initial mixture in Hechter has been tested in a patient population, let alone that it was found to be hypertonic. *Id.* Thus, Novel lacks clear and convincing evidence that Hechter teaches this limitation. Third, Hechter actually teaches away from administering a hypertonic solution, stating that its solution needs to be isotonic in order to avoid clinically significant electrolyte shifts. *See* Hechter col. 2 ll. 9-39, col. 2 ll. 60-67, col. 3 ll. 15-16, col. 3 ll. 38-40. For at least these three reasons, we affirm the district court's finding that Hechter does not anticipate the asserted claims of the '149 patent.

2. Obviousness

Obviousness is a question of law, reviewed de novo, based on underlying factual findings, reviewed for clear error. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). The district court found that Novel, which relied on sixteen prior art references, failed to prove obviousness by clear and convincing evidence. *Validity Opinion* at *24. "[D]iscount[ing] [Novel's expert's] testimony on credibility grounds because some of his conclusions did not appear to be as reasonable," the district court found that the prior

art "did not direct a [skilled artisan] to combine sodium sulfate, magnesium sulfate, and potassium sulfate in a small volume hypertonic solution that causes purgation, does not produce clinically significant electrolyte shifts, and does not contain phosphate." *Id.* at *22. The district court also found that the inventor's "detailed experimentation" was far from the "tweaking" and "modifying" that Novel's expert claimed. *Id.* at *23.

Novel relies on many references as an attempt to demonstrate that, at the time of the invention, one of skill in the art knew that: (1) sulfate salts caused purgation of the colon; (2) hypertonic, low-volume colon-cleansing solutions were preferable; (3) clinically significant electrolyte shifts should be avoided; (4) bowel preps should be administered in a split-dose regimen; and (5) bowel preps should typically avoid phosphates. It adds that the prior art consisted only of a limited number of known agents that may be combined to cleanse the colon without ingesting phosphate and without producing clinically significant electrolyte shifts. Further, Novel argues that all components in the asserted claims were known purgatives at the time of invention. Thus, Novel alleges that the asserted claims "'simply arrange[] old elements with each performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement, [so] the combination is obvious." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) (citation omitted). Finally, Novel argues that before the '149 patent's priority date, there was a need to: (1) avoid the use of phosphates in particular patient populations; and (2) develop a low-volume solution to improve patient compliance and efficacy. Novel claims the district court failed to consider the limited number of choices to meet those market preferences and pressures.

We disagree. As the district court correctly noted, Novel did not prove that one of skill in the art would have been motivated to combine so many references. In other

words, it failed to prove a "plausible rational[e] as to why the prior art references would have worked together." *Power-One, Inc. v. Artesyn Techs., Inc.*, 599 F.3d 1343, 1352 (Fed. Cir. 2010). Further, in building its obviousness case, Novel relies on expert testimony which the district court found to be less credible. *Validity Opinion* at *25. And the prior art, including Hechter, taught that safe bowel preps should be isotonic, not hypertonic like the claimed compositions. *See, e.g.*, Hechter col. 2 ll. 60-64. Therefore, we conclude that the district court did not err in finding that Novel failed to demonstrate that the asserted claims of the '149 patent would have been obvious at the time of the invention.

3. Indefiniteness

We review de novo the district court's decision regarding indefiniteness, as it is a question of law. *Ergo Licensing, LLC v. CareFusion 303, Inc.*, 673 F.3d 1361, 1363 (Fed. Cir. 2012). The district court found that Novel failed to prove the claims indefinite by clear and convincing evidence. *Validity Opinion* at *25-26. It rejected Novel's argument that a skilled artisan would not understand the word "copious"—a term not used in any claim and only found in the district court's construction of "purgation." *Id.* at *25. On appeal, Novel argues that the district court noted but then ignored the clear import of the testimony from the inventor, who admitted explicitly that the term purgation "does not have a defined volume." J.A. 21048-49. It points to further testimony on the record from a Braintree employee, in which the employee admitted: "I don't think there's any clear definition about what copious diarrhea means." J.A. 21304.

We are not persuaded by Novel's indefiniteness argument. It has failed to show why the word "copious," a word that is not found in the claims but rather is used in the district court's construction of "purgation," is indefinite in this context. Descriptive words like "copious" are

commonly used in patent claims, to "avoid[] a strict numerical boundary to the specified parameter." *See Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1217 (Fed. Cir. 1995). Further, when asked what copious would mean to one of skill in the art, Braintree's expert witness stated "[w]ell, copious is a lot. . . . I think anyone who has taken a bowel prep prior to [a] colonoscopy, knows that it's quite a bit of diarrhea that comes out." J.A. 20161. We agree, and therefore we conclude that one of skill in the art would understand what a "copious" amount of diarrhea is in this context.

IV. CONCLUSION

For the foregoing reasons, we affirm the district court's claim construction of "purgation." However, we conclude that the district court erred in construing the claim term "clinically significant electrolyte shifts." We reverse its claim construction and vacate its grant of summary judgment of infringement. Regarding validity, we affirm the district court's findings that the asserted claims of the '149 patent are not anticipated, not obvious, and not indefinite. We remand this case to the district court for further proceedings consistent with this opinion.

AFFIRMED-IN-PART, REVERSED-IN-PART, VACATED-IN-PART, AND REMANDED

United States Court of Appeals for the Federal Circuit

BRAINTREE LABORATORIES, INC.,
Plaintiff-Appellee,

v.

NOVEL LABORATORIES, INC.,
Defendant-Appellant.

2013-1438

Appeal from the United States District Court for the District of New Jersey in No. 11-CV-1341, Judge Peter G. Sheridan.

DYK, *Circuit Judge*, concurring in part, dissenting in part, and concurring in the result.

I agree with Judge Prost that the district court erred in its construction of "clinically significant electrolyte shifts" and that the correct construction of that term is "alterations in blood chemistry that are outside the normal upper or lower limits of their normal range or other untoward effects." Op. of Prost, J., at 9. Although it seems to me that Novel established non-infringement as a matter of law under the correct "clinically significant electrolyte shifts" construction, I join the remand to the

district court for further proceedings on that issue.[1] I also agree that the asserted claims of the '149 patent are not invalid. Thus I join parts I–II, III(A)(2), III(B) (except the second paragraph) and III(C).

However, I respectfully dissent from the majority's conclusion that Novel's ANDA meets the volume limitation of the asserted claims. Under the proper interpretation of the volume limitation, Novel established non-infringement as a matter of law. In my view, the majority's contrary conclusion is inconsistent with established authority under the Hatch-Waxman Act.

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[1] The sole evidence in the summary judgment record concerning the percentage of individuals experiencing such electrolyte shifts is data from two clinical studies of SUPREP, and those data are sufficient to show that the claim limitation was not met. The first, BLI800-202, a Phase II study of eighteen patients, showed that a majority of patients experienced clinically significant electrolyte shifts. J.A. 5059–69; 6642, 6683; 6756, 6759; 6831; 6912; 7000, 7002; 7094, 7100; 7386; Def.'s Br. in Supp. of Mot. for Summ. J. 8, *Braintree Labs., Inc. v. Novel Labs., Inc.*, No. 3:11-cv-1341 (D.N.J. Oct. 9, 2012), ECF No. 159-1. The second, BLI800-303, a Phase III study of sixty-three patients, showed that a significant minority or about one-third of patients experienced clinically significant electrolyte shifts. J.A. 9679 (expert report of Dr. Goldfarb (Novel's expert witness) summarizing BLI800-303 data). Braintree's expert witness Dr. Peura also testified that "abnormal electrolyte values have been observed in some patients taking SUPREP." J.A. 10322 (emphasis removed).

I

I agree with the majority that the district court's construction of "purgation" was correct. But even under that construction, Novel's ANDA does not meet the claimed volume limitation. The asserted claims include a volume limitation that requires that the solution be between 100-500 mL, as seen in representative claim 15:

> A composition for inducing purgation of the colon of a patient, the composition *comprising from about 100 ml to about 500 ml* of an aqueous hypertonic solution . . . wherein the composition does not produce any clinically significant electrolyte shifts . . . .

Ex Parte Reexamination Certificate No. 6,946,149C1 col. 2 ll. 23–30 (emphasis added). The asserted claims also include claims 18–20, and 23. Claims 19–20 and 23 are method of use claims.

In ANDA litigation, because a generic company seeking FDA approval does not yet "make[], use[], offer[] to sell, or sell[]" the product and therefore cannot infringe under 35 U.S.C. § 271(a), pharmaceutical companies must rely on 35 U.S.C. § 271(e)(2)(A), which creates an "artificial" act of infringement when the generic company submits an ANDA *seeking approval* "'for a drug claimed in a patent or the use of which is claimed in a patent.'" *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 675, 676 (1990) (quoting § 271(e)(2)(A)). The infringement occurs only if the generic company seeks approval for a patented composition or use *that has been approved by the FDA*. *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1319 (Fed. Cir. 2012) (citing *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1356 (Fed. Cir. 2003) ("'[T]he use' in § 271(e)(2)(A) refers to the use for which the FDA has granted an NDA.")); *Glaxo, Inc. v. Novopharm, Ltd.*,

110 F.3d 1562, 1567–68 (Fed. Cir. 1997) (composition is determined by the composition in the ANDA).[2]

Under the Hatch-Waxman Act, the infringement inquiry "must focus on what the ANDA applicant will likely market if its application is approved." *Id.* at 1569. Novel's ANDA does not cover administration of the drug for purgation sufficient for "evacuation of a copious amount of stool from the bowels." *Claim Construction Order* at *6. Rather, Novel's ANDA states specifically that the drug "is indicated for cleansing of the colon as a preparation for colonoscopy in adults." J.A. 5280. The ANDA limits its dose regimen (the SUPREP regimen) as follows: "The *dose* for colon cleansing requires *administration of two bottles* of [oral solution]. Each bottle is administered as 16 oz [*i.e.*, 473 mL] of [oral solution] . . . ." J.A. 5280 (emphases added). Therefore, the volume of the dose in Novel's ANDA is 946 mL.[3] Braintree's infringement argument,

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[2] Section 271(e)(2)(A) reads as follows:

> (2) It shall be an act of infringement to submit—
>
> (A) an application under [21 U.S.C. § 355(j)] or described in [21 U.S.C. § 355(b)(2)] for a drug claimed in a patent or the use of which is claimed in a patent.

35 U.S.C. § 271(e)(2)(A).

[3] *See also* J.A. 22172 (Braintree's Patent Term Extension Request) ("The SUPREP product . . . contains only 2 x 16 ounces of solution (*i.e.*, approximately 2 x 0.47 L = .94L of solution), as indicated in the approved label . . . ."); J.A. 4262 (Jack A. Di Palma et al., *A Randomized Clinical Study Evaluating the Safety and Efficacy of a New, Reduced-Volume, Oral Sulfate Colon-Cleansing Preparation for Colonoscopy*, 104 Am. J. Gastroenterology 2275, 2276

adopted by the district court and by the majority here, is the "one bottle" infringement theory, which asserts that because one (half-dose) bottle of Novel's proposed generic falls within the 100-500 mL volume range and would cause a "purgation," the ANDA infringes.

Here, "one bottle" consisting of 473 mL is *not* the dose approved by the FDA. The approved NDA for SUPREP does not permit a dose regimen of *only* one 16 oz bottle (473 mL), but requires both administrations of the "split-dose" regimen of two bottles (946 mL). Nor does the NDA recommend a one bottle dose to induce purgation as a possible alternative. Since no clinical studies have been conducted to support a one bottle regimen for purgation, the FDA has not approved such a use. *See* 21 U.S.C. § 355(d)(1). Because there is no underlying NDA approval for a one bottle regimen for purgation, Novel is precluded from seeking an ANDA for such a regimen.[4] Instead, Novel's ANDA properly seeks approval for a 946 mL, two bottle regimen to induce colon cleansing, based on Braintree's approved NDA. Therefore, Novel's ANDA does not infringe the '149 patent, which claims a composition with a volume of 100-500 mL for inducing purgation and a method of using the same.

(2009)) ("The total preparation volume [of SUPREP] is 960 ml.").

[4] A generic may not file an ANDA that differs from the approved NDA in "route of administration, dosage form, or strength" unless it has obtained special permission from the FDA to do so, 21 U.S.C. § 355(j)(2)(C), and Novel neither sought nor received such permission here. A generic may not seek approval for a *use* that differs from the approved NDA under any circumstances. *See Warner-Lambert*, 316 F.3d at 1356 (citing § 355(j)(2)(A)(i)).

The majority's contrary interpretation is inconsistent with this court's longstanding precedent. An ANDA cannot infringe an asserted patent when the FDA-approved dose is not the dose claimed in the patent. As we held in *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1332 (Fed. Cir. 2003), "a method of use patent holder may not sue an ANDA applicant for induced infringement of its patent, if the ANDA applicant is not seeking FDA approval *for the use claimed in the patent and if the use claimed in the patent is not FDA-approved*." (emphasis added) (citing *Warner-Lambert*, 316 F.3d at 1354–55). While the patent here includes both composition and method of use claims, all claims are limited to the use of a specified volume of the composition.

In particular, the majority's decision is contrary to our decision in *Bayer Schering*, where we held that because "the FDA has not approved [the use claimed in the patent] . . . the defendants cannot be held liable for infringement of the patent." 676 F.3d at 1326. There, the patent claimed the use of a particular drug to achieve three effects simultaneously, "a contraceptive effect, an antiandrogenic effect, and an antialdosterone effect." *Id.* at 1319 (quoting U.S. Patent No. 5,569,652). But the FDA-approved NDA and label indicated the use of the branded drug only "for oral contraception." *Id.* (internal quotation marks omitted). We held that the accused ANDAs did not infringe because they did not seek approval for two of the claimed uses. *Id.* at 1326. There was no infringement under § 271(e)(2)(A) because "the defendants' ANDAs [sought] approval to market the generic [drug] for contraceptive use, and there is no valid patent on the use of the drug for that purpose alone." *Id.*

Crucially, we found it irrelevant that the drug did, in fact, cause the three claimed effects simultaneously—simply because a patient *could* practice the claims by using the drug to achieve all three effects did not mean

that the corresponding ANDA infringed. *Id.* at 1325–26. "[Nothing] on the [approved] label provide[d] any safety or efficacy information associated with the possible use of [the drug] in treating patients who are in need of those [claimed] effects." *Id.* at 1322. As we noted there:

> [T]he point is not simply that the method of use [claimed in the patent] was not described in the Indications and Usage section that shows lack of FDA approval; the point is that the label, taken in its entirety, fails to recommend or suggest to a physician that [the drug] is safe and effective for inducing the claimed combination of effects in patients in need thereof.

Id. at 1324. So too here—just because a patient *could* ingest only one bottle of Novel's generic to achieve a purgation does not make Novel's ANDA infringing. It is undisputed that Novel's proposed label fails to recommend or suggest to a physician that the solution should be taken to achieve purgation, rather than cleansing, or that it suggests taking a dosage below the 946 mL level for any purpose.

Similarly, in *Warner-Lambert*, 316 F.3d at 1356, we held that "because an ANDA may not seek approval for an unapproved or off-label use of a drug . . . it necessarily follows that 35 U.S.C. 271(e)(2)(A) does not apply to a use patent claiming only such [an unapproved or off-label] use." *See also AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1059–60 (Fed. Cir. 2010) (assuming that an ANDA seeking approval for a twice-daily dose regimen could not infringe a patent claiming a once-daily dose regimen). In short, Braintree's patent claims a composition and a method, both of which require using a 100-500 mL solution. Novel's ANDA seeking FDA approval for a 946 mL solution cannot infringe the '149 patent.

II

Even if there were no Hatch-Waxman issue, Braintree's theory would be unsupportable. Braintree's "one bottle" theory rests on a demonstrably incorrect claim construction. Here, "volume" refers to the total volume of the recommended dosage and not some portion of that total volume—whether or not the recommended dosage is given in one bottle or two bottles.

The '149 patent specification describes the two categories of bowel cleansing options in the prior art to the '149 patent, each with its own disadvantages. The first were "large volume" isotonic solutions that did not cause electrolyte shifts in patients. '149 patent col. 1 ll. 31, 48–53. The second were "small volume" hypertonic preparations that caused severe electrolyte shifts in many patients, often with life-threatening results. *Id.* col. 2 ll. 41–44, col. 4 ll. 23–26. The inventors of the '149 patent further recognized that although "[c]linical trials have shown use of the 4 liter [*i.e.*, large volume] [isotonic] solution to be safe and efficacious [*i.e.*, did not cause electrolyte shifts]," that patient "compliance [with ingesting such solutions] is poor because of the large volume of solution." *Id.* col. 4 ll. 1–5. The '149 patent attempted to address both issues by creating a small volume solution for patient ingestion that did not cause clinically significant electrolyte shifts. The volume limitation was critical to distinguish the '149 patent from the prior art. The specification explains that the prior art solutions were customarily ingested in multiple administrations, such that a solution with a *total* volume of 4 liters would be divided into administrations of 500 mL or less.[5] The specification suggested the same

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[5] *See, e.g.*, '149 patent col. 1 ll. 53–56 ("Because the [large] solutions are isotonic, patients are required to ingest a significant amount of volume of these solutions,

method of dividing the *total* volume for ingesting the claimed solution:

> Optimally, the effective *dose* may be divided and administered, to the patient in *two, or more* administrations over an appropriate time period. Generally, 2 doses administered of equal portions of the effective dose, separated by 6 to 24 hours produce satisfactory purgation.

Id. col. 5 ll. 19–24 (emphasis added). The specification thus makes clear that the total volume is the combination of the divided doses. Under the correct construction as envisioned by drafters of the '149 patent, "volume" referred to the *total* claimed 100-500 mL volume of solution ingested by the patient as the recommended dose to induce purgation, even if this total volume has been divided into smaller administrations of unspecified size. This ensured that the claimed volume limitation did not run afoul of the prior art solutions such as Hechter, which suggested dividing a "large volume" solution of 4 liters into individual administrations of about eight ounces or 237 mililiters. Hechter col. 4 ll. 2–12, col. 6 ll. 14–35.

Indeed, Braintree's own arguments that Hechter does not anticipate the '149 patent focus on the *total* volume of the disclosed Hechter solution and are inconsistent with its "one bottle" infringement theory. Hechter disclosed a 4 liter isotonic solution that would be created from a 1 liter hypertonic stock solution. Hechter col. 3 ll. 55–62.

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up to one *eight ounce* glass [*i.e.*, 237 mL] every ten minutes for a *total* of one gallon of fluid [*i.e.*, about 4 L] to achieve effective purging." (emphasis added)); *id.* col. 2 ll. 32–34 ("Patients are typically required to take two (2) three ounce doses of [Fleets Phospho-Soda] separated by a three to 12 hour interval for a total of six ounces (180 ml).").

Novel argued that because Hechter taught that only 40% of the 4 liter isotonic solution must be ingested to achieve colon-cleansing, it inherently disclosed a 400 mL hypertonic stock solution capable of colon-cleansing. Appellant's Br. 47–49. But Braintree's expert witness in this case disagreed, objecting that there could be no anticipation from consuming only a portion of the recommended dose. *See* J.A. 21624 (Peura direct testimony) at 962:7–13 (explaining that he disagreed with Novel's inherent disclosure theory, because "[w]ell, a liter is a liter. You know, there may be two 500 milliliters components to a liter or four 250, or ten 100; there's no teaching in Hechter that would suggest that . . . this liter would ever be administered to anybody, and there's surely no teaching that you can divide this liter into component parts."). Braintree's own argument that Hechter does not anticipate the claimed invention depends, in part, on an assumption that the relevant volume is the total amount of a disclosed solution, not the volume of individual administrations or separate components of that solution.

In short, the specification of the '149 patent and Braintree's own expert made clear that the invention was directed at "small volume" solutions of 100-500 mL *total*—not large volume solutions that could be divided into 100-500 mL administrations. Braintree's "one bottle" theory of infringement therefore leads to the surprising result that although large volume solutions of 4 liters are derogated in the specification, if administered in 500 mL increments, such solutions would infringe the '149 patent. Therefore, the entire premise of the '149 patent—that a recommended dosage of a small volume would improve patient compliance—is ignored by Braintree's one bottle theory.

Because Novel's ANDA does not meet the volume limitation of the asserted claims, under this court's ANDA infringement precedent and under the language of the

specification, it cannot infringe the '149 patent. I respectfully dissent from the contrary conclusion reached by the majority.

United States Court of Appeals for the Federal Circuit

BRAINTREE LABORATORIES, INC.,
Plaintiff-Appellee,

v.

NOVEL LABORATORIES, INC.,
Defendant-Appellant.

2013-1438

Appeal from the United States District Court for the District of New Jersey in No. 11-CV-1341, Judge Peter G. Sheridan.

MOORE, *Circuit Judge*, dissenting.

I join the majority opinion except for Part III-B because I disagree with the majority's construction of "a patient." I agree with the district court that "a patient" means "one or more patients" in accordance with the plain language of the asserted claims and with our precedent. I would affirm the district court's summary judgment of infringement because undisputed evidence shows that at least one patient who was treated with the accused composition has experienced "clinically significant electrolyte shifts" within the meaning of the claims. Therefore, I respectfully dissent.

Reexamined claim 15 of U.S. Patent No. 6,946,149 ('149 patent), which is representative of the asserted

claims, recites "[a] composition for inducing purgation of the colon of a patient, . . . wherein the composition does not produce any clinically significant electrolyte shifts . . . ." Everyone agrees that the preamble term "a patient" limits the scope of the claim. The disagreement centers on the meaning of "a patient." The district court held that it meant one or more patients. The majority concludes that it means "a general class of persons," or "a patient population." Maj. Op. at 11–12.

The plain and ordinary meaning of "a patient" is one or more patients. We have, on many occasions, construed the article "a." Not surprisingly, this word appears in many patent claims. We have repeatedly held that "a," when used in a "comprising" claim, means one or more. "As a general rule, the words 'a' or 'an' in a patent claim carry the meaning 'one or more.' The exceptions to this rule are extremely limited: a patentee must evince a clear intent to limit 'a' or 'an' to 'one.'" *01 Communique Lab., Inc. v. LogMeIn, Inc.*, 687 F.3d 1292, 1297 (Fed. Cir. 2012); *see also SanDisk Corp. v. Kingston Tech. Co., Inc.*, 695 F.3d 1348, 1360–61 (concluding that "a" means "one or more"); *Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1342 (Fed. Cir. 2008) ("[T]his court has repeatedly emphasized that the indefinite article 'a' or 'an' in patent parlance carries the meaning of 'one or more' in open-ended claims containing the transitional phrase 'comprising.'"). In the few instances where we have ever deviated from this general rule, we concluded that the intrinsic evidence made it clear that the patentee intended "a" to mean one and only one. *See Tivo, Inc. v. EchoStar Commc'ns Corp.*, 516 F.3d 1290, 1303–04 (Fed. Cir. 2008); *Insituform Techs., Inc. v. Cat Contracting, Inc.*, 99 F.3d 1098, 1105–06 (Fed. Cir. 1996).

Strangely, the majority does not conclude that "a patient" means "one or more," consistent with our general rule, or that it means "only one," consistent with the only exception that we have allowed. "A patient," according to

the majority, *requires* multiple patients, a patient population, or patient class. But there is no plain meaning of "a" that excludes the singular. We give claim terms their plain and ordinary meaning unless the patentee acted as its own lexicographer or there was a disavowal of claim scope. *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012). Neither of these circumstances is present here. Although the majority is correct that the specification sometimes uses the plural "patients," at other places it uses the singular "patient." *See* '149 patent col. 2 ll. 43–44, col. 2 l. 65, col 3 l. 3, col. 5 l. 21. The patentee obviously knew how to refer to "patients" generally or as a class, but chose to draft the claims to recite only "a patient." Nothing in the specification of the '149 patent or its prosecution history defines the singular "a patient" as a plural "patient population" contrary to the words of the claims. In fact, the patent lists only one object of the invention—and it is described in terms of impact on a single patient: "One purpose of the present research was to develop a safe, effective, and well tolerated small volume solution made up of a high concentration of poorly absorbable salts that induce colon cleansing catharsis after oral ingestion without clinically significant alternation [sic] of sodium, chloride, bicarbonate, potassium, calcium, and phosphate level and balance or other untoward effects on *the recipient.*" *Id.* col. 3 ll. 32–38.

I agree with the majority that the patent defines "clinically significant electrolyte shifts" as "alterations in blood chemistry that are outside the normal upper or lower limits of their normal range or other untoward effects." *Id.* col. 2 ll. 47–51. According to the patent, clinical significance is measured in an individual patient. Namely, are the electrolyte shifts in an individual patient clinically significant, *i.e.*, are they outside the normal range? "Clinical significance" can sometimes refer to a measure of statistical significance and other times to a

measure of deviation from normal in an individual patient. This patent, as discussed above, expressly defines it as a measure in an individual patient. *See also id.* col. 2 ll. 43–44 (the invention avoids electrolyte shifts that are "clinically significant to *the patient*"); *id.* col. 3 ll. 66–67 ("clinically significant electrolyte shifts on *bodily chemistry*"); *id.* col. 3 ll. 35–38 ("clinically significant alternation [sic] . . . or other untoward effects on *the recipient*"). Extrinsic evidence of record likewise demonstrates that clinical significance is a measure applied to a single patient. For example, the record includes a laboratory report *on an individual patient* that directs the analyst to indicate whether the test results were "Clinically Significant" or "Not Clinically Significant" for that patient, J.A. 6756, and expert reports confirm this single-patient meaning of the term, *see* J.A. 5059; J.A. 5153–54. Indeed, the use of the term "clinical significance" to refer to individual patients is well-established in the medical arts. *See, e.g.*, Alan E. Kazdin, *The Meanings and Measurement of Clinical Significance*, 67 J. Consulting & Clinical Psychol. 332, 332–33 (1999) (asking whether "the criterion of clinical significance may not be met" when "*the client* improves, but at the end of treatment *the client's behavior* has not changed enough for it to fall within the normative range"). I see no basis in the specification or the prosecution history to rewrite the patent claims.

This claim covers "[a] composition for inducing purgation of the colon of a patient . . . wherein the composition does not produce any clinically significant electrolyte shifts . . . ." To infringe, the composition must induce purgation in the colon of a patient without producing clinically significant electrolyte shifts (*i.e.*, shifts outside the normal range) in that patient. Infringement is proven if the composition causes these reactions in a single patient. The majority believes this to be an "absurd result" because it would allow "a composition to meet the claims even if 99 patients out of 100 experienced clinically

significant electrolyte shifts, as long as one patient did not."[1] Maj. Op. 11. I understand the majority's concern. But this is a question of damages, not infringement.

Infringement, whether on a large or small scale, is still infringement.[2] *See, e.g.*, *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1318 (Fed. Cir. 2009). *Lucent* makes clear that there is no "rare infringement" exception to liability, and that even one instance of infringement is adequate to support a judgment of infringement. *Id.* (affirming a finding of direct infringement where a jury "could have reasonably concluded that . . . more likely than not *one person somewhere in the United States* had performed the claimed method"); *see also Broadcom Corp. v. Emulex Corp.*, 732 F.3d 1325, 1333 (Fed. Cir. 2013) ("It is well settled that an accused device that sometimes, but not always, embodies a claim nonetheless infringes."). The law responds to rare infringement not by eliminating liability, but by providing for a correspondingly low award of damages. *See Lucent*, 580 F.3d at 1334 ("The damages award ought to be correlated, in some respect, to the extent the infringing method is used by consumers."). Likewise, the decision whether to award injunctive relief in a patent infringement suit, which is at the discretion of the district court, includes consideration of the extent of infringement or harm to the patentee. *See Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1148–50 (Fed. Cir. 2011).

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[1] To be sure, there is evidence in the record in this case that the claimed composition infringes in numerous instances, not just one. *See* Maj. Op. at 12.

[2] It may be that the FDA would not approve a drug that has efficacy in a small percentage of the patients who take it, but that is not the standard we use in assessing infringement of patent claims.

And here lies the heart of the majority's problem. This is an ANDA case. In ANDA cases in which the accused product has not yet been marketed, a damages remedy is of course not available. Instead, the district court "*shall* order the effective date of any approval of the drug . . . involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed," and the court "may" grant "injunctive relief." 35 U.S.C. § 271(e)(4)(A), (B). Thus, while the injunction remedy rests within the discretion of the district court, the order to delay the approval of the ANDA until patent expiration is *not* discretionary. *Id.* I don't like this result either, but this is exactly what the statutory language commands. The statute requires the court to delay approval until expiration of the patent, even if there is only a single infringement. And since the generic can't launch without FDA approval, the statute creates a de facto injunction.

In an effort to avoid this outcome, the majority rewrites the claim language to allow infringement only if the drug works in a patient population rather than a patient.[3] But this we cannot do. *Chef Am., Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1374 (Fed. Cir. 2004) ("[W]e construe the claim as written . . . ."); *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357 (Fed. Cir. 1999)

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[3] Changing "a patient" to "a patient population" is pernicious for practical reasons as well. Infringement will now be measured by whether a patient population experiences purgation without abnormal shifts in electrolytes. What percentage of people constitutes a patient population? Is the patient population everyone who takes the drug? A statistically significant number of people who take the drug—which would be 99.5%? A majority? And have we now written an indefinite or unsupported claim for the patentee?

("[A] nonsensical result does not require the court to redraft the claims . . . ."). If the result commanded by the statute is unsatisfactory, the proper response is for Congress to amend the statute, making the delayed approval discretionary rather than mandatory, not for us to redraft the patent to avoid such a result. For these reasons, I respectfully dissent. I would affirm the district court's summary judgment of infringement.