***Braintree v. Novel*: When "a" excludes the singular**

In *Braintree Labs., Inc. v. Novel Labs., Inc*., __ F.3d __ (Fed. Cir. 2014)(Prost, J.), the principal opinion reached the surprising conclusion that "a" excludes the singular. One member of the panel explained that:

"The plain and ordinary meaning of 'a patient' is one or more patients. * * * '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."
Braintree, __ F.3d at __ (Moore, J., dissenting)(original emphasis)

The third member of the panel had a lengthy opinion on a variety of issues, , __ F.3d at __ (Dyk, J., concurring in part, dissenting in part, and concurring in the result)

Petition for Rehearing *En Banc*: In support of a petition for rehearing en banc BIO and Pharma have jointly filed an *amicus* brief. The brief, together with the opinion by Moore, J., are included in the attachment.

Regards,

Hal

No. 2013-1438

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRAINTREE LABORATORIES, INC.,
Plaintiff-Appellee,

v.

NOVEL LABORATORIES, INC.,
Defendant-Appellant.

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

BRIEF OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION & THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICI CURIAE* IN SUPPORT OF REHEARING OR REHEARING *EN BANC*

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INTEREST OF *AMICI CURIAE*[1]

The Biotechnology Industry Organization ("BIO") is the country's largest biotechnology trade association, representing over 1100 companies, academic institutions, and biotechnology centers in all 50 states and in countries around the world. BIO members research and develop biotechnological healthcare, agricultural, environmental, and industrial products. These members are a diverse group that range from start-up businesses and university spin-offs to Fortune 500 corporations.

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is an association dedicated to representing the Nation's leading pharmaceutical and biotechnology companies. PhRMA members' research and development efforts produce the innovative medicines, treatments, and vaccines that save and improve the lives of countless individuals around the world every day. Over the past decade, PhRMA's members have invested over $500 billion in the research and development of new drugs, with roughly $51.1 billion invested in 2013 alone.

Both BIO and PhRMA regularly participate as *amici* in cases raising important issues concerning the consistency and predictability of this Court's decisions, including on questions of claim construction. BIO's and PhRMA's members rely heavily on patents to protect their substantial investments of time, resources,

[1] Pursuant to Federal Rule of Appellate Procedure 29(c)(5), *amici* certify that no counsel for a party authored this brief in whole or in part, and no one but *amici* and its counsel contributed financially to the brief's preparation and submission.

and capital necessary to produce new innovations. Uncertainty in claim scope devalues patent assets, which in turn leads to reduced incentives for companies to research, develop, and commercialize new products that heal, feed, and fuel the world. To ensure enforceable patent rights, patent owners need clarity regarding the meaning of claim terms and how courts will interpret them. The panel majority's decision in this case conflicts with prior decisions of this Court and disrupts the consistency and predictability that BIO's and PhRMA's members need to conduct their businesses efficiently and in the public interest.

ARGUMENT

As Judge Moore explained in her dissent, the panel majority's interpretation of "a patient" to mean the precise opposite of its plain and ordinary meaning is "pernicious." J. Moore Dissent 6 n.3. The majority abandoned the presumptively correct meaning of "a patient" that is compelled by this Court's precedents—i.e., one or more patients—in favor of the unsupported view that this phrase has exactly the opposite meaning—a patient population, but *not* a single patient. *See id.* at 3 ("[T]here is no plain meaning of 'a' that excludes the singular."). The majority's decision lacks any basis in language or logic and will have significant adverse effects on future cases. The new rule espoused by the panel majority will not be confined to this case, or Hatch-Waxman Act cases, but will have far-reaching and harmful effects on numerous patents. The Court should grant the petition and vacate the panel's decision.

A. The Majority's Erroneous Construction of "A Patient" Creates a Conflict with this Court's Precedent.

The majority's construction of "a patient" as "the general class of persons to whom the patented compositions are directed, i.e., a patient population," Maj. Op. 11–12, is wrong and creates a conflict with this Court's precedents. As Judge Moore correctly explained, this Court has "repeatedly held" that "a" means "one or more," not exclusively "more." J. Moore Dissent 2.[2]

On occasion the Court has deviated from its general one-or-more rule when it is "clear that the patentee intended 'a' to mean one and only one." *Id.*[3] But never—at least prior to the panel decision in this case—has the Court interpreted "a" to mean "a population of," thereby precluding the singular. The panel had no authority to overrule this Court's prior precedent, which it purported to do without any discussion notwithstanding Judge Moore's cogent dissent.

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[2] *See SanDisk Corp. v. Kingston Tech. Co.*, 695 F.3d 1348, 1360 (Fed. Cir. 2012); *01 Communique Lab., Inc. v. LogMeIn, Inc.*, 687 F.3d 1292, 1297 (Fed. Cir. 2012); *Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1342 (Fed. Cir. 2008); *Lava Trading, Inc. v. Sonic Trading Mgmt., LLC*, 445 F.3d 1348, 1354 (Fed. Cir. 2006); *Free Motion Fitness, Inc. v. Cybex Int'l, Inc.*, 423 F.3d 1343, 1350–51 (Fed. Cir. 2005); *KJC Corp. v. Kinetic Concepts, Inc.*, 223 F.3d 1351, 1356–57 (Fed. Cir. 2000); *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 977 (Fed. Cir. 1999).

[3] *See Tivo, Inc. v. EchoStar Commc'ns Corp.*, 516 F.3d 1290, 1303–04 (Fed. Cir. 2008); *Norian Corp. v. Stryker Corp.*, 432 F.3d 1356, 1359 (Fed. Cir. 2005); *Abbot Labs. v. Baxter Pharm. Prods., Inc.*, 334 F.3d 1274, 1281 (Fed. Cir. 2003); *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1023–27 (Fed. Cir. 1997); *Insituform Techs., Inc. v. Cat Contracting, Inc.*, 99 F.3d 1098, 1105–06 (Fed. Cir. 1996); *N. Am. Vaccine, Inc. v. Am. Cyanamid Co.*, 7 F.3d 1571, 1575–77 (Fed. Cir. 1993).

The panel's failure to address the conflict it created will cause severe turmoil in future cases. Previously, it was well understood that reference to "a" thing in a claim usually meant one or more of that thing, and occasionally only one of that thing. Following the panel decision, however, "a" may also mean the exact opposite—an entire population or group, but *not* just one.

And the majority provided no guidance for determining when its new rule of construction will apply. Nothing in the particular patent claim here offers any guidance. The claim recites "'[a] composition for inducing *purgation* of the colon of *a patient*.'" Maj. Op. 3. The phrase "*a* patient" is obviously singular: the article "a" is used "before singular nouns," *see Merriam-Webster Online Dictionary*, "a," http://www.merriam-webster.com/dictionary/a (last visited June 4, 2014), and the noun "patient" is singular. Moreover, the claim refers to "the *colon* of a patient." A population obviously does not share a single colon. And as Judge Moore explains, the specification "expressly defines" the relevant measure as one "in an individual patient." J. Moore Dissent 4. Thus, the majority's new exception cannot be limited by the particular claim text.

Nor is there any other apparent limit on how far the majority's new rule extends. Is it limited to colon cleansers? Plainly not: the majority identified nothing specific to the '149 patent that compelled its result. Is it limited to the particular phrase "a patient"? Again, no, because the majority identified nothing inherent in that phrase to distinguish it from all other phrases that this Court has addressed. In-

deed, there is no apparent reason *not* to apply the majority's new rule to all claim terms reciting "a" thing or object, such as "a cell," "an animal," or even "a telecommunications device." This could have sweeping and harmful consequences for numerous patentees, who hold patents issued under this Court's once-consistent case law.

Further complicating matters, the majority provided no guidance for determining what constitutes a "population." *See* J. Moore Dissent 6 n.3. Consider a claim that recites "a device for cutting a wire." Under the majority's rule, one construction of this claim would require a device that cuts a population of wires. But does the population include both thin steel wires and thick titanium ones, or just groups of one or the other? The majority offered nothing on this, leaving claim drafters, litigants, and courts completely lost on how to invoke, avoid, or apply its new rule.[4]

B. The Majority's Absurdity Rationale Ignores Basic Science.

The majority reached its erroneous construction of "a patient"—notwithstanding the plain meaning of the phrase and explicit teachings of the spec-

[4] The panel majority's erroneous rule could also have other unintended consequences. In dissent, Judge Moore notes that the majority's contorted construction may well have created an issue of invalidity under 35 U.S.C. § 112. J. Moore Dissent 6 n.3 ("[H]ave we now written an indefinite or unsupported claim for the patentee?"). This is so even though claims must be interpreted to preserve their validity. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1327 (Fed. Cir. 2005) (en banc). And because the majority's opinion could be applied to a wide variety of patent claims, the potential for widespread problems under § 112 is considerable.

ification, *see* J. Moore Dissent 4—based principally on the notion that a natural reading of the phrase would lead to a finding of infringement even if a product would not work for everyone, and that such an "absurd[ity]" warranted a new rule. Maj. Op. 11. As Braintree's petition explains, the majority's absurdity rationale, on its own terms, cannot justify its erroneous construction. Pet. 7–8. But there is in fact no absurdity. To call the result it avoided absurd, the majority ignored the scientific reality that no drug works for all patients, and by doing so will create further confusion about its new rule.

To give an example: It is well-accepted that common over-the-counter combination drugs containing aspirin, acetaminophen, and caffeine are effective at treating migraines, significantly more so than a placebo. But according to the panel majority, determining infringement of a method for alleviating migraine pain in "a patient" could potentially create an "absurdity" that would warrant altering a claim's construction because the combination is not effective in 100% of patients.[5] In studies, approximately one-third to one-half of the patient population taking the

[5] *See, e.g.*, Richard B. Lipton et al., *Efficacy and Safety of Acetaminophen, Aspirin, and Caffeine in Alleviating Migraine Headache Pain*, 55 Arch. Neurol. 210, 210 (Feb. 1998), *available at* https://jamanetwork.com/data/Journals/NEUR/7648/noc7184.pdf ("Significantly greater reductions in migraine headache pain intensity 1 to 6 hours after dose were seen in patients taking the acetaminophen, aspirin, and caffeine combination than in those taking placebo in each of the 3 studies. Pain intensity was reduced to mild or none 2 hours after dose in 59.3% of the 602 drug-treated patients compared with 32.8% of the 618 placebo-treated patients … ; at 6 hours after dose, 79% vs 52%, respectively, had pain reduced to mild or none …. In addition, by 6 hours after dose, 50.8% of the drug-treated patients were pain free compared with 23.5% of the placebo-treated patients….").

drugs did not improve—does this constitute a "large percentage" that warrants a change in the natural reading of the claim? The majority does not say. *But see* Concurring Op. 2 n.1. Moreover, many patients in the placebo group also improved, despite receiving no drug—does this require courts to investigate who improved after taking the drug, who would have improved anyway, and whether their improvement was actually attributable to the drug? The majority's decision will require litigation on these types of issues, which is particularly unwarranted given that FDA found the effectiveness of the drug combination for treating migraine pain well established. This Court should not countenance a situation where facts sufficient for FDA approval would result in "absurdities" that warrant altering claim language.

Even a basic drug like aspirin may be inappropriate for some patients on occasion (when there is a risk of severe bleeding) or always (in case of an allergy to aspirin). Similarly, cutting-edge cancer therapies work for only a portion of patients, but are still life-saving drugs to tens of thousands of people. A recent report noted that trials demonstrating success in only "28 percent of melanoma patients, 27 percent of people with kidney cancer and 18 percent of those with advanced lung cancer" were considered very promising.[6] This shows that even if a large per-

[6] Naomi Kresge & Robert Langreth, *$35 Billion Market for Immune Therapy To Treat Cancer Creating Research Push*, BNA (May 29, 2014), *available at* http://healthlawrc.bna.com/hlrc/4246/split_display.adp?fedfid=47229189&vname=lslrnotallissues&jd=a0f0z1x0k7&split=0.

centage of patients might, for instance, experience "clinically significant electrolyte shifts"—like the large percentage of melanoma patients who did not experience success in the trials—there is no basis to call the result absurd. It is simply not bizarre or ridiculous that some drugs will not work for all people. And the growing importance of personalized medicine underscores that the most effective medical treatments may not be one-size-fits-all.[7]

This stark reality cannot be considered an "absurdity" that could justify an unnatural reading of claim language, or warrant a newly minted rule of claim construction. As Judge Moore correctly explains, this should be an issue of damages, not a reason to grossly distort the law of claim construction to achieve complete noninfringement. J. Moore Dissent 5.[8] This Court's precedents already "make[] clear that there is no 'rare infringement' exception to liability, and that even one

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[7] *See, e.g.*, Energy & Commerce Comm., House of Representatives, *21st Century Cures: A Call to Action* at 3 (May 1, 2014) (questioning whether traditional clinical trials are appropriate for personalized medicine), *available at* http://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/analysis/21stCenturyCures/20140501WhitePaper.pdf.

[8] Members of the panel seemed uncomfortable that, under the Hatch-Waxman Act, some amount of infringement could delay approval of an abbreviated new drug application ("ANDA") when there was a significant amount of noninfringing conduct. But simply declaring both types of administration to be noninfringing (as the panel did) would be a gross injustice against the patentee, would ignore the plain fact that administration will in fact result in infringement, would ignore the statute, and would deprive the patentee of any and all remedies for such infringement—a truly irreparable harm. And approving the ANDA in part is simply not possible *ex ante*. Finally, delaying the approval of an ANDA when administration of a drug actually infringes a patent—even if not in all circumstances, because it is unsuccessful or causes adverse events—in no way disserves the public interest.

instance of infringement is adequate to support a judgment of infringement." *Id.* (quoting *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1318 (Fed. Cir. 2009)). There is no "absurdity" that can justify the erroneous construction here.

C. The Majority's New Rule Upsets Settled Expectations Underlying Enormous Investments.

The majority's erroneous new rule will not be limited to the '149 patent, and may affect a significant number of future cases involving patents covering a wide variety of therapeutic compounds or methods of treatment, because such patents often recite the phrase "a patient" or similar language.

A sample of recent cases confirms the potential reach of the panel's erroneous decision. For example, this Court affirmed a judgment of validity and infringement of patent claims reciting compositions for treating "a migraine patient" and "a migraine headache patient" in *Pozen Inc. v. Par Pharmaceutical, Inc.*, 696 F.3d 1151, 1157–58 (Fed. Cir. 2012), without rewriting the language of the claims. Similarly, in *Cephalon, Inc. v. Watson Pharmaceuticals*, 707 F.3d 1330 (Fed. Cir. 2013), this Court reversed a district court's finding of invalidity for a claim that recited "'a patient.'" In *Endo Pharmaceuticals Inc. v. Actavis, Inc.*, 746 F.3d 1371 (Fed. Cir. 2014), this Court vacated the denial of a preliminary injunction and remanded for further proceedings regarding three patents having claim language such as "administering … to a patient," "[a] method of treating pain in a subject in need thereof," and "a subject in need of an analgesic effect."

Moreover, the panel majority's new interpretive rule is not limited to claims reciting "a patient" and the like. *See supra*, pp. 4–5. The erroneous rule on its face extends to other claim language. For instance, it would readily apply to the claim found valid in *Allergan, Inc. v. Sandoz Inc*., 726 F.3d 1286 (Fed. Cir. 2013), which addressed "'[a] method of treating … an eye of a person.'" It could also apply to the claim upheld in *Sanofi-Aventis Deutschland GmbH v. Glenmark Pharmaceuticals Inc., USA*, __ F.3d __, 2014 WL 1552167, at *3 (Fed. Cir. Apr. 21, 2014), which recited a "'pharmaceutical composition … in amounts effective for treating hypertension.'" In none of these cases did this Court suggest that the claims required effectiveness for treating a particular population. And the Court certainly saw no need to adopt this construction *sua sponte*. Orange Book listings show that there are many other important patents that could be affected by the panel majority's decision.[9]

CONCLUSION

For the foregoing reasons, the Court should grant Braintree's rehearing petition.

[9] For example, U.S. Patent No. 8,399,445 col. 9:16–30 (for Acetadote) recites "A method of treating acetaminophen overdose, comprising … administering the diluted composition to *a patient* in need thereof." (emphasis added).

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Respectfully submitted,

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United States Court of Appeals for the Federal Circuit

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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.