United States Court of Appeals for the Federal Circuit

TEVA PHARMACEUTICALS INTERNATIONAL GMBH, TEVA PHARMACEUTICALS USA, INC.,
Plaintiffs-Appellants

v.

ELI LILLY AND COMPANY,
Defendant-Appellee

2024-1094

Appeal from the United States District Court for the District of Massachusetts in No. 1:18-cv-12029-ADB, Judge Allison Dale Burroughs.

Decided: April 16, 2026

KEVIN P. MARTIN, Goodwin Procter LLP, Boston, MA, argued for plaintiffs-appellants. Also represented by ELAINE BLAIS; GABRIEL FERRANTE, New York, NY.

WILLIAM BARRETT RAICH, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, Washington, DC, argued for defendant-appellee. Also represented by CHARLES COLLINS-CHASE, DANIELLE ANDREA DUSZCZYSZYN, J. MICHAEL JAKES.

Before PROST and CUNNINGHAM, *Circuit Judges*, and ANDREWS, *District Judge*.[1]

PROST, *Circuit Judge*.

Teva Pharmaceuticals International GmbH and Teva Pharmaceuticals USA, Inc. (collectively, "Teva") sued Eli Lilly and Company ("Lilly") for infringing Teva's U.S. Patent Nos. 8,586,045 ("the '045 patent"), 9,884,907 ("the '907 patent"), and 9,884,908 ("the '908 patent") (collectively, the "headache patents").

A jury found that Lilly willfully infringed the headache patents and failed to prove their asserted claims invalid. The U.S. District Court for the District of Massachusetts then granted judgment as a matter of law ("JMOL") that those claims are invalid for failure to satisfy both the written-description and enablement requirements of 35 U.S.C. § 112. Teva appeals. We reverse and remand.

BACKGROUND

I

CGRP is a protein found in humans. When it binds to receptors on certain cells, the cells expand and increase blood flow through blood vessels—a phenomenon associated with headache.

Antibodies are proteins that an immune system produces to fight disease. They do so by identifying and binding to antigens, like CGRP. Relevant to this appeal are anti-CGRP antagonist antibodies, which bind to CGRP so as to "antagonize" (i.e., inhibit) CGRP and its headache-associated activity. These antibodies can exist in mice. A process for converting a murine (i.e., mouse) antibody into

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[1] Honorable Richard G. Andrews, District Judge, United States District Court for the District of Delaware, sitting by designation.

a form that the human immune system will not reject is known as humanization, and it results in "humanized" antibodies.

The headache patents, which have a November 2006 priority date, concern using humanized anti-CGRP antagonist antibodies to treat headache. *See, e.g.*, '045 patent Abstract, col. 1 ll. 18–21, col. 4 ll. 50–51, claim 30.[2] The specification observes that anti-CGRP antagonist antibodies were "known in the art," and it cites prior art regarding murine antibodies of this sort. *See id.* at col. 25 ll. 59–63. For example, the specification references murine anti-CGRP antagonist antibody "4901" and cites a product catalog offering this antibody for sale. *See id.* at col. 25 ll. 61–62 (citing product catalog shown at J.A. 18046); *see also id.* at col. 51 ll. 5–27, col. 55 ll. 22–23 (disclosing other murine anti-CGRP antagonist antibodies). The specification also states that "anti-CGRP antagonist antibodies may be made by any method known in the art." *Id.* at col. 27 ll. 41–42. And although the specification disclosed just one *humanized* anti-CGRP antagonist antibody—"G1," which is the active ingredient in Teva's Ajovy product, *see, e.g.*, *id.* at cols. 72–73—it also disclosed prior-art methods of humanization, *see id.* at col. 28 l. 55–col. 29 l. 28.

Claim 30 of the '045 patent is representative of the asserted claims for purposes of this appeal.[3] Rewritten together with claim 17, from which it depends, claim 30 recites:

> A method for reducing incidence of or treating headache in a human, comprising administering to

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[2] Because the headache patents share a substantively identical specification, for convenience, we cite only the '045 patent's specification.

[3] The asserted claims are claim 30 of the '045 patent and claims 5 and 6 of each of the '907 and '908 patents.

> the human an effective amount of an anti-CGRP antagonist antibody, wherein said anti-CGRP antagonist antibody is a . . . humanized monoclonal antibody.

Id. at claims 17, 30.

II

Between August and October 2018, Lilly filed petitions for inter partes review ("IPR") with the Patent Trial and Appeal Board ("Board") challenging several of Teva's patents. Those patents fell into two groups. One was the headache patents—which, as noted above, claim a method of using humanized anti-CGRP antagonist antibodies to treat headache. The other group we refer to as the "antibody patents," because they claimed humanized anti-CGRP antagonist antibodies *themselves*.[4]

In arguing that claims of the antibody patents are unpatentable for obviousness, Lilly maintained that, by November 2006, anti-CGRP antagonist antibodies "were well known in the art"—indeed, that the prior art was "replete with exemplary disclosures of anti-CGRP antagonist antibodies." J.A. 21417 (capitalization normalized); J.A. 21513. Techniques for making such antibodies were also, according to Lilly, "extensively described in the prior art." J.A. 21442; *see also* J.A. 21417 ("[S]everal publications had described anti-CGRP antagonist antibodies and methods of making them."). And, as to humanization, Lilly maintained that it "was a well-established and routine procedure" by November 2006. *See* J.A. 21407.

The Board determined that, although the antibody patents' challenged claims were unpatentable, those of the

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[4] The antibody patents are U.S. Patent Nos. 9,340,614; 9,266,951; 9,890,210; 9,346,881; 9,890,211; and 8,597,649.

headache patents were not. Each Board decision was appealed to this court, and we affirmed as to each. *See Teva Pharms. Int'l GmbH v. Eli Lilly & Co.*, 8 F.4th 1349 (Fed. Cir. 2021) (three of the antibody patents); *Teva Pharms. Int'l GmbH v. Eli Lilly & Co.*, 856 F. App'x 312 (Fed. Cir. 2021) (the other three antibody patents); *Eli Lilly & Co. v. Teva Pharms. Int'l GmbH*, 8 F.4th 1331 (Fed. Cir. 2021) (the headache patents).

III

Teva brought this suit against Lilly in September 2018, alleging that Lilly indirectly infringed the headache patents via its Emgality product.[5]

At the ensuing trial, the jury returned a verdict for Teva, finding that Lilly willfully infringed the asserted claims and did not prove them invalid for lack of written description or enablement. It awarded Teva damages accordingly.

Lilly then moved for JMOL of invalidity on written description and enablement, which the district court granted. *See Teva Pharms. Int'l GmbH v. Eli Lilly & Co.*, No. 18-cv-12029, 2023 WL 6282898 (D. Mass. Sep. 26, 2023) ("*JMOL Op.*"). The district court acknowledged that the jury could have permissibly found that murine anti-CGRP antagonist antibodies were known in the art and disclosed in the specification. *See id.* at *12. The court also acknowledged that a person of ordinary skill in the art would have (1) known methods for making murine anti-CGRP antagonist antibodies; (2) known that humanizing antibodies was routine; and (3) understood from the specification that *all* humanized anti-CGRP antagonist antibodies would treat headache. *See id.* at *4, *12, *19 n.23. The court nonetheless

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[5] Teva also alleged infringement of the antibody patents, but it dismissed those claims after we affirmed the Board's unpatentability decisions as to those patents.

concluded that, as a matter of law, the asserted claims are invalid for lack of both written description and enablement.

Teva timely appealed.[6] We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

We review grants of JMOL under the law of the regional circuit—here, the First Circuit. *See Akamai Techs., Inc. v. Limelight Networks, Inc.*, 805 F.3d 1368, 1374 (Fed. Cir. 2015). We therefore review the district court's JMOL de novo and will reinstate the jury verdict "unless the facts and inferences, viewed in the light most favorable to the verdict, point so strongly and overwhelmingly" in Lilly's favor "that a reasonable jury could not have returned the verdict." *See Acevedo-Diaz v. Aponte*, 1 F.3d 62, 66 (1st Cir. 1993) (cleaned up); *see also Pac. Biosciences of Cal., Inc. v. Oxford Nanopore Techs., Inc.*, 996 F.3d 1342, 1350 (Fed. Cir. 2021) (noting that, in reviewing a JMOL, we generally "treat the jury as having made all verdict-supporting factual findings that are supported by substantial evidence").

The JMOL inquiry accounts for the applicable burden and standard of proof, *see Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250–55 (1986), and here, Lilly had the burden to prove facts underlying its invalidity case by clear and convincing evidence, *see, e.g.*, *BASF Corp. v. SNF Holding Co.*, 955 F.3d 958, 963 (Fed. Cir. 2020). So, if a reasonable jury could have found that Lilly failed to prove its invalidity case by clear and convincing evidence, we must reverse the JMOL. *See Boehringer Ingelheim Vetmedica, Inc. v.*

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[6] Lilly conditionally cross-appealed regarding damages but later voluntarily dismissed that appeal. *See* Order (Sep. 8, 2025), ECF No. 64.

Schering-Plough Corp., 320 F.3d 1339, 1353 (Fed. Cir. 2003).

The invalidity issues in this case concern 35 U.S.C. § 112 ¶ 1,[7] which states in relevant part:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same . . . .

This provision contains two separate requirements: written description and enablement. *See, e.g.*, *Centrak, Inc. v. Sonitor Techs., Inc.*, 915 F.3d 1360, 1366 (Fed. Cir. 2019) (citing *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc)).

We first discuss written description, then enablement. Because the parties focus more on written description, we do the same.

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[7] The Leahy-Smith America Invents Act ("AIA") essentially redesignated § 112 ¶ 1 as § 112(a). *See* AIA, Pub. L. No. 112-29, sec. 4(c), 125 Stat. 284, 296 (2011). Given the filing dates of the applications for the headache patents, the pre-AIA version applies to the '045 patent, whereas the AIA version applies to the other two patents. *See id.* sec. 4(e), 125 Stat. at 297 (applying AIA version to any patent application filed on or after September 16, 2012). Because any difference between the two versions is immaterial to this opinion's discussion, and because we cite only the '045 patent's specification, we refer to the pre-AIA version throughout this opinion.

I

To satisfy the written-description requirement of § 112 ¶ 1, a patent's specification must "reasonably convey[]" that, as of the filing date, "the inventor[s] had possession of the claimed subject matter"—i.e., that they "actually invented the invention claimed." *See Ariad*, 598 F.3d at 1351. This test requires an "objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art," *id.*, who "comes to the patent with the knowledge of what has come before," *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1366 (Fed. Cir. 2006) (cleaned up). Whether a patent satisfies the written-description requirement is a question of fact, and what it takes to satisfy that requirement varies depending on the context, including the nature and scope of the claims. *Ariad*, 598 F.3d at 1351; *see Capon v. Eshhar*, 418 F.3d 1349, 1358 (Fed. Cir. 2005) ("The 'written description' requirement states that the patentee must describe the invention; it does not state that every invention must be described in the same way.").

For claims to a genus, adequate written description requires disclosure of "either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can visualize or recognize the members of the genus." *Ariad*, 598 F.3d at 1350 (cleaned up). As with written description generally, there are no "bright-line rules governing . . . the number of species that must be disclosed to describe a genus claim, as this number necessarily changes with each invention." *Id.* at 1351.

The written-description dispute in this case concerns whether the specification disclosed a representative number of species of the asserted claims' genus of humanized

anti-CGRP antagonist antibodies.[8] We first discuss relevant precedent and why it supports the jury's finding regarding written description. We then address, and reject, Lilly's arguments for JMOL on this issue.

A

Several of our cases are particularly instructive for analyzing written description in circumstances like those here—where a claim pertains to a well-known genus that is not, itself, the invention.

In *Ajinomoto*, for example, the patent disclosed that enhancing the activity of a bacterium's *yddG* gene would increase the bacterium's production of particular amino acids. The patent also disclosed several ways of enhancing that activity, one of which was substituting a "more potent promoter" in the bacterium's DNA. *See Ajinomoto Co. v. ITC*, 932 F.3d 1342, 1346–47 (Fed. Cir. 2019). The claim covered a method of producing particular amino acids from a bacterium having a "more potent promoter" for its *yddG* gene substituted. The patent challenger argued that the genus of "more potent promoters" lacked adequate written description because the specification did not disclose a representative number of species. The ITC rejected that argument, and on appeal, we affirmed. We initially observed that, because the patent disclosed four examples of "potent promoters" and cited an article disclosing examples thereof, substantial evidence supported the ITC's finding that "enhancing promoter activity was well-known" and that a skilled artisan "would have been able to identify more potent promoters by employing common tools." *Id.* at 1359 (cleaned up). We then reasoned that the patent "ma[de] clear" that its invention was identifying the *yddG*

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[8] On appeal, Teva does not argue that the specification disclosed structural features common to the members of that genus.

gene and discovering that enhancing its activity increased the amino acids' production; it was "*not the well-known techniques*" for enhancing that activity. *Id.* (emphasis added). Because "the genus of more potent promoters was already well explored" in the art by the time of the patent's invention, the ITC "permissibly found in the specification, read in light of the background knowledge in the art, a representative number of species." *Id.*

Our predecessor court confronted a similar situation in *Herschler*. There, the inventor discovered that a certain chemical, DMSO, enhances skin penetration of other materials. The claim was to a method of enhancing skin penetration of a "physiologically active steroidal agent" by applying it together with DMSO. *In re Herschler*, 591 F.2d 693, 695 (CCPA 1979). The court concluded that the specification adequately described the genus of "physiologically active steroidal agent[s]" because, even though it disclosed just one species thereof, a skilled artisan reading the specification would understand that any member of the genus would work in the claimed method. *See id.* at 700–01. In reaching this conclusion, the court repeatedly distinguished between claims to a genus *itself* (particularly a novel one) and claims that, like the one at issue, concerned a known genus used as part of a different invention. *See id.* at 701–02. For example, it acknowledged that while steroids "*as drugs*" might vary broadly in their physiological activity, steroids "*as a class of compounds carried through a layer of skin by DMSO*" appeared on the record to be "quite similar." *Id.* at 701 (emphasis added); *see also id.* at 702 (distinguishing between claims to "classes of new compounds per se or . . . processes using those new compounds" and "claims drawn to the *use* of *known* . . . compounds in a manner auxiliary to the invention" (some emphasis removed)); *id.* at 701 (observing that, "[w]ere this application drawn to novel 'steroidal agents,' a different question would be posed").

The plurality opinion in *Fuetterer* was key to the court's reasoning in *Herschler*. *See Herschler*, 591 F.2d at 701–02 (citing *In re Fuetterer*, 319 F.2d 259 (CCPA 1963) (Rich, J.)).[9] In *Fuetterer*, the claim was to a composition for tire-tread stock, one component of which was "an inorganic salt that is capable of holding a mixture . . . in colloidal suspension in water." 319 F.2d at 260–61. The specification disclosed only four such salts. *Id.* at 265. The Patent and Trademark Office had rejected the claim under § 112 ¶ 1,[10] "believing that not all inorganic salts are capable of performing" the specified function and that "one skilled in the art would not know offhand which inorganic salts are capable of so functioning." *Id.* On appeal, the court reversed. As the plurality opinion explained:

> Appellant's invention is the *combination* claimed and not the discovery that certain inorganic salts have colloid suspending properties. We see nothing in patent law which requires appellant to discover which of all those salts have such properties and which will function properly in his combination. The invention description clearly indicates that

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[9] We appreciate that the plurality opinion in *Fuetterer* is not binding, given that only two judges of the five-judge panel joined it (a third concurred in the result). *See* 319 F.2d at 266. Yet *Herschler*, which *is* binding, relied heavily on the plurality opinion in *Fuetterer*. *See Herschler*, 591 F.2d at 701 ("We wish to maintain the line first clearly drawn in [*Fuetterer*]."). And, regardless of its status as binding precedent, we may (and do) consider it persuasive authority.

[10] Technically, the rejection was for "undue breadth," but we later explained that such a rejection was "based on the first paragraph of § 112" for insufficient disclosure. *In re Hyatt*, 708 F.2d 712, 714–15 (Fed. Cir. 1983) (citing *In re Borkowski*, 422 F.2d 904, 909 (CCPA 1970)).

> any inorganic salt which has such properties is usable in his combination. If others in the future discover what inorganic salts additional to those enumerated do have such properties, it is clear appellant will have no control over them per se, and equally clear his claims should not be so restricted that they can be avoided merely by using some inorganic salt not named by appellant in his disclosure.

Id. at 265 (emphasis in original); *see id.* at 266 (reiterating that the appellant "has not invented, and is not claiming, colloid suspending agents").[11]

The circumstances here fit well within this line of precedent. The headache patents make clear that their claimed invention is the use of anti-CGRP antagonist antibodies, or humanized versions thereof, *to treat headache*—not such antibodies themselves. *See, e.g.*, '045 patent claim 30. A reasonable jury could have found that anti-CGRP antagonist antibodies *themselves* and methods of making them were well known, replete, or extensively described in the prior art—based on Lilly's own statements that they were "well known," "replete," or "extensively described" in the

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[11] *See also Erfindergemeinschaft UroPep GbR v. Eli Lilly & Co.*, 276 F. Supp. 3d 629, 648 (E.D. Tex. 2017) (Bryson, J., sitting by designation) ("It is often the case that a patent claiming the invention of a new genus, or the use of a new genus, must provide more detail regarding that genus, such as disclosing a number of representative species . . . . On the other hand, *when a genus is well understood in the art and not itself the invention but is instead a component of the claim*, background knowledge may provide the necessary support for the claim." (emphasis added)), *aff'd*, 739 F. App'x 643 (Fed. Cir. 2018) (nonprecedential).

prior art.[12] *See* J.A. 21417 (capitalization normalized); J.A. 21513; J.A. 21442. A reasonable jury could have also found that humanization was a well-established and routine procedure by the priority date—again, based on Lilly's own statements that it "was a well-established and routine procedure" by the priority date.[13] J.A. 21407. And, as Lilly does not dispute, a reasonable jury could have found that a skilled artisan would have understood from the specification that all humanized anti-CGRP antagonist antibodies treat headache. *See, e.g.*, J.A. 4174, 4272; *see also JMOL Op.*, 2023 WL 6282898, at *12, *19 n.23.

Taken together, these fact findings (which we treat the jury as having made)—along with the specification's disclosures—suffice to support the jury's rejection of Lilly's written-description challenge. The asserted claims are to methods of using humanized anti-CGRP antagonist antibodies to treat headache. Although the specification disclosed just one humanized anti-CGRP antagonist antibody, it also disclosed several murine versions and prior-art methods of humanization—against a backdrop of anti-CGRP antagonist antibodies (and methods of making them) being well known and humanization being routine. And, critically, a skilled artisan would have understood from the specification that *all* humanized anti-CGRP antagonist antibodies treat headache. The jury therefore could have reasonably found that the specification disclosed a representative number of species of humanized

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[12] Substantial evidence apart from Lilly's statements also supported such a finding. *See, e.g.*, J.A. 4059, 4063–67, 4119–26 (testimony of Teva's expert Dr. Hill); J.A. 4209–14 (testimony of Teva's expert Dr. Hale).

[13] Again, substantial evidence apart from Lilly's statements also supported such a finding. *See, e.g.*, J.A. 4220–24 (testimony of Teva's expert Dr. Hale); J.A. 3295–96 (testimony of Lilly's expert Dr. McDonnell).

anti-CGRP antagonist antibodies for purposes of the claimed invention, thus rendering JMOL of no written description improper.

B

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Lilly tries, unsuccessfully, to distinguish the foregoing precedent. Its attempt focuses on the requirement that the antibodies be humanized.

Specifically, Lilly notes that, however one views the prior-art status of anti-CGRP antagonist antibodies generally,[14] humanized versions of those antibodies were not known—indeed, were absent from the prior art altogether. Lilly also observes that the specification disclosed only one humanized version. And, as to the murine anti-CGRP antagonist antibodies disclosed in the specification, Lilly maintains that they cannot count towards representativeness of the genus of *humanized* antibodies, because they are not truly members of that genus. Lilly therefore maintains that the circumstances here cannot fit within the line of precedent discussed above concerning a well-known genus used as part of a different invention.

Lilly's focus on humanization to show lack of written description is unpersuasive. As already discussed, a reasonable jury could have found that, by the priority date, (1) anti-CGRP antagonist antibodies and methods of making them were well known, and (2) humanization was a routine procedure. The specification also disclosed several examples of murine anti-CGRP antagonist antibodies and

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[14] To the extent Lilly suggests that anti-CGRP antagonist antibodies generally—even murine ones—were not well known as of the priority date, *see* Appellee's Br. 49, 51, 61, the jury could have readily found otherwise, for reasons already discussed.

prior-art methods of humanization. *See* '045 patent col. 25 ll. 59–63, col. 51 ll. 5–27 (murine anti-CGRP antagonist antibodies); *id.* at col. 28 l. 55–col. 29 l. 28 (prior-art humanization methods). As the jury could have seen it, murine versions—themselves well known, with several examples disclosed—were just a routine (and likewise disclosed) procedure away from being humanized. That being so, and because a specification need not show an actual reduction to practice in order to satisfy the written-description requirement, *e.g.*, *Ariad*, 598 F.3d at 1352, the humanization requirement does not undermine the well-known status of the *non*-humanized anti-CGRP antagonist antibodies or otherwise render the above-discussed line of precedent inapplicable.

Lilly nonetheless insists that, even if humanizing these antibodies might have been *obvious* in view of the specification, "a description that merely renders the invention obvious does not satisfy" the written-description requirement. *See* Appellee's Br. 52 (quoting *Ariad*, 598 F.3d at 1352). This principle, while correct, does not help Lilly. The specification did not merely render humanizing these antibodies obvious; it explicitly disclosed as much, along with how to do it, via prior-art methods that a reasonable jury could have found were routine. *See, e.g.*, '045 patent col. 4 ll. 50–51 ("In some embodiments, the anti-CGRP antagonist antibody is humanized."); *id.* at col. 28 l. 55–col. 29 l. 28 (prior-art humanization methods).

Lilly also argues that, because humanizing an anti-CGRP antagonist antibody requires knowing its amino acid sequence, and because no such sequences were disclosed in the specification or prior art, adequate written description is lacking. *See* Appellee's Br. 49–51. We are unpersuaded. Substantial evidence showed that if a skilled artisan possessed an anti-CGRP antagonist antibody, he or she could "determin[e] its amino acid sequence through known sequencing techniques." *See* J.A. 21675

(declaration of Lilly's own expert concerning a prior-art reference that is also cited in the '045 patent). And there seems to be no dispute that the inventors possessed at least the particular anti-CGRP antagonist antibodies disclosed in the specification. Further, substantial evidence shows that, more generally, anti-CGRP antagonist antibodies were accessible before the priority date. *See* J.A. 18046 (product catalog offering antibody "4901" for sale); J.A. 4122 (testimony regarding a researcher who received seven such antibodies as a gift from another researcher); *see also supra* note 12. Accordingly, a reasonable jury could have found that the specification demonstrates that the inventors possessed sequences necessary to humanize anti-CGRP antagonist antibodies.

Finally, even apart from humanization, Lilly takes issue with the distinction we have drawn between (1) claims to a method of using humanized anti-CGRP antagonist antibodies *to treat headache* and (2) claims to such antibodies themselves. According to Lilly, this is a "semantic distinction without a difference." *See* Appellee's Br. 61 (quoting *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 926 (Fed. Cir. 2004)); *see also id.* (citing *Ariad*, 598 F.3d at 1355). We disagree with Lilly—for at least two related reasons.

First, the above-discussed line of precedent supports this distinction, *see, e.g.*, *Herschler*, 591 F.2d at 701–02, and Lilly has not shown why that precedent does not apply here.

Second, the cases Lilly relies on for its "semantics" argument are easily distinguished. For example, in *Rochester*, the claims were to methods of selectively inhibiting the activity of a particular gene product (PGHS-2) by administering a compound that selectively inhibits such activity. *See* 358 F.3d at 918. In maintaining that adequate written description existed, the patentee argued that the claims were to methods, not the compounds themselves. *See id.*

at 926. We deemed this a "semantic distinction without a difference," because the specification did not disclose any compounds usable in the claimed methods, nor was there any evidence that such compounds were known. *See id.* at 926–27. That is not the case here, where anti-CGRP antagonist antibodies were well known in the prior art and disclosed in the specification. Likewise, in *Ariad*, the claims were to methods of reducing the activity of a particular transcription factor (NF-êB). 598 F.3d at 1341. We said that demonstrating possession of the claimed methods required "sufficiently disclosing molecules capable of reducing NF-êB activity." *Id.* at 1355. The problem was that the specification did not sufficiently disclose such molecules; instead, of the three types of molecules it "hypothesize[d]," two had no adequately disclosed examples at all, and the third had insufficient disclosure of its ability to reduce NF-êB activity. *See id.* at 1355–58.

Moreover, in *Rochester*, the claims were to methods of selectively inhibiting PGHS-2's activity by administering a compound that selectively inhibits PGHS-2's activity. In effect, the claims were to methods of doing X using "something that does X." Thus, not only was the compound in *Rochester* not disclosed or otherwise known, the use to which it was put could not fairly be considered part of a different invention. *Ariad* presented a similar situation: the claims were to methods of doing X, and the claims "encompass[ed] the use of all substances" that did X. *See* 598 F.3d at 1341. Here, in contrast, the asserted claims are not to "methods of antagonizing CGRP using humanized antibodies that antagonize CGRP"; they are to methods of treating headache using such antibodies—something different from the function that characterizes these antibodies.

Simply put, neither of these cases presented the circumstances of the above-discussed line of precedent and this case—i.e., a well-known genus used as part of a different invention.

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Lilly's other arguments for JMOL of no written description generally concern structural or functional differences among the genus of humanized anti-CGRP antagonist antibodies.[15] These arguments are likewise unpersuasive.

For example, Lilly notes that CGRP has three regions to which an anti-CGRP antagonist antibody might bind—namely, the C-terminal, mid-region, and N-terminal. It then argues that, because the anti-CGRP antagonist antibodies disclosed in the specification bind only to the C-terminal, adequate written description is lacking. *See* Appellee's Br. 15, 45. We reject this argument. Initially, a reasonable jury could have found that, for each of the three regions, an anti-CGRP antagonist antibody that binds to it was known in the prior art. *See, e.g.*, J.A. 3321–24, 4125, 21998. More importantly, as the district court recognized—and as Lilly does not dispute—a reasonable jury could have found that a skilled artisan reading the specification would have understood that "anti-CGRP antagonist antibodies could bind to different regions of CGRP and still accomplish the claimed function of treating headache." *See JMOL Op.*, 2023 WL 6282898, at *14. Thus, like the steroids in *Herschler*—which might have varied broadly *as drugs* but performed quite similarly in the claimed method, *see* 591 F.2d at 701—here, the differences in binding regions among humanized anti-CGRP antagonist antibodies do not prevent those antibodies from performing in the claimed method of treating headache. Those differences

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[15] Although Lilly also advances an argument concerning the purported breadth associated with the genus, *see* Appellee's Br. 36–39, it makes essentially the same argument in the context of enablement, *see id.* at 54–58, which is where we deem the argument better addressed, *see infra* Discussion Part II.

therefore do not demonstrate inadequate written description for that method.

Relatedly, Lilly argues that, because *its* product differs structurally and functionally from G1 (the sole humanized anti-CGRP antagonist antibody disclosed in the specification), written description must be inadequate. For this argument, Lilly cites *AbbVie* as having required disclosure of an antibody "structurally similar" to the accused antibody in order to show representativeness. *See* Appellee's Br. 40–41 (quoting *AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1301 (Fed. Cir. 2014)).[16] We reject this argument as well. Lilly has not explained, nor do we see, why we should treat any of the alleged structural or functional differences between Lilly's product and G1 differently from the way we treat the various possible binding regions discussed above. In both cases, the relevant point remains: a reasonable jury could have found that a skilled artisan reading the specification would have understood that anti-CGRP antagonist antibodies were well known (and disclosed), that humanizing was routine (and disclosed), and that, *insofar as treating headache is concerned*, all humanized versions of such

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[16] Lilly also suggests that *Juno* supports such a requirement for representativeness. *See* Appellee's Br. 41–42 (citing *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330, 1339 (Fed. Cir. 2021)). *Juno*, however, did not directly address any specific requirement to disclose a composition structurally similar to the *accused* composition in order to satisfy representativeness. Further, the portion of *Juno* that Lilly cites for this argument concerned "structural features common to the members of the genus," 10 F.4th at 1338–39—not representativeness. And Teva does not argue that the specification disclosed structural features common to the members of the genus of humanized anti-CGRP antagonist antibodies. *Supra* note 8.

antibodies work. The specification therefore disclosed members of the genus that are sufficiently representative for purposes of the claimed invention.[17]

Further, while this court did conclude in *AbbVie* that adequate written description was lacking—in part because there was no evidence that any disclosed antibody was "structurally similar to, *and thus representative of*," the accused product, 759 F.3d at 1301 (emphasis added)—we do not understand *AbbVie* to have set forth a bright-line, always-applicable rule that representativeness requires disclosure of a composition structurally similar to the accused product. Indeed, as the above-discussed line of precedent demonstrates, the representativeness inquiry accounts for the specific circumstances of the invention, *see, e.g.*, *Ajinomoto*, 932 F.3d at 1359; *see also Ariad*, 598 F.3d at 1351 (observing that there are no "bright-line rules governing . . . the number of species that must be disclosed to describe a genus claim, as this number necessarily changes with each invention"), and *AbbVie* did not involve the circumstances relevant here and in that precedent—i.e., a well-known genus used as part of a different invention.

Thus, for the foregoing reasons, we conclude that JMOL of no written description was improper.

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[17] Although Lilly also maintains that adequate written description is lacking because its product treats "cluster" headache, whereas G1 does not, a reasonable jury could have found that Lilly's support for these factual propositions was less than clear and convincing. *See, e.g.*, J.A. 4018–21 (testimony of Teva's expert Dr. Blumenfeld regarding the impact of different study designs on efficacy of cluster-headache treatment).

II

Enablement and written description "often rise and fall together." *Ariad*, 598 F.3d at 1352. So it is here.

To satisfy the enablement requirement of § 112 ¶ 1, a patent's specification "must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation." *MagSil Corp. v. Hitachi Glob. Storage Techs., Inc.*, 687 F.3d 1377, 1380 (Fed. Cir. 2012) (cleaned up); *see also* § 112 ¶ 1 (requiring a description of the invention "and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable" a skilled artisan "to make and use the same"). The specification's teachings in this regard must be "at least commensurate with the scope of the claims." *E.g.*, *Amgen Inc. v. Sanofi*, 987 F.3d 1080, 1084 (Fed. Cir. 2021) (cleaned up), *aff'd*, 598 U.S. 594 (2023). Although whether a claim is enabled is a question of law that we review de novo, in the context of a jury trial, any factual underpinnings are reviewed for substantial evidence. *See, e.g.*, *Trs. of Bos. Univ. v. Everlight Elecs. Co.*, 896 F.3d 1357, 1361 (Fed. Cir. 2018).

Lilly's no-enablement argument concerns the purported breadth associated with the genus of humanized anti-CGRP antagonist antibodies. Lilly maintains that the number of candidate antibodies for inclusion in this genus is very large and that the specification does not tell a skilled artisan how to determine in advance which ones will antagonize CGRP. Instead, Lilly says, the inventors left to others the "research assignment" of screening and testing those candidates to make that determination. In Lilly's view, these efforts would have been so time-consuming and expensive as to constitute undue experimentation. *See* Appellee's Br. 54–58.

In addressing Lilly's no-enablement argument, we will assume two things in its favor, solely for argument's sake. First, we will assume that a reasonable jury could have

only found that making all anti-CGRP antagonist antibodies would have required screening and testing a very large number of candidate antibodies to determine which ones do, in fact, antagonize CGRP. Second, we will assume that, even if a reasonable jury could have found that such making, screening, and testing would have been routine in this field as of the priority date, *see, e.g.*, J.A. 4212–14, 4250, the amount of time and expense required to make (and humanize) all anti-CGRP antagonist antibodies would have constituted undue experimentation, *see, e.g.*, *Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1163 (Fed. Cir. 2019) (observing that a substantial amount of experimentation, "even if routine," can be undue (cleaned up)).

With these assumptions in mind, we note that Lilly's argument might be more persuasive if the asserted claims were to the genus of humanized anti-CGRP antagonist antibodies themselves. If that were so, this case would resemble *Amgen*. There, the claims were to the entire genus of antibodies that (1) bind to specific amino acid residues on the protein PCSK9 and (2) block PCSK9 from binding to certain receptors. *Amgen*, 598 U.S. at 602. Yet, although the patentee laid claim to that entire genus (for any and all purposes), its specification failed to teach a skilled artisan how to find more of these antibodies without engaging in an unreasonable amount of experimentation. The specification's mere disclosure of steps by which a skilled artisan might find more was, in the context of that invention, not enablement; instead, it was "little more than [a] research assignment[]" comprised of "painstaking" trial and error. *Id.* at 614 (cleaned up). We later applied a similar analysis and reached a similar conclusion in *Baxalta*, which involved facts "materially indistinguishable from those in *Amgen*." *Baxalta Inc. v. Genentech, Inc.*, 81 F.4th 1362, 1366 (Fed. Cir. 2023).

The asserted claims here are unlike the claims in *Amgen* and *Baxalta*, however, because they do not claim

humanized anti-CGRP antagonist antibodies *themselves*; instead, they claim only the use of such antibodies for the different, limited purpose of treating headache. In light of the well-known status of anti-CGRP antagonist antibodies and the routine nature of humanization, the more relevant "research assignment" in this case would have been determining which humanized anti-CGRP antagonist antibodies *treat headache*. *See Amgen*, 987 F.3d at 1084 (observing that the specification's teachings must be "at least commensurate with the scope of the claims"). That assignment was completed; the specification disclosed that *all* such antibodies work for that purpose. Given that anti-CGRP antagonist antibodies (and methods of making them) were already well known, humanizing them would have been routine, such humanized antibodies themselves are not claimed here, and all of them work in the claimed method, undertaking to find or make all of them would—in the context of these claims—be more akin to extra credit than a necessary research assignment left to others to complete.

Finally, we conclude that the circumstances here are distinguishable from *Idenix*, a case upon which Lilly relies heavily. There, the claim was to a method of using a 2'-methyl-up nucleoside to treat the hepatitis C virus ("HCV"), and the number of potential 2'-methyl-up nucleosides was quite large. We framed the "key enablement question" as "whether a person of ordinary skill in the art would know, without undue experimentation, which 2'-methyl-up nucleosides would be effective for treating HCV." *Idenix*, 941 F.3d at 1156. The patentee argued on appeal that the number of potential 2'-methyl-up nucleosides—and the amount of screening necessary to determine which ones treated HCV—was unimportant because "the jury could have [found] that *all* 2'-methyl-up" nucleosides treated HCV. *See id.* at 1159 (emphasis in original). We rejected this argument because the evidence there did not support such a finding. *Id.* Accordingly, that the claim encompassed "at least many, many thousands of 2'-methyl-up

nucleosides" that "need[ed] to be screened for HCV efficacy" rendered the amount of necessary experimentation high, thus weighing in favor of non-enablement. *Id.* Here, in contrast, it is undisputed that a reasonable jury could have found that all humanized anti-CGRP antagonist antibodies treat headache, thereby obviating any extensive screening to determine which ones do.

In sum, given the nature of the asserted claims and the jury's supportable findings, we conclude that JMOL of no enablement was improper.

CONCLUSION

We have considered Lilly's remaining arguments and find them unpersuasive. For the foregoing reasons, we reverse the district court's JMOL and remand for any necessary or appropriate further proceedings consistent with this opinion.

REVERSED AND REMANDED

COSTS

Costs to Teva.