United States Court of Appeals for the Federal Circuit

SEAGEN INC.,
Plaintiff-Appellee

v.

DAIICHI SANKYO COMPANY, LTD., ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LTD.,
Defendants-Appellants

2023-2424, 2024-1176

Appeals from the United States District Court for the Eastern District of Texas in No. 2:20-cv-00337-JRG, Judge J. Rodney Gilstrap.

Decided: December 2, 2025

SARA TONNIES HORTON, Willkie Farr & Gallagher LLP, Chicago, IL, argued for plaintiff-appellee. Also represented by DEVON WESLEY EDWARDS, New York, NY; DANE SOWERS, Washington, DC; MATTHEW A. CHIVVIS, MATTHEW IAN KREEGER, Morrison & Foerster LLP, San Francisco, CA; SETH W. LLOYD, BRIAN ROBERT MATSUI, Washington, DC; BRYAN J. WILSON, Palo Alto, CA.

CHRISTOPHER NEIL SIPES, Covington & Burling LLP, Washington, DC, argued for defendants-appellants. Also

represented by BRADLEY KEITH ERVIN, NICHOLAS LANE EVOY, ROBERT JASON FOWLER.

Before LOURIE, REYNA, and CHEN, *Circuit Judges*.

LOURIE, *Circuit Judge*.

A jury in the United States District Court for the Eastern District of Texas found that claims 1–5, 9, and 10 of Seagen Inc.'s ("Seagen") U.S. Patent 10,808,039 ("the '039 patent") were not invalid for lack of written description or enablement. J.A. 57. The jury further found that Daichii Sankyo Company, Ltd. AstraZeneca Pharmaceuticals LP, and AstraZeneca UK Ltd., (collectively, "Daichii") willfully infringed at least one of the claims, and awarded Seagen damages exceeding $41 million. J.A. 56, 58–59. The district court denied Daichii's post-trial motion for judgment as a matter of law ("JMOL") and entered final judgment in favor of Seagen. J.A. 32–52. Because we conclude that the district court erred in failing to grant JMOL for lack of written description and enablement, we reverse.

BACKGROUND

I

This case concerns a type of cancer treatment known as an antibody-drug conjugate ("ADC"). An ADC generally consists of three components: (1) an antibody, (2) a cytotoxic (cell-killing) drug, and (3) a "linker" protein, which connects the antibody and drug. J.A. 3689 (depicting a simplified ADC). A linker may include different subcomponents. *See* J.A. 3548. Most relevant to this appeal is one potential subcomponent called a "peptide unit," which is made of a chain of amino acids. *See* J.A. 3107 (215:2–4). Peptide units that include two amino acids are called dipeptides, those with three amino acids are called tripeptides, etc. J.A. 3144 (31:20–32:8). Another subcomponent that may be included in a linker protein is a "spacer unit,"

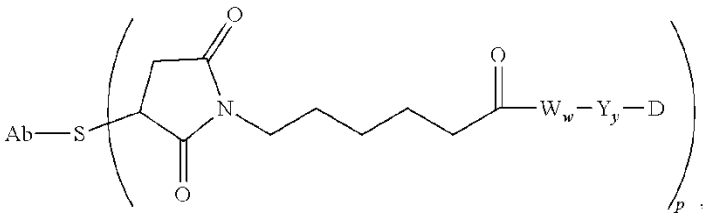
which is the part of the linker that is directly connected to the drug moiety (the moiety is the active ingredient within the drug compound), when present. *See* J.A. 3548.

Unlike traditional chemotherapies, which are relatively non-selective with respect to the cells they kill, by combining the cell-targeting abilities of antibodies with the cell-killing abilities of cytotoxic drugs, an ADC is designed to kill only cancer cells while sparing healthy cells. J.A. 3139–40 (11:16–13:3). One way in which an ADC functions is through a mechanism called "intracellular cleavage." In principle, when an ADC administered to a patient is designed to intracellularly cleave, the antibody recognizes and targets specific cells, bringing along with it the linker and drug moiety. J.A. 3139 (12:17–23). Then, once the ADC reaches the target cell, it is absorbed into the cell, and the linker is cleaved (severed) from the antibody, releasing the drug moiety that kills the target cancer cell. J.A. 3141 (18:2–19:22).

Whether and how a drug moiety is cleaved from the ADC is determined, in part, by the components of the linker protein. J.A. 3140 (13:20–14:13). Improper release of the drug moiety can have deleterious effects. If, for example, the ADC releases the moiety before reaching the target cell, or instead does not release the moiety once internalized, then the target cell may not receive the optimal dose, and healthy cells may be exposed to the toxic drug. J.A. 3106 (209:25–210:17).

Claim 1, the sole independent claim of the '039 patent, which is representative, reads as follows:

An antibody-drug conjugate having the formula:

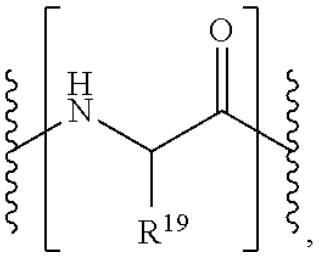


or a pharmaceutically acceptable salt thereof, wherein:

Ab is an antibody,

S is sulfur,

each —W_w— unit is a tetrapeptide; wherein each —W— unit is independently an Amino Acid unit having the formula denoted below in the square bracket:



wherein R^{19} is hydrogen or benzyl,

Y is a Spacer unit,

y is 0, 1 or 2,

D is a drug moiety, and

p ranges from 1 to about 20,

wherein the S is a sulfur atom on a cysteine residue of the antibody, and

wherein the drug moiety is intracellularly cleaved in a patient from the antibody of the antibody-drug

> *conjugate* or an intracellular metabolite of the antibody-drug conjugate.

'039 patent col. 331 l. 36–col. 332 l. 40 (emphases added).

The "W_w" and "Y" limitations of the '039 patent correspond to the peptide and spacer units that can be included in the linker protein. J.A. 3147–48 (44:22–45:1). The limitation reciting, "each —W_w— unit is a tetrapeptide," requires that the claimed peptide unit is a Gly/Phe-only tetrapeptide. Each of the four —W— units must be the amino acid depicted in the formula recited in the square bracket, wherein "R^{19} is hydrogen or benzyl." When R^{19} is hydrogen, the —W— unit is glycine (abbreviated "Gly" or "G"), and when R^{19} is benzyl, the —W— unit is phenylalanine (abbreviated "Phe" or "F"). J.A. 3148 (45:8–21). Accordingly, the W_w unit must be a four-amino-acid-long unit in which each amino acid is either glycine or phenylalanine—*i.e.*, "a Gly/Phe-only tetrapeptide." J.A. 3148 (45:8–24). Because phenylalanine can exist in either of two different stereoisomers (spatial arrangements) in addition to glycine's one, there are three different options for each amino acid of the claimed Gly/Phe-only tetrapeptide. Therefore, the subgenus of peptide units claimed in the '039 patent encompasses 81 (*i.e.*, 3^4) different species. *See* J.A. 3119 (264:21–24). The "Y is a Spacer unit" limitation does not require any specific amino acid sequence, and is not at issue in this appeal. '039 patent col. 331 l. 63.

The '039 patent, which was filed in July 2019, is a continuing application of U.S. Application 10/983,340, filed in November 2004 ("the 2004 application"), from which it claims priority. '039 patent, Related U.S. Application Data; *see* J.A. 5628–5895. The 2004 application describes an ADC with the same general formula as the '039 patent—*i.e.*, an antibody, a drug moiety, and a linker protein with a peptide unit ("W_w") that connects the two, J.A. 5711–14, but the 2004 application does not explicitly disclose a Gly/Phe-only tetrapeptide. That was the particular

difference between the claims of the '039 patent and the 2004 application. The 2004 application only discloses that the linker protein may contain a peptide unit which is a tetrapeptide, and that glycine and phenylalanine are possible amino acid options for the peptide unit. J.A. 5722–23. The 2004 application does disclose an exemplary tetrapeptide with the formula: glycine, phenylalanine, *leucine* (abbreviated "Leu" or "L"), glycine ("GFLG"). J.A. 5727; *see* J.A. 5724 (Table IX: "H," "benzyl," "isobutyl," and "H"), J.A. 3148 (48:8–21 (the amino acid with isobutyl is leucine)), but, again, no disclosure of a tetrapeptide containing only glycine and phenylalanine. The 2004 application's description of specific ADCs is also limited to the class of drugs known as dolastatin/auristatin derivatives ("D/A-type drugs"). J.A. 5642.

In November 2011, Daichii invented DS-8201, an ADC marketed under the brand name Enhertu®, used to treat various types of cancer. J.A. 3113 (240:20–21), 3196 (239:11–16), 3198 (248:7–8). Enhertu contains an amino acid unit with the sequence: Gly-Gly-Phe-Gly, a Gly/Phe-only tetrapeptide. J.A. 3196 (240:22–241:7). Enhertu's structure and mechanism of action were made publicly known in December 2015. J.A. 3242 (126:8-10). One cannot avoid the suspicion that the '039 patent was filed specifically to encompass Enhertu, which of course is permissible if it was entitled to a filing date antedating any public disclosure of Enhertu. That is the primary issue in this case.

II

In October 2020, shortly after the '039 patent was granted, Seagen filed suit against Daichii in the Eastern District of Texas, asserting infringement of claims 1–5, 9, and 10 of the '039 patent. J.A. 10846–58. AstraZeneca, a later collaborator on Enhertu, subsequently intervened in the litigation, joining Daichii as a codefendant. J.A. 10859–61. In parallel with the district court proceedings,

in December 2020, Daichii and AstraZeneca petitioned for post-grant review ("PGR") of the asserted claims, which the United States Patent Trial and Appeal Board ("the Board") granted. *Daiichi Sankyo, Inc. v. Seagen Inc.*, No. PGR2021-00030 (P.T.A.B. Feb. 14, 2023), Paper 36 (institution decision).

At claim construction before the district court, the parties disputed the meaning of the term "D is a drug moiety" as used in claim 1 of the '039 patent. J.A. 1286–87. Daichii contended that the term should be confined to D/A-type drugs, but the district court rejected that argument. J.A. at 1286. The district court reasoned that because neither the text of the claim nor the specification requires the drug used in the ADC to be a particular type of drug, "D is a drug moiety" should be given its plain meaning, encompassing any drug moiety. J.A. at 1287–92.

At trial, the parties disputed both validity and infringement. The issues, in part,[1] converged on whether the 2004 application provided written description support for a Gly/Phe-only tetrapeptide, the W_w peptide unit recited in claim 1, thus entitling the '039 patent to the 2004 application's November 2004 priority date. Because the jury had found that Enhertu meets each limitation of one of the asserted claims, the priority date of the '039 patent became critical: If the 2004 application provided adequate written description support for its claims, Enhertu would infringe a valid '039 patent. But if the 2004 application did not provide adequate written description support for its claims, the public disclosure of Enhertu would anticipate them, and thus invalidate, with, accordingly, no infringement.

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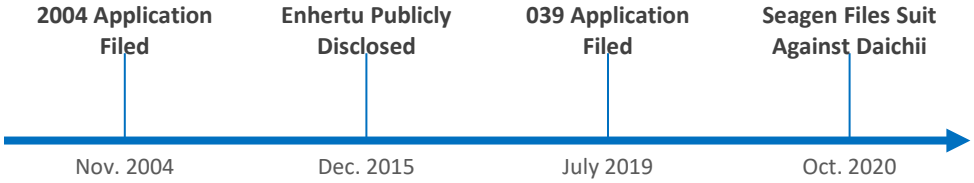
[1] Daichii presented separate arguments as to why Enhertu did not infringe the '039 patent, but those arguments are not at issue in this appeal.

The below timeline illustrates the key events and dates.



At the conclusion of a five-day trial, the jury reached a verdict in Seagen's favor, finding that (1) Daichii failed to prove any of the asserted claims were invalid, (2) Seagen proved Daichii's Enhertu infringed at least one of the asserted claims and that such infringement was willful, and (3) Seagen proved Daichii owed an upfront royalty of $41,820,000 (based on Daichii's net revenue during the period of infringement) and an 8% running royalty. J.A. 53–60. Daichii moved for JMOL, arguing, in relevant part, that (1) the claims were not supported by a sufficient written description, (2) the claims were not enabled, and (3) there was not a logical nexus between the licenses relied upon by Seagen's damages expert and the hypothetical negotiation between Seagen and Daichii in arriving at the 8% royalty rate. J.A. 2134–65, 2191–96. The district court denied Daichii's motion for JMOL, J.A. 32–49, and entered final judgment. J.A. 50–52.

Daichii timely appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

In January 2024, in the separate PGR proceeding, the Board issued a final written decision holding the claims asserted in the district court litigation unpatentable on the same grounds asserted by Daichii in the district court case. *Daiichi*, No. PGR2021-00030, Paper 57. Seagen has appealed the Board's decision to this court, which has been designated as a companion case to the instant appeal, and which we dismiss as moot in a separate decision. *See Seagen Inc. v Daichii Sankyo, Inc.* No. 24-1878, slip. op. at 3 (Fed. Cir. 2025).

DISCUSSION

On appeal, Daichii argues that the district court erred in denying JMOL on each of the above issues that Daichii raised in its post-trial briefing; it does not challenge the jury's finding that Enhertu infringes at least one claim of the '039 patent. Daichii Br. 38–76. Daichii's liability therefore rises and falls with its invalidity arguments. Because the record does not contain substantial evidence that the 2004 application provides written description support for a Gly/Phe-only tetrapeptide or that the '039 patent enables a skilled artisan to make and use the full scope of the claimed ADCs without undue experimentation, we conclude that all of its claims are invalid. We therefore need not reach Daichii's challenge to Seagen's damages award.

We review the denial of a motion for JMOL under regional circuit law. *Freshub, Inc. v. Amazon.com, Inc.*, 93 F.4th 1244, 1249 (Fed. Cir. 2024). JMOL is appropriate only where "the facts and inferences point so strongly and overwhelmingly in favor of one party that the court concludes that reasonable jurors could not arrive at a contrary verdict." *Orion IP, LLC v. Hyundai Motor Am.*, 605 F.3d 967, 973 (Fed. Cir. 2010) (applying Fifth Circuit law). We affirm a district court's denial of judgment as a matter of law when there was substantial evidence to support the jury's verdict. *Power-One, Inc. v. Artesyn Techs., Inc.*, 599 F.3d 1343, 1350–51 (Fed. Cir. 2010) (applying Fifth Circuit law). Federal Circuit law applies to issues of substantive patent law. *See e.g.*, *Colibri Heart Valve LLC v. Medtronic CoreValve, LLC*, 143 F.4th 1367, 1376 (Fed. Cir. 2025).

I. Written Description

In order for a later-filed patent "to gain the benefit" of an earlier application's priority date, inter alia, the earlier application must disclose an invention "in the manner provided by section 112(a) [of the Patent Act]." *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1571 (Fed. Cir. 1997); 35 U.S.C. § 120. Section 112(a) of the Patent Act provides that

a patent "specification shall contain a written description of the invention." 35 U.S.C. § 112(a). A specification adequately describes an invention when it "reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (citation omitted). "[T]he hallmark of written description is disclosure" in the "four corners of the specification." *Id.* Whether a patent complies with the written description requirement is a question of fact, and "we review a jury's determinations of facts relating to compliance with the written description requirement for substantial evidence." *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330, 1335–36 (Fed. Cir. 2021) (quoting *Ariad*, 598 F.3d at 1355).

Daichii argues that no reasonable jury could have found that the 2004 application sufficiently discloses the claimed 81-member subgenus[2] of Gly/Phe-only tetrapeptides corresponding to the "—W_w— unit" recited in claim 1. We agree and therefore conclude that substantial evidence does not support the jury's finding of adequate written description.

A

The 2004 application only broadly outlines the possible structures of the W_w peptide unit that are included in the linker protein. It states that "when present," the peptide unit "W_w" can be any of "a dipeptide, tripeptide, tetrapeptide, pentapeptide, hexapeptide, heptapeptide, octapeptide, nonapeptide, decapeptide, undecapeptide or

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[2] We use the term "subgenus" here because the parties have. Claim 1 is of course a subgenus of a larger genus described in the 2004 application. But claim 1 might equally be called a genus, as it certainly is, in fact, a rather large one, as can be seen here.

dodecapeptide unit." J.A. 5722–23. That is, if the peptide unit is included in the ADC described in the 2004 application, it can include anywhere from two to twelve amino acids. J.A. 5722–23. The 2004 application then describes 39 different amino acids that can constitute the R^{19} group, which determines the identity of the —W— unit. J.A. 5723. When different isomers of the identified amino acids are included, there are 83 unique options for each "—W—" unit. *See* J.A. 3243 (130:16–132:24). Accordingly, just with respect to tetrapeptides, over 47 million different tetrapeptide units (*i.e.*, 83^4) are encompassed in the 2004 application.[3] Seagen and Daichii's witnesses agreed on this point at trial. J.A. 3120 (265:3–10) (lead named inventor Dr. Peter Senter admitting that "[t]he number of options" in the 2004 application "for just the tetrapeptide category alone is over 47 million"), 3243 (132:19–24) (Daichii expert Dr. John Lambert stating that in "[I]n tetrapeptides alone[,] there are 47 million options" possible in the 2004 application).

But such evidence is insufficient to support the jury's finding of adequate written description in the 2004 application. As we have consistently held, a patent's disclosure of a "broad genus," without more, is inadequate to satisfy the written description requirement for claims directed to a "particular subgenus or species contained therein." *See, e.g.*, *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1346 (Fed. Cir. 2013).

Our predecessor court's decision in *In re Ruschig* is instructive. 379 F.2d 990 (CCPA 1967). There, the claim recited a single compound, which was "encompassed" in the application's "general disclosure of . . . something like half

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[3] The number of peptides encompassed by the 2004 application with each additional amino acid unit grows exponentially—*e.g.*, almost four billion pentapeptides are included (83^5).

a million possible compounds." *Id.* at 993, 996. The applicant urged that such a disclosure was adequate. The Court of Customs and Patent Appeals ("CCPA") rejected that argument, explaining that claims to a particular species or subgenus require "reasonably specific supporting disclosure" to show that the inventor possessed the specific compound. *Id.* at 994.

Similarly, here, it was undisputed at trial that the 2004 application broadly discloses an extraordinary number of peptide units—*e.g.*, with respect to just the tetrapeptides covered, over 47 million species based on 83 different amino acids. J.A. 3120 (265:3–10), 3243 (132:19–24). And although the 81 claimed Gly/Phe-tetrapeptides are "encompassed" within those 47 million, *see* J.A. 3148 (46:8–11), 3256–57 (184:23–185:22), they are merely an infinitesimal fraction of those peptide units generally included. Under *Ruschig*, such evidence does not provide "reasonably specific supporting disclosure" for the claimed subgenus of 81 Gly/Phe-only tetrapeptides. 379 F.2d at 993–94. Accordingly, the above evidence was not substantial evidentiary support for the jury's finding of adequate written description.

The '039 patent thus cannot claim priority from the 2004 application, meaning that the December 2015 public disclosure of Enhertu, which was found to contain each limitation of at least claim 1 (the sole independent claim), anticipates, and thus invalidates the '039 patent. *Bristol-Myers Squibb Co. v. Ben Venue Laby's, Inc.*, 246 F.3d 1368, 1378 (Fed. Cir. 2001 ("[T]hat which would literally infringe if later anticipates if earlier.").

Attempting to distinguish cases like *Ruschig*, Seagen principally relies on another of our predecessor court's decisions, *In re Driscoll*, 562 F.2d 1245 (CCPA 1977). Seagen Br. 35–36. There, the patent claim recited a subgenus of chemical compounds with a specific moiety, and an earlier application which the patent claimed priority from recited

fourteen moieties, including the one claimed. *Driscoll*, 562 F.2d at 1249. The CCPA held that the earlier application provided written description support for the claim because "the exact subgenus claimed is clearly discernible in the generalized formula" and therefore "a skilled artisan would recognize from the disclosure of [the specification]" that the inventor possessed each of the "fourteen distinct [moieties]." *Id.* at 1249–50.

Seagen's reliance on *Driscoll* is misplaced. Here, as discussed, there are effectively countless peptide units encompassed by the 2004 application—a far cry from the 14 moieties individually listed in the specification in *Driscoll*. And the claimed subgenus of 81 Gly/Phe-only tetrapeptides is never mentioned in the 2004 application, and therefore is not "clearly discernible in the generalized formula" in the way the CCPA found sufficient in *Driscoll*. *Id.* at 1250.

The conclusion that the 2004 application does not provide adequate written description support is further supported by admissions from the '039 patent's named inventors that they had never contemplated an ADC with a Gly/Phe-only tetrapeptide as of the 2004 application's priority date. *See Nuvo Pharms. (Ireland) Designated Activity Co. v. Dr. Reddy's Lab'ys Inc.*, 923 F.3d 1368, 1381 (Fed. Cir. 2019) (inventor testimony can "illuminate[] the absence of critical [written] description").

Specifically, lead inventor Dr. Senter admitted that the "first time . . . [he] ever saw a G/F-only tetrapeptide in an ADC . . . was in Dacihii Sankyo's Enhertu," which was publicly disclosed in 2015. J.A. 3119 (261:22–23). Similarly, inventor Dr. Svetlana Doronina admitted that "the claims of the '039 patent," filed in 2019, were "the first time" she had "seen described a genus of tetrapeptide linkers that's limited to glycine [and] phenylalanine." J.A. 3295 (74:9–12). Named inventors Dr. Brian Toki and Dr. Toni Kline testified to similar effect. J.A. 3292 (62:13–63:4) (Dr. Toki); 3297 (84:1–9). Because "one cannot describe what one has

not conceived," *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993), the inventors' admissions bolster the conclusion that they did not possess the claimed subgenus of Gly/Phe-only tetrapeptides as of the November 2004 priority date.

Dr. Senter's additional testimony that the inventors created ADC linkers comprising "almost any peptide" prior to the 2004 application's priority date is not sufficient to overcome his above admission for the same reason that the disclosures in the 2004 application are inadequate. Seagen Br. 38 n.12; J.A. 3110 (229:6–8). Dr. Senter's testimony does not show that the 2004 application provides "reasonably specific supporting disclosure" for the claimed Gly/Phe-only tetrapeptides, or that the inventors had possession of that subgenus of tetrapeptides. *Ruschig*, 379 F.2d at 994.

B

Separately, Seagen asserts that the finding of adequate written description was supported by substantial evidence because the jury heard testimony that the 2004 application would "direct[]" a skilled artisan to the claimed subgenus of Gly/Phe-only tetrapeptides. Seagen Br. 40–45. We have often analyzed such theories by analogizing a genus and its constituent subgenuses or species to a forest and trees:

> It is an old custom in the woods to mark trails by making blaze marks on the trees. It is no help in finding a trail or in finding one's way through the woods where the trails have . . . not yet been made . . . to be confronted simply by a large number of unmarked trees. . . . *We are looking for blaze marks which single out particular trees.*

Ruschig, 379 F.2d at 994–95 (emphasis added).

Seagen presented its "blaze-mark" theory through Dr. Carolyn Bertozzi. Dr. Bertozzi provided considerable testimony purporting to show how a skilled artisan could have made certain changes in the compounds disclosed to arrive

at a compound within the scope of the claimed subgenus. Specifically, Dr. Bertozzi testified that, based on the 2004 application's disclosure of the tetrapeptide, GFLG, together with several *tri*peptides where phenylalanine is at the second position, a skilled artisan would understand that "F at [position] 2" was a possible substitution for leucine in GFLG. J.A. 3299–3300 (91:19–93:5). The highlight of that testimony stated that it would be a "straightforward leap" for a skilled artisan "to go from GFLG . . . to a [tetra]peptide that's all G and F." J.A. 3149 (50:25–51:2).

But that testimony dooms Seagen's case. That which one must leap to is obviously not there. It is thus axiomatic that a skilled artisan need not make a "leap" to "a [tetra]peptide that's all G and F" if the skilled artisan were to understand that the 2004 application *itself* disclosed such a peptide. J.A. 3149 (50:25–51:2). That testimony is accordingly self-defeating: It in effect admits that a skilled artisan would not understand the inventors of the 2004 application to have "possession" of GFFG. *Ariad*, 598 F.3d at 1351; *see also Lockwood*, 107 F.3d at 1572. ("It is not sufficient for purposes of . . . written description . . . that the disclosure, when combined with the knowledge in the art, would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose."); *Regents of the Univ. of Minn. v. Gilead Scis. Inc.*, 61 F.4th 1350, 1358 (Fed. Cir. 2023) (lack of written description where the priority documents blaze a trail "that runs close by the later-claimed tree," but "'do[ ] not direct one to the proposed tree in particular, and do[ ] not teach the point at which one should leave the trail to find it.'" (alterations in original) (quoting *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571 (Fed. Cir. 1996))).

In sum, the 2004 application's broad disclosure of effectively countless options for the peptide unit fails to show the subgenus of Gly/Phe-only tetrapeptides claimed in the '039 patent. Moreover, there are no adequate blaze marks that would lead a skilled artisan to the 81-member

Gly/Phe-only tetrapeptide subgenus or any species within it. A reasonable jury therefore did not have sufficient evidence to find that the '039 patent provided written description support for what it claimed. Accordingly, the district court erred in denying Daichii's motion for JMOL on that ground.

II. Enablement

Another issue at trial relating to validity was whether the '039 patent satisfied the enablement requirement. Specifically, the parties disputed whether the '039 patent sufficiently enabled a skilled artisan to make and use ADCs with the claimed structure and function. Seagen's witnesses asserted that undue experimentation was not necessary to make and use the full scope of claimed ADCs.

The enablement requirement is distinct from the written description requirement. *Ariad*, 598 F.3d at 1351. A patent's specification must describe the invention and "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 . . . to make and use the same." 35 U.S.C. § 112(a). This means that "the specification must enable the full scope of the invention as defined by its claims," allowing for "a reasonable amount of experimentation." *Amgen v. Sanofi*, 598 U.S. 594, 610, 612 (2023). Put differently, "[t]o be enabling, the specification of a patent 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). "Whether a claim satisfies § 112's enablement requirement is a question of law [that] we review de novo; however, in the context of a jury trial, we review the factual underpinnings of enablement for substantial evidence." *Trs. of Bos. Univ. v. Everlight Elecs. Co.*, 896 F.3d 1357, 1361 (Fed. Cir. 2018) (citation omitted).

Daichii argues that the '039 patent failed to provide an enabling disclosure of the subject matter of the claims. We agree with Daichii. No reasonable jury could have found that the specification of the '039 patent teaches a skilled artisan how to make and use the full scope of the claimed invention. We therefore conclude that substantial evidence does not support the jury's finding of enablement for any of the asserted claims.

The Supreme Court's decision in *Amgen v. Sanofi*, unanimously affirming our decision, is relevant here. In *Amgen*, the patents claimed "the entire genus of antibodies" that (1) bind to specific amino acid residues on a protein and (2) block that protein from binding to receptors involved in removing a certain harmful cholesterol from the bloodstream. 598 U.S. at 602 (internal quotations omitted). It was undisputed that the claims covered "at least millions" of antibodies with the recited functionalities. *Id.* at 613. The patents' specification identified 26 antibodies that perform the two recited functions along with their relevant structures, *id.* at 602–03, as well as two methods for testing whether a particular antibody performs the two recited functions. *Id.* at 603.

Amgen, the patent owner, contended that the specification's disclosure of the two methods was sufficient to enable a skilled artisan to make and use the full scope of the claimed invention. *Id.* at 613–14. The Court rejected that argument. It explained that—in light of the unpredictability of antibody science where even a minor change of chemical structure can alter an antibody's functionality—without disclosing "a quality common to every functional embodiment," both methods effectively amounted to telling a skilled artisan to perform "trial-and-error discovery" to determine if any one antibody may possess the recited functionalities. *Id.* at 600, 614–15.

So too here. The district court construed the limitation "D is a drug moiety" to encompass any type of drug moiety.

J.A. 1287–92. Further, the '039 patent recites a functional limitation: "the drug moiety is intracellularly cleaved in a patient from the antibody." '039 patent col. 332 ll. 37–39; *see Nevro Corp. v. Bos. Sci. Corp.*, 955 F.3d 35, 39 (Fed. Cir. 2020) ("[A] functional term [is] defined by what it does rather than what it is."). Taken together, these two limitations mean that the '039 patent covers an ADC containing *any* drug moiety with the recited function of cleaving in a patient. But the specification does not disclose "a quality common to every functional embodiment" of the patent. *Amgen*, 598 U.S. at 614. Rather, it is undisputed that ADC science was so unpredictable that a skilled artisan would be required to use an assay to test whether any given ADC with a given drug moiety meets that functional limitation. J.A. 3296 (78:21–79:1) (inventor Dr. Kline admitting that a skilled artisan would need to conduct an assay to determine whether a given ADC is "is going to be successfully intracellularly cleaved"); Seagen Br. 56–57 (listing various assays a skilled artisan would know to use to determine whether a given ADC's drug moiety is intracellularly cleaved). Therefore, just as in *Amgen*, a skilled artisan would be left to perform far-ranging "trial-and-error discovery" to make and use the ADCs within the scope of the '039 patent. *Amgen*, 598 U.S. at 615.[4] Under these circumstances, where the scale of trial and error is so vast and the science so unpredictable, such experimentation is undue under *Amgen*, *see id.* Thus, the jury did not have substantial evidence to conclude that the '039 patent was enabled.

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[4] The amount of trial-and-error discovery that would be required to determine whether an ADC with a given drug intracellularly cleaves is further increased by the need to test each ADC with the recited structural limitations.

CONCLUSION

We have considered Seagen's remaining arguments and find them unpersuasive. For the foregoing reasons, we reverse the district court's denial of judgment as a matter of law that the '039 patent is not invalid for failure to meet the written description and enablement requirements. The '039 patent is therefore invalid. We vacate the jury's finding of willful infringement and assessment of damages.

REVERSED