United States Court of Appeals for the Federal Circuit

BAYER HEALTHCARE LLC,
Plaintiff-Cross-Appellant

v.

BAXALTA INC., BAXALTA US INC.,
Defendants-Appellants

NEKTAR THERAPEUTICS,
Defendant-Appellee

2019-2418, 2020-1017

Appeals from the United States District Court for the District of Delaware in No. 1:16-cv-01122-RGA, Judge Richard G. Andrews.

Decided: March 1, 2021

BRADFORD J. BADKE, Sidley Austin LLP, New York, NY, argued for plaintiff-cross-appellant. Also represented by SONA DE, CHING-LEE FUKUDA; JOSHUA JOHN FOUGERE, RYAN C. MORRIS, PAUL ZEGGER, Washington, DC.

EDGAR HAUG, Haug Partners LLP, New York, NY, argued for defendants-appellants and defendant-appellee. Also represented by KAITLIN ABRAMS, NICHOLAS F. GIOVE, JONATHAN HERSTOFF, ERIKA SELLI.

Before NEWMAN, LINN, and STOLL, *Circuit Judges*.

STOLL, *Circuit Judge*.

This patent infringement case presents various issues of claim scope, infringement, validity, and damages. Bayer HealthCare LLC sued Baxalta Inc. and Baxalta US Inc. (collectively, "Baxalta") and Nektar Therapeutics, alleging that Baxalta's biologic product Adynovate® infringes certain claims of Bayer's U.S. Patent No. 9,364,520. The jury found that the asserted claims were enabled and infringed, and that Bayer was entitled to reasonable-royalty damages. The district court did not, however, send the question of willful infringement to the jury, instead holding as a matter of law that Baxalta's conduct did not meet the requirements for willfulness. Baxalta now appeals the district court's denial of its motions for judgment as a matter of law or a new trial on the issues of infringement, enablement, and damages, along with the court's award of preverdict supplemental damages. Bayer cross-appeals, challenging the district court's denial of its motion for a new trial on willfulness. We affirm.

BACKGROUND

I

The '520 patent is directed to recombinant forms of human factor VIII (or FVIII). FVIII is a protein that is produced, and released into the bloodstream, by the liver. FVIII comprises 2,332 amino acids and has six different structural domains: A1-A2-B-A3-C1-C2. Most relevant to this case is the domain of FVIII known as the "B-domain."

As "a critical component of the intrinsic pathway of blood coagulation," FVIII is useful in the treatment of hemophilia A. '520 patent col. 1 ll. 29–30. Hemophilia A is the "most common hereditary coagulation disorder" and is "caused by deficiency or structural defects in" naturally

occurring FVIII. *Id.* at col. 1 ll. 27–29. Because FVIII has a "short half-life" of "only about 11 hours," as a therapeutic it "must be administered frequently." *Id.* at col. 1 ll. 52–55. The '520 patent recognizes that "[t]he need for frequent intravenous injection creates tremendous barriers to patient compliance" and, thus, "[i]t would be more convenient for the patients if a FVIII product could be developed that had a longer half-life and therefore required less frequent administration." *Id.* at col. 1 ll. 56–60; *see id.* at col. 2 ll. 47–49. Moreover, "the cost of treatment could be reduced if the half-life were increased because fewer dosages may then be required." *Id.* at col. 1 ll. 60–62.

The patent explains that a process called "PEGylation" has "been demonstrated to increase the in vivo half-life of a protein." *Id.* at col. 3 ll. 34–35. PEGylation is the conjugation (or attachment) of a polymer called polyethylene glycol (PEG) to a protein such as FVIII. *See id.* at col. 3 ll. 35–37; *see also id.* at col. 9 ll. 12–14. PEG is a type of polyalkylene oxide. *See id.* at col. 8 ll. 41–43.

The patent further teaches that "random" modification of FVIII by PEGylation was known and that certain randomly PEGylated proteins had been approved as therapeutics. The inventors sought, however, "a more specific method for PEGylating FVIII" because the prior-art "random" approach had several drawbacks:

> Random modification of FVIII by targeting primary amines (N-terminus and lysines) with large polymers such as PEG and dextran has been attempted with varying degree[s] of success . . . .
>
> This random approach . . . is much more problematic for the heterodimeric FVIII. FVIII has hundreds of potential PEGylation sites, including the 158 lysines, the two N-termini, and multiple histidines, serines, threonines, and tyrosines, all of which could potentially be PEGylated with reagents primarily targeting primary amines.

Id. at col. 3 l. 50–col. 4 l. 1, col. 4 ll. 19–20.

The patent identifies as an "additional drawback to not controlling the site of PEGylation on FVIII" the "potential activity reduction if the PEG were to be attached at or near critical active sites, especially if more than one PEG or a single large PEG is conjugated to FVIII." *Id.* at col. 4 ll. 7–11. Furthermore, "[b]ecause random PEGylation will invariably produce large amounts of multiply PEGylated products, purification to obtain only mono-PEGylated products will drastically lower overall yield." *Id.* at col. 4 ll. 11–14. Finally, the patent explains that "the enormous heterogeneity in product profile will make consistent synthesis and characterization of each lot nearly impossible" and constitutes "a barrier to commercialization," since "good manufacturing requires a consistent, well-characterized product." *Id.* at col. 4 ll. 14–19; *see id.* at col. 4 ll. 4–7 ("[H]eterogeneous processing of full length FVIII can lead to a mixture of starting material that leads to further complexity in the PEGylated products.").

Thus, the inventors recognized "a need for an improved FVIII variant that possesses greater duration of action in vivo . . . while retaining functional activity," and that is desirably "produced as a homogeneous product in a consistent manner." *Id.* at col. 4 l. 65–col. 5 l. 3. The patent purports to overcome the drawbacks of "random" PEGylation by using "site-directed" PEGylation at the B-domain of FVIII:

> The present invention is based on the discovery that polypeptides having FVIII activity can be covalently attached at a predefined site to a biocompatible polymer that is not at an N-terminal amine, and that such polypeptides substantially retain their coagulant activity. Furthermore, these polypeptide conjugates have improved circulation time and reduced antigenicity. The conjugates of the invention are advantageous over the prior art conjugates that had random polymer attachments to

> FVIII or attachments at an N-terminal. Site-directed attachment allows one to design modifications that avoid the regions required for biological activity and thereby to maintain substantial FVIII activity. . . . Site-directed attachment also allows for a uniform product rather than the heterogeneous conjugates produced in the art by random polymer coupling.

Id. at col. 8 ll. 15–30; *see id.* at col. 15 ll. 9–13 (explaining that the "retained activity" of the claimed conjugates was "surprising" given "the problems with past polymeric conjugates causing nonspecific addition and reduced activity").

Claim 1 is the only asserted independent claim and recites:

> 1. *An isolated polypeptide conjugate* comprising a functional factor VIII polypeptide and one or more biocompatible polymers, wherein the functional factor VIII polypeptide comprises the amino acid sequence of SEQ ID NO: 4 or an allelic variant thereof and has a B-domain, and further wherein the biocompatible polymer comprises polyalkylene oxide and is covalently attached to the functional factor VIII polypeptide *at the B-domain*.

Id. at col. 61 ll. 9–16 (emphases added to the disputed claim terms).

II

Bayer sued Baxalta and Nektar, Baxalta's collaborator on its Adynovate® product, for patent infringement. Adynovate® is a recombinant PEGylated FVIII product used to treat hemophilia A. Adynovate® is made by PEGylating to amino acids in FVIII that have amine groups, including the amino acid lysine. We hereafter refer to this process as "amine/lysine" PEGylation.

The district court construed the claim term "an isolated polypeptide conjugate" in claim 1 to mean "a polypeptide conjugate where conjugation was not random." *Bayer Healthcare LLC v. Baxalta Inc.*, No. 16-cv-1122, 2018 WL 3212425, at *2 (D. Del. June 29, 2018) (*Claim Construction Op.*). The district court determined that, during prosecution of the '520 patent, Bayer had "clearly and unmistakably disclaimed any 'polypeptide conjugate where conjugation was random.'" *Id.* at *4.

In addition, the district court construed the claim term "at the B-domain" in claim 1 to mean "attachment at the B-domain such that the resulting conjugate retains functional factor VIII activity." *Id.* at *8. The district court rejected Baxalta's proposed construction of the term to mean "at a site that is not any amine or carboxy site in factor VIII and is in the B-domain," finding that Bayer did not disclaim PEGylation at amine or carboxy sites. *Id.* at *8–9.

Baxalta moved for summary judgment of noninfringement and invalidity for lack of enablement. The district court denied Baxalta's motions due to genuine factual disputes. *See Bayer HealthCare LLC v. Baxalta Inc.*, No. 16-cv-1122, 2018 WL 6727054, at *3–7 (D. Del. Dec. 21, 2018) (*Summ. J. Op.*). Baxalta also moved in limine requesting that the district court clarify the meaning of "random" in its construction of "an isolated polypeptide conjugate." The district court denied Baxalta's motion, "again reject[ing] [Baxalta's] argument that [Bayer] defined 'random' conjugation as 'any conjugation at amines or carboxy sites.'" *Bayer HealthCare LLC v. Baxalta Inc.*, No. 16-cv-1122, 2019 WL 10890386, at *1 (D. Del. Jan. 3, 2019) (*Mot. in Lim. Order*).

Prior to trial, Baxalta moved to exclude the testimony of Bayer's damages expert, Dr. Addanki, regarding his proposed reasonable-royalty rate. In his expert report, Dr. Addanki opined that Bayer was entitled to a royalty rate of 23.75%—the midpoint of the bargaining range of 5.1% to

42.4%—based on the Nash Bargaining Solution. The district court concluded that the expert failed to tie his 50/50 split to the facts of the case, and thus excluded his "opinion that a reasonable royalty rate is 'the mid-point of the bargaining range' . . . , including any subsequent opinions that rely on that mid-point rate." *Bayer HealthCare LLC v. Baxalta Inc.*, No. 16-cv-1122, 2019 WL 330149, at *8 (D. Del. Jan. 25, 2019) (*Daubert Order*). The district court denied, however, Baxalta's request to prohibit Dr. Addanki from testifying as to his proposed bargaining range of 5.1% to 42.4%.

The case then proceeded to a jury trial. The district court granted Baxalta's pre-verdict motion for JMOL of no willful infringement. Thereafter, the jury found that Baxalta infringed asserted claims 1–3 and 8 of the '520 patent, and that none of those claims were invalid for lack of enablement. J.A. 1889–90, 1892. The jury also found that Bayer was entitled to $155,190,264 in reasonable-royalty damages for the time period from June 14, 2016 through November 30, 2018 based on a 17.78% royalty rate applied to a $872,836,128 royalty base. J.A. 1893.

Following the verdict, Baxalta moved for JMOL or a new trial on the issues of infringement, enablement, and damages. The district court denied Baxalta's motions. *See generally Bayer Healthcare LLC v. Baxalta Inc.*, 407 F. Supp. 3d 462 (D. Del. 2019) (*JMOL Op.*). For its part, Bayer moved under Rule 59 of the Federal Rules of Civil Procedure for an award of pre-verdict supplemental damages for the time period from December 1, 2018 through February 8, 2019, the date of the district court's judgment. The district court granted Bayer's motion and awarded Bayer supplemental damages in the amount of $18,324,562 based on the actual sales data for that period and the jury's 17.78% royalty rate. *Bayer Healthcare LLC v. Baxalta Inc.*, No. 16-cv-1122, 2019 WL 4016235, at *6 (D. Del. Aug. 26, 2019) (*Rule 59 Op.*); Final Judgment at 2, *Bayer Healthcare LLC v. Baxalta Inc.*, No. 16-cv-1122

(D. Del. Sept. 10, 2019), ECF No. 507. Bayer also moved for a new trial under Rule 59(a) on the issue of willfulness, but the district court denied its motion. *Rule 59 Op.*, 2019 WL 4016235, at *8–9.

Bayer and Baxalta appeal. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

This case presents various issues on appeal and cross-appeal. We start by addressing Baxalta's challenges to the district court's construction of the claim term "at the B-domain" and its interpretation of the word "random" in its construction of the claim term "an isolated polypeptide conjugate." We then turn to Baxalta's challenges to the district court's judgments of infringement and enablement, along with the court's awards of damages and pre-verdict supplemental damages. Finally, we address Bayer's challenge to the district court's judgment of no willful infringement.

I

We first address Baxalta's challenge to the district court's construction of the disputed term "at the B-domain" in claim 1. Baxalta contends that the district court erred in failing to construe the term to exclude amine/lysine conjugation. Neither the parties nor the district court considered extrinsic evidence in construing this claim term. "Claim construction based on the intrinsic evidence is a question of law that this court reviews de novo." *Hologic, Inc. v. Minerva Surgical, Inc.*, 957 F.3d 1256, 1269 (Fed. Cir. 2020) (citing *Trs. of Columbia Univ. v. Symantec Corp.*, 811 F.3d 1359, 1362 (Fed. Cir. 2016)). "The construction of claim terms based on the claim language, the specification, and the prosecution history are legal determinations." *Id.* (quoting *Trs. of Columbia Univ.*, 811 F.3d at 1362). Based on our review of the claim language, specification, and prosecution history, we conclude that the

district court did not err in construing the disputed claim term.

A

The plain claim language recites "[a]n isolated polypeptide conjugate" in which PEG "is covalently attached to the functional factor VIII polypeptide at the B-domain." The plain language of claim 1 does not require PEGylation at any particular amino acid sites in the B-domain, let alone exclude from its scope any specific amino acids as attachment sites in the B-domain. Rather, claim 1 more broadly requires PEGylation at the B-domain as a region.

B

Statements in the specification support this view of the claims and indicate that site-directed PEGylation targeting the B-domain, rather than particular amino acid sites within it, achieved the desired benefit of retaining coagulation activity. *See, e.g.*, '520 patent col. 4 ll. 7–9 ("An additional drawback to not controlling the site of PEGylation on FVIII is a potential activity reduction if the PEG were to be attached at or near critical active sites . . . ."); *id.* at col. 8 ll. 23–26 ("Site-directed attachment allows one to design modifications that avoid the regions required for biological activity and thereby to maintain substantial FVIII activity."). We acknowledge that the specification discloses embodiments of site-directed PEGylation at cysteine amino acids within the B-domain. *See, e.g.*, *id.* at col. 5 ll. 46–57, col. 20 l. 56–col. 21 l. 5. But the specification does not state that this is the only embodiment or otherwise indicate that the invention is limited to site-directed PEGylation at cysteine amino acids within the B-domain and, as noted above, the claim language is not so limited.

On appeal, Baxalta contends that the specification disparages amine/lysine conjugation. In particular, it points to the "Background of the Invention," which discloses that "[r]andom modification of FVIII by targeting primary

amines (N-terminus and *lysines*) with large polymers such as PEG" has "been attempted with varying degrees of success," and that "*[t]his random approach, however, is much more problematic*" because FVIII has "hundreds of potential PEGylation sites." Appellants' Br. 24 (quoting '520 patent col. 3 l. 50–col. 4 l. 1). To support its disparagement argument, Baxalta cites *Indivior Inc. v. Dr. Reddy's Laboratories, S.A.*, 930 F.3d 1325 (Fed. Cir. 2019), and *SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc.*, 242 F.3d 1337 (Fed. Cir. 2001). Although Baxalta presents a close question as to disparagement, the facts here differ from those of cases finding disclaimer based on the specification.

In *Indivior*, the asserted patent claimed pharmaceutical films with uniform distribution of the active ingredient. 930 F.3d at 1331. The claims identified "drying" as a parameter that contributes to film uniformity. *Id.* at 1332. The specification taught that using conventional drying methods, which applied hot air to the top of the film, produced nonuniform films. *Id.* The specification also disclosed controlled drying methods that differed from conventional techniques. *Id.* The district court construed the drying limitation to mean "dried without solely employing conventional convection air drying from the top" based on its conclusion that the patentee disclaimed drying films using solely conventional top air drying. *Id.* at 1336. We agreed with the district court's construction, concluding that "the specification repeatedly disparages conventional top air drying because such drying does not produce uniform films, the central object of the claimed invention." *Id.* at 1337. The "specification also provide[d] examples that demonstrate[d] the failure of conventional drying methods to achieve uniformity." *Id.*

Similarly, we concluded in *SciMed* that the shared specification of the patents-in-suit disclaimed an embodiment from the scope of the asserted claims. The patents were drawn to balloon dilatation catheters containing two

passageways, or lumens. 242 F.3d at 1338–39. Two arrangements of the lumens were practiced in the art: the dual lumen configuration and the coaxial lumen configuration. *Id.* at 1339. The district court construed the asserted claims to be limited to catheters with coaxial lumens, and not to read on catheters with dual lumens. *Id.* We agreed with the district court's construction because the specification unequivocally limited "all embodiments" of the claimed invention to a coaxial lumen configuration. *Id.* at 1340, 1343–44. In particular, the specification repeatedly defined "the invention" as catheters having a coaxial lumen structure and discussed the disadvantages of prior-art catheters having a dual lumen configuration. *Id.* at 1342–44.

We likewise determined that the patent owner in *Gaus v. Conair Corp.*, 363 F.3d 1284 (Fed. Cir. 2004), unequivocally disclaimed a particular embodiment from its claims' scope and therefore could not rely on the doctrine of equivalents to cover that embodiment. The patent at issue claimed a device, such as a hairdryer, comprising "an electrical operating unit and a pair of spaced-apart electrically exposed conductive probe networks." *Id.* at 1287. The specification "made clear that it is essential to [the] invention that the pair of probe networks be separate from the voltage-carrying components of the appliance, i.e., the 'electrical operating system.'" *Id.* at 1291. By contrast, the specification "criticized prior art in which the protective device relied on the fluid coming in contact with the voltage-carrying portions of the system." *Id.* Thus, we concluded that the patent owner "disavowed coverage of devices in which the two components are not separate and in which the protective cut-off mechanism is not triggered until the water reaches the electrical operating system." *Id.*

Each of these cases presented a strong case of disclaimer of a particular feature from the scope of a claim because the specification made clear that the invention did not include that feature. *See Indivior*, 930 F.3d at 1337;

SciMed, 242 F.3d at 1342–44; *Gaus*, 363 F.3d at 1291. The specification of the '520 patent disparages random PEGylation of FVIII, including random PEGylation targeting amines like lysines, but nowhere disparages non-random, site-directed amine/lysine PEGylation at the B-domain. Thus, we agree with the district court that Bayer did not unequivocally disclaim non-random amine/lysine PEGylation in the specification.

C

We turn next to the prosecution history, which can be helpful in understanding the proper claim construction. We are not persuaded that the prosecution history includes a clear and unmistakable surrender of claims directed to non-random amine/lysine PEGylation. Nor are we persuaded that Bayer's statements during prosecution otherwise require a claim construction that would exclude such conjugates.

During prosecution of the '520 patent, the Examiner rejected the pending claims as inherently anticipated by a patent application filed by Nektar: Bossard.[1] On appeal to the Patent Trial and Appeal Board, Bayer argued that Bossard did not teach the claimed conjugates because Bossard's "alleged showing of B-domain attachment is random PEGylation and does not ensure that attachment occurs at the B-domain." J.A. 3507. Bayer also argued that its then-rejected claim 58, which ultimately issued as claim 1, "excludes compositions of randomly PEGylated factor VIII in which some conjugates have PEGylation at the B-domain but a large number do not." *Id.* Bayer continued by stating that:

> The Patent Office . . . relies on passages in Bossard that show random PEGylation at any one of numerous amino acid residues in the 2,332-amino

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[1] U.S. Patent. Pub. No. 2004/0235734.

> acid protein that have the disclosed functionality. Specifically, the Patent Office asserts that Bossard et al. "teach many polymer attachment sites such as '*lysine*, cysteine and/or arginine', '*amine groups*' and/or 'carboxyl groups' for the site of attachment to factor VIII, wherein said many polymer attachment sites are presented in the B-domain . . . ." These types of sites are present in the B-domain, but they are also present in many other domains of factor VIII. *This description does not ensure that attachment occurs at the B-domain, and does not disclose isolated conjugates with attachment at the B-domain.*

J.A. 3507–08 (second ellipsis in original) (citations omitted) (emphases added). In response to the Examiner's Answer and specifically the Examiner's arguments based on Bossard, Bayer argued in its reply brief to the Board that:

> Much of the Patent Office's prior arguments relied upon possible conjugation at *amines or carboxy sites*, which are present not only in the B-domain but in other domains. *Any conjugation with these reactive groups is random and does not ensure that attachment occurs at the B-domain.*

J.A. 4599 (emphases added).

Baxalta's disclaimer arguments based on Bayer's statements to the Board have some merit. Ultimately, however, we agree with the district court's view as to how a person of ordinary skill in the art would have understood the prosecution history as a whole. Specifically, we agree with the district court that when the "entire passage" from Bayer's reply brief is "read together, it is clear that '[a]ny conjugation' refers to the conjugations allegedly *disclosed by Bossard*." *Summ. J. Op.*, 2018 WL 6727054, at *4. Specifically, though Bossard "may have taught conjugations at various sites on factor VIII, such as amines or carboxy sites," Bayer "argued that the conjugations were not

targeted to particular sites" and, thus, "described '[a]ny conjugation' in Bossard as random." *Id.* As the district court reasoned, it "does not follow" that Bayer "defined all conjugations with amines or carboxy sites as random." *Id.*; *see also Claim Construction Op.*, 2018 WL 3212425, at *9 ("[Bayer] stated that conjugation at amines and carboxy sites cannot ensure PEGylation at the B-domain—not that conjugation cannot occur at amines and carboxy sites."). We agree with the district court that Bayer distinguished the prior art on the ground that it did not teach non-random PEGylation at the B-domain, and that Bayer did not clearly and unmistakably disclaim all PEGylation at amines and carboxy sites.

Additional sections of the prosecution history support our conclusion. First, the prosecution history reveals that Bossard randomly PEGylated at both lysines *and* cysteines on FVIII, which undermines Baxalta's position that Bayer disclaimed the former but not the latter as sites for PEGylation. Second, the Board reversed the Examiner's anticipation rejection based on a separate prior-art reference, Rostin.[2] The Examiner argued that Rostin's PEG attached to the lysine in Rostin's shortened B-domain, and thus inherently anticipated Bayer's claims. The Board disagreed, holding that Rostin's PEG did not "necessarily attach[] to the single lysine located in the [shortened] B-domain" because there were many other lysines throughout FVIII. J.A. 3589–90. These passages suggest that the Examiner and the Board understood that lysine PEGylation at the B-domain was within the scope of Bayer's claims.

Finally, Baxalta's reliance on the applicants' statements during prosecution of the '520 patent's European

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[2] Rostin, J., et al., *B-Domain Deleted Recombinant Coagulation Factor VIII Modified with Monomethoxy Polyethylene Glycol*, Bioconjugate Chem., 11:387–96 (2000).

counterpart[3] is misplaced. To overcome an anticipation rejection, the applicants argued that the asserted prior-art reference "teaches random PEGylation at any *lysine* on the FVIII molecule and therefore does not anticipate the presently claimed isolated conjugates in which essentially all the molecules have a polymer attached at the B-domain." J.A. 7702 (emphasis added). A skilled artisan would not read this statement as a clear and unmistakable exclusion of non-random lysine PEGylation at the B-domain from the asserted '520 patent claims' scope. Rather, when read in context of the entire response, this statement appears to distinguish the process claimed in the European application from the process of random PEGylation using lysine in the prior art. Indeed, the applicants argued that "none of the references cited by the Examiner anticipate the present claims, as they disclose only random modification and not specific conjugation at the B-domain." J.A. 7701–02. Moreover, the district court correctly noted this court's admonition that "varying legal and procedural requirements for obtaining patent protection in foreign countries might render consideration of certain types of representations inappropriate for consideration in a claim construction analysis of a United States counterpart."[4] *Claim Construction Op.*,

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[3] Eur. Pat. Appl. No. 11153287.4.

[4] We also consider unpersuasive Baxalta's reliance on Bayer's statements during prosecution of U.S. Patent Application No. 13/748,983, a continuation of the application that issued as the '520 patent. Similar to the '520 patent specification, Bayer told the Examiner that "[r]andom modification of Factor VIII such as by targeting primary amines with large polymers such as PEG had been attempted," but that this "random approach, however, results in a heterogenous product with polymer attachment possible at many potential sites." J.A. 9093. The claims of the continuation application recited polymer attachment to

2018 WL 3212425, at *5 (quoting *AIA Eng'g Ltd. v. Magotteaux Int'l S/A*, 657 F.3d 1264, 1279 (Fed. Cir. 2011)).

Although Baxalta's challenge presents close questions, we conclude that the claim language, specification, and prosecution history are more aligned with the district court's construction.

II

We next consider Baxalta's challenge to the district court's refusal to define the term "random" in its construction of "an isolated polypeptide conjugate" in claim 1. Baxalta contends that the district court's decision not to construe "random" improperly delegated to the jury the task of determining claim scope and warrants a new trial on infringement. We disagree.

"When the parties present a fundamental dispute regarding the scope of a claim term, it is the court's duty to resolve it." *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008). "This duty resides with the court because, of course, 'the ultimate question of construction [is] a legal question.'" *Eon Corp. IP Holdings v. Silver Spring Networks, Inc.*, 815 F.3d 1314, 1318 (Fed. Cir. 2016) (alteration in original) (quoting *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 842

FVIII "at only the heavy chain," not "at the B-domain." J.A. 9091, 9094. Thus, the cited statement is not relevant to the construction of the '520 patent's different claim term. *See Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340, 1349 (Fed. Cir. 2004) ("[T]he prosecution history of one patent is relevant to an understanding of the scope of a *common term* in a second patent stemming from the same parent application." (emphasis added)). Even if this statement were relevant, it still demonstrates, at most, a disclaimer of random PEGylation.

(2015)). We have observed, however, that "a sound claim construction need not always purge every shred of ambiguity." *Id.* (quoting *Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 806 (Fed. Cir. 2007)).

We conclude that the district court did not violate its duty to interpret the claims in declining to provide a detailed interpretation of the term "random" in its claim construction instructions to the jury. The district court construed the claim term "an isolated polypeptide conjugate" to mean "a polypeptide conjugate where conjugation was not random." The district court resolved the parties' controversies as to the meaning of "random." Specifically, the district court addressed and rejected Baxalta's two arguments: (1) that "random" conjugation means any conjugation at amines or carboxy sites; and (2) that "random" conjugation means all heterogenous conjugation.

In construing the claim term "an isolated polypeptide conjugate," the district court rejected Baxalta's argument that the specification disclaimed "heterogeneous conjugates" by disparaging such conjugates. *Claim Construction Op.*, 2018 WL 3212425, at *3. The district court observed that the patent "never distinguishes B-domain pegylated conjugate products" having "any degree" or "even the slightest degree" of heterogeneity. *Id.* The district court explained that, instead, the specification "disparage[s] products with a high degree of heterogeneity." *Id.*; *see id.* at *4 (concluding that the specification disparages random conjugation in stating that such conjugation is "problematic" for FVIII because it yields "enormous heterogeneity in its product profile" (quoting '520 patent col. 8 ll. 28–30)).

The district court reiterated its conclusion when it denied Baxalta's motion for summary judgment of noninfringement. Specifically, the district court stated that it had "determined during claim construction that non-random conjugation does not require total homogeneity," and that it had disagreed with Baxalta that Bayer "disclaimed

all heterogeneous conjugation." *Summ. J. Op.*, 2018 WL 6727054, at *4. The district court made clear that it was referring to heterogeneity among FVIII conjugates in a product *and* heterogeneity within each individual FVIII conjugate. *Id.* In other words, according to the district court, non-random conjugation neither required that each FVIII protein in a product such as Adynovate® be PEGylated in the same places (homogeneity among conjugates in the product) nor required that every PEG on each FVIII protein be in the B-domain (homogeneity within each conjugate). Thus, it rejected Baxalta's noninfringement position that "the fact that some pegylation occurs outside the B-domain is sufficient to show that Adynovate is made by random conjugation." *Id.*

The district court further reiterated this conclusion in its orders denying Baxalta's pre-trial motions. First, the district court denied Baxalta's motion in limine seeking further construction of "random" to mean "any conjugation at amines or carboxy sites" or, alternatively, that PEG "may attach at any available site of reaction throughout the protein." J.A. 29244. The district court found it unnecessary "to further construe [its] construction by explicitly defining 'random,'" given its earlier holdings at claim construction and summary judgment. *Mot. in Lim. Order*, 2019 WL 10890386, at *1. Furthermore, in denying Baxalta's motion to exclude Bayer's damages expert, the district court reiterated once again that "infringement does not require complete homogeneity—that is, some PEGs may attach outside the B-domain." *Daubert Order*, 2019 WL 330149, at *9. Having resolved this issue, the district court then left it to the parties to present evidence to the jury as to whether or not Adynovate® is the result of random or non-random conjugation.

That the district court resolved this issue is further supported by the fact that Baxalta did not ask the district court to give additional jury instructions on the meaning of "random." J.A. 1595–96 (Tr. 1374:18–1375:25). In fact,

Baxalta "object[ed] to anything going to the jury about claim construction other than [the district court's] claim construction order." J.A. 1595 (Tr. 1374:19–21).

Moreover, Baxalta's argument as to the district court's use of "random" is another attempt to arrive at the same construction Baxalta sought for the claim term "at the B-domain" because it attempts to equate "random" with amine/lysine PEGylation. For the reasons discussed above regarding the district court's construction of "at the B-domain," we again reject Baxalta's argument that amine/lysine PEGylation is outside the scope of the asserted claims.

III

We next turn to Baxalta's challenge to the jury's infringement finding, which is a question of fact that we review for substantial evidence. *Eon Corp.*, 815 F.3d at 1318. We hold that substantial evidence supports the jury's infringement verdict and, therefore, the district court did not err in denying Baxalta's motion for JMOL of noninfringement.

This court reviews the denial of a motion for JMOL under regional circuit law, here, Third Circuit law. *Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1153 (Fed. Cir. 2019) (citing *Tr. of Boston Univ. v. Everlight Elecs. Co.*, 896 F.3d 1357, 1361 (Fed. Cir. 2018)). Applying Third Circuit law, we "exercise plenary review over a district court's rulings on motions for JMOL, applying the same standard as the district court." *Id.* (quoting *Agrizap, Inc. v. Woodstream Corp.*, 520 F.3d 1337, 1341–42 (Fed. Cir. 2008)); *see Gagliardo v. Connaught Labs., Inc.*, 311 F.3d 565, 568 (3d Cir. 2002). "A grant of JMOL is appropriate 'where a party has been fully heard on an issue during a jury trial and the court finds that a reasonable jury would not have had a legally sufficient evidentiary basis to find for the party on that issue.'" *Idenix*, 941 F.3d at 1153–54 (quoting *Agrizap*, 520 F.3d at 1342); *see also* Fed. R. Civ. P. 50(a). The court should grant JMOL

"sparingly" and "only if, viewing the evidence in the light most favorable to the nonmovant and giving it the advantage of every fair and reasonable inference, there is insufficient evidence from which a jury reasonably could find liability." *Marra v. Phila. Hous. Auth.*, 497 F.3d 286, 300 (3d Cir. 2007) (citations omitted).

Bayer presented documentary evidence and expert witness testimony demonstrating that Adynovate® meets the limitations of claim 1 of the '520 patent as construed by the district court. Bayer's biochemistry and protein chemistry expert, Dr. Ploegh, testified about Baxalta's letter to the U.S. Food and Drug Administration seeking support for Orphan Drug designation for its recombinant FVIII product BAX 855, which it later named Adynovate®. J.A. 654–55 (Tr. 433:9–434:25). In its submission, Baxalta represented to the FDA that "BAX 855 is a modified recombinant FVIII protein created by the pre-translational inclusion of the B-domain, and *controlled*, *targeted* chemical addition of 20 [kilodalton] PEG conjugates to this FVIII B-domain." J.A. 36942 (emphases added). Baxalta's submission also stated that "evidence suggests that the B-domain is more surface-exposed than the other domains, and becomes accessible to the PEG-reagent under the specific reaction conditions utilized for the *controlled* chemical PEGylation of the FVIII molecule." J.A. 36944 (emphasis added). Dr. Ploegh explained that Baxalta's statements show that it "exert[s] control [over] how [it] chemically modif[ies] this protein and the net result is the attachment of 20 kilodalton preferable to the B-domain of Factor VIII," J.A. 655 (Tr. 434:7–11), and that Baxalta made specific reaction condition choices to "allow[] [it] to target the PEGylation reaction to the B-domain" of FVIII, *id.* (Tr. 434:20–25). Dr. Ploegh also walked the jury through the reaction condition choices Baxalta made to achieve controlled PEGylation at the B-domain. J.A. 656–61 (Tr. 435:1–440:25); J.A. 670 (Tr. 449:13–22).

Bayer's expert, Dr. Ravetch, a professor of molecular genetics and immunology and expert on protein structure, function, and modification, also testified about Baxalta's letter to the FDA. In his view, Baxalta's representations showed that "the reaction was controlled in such a way to result in the targeted addition of th[e] PEG to the B-domain and that is a nonrandom process." J.A. 756 (Tr. 535:2–4). Dr. Ravetch opined that random PEGylations are neither "controlled" nor "targeted," and that based on its representations to the FDA, "Baxalta use[d] conjugation that was not random." *Id.* (Tr. 535:6–12). Dr. Ravetch testified that based on the FDA documents, testimony from Baxalta and Nektar scientists, and Dr. Ploegh's testimony, in his opinion Adynovate® met the "isolated polypeptide conjugation element" because Baxalta "uses a non-random conjugation method to generate Adynovate." J.A. 760 (Tr. 539:7–11).

Dr. Ravetch further opined that Adynovate® contains PEG attached at the B-domain based on test results reported in Baxalta's Biologics License Application for Adynovate®, which indicated to him that "there's a consistent PEGylation in a particular region predominantly on B-domain" and "B-domain PEGylation was observed as a predominant aspect of the product." J.A. 774–75 (Tr. 553:4–554:3); *see also* J.A. 38063 ("[T]he consistency of the region-specific PEGylation predominantly on the B-domain was confirmed."). Dr. Ravetch also discussed additional FDA submissions in which Baxalta provided the FDA with data showing that 40 out of 55 (or 73%) of the PEG attachment sites are in the B-domain, which supported his opinion that Adynovate® is formed by a non-random process in which PEGylation is region specific and predominant at the B-domain. J.A. 775–76 (Tr. 554:12–555:13 (discussing J.A. 37097)). In one such submission, a technical report identifying the PEGylation sites of BAX 855, Baxalta stated: "PEGylation sites are distributed over the whole rFVIII molecule but *clustered on the B-domain*. . . . The

basis for *preferential PEGylation of the B-domain* is the higher density of lysine residues in the B-domain and in addition the higher flexibility and surface exposure. By *preferential PEGylation the B-domain* carries now a new function in BAX 855 – the prolongation of action of rFVIII." J.A. 37077 (emphases added).

We conclude that this is substantial evidence to support the jury's finding that Adynovate® meets the claim limitations. Baxalta's expert, Dr. Zalipsky, provided contrary testimony to Drs. Ploegh and Ravetch, but the jury was in the best position to determine whether it found Dr. Zalipsky or Bayer's experts more persuasive. *See MobileMedia Ideas LLC v. Apple Inc.*, 780 F.3d 1159, 1168 (Fed. Cir. 2015) ("[W]hen there is conflicting testimony at trial, and the evidence overall does not make only one finding on the point reasonable, the jury is permitted to make credibility determinations and believe the witness it considers more trustworthy."). We discern no error in the district court's conclusion that substantial evidence supported the jury's infringement verdict.

IV

We turn next to Baxalta's argument that no reasonable jury could find that the '520 patent enables the full scope of the claims because it does not enable non-random lysine PEGylation. "Whether a claim satisfies the 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.'" *Idenix*, 941 F.3d at 1154 (quoting *Everlight*, 896 F.3d at 1361)). On the record before us, we conclude that substantial evidence supports the jury's verdict that Baxalta failed to prove by clear and convincing evidence that the asserted claims are invalid for lack of enablement.

"Enablement requires that 'the specification teach those in the art to make and use the invention without undue experimentation.'" *Id.* (quoting *In re Wands*, 858 F.2d

731, 737 (Fed. Cir. 1988)). "A claim is not enabled when, 'at the effective filing date of the patent, one of ordinary skill in the art could not practice their full scope without undue experimentation.'" *Id.* (quoting *Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380, 1384 (Fed. Cir. 2013)). Factors for assessing whether a disclosure would require undue experimentation include: "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *Wands*, 858 F.2d at 737.

The specification of the '520 patent includes detailed instructions as to the reaction conditions required to practice the claimed invention using cysteine PEGylation, and includes a working example for non-random cysteine PEGylation at the B-domain. *See* '520 patent col. 20 l. 56–col. 21 l. 5. Additionally, Bayer presented evidence to the jury bridging the gap between the patent's disclosures about cysteine PEGylation on the one hand and non-random PEGylation, including non-random lysine PEGylation, on the other. For example, '520 patent inventor Dr. Murphy testified that at the time of the invention, he did not believe that cysteine conjugation would be the only way to achieve the claimed B-domain PEGylation of FVIII. J.A. 574 (Tr. 353:5–8).

In addition, multiple witnesses testified that random lysine PEGylation was known at the time of the invention. *E.g.*, J.A. 1248 (Tr. 1027:8–16) ('520 patent inventor Dr. Pan testifying that nonspecific "lysine PEGylation has been around for 20, 30 years" and was a "very old technology"); J.A. 1563 (Tr. 1342:20–22) (Dr. Ravetch testifying that lysine PEGylation had been known in the art "20, 30 years prior to these patents[,] [s]o a long time"); J.A. 1456 (Tr. 1235:21–25) (Dr. Zalipsky testifying that random lysine PEGylation had been performed by 2005).

Moreover, Dr. Russell, Bayer's expert in protein modification, including PEGylation, testified that lysine PEGylation can be either random or non-random, and that skilled artisans would have known that various factors, including reaction conditions and process steps, can be manipulated to achieve either random or non-random PEGylation.[5] *See* J.A. 1527–28 (Tr. 1306:23–1307:10). Consistent with this, the jury was also entitled to rely on Dr. Ravetch's testimony that, at the time of the invention, "protein chemistry [wa]s a well-defined field" going back 150 years and that the "sophistication and knowledge" in this field regarding proteins and amino acids had "accumulated over time." J.A. 1564 (Tr. 1343:4–18). Similarly, in response to Dr. Zalipsky's testimony that ordinarily skilled artisans would not have known from reading the specification how to non-randomly PEGylate FVIII with any amino acid other than cysteine, Dr. Ravetch opined that skilled artisans would have understood that "some amino acids are more amenable than other amino acids for modification" based on the amino acids' known reactivities under different conditions. J.A. 1564–65 (Tr. 1343:4–1344:1). In short, Dr. Ravetch explained to the jury that the advanced knowledge concerning amino acids—along with the fact that only a certain subset could be used for PEGylation—would have aided skilled artisans in applying the teachings in the patent to prepare a non-random lysine PEGylated conjugate without undue experimentation. Baxalta, in

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[5] Though Dr. Russell referenced Baxalta's Adynovate® product in his discussion of random and non-random lysine PEGylation, his testimony, when read in context, more generally concerned what was known in the art at the time of the invention based on his experience in protein modification. *See* J.A. 1528 (Tr. 1307:3–10) (responding to the question: "what determines whether you have random PEGylation as opposed to non-random PEGylation?").

turn, chose not to cross-examine Dr. Ravetch. J.A. 1565 (Tr. 1344:21).

Based on the record before us, we conclude that substantial evidence supports the jury's verdict, and the jury was not obliged to credit Baxalta's expert Dr. Zalipsky over Bayer's contrary evidence. Bayer presented substantial evidence from which a reasonable juror could find that the specification's disclosure of instructions as to the reaction conditions required to practice the claimed invention using cysteine PEGylation were sufficient to enable not only non-random cysteine PEGylation at the B-domain, but also non-random lysine PEGylation at the B-domain.

Baxalta contends that the district court legally erred in resorting to the knowledge of a person of ordinary skill as a "substitute for the specification's lack of a basic enabling disclosure." Appellants' Br. 59. Baxalta focuses on the absence of working examples of lysine PEGylation in the specification. As the district court correctly recognized, however, that the "novel aspect" of the asserted claims is non-random PEGylation at the B-domain "does not mean the specification must disclose an embodiment for non-random pegylation at each amino acid in the B-domain." *JMOL Op.*, 407 F. Supp. 3d at 472. As this court has repeatedly made clear, the specification need not include a working example of every possible embodiment to enable the full scope of the claims. *See Alcon Rsch. Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1189–90 (Fed. Cir. 2014); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1336–37 (Fed. Cir. 2003). We are thus not persuaded that the district court erred in considering the knowledge of an ordinarily skilled artisan to determine whether undue experimentation would have been required to practice the invention with lysine. Indeed, whether a patent is enabled—or requires undue experimentation—are questions that must be viewed "from the perspective of one of ordinary skill in the art." *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1365 (Fed. Cir. 2006) (concluding that the Board of

Patent Appeals and Interferences did not err in concluding that claims directed to a poxvirus-based vaccine were enabled by the specification's detailed teachings of a herpesvirus-based vaccine and the knowledge of a skilled artisan regarding the two viruses); *see also McRO, Inc. v. Bandai Namco Games Am. Inc.*, 959 F.3d 1091, 1102 (Fed. Cir. 2020) ("An 'artisan's knowledge of the prior art and routine experimentation can often fill gaps, interpolate between embodiments, and perhaps even extrapolate beyond the disclosed embodiments, depending upon the predictability of the art,' and a 'patent need not teach, and preferably omits, what is well known in the art.'" (first quoting *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1244 (Fed. Cir. 2003); and then quoting *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1534 (Fed. Cir. 1987))).

Baxalta also contends that it was legal error for the district court to rely on testimony by Bayer's experts concerning post-priority lysine PEGylation used in Baxalta's Adynovate®'s manufacture. *See* Appellants' Br. 62–63. We agree that post-priority knowledge about the "reaction conditions" for the accused product cannot support the jury verdict of enablement. But any error was harmless because the district court also cited other testimony, including Dr. Ravetch's testimony regarding the depth of knowledge in the art about protein chemistry and PEGylation at the time of the invention, J.A. 1563–65 (Tr. 1342:3–1344:1), and Dr. Russell's testimony concerning the knowledge regarding reaction conditions and process steps, among other factors, that determine whether PEGylation is random or non-random, J.A. 1527–28 (Tr. 1306:23–1307:10). Furthermore, contrary to Baxalta's assertion, the specification's purported "teaching away" from random PEGylation at amines such as lysines does not render the asserted claims non-enabled as to *non-random* lysine PEGylation.

For all these reasons, we conclude that the district court did not err in its legal analysis. In addition, we

cannot say that a reasonable jury could not find the claims enabled. Accordingly, the district court correctly denied Baxalta's motion for JMOL of invalidity for lack of enablement.

V

We next turn to the issue of damages. Baxalta contends that the district court correctly held that Bayer's damages expert's (Dr. Addanki's) 50-50 split royalty rate was not properly tied to the facts of the case. According to Baxalta, however, the district court thereafter committed several errors. We address each argument in turn.

First, Baxalta argues that the district court erroneously permitted Bayer to rely on a flawed and speculative methodology—namely, asking the jury to pick a rate between the range of feasible rates presented by Dr. Addanki as the reasonable rate. We review a district court's decision to admit expert testimony for abuse of discretion. *Amgen Inc. v. Hospira, Inc.*, 944 F.3d 1327, 1341 (Fed. Cir. 2019) (citing *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)); *see also SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 926 F.2d 1161, 1164 (Fed. Cir. 1991) (noting that "subsidiary decisions underlying a damage[s] theory," such as "the methodology for arriving at a reasonable royalty," are reviewed for abuse of discretion (citations omitted)).

The district court properly exercised its discretion in allowing Bayer to ask the jury to select a rate between the range presented. While an expert must use reliable methodology for determining the range of possible hypothetical negotiation royalty rates, we are aware of no precedent that requires an expert to provide a single proposed royalty rate. As an initial matter, a jury is "entitled to choose a damages award within the amounts advocated by the opposing parties" and is "not bound to accept a rate proffered by one party's expert but rather may choose an intermediate royalty rate." *Powell v. Home Depot U.S.A., Inc.*,

663 F.3d 1221, 1241 (Fed. Cir. 2011) (quoting *Spectralytics, Inc. v. Cordis Corp.*, 649 F.3d 1336, 1347 (Fed. Cir. 2011)). In addition, we have previously held that a jury's damages award that fell within the range suggested by the patentee's damages expert was supported by substantial evidence. *See Rembrandt Wireless Techs., LP v. Samsung Elecs. Co.*, 853 F.3d 1370, 1382 (Fed. Cir. 2017). In granting-in-part Baxalta's *Daubert* motion, the district court determined that Dr. Addanki's expert report included "substantial analyses to determine 'end points of the bargaining range for the hypothetical negotiation,'" including "deriv[ing] a maximum royalty rate from the incremental profits Baxalta would expect to earn from Adynovate, and a minimum royalty rate from the profits Bayer would expect to lose by granting a license to Baxalta." *Daubert Order*, 2019 WL 330149, at *7. Dr. Addanki's testimony further demonstrates that he considered and discussed the appropriate *Georgia-Pacific* factors at length in determining the range of reasonable royalties, *see* J.A. 962–1020, and Bayer in its closing statement explained to the jury that its damages award should fall within that range, J.A. 1728 (Tr. 1507:16–25). Moreover, the district court permitted Baxalta to cross-examine Dr. Addanki on his end points and range and to present the testimony of its own damages expert. Under these circumstances, we conclude that the district court did not err in allowing the jury to hear Dr. Addanki's testimony regarding a range of possible hypothetical reasonable royalty rates instead of a single proposed royalty rate.

Second, Baxalta argues that the district court should have excluded Dr. Addanki's testimony that the entire range of rates was reasonable because such a conclusion was not in his expert report. The district court rejected Baxalta's argument that Dr. Addanki presented new opinions at trial in violation of Rules 26(a)(2)(B) and 37(c) of the Federal Rules of Civil Procedure. Such evidentiary rulings are also reviewed for an abuse of discretion. *See Siemens*

Med. Sols. USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc., 637 F.3d 1269, 1286–87 (Fed. Cir. 2011). We agree with the district court that Dr. Addanki's opinions in his expert reports are consistent with his trial testimony about a range of royalty rates and were not limited to the single rate that the district court had excluded. For instance, Dr. Addanki had opined in his reply expert report that "as a matter of economics, *any of these royalty rates* [between 5.1% and 42.4%] would be a feasible outcome to the negotiation" and the "reasonable royalty is the likely outcome within that range." J.A. 21887 (emphasis added). The district court exercised its sound discretion in permitting Dr. Addanki's testimony. J.A. 233 (Tr. 12:6–10).

Third, Baxalta appears to challenge the jury's determination of the amount of damages, which is an issue of fact that we review for substantial evidence. *Amgen*, 944 F.3d at 1341 (citing *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1310 (Fed. Cir. 2009)). "A jury's damages award 'must be upheld unless the amount is grossly excessive or monstrous, clearly not supported by the evidence, or based only on speculation or guesswork.'" *Id.* (quoting *Lucent*, 580 F.3d at 1310). We agree with the district court that substantial evidence supports the jury's 17.78% royalty rate, which was "within the range encompassed by the record as a whole." *JMOL Op.*, 407 F. Supp. 3d at 480 (quoting *Unisplay, S.A. v. Am. Elec. Sign Co.*, 69 F.3d 512, 519 (Fed. Cir. 1995)). Dr. Addanki provided ample guidance to the jury to help it determine the royalty rate. *E.g.*, J.A. 962–67 (explaining the *Georgia-Pacific* factors, the concept of the hypothetical negotiation, and determining maximum and minimum points in a range), J.A. 967–68, 970–1005, 1008–13 (explaining how he applied the hypothetical negotiation analysis and determined the specific end points of 5.1% and 42.4% in this case), J.A. 1014–20 (discussing each of the *Georgia-Pacific* factors and explaining whether and how each one applied in his analysis).

Finally, we note that Baxalta's criticisms about the jury's royalty rate are more appropriate for cross-examination of the expert. Indeed, Baxalta cross-examined Dr. Addanki about his methodology and presented testimony of its own damages expert, Dr. Rausser, who opined that a reasonable-royalty rate would be 1%. J.A. 1485–93 (Tr. 1264:22–1272:14). While Baxalta complains that it could not cross-examine Dr. Addanki on his prior selection of a single, mid-point rate, Baxalta still could have—and in fact did—cross-examine Dr. Addanki on why the upper end of his proposed range would not result in an absurd rate in an effort to undermine Dr. Addanki's credibility. A party need not present expert testimony on damages or, as a corollary, on every aspect of damages, such as a single royalty rate. *See Dow Chem. Co. v. Mee Indus., Inc.*, 341 F.3d 1370, 1382 (Fed. Cir. 2003) ("[S]ection 284 is clear that expert testimony is not necessary to the award of damages, but rather '*may* [be] receive[d] . . . as an aid.'" (annotations in original) (quoting 35 U.S.C. § 284)). A party runs the risk, however, of loss to its expert's credibility on cross-examination if the expert does not identify a single royalty rate. But "[w]here the methodology is sound and the evidence relied upon is sufficiently related to the case, disputes over the expert's credibility or over the accuracy of the underlying facts are for the jury." *Summit 6, LLC v. Samsung Elecs. Co.*, 802 F.3d 1283, 1299 (Fed. Cir. 2015) (citing *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 852 (Fed. Cir. 2010)). Here, Baxalta cross-examined Dr. Addanki and, ultimately, the jury evaluated his opinions and adopted a rate within his proposed range. The district court did not err in denying Baxalta's motion for JMOL or a new trial on damages.

VI

We turn to the final issue raised in Baxalta's appeal—whether the district court violated Baxalta's Seventh Amendment right to a jury trial by amending its judgment under Rule 59 to award Bayer pre-verdict supplemental

damages. We disagree with Baxalta that the Seventh Amendment right to a jury trial attaches to the award of pre-verdict supplemental damages in this case. We also conclude that the district court acted within its discretion in awarding supplemental damages.

This court reviews "the constitutional question of whether a party is entitled to a jury trial" de novo. *TCL Commc'n Tech. Holdings Ltd. v. Telefonaktiebolaget LM Ericsson*, 943 F.3d 1360, 1371 (Fed. Cir. 2019) (quoting *Tegal Corp. v. Tokyo Electron Am., Inc.*, 257 F.3d 1331, 1339 (Fed. Cir. 2001)). The Seventh Amendment provides that, "[i]n Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved . . . ." U.S. CONST. amend. VII. Under the Patent Act, "[u]pon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement," and "[w]hen the damages are not found by a jury, the court shall assess them." 35 U.S.C. § 284. "The methodology of assessing and computing damages under 35 U.S.C. § 284 is within the sound discretion of the district court." *TWM Mfg. Co. v. Dura Corp.*, 789 F.2d 895, 898 (Fed. Cir. 1986) (citations omitted).

The jury was asked to calculate the royalty rate, royalty base, and total damages for the time period between June 14, 2016 through November 30, 2018. The jury rendered its verdict on February 4, 2019, and the district court entered judgment on February 8, 2019. Bayer thereafter sought pre-verdict supplemental damages for the period from December 1, 2018 through February 8, 2019. The district court granted Bayer's motion and determined that supplemental damages should be based on the actual sales data for that period—which Baxalta had produced after trial—and the jury's 17.78% royalty rate. *Rule 59 Op.*, 2019 WL 4016235, at *6. The district court rejected Baxalta's contentions that Bayer should have used the projected sales data Baxalta had produced before trial and

that awarding supplemental damages would violate Baxalta's Seventh Amendment right to a jury trial.

We have on occasion reviewed decisions by district courts awarding pre-verdict supplemental damages without directly addressing the constitutionality of such awards. *See, e.g.*, *Finjan, Inc. v. Secure Computing Corp.*, 626 F.3d 1197 (Fed. Cir. 2010) (addressing a challenge to the district court's refusal to award additional supplemental damages for post-verdict sales up until the date of its injunction while noting that pre-verdict supplemental damages had been awarded); *Godo Kaisha IP Bridge 1 v. TCL Commc'n Tech. Holdings Ltd.*, 967 F.3d 1380, 1382 (Fed. Cir. 2020) (affirming the district court's grant of patent owner's request for "supplemental damages and an accounting of infringing sales of all adjudicated products through the date of the verdict"). Here, Baxalta contends that the district court's award of pre-verdict supplemental damages "constitutes an impermissible additur." Appellants' Br. 82. Baxalta cites *Dimick v. Schiedt*, 293 U.S. 474 (1935), for the proposition that "a court has no power to consider new facts to award additional damages that are not part of the verdict, as it would invade the constitutional right to a trial by jury." Appellants' Br. 81–82. In *Dimick*, the plaintiff moved the district court for a new trial, arguing that the jury's damages award was inadequate. 293 U.S. at 475. The district court entered a "conditional order" for a new trial whereby it would grant the plaintiff's request "unless [the defendant] would consent to an increase of the damages to the sum of $1,500." *Id.* at 475–76. The Supreme Court held that this practice of additur violates the Seventh Amendment. *Id.* at 486–87.

Calculating pre-verdict supplemental damages in this case merely required applying the jury's royalty rate to the undisputed actual infringing sales base. That royalty rate was based on a hypothetical negotiation as of the date of first infringement (June 14, 2016), and was applied by the jury to the actual infringing sales base from the date of first

infringement through November 30, 2018. Under these circumstances, we are not persuaded that the district court's award constitutes an impermissible additur or an otherwise "bald addition of something which in no sense can be said to be included in the verdict." *Id.* at 486. Nor are we convinced that our conclusion conflicts with *WEGCO, Inc. v. Griffin Services, Inc.*, 19 F. App'x 68, 73–74 (4th Cir. 2001), where the district court's erroneous supplemental damages award was based on its "own findings regarding what monies were owed" to the plaintiff and was "not based on any findings made by the jury." Similarly inapposite is *Ohio-Sealy Mattress Manufacturing Co. v. Sealy, Inc.*, 669 F.2d 490 (7th Cir. 1982), which concerned a plaintiff's ability to obtain future damages in an antitrust context, and which was silent as to the Seventh Amendment.

Moreover, the district court acted within its discretion in awarding supplemental damages. In the district court's view, "it was reasonable for Bayer to limit its damages at trial to the period for which it had actual sales data." *Rule 59 Op.*, 2019 WL 4016235, at *6. The district court also observed that the "projected sales were substantially higher than the actual sales" and, thus, Baxalta would have faced higher damages if Bayer had used projected sales. *Id.* Baxalta cites *TransPerfect Global, Inc. v. MotionPoint Corp.*, No. 10-cv-2590, 2014 WL 6068384 (N.D. Cal. Nov. 13, 2014), to support its argument that "fail[ing] to present the jury with extrapolated damages despite having the opportunity to do so" warrants denying pre-verdict supplemental damages. Appellants' Br. 83. In *TransPerfect*, the district court denied the patentee's motion to amend the judgment to award pre-verdict supplemental damages, noting that the patentee "could have sought to ask the jury to extrapolate post-2012 damages from the pre-2012 financial records and analysis." 2014 WL 6068384, at *4. Unlike this case, it was "not even clear" to the district court "that the jury did not award

damages for the full [pre-verdict] period," and unlike Bayer, the patentee had not sought updated financial information during discovery. *Id.* Based on the facts of this case, we conclude that the district court did not abuse its discretion in awarding pre-verdict supplemental damages.

VII

Lastly, we address Bayer's challenge in its cross-appeal of the district court's judgment as a matter of law that Baxalta did not willfully infringe the asserted claims. In Bayer's view, it presented sufficient evidence of willfulness at trial to send the question to the jury. We disagree.

Willful infringement is a question of fact. *Polara Eng'g Inc. v. Campbell Co.*, 894 F.3d 1339, 1353 (Fed. Cir. 2018). To establish willfulness, the patentee must show the accused infringer had a specific intent to infringe at the time of the challenged conduct. *See Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 136 S. Ct. 1923, 1933 (2016). As the Supreme Court stated in *Halo*, "[t]he sort of conduct warranting enhanced damages has been variously described in our cases as willful, wanton, malicious, bad-faith, deliberate, consciously wrongful, flagrant, or—indeed—characteristic of a pirate." *Id.* at 1932. A patentee needs to show by a preponderance of the evidence the facts that support a finding of willfulness. *Id.* at 1934.

In granting Baxalta's motion for JMOL of no willful infringement, the district court concluded that Bayer failed to present sufficient evidence of the "state of mind" necessary for a finding of willfulness. J.A. 1355–56 (Tr. 1134:24–1135:3). According to the district court, there was no dispute that Baxalta was "aware of the '520 patent," and that Bayer merely "assume[d] that [Baxalta] knew Adynovate infringed because it involved pegylation at the B-domain of factor VIII." *Rule 59 Op.*, 2019 WL 4016235, at *9. The district court concluded that this was not "enough for a reasonable jury to find that infringement was

'either known or so obvious it should have been known.'" *Id.* (quoting *Halo*, 136 S. Ct. at 1930).

On appeal, Bayer identifies evidence that purportedly satisfies the state of mind requirement for willfulness. Specifically, Bayer presented testimony of Baxalta and Nektar witnesses concerning their awareness of the patent application that issued as the '520 patent. J.A. 634–38. Additionally, Bayer presented evidence of Baxalta's representations to the FDA that Adynovate®'s activity was due to controlled, targeted PEGylation at the B-domain. J.A. 654–55 (Tr. 433:9–434:25); J.A. 718–20 (Tr. 497:7–499:5); J.A. 755–60 (Tr. 534:1–539:11); J.A. 774–77 (Tr. 553:12–556:18); J.A. 897–98 (Tr. 676:14–677:17). Bayer further contends that the jury heard evidence showing that Baxalta's internal documents described Adynovate®'s PEGylation process as controlled and consistent. J.A. 1238–43 (Tr. 1017:9–1022:21); J.A. 38368–90. Bayer also presented testimony by Baxalta and Nektar witnesses that the companies' initial approach with FVIII conjugates was random PEGylation, and that they switched to targeted, B-domain PEGylation. J.A. 713–16 (Tr. 492:8–495:19); J.A. 722–23 (Tr. 501:1–502:13); J.A. 1121–23 (Tr. 900:12–902:19). In Bayer's view, this evidence shows that "Baxalta knew from prior dealings that random pegylation had failed, found out about Bayer's B-domain pegylation work that underpins the '520 patent, and consciously redirected its own research to B-domain pegylation after learning about Bayer's invention."[6] Cross-Appellant's Reply 4.

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[6] As additional support for its willfulness case, Bayer identifies a poster regarding FVIII PEGylation that Bayer had purportedly presented to a conference attended by Baxalta scientists in 2007 and that Baxalta subsequently circulated internally. The district court initially excluded

Even when accepting Bayer's evidence as true and weighing all inferences in Bayer's favor, we conclude that the record is insufficient to establish that Baxalta's "conduct rose to the level of wanton, malicious, and bad-faith behavior required for willful infringement." *SRI Int'l, Inc. v. Cisco Sys., Inc.*, 930 F.3d 1295, 1309 (Fed. Cir. 2019). The evidence adduced at trial merely demonstrates Baxalta's knowledge of the '520 patent and Baxalta's direct infringement of the asserted claims. Knowledge of the asserted patent and evidence of infringement is necessary, but not sufficient, for a finding of willfulness. Rather, willfulness requires deliberate or intentional infringement. *Eko Brands, LLC v. Adrian Rivera Maynez Enters., Inc.*, 946 F.3d 1367, 1378 (Fed. Cir. 2020).

Accordingly, we conclude that the district court did not err in granting Baxalta's motion for JMOL of no willfulness or denying Bayer's motion for a new trial.

CONCLUSION

We have considered the parties' other arguments, but we do not find them persuasive. For the foregoing reasons, we affirm the district court's judgments of infringement, enablement, damages, pre-verdict supplemental damages, and no willfulness.

AFFIRMED

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this poster on relevance grounds. The district court then stated that it was "going to keep th[e poster] out for now," and that Bayer could "bring it up again in a day or two if things have changed." J.A. 536 (Tr. 315:21–23). Bayer did not, however, raise the issue of the poster's admissibility again. On appeal, Bayer does not argue that the district court abused its discretion in excluding the poster. We do not consider the poster here.

COSTS

No costs.