United States Court of Appeals for the Federal Circuit

ABBVIE DEUTSCHLAND GMBH & CO., KG, ABBVIE BIORESEARCH CENTER, INC., AND ABBVIE BIOTECHNOLOGY, LTD.,
Plaintiffs-Appellants,

v.

JANSSEN BIOTECH, INC. AND CENTOCOR BIOLOGICS, LLC,
Defendants-Appellees.

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JANSSEN BIOTECH, INC.,
Plaintiff–Appellee,

v.

ABBVIE DEUTSCHLAND GMBH & CO., KG,
Defendant-Appellant.

2013-1338, -1346

Appeals from the United States District Court for the District of Massachusetts in Nos. 09-CV-11340-FDS, 10-CV-40003-FDS, and 10-CV-40004-FDS, Judge F. Dennis Saylor, IV.

Decided: July 1, 2014

WILLIAM F. LEE, Wilmer Cutler Pickering Hale and Dorr LLP, of Boston, Massachusetts, argued for appellants. With him on the brief were ROBERT J. GUNTHER, JR., JANE M. LOVE, and VIOLETTA WATSON, of New York, New York; WILLIAM G. MCELWAIN, THOMAS G. SAUNDERS, RACHEL L. WEINER, and MATTHEW GUARNIERI, of Washington, DC; and ARTHUR W. COVIELLO, of Palo Alto, California. Of counsel was MARK C. FLEMING, of Boston, Massachusetts.

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JAMES J. KELLEY, Eli Lilly and Company, of Indianapolis, Indiana, for amicus curiae Eli Lilly and Company. With him on the brief were TED J. EBERSOLE, ALEXANDER WILSON, and SANJAY JIVRAJ. On the brief for amicus curiae Pfizer Inc. was JEFFREY J. OELKE, White and Case LLP, of New York, New York.

OSKAR LIIVAK, Cornell Law School, of Ithaca, New York, for amicus curiae Professor Oskar Liivak.

Before LOURIE, O'MALLEY, and CHEN, *Circuit Judges*.

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

Concurring opinion filed by *Circuit Judge* O'MALLEY.

LOURIE, *Circuit Judge*.

AbbVie Deutschland GmbH & Co., KG, AbbVie Bioresearch Center, Inc., and AbbVie Biotechnology Ltd. (formerly Abbott, collectively "AbbVie") appeal from the final judgments of the United States District Court for the District of Massachusetts in a patent infringement action and a patent interference action. In the infringement action, patent owner AbbVie sued Janssen Biotech, Inc. and Centocor Biologics, LLC (collectively "Centocor") for infringement of claims 29, 30, and 32 and claim 64 as depending from claim 29 of U.S. Patent 6,914,128 (the "'128 patent") and claim 11 as depending from claim 2 of U.S. Patent 7,504,485 (the "'485 patent") (collectively "the asserted claims").[1] In the interference action, Centocor sought the district court's review under 35 U.S.C. § 146 (2006) of the decisions of the United States Patent and Trademark Office ("PTO") Board of Patent Appeals and Interferences (the "Board") in an interference between U.S. Patent Application 10/912,994 (the "'994 application") owned by Centocor and AbbVie's '128 patent, in which the Board awarded priority to AbbVie and held that the contested claims in the '128 patent were not invalid for obviousness.[2]

After a trial on validity in the infringement action, the jury determined that all of the asserted claims were invalid on the grounds of written description, enablement, and obviousness. The district court denied AbbVie's post-

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[1] Claims 11 and 64 are multiply-dependent from other claims that are not at issue in these appeals.

[2] 35 U.S.C. § 146 has been amended by the Leahy-Smith American Invents Act ("AIA"), Pub. L. No. 112-29, §§ 3, 9, 125 Stat. 284, 290–91, 316, which was enacted on September 16, 2011. We refer to the pre-AIA version of the statute because the interference action was filed before the enactment date of the AIA.

trial motions for judgment as a matter of law ("JMOL"), and in the alternative, for a new trial, and entered judgments of invalidity in both the infringement and the interference actions.

In these consolidated appeals, AbbVie challenges the district court's denial of: (1) its motion for summary judgment, in which the district court held that Centocor was not collaterally estopped from raising invalidity defenses in the infringement action after the interference proceeding at the PTO; (2) its motion for JMOL on the issues of written description and enablement; and (3) its motion for a new trial for alleged errors in the court's evidentiary rulings and jury instructions. *See Abbott GmbH & Co. v. Centocor Ortho Biotech, Inc.*, 870 F. Supp. 2d 206 (D. Mass. 2012) (summary judgment order); *Abbott GmbH & Co. v. Centocor Ortho Biotech, Inc.*, 971 F. Supp. 2d 171 (D. Mass. 2013) (order denying JMOL); *Abbott GmbH & Co. v. Centocor Ortho Biotech, Inc.*, No. 09-11340, ECF No. 542 (D. Mass. Mar. 14, 2013) (bench ruling denying new trial).

We conclude that because the interference action under § 146 was pending at the district court, the Board's decision lacked the requisite finality for purposes of collateral estoppel. We also hold that record evidence sufficiently supported the jury verdict that the asserted claims lacked adequate written description under 35 U.S.C. § 112, ¶ 1 (2006).[3] We further find no reversible

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[3] Paragraph 1 of 35 U.S.C. § 112 was replaced with newly designated § 112(a) by § 4(c) of the AIA and § 4(e) of the AIA makes those changes applicable "to any patent application that is filed on or after" September 16, 2012. Pub. L. No. 112-29, § 4, 125 Stat. at 296–97. Because the applications resulting in the patents at issue in this case were filed before that date, we refer to the pre-AIA version of § 112.

error in the contested evidentiary rulings and jury instructions relating to the issue of written description sufficient to warrant a new trial. Because all of the asserted claims are invalid for failing to satisfy the written description requirement, we need not address AbbVie's validity arguments concerning enablement or its procedural challenges to the district court's obviousness judgments. We therefore *affirm* the judgments of invalidity in both the infringement and the interference actions.

BACKGROUND

The technology in these appeals involves antibodies that are useful for treating diseases. An antibody is a protein that binds to a foreign substance, called an antigen, to facilitate its removal from the body. The portion of the antigen that binds to the antibody is called the epitope. Each antibody consists of four chains of amino acids, two identical heavy chains and two identical light chains, which are folded into a three-dimensional structure. Each of the heavy and light chains consists of a constant region and a variable region. The variable region is the portion of the antibody in its three-dimensional structure that binds to the antigen and each variable region has three complementarity determining regions ("CDRs") that interact closely with the epitope of the antigen. Among human antibodies, the variable region of the heavy chains can be divided into seven families: V_H1 to V_H7; and the variable region of the light chains can be divided into two classes: Kappa and Lambda. The binding affinity of an antibody to an antigen can be measured by k_{off}, the rate at which the antigen dissociates from the antibody after binding, wherein a smaller k_{off} value represents a tighter binding.

AbbVie owns the '128 and '485 patents, directed to fully human antibodies that bind to and neutralize the activity of human interleukin 12 ("IL-12"). IL-12 is a signaling protein secreted by the human body, the over-

production of which can cause psoriasis and rheumatoid arthritis. Because the human body does not typically make antibodies to neutralize its own proteins, it does not produce IL-12 antibodies naturally. Antibodies from a non-human species often lack the desirable safety profile of a drug because non-human antibodies can cause adverse immune reactions in human patients. Researchers therefore sought to genetically engineer fully human IL-12 antibodies that are derived from human DNA and thus less likely to trigger an immune response.

The techniques that could be used to develop a fully human IL-12 antibody have included phage display and transgenic mice. AbbVie developed its IL-12 antibodies using phage display, which involved creating a large library of human DNA fragments and screening for those fragments that encoded an antibody fragment with IL-12 binding affinity. AbbVie identified a lead through screening that it named "Joe-9", which had the ability to bind to and neutralize the activity of IL-12, albeit with low affinity. '128 patent col. 104 ll. 23–29. In order to improve IL-12 affinity, AbbVie introduced mutations to the CDRs of Joe-9 and identified an improved antibody that it named "Y61". *Id.* col. 104 l. 39–col. 107 l. 6. AbbVie then used site-directed mutagenesis to alter individual amino acids at selected positions in Y61 and generated additional antibodies, among which an antibody that it named "J695" showed a significant increase in IL-12 binding and neutralizing activity. *Id.* col. 108 ll. 14–65.

The '128 and '485 patents share the same written description and both claim priority from a provisional application filed in 1999. The patents describe the amino acid sequence of about 300 antibodies having a range of IL-12 binding affinities. *Id.* fig. 1A–2H, col. 95–102. Joe-9, the initial lead, has V_H3 type heavy chains and Lambda type light chains. *Id.* col. 104 ll. 33–35. Because the IL-12 antibodies described in the patents were all derived from Joe-9, they all have V_H3 type heavy chains and Lambda

type light chains. J.A. 7547–52. The described antibodies share a 90% or more amino acid sequence similarity in the variable regions. *Id.* And over 200 of those antibodies were generated by site-directed mutagenesis of Y61 and thus differ from Y61 by only one amino acid and share a 99.5% sequence similarity in the variable regions. '128 patent fig. 2A–2H; J.A. 7008.

The '128 and '485 patents also teach that "the amino acid sequence identity within the entire V_H3 family is high," which "results in certain amino acid residues being present at key sites in the CDR and framework regions of the VH chain," and thus that "other V_H3 family members could also be used to generate antibodies that bind to human IL-12." '128 patent col. 41 ll. 15–17, 27–31, 54–57. The patents similarly teach that "other $V_\lambda1$ [Lambda 1] family members may also be used to generate antibodies that bind to human IL-12." *Id.* col. 42 ll. 5–8. The patents, however, do not describe any IL-12 antibody having heavy chains outside of the V_H3 family or light chains outside of the Lambda family. J.A. 7549.

The claims of the '128 and '485 patents at issue in these appeals define the claimed antibodies by their function, *i.e.*, IL-12 binding and neutralizing characteristics, rather than by structure. Claim 29 of the '128 patent is representative and reads as follows:

> 29. A neutralizing isolated human antibody, or antigen-binding portion thereof that binds to human IL-12 and disassociates from human IL-12 with a k_{off} rate constant of $1x10^{-2}$ s^{-1} or less, as determined by surface plasmon resonance.

'128 patent col. 386 ll. 55–59. Claims 30 and 32 likewise require the k_{off} rates to be $1x10^{-4}$ s^{-1} or less and $1x10^{-3}$ s^{-1} or less, respectively. *Id.* col. 386 ll. 60–63, col. 387 ll. 1–4. Claim 64 is directed to a pharmaceutical composition comprising the functionally claimed antibody. *Id.* col. 389 ll. 1–4. Claim 11 of the '485 patent similarly defines the

claimed antibody by its IL-12 binding profile. '485 patent col. 381 ll. 33–40, col. 382 ll. 40–44.

Centocor developed its human IL-12 neutralizing antibody drug marketed under the brand name Stelara® ("Stelara") using the transgenic mice technology, which involved mice that are genetically modified with human antibody genes and capable of producing human antibodies when exposed to an antigen such as IL-12. Stelara has V_H5 type heavy chains, not V_H3, and Kappa type light chains, not Lambda, and about 50% sequence similarity in the variable regions as compared to the Joe-9 antibodies described in the '128 and '485 patents, which is significantly lower than the 90% sequence similarity shared among the Joe-9 antibodies. J.A. 14958. The U.S. Food and Drug Administration approved Stelara in 2009. *Abbott*, 870 F. Supp. 2d at 218.

Centocor filed the '994 application directed to human IL-12 antibodies, which claimed priority from two provisional applications filed in 2000, and provoked an interference with the '128 patent on December 12, 2007. *Id.* Claims 1–15, 27–40, and 50–64 of the '128 patent correspond to the sole count of the interference. Although Centocor indicated at an early stage of the interference that it intended to challenge the validity of the '128 claims on the grounds of written description, enablement, definiteness, and obviousness, Centocor only filed invalidity motions on the issue of obviousness. Centocor also filed motions on the priority issue. On August 6, 2009, the Board awarded priority to AbbVie, held that the '128 patent claims were not invalid for obviousness, and therefore entered judgment in favor of AbbVie. *Centocor, Inc. v. Abbott GmbH & Co.*, Interference No. 105,592, Paper No. 417, 418, 419 (B.P.A.I. Aug. 6, 2009) (priority decision, nonobviousness decision, and judgment, respectively).

On August 10, 2009, AbbVie filed an infringement action against Centocor in the district court for the District of Massachusetts, asserting that Stelara infringed the '128 and '485 patents. *Abbott*, 870 F. Supp. 2d at 218. Shortly thereafter, on August 28, 2009, Centocor filed two actions in the district court for the District of Columbia, seeking judicial review of the Board's interference decisions under § 146 and seeking a declaratory judgment of noninfringement and invalidity of the '128 and '485 patents. *Id.* Centocor's two actions were transferred to Massachusetts, where the district court consolidated the declaratory judgment action with the infringement action for all purposes and consolidated the interference action with the infringement action for purposes of discovery. *Id.*

AbbVie moved for summary judgment that Centocor was collaterally estopped from challenging the validity of the '128 patent in the infringement action because Centocor had failed to invalidate the '128 patent claims in the interference proceeding at the PTO. The district court denied the motion, reasoning that the Board's decisions were not final for purposes of collateral estoppel in view of the pending § 146 action. *Id.* at 223. The court also decided to proceed with the infringement action first in order to preserve Centocor's right to a jury trial. *Id.* at 226.

After construing the claims, the court entered summary judgment that Centocor infringed claims 29, 32, and 64 of the '128 patent and claim 11 of the '485 patent. *Id.* at 249. The parties then stipulated that claim 30 of the '128 patent was also infringed. *Abbott GmbH & Co. v. Centocor Ortho Biotech, Inc.*, No. 09-11340, ECF No. 400 (D. Mass. Aug. 10, 2012). AbbVie also stipulated that it would only assert those five claims in the infringement action and Centocor stipulated that it would not seek review of the PTO's nonobviousness ruling with respect to other claims of the '128 patent that were at issue in the

interference action. *Abbott GmbH & Co. v. Centocor Ortho Biotech, Inc.*, No. 09-11340, ECF No. 454 (D. Mass. Sept. 7, 2012).

The validity of the asserted claims was tried before a jury in the infringement action. The district court excluded evidence of the PTO interference proceeding under Federal Rule of Evidence 403. J.A. 323, 6421–22, 6467–69, 6780–81. The court allowed AbbVie's expert, Dr. Marks, to testify that the PTO had considered the issues of written description, enablement, and obviousness and concluded that the asserted claims met those requirements before it granted the patents. *Id.* at 7260–63, 7284. The court, however, precluded Dr. Marks from testifying in detail about the reasoning of the PTO or prosecution arguments considered by the PTO. *Id.* at 7281–86.

Centocor raised four invalidity defenses on the bases of written description, enablement, obviousness, and anticipation by prior invention. To support its invalidity challenges under § 112, Centocor presented evidence seeking to establish that the antibodies described in AbbVie's patents were not representative of other members of the functionally claimed genus, which included Stelara. Centocor presented expert testimony that the antibodies described in the patents were structurally similar, but that they differed from Stelara in many respects, set out below:

	Stelara	J695	Joe-9
Sequence Similarity	50%	90%	90%
CDR Length	Different	Identical	Identical
Epitope Binding Site	Side Binder	Bottom Binder	Bottom Binder
V_H Family	V_H5	V_H3	V_H3
Light Chain Type	Kappa	Lambda	Lambda

Id. at 14958. Among the five structural distinctions, the distinction on epitope binding sites was based in part on a crystal structure of J695 binding to IL-12, which was obtained from AbbVie during discovery. Centocor informed the jury that the PTO did not have that information when it issued the patents. *Id.* at 7616, 7625.

To support its invalidity challenge based on obviousness, Centocor relied on prior art references including an article by Meager, which showed that human antibody genes were capable of making antibodies that neutralize IL-12 and thus that the transgenic mice technology could potentially generate human IL-12 antibodies. *Id.* at 6676–77, 6805, 7631–33. Centocor informed the jury that the PTO did not consider the Meager article before it issued the patents and that the jury "may consider that it makes it easier for Centocor to prove that the claims are not valid because there was key information that the examiner did not have." *Id.* at 7632–33. Centocor, however, did not present any evidence to substantively compare the disclosure in the Meager article with prior art references considered by the PTO because its expert, Dr. Siegel, did not review the *ex parte* prosecution history. *Id.* at 6791, 7485.

At the close of the jury trial, the district court instructed the jury that Centocor had the burden of proving invalidity by clear and convincing evidence. *Id.* at 349. Regarding evidence that was presented at trial but not considered by the PTO, the court instructed the jury, over AbbVie's objection, that:

> You should consider whether that additional information would have been "material" to the PTO's decision to grant the patents. Information is "material" if there is a substantial likelihood that a reasonable patent examiner would consider it important in deciding whether to allow the application to issue as a patent. . . . If the PTO did not have all the material information before it when it made its decision as to a particular claim, Centocor's burden may be easier to meet. That is particularly true if the additional information was not only material, but would have carried significant weight had it been considered by the PTO. But if the additional information was not material, or it would not have carried significant weight, Centocor's burden may be more difficult to meet.

Id. at 350.

The jury found in AbbVie's favor on the issue of anticipation, but determined that each of the asserted claims was invalid for lack of an adequate written description, lack of enablement, and obviousness. *Abbott GmbH & Co. v. Centocor Ortho Biotech, Inc.*, No. 09-11340, ECF No. 492 (D. Mass. Sept. 25, 2012). AbbVie moved for JMOL challenging the invalidity verdict on all of those grounds on which it lost, and in the alternative, for a new trial for alleged errors in the court's evidentiary rulings and jury instructions. The court denied both motions and entered judgment based on the jury verdict in the infringement action. *Abbott*, 971 F. Supp. 2d at 180–81, 186; *Abbott*, ECF No. 542, at 4. Because the jury found the asserted

claims invalid under the clear and convincing evidence standard and because the § 146 action permitted a lower burden for proving invalidity, the court also entered judgment of invalidity in the § 146 action, reversing the Board's nonobviousness ruling on claims 29, 30, and 32 and claim 64 as depending from claim 29 of the '128 patent. *Abbott*, ECF No. 542, at 4.

AbbVie timely appealed and we have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1) and (a)(4)(C).

DISCUSSION

In patent appeals, we apply the law of the regional circuit "to which district court appeals normally lie, unless the issue pertains to or is unique to patent law." *Molins PLC v. Quigg*, 837 F.2d 1064, 1066 (Fed. Cir. 1988). Accordingly, we apply the law of the regional circuit in which the district court sits, here, the First Circuit, in reviewing the grant or denial of a motion for summary judgment, the denial of a motion for JMOL or for a new trial, and challenges to a district court's evidentiary rulings and jury instructions. *See Bd. of Trs. of Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc.*, 583 F.3d 832, 839 (Fed. Cir. 2009) (grant or denial of summary judgment), *aff'd*, 131 S. Ct. 2188 (2011); *Voda v. Cordis Corp.*, 536 F.3d 1311, 1328 (Fed. Cir. 2008) (jury instructions); *Riverwood Int'l Corp. v. R.A. Jones & Co.*, 324 F.3d 1346, 1352 (Fed. Cir. 2003) (denial of motion for JMOL or for a new trial); *Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc.*, 265 F.3d 1294, 1308 (Fed. Cir. 2001) (evidentiary rulings and denial of motion for a new trial).

Moreover, we review the application of general collateral estoppel principles under the law of the regional circuit in which the district court sits. *Pharmacia & Upjohn Co. v. Mylan Pharm., Inc.*, 170 F.3d 1373, 1381 n.4 (Fed. Cir. 1999). "However, for any aspects that may have special or unique application to patent cases, Feder-

al Circuit precedent is applicable." *Aspex Eyewear, Inc. v. Zenni Optical Inc.*, 713 F.3d 1377, 1380 (Fed. Cir. 2013).

I. COLLATERAL ESTOPPEL

The First Circuit reviews the denial of a motion for summary judgment *de novo*. *OneBeacon Am. Ins. Co. v. Commercial Union Assur. Co. of Can.*, 684 F.3d 237, 241 (1st Cir. 2012). In addition, the application of the doctrine of collateral estoppel is a question of law reviewed *de novo*. *Manganella v. Evanston Ins. Co.*, 700 F.3d 585, 590 (1st Cir. 2012). A party seeking to invoke the doctrine of collateral estoppel must establish that:

> (1) the issue sought to be precluded in the later action is the same as that involved in the earlier action; (2) the issue was actually litigated; (3) the issue was determined by a valid and binding final judgment; and (4) the determination of the issue was essential to the judgment.

Ramallo Bros. Printing, Inc. v. El Dia, Inc., 490 F.3d 86, 90 (1st Cir. 2007).

AbbVie argues that Centocor's invalidity defenses as to the '128 patent should not have been tried to the jury because of the preclusive effect of the Board's prior judgment. AbbVie contends that although the § 146 action was a hybrid proceeding in which Centocor could present new evidence, it remained a proceeding to review the Board's decision and thus was akin to an appeal. AbbVie therefore maintains that the pending § 146 action did not impair the finality of the Board's judgment. AbbVie also asserts that Centocor provoked the interference and had a full and fair opportunity to litigate in the forum of its choice and that the Board's procedures did not unduly constrain Centocor from developing its case.

Centocor responds that the Board's decision was not a final judgment because it was the subject of Centocor's timely filed § 146 action, in which Centocor was permitted

to and did present new evidence. Centocor maintains that it did not have a full and fair opportunity to litigate in the interference proceeding because PTO regulations limited the nature and extent of discovery and the type of evidence that could be presented to the Board. Centocor also argues that AbbVie waived its collateral estoppel argument under First Circuit law because AbbVie did not renew it in the post-verdict JMOL motion.

We agree with Centocor that the Board's judgment was not a final judgment for purposes of collateral estoppel because the interference action under § 146 was still pending at the district court. Accordingly, we need not decide whether AbbVie waived the issue for appeal under First Circuit law.

Section 146 of the patent statute provides, in part, that "[a]ny party to an interference dissatisfied with the decision of the [Board] on the interference, may have remedy by civil action, if commenced within such time after such decision, not less than sixty days" and that "the record in the [PTO] shall be admitted on motion of either party upon the terms and conditions as to costs, expenses, and the further cross-examination of the witnesses as the court imposes, *without prejudice to the right of the parties to take further testimony*." 35 U.S.C. § 146 (emphasis added). Thus, a party seeking review of a decision of the Board under § 146 may "shor[e] up evidentiary gaps" in the agency record by presenting live testimony, which could not be presented to the PTO. *Agilent Techs., Inc. v. Affymetrix, Inc.*, 567 F.3d 1366, 1380 (Fed. Cir. 2009). When additional evidence is presented, the district court makes a *de novo* finding of facts in light of the new evidence, "while treating the record before the Board when offered by a party as if it was originally taken and produced in the district court." *Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1347 (Fed. Cir. 2000) (internal quotation marks omitted); *see also Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 659 F.3d 1186, 1196 (Fed. Cir.

2011) ("The purpose of § 146 is to bring to bear, upon the contested issues . . . , the procedures and rules of federal litigation."); *Rexam Indus. Corp. v. Eastman Kodak Co.*, 182 F.3d 1366, 1370 (Fed. Cir. 1999) (A § 146 action "is derivative of the interference conducted in the PTO."); *Estée Lauder Inc. v. L'Oreal, S.A.,* 129 F.3d 588, 592 (Fed. Cir. 1997) ("Section 146 actions have been described as a hybrid of an appeal and a trial *de novo*.").

The patent statute provides alternative paths for judicial review of an interference decision of the Board. A party to an interference dissatisfied with a Board decision may file a direct appeal to this court pursuant to 35 U.S.C. § 141 (2006).[4] Unlike a § 146 action, a direct appeal under § 141 is based solely on the agency record and reviewed under the standard established by the Administrative Procedure Act and is therefore more akin to a traditional appeal from a district court decision. *Streck*, 659 F.3d at 1190. The statute, however, provides that such a direct appeal "shall be dismissed if any adverse party to such interference, within twenty days after the appellant has filed notice of appeal . . . files notice with the Director that the party elects to have all further proceedings conducted as provided in section 146." 35 U.S.C. § 141. Consequently, the statutory election procedure allows a party to elect further proceedings under § 146, in which it could reopen and supplement the factual record at the district court, even when a direct appeal is filed first by another party.

As indicated, when a party elects to seek review of a Board decision under § 146, the factual record remains open with respect to the issues contested at the PTO. Because a district court can make a *de novo* determina-

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[4] 35 U.S.C. § 141 has been amended by the AIA, Pub. L. No. 112-29, § 7, 125 Stat. at 314. We refer to the pre-AIA version of the statute.

tion of facts upon the submission of new evidence, a Board decision that is reviewed under § 146 is not a "binding final judgment" to preclude a losing party from litigating the same or related issues in a parallel proceeding. Whether a Board's interference decision that is on appeal under § 141 can have collateral estoppel effect on issues raised in a co-pending litigation is another question, one we need not address here. Here, Centocor initiated the § 146 action at the district court within the statutorily prescribed time period and was thus entitled to present new evidence at least with respect to the issues of priority and obviousness in the underlying interference action. The factual record in the interference action was therefore open as to those issues, subject to a *de novo* determination by the district court. Consequently, the Board's priority and nonobviousness decisions lacked the requisite finality for purposes of collateral estoppel.

We therefore hold that Centocor was not collaterally estopped from raising invalidity defenses in the infringement action.

II. WRITTEN DESCRIPTION[5]

The First Circuit reviews the denial of a motion for JMOL *de novo*, applying the same standard as the district court. *Interstate Litho Corp. v. Brown*, 255 F.3d 19, 27 (1st Cir. 2001). JMOL is appropriate when "a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue." Fed. R. Civ. P. 50(a)(1). Applying First Circuit law, we consider the evidence presented to the jury and all reasonable infer-

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[5] AbbVie did not substantively challenge the district court's holding of obviousness of the asserted claims. It might therefore be concluded that we could affirm that court's obviousness holding and proceed no further. However, as an "inferior" court, we are well-advised to review more than one issue raised before us on appeal, lest higher authority find error in any basis for a more limited review. *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 97–98 (1993) ("[T]he Federal Circuit is not a court of last resort. . . . [Its] decision to rely on one of two possible alternative grounds (noninfringement rather than invalidity) did not strip it of *power* to decide the second question, particularly when its decree was subject to review by this Court." (emphasis in original)); *see also Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, 683 F.3d 1356 (Fed. Cir. 2012) (affirming invalidity based on anticipation and obviousness); *Verizon Servs. Corp. v. Cox Fibernet Va., Inc.*, 602 F.3d 1325 (Fed. Cir. 2010) (same); *Union Pac. Res. Co. v. Chesapeake Energy Corp.*, 236 F.3d 684 (Fed. Cir. 2001) (affirming invalidity based on indefiniteness and lack of enablement). Because the written description issue constituted the principal basis of AbbVie's appeal to this court, we proceed to consider the written description issue rather than affirm merely on any procedural defect or omission relating to the obviousness issue.

ences that may be drawn therefrom in the light most favorable to the jury verdict. *Osorio v. One World Techs., Inc.*, 659 F.3d 81, 84 (1st Cir. 2011). We will only reverse the district court's denial of JMOL "if the facts and inferences point so strongly and overwhelmingly in favor of the movant that a reasonable jury could not have reached a verdict against that party." *Id.* (citation and internal quotation marks omitted).

Whether a patent claim is supported by an adequate written description is a question of fact, and we review a jury's factual determination relating to compliance with the written description requirement for substantial evidence. *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1355 (Fed. Cir. 2010) (en banc). Furthermore, patents are presumed to be valid, and overcoming this presumption requires clear and convincing evidence. 35 U.S.C. § 282; *Microsoft Corp. v. i4i Ltd.*, 131 S. Ct. 2238, 2243 (2011); *Ariad*, 598 F.3d at 1354.

AbbVie argues that each of the asserted claims is limited to a small genus of antibodies that are rare and difficult to obtain and that its patents describe a representative number of antibodies commensurate with the scope of the claims. AbbVie maintains that the disclosed antibodies reflect the variation of the entire genus because they cover the full range of the claimed feature, the k_{off} rate. AbbVie also asserts that it disclosed the amino acid sequence of all known species covered by the claims except for Stelara and that its patents were not required to provide individual written description of an infringing product. AbbVie argues that Centocor incorrectly seeks to distinguish Stelara on the basis of unclaimed structural features that are legally irrelevant and have no correlation to the claimed k_{off} rate. AbbVie maintains that even if the structural variations are relevant at all, AbbVie's patents disclose a variety of amino acid sequences of the CDRs of its antibodies.

Centocor responds that the jury verdict of invalidity for inadequate written description is supported by substantial evidence. Centocor maintains that AbbVie's patent disclosure is limited to a family of closely related, structurally similar antibodies that are all derived from Joe-9, whereas AbbVie's functionally defined claims cover antibodies having widely varying structures including Stelara. Centocor therefore argues that the antibodies disclosed in AbbVie's patents are not representative of the entire genus. Centocor also responds that AbbVie's argument that structural differences are legally irrelevant is contrary to the law of written description. Centocor contends that the functional requirement of the claims, *i.e.*, the k_{off} rate, is dependent on the structure of the antibody and that AbbVie's evidence purporting to show the disclosure of representative species is irrelevant.

We agree with Centocor that substantial evidence supports the jury verdict that the asserted claims are invalid for lack of an adequate written description. The written description requirement has long been part of our patent law. It is provided for in the statute, and drafters of patent applications know that they must describe their inventions as well as disclose how to enable their use. This court en banc held in *Ariad* that the written description requirement is separate from the enablement requirement. *Ariad*, 598 F.3d at 1344. We also explained that the requirement for an adequate written description serves a different purpose from that of the claims. *Id.* at 1347 ("Claims define and circumscribe, the written description discloses and teaches.").

The essence of the written description requirement is that a patent applicant, as part of the bargain with the public, must describe his or her invention so that the public will know what it is and that he or she has truly made the claimed invention. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736 (2002) ("The[] requirements must be satisfied before issuance of

the patent, for exclusive patent rights are given in exchange for disclosing the invention to the public. What is claimed by the patent application must be the same as what is disclosed in the specification . . . ." (internal citations omitted)); *O'Reilly v. Morse*, 56 U.S. 62, 120–21 (1853) ("The evil is the same if he claims more than he has invented, although no other person has invented it before him. He prevents others from attempting to improve upon the manner and process which he has described in his specification and may deter the public from using it.").

We have explained that "requiring a written description of the invention plays a vital role in curtailing claims . . . that have not been invented, and thus cannot be described." *Ariad*, 598 F.3d at 1352. "[T]he purpose of the written description requirement is to 'ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification.'" *Id.* at 1353–54 (quoting *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 920 (Fed. Cir. 2004)). We have held that the written description requirement with respect to particularly claimed subject matter is met if the specification shows that the stated inventor has in fact invented what is claimed, that he had possession of it. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563–64 (Fed. Cir. 1991). We have stated that possession is shown by disclosure in the patent. *Ariad*, 598 F.3d at 1351 ("[T]he hallmark of written description is disclosure . . . the test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art.").

One particular question regarding the written description requirement has been raised when a genus is claimed but the specification only describes a part of that genus that is insufficient to constitute a description of the genus. In *Regents of the University of California v. Eli*

Lilly & Co., 119 F.3d 1559, 1568 (Fed. Cir. 1997), we held that a genus of mammalian insulin DNA was not supported by a description of rat insulin DNA. Without doubt, rats are different from other mammals, including humans. A description of one does not describe or show that one has invented the whole genus of mammals. Whether the written description requirement for a genus is met by a particular disclosure depends upon the facts. *Ariad*, 598 F.3d at 1351. This case presents such a question. The jury found that the requirement was not met, and we agree.

"For generic claims, we have set forth a number of factors for evaluating the adequacy of the disclosure, including 'the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue.'" *Id.* (quoting *Capon v. Eshhar*, 418 F.3d 1349, 1359 (Fed. Cir. 2005)). When a patent claims a genus using functional language to define a desired result, "the specification must demonstrate that the applicant has made a generic invention that achieves the claimed result and do so by showing that the applicant has invented species sufficient to support a claim to the functionally-defined genus." *Id.* at 1349. We have held that "a sufficient description of a genus . . . requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus." *Id.* at 1350 (quoting *Eli Lilly*, 119 F.3d at 1568–69).

Here, the claimed invention is a class of fully human antibodies that are defined by their high affinity and neutralizing activity to human IL-12, a known antigen. AbbVie's expert conceded that the '128 and '485 patents do not disclose structural features common to the members of the claimed genus. J.A. 7430–31. The question

therefore is whether the patents sufficiently otherwise describe representative species to support the entire genus.

One factor in considering the question is how large a genus is involved and what species of the genus are described in the patent. If the genus is not large or, even if it is, the specification discloses species representing the genus throughout its scope, the requirement may be met. On the other hand, analogizing the genus to a plot of land, if the disclosed species only abide in a corner of the genus, one has not described the genus sufficiently to show that the inventor invented, or had possession of, the genus. He only described a portion of it. That is the case here.

It is important not to take the analogy of a plot of land too far in thinking of written description issues because, even if one builds a house only in one corner of the plot, one may still own the whole plot. One describes a plot of land by its furthest coordinates, in effect drawing a perimeter fence around it. That may be akin to the function of patent claims to particularly point out and distinctly circumscribe the outer boundaries of a claimed invention. With the *written description* of a genus, however, merely drawing a fence around a perceived genus is not a description of the genus. One needs to show that one has truly invented the genus, *i.e.*, that one has conceived and described sufficient representative species encompassing the breadth of the genus. Otherwise, one has only a research plan, leaving it to others to explore the unknown contours of the claimed genus. *See Ariad*, 598 F.3d at 1353 (The written description requirement guards against claims that "merely recite a description of the problem to be solved while claiming all solutions to it and . . . cover any compound later actually invented and determined to fall within the claim's functional boundaries.").

Here, the jury heard ample evidence that AbbVie's patents only describe one type of structurally similar anti-

bodies and that those antibodies are not representative of the full variety or scope of the genus. *Abbott*, 971 F. Supp. 2d at 176–77. All of the antibodies described in AbbVie's patents were derived from Joe-9 and have V_H3 type heavy chains and Lambda type light chains. Although the described antibodies have different amino acid sequences at the CDRs, they share 90% or more sequence similarity in the variable regions and over 200 of those antibodies differ from Y61 by only one amino acid. The patents describe that other V_H3/Lambda antibodies may be modified to attain IL-12 binding affinity. However, the patents do not describe any example, or even the possibility, of fully human IL-12 antibodies having heavy and light chains other than the V_H3 and Lambda types.

In contrast, Centocor's Stelara, which falls within the scope of the claimed genus, differs considerably from the Joe-9 antibodies described in AbbVie's patents. Stelara has V_H5 type heavy chains and Kappa type light chains. The variable regions of Stelara only share a 50% sequence similarity with the Joe-9 antibodies, which is far lower than the 90% sequence similarity shared among the Joe-9 antibodies described in AbbVie's patents. Centocor's expert testified that antibodies with 80% sequence similarity to J695 could bind to completely different antigens, J.A. 6496–97, thus illustrating the significant structural differences between Stelara and the Joe-9 antibodies and the unpredictability of the field of invention. Centocor also presented evidence of other differences between Stelara and the Joe-9 antibodies, such as CDR length and epitope binding site. J.A. 14958.

Because each of the asserted claims encompasses both the Joe-9 antibodies and the allegedly infringing Stelara, the claimed genus covers structurally diverse antibodies. The '128 and '485 patents, however, only describe species of structurally similar antibodies that were derived from Joe-9. Although the number of the described species appears high quantitatively, the described species are all

of the similar type and do not qualitatively represent other types of antibodies encompassed by the genus. *See Ariad*, 598 F.3d at 1351 ("[No] bright-line rules govern[] the number of species that must be disclosed to describe a genus claim, as this number necessarily changes with each invention, and it changes with progress in a field.").

It is true that AbbVie's patents need not describe the allegedly infringing Stelara in exact terms. *Eli Lilly*, 119 F.3d at 1568 ("[E]very species in a genus need not be described in order that a genus meet the written description requirement."). However, the patents must at least describe some species representative of antibodies that are structurally similar to Stelara. On review of the record, there is no evidence to show any described antibody to be structurally similar to, and thus representative of, Stelara. There is also no evidence to show whether one of skill in the art could make predictable changes to the described antibodies to arrive at other types of antibodies such as Stelara.

Instead, AbbVie argues that structural differences are legally irrelevant and inappositely attempts to rely on the k_{off} rates to show representativeness. The k_{off} rate is merely a desired result, rather than the actual means for achieving that result. The asserted claims are directed to new compositions, *i.e.*, fully human antibodies having desired IL-12 binding characteristics. It is undisputed that the structure of the antibody determines its antigen binding characteristic. In order to demonstrate that it has invented what is claimed, AbbVie's patents must adequately describe representative antibodies to reflect the structural diversity of the claimed genus. *See Eli Lilly*, 119 F.3d at 1568 ("[N]aming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material."); *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993) ("Claiming all DNA[s] that achieve a result without defining what means will do so is not in compli-

ance with the description requirement; it is an attempt to preempt the future before it has arrived.").

Functionally defined genus claims can be inherently vulnerable to invalidity challenge for lack of written description support, especially in technology fields that are highly unpredictable, where it is difficult to establish a correlation between structure and function for the whole genus or to predict what would be covered by the functionally claimed genus. *Ariad*, 598 F.3d at 1351 ("[T]he level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology."); *see also Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341, 1352 (Fed. Cir. 2011) (noting the technical challenges in developing fully human antibodies of a known human protein). It is true that functionally defined claims can meet the written description requirement if a reasonable structure-function correlation is established, whether by the inventor as described in the specification or known in the art at the time of the filing date. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002). However, the record here does not indicate such an established correlation. Instead, AbbVie used a trial and error approach to modify individual amino acids in order to improve the IL-12 binding affinity. Moreover, the '128 and '485 patents do not describe any common structural features of the claimed antibodies. The asserted claims attempt to claim every fully human IL-12 antibody that would achieve a desired result, *i.e.*, high binding affinity and neutralizing activity, and cover an antibody as different as Stelara, whereas the patents do not describe representative examples to support the full scope of the claims.

We therefore conclude that substantial evidence supports the jury verdict of invalidity for lack of an adequate

written description of the claimed genus and affirm the district court's denial of JMOL on that issue.[6] Consequently, we need not address AbbVie's argument regarding enablement.

III. NEW TRIAL

The First Circuit reviews the denial of a motion for a new trial for an abuse of discretion. *Granfield v. CSX Transp., Inc.*, 597 F.3d 474, 488 (1st Cir. 2010). Challenges to a district court's evidentiary rulings are also reviewed under an abuse of discretion standard. *Lynch v. City of Boston*, 180 F.3d 1, 15 (1st Cir. 1999). "In the event we discern error, we must determine whether the error was harmless." *Id.* "Our inquiry is whether exclusion or admission of the evidence affected plaintiff's substantial rights." *Id.* (citation and internal quotation marks omitted).

Moreover, the First Circuit reviews preserved challenges to jury instructions *de novo* and "look to the challenged instructions in relation to the charge as a whole, asking whether the charge in its entirety—and in the context of the evidence—presented the relevant issues to the jury fairly and adequately." *Sony BMG Music Entm't v. Tenenbaum*, 660 F.3d 487, 503 (1st Cir. 2011) (internal quotation marks omitted). "Even if the instructions were erroneous, we reverse only if the error is determined to have been prejudicial based on a review of the record as a whole." *Id.* (internal quotation marks omitted). "A new trial is necessary only 'if the error could have affected the result of the jury's deliberation.'" *Romano v. U-Haul Int'l*, 233 F.3d 655, 667 (1st Cir. 2000) (quoting *Allen v. Chance Mfg. Co.,* 873 F.2d 465, 469 (1st Cir. 1989)). "In making

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[6] We were aided in our consideration of this issue by amicus curiae briefs filed by Eli Lilly and Co. *et al.* and Professor Oskar Liivak of Cornell Law School.

that determination, we consider whether we can say 'with fair assurance that the judgment was likely unaffected.'" *Id.* (quoting *Putnam Res. v. Pateman,* 958 F.2d 448, 471 (1st Cir. 1992)).

A. Evidentiary Rulings

AbbVie argues that the district court's exclusion of the interference file history from evidence allowed Centocor to relitigate invalidity from a clean slate. AbbVie asserts that it was unfairly precluded from using the file history to demonstrate that much of Centocor's case was cumulative of what the PTO had already considered, such as the phage display prior art relevant to the obviousness determination. AbbVie further argues that the district court erred in excluding expert testimony on the detailed reasoning of the PTO on the issues of written description, enablement, and obviousness during *ex parte* prosecution.

Centocor responds that the district court did not abuse its discretion in excluding certain evidence to avoid time delay and jury confusion. Centocor argues that it proposed that the parties stipulate to a list identifying art references considered by the PTO for the jury, but AbbVie never accepted that invitation. Centocor maintains that the *ex parte* prosecution history was admitted into evidence, but AbbVie failed to introduce witness testimony on prior art considered by the PTO. Centocor also responds that AbbVie has not shown that its substantive rights were so affected as to warrant a new trial.

Because we hold that substantial evidence supported the jury verdict of invalidity for lack of written description support, we need only address whether the evidentiary rulings affected AbbVie's substantive rights concerning that verdict. The evidence of the interference or other proffered evidence concerning obviousness is of little probative value to the written description determination. The Board only decided the issues of obviousness and anticipation by prior invention and the parties did not file

substantive motions on written description in the interference proceeding. Moreover, as indicated, the interference did not collaterally estop Centocor from presenting invalidity defenses in the infringement action and thus the court properly excluded evidence of Centocor's participation in the interference. We find no error in the exclusion of those pieces of evidence.

We also find no reversible error in the district court's exclusion of Dr. Marks' proffered testimony on the detailed reasoning of the PTO. The district court allowed Dr. Marks to testify before the jury that "the Patent Office in the file history considered the written description issue" and "concluded that the written description requirement was met." J.A. 7261. When AbbVie attempted to guide Dr. Marks through the details of the file history, the court excluded the additional testimony. J.A. 7285. Based on Dr. Marks' expert report, the proffered testimony likely would summarize prosecution *arguments* made to the PTO, specifically that "the claims were rejected as being non-enabled or lacking written description by the specification," and that "these rejections were overcome because the applicants pointed out that the specification provides numerous examples of fully human antibodies that bind IL-12 with high affinity." J.A. 10741. In view of the record as a whole, including the substantial evidence of structural differences between Stelara and the Joe-9 antibodies and the fact that the jury considered the number of structurally similar antibodies disclosed in AbbVie's patents, we conclude that the district court did not abuse its discretion in excluding that additional testimony. *Kelley v. Airborne Freight Corp.*, 140 F.3d 335, 346 (1st Cir. 1998) ("Only rarely—and in extraordinarily compelling circumstances—will [the First Circuit] from the vista of a cold appellate record, reverse a district court's on the spot judgment, concerning the relative weighing of probative value and prejudicial effect." (internal quotation marks omitted)).

B. Jury Instructions

Finally, as a last ditch argument, AbbVie argues that the prejudicial effect of the contested evidentiary rulings was exacerbated by the jury instruction that new information presented at trial that was not considered by the PTO would make it easier for Centocor to carry its burden of proving invalidity by clear and convincing evidence. AbbVie weakly argues that the district court erroneously concluded that the Supreme Court decision in *Microsoft v. i4i* overruled *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452 (Fed. Cir. 1984) and erroneously refused to instruct the jury that the new information must be more relevant than information considered by the PTO. AbbVie maintains that a proper instruction would have required the jury to assess whether Centocor made the necessary comparison, which Centocor had failed to do. AbbVie also argues that the district court erred in interpreting the "materially new" phrase in *Microsoft v. i4i* and incorrectly instructed the jury on "materiality" using a "reasonable examiner" standard.

Centocor responds that the jury instruction concerning additional information presented at trial followed the language and logic of the *Microsoft v. i4i* decision. Centocor maintains that it was not Centocor's burden to prove that the new information was more material than information considered by the PTO and that AbbVie could have made that comparison for the jury. Centocor maintains that it informed the jury that the Meager article and the J695/IL-12 crystal structure were not considered by the PTO, which is objectively true. Centocor thus responds that even if there were a legal error in the jury instruction, AbbVie failed to show that the purported error resulted in any prejudice to warrant a new trial.

Again, we need only address whether the challenged instructions constitute reversible error with respect to the

jury's written description verdict. And we conclude that they do not. Based on a review of the record as a whole, including the evidence presented on the issue of written description as well as the jury instruction on burden of proof in its entirety, we conclude that there was no prejudicial error to warrant a new trial on the issue of written description.

We previously held in *American Hoist*, in the context of a validity challenge based on obviousness, that "the clear and convincing standard may more easily be met when such non-considered art is more pertinent than the cited art" and that "determination of whether the patent challenger has met its burden turns on the relationship of the uncited art to the claimed invention." *Am. Hoist*, 730 F.2d at 1459. We also held that to the extent that consideration of the uncited art is material, the burden is on the *challenger* to show that the uncited art is more relevant than that cited. *Id.* at 1460.

The issue of pertinence or cumulativeness of non-considered art relative to considered art often arises in the context of validity challenges based on anticipation or obviousness. *See, e.g.*, *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1050 (Fed. Cir. 1988) (obviousness); *Alco Standard Corp. v. TVA*, 808 F.2d 1490, 1498 (Fed. Cir. 1986) (obviousness); *RCA Corp. v. Applied Digital Data Sys., Inc.*, 730 F.2d 1440, 1444 (Fed. Cir. 1984) (anticipation and obviousness). Here, because we substantively affirm the written description verdict, we need not decide whether the district court's refusal to give instructions on the pertinence or cumulativeness of non-considered art, such as the Meager article, resulted in prejudicial error in the jury's obviousness verdict. Likewise, we need not address whether Centocor failed to carry its burden to compare the Meager article with references considered by the PTO in order to benefit from the greater weight given to non-considered art.

Concerning the J695/IL-12 crystal structure, which is relevant to the jury's written description verdict, we conclude that the alleged errors are not sufficiently prejudicial to warrant a new trial. The Supreme Court stated in *Microsoft v. i4i* that "if the PTO did not have all material facts before it, its considered judgment may lose significant force" and that "the challenger's burden to persuade the jury of its invalidity defense by clear and convincing evidence may be easier to sustain." *Microsoft*, 131 S. Ct. at 2251. The Court also stated that:

> When it is disputed whether the evidence presented to the jury differs from that evaluated by the PTO, the jury may be instructed to consider that question. In either case, the jury may be instructed to evaluate whether the evidence before it is *materially new*, and if so, to consider that fact when determining whether an invalidity defense has been proved by clear and convincing evidence.

Id. (emphasis added).

The district court rephrased "materially new" in its jury instruction as "additional information [that] would have been 'material' to the PTO's decision to grant the patents." J.A. 350. The district court then instructed the jury that information is "material" if "there is a substantial likelihood that a reasonable patent examiner would consider it important in deciding whether to allow the application to issue as a patent." *Id.* The court further instructed the jury that "if the additional information was not material, *or it would not have carried significant weight,* Centocor's burden may be more difficult to meet." *Id.* (emphasis added). Taken as a whole, the jury instruction reasonably apprised the jury on weighing evidence relevant to the written description issue, such as the J695 crystal structure.

Moreover, even without the J695 crystal structure information, substantial evidence would have supported the

jury verdict of invalidity for inadequate written description. As the record shows, Centocor presented to the jury five categories of structural differences between Stelara and the Joe-9 antibodies described in AbbVie's patents: (1) sequence similarity; (2) heavy chain type; (3) light chain type; (4) CDR length; and (5) epitope binding site. The information on Stelara in and of itself constituted new information not considered by the PTO, which would have carried more weight. AbbVie's patent specification only describes the amino acid sequence, the heavy and light chain types, and the CDR length of the Joe-9 antibodies. Centocor also compared the J695 crystal structure with the three-dimensional structure of Stelara to show that they bind to IL-12 at different sites. That distinction was only one of the five distinctions made by Centocor, the absence of which most likely would not have affected the jury's written description verdict. Accordingly, in view of the record as a whole, we do not discern any reversible, prejudicial error in the jury's written description verdict.

We therefore conclude that the district court did not abuse its discretion in denying the motion for a new trial based on the contested evidentiary rulings and jury instructions.

CONCLUSION

For the foregoing reasons, we conclude that Centocor was not collaterally estopped from raising invalidity defenses in the infringement action. We also hold that substantial evidence supports the jury verdict that the asserted claims are invalid for lack of an adequate written description. We further conclude that the district court did not abuse its discretion in denying AbbVie's motion for a new trial with respect to the jury's written description verdict. We therefore *affirm* the district court's judgments in both the infringement action and the interference action.

AFFIRMED

United States Court of Appeals for the Federal Circuit

ABBVIE DEUTSCHLAND GMBH & CO., KG, ABBVIE BIORESEARCH CENTER, INC., AND ABBVIE BIOTECHNOLOGY, LTD.,
Plaintiffs-Appellants,

v.

JANSSEN BIOTECH, INC. AND CENTOCOR BIOLOGICS, LLC,
Defendants-Appellees.

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JANSSEN BIOTECH, INC.,
Plaintiff–Appellee,

v.

ABBVIE DEUTSCHLAND GMBH & CO., KG,
Defendant-Appellant.

2013-1338, -1346

Appeals from the United States District Court for the District of Massachusetts in Nos. 09-CV-11340-FDS, 10-CV-40003-FDS, and 10-CV-40004-FDS, Judge F. Dennis Saylor, IV.

O'MALLEY, *Circuit Judge*, concurring in judgment.

I agree that Centocor was not collaterally estopped from raising invalidity defenses in this infringement action by virtue of the Board's prior finding that the relevant claims in the '128 patent were not invalid as obvious. I also agree that we should affirm the trial court's judgment invalidating the asserted claims in the '128 and '485 patents. I would premise the latter judgment on the lower court's obviousness finding however, a finding from which AbbVie does not appeal. As AbbVie conceded at oral argument, the validity of the patents rests entirely on whether the jury was properly instructed as to the parties' respective burdens of proof. Oral Argument at 7:12, *AbbVie Deutschland GMBH & Co. v. Janssen Biotech, Inc.*, 2013-1338, available at http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2013-1338.mp3 ("We have moved for a new trial on [the obviousness] judgment. We didn't move for JMOL on that judgment, but it does not mean that we didn't move for a new trial on that judgment. The jury instruction infected all of the invalidity verdicts. And, that's the distinction we made following this court's admonition not to just appeal everything. The [obviousness] JMOL *we thought in fairness we couldn't and shouldn't appeal*." (emphasis added)).

In other words, because AbbVie did not appeal the district court's finding of obviousness, our decision on the jury instruction issue controls the outcome of this case. If we find no prejudicial error in the challenged jury instruction, the finding of obviousness stands and the patent is invalid. Alternatively, if we hold that the jury instruction is erroneous, AbbVie is entitled to a new trial on all validity issues. I express no opinion regarding the thoughtful written description analysis in the majority opinion. I simply do not think it necessary or dispositive to the outcome of this case. *Nat'l Am. Ins. Co. v. United States*, 498 F.3d 1301, 1306 (Fed. Cir. 2007) ("Dicta, as

defined by this court, are 'statements made by a court that are unnecessary to the decision in the case, and therefore[,] not precedential . . . .' " (internal quotation marks omitted) (quoting *C-Steel Raritan, Inc. v. Int'l Trade Comm'n*, 357 F.3d 1294, 1307 (Fed. Cir. 2004))).

We review the legal sufficiency of jury instructions on an issue of patent law de novo. *Bettcher Indus., Inc. v. Bunzl USA, Inc.*, 661 F.3d 629, 638 (Fed. Cir. 2011). We will order a new trial only when legal errors in the instruction as a whole had a prejudicial effect. *Id.* at 638–39. Importantly, however, we cannot do as the majority does and address the jury instruction error alleged only as it applies to the written description judgment. Maj. Op. at 30–33. AbbVie argues that the improper jury instruction "infected all of the invalidity verdicts." Oral Argument at 7:25. It points out that the trial court placed the challenged instruction at the start of the jury instructions, making clear that it—the only instruction regarding the defendant's burden of proof—applied to all of Centocor's invalidity challenges. Oral Argument at 10:50. As AbbVie explains, moreover, the challenged portion of the instruction pertaining to the impact of material not previously before the PTO, was relevant to and, thus, impacted the jury's consideration of all four of the validity defenses/challenges. Specifically as to written description, AbbVie argues that Centocor's central argument on the § 112 defense was "that the crystal structure of J695 was 'additional information' that made its burden easier to carry." Appellant's Reply 29.

About this, there is no dispute. Janssen concedes that what the parties and majority refer to as the *i4i* jury instruction applied to the § 112 issues just as much as it did to the obviousness claim. Indeed, when asked if the challenged jury instruction "impacts all grounds of invalidity," Janssen's counsel responded "exactly." Oral Argument at 20:09 (admitting that the *i4i* instruction is "not just about 103, it's about all the 112" issues as well).

Because both parties agree that our evaluation of AbbVie's challenge to the jury instruction regarding Centocor's burden of proof on all of its validity challenges is determinative of errors alleged, I would assess that jury instruction, determine whether it is legally accurate and, if not, whether it was prejudicial. That exercise would resolve fully the appeal before us.

Having conducted that exercise for both the obviousness and written description judgments, I believe that "[t]aken as a whole, the jury instruction reasonably apprised the jury on weighing evidence relevant to" both the written description and obviousness findings. Maj. Op. at 32. I, thus, concur in the decision to affirm the lower court's judgment. Because AbbVie is not entitled to a new trial because of a legally erroneous jury instruction, its patents stand invalid based on the jury's obviousness finding.

For these reasons, I concur in the result the majority reaches, but not in the reasoning for doing so.