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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SANOFI-AVENTIS U.S. LLC, GENZYME CORP., and REGENERON PHARMACEUTICALS, INC.,
Petitioner,

v.

IMMUNEX CORPORATION,
Patent Owner.

Case IPR2017-01879
Patent 8,679,487 B2

Before JAMES T. MOORE, GRACE KARAFFA OBERMANN, and TINA E. HULSE, *Administrative Patent Judges*.

HULSE, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

Sanofi-Aventis U.S. LLC, Genzyme Corp., and Regeneron Pharmaceuticals, Inc. (collectively, "Petitioner") filed a Petition requesting an *inter partes* review of claims 1–14, 16, and 17 of U.S. Patent No. 8,679,487 B2 (Ex. 1001, "the '487 patent"). Paper 1 ("Pet."). Immunex Corporation ("Patent Owner") filed a Preliminary Response to the Petition. Paper 10 ("Prelim. Resp."). With our authorization, Petitioner filed a Reply to the Preliminary Response (Paper 13), and Patent Owner filed a Surreply (Paper 15). On February 15, 2018, we instituted an *inter partes* review of claims 1–14, 16, and 17 on one anticipation ground. Paper 19 ("Dec. Inst."), 15.

Patent Owner filed a response to the Petition. Paper 35 ("PO Resp."). Petitioner filed a Reply. Paper 49 ("Reply"); Paper 86 (public version). With our authorization, Patent Owner filed a Surreply (Paper 63, "Surreply"), and Petitioner filed a Sur-Surreply (Paper 72, "Sur-surreply").

The parties also filed motions to exclude certain evidence. Paper 60 (Patent Owner's motion); Paper 65 (Petitioner's motion). The parties filed responsive papers to those motions. Paper 70 (Petitioner's opposition); Paper 77 (Patent Owner's reply); Paper 68 (Patent Owner's opposition); Paper 76 (Petitioner's reply).

An oral hearing was held on November 14, 2018, a transcript of which has been entered in the record. Paper 82 ("Tr.").

We have authority under 35 U.S.C. § 6(c). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

For the reasons that follow, we determine Petitioner has not shown by a preponderance of the evidence that claims 1–14, 16, and 17 of the ’487 patent are unpatentable over the reference asserted here.

A. Related Proceedings

Patent Owner has asserted the ’487 patent against Petitioner in a pending lawsuit styled *Immunex Corp. v. Sanofi*, No. 2:17-cv-02613 (C.D. Cal., filed April 5, 2017). Pet. 9; Paper 7, 2.

Petitioner also filed a petition for *inter partes* review of the ’487 patent on different grounds in IPR2017-01884. Pet. 9; Paper 7, 2. We instituted trial and enter a Final Written Decision in that proceeding concurrently with this decision.

Patent Owner also identifies certain applications and patents that “claim or may claim the benefit of the priority of the filing date of [the ’487 patent].” Paper 7, 1–2.

B. The ’487 Patent

The ’487 patent relates to compositions and methods for treating certain conditions induced by interleukin-4 (IL-4) by administering an IL-4 antagonist to a patient with such a condition. Ex. 1001, 3:9–14. IL-4 has a broad spectrum of biological activities, including growth co-stimulation of T cells, mast cells, granulocytes, megakaryocytes, and erythrocytes. *Id.* at 1:29–36. IL-4 binds to specific cell surface receptors called interleukin-4 receptors (IL-4R). *Id.* at 1:49–51. Binding of IL-4 to IL-4R results in transduction of a biological signal to cells, including various immune effector cells. *Id.* IL-4 has been implicated in a number of disorders, including allergy and asthma. *Id.* at 2:1–2, 4:11–31.

Different IL-4 antagonists may act at different sites or by different mechanisms of action. *Id.* at 10:47–48. According to the ’487 patent,

examples include antagonists that interfere with binding of IL-4 to cell surface receptors or that inhibit signal transduction. *Id.* at 10:48–50. The site of action may be intracellular, on a cell surface, or extracellular. *Id.* at 10:50–53. Antagonists may bind to either IL-4 or to the receptor. *Id.* at 10:53–54. Examples of IL-4 antagonists include IL-4 receptors, antibodies that bind to IL-4 or IL-4R, other IL-4 binding molecules, and IL-4 muteins. *Id.* at 10:36–38.

Blocking antibodies that interfere with the binding of IL-4 to IL-4R may be raised against either IL-4 or IL-4R. The antibodies can be screened in conventional assays for their ability to interfere with binding of IL-4 to IL-4R. *Id.* at 18:40–45. Because it has been found that IL-4R is a component of certain multi-subunit IL-13 receptor complexes, some antibodies raised against IL-4R may interfere with the binding of IL-13 to those complexes. *Id.* at 18:50–57. Those antibodies may inhibit both IL-4 induced biological activity and IL-13 induced activity and therefore may be used in treating conditions induced by either or both cytokines. *Id.* at 18:58–62. Such conditions include IgE-mediated conditions, asthma, allergic conditions, allergic rhinitis, and dermatitis. *Id.* at 18:62–65.

The ’487 patent identifies examples of IL-4R human monoclonal antibodies (MAbs) produced by immunizing transgenic mice. The examples are designated MAbs 6-2, 12B5, 63, 1B7, 5A1, and 27A1. *Id.* at 21:6–11. MAbs 12B5, 63, and 1B7 are preferred fully human antibodies capable of inhibiting activity of both IL-4 and IL-13. *Id.* at 21:11–15.

The ’487 patent presents the encoded amino acid sequence of the variable region of the light chain MAb 12B5 in SEQ ID NO:10, and of the variable region of the heavy chain in SEQ ID NO:12. *Id.* at 22:36–41.

C. Illustrative Claim

Petitioner challenges claims 1–14, 16, and 17 of the '487 patent, of which claim 1 is the only independent claim. Claim 1 is illustrative and is reproduced below:

> 1. An isolated human antibody that competes with a reference antibody for binding to human IL-4 interleukin-4 (IL-4) receptor, wherein the light chain of said reference antibody comprises the amino acid sequence of SEQ ID NO:10 and the heavy chain of said reference antibody comprises the amino acid sequence of SEQ ID NO:12.

Ex. 1001, 77:26–31.

D. The Asserted Ground of Unpatentability

We instituted trial on the ground that claims 1–14, 16, and 17 of the '487 patent are unpatentable as anticipated by the '132 Publication[1] under 35 U.S.C. § 102(e).[2]

II. ANALYSIS

A. Person of Ordinary Skill in the Art

Petitioner asserts that a person of ordinary skill in the art would have had at least a Ph.D. or an M.D. with research experience in immunology, biochemistry, cell biology, molecular biology, or a related field or at least

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[1] John D. Pluenneke, US 2002/0002132 A1, published Jan. 3, 2002 ("the '132 Publication," Ex. 1016).

[2] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, which was enacted on September 16, 2011, made amendments to 35 U.S.C. § 102. AIA § 3(b). Those amendments became effective eighteen months later on March 16, 2013. *Id.* § 3(n). Because the application from which the '487 patent issued was filed before March 16, 2013, any citations to 35 U.S.C. § 102 in this Decision are to the pre-AIA version of the statute.

2–3 years of professional experience in one or more of those fields. Pet. 22–23. According to Petitioner, such a person would have had an understanding of "how one generates antibodies to a chosen antigen from animals (*e.g.*, mice), and how one isolates human antibodies by generating human antibodies directly from transgenic animals or transforming animal antibodies into human antibodies." *Id.* at 23 (citing Ex. 1200 ¶ 22). Patent Owner does not address the level of ordinary skill in the art in its Patent Owner Response.

We agree with and adopt Petitioner's uncontested definition of the level of ordinary skill in the art. We further note that the prior art itself corroborates this finding and demonstrates the level of skill in the art at the time of the invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required "where the prior art itself reflects an appropriate level and a need for testimony is not shown" (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985))).

B. Claim Construction

In an *inter partes* review, the Board interprets claim terms in an unexpired patent according to the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b) (2016);[3] *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016) (affirming applicability of broadest reasonable construction

[3] A recent amendment to this rule does not apply here, because the Petition was filed before November 13, 2018. *See* "Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board," 83 Fed. Reg. 51,340 (Oct. 11, 2018) (to be codified at 37 C.F.R. pt. 42).

standard to *inter partes* review proceedings). Under that standard, and absent any special definitions, we generally give claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definitions for claim terms must be set forth in the specification with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Petitioner proposes constructions for the claim terms "human" and "antibody." Pet. 32–35. Patent Owner asserts that no claim construction is necessary to reach a decision on the Petition. PO Resp. 7.

Based on the arguments and evidence presented during trial, we determine that it is unnecessary to construe any claim terms expressly for purposes of this Decision. *See Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) ("[C]laim terms need only be construed 'to the extent necessary to resolve the controversy.'" (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

C. Anticipation by the '132 Publication

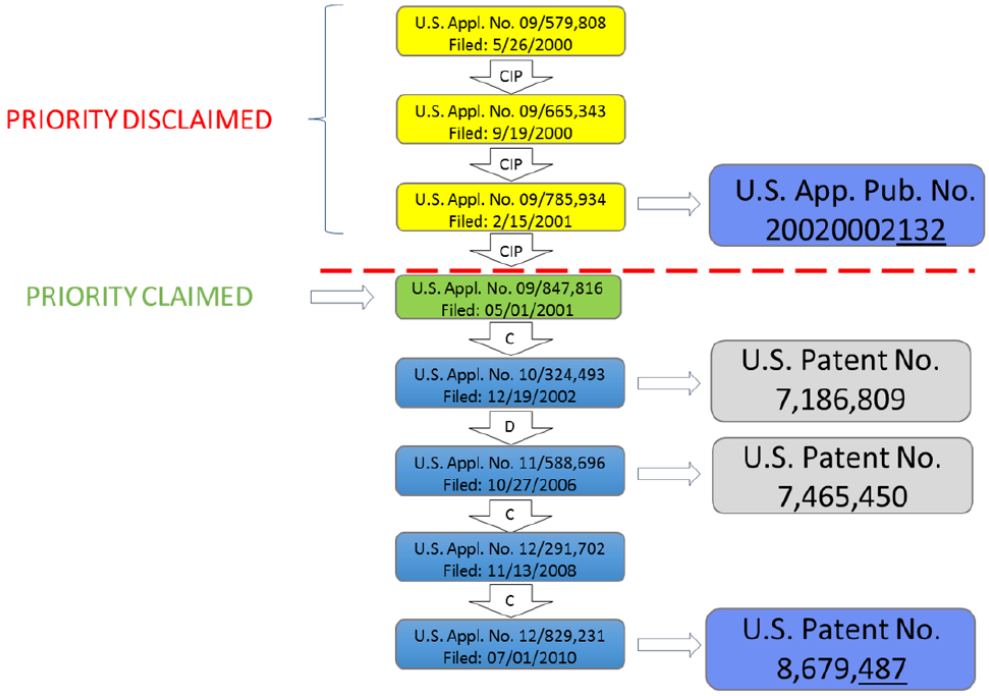
Petitioner asserts that claims 1–14, 16, and 17 of the '487 patent are anticipated by the '132 Publication. Pet. 40–61. Patent Owner opposes Petitioner's assertion. PO Resp. 7–46. Having considered the arguments and evidence presented during trial, we determine that Petitioner has not established by a preponderance of the evidence that the challenged claims are anticipated by the '132 Publication under 35 U.S.C. § 102(e).

1. The '132 Publication (Ex. 1016)

The '132 Publication, entitled "Use of Interleukin-4 Antagonists and Compositions Thereof," identifies John D. Pluenneke as the sole inventor and is the publication of U.S. Application No. 09/785,934 ("the '934

application"). Ex. 1016, [21], [54], [76]. The '934 application is the parent of U.S. Application No. 09/847,816, to which the '487 patent claims priority. Ex. 1001, [60]. Patent Owner, however, expressly disclaimed priority to the '132 Publication (and the earlier applications) during prosecution of the '487 patent. Ex. 1002, 145.

Petitioner provides an illustration, reproduced below, of the chain of applications leading to the '487 patent, including the disclaimed applications:



Pet. 3. The illustration shows the '816 application is a continuation-in-part of the '132 Publication. Here, the disclosure of the '132 Publication is a subset of that of the '487 patent. *See* Ex. 1203 (redline comparison of the disclosures of the '132 Publication with the '487 patent). For example, the '487 patent adds a portion of Example 6, all of Examples 8 and 9, and the disclosure of SEQ ID NOS: 4–26. Pet. 37 n.6.

In particular, the ’132 Publication discloses as Example 6 a hybridoma cell line designated “6-2” that secretes mAb 6-2. Ex. 1016 ¶ 246. Paragraph 246 states:

> One hybridoma cell line generated by procedures described above (see example 4) is designated 6-2. The anti-IL-4R monoclonal antibody secreted by this hybridoma is a blocking antibody, as determined in a conventional plate binding assay, and thus functions as an IL-4 antagonist. The monoclonal antibody produced by 6-2 also exhibits the ability to reduce an IL-13-induced biological activity.

Id.

2. Analysis

Anticipation requires that “each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (citation omitted). “To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.’” *Id.* (citation omitted).

Regarding claim 1, Petitioner asserts that the ’132 Publication discloses, expressly or inherently, each limitation of the claim. For example, Petitioner contends that the ’132 Publication’s teaching of mAb 6-2, which was isolated and screened according to Examples 4–6, discloses “an isolated human antibody.” Pet. 40–42 (citing Ex. 1016 ¶¶ 232–241, 243, 246). Petitioner further contends that the mAb 6-2 antibody of the ’132 Publication inherently “competes with a reference antibody for binding to human IL-4 interleukin (IL-4) receptor, wherein the light chain of said reference antibody comprises the amino acid sequence of SEQ ID NO:10 and the heavy chain of said reference antibody comprises the amino acid

sequence of SEQ ID NO:12." *Id.* at 43–49; Ex. 1200 ¶¶ 128–129. Specifically, Petitioner's expert, Dr. Gerard Zurawski, testifies that he confirmed experimentally that the mAb 6-2 antibody competes with the claimed reference antibody (i.e., mAb 12B5). Ex. 1200 ¶¶ 79–106. Dr. Zurawski states that he used the competition assay described in Perez de la Lastra (1999), which was endorsed by Patent Owner during a European Opposition proceeding. *Id.* ¶ 97.

In response, Patent Owner argues that the '132 Publication does not qualify as prior art under § 102(e) because it does not disclose an invention "by another," as required by § 102(e). PO Resp. 7–35. Patent Owner also argues that the '132 Publication does not anticipate because Petitioner has failed to show the '132 Publication enables how to make the mAb 6-2 recited in the claims. *Id.* at 37–46.

Based on the arguments and evidence presented during trial, we first consider the issue of whether the '132 Publication discloses the work of the '487 patent inventors. Because this issue is dispositive, we do not reach Patent Owner's assertion that the '132 Publication is not enabling. *See* PO Resp. 37–46.

a. Legal Background

Under § 102(e), a claim is anticipated if "the invention was described in . . . an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent." Thus, "there are two conditions expressed in section 102(e): (1) the application for the reference patent must have been by one who is legally 'another' and (2) the filing date must be 'before the invention . . . by the applicant.'" *In re Land*, 368 F.2d 866, 879 (CCPA 1966). To overcome a prior art reference under §102(e), the applicant or patentee may antedate the

invention by establishing prior conception and reduction to practice relative to the filing date of the prior application. *In re Costello*, 717 F.2d 1346, 1351 (Fed. Cir. 1983). Alternatively, the applicant or patentee may "establish that the relevant disclosure [in the prior application] describes their own invention." *Id.*

Thus, determining whether the prior application has a different inventive entity on its face than the challenged patent does not end the inquiry. We must also determine "whether the portions of the reference relied on as prior art, and the subject matter of the claims in question, represent the work of a common inventive entity." *EmeraChem Holdings, LLC v. Volkswagen Grp. of Am., Inc.*, 859 F.3d 1341, 1345 (Fed. Cir. 2017) (quoting *Riverwood Int'l Corp. v. R.A. Jones & Co.*, 324 F.3d 1346, 1356 (Fed. Cir. 2003)); *see also Costello*, 717 F.2d at 1349 ("An applicant may also overcome a reference by showing that the relevant disclosure is a description of the applicant's own work. The pertinent inquiry is under 35 U.S.C. § 102(e).").

In *Dynamic Drinkware, LLC v. National Graphics, Inc.*, 800 F.3d 1375 (Fed. Cir. 2015), the Federal Circuit explained the shifting burden of production in an *inter partes* review with respect to showing whether a reference is prior art. *Id.* at 1379–80. Here, although the burden of persuasion never shifts to Patent Owner, Petitioner satisfied its initial burden of production by arguing that the '132 Publication anticipates the challenged claims under § 102(e). *See id.* at 1379 (stating the petitioner satisfied its initial burden of production by arguing that the prior art anticipated the claims under § 102(e)(2)). The burden of production then shifted to Patent Owner to argue or produce evidence that the '132 Publication does not anticipate or that the '132 Publication is not prior art. Having argued and

produced evidence that the ’132 Publication is not prior art because it is not enabling and is not work “by another,” the burden of production shifted back to Petitioner to prove that the ’132 Publication actually anticipates and constitutes prior art under § 102(e). *See id.* at 1380.

Under these legal guidelines, we consider the arguments and evidence presented by the parties as to whether the ’132 Publication is § 102(e) prior art.

b. Whether the ’132 Publication Is § 102(e) Prior Art

The ’132 Publication lists John D. Pluenneke as its sole inventor. Ex. 1016, [76]. The ’487 patent lists Richard Armitage, Jose Carlos Escobar, and Arvia E. Morris as the inventors. Ex. 1001, [75]. Thus, we agree with Petitioner that, on its face, the ’132 Publication has a different inventive entity than the ’487 patent. *See* Reply 1. As explained above, however, that does not end the analysis. *See EmeraChem*, 859 F.3d at 1345. We must now determine whether the portions of the ’132 Publication relied upon for anticipation represent the work of the ’487 patent inventors.[4] *See id.*

i. The Scope of the Petition

As an initial matter, the parties dispute the scope of the Petition and what Petitioner relies on to show the ’132 Publication anticipates the

[4] Patent Owner asserts that we exceeded our statutory authority under 35 U.S.C. § 314(a) by instituting trial despite describing the evidence it presented with its Preliminary Response as “compelling.” PO Resp. 46–47. As explained in our Decision on Institution, however, Patent Owner’s testimonial evidence raised a genuine issue of material fact that was viewed in the light most favorable to Petitioner for the purposes of the Decision on Institution. Dec. 14 (citing 37 C.F.R. § 42.108(c)).

challenged claims. Patent Owner contends that Petitioner relies solely on the '132 Publication's disclosure of mAb 6-2 for anticipation. PO Resp. 12; Surreply 12–13. Petitioner, on the other hand, argues that the Petition is broader than that, and encompasses antibodies "like mAb 6-2." Tr. 51:6–52:6.

The parties appear to agree that the Petition relies on twenty-seven paragraphs from the '132 Publication: ¶¶ 16, 17, 131, 145, 149, 151, 180, 183, 218–220, and 232–247. *See* PO Resp. 12; Tr. 52:4–6 (Petitioner's counsel referring to the "27 relied-upon paragraphs"). Although we recognize the Petition relies on various portions of the '132 Publication for background and context, when considering the Petition as a whole, we agree with Patent Owner that the Petition relies solely on mAb 6-2 for purposes of anticipation.[5]

Throughout the Petition, Petitioner focuses on the '132 Publication's disclosure of mAb 6-2 as anticipating. Pet. 6 (arguing "the '487 Patent ensnares its own prior art patent publication—the '132 Publication—which discloses mAb 6-2"); *id.* at 12 ("Specifically, this Petition relies on Patent Owner's own '132 Publication—which was filed February 15, 2001 and is prior art to the '487 Patent based on its purported May 1, 2001 priority date—the '132 Publication's disclosure of the fully human anti-hIL-4R antibody referred to specifically as mAb 6-2, and testing of mAb 6-2 to

[5] We note the Petition appears to cite paragraphs from the '132 Publication other than the "relied-upon paragraphs." *See, e.g.*, Pet. 19 (citing Ex. 1016 ¶¶ 10, 155). Those citations, however, also describe background information regarding the field of technology. Thus, even including those additional paragraphs, our finding that the Petition relies solely on mAb 6-2 for anticipation remains the same.

demonstrate that it inherently satisfies the challenged claims."); *id.* at 37–39 (focusing on mAb 6-2 when describing the scope of the '132 Publication).

To the extent the Petition refers to antibodies "like mAb 6-2" (*see* Pet. 38; Tr. 50:6–51:10), it does so as background for its argument that the '132 Publication teaches how to make, screen, and test mAb 6-2:

> In addition to disclosing the 6-2 antibody, the '132 Publication also discloses how the 6-2 antibody was made, screened, and tested. This includes: (1) disclosure of the generation of transgenic mice in Example 3; (2) disclosure of how to generate and screen for anti-hIL-4R mAbs like mAb 6-2 from transgenic mice as shown in Examples 1 and 4; and (3) disclosure of how to assay generated antibodies like mAb 6-2 for IL-4 and IL-13 blocking activity as described in Example 5.

Pet. 38 (citations omitted). Thus, we are not persuaded that the Petition relies on antibodies "like mAb 6-2" for its argument that the '132 Publication anticipates the claims. Rather, the Petition relies solely on the '132 Publication's disclosure of mAb 6-2 for anticipation. Indeed, counsel for Petitioner admitted as much during the oral hearing:

> JUDGE HULSE: [C]an you point us to something in the actual analysis of the grounds, where you were relying on something other than [mAb] 6-2?
>
> MR. GARVISH: No, Your Honor, because we didn't need to. Our argument was mAb 6-2, and the inherency that was related to mAb 6-2. Our petition is broader than that, it includes the 27 relied-upon paragraphs, and it includes monoclonal antibodies like 6-2 as described in the petition.
>
> JUDGE HULSE: As described in the background section of the petition, right. But you[r] argument itself relies on mAb 6-2?
>
> MR. GARVISH: That's correct, Your Honor.

Tr. 51:24–52:9.

Thus, when considering whether the "relied-upon portions" of the '132 Publication are the work of another, we focus—as Petitioner has—on the disclosure of mAb 6-2.

ii. Whether the '132 Publication's Disclosure of mAb 6-2 Represents the Work of Another

To satisfy its burden of production to show the '132 Publication's disclosure of mAb 6-2 is not the work of another, Patent Owner submits declarations from the '487 patent inventors, declarations from two corroborating witnesses who worked with the inventors, and various contemporaneous meeting minutes. *See* PO Resp. 11–12. Relying on this evidence, Patent Owner asserts that the portions of the '132 Publication disclosing mAb 6-2 represent solely the work of the '487 patent inventors. *Id.* at 16–30. Moreover, Patent Owner submits the disclaimer declaration of John D. Pluenneke—the named inventor identified on the '132 Publication— and asserts that he is not the inventor of mAb 6-2.[6] *Id.* at 13–16.

Each of the '487 inventors testifies that they worked together in the late 1990s to co-chair the Therapeutic Antibodies Group at Immunex. Ex. 2006 ¶ 9 (Escobar); Ex. 2007 ¶ 9 (Armitage); Ex. 2008 ¶ 9 (Morris). The purpose of the Group was to "develop antibodies directed against IL-4 receptor (IL-4R) capable of (i) blocking IL-4 binding to IL-4R and (ii) blocking IL-4-mediated and IL-13-mediated signaling." Ex. 2006 ¶ 9; Ex. 2007 ¶ 9; Ex. 2008 ¶ 9.

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[6] We are cognizant of the testimony of Patent Owner's expert, Stephen Kunin, said to be "an expert in U.S. patent practice and procedure." PO Resp. 3, Ex 2038. This panel, however, chooses not to address Mr. Kunin's testimony, as we need not reach it for purposes of this Decision. *See also* 37 C.F.R. § 42.65(a).

The ’487 patent inventors testify that the relied-upon portions of the ’132 Publication reflect the joint work of the ’487 patent inventors. Ex. 2006 ¶¶ 13–17; Ex. 2007 ¶¶ 13–17; Ex. 2008 ¶¶ 13–17. In particular, the inventors testify that they prepared a hybridoma called “fusion 6” and a hybridoma cell line called “6-2.” Ex. 2006 ¶ 15; Ex. 2007 ¶ 15; Ex. 2008 ¶ 15. The cell line secreted an anti-IL-4R antibody called 6-2 that was tested to show it blocks IL-4 from binding to IL-4R and blocks both IL-4 and IL-13 induced biological activity. Ex. 2006 ¶ 15; Ex. 2007 ¶ 15; Ex. 2008 ¶ 15.

To corroborate the inventors’ testimony, Patent Owner submitted contemporaneous meeting minutes that the inventors prepared after monthly group meetings. *See, e.g.*, Ex. 2013, 1 ¶ 3 (public summary of Ex. 2013 at Ex. 2018); Ex. 2014, 1 ¶¶ 2, 4, 5 (public summary of Ex. 2014 at Ex. 2019); Ex. 2016, 3 ¶ 2 (public summary of Ex. 2016 at Ex. 2021). Patent Owner also submitted the testimony of research associates Norman Boiani and Teri Aldrich, who worked in Mr. Escobar and Dr. Morris’s laboratories, respectively. Ex. 2009 ¶ 3; Ex. 2006 ¶ 9; Ex. 2010 ¶ 8; Ex. 2008 ¶ 9. Mr. Boiani and Dr. Aldrich testify that they worked under the inventors’ supervision and carried out experiments relating to mAb 6-2 under the inventors’ direction and control. Ex. 2008 ¶ 9; Ex. 2009 ¶ 9.

As further support, Patent Owner submits the testimony of Mr. Pluenneke, who testifies that the relied-upon portions of the ’132 Publication, including the disclosure of mAb 6-2, do not reflect his work. Ex. 2011 ¶ 8. He testifies that he “did not work on making anti IL-4R antibodies” and “did not work together with [the ’487 patent inventors] to make hybridoma 6-2 or antibody 6-2.” *Id.* Mr. Pluenneke testifies that he did not contribute to the conception of hybridoma 6-2 or mAb 6-2. Ex. 2032

¶ 9. Rather, Mr. Pluenneke testifies that he invented what is claimed in the '132 Publication (i.e., a method for treating septic arthritis by administering an IL-4 antagonist). Ex. 2011 ¶ 8; Ex. 2032 ¶ 8; Ex. 1016, 25.

Having considered the evidence presented by Patent Owner, we find Patent Owner has satisfied its burden of production to show the '132 Publication is not § 102(e) prior art. We find the testimony of the '487 patent inventors—as corroborated by the declarations of Mr. Boiani and Dr. Aldrich, the contemporaneous meeting minutes, and the disclaimer declaration of Mr. Pluenneke—to be persuasive evidence that the relied-upon portions of the '132 Publication represent the work of the '487 patent inventors. *See In re Mathews*, 408 F.2d 1393, 1396 (CCPA 1969) (finding applicant's declaration and prior art inventor's disclaimer declaration sufficient to overcome § 102(e) rejection).

The burden now shifts back to Petitioner to rebut Patent Owner's evidence and show the '132 Publication qualifies as § 102(e) prior art. In response, Petitioner challenges the sufficiency of Patent Owner's evidence and asserts that Mr. Boiani was a necessary contributor of mAb 6-2, thereby making the '132 Publication's disclosure "by another." Reply 2–3. We are not persuaded by Petitioner's arguments.

Regarding the sufficiency of the evidence, Petitioner argues the testimony of Patent Owner's declarants is conclusory and lacks corroboration by contemporaneous documentary evidence. Reply 8. Petitioner argues the declarants lack credibility because they contradicted each other and their sworn declarations. Reply 10. For example, Petitioner argues that the inventors testified in their declarations that the relied-upon portions of the '132 Publication (including Example 3) represent the collective work of the inventors, and yet the inventors testified during cross-

examination that Example 3 was not their work. *Id.* (citing Ex. 1234, 174:22–175:2; Ex. 1232, 126:5–16, 136:17–137:1); Sur-surreply 2–5 (citing Ex. 1233, 102:3–15; Ex. 1234, 174:22–175:2; Ex. 1235, 198:18–23). Example 3 teaches the generation of transgenic mice, which the '487 patent inventors testified they obtained from third-party Medarex. Ex. 1016 ¶¶ 232–236; Ex. 2006 ¶ 13; Ex. 2007 ¶ 13; Ex. 2008 ¶ 13. Petitioner also notes that much of Example 3 in the '132 Publication (Ex. 1016 ¶¶ 232–236) was copied verbatim from U.S. Patent No. 6,984,720 (Ex. 1240), which is a prior art patent to Medarex. Sur-surreply 3–4; *see also* Reply 15.

In response, Patent Owner asserts that the witnesses testified consistently that, "to the extent the relied-upon portions of the '132 publication relate to mAb 6-2, those portions reflect the work of the '487 patent inventors." Surreply 5 (citing Ex. 1233, 134:20–135:5; Ex. 1234, 182:15–183:13; Ex. 1235, 194:21–195:1; Ex. 1236, 171:1–6). Patent Owner argues that Petitioner has taken the witnesses' testimony out of context and that the allegedly anticipatory subject matter in the '132 Publication is mAb 6-2 and not transgenic mice or some other research tool. *Id.* at 6–7.

We agree with Patent Owner that that testimony must be taken in the context of the Petition and the rest of the witnesses' testimony. As explained above, we find the Petition relies on the '132 Publication's disclosure of mAb 6-2 for purposes of anticipation. The Petition relies on the remaining portions of the '132 Publication, such as the disclosure of transgenic mice in Example 3, for background or to show the '132 Publication is enabled. For example, the Petition cites Example 3 to show "the '132 Publication also discloses how the 6-2 antibody was made, screened, and tested." Pet. 38 (citing Ex. 1016 ¶¶ 232–236); *see also id.* at 41–42.

When asked during cross-examination, the inventors testified that they did not invent transgenic mice. *See*, *e.g.*, Ex. 1234, 174:22–175:2. Dr. Morris clarified, however, that "[t]o the extent that we contracted with Medarex to use transgenic mice to make human antibodies, that would be – that was work we did using these tools that Medarex had developed." Ex. 1235, 198:18–199:4. In other words, according to the inventors, they did not invent the Medarex mice, but they used Medarex mice to make the claimed invention. Although we agree the declarations are somewhat vague, we find Dr. Morris's explanation to be credible, as the inventors testified consistently that mAb 6-2, which they generated using Medarex mice, was a product of their collaborative work. *See* Ex. 1233, 134:20–135:5; Ex. 1234, 182:15–183:13; Ex. 1235, 194:21–195:1; Ex. 1236, 171:1–6.

Similarly, Petitioner argues that Mr. Pluenneke's disclaimer testimony lacks credibility because of his inconsistent testimony regarding who invented hybridoma 6-2. Sur-surreply 5–6. Specifically, Mr. Pluenneke is listed as an inventor along with Carl March and Larry O'Neal on the March Application. Ex. 1202.[7] The March Application includes a description of hybridoma 6-2 that is similar to the description in Example 6 of the '132 Publication. *Compare* Ex. 1202 ¶¶ 219–220, *with* Ex. 1016 ¶¶ 246–247. Petitioner argues that Mr. Pluenneke testified during cross-examination that "(1) the March Application was the *sole work* of *the inventors listed thereon*— Pluenneke, March, and O'Neal; and (2) he was not aware of any other individuals who contributed to it." Sur-surreply 5.

[7] Carl J. March, John D. Pluenneke, and Larry F. O'Neal, US 2002/0076409 A1, published Jun. 20, 2002 ("March Application," Ex. 1202).

We are not persuaded that Mr. Pluenneke's testimony lacks credibility. Regarding the inventorship of the March Application, Petitioner again takes the witness's testimony out of context. Counsel for Petitioner questioned Mr. Pluenneke about the inventor declaration he signed for the March Application, which states Mr. Pluenneke believes he is a joint inventor "of the subject matter which is claimed and for which a patent is sought on the invention entitled Methods for Treating Cancer." Ex. 1237, 58:12–21 (referring to Ex. 1219). Mr. Pluenneke then testified that his invention was to a "method for treating cancer involving administering an IL-4 antagonist . . . [w]ithin a specific claim in the back. And under the claims is what I invented. Which of those are specifically mine, I cannot state." *Id.* at 61:3–9. Counsel then asked whether Mr. Pluenneke invented various claims of the March application, to which Mr. Pluenneke testified that he could not remember. *Id.* at 61:10–63:9. Finally, counsel asked, "Is there anything in this application that wasn't invented by Carl March, John Pluenneke, or Larry O'Neal?" *Id.* at 63:10–12. Mr. Pluenneke responded, "Not to my knowledge." *Id.* at 63:15. Considering the testimony as a whole—and the fact that counsel did not ask specifically about Example 6 and hybridoma 6-2—we are not persuaded that Mr. Pluenneke necessarily understood the question to include the entire specification of the March Application. Rather, in light of the line of questioning, it is reasonable for Mr. Pluenneke to have understood counsel for Petitioner to be asking about who invented the subject matter of the March Application claims.

Petitioner also argues Mr. Pluenneke "cannot credibly credit the '487 patent inventors with anything" because he did not work with them and did not even know who they were. Sur-surreply 6–7. But Mr. Pluenneke did not specifically attribute the relied-upon portions of the '132 Publication to

the work of the ’487 patent inventors. Rather, he testified that those portions “do not reflect my work” and that he “did not work on making anti IL-4R antibodies” or work together with the ’487 patent inventors. Ex. 2011 ¶ 8. Thus, he properly testified based on his own personal knowledge of what he worked on himself and with whom. Contrary to Petitioner’s assertion, he did not testify regarding what the ’487 patent inventors invented.

Petitioner also argues the meeting minutes fail to provide the necessary details to corroborate Patent Owner’s assertions, such as whether mAb 6-2 is the invention solely of the named inventors and whether the work on mAb 6-2 was done under the direction and control of the named inventors. Reply 9. Petitioner also questions the accuracy of the minutes, asserting that they were not prepared contemporaneously, as some are dated months after the meeting occurred. *Id.* (citing Ex. 2012).

Corroboration is determined by a rule of reason analysis where “an evaluation of all pertinent evidence must be made so that a sound determination of the credibility of the inventor’s story may be reached.” *NFC Tech., LLC v. Matal*, 871 F.3d 1367, 1372 (Fed. Cir. 2017) (quoting *Singh v. Brake*, 317 F.3d 1334, 1341 (Fed. Cir. 2003)). Under the rule of reason, the evidence is considered as a whole and not individually. *Id.*

Applying the rule of reason, we find the meeting minutes to be sufficient for corroboration purposes, particularly in light of the accompanying testimony of Mr. Boiani and Dr. Aldrich. Even if the minutes alone did not contain the level of details sought by Petitioner, no one single piece of evidence needs to establish a particular fact. *See id.* (“[A]n inventor’s conception can be corroborated even though ‘no one piece of evidence in and of itself’ establishes that fact, and even through circumstantial evidence.” (citations omitted)).

We find the meeting minutes together with the testimony of Mr. Boiani and Dr. Aldrich sufficient to corroborate the inventors' testimony that mAb 6-2 was the collaborative product of the inventors' work. The meeting minutes from "Meeting B," where Mr. Escobar, Mr. Boiani, and Dr. Armitage gave presentations, demonstrate that the antibody produced by hybridoma 6-2 blocked IL-4 binding to IL-4R and IL-13 and IL-4 activity mediated through IL-4R. Ex. 2018 (summarizing Ex. 2013, 1 ¶¶ 3, 5). The meeting minutes from "Meeting C," where the '487 patent inventors, Mr. Boiani, and Dr. Aldrich gave presentations, demonstrate that an IgM antibody designated "6-2" showed binding activity to IL-4R and IL-4R-blocking activity. Ex. 2019 (summarizing Ex. 2014, 1 ¶ 2). Mr. Boiani testifies that the meeting minutes reflect their work on mAb 6-2, and that he "conducted isotyping experiments to determine the isotype of the 6-2 antibody." Ex. 2009 ¶¶ 15–18. He also testifies that he sent the hybridoma cell line 6-2 to Dr. Aldrich, who, under the direction of Dr. Morris, used it to produce an IgG1 form of the 6-2 antibody. *Id.* ¶ 19 (citing Ex. 2014, 1 ¶ 5; Ex. 2019); *see also* Ex. 2010 ¶ 17. Taken as a whole, we find Patent Owner's evidence sufficient to corroborate the inventors' testimony that mAb 6-2 was the product of their collective work.

As for Petitioner's assertion that there was a delay in preparing the meeting minutes, Mr. Escobar explained that the meeting minutes were typically written up on a rotating basis by the '487 patent inventors "within a week or so." Ex. 1234, 168:11–24. He also explained that the printout and signing of the minutes (such as that identified by Petitioner in Ex. 2012) "may have been not always timely," "[b]ut the minutes themselves were written up in a very timely fashion." *Id.* at 169:16–170:6. In light of the high level of detail provided in the meeting minutes (which might not be

expected if there were a lengthy delay in the write-up), we find credible Mr. Escobar's testimony that they prepared the minutes in a timely fashion.

Petitioner also argues that the relevant inquiry is whether the relied-upon portions of the '132 Publication "were conceived solely by the named inventors." Reply 1 (citing *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 969 (Fed. Cir. 2014)). Petitioner then argues that the '487 patent inventors were not the "sole contributors" of mAb 6-2 and that Norman Boiani "conceived MAb6-2 and other antibodies disclosed in the '132 Publication." *Id.* at 2–3.

According to Petitioner, Mr. Boiani created and isolated mAb 6-2 and is a necessary contributor to the '487 patent claims. Reply 17–18. Petitioner argues that although Patent Owner asserts that the named inventors directed or controlled Mr. Boiani's work, that is insufficient "to vest inventorship in a supervisor." *Id.* at 18. Petitioner argues that before the work of another can inure to the benefit of an inventor, the inventor must establish prior conception. *Id.* Because Patent Owner cannot show prior conception of mAb 6-2 by the inventors, Petitioner argues Patent Owner cannot attribute Mr. Boiani's work to the inventors. *Id.*

As Patent Owner notes, however, Patent Owner is not "swearing behind" the '132 Publication to show the '132 Publication is not § 102(e) prior art. Surreply 7. Rather, Patent Owner contends that the '132 Publication's disclosure of mAb 6-2 "represent[s] the work" of the '487 patent inventors. *See EmeraChem Holdings*, 859 F.3d at 1345.

Having considered the full trial record, we are not persuaded that Mr. Boiani's work on mAb 6-2 elevates him to the level of joint inventor, as Petitioner asserts. As explained above, the testimony of the inventors, as corroborated by the meeting minutes and the testimony of Mr. Boiani and Dr. Aldrich, establishes that Mr. Boiani conducted experiments and testing

on the 6-2 hybridoma cell line to produce mAb 6-2 at the direction and control of Mr. Escobar. *See, e.g.*, Ex. 2006 ¶¶ 15–17; Ex. 2009 ¶¶ 3, 14–19; *see also supra*. Mr. Boiani testified that Mr. Escobar had ideas and would tell him to do work for him because he was his boss. Ex. 1232, 171:15–24. Although Mr. Boiani had some level of discretion to perform his work, Mr. Boiani testified that he conducted his work according to "standard policy" and used "established protocols with [Mr. Escobar's] overall guidance." *Id.* at 172:3–174:8. Tellingly, Mr. Boiani characterized himself as "a pair of hands for [the inventors'] thoughts." Ex. 1232, 177:2–8; *see also* Ex. 2009 ¶¶ 3, 7.

In light of that evidence, we view Mr. Boiani as a technician for carrying out Mr. Escobar's instructions, and not a joint inventor. *See Mattor v. Coolegem*, 530 F.2d 1391, 1395 (CCPA 1976). There is no evidence in the record to show Mr. Boiani was involved in conceiving the claimed invention. On the contrary, the evidence presented demonstrates that Mr. Boiani conducted routine experiments to create mAb 6-2 at the direction of Mr. Escobar according to known techniques. *See Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613, 624 (Fed. Cir. 1985) ("An inventor 'may use the services, ideas, and aid of others in the process of perfecting his invention without losing his right to a patent.'" (citation omitted)).

Petitioner argues that Mr. Boiani had to have conceived mAb 6-2 because it is insufficient to define a chemical compound "solely by its principal biological property . . . because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property." Reply 20 (quoting *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991)); *see also* Sur-

surreply 9. The facts of *Amgen*, however, are distinguishable from the instant case. In *Amgen*, the claims recited a "purified and isolated DNA sequence" encoding human erythropoietin. 927 F.2d at 1206. At the time of the invention, however, the amino acid sequence for erythropoietin was unknown and there was no viable method to obtain the claimed subject matter until it was actually obtained and characterized. *Id.*

Here, Petitioner has not shown that there was similar uncertainty in the art at the time of the invention. The '487 patent claims an isolated human antibody that competes with a reference antibody for binding to IL-4R, where the reference antibody has a *known*, specific amino acid sequence. Ex. 1001, 77:25–78:49 (claims). The '487 patent inventors conceived of the claimed invention and specifically directed the research associates like Mr. Boiani on methods to make such antibodies. *See* Ex. 2008 ¶ 9; Ex. 2009 ¶ 9. Mr. Boiani then followed that direction and, using standard techniques, prepared mAB 6-2. Ex. 1232, 171:15–177:8. Ultimately, we find that to be consistent with the work of a laboratory technician, and not the work of a joint inventor.

Based on the arguments and evidence presented during trial, we determine that Petitioner has not satisfied its burden to prove the portions of the '132 Publication relied upon for anticipation (i.e., mAb 6-2) represent the work of another to qualify as prior art under § 102(e).

Accordingly, we find that Petitioner has not established by a preponderance of the evidence that any challenged claim of the '487 patent is unpatentable as anticipated by the '132 Publication.

III. MOTIONS TO EXCLUDE

The party moving to exclude evidence bears the burden of proving that it is entitled to the relief requested—namely, that the material sought to be excluded is inadmissible under the Federal Rules of Evidence ("FRE"). *See* 37 C.F.R. §§ 42.20(c), 42.62(a).

Petitioner filed a Motion to Exclude the testimony of Stephen G. Kunin. Paper 65. Patent Owner relies on the testimony of Mr. Kunin as an expert in U.S. patent practice and procedure and offered his opinion regarding whether Patent Owner's evidence is sufficient to show the '132 Publication is prior art to the '487 patent. PO Resp. 3; Ex. 2038. We do not rely on Mr. Kunin's testimony in rendering this Decision. Accordingly, we dismiss Petitioner's Motion to Exclude as moot.

Patent Owner filed a Motion to Exclude portions of testimony from Exhibits 1200 (Zurawski Decl.), 1232 (Boiani Dep.), 1233 (Armitage Dep.), 1234 (Escobar Dep.), 1235 (Morris Dep.), 1237 (Pluenneke Dep.), 1239 (Zurawski Rebuttal Decl.), and 2102 (Zurawski Dep.). Paper 60, 3–10, 13–15. Patent Owner also moves to exclude the entirety of Exhibits 1432 (Defendant's Invalidity Contentions) and 1455 (MAB 230 Data Sheet). *Id.* at 10–13. We do not rely on any of the challenged evidence for purposes of rendering this Decision. Accordingly, we dismiss Patent Owner's Motion to Exclude as moot.

IV. CONCLUSION

For the foregoing reasons, we conclude that Petitioner has not established by a preponderance of the evidence that claims 1–14, 16, and 17 of the '487 patent are unpatentable as anticipated by the '132 Publication.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–14, 16, and 17 of the ’487 patent are not held unpatentable as anticipated by the ’132 Publication;

FURTHER ORDERED that Petitioner’s Motion to Exclude is *dismissed as moot*;

FURTHER ORDERED that Patent Owner’s Motion to Exclude is *dismissed as moot*; and

FURTHER ORDERED that, because this is a Final Written Decision, the parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirement of 37 C.F.R. § 90.2.

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