Trials@uspto.gov
571-272-7822

Paper 12
Entered: October 6, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CELLTRION, INC.,
Petitioner,

v.

BIOGEN, INC.,
Patent Owner.

Case IPR2017-01095
Patent 9,296,821 B2

Before ERICA A. FRANKLIN, SHERIDAN K. SNEDDEN, and JACQUELINE T. HARLOW, *Administrative Patent Judges.*

FRANKLIN, *Administrative Patent Judge.*

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Celltrion, Inc. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–6 of U.S. Patent No. 9,296,821 B2 (Ex. 1001, "the '821 patent"). Paper 2 ("Pet."). Biogen, Inc. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 10 ("Prelim. Resp.").

We have authority under 35 U.S.C. § 314 to determine whether to institute an *inter partes* review. 35 U.S.C. § 314(b); *see also* 37 C.F.R. § 42.4(a). Upon considering the Petition and the Preliminary Response, we determine that Petitioner has shown a reasonable likelihood that it would prevail in showing the unpatentability of claims 1–3, 5, and 6. Accordingly, we institute an *inter partes* review with respect to those claims.

A. Related Proceedings

Petitioner and Patent Owner explain that they are not aware of any other pending proceedings involving the '821 patent. Pet. 4; Paper 6, 2. Petitioner has filed also petitions for *inter parties* review involving related U.S. Patent Nos. 8,329,172 B2 (IPR2017-01093) and 8,557,244 B1 (IPR2017-01094).

B. The '821 Patent

The '821 patent relates to methods of treating B-cell lymphomas, including low grade or follicular non-Hodgkin's lymphoma ("NHL"), by administering chimeric anti-CD20 antibodies in combination with chemotherapy, e.g., cyclophosphamide, vincristine, and prednisone ("CVP therapy"). Ex. 1001, 2:21–31, 4:24–26, 23:60–67 (claim 1). According to the Specification, "it has been found that treatment with anti-CD20 antibody provides a beneficial synergistic effect when administered in combination

with . . . chemotherapy." *Id*. at 2:24–28. A "preferred chimeric [anti-CD20] antibody is C2B8 (IDEC Pharmaceuticals, Rituximab)." *Id*. at 3:3–5.

C. Illustrative Claims

Each challenged claim is an independent claim. Claims 1 and 3 are illustrative and are reproduced below:

> 1. A method for treating low grade or follicular non-Hodgkin's lymphoma (NHL) comprising administering to a patient a therapeutically effective amount of rituximab during a chemotherapeutic regimen, wherein the chemotherapeutic regimen consists of cyclophosphamide, vincristine, and prednisone (CVP therapy), wherein the method comprises administering 375 mg/m^2 of rituximab, and wherein the method provides a beneficial synergistic effect in the patient.
>
> 3. A method for treating low grade or follicular non-Hodgkin's lymphoma (NHL) comprising administering to a patient 375 mg/m^2 of a chimeric anti-CD20 antibody during a chemotherapeutic regimen consisting of cyclophosphamide, vincristine, and prednisone (CVP therapy), wherein the chimeric anti-CD20 antibody is produced from nucleic acid encoding a light chain variable region comprising the amino acid sequence in SEQ ID NO: 1 and a heavy chain variable region comprising the amino acid sequence in SEQ ID NO: 2, and comprises human gamma 1 heavy-chain and kappa light-chain constant region sequences.

D. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–6 of the '821 patent on the following grounds:

Claims	Basis	References
1–6	Pre-AIA § 102	Marcus[1]
3 and 6	Pre-AIA § 103	Marcus and the '137 Patent[2]
1–3	Pre-AIA § 103	Czuczman,[3] IDEC 10-K/A,[4] Foon[5] and Dana[6]
4–6	Pre-AIA § 103	Czuczman, IDEC 10-K/A, Foon, Dana, Link,[7] and Piro[8]
3 and 6	Pre-AIA § 103	Czuczman, IDEC 10-K/A, Foon, Dana, Link, Piro, and the '137 Patent

[1] Marcus et al., *CVP chemotherapy plus rituximab compare with CVP as first-line treatment for advanced follicular lymphoma*, 105 BLOOD 1417–23 (2005) (Ex. 1005).
[2] U.S. Patent 5,736,137 issued to Anderson et al. on Apr. 7, 1998. (Ex. 1007).
[3] Czuczman et al., *IDEC-C2B8 and CHOP Chemoimmunotherapy of Low-Grade Lymphoma*, 86 BLOOD 10 Supp. 1:55a (Abstract 206) (1995) (Ex. 1011).
[4] IDEC Pharmaceuticals Corp., Form 10-K/A Annual Report for the Fiscal Year Ended Dec. 31, 1997, filed with the U.S. Securities and Exchange Comm. (Ex. 1006).
[5] Foon et al., Chapter 111: *Lymphomas*, Williams Hematology, 5th Ed. 1076–96 (1990) (Ex. 1008).
[6] Dana et al., *Long-Term Follow-Up of Patients with Low-Grade Malignant Lymphomas Treated with Doxorubicin-Based Chemotherapy or Chemoimmnotherapy*, 11 J. CLIN. ONCOL. 644–51 (1993) (Ex. 1009).
[7] Link et al., *Phase II Pilot Study of the Safety and Efficacy of Rituximab in Combination with CHOP Chemotherapy in Patients with Previously Untreated Intermediate- or High-Grade NHL, Program/Proceedings*, 17 AM. SOC. CLIN. ONCOL. 3a (Abstract 7) (1998) (Ex. 1010).
[8] Piro et al., *RITUXAN™ (rituximab, IDEC-C2B8): Interim analysis of a phase II study of once weekly times 8 dosing in patients with relapsed low-grade or follicular non-Hodgkin's lymphoma,* 90 BLOOD 10 Supp. 1:510a (Abstract 2272) (1997) (Ex. 1004).

Petitioner also relies upon the Declarations of Izidore Lossos, M.D. (Ex. 1002) and Walter Longo, M.D. (Ex. 1003).

II. ANALYSIS

A. 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); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016) (affirming applicability of broadest reasonable construction standard to *inter partes* review proceedings). Under that standard, and absent any special definitions, we 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. *In re Translogic Tech., Inc*., 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definitions for claim terms must be set forth with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

"beneficial synergistic effect"

Petitioner and Patent Owner propose constructions for the claim phrase "beneficial synergistic effect," recited by claims 1 and 4. Pet. 30–31; Prelim. Resp. 9–14. Petitioner asserts that the broadest reasonable construction of the claim phrase is "an improvement in clinical outcome." Pet. 31. Petitioner supports that proposed construction by referring to (a) the Specification description that "it has been found that treatment with anti-CD20 antibody provides a beneficial synergistic effect when administered in combination with cytokines, radiotherapy, myeloablative therapy, or chemotherapy," Ex. 1001, 2:24–28, and (b) a description in Applicant's

Supplemental Information Disclosure Statement that "[p]atients treated with R-CVP experienced median progression free survival (PFS) of 2.4 years compared with 1.4 years in patients treated with CVP only, demonstrating a beneficial synergistic effect in the patient." Ex. 1069, 120.[9] Petitioner has not explained, nor do we see, how those statements support its proposed construction.

Patent Owner asserts that Petitioner's proposed construction ignores the term "synergistic" by asserting that the claim phrase "beneficial synergistic effect" requires only some improvement in clinical response. Prelim. Resp. 12. According to Patent Owner the broadest reasonable construction should be "an effect better than the additive effects of rituximab and CVP administered alone." *Id*. at 10. Patent Owner supports its proposed construction by referring to the Specification description of the term "synergistic" in the context of a cytokine embodiment comprising administering a synergistic therapeutic combination by explaining that the "therapeutic effect" is "better than the additive effects of either therapy administered alone." *Id*. at 10–11 (quoting Ex. 1001, 3:45–47).

Patent Owner also demonstrates how the prosecution history supports its proposed construction. *Id*. at 11. For example, Patent Owner refers to a statement in an "Amendment and Reply" in response to an Office Action during the prosecution of the '821 patent's parent application, Application No. 11/840,956, that "[t]he complete responses (CRs) and extended median TTP achieved with the presently claimed combination [R-CVP] were more

[9] File history of the '821 patent (Application No. 13/524,896) (Ex. 1069).

than additive, *i.e.*, they were synergistic results." *Id*. (footnote omitted) (quoting Ex. 2006, 14–15).[10]

We agree with Patent Owner that Petitioner's proposed construction does not recognize the term "synergistic" in the claim phrase. In light of the Specification description of the term "synergy," we determine at this stage in the proceeding that the broadest reasonable construction of the claim phrase "beneficial synergistic effect" is "a clinical outcome resulting from combination therapy that reflects a greater beneficial effect than the additive effects of the uncombined therapies when administered alone."

In view of our analysis, we determine that construction of additional claim terms is not necessary for purpose of this Decision. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (only terms that are in controversy need to be construed, and only to the extent necessary to resolve the controversy).

B. Level of Ordinary Skill in the Art

The level of skill in the art is a factual determination that provides a primary guarantee of objectivity in an obviousness analysis. *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 1324 (Fed. Cir. 1999) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966); *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991)).

According to Petitioner, a person of ordinary skill in the art at the time of the invention would have been "a practicing physician specializing in hematology or oncology, with at least three years of experience in treating

[10] Amendment and Reply under 35 C.F.R. § 1.111 filed Aug. 25, 2010, in Application No. 11/840,956 (Ex. 2006).

patients with NHL." Pet. 31–32 (citing Ex. 1002 ¶ 24). Patent Owner does not address Petitioner's position on this matter and does not propose its own description for a person of ordinary skill in the art at the time of the invention.

At this stage in the proceeding, we determine that Petitioner's description of the level of ordinary skill in the art is supported by the current record. Moreover, we have reviewed the credentials of Dr. Lossos (Ex. 1002) and, at this stage in the proceeding, we consider him to be qualified to provide his opinion on the level of skill and the knowledge of a person of ordinary skill in the art at the time of the invention.[11] We also note that the applied prior art reflects the appropriate level of skill at the time of the claimed invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

C. The '821 Patent Priority Date

The '821 patent issued from U.S. Application No. 13/524,896 ("the '896 application") filed on June 15, 2012. Exs. 1001 and 1069. The '896 application is a divisional of U.S. Application No. 11/840,956, which is a continuation of U.S. Application No. 10/196,732, which is in turn a continuation of U.S. Application No. 09/372,202 ("the '202 application") filed on August 11, 1999. Exs. 1001, 1034, 2003, 2004, and 2005.

Petitioner asserts that none of the claims of the '821 patent are entitled to a priority date earlier than June 15, 2012, because each of those claims

---

[11] Petitioner does not rely Dr. Longo's testimony (Ex. 1003) to support its unpatentability contentions. *See, e.g.*, Pet. 17 (referring to Ex. 1003 as support for the public availability of the E1496 Protocol and Consent Form-a reference not included in any unpatentability ground).

lacks written description support in the specification of the '202 application. Pet. 18–30. Patent Owner disagrees, asserting that the disclosures of the '202 application demonstrate that the inventor had possession of the inventions set forth in the claims of the '821 patent. Prelim Resp. 8, 15–34. For the reasons that follow, based on the current record, we determine that Petitioner has shown persuasively that claims 4–6 are not supported by the disclosures of the '202 application. As for claims 1–3, we agree with Patent Owner that the '202 application provides written description support for those claims.

"Patent claims are awarded priority on a claim-by-claim basis based on the disclosure in the priority applications." *Lucent Technologies, Inc. v. Gateway, Inc.*, 543 F.3d 710, 718 (Fed. Cir. 2008). To receive the benefit of a previous application, *every feature* recited in a particular claim at issue must be described in the prior application. *See In re Van Langenhoven*, 458 F.2d 132, 137 (CCPA 1972) ("The fact that *some* of the elements of the breech claims have the support of the parent and foreign applications does not change the result. *As to given claimed subject matter, only one effective date is applicable.*" (emphases added)); *accord In re Chu*, 66 F.3d 292, 297 (Fed. Cir. 1995). As the Federal Circuit has noted, however, "[i]n order to satisfy the written description requirement, the disclosure as originally filed does not have to provide *in haec verba* support for the claimed subject matter at issue." *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000). Rather, "the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing

date." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010).

Regarding claim 1, Petitioner asserts that "[t]he '202 application does not describe the combination of administering rituximab *during CVP* chemotherapy to treat low-grade or follicular lymphoma, where the method provides a beneficial synergistic effect." Pet. 20–21. Petitioner recognizes that each of those individual elements are described in the '202 application, but contends that such disclosures are "dispersed throughout the specification" and not combined in the manner recited by claim 1. *Id*. at 21–22. Petitioner's attempt to require the '202 application to provide *in haec verba* support for the claimed subject matter is not well taken. *See Purdue Pharma*, 230 F.3d at 1323; *see also Ariad*, 598 F.3d at 1352 (written description need not be in any particular form or an *in haec verba* recitation of the claimed invention).

Significantly, Petitioner acknowledges that: (a) original claim 17 in the '202 application recites "[a] method for treating B-cell lymphoma comprising administering to a patient a therapeutically effective amount of anti-CD20 antibody before, during or subsequent to a chemotherapeutic regimen," Pet. 22 (quoting Ex. 1034, 58); (b) original claim 29 depends from claim 17 and describes "low grade/follicular" NHL as a subtype of B-cell lymphoma that can be treated with the method of claim 17, *id*. at 23 (citing Ex. 1034, 61); (c) the disclosure of CVP as a chemotherapeutic regimen used in combination with rituximab (375 mg/m^2) to treat low-grade NHL, *id*. at 25–26 (citing Ex. 1034, 32), and (d) the disclosure that "treatment with anti-CD20 antibody provides a beneficial synergistic effect when administered in combination with . . . chemotherapy," *id*. at 26 (quoting Ex.

1034, 6). Based upon our review, those descriptions are not separate, unrelated disclosures. Rather, the disclosures in (b) and (c) provide exemplary descriptions for certain method elements recited in (a), i.e., the B-cell lymphoma can be low grade NHL, the chemotherapeutic regimen can be CVP therapy, and the rituximab dose can be 375 mg/m^2. In terms of administering the rituximab "during" a chemotherapeutic regimen, the disclosure in (a) expressly recites that option.

Moreover, the disclosure in (d) reasonably conveys to those of skill in the art that the inventors understood that such a method of combining chemotherapy and rituximab provides a beneficial synergistic effect. That description is not diminished because the disclosure "makes no specific reference to a beneficial, synergistic effect of administering rituximab *during CVP* therapy," as Petitioner asserts. Pet. 26. Indeed, the disclosure does not limit the type of chemotherapy that may be combined with rituximab to achieve such synergy, or exclude CVP as such a chemotherapy.

Based on at least the foregoing, we agree with Patent Owner that the '202 application provides written description support for claim 1. Petitioner does not address the additional limitations set forth in claims 2 and 3 with respect to its priority assertions. For purposes of this Decision, we are satisfied that claims 2 and 3 are also adequately described in the '202 application. Accordingly, for purposes of institution, we are not persuaded that claims 1–3 are not entitled to receive benefit of the '202 application filing date of August 11, 1999.

Regarding claims 4–6, Petitioner contends that the '202 application fails to describe administering rituximab "once every 3 weeks for 8 doses," as recited by those claims. Pet. 28; Ex. 1001, 25:13–15, 26:1–8. Patent

Owner does not identify any portion of the Specification describing administering rituximab once every three weeks for eight doses. Rather, Patent Owner identifies specification descriptions of a dosing regimen involving administering rituximab with chemotherapy every three weeks for *six* doses, and the disclosure of a study wherein patients received eight *weekly* doses of rituximab. Prelim. Resp. 33–34 (citing Ex. 1034, 26, 32, and 40). Although "it is unnecessary to spell out every detail of the invention in the specification," satisfying the written description requirement still demands that enough detail "must be included to convince a person of skill in the art that the inventor possessed the invention." *Falkner v. Inglis*, 448 F.3d 1357, 1366 (Fed. Cir. 2006) (citation omitted). Patent Owner has not provided evidence demonstrating that the claimed dosing regimen for rituximab once every three weeks for eight doses was in the possession of the inventors. Patent Owner's reference to Dr. Lossos' discussion regarding a clinical practice of using CVP for 6 to 8 cycles in a declaration supporting the Petition is unpersuasive, as that discussion relates to Dr. Lossos' opinion regarding dosing regimens that would have been obvious to a skilled artisan at the time of the invention. Prelim. Resp. 33 (citing Ex. 1002 ¶ 118). "One shows that one is 'in possession' of *the invention* by describing *the invention*, with all its claimed limitations, not that which makes it obvious." *Lockwood v. American Airlines*, 107 F.3d 1565, 1572 (Fed. Cir. 1997) (citing *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563–64 (Fed. Cir. 1991)).

Based on the foregoing, we agree with Petitioner that the '202 application does not provide written description support for claims 4–6. Accordingly, for purposes of institution, we are persuaded that claims 4–6

are not entitled to receive benefit of the '202 application filing date of August 11, 1999. As discussed in the following sections II. D and E, this determination affects Petitioner's two grounds including Marcus.

D. Anticipation by Marcus

Petitioner asserts that claims 1–6 are unpatentable as anticipated by Marcus. Pet. 38–44.

1. Marcus

Marcus is a journal article discussing a randomized trial comparing the effects of administering CVP chemotherapy alone and in combination with rituximab as a first-line treatment for advanced follicular lymphoma. Ex. 1005, Title. The combination therapy included a maximum of 8 cycles of CVP and rituximab, wherein each rituximab dose was 375 mg/m^2. *Id*. at 4. Based upon the trial results, Marcus explains that "adding rituximab to CVP chemotherapy in previously untreated patients with advanced follicular lymphoma results in a major improvement in all clinical endpoints," with minimal additional side effects. *Id*. at 7–8. According to Marcus, the combination therapy "significantly increased the duration of response, disease-free survival, and time to progression compared with that obtained in patients receiving CVP only." *Id*.

2. Analysis

Claims 1–3

As discussed above in section II. C., we have determined, based on the current record, that claims 1–3 are entitled to receive benefit of the '202 application filing date of August 11, 1999. Petitioner acknowledges that Marcus was published in February 2005 and does not contend that the reference was publicly available before the August 11, 1999 priority date

recognized for claims 1–3. Pet. 32. Thus, Petitioner has not established that Marcus is prior art to claims 1–3. Consequently, Petitioner has not shown a reasonable likelihood of prevailing in its challenge to claims 1–3 based upon Marcus. Accordingly, we decline to institute an *inter partes* review of claims 1–3 as anticipated by Marcus.

Claims 4–6

As discussed above in section II. C., we have determined, based on the current record, that claims 4–6 are not entitled to receive benefit of the '202 application filing date of August 11, 1999. For purposes of this Decision, those claims have a priority date of June 15, 2012, the filing date of the '896 application. Thus, Marcus (2005) is recognized as prior art to claims 4–6.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987).

Petitioner asserts that Marcus discloses each element of claims 4–6. Pet. 38–44. On the current record, we agree with Petitioner that Marcus teaches a method for treating follicular NHL comprising administering a therapeutically effective amount or rituximab during CVP therapy, wherein the method comprises administering 375 mg/m^2 of rituximab once every 3 weeks for 8 doses grade. *Id*. at 38 (citing Ex. 1005, 3–4; Ex. 1002 ¶ 95). – Furthermore, we agree with Petitioner that, on this record, those disclosures meet the limitations of independent claim 5, directed to administering "C2B8." Patent Owner recognizes that "C2B8" is a designation for

rituximab and does not raise any substantive arguments regarding anticipation of claim 5 by Marcus. Prelim. Resp. 14.

Thus, based on the information presented at this stage of the proceeding, Petitioner has shown sufficiently that there is a reasonable likelihood that it would prevail in showing the unpatentability of claim 5. Accordingly, we institute an *inter partes* review of claim 5 as anticipated by Marcus.

As for independent claim 4, an additional limitation recites "wherein the method provides a beneficial synergistic effect in the patient." Petitioner asserts that Marcus discloses this element by reporting that patients receiving CVP in combination with rituximab demonstrated "major improvement in all clinical endpoints." Pet. 38 (citing Ex. 1005, 7). In particular, Petitioner relies on Marcus' statement that "[a]t a median follow-up of 30 months, the addition of rituximab to a standard CVP regimen significantly lengthened time to treatment failure and more than doubled time to progression, with significantly improved response rates, duration of response, disease-free survival, and time to next antilymphoma treatment." *Id*. (quoting Ex. 1005, 7).

It is apparent that Petitioner's argument is based upon the proposed claim construction for "beneficial synergistic effect" to mean "an improvement in clinical outcome," which we have not adopted. *Id*. at 31. As discussed in section II.A., we have construed the claim term "beneficial synergistic effect," for purposes of this Decision, as "a clinical outcome resulting from combination therapy that reflects a greater beneficial effect than the additive effects of the uncombined therapies when administered alone." Because Petitioner has not addressed whether Marcus discloses a

method wherein the combination therapy provides a clinical outcome that reflects a greater beneficial effect than the additive effects of rituximab and CVP when administered alone, we are not persuaded that Petitioner has demonstrated a reasonable likelihood of prevailing in showing the unpatentability of claim 4 as anticipated by Marcus. Accordingly, we decline to institute an *inter partes* review of claim 4 as anticipated by Marcus.

As for independent claim 6, the method requires administering "a chimeric anti-CD20 antibody," wherein such antibody "is produced from nucleic acid encoding a light chain variable region comprising the amino acid sequence in SEQ ID NO: 1 and a heavy chain variable region comprising the amino acid sequence in SEQ ID NO: 2, and comprises human gamma 1 heavy-chain and kappa light-chain constant region sequences." Petitioner asserts that limitation "is a description of the C2B8 chimeric antibody, which the '821 patent states is the preferred chimeric antibody," Pet. 42–43 (citing Ex. 1001, 3:3–5), and that the amino acid sequences disclosed in SEQ ID NO: 1 and SEQ ID NO: 2 "merely identify and characterize rituximab," also known as C2B8, *id*. at 39–40. For those reasons, Petitioner asserts that Marcus discloses the invention of claim 6. *Id*. at 39–40.

Patent Owner acknowledges and does not challenge Petitioner's assertion that "'Marcus inherently discloses rituximab's amino acid sequence, as depicted in SEQ ID NO: 1 and SEQ ID NO: 2 of the '821 patent' by disclosing use of rituximab." Prelim. Resp. 44 (quoting Pet. 39). According to Patent Owner, Petitioner fails to establish that Marcus anticipates claim 6 because the claim "require[s] that 'the chimeric anti-

CD20 antibody is produced from nucleic acid encoding' such amino acid sequences," and Petitioner says "nothing whatsoever about how the anti-CD20 antibody of Marcus was produced." Prelim. Resp. 44–45 (quoting Ex. 1001, Claim 6). Patent Owner further asserts that Petitioner also fails to "contend—let alone offer evidence—that the only way to produce an anti-CD20 antibody was from nucleic acid." *Id*. at 45.

We recognize that claim 6 recites a chimeric anti-CD20 antibody "produced from nucleic acid." However, Patent Owner's argument that Petitioner failed to show Marcus satisfies that requirement because Petitioner did not describe how the anti-CD20 antibody of Marcus was produced or offer evidence that the only way to produce an anti-CD20 antibody was from nucleic acid misses the point. *See* Prelim. Resp. 45. Petitioner explains that Marcus discloses that claim element by teaching a method comprising administering rituximab. Pet. 38–39. Patent Owner does not dispute that rituximab is also referred to as "C2B8" or that the '821 patent discloses C2B8 as a preferred chimeric anti-CD20 antibody. Prelim. Resp. 14; Ex. 1001, 3:3–5. In other words, it is undisputed that Marcus teaches the use of rituximab, a known and preferred chimeric anti-CD20 antibody. As Petitioner explains, the description in claim 6 of the antibody "merely identif[ies] and characterize[s] rituximab." Pet. 40. Indeed, those characterizations include the amino acid sequences and the manner of production. Neither of those characterizations impart patentability to the claim. *See In re Crish*, 393 F.3d 1253, 1258–1259 (Fed. Cir. 2004) (identification and characterization of a prior art material in a claim do not render the claim directed to the known material patentable); *see also In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985) (product in a claim is

unpatentable if it is the same as the product of the prior art, even if the prior product was made by a different process). Ex. 1001, 3:3–5

Thus, based on the information presented at this stage of the proceeding, Petitioner has shown sufficiently that there is a reasonable likelihood that it would prevail in showing the unpatentability of claim 6 as anticipated by Marcus. Accordingly, we institute an *inter partes* review of claim 6 as anticipated by Marcus.

E. Obviousness over Marcus and the '137 Patent

Petitioner asserts that claims 3 and 6 would have been obvious over Marcus and the '137 Patent. Pet. 44–45.

1. The '137 Patent

The '137 patent issued on April 7, 1998, from an application that was filed on November 3, 1993. Ex. 1007. The '137 patent is directed to therapeutic treatment protocols for B cell lymphoma. Ex. 1007, Abstract. The patent characterizes rituximab and discloses the amino acid sequences of rituximab. *Id*. at Figures 4 and 5 (SEQ ID NO: 6 and SEQ ID NO: 9).

2. Analysis

Claim 3

As discussed above in sections II. C. and D., Petitioner has not established that Marcus is prior art to claim 3. Consequently, Petitioner has not shown a reasonable likelihood of prevailing in its challenge of claim 3 based upon Marcus. Accordingly, we decline to institute an *inter partes* review of claim 3 as obvious over Marcus and the '137 patent.

Claim 6

As discussed above in sections II. C. and D., for purposes of this Decision, Marcus is recognized as prior art to claim 6. Petitioner relies on

Marcus in the same manner discussed regarding the anticipation challenge of claim 6. Petitioner combines the '137 patent in the obviousness challenge for its disclosure of the amino acid sequence of rituximab. Pet. 44. Patent Owner asserts that Petitioner "again ignores completely the requirement that the chimeric anti-CD20 antibody of claims 3 and 6 'is produced from nucleic acid.'" Prelim. Resp. 45. Based on the current record, we disagree with Patent Owner for the same reasons discussed regarding the anticipation challenge of claim 6. Further, for the same reasons discussed for that challenge, we determine, based on the current record, that Petitioner has shown sufficiently that there is a reasonable likelihood that it would prevail in showing the unpatentability of claim 6 over Marcus and the '137 patent. Accordingly, we institute an *inter partes* review of claim 6 as obvious over Marcus and the '137 patent.

F. Prior Art Status of IDEC 10-K/A

The IDEC 10-K/A is an annual report filed with the U.S. Securities and Exchange Commission ("SEC") by IDEC Pharmaceuticals Corporation. Ex. 1006, 1. In the remaining three obviousness grounds, Petitioner asserts that the IDEC 10-K/A is a prior art printed publication. According to Petitioner, the IDEC 10-K/A was publicly available in the SEC's Electronic Data Gathering, Analysis, and Retrieval system ("EDGAR") by at least March 3, 1998. Pet. 33. Petitioner asserts that federal securities law requires that "the information contained in any registration statement, application, report, or other document filed with the Commission . . . shall be made available to the public . . . ." *Id*. at 15 n.6 (quoting 15 U.S.C. § 80a-44). Petitioner asserts further that "[t]he EDGAR Filing Details indicate that the IDEC 10-K/A was accepted and filed on March 3, 1998." *Id*. at 33 n.11

(citing Ex. 1056).[12] As additional support, Petitioner states that "[t]he EDGAR Filer Manual from September 1996 explains that the public portions of live filings, such as the IDEC 10-K/A, are 'immediately disseminated to the public.'" *Id*. (citing Ex. 1055, 20).[13]

Patent Owner contends that Petitioner has not established that the IDEC 10-K/A is a prior art printed publication. Prelim. Resp. 35. According to Patent Owner, at most, the EDGAR Filer Manual (Ex. 1055) and the EDGAR Filing Details (Ex. 1056) establish that the IDEC 10-K/A was filed with the SEC on March 3, 1998, but not that those documents were publicly accessible on that date, catalogued or indexed in a way that might establish public accessibility, or that a person of ordinary skill would have looked to such an SEC filing for guidance on how to treat NHL patients. Prelim. Resp. 36–41.

We agree with Patent Owner. Petitioner has not established adequately that the IDEC10-K/A is a prior art printed publication by referring to the EDGAR Filer Manual (Ex. 1055) and the EDGAR Filing Details (Ex. 1056). *See* 35 U.S.C. § 311(b) (patentability of a claim may be challenged "only on the basis of prior art consisting of patents or printed publications"); *see also* 35 U.S.C. § 102(b) ("A person shall be entitled to a patent unless . . . the invention was patented or described in a printed publication in this or a foreign country . . . more than one year prior to the

---

[12] IDEC Pharmaceuticals Filing Details, SEC Next Generation EDGAR System, https://www.sec.gov/Archives/edgar/data/875045/0000936392-98-00361-index.html. (Ex. 1056).

[13] U.S. Securities and Exchange Commission, EDGAR FILER MANUAL: Guide for Electronic Filing with the U.S. Securities and Exchange Commission (September 1996) (Ex. 1055).

date of the application for patent . . . ."). The Federal Circuit has held that "public accessibility" is "the touchstone" in determining whether a reference is a printed publication. *In re Hall*, 781 F.2d 897, 899 (Fed. Cir. 1986). "A given reference is 'publicly accessible' upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence, can locate it." *SRI Int'l, Inc. v. Internet Sec. Sys., Inc.*, 511 F.3d 1186, 1194 (Fed. Cir. 2008) (quoting *Bruckelmyer v. Ground Heaters, Inc.*, 445 F.3d 1374, 1378 (Fed. Cir. 2006)).

Petitioner does not identify, nor do we see, any indication in Exhibits 1006, 1055, and 1056, that the IDEC 10-K/A was available in a manner and to an extent that "persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence" would have been able to locate it. *Id*. Nor has Petitioner provided testimonial evidence demonstrating that publication of the IDEC 10-K/A was in such a manner. Petitioner has not explained that interested persons would have looked for the IDEC 10-K/A to gain information relating to NHL subject matter, would have known that the IDEC 10-K/A existed, or upon looking, would have been able to access the IDEC 10-K/A on March 3, 1998, exercising reasonable diligence.

Thus, based on the information presented, Petitioner has not shown that the IDEC 10-K/A is a prior art printed publication. Accordingly, we analyze Petitioner's remaining grounds without considering the IDEC 10-K/A as a prior art printed publication.

G. Obviousness over Czuczman, Foon, and Dana

Petitioner asserts that claims 1–3 would have been obvious over the Czuczman, IDEC 10-K/A, Foon, and Dana. Pet. 45–54. As Petitioner has

not shown that the IDEC 10-K/A is a prior art printed publication, we consider the obviousness challenge over Czuczman, Foon, and Dana.

1. Czuczman

Czuczman is a journal abstract published in 1995 discussing the combination of the chimeric monoclonal anti-CD20 antibody IDEC-C2B8 and CHOP chemoimmunotherapy to treat low grade lymphoma. Ex. 1011, 1, 3. Czuczman explains that the "rationale for combination of IDEC-C2B8 with CHOP includes: single agent efficacy, noncross-resistant mechanism of action, synergy with chemotherapeutic agents and non-overlapping toxicities." *Id*. at 3. Patients were given a dose of 375 mg/m^2 on weeks 1, 7, 13, 20, and 21 (6 doses). *Id*. According to Czuczman, findings suggest "the anti-tumor activity of CHOP and IDEC-C2B8 is superior to CHOP therapy alone." *Id*.

2. Foon

Foon is a chapter on lymphomas published in Williams Hematology in 1995. Ex. 1008, 3, 23. Foon provides a table listing combination therapies, including CVP and CHOP, used to treat low grade lymphoma. *Id*. at 29. Foon states that "intensive combination regimens including doxorubicin also have demonstrated excellent responses for patients with follicular small cleaved cell lymphoma, but there is no evidence that such treatment prolongs survival." *Id*. at 30.

3. Dana

Dana is a journal article published in 1993 discussing a comparison of the effectiveness of CHOP on overall survival in patients with low grade NHL compared with the effectiveness of less-aggressive CVP programs. Ex. 1009, Abstract, 6. Dana explains that for patients with SLL and FSCL,

results of administering CHOP are "comparable" to those achieved with CVP. *Id*. at 6. According to Dana, those results indicate that "the addition of doxorubicin to CVP [i.e., CHOP] results in no improvement in survival." *Id*.

4. Analysis

"The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). "If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability." *Id*. at 417.

Claims 1–3 are directed to treating low grade or follicular NHL comprising administering to a patient 375 mg/m^2 of a chimeric anti-CD20 antibody (claim 3), namely, rituximab (claim 1), i.e., C2B8 (claim 2), in combination with CVP therapy. Claim 1 additionally requires that such method "provides a beneficial synergistic effect in the patient," and Claim 3 recites that the antibody is "produced from nucleic acid" encoding amino acid sequences in SEQ ID NO: 1 and SEQ ID NO:2.

Petitioner asserts that each of those claims would have been obvious to a person of ordinary skill in the art who considered the combined teachings of Czuczman, Foon, and Dana. Pet. 45. In particular, Petitioner asserts that Czuczman teaches using the combination of rituximab (IDEC-C2B8) and CHOP therapy to treat low grade NHL patients, wherein the dose of rituximab administered is 375 mg/m^2. *Id*. at 45, 46, 49. Petitioner asserts also that Czuczman explains that rituximab exhibits "synergy with chemotherapeutic agents," and the combined therapy provides improvements in clinical outcome for patients. *Id*. at 45, 50 (quoting Ex.

1011, 3). Petitioner asserts that in addition to synergy and efficacy, Czuczman teaches that combining rituximab with chemotherapy is also desirable due to non-cross-resistant mechanism of action and non-overlapping toxicities. *Id*.

Recognizing that Czuczman does not describe administering CVP with rituximab, as required by claims 1–3, Petitioner turns to the teachings of Foon and Dana. *Id*. at 47. Petitioner asserts that Foon teaches that both CVP and CHOP were known standard combination chemotherapies for the treatment of low-grade NHL, and that there is no evidence that CHOP prolongs survival. *Id*. (citing Ex. 1002 ¶ 106; Ex. 1008, 29 (Table 111-7)). Petitioner asserts also that Dana teaches that CHOP does not provide a survival advantage over CVP in advanced low grade NHL. *Id*. (citing Ex. 1009, Abstract, 2, 6; Ex. 1002 ¶ 106).

Based on those combined teachings, Petitioner explains persuasively that a person of skill in the art would have been motivated to combine rituximab with CVP instead of CHOP in Czuczman's method with a reasonable expectation of treating low grade NHL because Foon and Dana explain that CVP and CHOP are standard chemotherapy regimens to treat low grade NHL and, among other reasons, CVP is equally effective as CHOP. *Id*. at 51–54. Further, Petitioner explains persuasively, that a person of skill in the art would have a reasonable expectation that modifying Czuczman's method to include CVP in place of CHOP would similarly provide a beneficial synergistic effect because Czuczman taught that rituximab exhibits "synergy with chemotherapeutic agents," without describing any limitation on the type of chemotherapy, such as requiring it to include doxorubicin like CHOP. *Id*.

Regarding the characterization of the chimeric anti-CD20 antibody in claim 3, i.e., being produced from nucleic acid encoding amino acid sequences in SEQ ID NO:1 and SEQ ID NO:2, Petitioner relies, as in the anticipation ground, on the principle that "one cannot establish novelty by claiming a known material by its properties" or manner of production, explaining that the claim recitation regarding the production of the anti-chimeric anti-CD20 antibody is merely a description of the antibody disclosed in Czuczman. *Id*. at 48, 51.

Patent Owner asserts that Petitioner has not shown that a person of ordinary skill in the art would have modified Czuczman by substituting CVP for CHOP, because, unlike CHOP, CVP does not contain doxorubicin. Prelim. Resp. 48. Patent Owner asserts that a person of ordinary skill in the art would not have performed that substitution "[b]ecause rituximab was known to be synergistic with doxorubicin." *Id*. Patent Owner refers to a statement in a journal abstract authored by some of the same authors of Czuczman that explains "[t]he standard CHOP regimen . . . was chosen for combination therapy with rituximab because . . . there is evidence of *in vitro* synergy between the antibody and doxorubicin." *Id*. (quoting Ex. 1041, 3). Patent Owner refers also to a second reference, not authored by any of the Czuczman authors, making essentially the same statement about Czuczman's combination of rituximab and CHOP. *Id*. (citing Ex. 2009, 1).

We are not persuaded by Patent Owner's assertion that Petitioner fails to establish a motivation to substitute CVP for CHOP. As discussed above, Czuczman does not limit its teaching that rituximab exhibits "synergy with chemotherapeutic agents" to doxorubicin or to chemotherapy comprising doxorubicin. Patent Owner has not shown otherwise by referring to Exhibits

1041 and 2009. Indeed, just before the portion cited by Patent Owner, the authors of Exhibit 1041 state that "[m]echanisms of action of IDEC-C2B8 include complement-mediated cytotoxicity, antibody-dependent cellular cytotoxicity, induction of apoptosis (in vitro data), and synergistic antitumor activity with certain chemotherapeutic agents (including doxorubicin)." Ex. 1041, 3. In other words, the authors again explain that rituximab has a synergistic effect with chemotherapeutic agents in addition to, i.e., "including" doxorubicin. That the author in Exhibit 2009 otherwise characterizes Czuczman is unavailing, as Patent Owner has not asserted or established that a person of skill in the art would have understood that article to further define or limit the teachings by Czuczman and its authors.

Nor are we persuaded by Patent Owner's assertion that the Demidem study provides "evidence that a POSA would not have understood Czuczman to be suggesting synergy between rituximab and chemotherapy generally, or between rituximab and . . . CVP." Prelim. Resp. 51 (citing Ex. 1079). As Patent Owner acknowledges, Demidem did not study the combination of rituximab and CVP. *Id.* Nor does Demidem discuss such a combination. Rather, Demidem studied other cytotoxic agents and explains that its findings demonstrate that "C2B8 antibody potentiates the sensitivity of DHL-4 tumor cells to *several* cytotoxic agents." Ex. 1079, 2 (Abstract), 6 (emphasis added).

Moreover, Patent Owner's synergy argument is not well-taken as it cuts against its argument raised in the context of whether the '202 application described the combination of rituximab and CVP as providing a beneficial synergistic effect. In that portion of the Preliminary Response Patent Owner supports its contention that the inventor "had possession of

such methods that produce beneficial synergistic effects, as required by claims 1 and 4," directed to CVP combination therapy, based only upon a disclosure stating "it has been found that treatment with anti-CD20 antibody provides a beneficial synergistic effect when administered in combination with cytokines, radiotherapy, myeloablative therapy, or chemotherapy." Prelim. Resp. 27 (quoting Ex. 1034, 6). In other words, for its priority contention, Patent Owner recognized that a general disclosure describing the synergistic effects of combining rituximab with chemotherapy includes combinations comprising rituximab and CVP.

Patent Owner asserts also that Petitioner fails to demonstrate that alleged toxicity concerns with CHOP would have motivated a skilled artisan to substitute it for CVP. Prelim. Resp. 53. Even if we agree with Patent Owner regarding that point, Petitioner has provided additional rationale for substituting CVP for CHOP, i.e., a skilled artisan would have understood from Foon and Dana that CVP and CHOP are standard chemotherapy regimens to treat low grade NHL, and CVP is equally effective as CHOP in doing so. Pet. 51. In other words, based on the current record, Foon and Dana suggest that Petitioner's proposed modification of Czuczman amounts to a simple substitution of one known low grade NHL chemotherapy for another. *KSR*, 550 U.S. at 416–417. We are not persuaded otherwise by Patent Owner's reliance on the Board's determination in another proceeding that the petitioner in that case had not shown that a person of skill in the art would have substituted CVP for CHOP. Prelim. Resp. 56–57 (citing *Boehringer Ingelheim Int'l GmbH v. Biogen Inc.*, IPR2015-00418, Paper 14 at 19 (July 13, 2015) (Ex. 2010)). The facts in that case are distinguishable from here. Significantly, in that proceeding, the petitioner relied upon

different prior art, and the Board's decision was based upon a teaching in that prior art describing an alternative to CHOP therapy other than CVP. As discussed, Petitioner in this proceeding has provided prior art references teaching that CVP and CHOP are "comparable" in the treatment of low grade NHL. *See, e.g.*, Ex. 1009, 6.

Patent Owner asserts also that a person of skill in the art would not have substituted CVP for CHOP because Czuczman taught that rituximab-CHOP therapy is able to clear bcl-2 positivity from marrow, while CHOP alone is unable to do so. Prelim. Resp. 57–58. According to Patent Owner, that achievement would have discouraged a skilled artisan from substituting CVP for CHOP. *Id.* However, Patent Owner has not addressed whether the skilled artisan would have understood from Czuczman that such achievement is attributable to a unique mechanism of action between rituximab and CHOP, and not a function of the same synergistic effect Czuczman teaches occurs with the combination of rituximab and chemotherapeutic agents. Indeed, as Patent Owner acknowledges, Czuczman explains that it is the "[s]tandard-dose" CHOP alone that is incapable of converting bcl-2-positive bone marrow to PCR negativity. Prelim. Resp. 58 (quoting Ex. 1011, 3). In other words, Patent Owner has not addressed whether a skilled artisan would understand from Czuczman's teachings, as a whole, that it is a synergized dose of CHOP that proved sufficient to convert bcl-2 positivity, and that a synergized dose of other chemotherapeutic agents would be expected to do so also. Without such consideration, based on the current record, we remain unpersuaded that a person of skill in the art would not have been motivated to simply substitute CVP for CHOP in Czuczman's method of treating low-grade NHL.

Patent Owner asserts also that Petitioner has failed to establish that a person of skill in the art would have had a reasonable expectation of successfully treating patients in the manner claimed, and providing the recited synergistic beneficial effect. Prelim. Resp. 60–62. As those assertions rely on the same arguments raised by Patent Owner regarding a motivation to substitute CVP for Czuczman's CHOP, we are unpersuaded by them, on the current record, for at least the same reasons discussed regarding those earlier arguments.

Thus, based on the information presented, we determine that Petitioner has shown sufficiently that there is a reasonable likelihood that it would prevail in showing the unpatentability of claims 1–3 over Czuczman, Foon, and Dana. Accordingly, we institute an *inter partes* review of claims 1–3 as unpatentable over Czuczman, Foon, and Dana.

H. Obviousness over Czuczman, Foon, Dana, Link, and Piro

Petitioner asserts that claims 4–6 would have been obvious over Czuczman, IDEC 10-K/A, Foon, Dana, Link, and Piro. Pet. 54–61. As Petitioner has not shown that the IDEC 10-K/A is a prior art printed publication, we consider the obviousness challenge over Czuczman, Foon, Dana, Link, and Piro.

1. Link

Link is a journal abstract published 1998 describing a phase II pilot study of the safety and efficacy of administering Rituxan (rituximab, IDEC-C2B8) in combination with CHOP chemotherapy to 31 patients with previously untreated intermediate- or high grade non-Hodgkin's NHL. Ex. 1010, 2 (Abstract 7). The dose of rituximab was 375 mg/m^2 on day 1 of

each 21-day cycle, for 6 cycles. *Id*. According to Link, the study regimen "represents a tolerable therapy . . . and may offer higher response rates," than seen with conventional CHOP therapy alone. *Id*.

2. Piro

Piro is a journal abstract published in 1997 describing a phase II study involving administering Rituxan (rituximab) once weekly for 8 doses to treat patients with relapsed or refractory low grade or follicular NHL. Ex. 1004, 1, 3. Piro explains that an interim analysis suggest that an 8-week course of Rituxan may be associated with a somewhat higher response rate than a 4-week course. *Id*. at 3.

3. Analysis

Petitioner asserts that the combination of Czuczman, Foon, and Dana teaches or suggests the method of treating low grade or follicular NHL comprising administering 375 mg/m^2 of rituximab during CVP therapy for the same reasons asserted for that combined art regarding claims 1–3. Pet. 54. Each of claims 4–6 additionally require that the rituximab dose is administered "once every 3 weeks for 8 doses." Ex. 1001, 25:8–26:16. For that dosing schedule, Petitioner relies on additional teachings from Czuczman, Link, and Piro. In particular, Petitioner asserts that: (a) Czuczman teaches administering 375 mg/m^2 of rituximab for six cycles to treat low grade or follicular NHL, Pet. 54 (citing Ex. 1011, 3); (b) Link teaches administering 375 mg/m^2 of rituximab every 3 weeks for 6 doses to treat intermediate or high grade NHL, *id*. at 55 (citing Ex. 1010, 2); and Piro teaches administering 375 mg/m^2 of rituximab every week for 8 doses, *id*. (citing Ex. 1004, 3). According to Petitioner and Dr. Lossos, those teachings would have provided a person of skill in the art motivation "to optimize the

dosing regimens taught in Czuczman, Link and Piro by extending the rituximab dosing regimen of once every 3 weeks for 6 doses to once every 3 weeks for 8 doses," with a reasonable expectation of success. *Id*. at 59–61 (citing Ex. 1002 ¶ 118).

Patent Owner asserts, among other things, that Petitioner has not demonstrated that a person of ordinary skill in the art would have arrived at the dosing regimen required by claims 4–6 by combining the asserted teachings of the cited references. Prelim. Resp. 63. We agree with Patent Owner for at least the following reasons. To begin, none of the cited references teaches or suggests treating low grade or follicular NHL on a schedule of "once every 3 weeks." Petitioner relies on Link for that schedule, and as the proposed starting point for optimization. Pet. 55, 59. Link, however, is directed to treating a different type of NHL than the claimed methods. Petitioner has not explained, or referred us to a portion of Dr. Lossos' declaration explaining, why a skilled artisan would have found it appropriate to treat low grade NHL with a Link's dosing schedule for treating intermediate or high grade NHL. Consequently, the basis for Petitioner's optimization argument is inadequately supported.

Thus, based on the information presented, we determine that Petitioner has not shown sufficiently that there is a reasonable likelihood that it would prevail in showing the unpatentability of claims 4–6 over Czuczman, Foon, Dana, Link, and Piro. Accordingly, we decline to institute an *inter partes* review of claims 4–6 as unpatentable over Czuczman, Foon, Dana, Link, and Piro.

I. Obviousness over Czuczman, Foon, Dana, Link, Piro, and the '137 Patent

Petitioner asserts that claims 3 and 6 would have been obvious over Czuczman, IDEC 10-K/A, Foon, Dana, Link, Piro, and the '137 Patent. Pet. 62–63. As Petitioner has not shown that the IDEC 10-K/A is a prior art printed publication, we consider the obviousness challenge over Czuczman, Foon, Dana, Link, Piro, and the '137 Patent.

Regarding claim 3, Petitioner relies on the same arguments regarding the combination of Czuczman, Foon, and Dana asserted for the challenge of claim 3 discussed above in section II. G. Pet. 62. Petitioner explains that the '137 patent is added in this ground for its disclosure of the sequence of rituximab. *Id*. Petitioner, however, does not explain how the teachings of Link and Piro support its challenge of claim 3. Therefore, we recognize this challenge of claim 3 over Czuczman, Foon, Dana, and the '137 Patent. Patent Owner asserts only that this ground fails for at least the same reasons asserted regarding the challenge of claim 3 over Czuczman, Foon, and Dana. Prelim. Resp. 67.

Based on the information presented, we remain persuaded that Petitioner has shown sufficiently that there is a reasonable likelihood that it would prevail in showing the unpatentability of claim 3 over Czuczman, Foon, Dana, and the '137 patent for at least the same reasons discussed in section II. G. Accordingly, we institute an *inter partes* review of claim 3 as unpatentable over Czuczman, Foon, Dana, and the '137 Patent.

Regarding claim 6, Petitioner relies on its same arguments regarding the combination of Czuczman, Foon, Dana, Link, and Piro asserted regarding the challenge of claim 6 discussed above in section II. H. Pet. 62. Petitioner explains that the '137 patent is added in this ground for its disclosure of the sequence of rituximab. *Id*. Petitioner does not rely on the '137 patent in a manner that addresses or cures the deficiencies we discussed regarding the dosing schedule for rituximab required by claim 6.

Accordingly, based on the information presented, we remain unpersuaded that Petitioner has shown sufficiently that there is a reasonable likelihood that it would prevail in showing the unpatentability of claim 6 over Czuczman, Foon, Dana, Link, Piro, and the '137 patent for the same reasons discussed in section II. H. Accordingly, we decline to institute an *inter partes* review of claim 6 as unpatentable over Czuczman, Foon, Dana, Link, Piro, and the '137 Patent.

III. CONCLUSION

For the foregoing reasons, we conclude that the information presented in the Petition establishes a reasonable likelihood that Petitioner would prevail in showing that claims 1–3, 5, and 6 of the '821 patent are unpatentable.

At this stage of the proceeding, the Board has not made a final determination as to the patentability of any challenged claim or the construction of any claim term.

ORDER

Accordingly, it is hereby:

ORDERED that pursuant to 35 U.S.C. § 314, an *inter partes* review is instituted as to claims 1–3, 5, and 6 of the ’821 on the following grounds of unpatentability:

A. Claims 5 and 6 under 35 U.S.C. § 102(b) as anticipated by Marcus;

B. Claim 6 under 35 U.S.C. § 103(a) as obvious over Marcus and the ’137 patent;

C. Claims 1–3 under 35 U.S.C. § 103(a) as obvious over Czuczman, Foon, and Dana; and

D. Claim 3 under 35 U.S.C. § 103(a) as obvious over Czuczman, Foon, Dana, and the ’137 patent;

FURTHER ORDERED that no other proposed grounds of unpatentability are authorized; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial commencing on the entry date of this Decision.

IPR2017-01095
Patent 9,296,821 B2

PETITIONER:
Michelle S. Rhyu
James Brogan
Lauren J. Krickl
COOLEY LLP
rhyums@cooley.com
jbrogan@cooley.com
lkrickl@cooley.com

PATENT OWNER:
Michael R. Fleming
Gary N. Frischling
Keith A. Orso
Yite John Lu
David Gindler
IRELL & MANELLA LLP
mfleming@irell.com
gfrischling@irell.com
korso@irell.com
yjlu@irell.com
dgindler@irell.com