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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PFIZER, INC.,
Petitioner,

v.

BIOGEN, INC.,
Patent Owner.

Case IPR2018-00186
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
35 U.S.C. § 314

I. INTRODUCTION

Pfizer, 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 9 ("Prelim. Resp."). Petitioner filed an authorized Reply to the Patent Owner Preliminary Response and Patent Owner filed an authorized Sur-reply.[1] Papers 12 and 13.

We have authority under 35 U.S.C. § 314 to determine whether to institute an *inter partes* review. *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 at least one of the claims challenged in the petition. 35 U.S.C. § 314(a). Accordingly, we institute an *inter partes* review of all challenged claims.

A. Related Proceedings

On October 6, 2017, we instituted an *inter partes review* of claims 1–6 of the '821 patent in another proceeding involving a different petitioner, Celltrion, Inc. IPR2017-01095, (the "Celltrion proceeding") Paper 12 (instituting review of claims 1–3, and 5–6), Paper 39 (including claim 4 in the *inter partes* review). A Final Written Decision has not been entered in

[1] We authorized the Reply and Sur-reply only to address factors considered by the Board when evaluating whether to exercise discretion under § 314(a), in view of the designation of *General Plastic Industrial Co. v. Canon Kabushiki Kaisha*, Case IPR2016-01357, Paper 19 (PTAB Sept. 6, 2017) as precedential. *See* Paper 11.

that proceeding. The parties additionally identify prior Board decisions denying petitions or otherwise terminating proceedings involving a related patent, U.S. Patent No. 8,329,172. Pet. 5–6; Paper 5, 2.

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 4 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.
>
> 4. 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 once every 3 weeks for 8 doses, and wherein the method provides a beneficial synergistic effect in the patient.

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	§ 103(a)	Steward,[2] Czuczman,[3] and Maloney[4]
1–3	§ 103(a)	Czuczman, Foon,[5] and Dana[6]
4–6	§ 102(b)	Marcus[7]

[2] Steward et al., *Maintenance Chlorambucil After CVP in the Management of Advanced Stage, Low-Grade Histologic Type Non-Hodgkin's Lymphoma: A Randomized Prospective Study With an Assessment of Prognostic Factors*, 61 CANCER 441–47 (1988) (Ex. 1003).
[3] Czuczman et al., *IDEC-C2B8 and CHOP Chemoimmunotherapy of Low-Grade Lymphoma*, 86 BLOOD 10 Supp. 1:55a (Abstract 206) (1995) (Ex. 1004).
[4] Maloney et al., *IDEC-C2B8 (Rituximab) Anti-CD20 Monoclonal Antibody Therapy in Patients With Relapsed Low-Grade Non-Hodgkin's Lymphoma*, 90 BLOOD. 2188–95 (1997) (Ex. 1005).
[5] Foon et al., Chapter 111: *Lymphomas*, *in* WILLIAMS HEMATOLOGY, 5TH ED. 1076–96 (1990) (Ex. 1006).
[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. 1007).
[7] Marcus et al., *CVP chemotherapy plus rituximab compare with CVP as first-line treatment for advanced follicular lymphoma*, 105 BLOOD 1417–23 (2005) (Ex. 1008).

Claims	Basis	References
4–6	§ 103(a)	Marcus, Czuczman, and Pinter-Brown[8]

Petitioner also relies on the Declaration of Howard Ozer, M.D., Ph.D. (Ex. 1002).

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 note our initial construction in the Celltrion proceeding for the claim phrase "beneficial synergistic effect," recited by claims 1 and 4, and agree that term should be construed in the

[8] Pinter-Brown et al., *Hodgkin and Non-Hodgkin Lymphoma*, *in* MANUAL OF CLINICAL ONCOLOGY 6TH ED. 431–70 (1997) (EX. 1009).

same manner in this proceeding. Pet. 22; Prelim. Resp. 15 (citing Ex. 1022,[9] 7). Specifically, we determined, for purposes of the Decision on Institution 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." Ex. 1022, 7. Petitioner asserts, however, that the phrase is non-limiting as to claim 4. Pet. 23.[10]

Petitioner asserts that claim 4 "recites the express dosage and frequency of treatment required — namely, 375 mg/m^2 of rituximab with CVP every three weeks for eight cycles." *Id*. at 23–24. Petitioner asserts also that "the specification assumes a standard CVP dosage and frequency," without teaching or suggesting that the amount of CVP must be varied to achieve beneficial synergistic effects. *Id*. at 24 (citing Ex. 1001, 13:16, Ex. 1002 ¶ 31). According to Petitioner, because claim 4 "requires fixed or standard dosing regimens, the term 'beneficial synergistic effect' is non-limiting because it 'essentially duplicates the dosage amounts recited in the claims' and is nothing more than 'an expression of intended result.'" *Id*. (quoting *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1375 (Fed. Cir. 2001)). Patent Owner notes Petitioner's contention, but does not otherwise address it. Prelim. Resp. 15, 17.

We agree with the parties that, at this stage in the proceeding, our initial construction for the claim term "beneficial synergistic effect" in the

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[9] IPR2017-01095, Paper 12 (Decision on Institution)
[10] Petitioner asserts, without explanation, that the phrase is non-limiting as to claim 1 also. *See* Pet. 23–24 and n.4. As Petitioner does not pursue that assertion, we decline to address further in this Decision.

Celltrion proceeding applies here too. As explained in the Decision on Institution in that proceeding, *see* Ex. 1022, 6–7, the Specification describes the term "synergistic," in one embodiment, as comprising "administering a synergistic therapeutic combination . . . wherein the therapeutic effect is better than the additive effects of either therapy administered alone." Ex. 1001, 3:43–47).

Further, at this stage in the proceeding, we are persuaded that the claim term "beneficial synergistic effect" is non-limiting with respect to claim 4, as that claim recites a specific dosing regimen for rituximab, i.e., 375 mg/m^2 of rituximab every three weeks for eight cycles, and refers to the chemotherapeutic regimen as "CVP therapy." Ex. 1001, 25:11–16. As Petitioner notes, the Specification refers only to a "standard CVP therapy." Pet. 24 (citing Ex. 1001, 13:16). The Specification does not describe the dosage amounts and frequency of the cyclophosphamide, vincristine, and prednisone comprising a "standard" CVP therapy. However, Petitioner and Patent Owner agree that the claim recitation of "CVP therapy" refers to "standard CVP therapy," and that such therapy was known. *See* Pet. 24, 34; Prelim. Resp. 63. Thus, based on the current record, we read claim 4 as requiring a specific dosing regimen of rituximab and CVP that renders the recitation of providing a "beneficial synergistic effect" an intended result of administering the combination in the recited manner.

"C2B8"

Patent Owner asserts that "C2B8," recited in claims 2 and 5, should be construed to mean rituximab. Prelim. Resp. 18. Petitioner does not address this term. We agree with Patent Owner as the Specification defines "C2B8"

as rituximab. Ex. 1001, 3:3–5 ("preferred chimeric [anti-CD20] antibody is C2B8 (IDEC Pharmaceuticals, Rituximab).").

"the chimeric anti-CD20 antibody is produced from [particular nucleic acid]"

Petitioner asserts that the recitations in claims 3 and 6 describing the "chimeric anti-CD20 antibody" in terms of its production, i.e., "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," should be construed to mean, or at least include, rituximab. Pet. 24–25. Petitioner supports its proposed construction by demonstrating that the '137 patent, referenced on the title page of the '821 patent, discloses that rituximab is produced from the nucleic acid recited in claims 3 and 6. *Id*. at 24–29 (citing Ex. 1010, 21:19–22:15; Ex. 1002 ¶¶ 32–33). Patent Owner does not address Petitioner's argument or propose a different construction for this claim phrase.

Based on the current record, and for the reasons discussed by Petitioner, we determine that the broadest reasonable construction of the claim phrase

> 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

includes, at least, rituximab.

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 "include a practicing oncologist with at least an M.D. degree and several years of experience treating patients with NHL and/or researching treatments for NHL, including with chemotherapeutic drugs." Pet. 9 (citing Ex. 1002 ¶ 15). Patent Owner does not address Petitioner's position on this matter and does not propose its own description for the level 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. Ozer (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. 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

"Patent claims are awarded priority on a claim-by-claim basis based on the disclosure in the priority applications." *Lucent Tech., 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) ("[T]he 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).

The '821 patent issued from U.S. Application No. 13/524,896 ("the '896 application") filed on June 15, 2012. Ex. 1001. 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, 1024, 1031, and 2001.

Petitioner and Patent Owner do not dispute our preliminary determination in the Decision on Institution for the Celltrion proceeding that claims 1–3 are entitled to receive benefit of the '202 application filing date of August 11, 1999. Pet. 20; Prelim. Resp. 62; Ex. 1022, 11. In the Decision on Institution, we also made a preliminary determination that claims 4–6 are not entitled to receive benefit of the '202 application filing date of August 11, 1999, because Patent Owner did not demonstrate written description support for each of those claims in the specification of the '202 application for the claimed dosing regimen for rituximab "once every three weeks for eight doses." *Id*. at 12. As a result, we recognized a priority date of June 15, 2012, the filing date of the '896 application, for claims 4–6 in the Decision on Institution. *Id*. at 12–13. Petitioner does not dispute that determination. Pet. 21. Patent Owner asserts that claims 4–6 are entitled to an August 11, 1999 priority date. Prelim. Resp. 62.

According to Patent Owner, each recited feature of claims 1–4 is described in the '202 application. *Id*. In particular, regarding the recitation of administering rituximab "once every three weeks for eight doses," Patent Owner asserts that the '202 application describes (a) "CVP as a chemotherapeutic regimen used in combination with rituximab (375 mg/m^2) to treat low-grade NHL," (b) "administering rituximab on day one of 21-day chemotherapy cycles— *i.e.*, once every 3 weeks," (c) an example describing "'Rituximab® [] administered on Day 1 and CHOP [] given on Days 1-3 every 21 days for 6 cycles'— and thus, with six cycles of CHOP in this example, administering rituximab on day one of each 21-day cycle meant

every 3 weeks for six doses," (d) "treating . . . [low grade and follicular NHL] with rituximab (375 mg/m^2) in combination with 'standard CVP therapy.'" *Id*. at 62–63 (citing Ex. 2001, 51).

According to Patent Owner, in the Celltrion proceeding, Celltrion's expert provides testimony that "standard CVP therapy" was understood in 1999 to be six to eight cycles of CVP spaced three weeks apart. *Id*. at 63 (citing Ex. 2007, 10:16–13:10). Patent Owner directs us also to Petitioner's assertion that "standard" CVP therapy was known to be "for between six and ten, more usually six and eight, cycles." *Id*. (citing Pet. 34). As a result, Patent Owner asserts that a person of ordinary skill in the art would have understood that by referring to "standard CVP therapy," in the '202 application, the inventor had possession of CVP dosing regimens for use with rituximab including a regimen of eight cycles every three weeks. *Id*.

Fundamentally, Patent Owner's argument relies on the '202 application as describing the use of "standard CVP therapy" to treat low grade NHL, and an assertion that a person of skill in the art would then administer rituximab according to the same schedule. *See* Prelim. Resp. 62–63 (citing Ex. 2001, 51). However, Patent Owner does not address the context of the "standard CVP therapy" disclosure upon which it relies. That disclosure involves a study "comparing the combination of cyclophosphamide and fludarabine (Arm A) with standard CVP therapy (Arm B)" as a treatment for low grade NHL. Ex. 2001, 51. The '202 application explains that "[r]esponders in both arms will undergo a second randomization to Rituximab® maintenance therapy (375 mg/m^2[)] weekly times 4 every 6 months for 2 years (Arm C) or to observation (Arm D)." *Id*. What is missing from Patent Owner's assertion is an explanation of how the

'202 application disclosure of treating low grade NHL with standard CVP therapy and then a specific rituximab *weekly* dosing regimen demonstrates that a person of ordinary skill in the art would have understood that the inventors had possession of treating low grade NHL by instead administering rituximab on the same schedule as standard CVP therapy, i.e., once every three weeks for eight doses, for such treatment. Thus, at this stage in the proceeding, without more, we do not find that Patent Owner has adequately demonstrated written description support in the '202 application for the claimed dosing regimen for rituximab "once every three weeks for eight doses."

Accordingly, for purposes of this Decision, we recognized a priority date of June 15, 2012, the filing date of the '896 application, for claims 4–6. *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1366 (Fed. Cir. 2006) (citation omitted) (satisfying the written description requirement demands that enough detail in the prior application "must be included to convince a person of skill in the art that the inventor possessed the invention"); *Lockwood v. Am. Airlines, Inc.*,107 F.3d 1565, 1572 (Fed. Cir. 1997) (citing *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563–64 (Fed. Cir. 1991)) ("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."). As discussed, infra, this determination affects Petitioner's reliance on Marcus and Pinter-Brown.

D. Obviousness over Marcus, Czuczman, and Pinter-Brown

Petitioner asserts that claims 4–6 are unpatentable over the combined teachings of Marcus, Czuczman, and Pinter-Brown. Pet. 57–61. Patent Owner disagrees. Prelim. Resp. 63–65. 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. The parties do not dispute that Marcus was published in 2005 and Pinter-Brown was publishes in 2009. Pet. 14; Prelim. Resp. 65. Thus, Marcus and Pinter-Brown, along with Czuczman (1995), are recognized as prior art to claims 4–6.

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. 1008, 9 (Title). Patients were treated with CVP and rituximab every 21 days for a maximum of 8 cycles, wherein a rituximab dose of 375 mg/m^2 was administered on day one of each therapy cycle. *Id*. at 10. 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 13–14. 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*. at 13.

2. 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. 1004,

11. Czuczman explains that the "rationale for combination of IDEC-C2B8 with CHOP includes: single agent efficacy, non cross-resistant mechanism of action, synergy with chemotherapeutic agents and non-overlapping toxicities." *Id.* 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.*

3. Pinter-Brown

Pinter-Brown is book chapter describing various aspects of NHL, including therapeutic options for Stage III and IV disease. Ex. 1009, 46. Pinter-Brown explains that rituximab is a "chimeric humanized anti-CD20 monoclonal antibody approved for treatment of refractory or relapsed indolent B-cell lymphoma, and the first-line therapy of follicular lymphoma when combined with CVP." *Id.* Additionally, Pinter-Brown explains that "[c]ombinations of rituximab with a variety of chemotherapy regimens are feasible and are believed to be synergistic, with documented increased disease-free survival." *Id.*

4. Analysis

Petitioner asserts that Marcus discloses each element of claims 4–6. Pet. 53–58. On the current record, we agree with Petitioner that Marcus teaches a method for treating follicular NHL comprising administering a therapeutically effective amount of rituximab in combination with CVP therapy, wherein the method comprises administering 375 mg/m^2 of rituximab once every 3 weeks for 8 doses. Pet. 54; Ex. 1008, 11; Ex. 1002 ¶ 95. Further, we agree with Petitioner that, on this record, those disclosures

meet the limitations of independent claim 5, directed to administering "C2B8," and claim 6, directed to 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." *See* Pet. 55–56. As we discuss supra, in Section II. A., for purposes of this Decision, we construe each of those limitations in claims 5 and 6 as including rituximab.

As for the recitation in claim 4, "wherein the method provides a beneficial synergistic effect in the patient," Petitioner asserts that the term is non-limiting. We agree with Petitioner, as discussed supra, in Section II. A.

Additionally (and alternatively), Petitioner asserts that if the claim recitation "wherein the method provides a beneficial synergistic effect in the patient," is determined to be limiting, such limitation would have been obvious over the combined teachings of Marcus, Czuczman, and Pinter-Brown. Pet. 57. In particular, Petitioner asserts that Marcus disclosed that "[d]ata from in vitro studies suggest that rituximab can sensitize lymphoma cell lines to chemotherapy," and "a synergistic effect between rituximab and various cytotoxic agents has been demonstrated." *Id*. (quoting Ex. 1008, 10). Petitioner asserts that "Czuczman taught that '[t]he rationale for combination of IDEC-C2B8 [rituximab] with CHOP includes: single agent efficacy, non cross-resistant mechanism of action, synergy with chemotherapeutic agents and non-overlapping toxicities.'" *Id*. at 58–59 (quoting Ex. 1004, 11) (emphasis added by Petitioner). Additionally Petitioner asserts that Pinter-Brown taught that rituximab was "first-line

therapy [for low-grade NHL] when combined with CVP," and that "[c]ombinations of rituximab with a variety of chemotherapy regimens are feasible and are believed to be synergistic." *Id*. at 59 (quoting Ex. 1009, 459). Based on the current record, we agree with Petitioner, *id*. at 59–60, that a person of skill in the art would have viewed those combined teachings as providing a reasonable expectation that combining rituximab with CVP in the manner disclosed by Marcus would have provided a beneficial synergistic effect. Patent Owner has not established otherwise by asserting that the challenged claims are entitled to the benefit of at least an August 11, 1999 priority date. Prelim. Resp. 62–65. As we discussed in Section II. C., for purposes of this Decision, we recognize a priority date of June 15, 2012, for claims 4–6.

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 claims 4–6 over Marcus, Czuczman, and Pinter-Brown.

E. Discretionary Denial Arguments

Patent Owner asserts that we should exercise our discretion to deny the Petition under 35 U.S.C. § 325(d) because two of Petitioner's asserted grounds reflect grounds already being considered by the Board in the Celltrion proceeding, and the remaining two grounds rely on substantially the same art and arguments previously presented. Prelim. Resp. 19. Petitioner asserts that it presents additional combinations of prior art and additional claim construction arguments than were presented by petitioner Celltrion. Pet. 5.

Based upon our review, we agree with Patent Owner that Petitioner's obviousness challenge of claims 1–3 over the combination of Czuczman, Foon, and Dana presents the same or substantially the same prior art and arguments presented in the Celltrion petition. *Compare* Pet. 51–52, *with* Ex. 1023, 38–44. Indeed, in presenting that ground, Petitioner refers to and relies upon our Decision on Institution in the Celltrion proceeding. *See, e.g.*, Pet. 51. Although we find similarities in Petitioner's remaining challenges, we do not consider them to be substantially the same as those raised by the Celltrion petition. In particular, we note that the remaining challenges include consideration of claim 4, which includes the claim term "beneficial synergistic effect." In this proceeding, unlike in the Celltrion petition, Petitioner argues that the claim term is non-limiting in view of the specific dosing regimen recited by the claim. *See* Pet. 22–24. As we discuss in Section II. A., above, we find that argument persuasive on the current record and, thus, determine that Petitioner has established a reasonable likelihood of prevailing in showing the unpatentability of claim 4.

On April 24, 2018, the Supreme Court held that a decision to institute under 35 U.S.C. § 314 may not institute on less than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 148, 1360–61 (2018). Moreover, the Office has determined that "if the PTAB institutes a trial, the PTAB will institute on all challenges raised in the petition." *Guidance on the impact of SAS on AIA trial proceedings* (April 26, 2018) (https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial). Accordingly, when considering whether to exercise our discretion to deny institution under 35 U.S.C.

§ 325(d), we must consider not simply whether to deny institution regarding certain claims or certain challenges, but whether to do so regarding the petition, as a whole. As Petitioner has presented a new argument regarding the construction of a phrase recited in a claim challenged differently in the prior proceeding, and such argument contributes to our determination that Petitioner in this proceeding has established a reasonable likelihood of prevailing in showing the unpatentability of that claim, we decline to exercise our discretion to deny the Petition based upon the presentation of prior art and arguments raised elsewhere in the Petition that represent the same or substantially the same prior art and/or arguments previously presented to the Office in the Celltrion proceeding.

Patent Owner additionally requests that we exercise our discretion to deny the Petition under 35 U.S.C. § 314 (a) based upon an application of *General Plastic Industrial Co. v. Canon Kabushiki Kaisha*, Case IPR2016-01357, Paper 19 (PTAB Sept. 6, 2017). Prelim Resp. 24. Petitioner asserts the *General Plastic* factors are not applicable when a later petition is filed by a new petitioner. Paper 12. Patent Owner disagrees. Paper 13.

In *General Plastic*, the Board identified seven nonexclusive factors that bear on the issue of whether the Board should invoke its discretion to deny institution of an inter partes review, based on a follow-on petition on the same patent, under 35 U.S.C. § 314(a), wherein the first factor inquires "[w]hether the same petitioner previously filed a petition directed to the same claims of the same patent." *General Plastic*, slip. op. at 15–16 (citing *NVIDIA Corp. v. Samsung Elec. Co.*, IPR2016-00134 (PTAB May 4, 2016) (Paper 9, slip op. at 6–7)). When considering whether to apply these factors, we contemplate not only the congressional intent that *inter partes* review

proceedings provide an effective and efficient alternative to district court litigation, but also the potential for abuse of the review process through repeated attacks by the same petitioner with respect to the same patent. *See General Plastic*, slip. op. at 18 n.1 (citing H.R. Rep. No. 112- 98, pt. 1, at 48 (2011) ("Allowing similar, serial challenges to the same patent, by the same petitioner, risks harassment of patent owners and frustration of Congress's intent in enacting the Leahy-Smith America Invents Act")).

In this case, Patent Owner acknowledges that Petitioner is not a petitioner on any previously or concurrently filed petitions involving the '821 patent. Prelim. Resp. 28. Patent Owner further acknowledges that *General Plastic* involved follow-on petitions by the same petitioner. *Id*. at 27. In any event, Patent Owner asserts that we should expand *General Plastic* to a new petitioner because the Petition has a "'high degree of similarity' with the previously-filed petition," Prelim. Resp. 28, and the inquiry whether Petitioner was the same as the prior filer "is simply one of seven non-exclusive factors concerning 'follow-on petitions,'" Paper 13, 1.

Upon considering the respective positions of the parties, we decline to expand *General Plastic* to the facts and circumstances of this case, and determine that it is more appropriate to limit our analysis for discretionary denial of *inter partes* review for a new petitioner to Section 325(d). *See Pfizer, Inc. v. Genentech, Inc.*, IPR2017-01923 (PTAB Apr. 4, 2016) (Paper 14, slip op. at 23–25).

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 at least one claim of the '821 patent is unpatentable.

Accordingly, we institute an *inter partes* review of each of the challenged claims based upon each of the challenged grounds.

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 the challenged claims of the ’821 patent on each of the following asserted grounds of unpatentability:

A. Claims 1–6 under 35 U.S.C. § 103(a) as obvious over Steward, Czuczman, and Maloney;

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

C. Claims 4–6 under 35 U.S.C. § 102(b) as anticipated by Marcus; and

D. Claims 4–6 under 35 U.S.C. § 103(a) as obvious over Marcus, Czuczman, and Pinter-Brown;

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.

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