

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. REDDY's LABORATORIES, INC.,
Petitioner,

v.

GENENTECH, INC., HOFFMAN-LA ROCHE AG, and ABBVIE INC.,
Patent Owner.

IPR2023-00052
Patent 11,110,087 B2

Before JEFFREY N. FREDMAN, ZHENYU YANG, and
ROBERT A. POLLOCK, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Dr. Reddy's Laboratories, Inc. ("Petitioner") filed a Petition (Paper 1, "Pet.") requesting *inter partes* review of claims 1–4, 8–14, and 18–26 (the "challenged claims") of U.S. Patent No. 11,110,087 B2 (Ex. 1001, "the '087 patent"). Genentech, Inc., Hoffman-La Roche AG, and Abbvie Inc. ("Patent Owner") filed a Preliminary Response. Paper 6 ("Prelim. Resp.").

We have authority under 35 U.S.C. § 6 and 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted unless the information presented in the Petition "shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."

A decision to institute under § 314 may not institute on fewer than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018). In addition, if the Board institutes trial, it will "institute on all grounds in the petition." PTAB Consolidated Trial Practice Guide, 5–6 (Nov. 2019); *see also PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (interpreting the statute to require "a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition").

Having considered the arguments and evidence presented in the Petition and the Preliminary Response, for the reasons described below, we institute *inter partes* review.

II. REAL PARTIES-IN-INTEREST

Petitioner identifies Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc. as the real parties-in-interest. Pet. 3. Patent Owner states "the real parties-in-interest are Genentech, Inc., Hoffmann-La Roche Inc.,

and AbbVie Inc., the assignees of record for U.S. Patent No. 11,110,087.”
Paper 4, 1.

III. RELATED MATTERS

Petitioner identifies the '087 patent as a continuation of US 10,993,942 (“’942 patent”) and related to three pending applications, US 17/395,366, 17/709,324, and 17/834,709. Pet. 4. Petitioner identifies two district court cases directly related to the '087 and '942 patents: *AbbVie Inc. v. Alembic Pharms., Ltd.*, No. 20-cv-01009 (D. Del.) and *AbbVie Inc. v. Dr. Reddy’s Labs., Ltd.*, No. 20-cv-00968 (D. Del.). Petitioner also identifies a related instituted post grant review (“PGR”) challenge: *Dr. Reddy’s Labs., Inc. v. Genentech, Inc.*, PGR2022-00023, Paper 8 (PTAB July 25, 2022).

IV. THE '087 PATENT and RELEVANT BACKGROUND

The '087 patent states the “invention is directed to a combination therapy involving a type II anti-CD20 antibody and a selective Bcl-2 inhibitor for the treatment of a patient suffering from cancer, particularly a CD20-expressing cancer.” Ex. 1001, 1:22–25. The '087 patent teaches, in one embodiment, that “the selective Bcl-2 inhibitor is GDC-0199.” *Id.* at 4:6–7. The '087 patent teaches the treatment may comprise “administering to said human a GA101 antibody and/or GDC-0199 in multiple dosing cycles. In an embodiment, each dosing cycle of the multiple dosing cycle is for at least 1 week.” *Id.* at 4:12–15. According to Patent Owner GDC-0199 is “now known as venetoclax” and marketed “as the FDA-approved drug Venclexta®.” POPR 1. *See also* Ex. 1020 ¶ 2 (Dr. Oleksowicz’s testimony that GDC-0199 is synonymous with Venclexta).

V. ILLUSTRATIVE CLAIMS

Petitioner challenges claims 1–4, 8–14, and 18–26, of which only claims 1 and 19 are independent:

1. A method for treating lymphoma or leukemia in a human patient, the method comprising orally administering once daily GDC-0199 to the patient in dosing cycles comprising escalating doses, wherein the escalating doses comprise a dose of 100 mg of GDC-0199 per day, followed by orally administering to the patient a dose of 200 mg of GDC-0199 per day, followed by orally administering to the patient a dose of 400 mg of GDC-0199 per day.
19. A method for treating lymphoma or leukemia in a human patient, the method comprising orally administering once daily GDC-0199 in escalating doses to the patient, wherein the escalating doses comprise a daily dose of 100 mg of GDC-0199.

Ex. 1001, 35:26–34; 36:45–49.

VI. ASSERTED GROUND

Petitioner contends that the challenged claims are unpatentable based on the following ground. Pet. 6.

Reference	Basis	Claims Challenged
Venclexta Label (November 2018) (Ex. 1053).	§ 102	1–4, 8–14, 18–26

Petitioner relies also on the Declaration of Leslie Oleksowicz, M.D.
See Ex. 1020.

VII. CLAIM INTERPRETATION

Petitioner contends that the preamble recitation to treat particular cancers is a limitation “because it both frames and governs the ultimate timing and dosing choices of the claimed method of treatment.” Pet. 26.

Patent Owner contends that “[a]lthough Patent Owners agree that the preamble is limiting, construing the preamble is unnecessary to resolve any controversy.” Prelim. Resp. 15.

The parties do not identify any issue relating to the preamble that would impact our analysis. We therefore find that there are no terms that need claim construction. *See, e.g., 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)).

VIII. LEVEL OF ORDINARY SKILL IN THE ART

Petitioner asserts

A person of ordinary skill in the art (“POSA”) in the field of the patent between 2012 and 2021 would have held an MD with experience in clinical oncology or pharmacology; a PhD in pharmacology, pharmaceutical chemistry, cancer biology, or a related discipline; or a PharmD with experience in clinical oncology. Ex. 1020 ¶ 29. A POSA would also have practical working knowledge of oncology (Ex. 1020 ¶ 29) and experience with the design of studies necessary for drug development. This description is approximate, and additional experience could make up for less education and vice versa. Ex. 1020 ¶ 29.

Pet. 15–16. Patent Owner asserts “that a POSA for purposes of the ’087 Patent would have had at least an M.D. and several years of experience treating patients with hematological malignancies (*i.e.*, blood cancers).” Prelim. Resp. 13. Patent Owner asserts “Petitioner’s definition fails to require experience specific to hematological malignancies or blood cancers. Patent Owners’ definition of a POSA, on the other hand, accounts for the claims’ focus on lymphoma and leukemia.” *Id.* at 14.

At this stage in the proceeding, we find that Patent Owner’s analysis more precisely establishes the level of ordinary skill in the art as it directly relates to those deciding prescribing information based on the prior art reference. *See* Ex. 1011, 2. The level of ordinary skill in the art usually is evidenced by the prior art references themselves. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001); *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995).

IX. PRINCIPLES OF LAW

“In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify “with particularity . . . the evidence that supports the grounds for the challenge to each claim”)). This burden of persuasion never shifts to the patent owner. *See Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in *inter partes* review).

“[T]o gain the benefit of the filing date of an earlier application under 35 U.S.C. § 120, each application in the chain leading back to the earlier application must comply with the written description requirement of 35 U.S.C. § 112.” *Zenon Envtl., Inc. v. U.S. Filter Corp.*, 506 F.3d 1370, 1378 (Fed. Cir. 2007); *see also In re Hogan*, 559 F.2d 595, 609 (CCPA 1977) (“[T]here has to be a continuous chain of copending applications each of which satisfies the requirements of § 112 with respect to the subject matter presently claimed.”)

“[T]he test for [compliance with the written description requirement of § 112, ¶ 1] 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). “[W]hile the description requirement does not demand any particular form of disclosure, or that the specification recite the claimed invention *in haec verba*, a description that merely renders the invention obvious does not satisfy the requirement.” *Id.* at 1352 (citations omitted). “[T]he test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art.” *Id.* at 1351.

“Determining whether claims are anticipated involves a two-step analysis. The first step involves construction of the claims of the patent at issue. Claim construction is a question of law reviewed *de novo*.” *In re Aoyama*, 656 F.3d 1293, 1296 (Fed.Cir.2011). “The second step [of an anticipation analysis] involves comparing the claims to the prior art. Anticipation is a question of fact reviewed for substantial evidence.” *In re Aoyama*, 656 F.3d at 1296. “A prior art reference anticipates a patent claim under 35 U.S.C. § 102(b) if it discloses every claim limitation.” *In re Montgomery*, 677 F.3d 1375, 1379 (Fed. Cir. 2012).

We analyze the asserted ground of unpatentability in accordance with the above-stated principles.

X. DISCRETION TO DECLINE TO INSTITUTE

A. Patent Owner’s position

Patent Owner urges us to decline to institute the asserted grounds under 35 U.S.C. § 314(a) and § 311(b). Prelim. Resp. 50. Patent Owner

asserts the “Board should deny the Petition because it violates 35 U.S.C. § 311(b), which permits challenges ‘only on a ground that could be raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications.’” Prelim. Resp. 51. Patent Owner asserts

Petitioner plainly asks the Board to review claims for validity under Section 112. *See* Petition at 6 (“The ’087 patent should be reviewed under AIA §§ 102 and 112.”). Petitioner also argues that the entire priority chain, including the ’087 Patent itself, lacks an enabling disclosure . . . But a challenge based purely on alleged lack of written description or enabling disclosure under Section 112 is impermissible in an IPR. 35 U.S.C. § 311(b).

Prelim. Resp. 51–52. Patent Owner asserts “the Petition is an improper attempt to circumvent the statutory deadline to bring a post-grant review challenge.” Prelim. Resp. 52. Patent Owner asserts a “Section 112 challenge may properly be brought in a *PGR*, but such a challenge ‘may only be filed not later than the date that is 9 months after the date of the grant of the patent.’ 35 U.S.C. § 321(c).” Prelim Resp. 52–53.

Patent Owner further asserts that “Petitioner indisputably was aware of the ’087 Patent and had almost eight months to take advantage of the expanded grounds available in a *PGR*, but chose not to do so.” Prelim. Resp. 55. Patent Owner asserts

by styling its *PGR* as an IPR, Petitioner also improperly seeks to lower the threshold for institution of its Section 112 challenge; had Petitioner filed under the *PGR* statute, the Board would have applied the higher “more likely than not” standard to determine whether Petitioner had met its burden for institution of review.

Prelim. Resp. 55.

Patent Owner acknowledges that “*Arthrex* held only that the Board *may* consider a Section 112 issue to resolve the proper Section 102/103

grounds raised in an IPR. *Arthrex [, Inc. v. Smith & Nephew, Inc., 35 F.4th 1328, 1344–45 (Fed. Cir. 2022)]*.” Prelim. Resp. 57. Patent Owner asserts

Arthrex involved a priority challenge where the specification of the challenged patent added new matter from the specifications of the priority applications. . . . The [instant] Petition is not premised on a priority date analysis and evaluation of intervening prior art. Rather, Petitioner argues that the claims are not entitled to *any* priority date and are unpatentable.

Prelim. Resp. 57–58; *see also* Prelim. Resp. 60, citing *Agilent Techs., Inc. v. Bio-Rad Labs, Inc.*, IPR2019-00266, Paper 8 at 12–13 (PTAB May 16, 2019).

B. Petitioner’s position

Petitioner asserts the “Board should not exercise its discretion to deny institution § 314(a) or § 325(d).” Pet. 60. Petitioner asserts, as to § 325(d), that the “Examiner did not challenge the asserted priority claim, and so that issue has not been considered—much less the specific arguments and evidence presented in this Petition.” Pet. 60. Petitioner asserts as to § 314(a) that “the parallel district-court proceedings do not justify discretionary denial under the factors identified in *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) (precedential) [T]he *Fintiv* factors are all neutral or favor institution.” Pet. 61.

C. Analysis

35 U.S.C. § 314(a) provides that:

The Director [of the USPTO] may not authorize an *inter partes* review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.

Section 314(a) does not require the Director to institute an *inter partes* review. The patent statute provides that “a person who is not the owner of a patent may file with the Office a petition to institute an *inter partes* review of the patent.” 35 U.S.C. § 311(a) (2018).

This case differs from other situations where the Board has exercised discretion under § 314(a) to deny institution. For example, we are not presented with a later-filed petition after having considered an earlier-filed petition challenging the same patent. *See, e.g., General Plastic Indus. Co., Ltd. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19, 6–11, 15–22 (PTAB Sept. 6, 2017) (precedential)). This is the first petition filed against this patent and contains only a single ground. Also, as Petitioner asserts, and Patent Owner does not contest, the *Fintiv* factors are neutral or favor institution. *See* Pet. 61–63.

Instead, Patent Owner asks us to deny institution because Petitioner chose to challenge claims using *inter partes* review rather than post-grant review. *See* Prelim. Resp. 50–60. Petitioner filed this *inter partes* review within the 1 year time frame required by 35 U.S.C. § 315(b), specifically based on when Patent Owner amended its complaints to assert the ’087 patent on October 19, 2021. *See* Pet. 4; Ex. 1004 ¶¶ 1, 106–12.

Under the circumstances and record here, we do not view Petitioner’s challenge to the ’087 patent as contrary to the AIA’s purposes. “The AIA was designed to encourage the filing of meritorious patentability challenges, by any person who is not the patent owner, in an effort to further improve patent quality.” *Coalition for Affordable Drugs VI, LLC v. Celgene Corp.*, IPR2015-01092, Paper 19 at 4 (PTAB Sept. 25, 2015). Moreover, “[i]n 2011, Congress enacted the Leahy-Smith America Invents Act (‘AIA’), Pub.

L. No. 112–29, 125 Stat. 284 (2011), to ‘improve patent quality and limit unnecessary and counterproductive litigation costs.’” *Regents of the Univ. of Minnesota v. LSI Corp.*, 926 F.3d 1327, 1335 (Fed. Cir. 2019) (quoting H.R. Rep. 112–98, pt. I, at 40 (2011)).

While we appreciate that there is a difference between the “reasonable likelihood that the petitioner would prevail” standard in *inter partes* review in § 314(a) and the “more likely than not” standard in post-grant review in § 324(a), Patent Owner provides no caselaw or persuasive reason that would require a Petitioner, during the period when US 11,110,087 was eligible, to file a post-grant review instead of an *inter partes* review. In addition, Patent Owner does not provide any caselaw or persuasive reason why it would be improper for Petitioner to prefer estoppel under 35 U.S.C. § 315(e)(2) rather than estoppel under 35 U.S.C. § 325(e)(2).

We recognize that while Petitioner’s single challenge is under 35 U.S.C. § 102, that analysis will substantively require consideration of written description issues under 35 U.S.C. § 112(a) to determine whether the claims at issue receive the benefit of priority to the original Specification. *See* Pet. 6 (stating that “[t]he ’087 patent should be reviewed under AIA §§ 102 and 112,” but further stating that “Petitioner requests *inter partes* review and cancellation of claims 1–4, 8–14, and 18–26 of the ’087 patent under 35 U.S.C. § 102” and asserting a single ground based on anticipation), 53 (asserted ground based on anticipation). The Federal Circuit has considered written description in the context of *inter partes* review in *Indivior UK Limited v. Dr. Reddy’s Labs. S.A.*, 18 F.4th 1323 (Fed. Cir. 2021). *Indivior* addressed a fact pattern similar to the situation at issue here, which is whether the specification itself provided descriptive support for

numerical values in the claims such that they received benefit of priority. *Id.* at 1328. *Indivior* was also concerned with intervening prior art applied to claims in a patent issued from a fifth continuation of the original application that necessarily shared an identical specification with the original application. *Id.* at 1325. Thus, consistent with *Indivior*, we are not persuaded by Patent Owner’s argument that *inter partes* review is improper because the analysis involves whether the claims at issue in the current patent receive benefit of priority to the original application.

We therefore decline to exercise our discretion under § 314(a) and § 311(b) to deny institution of an *inter partes* review proceeding on the ’087 patent.

XI. ANALYSIS

A. Enablement

In addition to Ground 1, Petitioner raises an enablement issue regarding the claims at issue in this *inter partes* review, especially claim 19. *See* Pet. 41–53. However, Petitioner chose to file an *inter partes* review rather than a post-grant review. “A petitioner in an *inter partes* review may request to cancel as unpatentable 1 or more claims of a patent only on a ground that could be raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications.” 35 U.S.C. § 311(b). On the current record, Petitioner’s attempt to rely upon enablement or scope of enablement under 35 U.S.C. § 112(a) is therefore unavailing because enablement is not an allowable ground in an *inter partes* review proceeding.

We note that Petitioner points to no authority that allows raising this enablement issue in an *inter partes* review proceeding. We think this limitation on raising an enablement issue carries additional force when post-

grant review would have been available. Indeed, Petitioner filed PGR2022-00023 on February 3, 2022, within 9 months of the issue of US 10,993,942 on May 4, 2021. Petitioner therefore evinced an awareness of this patent family, and the '087 patent issued on September 7, 2021, and Patent Owner's complaint was filed October 19, 2021, leaving Petitioner several additional months to file a post-grant proceeding. However, Petitioner chose to file an *inter partes* review on October 14, 2022, more than a year of issuance of the '087 patent. As a consequence of Petitioner's selection of *inter partes* review, Petitioner chose to limit the issues to grounds under § 102 and § 103.

B. Priority claims and written description

As indicated above in Section X.C, the anticipation challenge of Ground 1 is predicated on whether the claims at issue receive the benefit of priority to the original Specification—which in turn requires us to consider whether the challenged claims find adequate written descriptive support in the priority document. Where, as with Ground 1, the effective filing date of a claim is an issue in a § 102 or § 103 analysis, courts have considered whether the priority document provides descriptive support for the claim. *See, e.g., Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1571 (Fed. Cir. 1997); *Arthrex, Inc. v. Smith & Nephew, Inc.*, 35 F.4th 1328, 1343 (Fed. Cir. 2022).

1. Petitioner's position

Petitioner contends that the “independent claims lack written-description support for two reasons: (1) the specification does not provide adequate guidance to pick and choose various laundry-listed elements to reach the claimed dosing regimens, and (2) the specification does not

describe a GDC-0199 monotherapy at all.” Pet. 31. Petitioner contends, regarding the nonprovisional priority application, that “claims are not found in a single embodiment or example from an asserted priority document.” Pet. 31.

Petitioner contends

no example or embodiment discloses the claim limitations. The mention of escalating doses is brief. *See* Ex. 1001, 24:3-36. The description quickly mentions Figure 2. *Id.* at 24:6-10. Then, after explaining that the GDC-0199 doses are used specifically “prior to” or “after” antibody administration, *see id.* at 24:11-16, the description lists a scattered array of doses, *see id.* at 24:17-29. And as in the provisional, general aspects of the dosing regimen (e.g., dose amount and timing) are recited in laundry-list fashion in sections of the description devoted only to combination therapy or specific cancers like NHL and AML.

Pet. 33. Petitioner contends the “specification provides no ‘guidance’ on how or why one would pick these doses, in this order, for these time periods, in the absence of an antibody to fight an antibody-prone cancer. Ex. 1020 ¶¶ 106-08, 147-48, 204.” Pet 35. Petitioner contends that:

During prosecution, Patent Owner argued that the escalating dosing regimen was critical to avoid toxicity. *See* Ex. 1013, 71-73. But the specification provides no insight into what timing or dose sizes reach that result—or that such a problem even exists, much less its solution. Ex. 1020 ¶¶ 58, 190. And later clinical trials demonstrated that some dosing regimens would *not* avoid that toxicity. Ex. 1020 ¶¶ 113, 191. Still, even if a skilled artisan could fill in the blanks, “a description that merely renders the invention obvious does not satisfy the requirement.” *Ariad*, 598 F.3d at 1352.

Pet. 35. Petitioner contends “[b]oth *ICU Medical* and *Gentry Gallery* parallel this case. The disclosure, through its title, summary, descriptions,

and examples, covers only combination therapy: there is no description of an “antibody-less” method of treatment.” Pet. 37.

Petitioner separately contends, regarding dependent claims, that “[b]ecause the limitations of independent claims 1, 9, and 19 are not described in the provisional application, their corresponding dependent claims are also not supported.” Pet. 40. Petitioner contends that “[c]laims 4, 14, and 25 require that dosing “is continued until disease progression,” but this limitation is independently not disclosed in a priority document in any sense, much less in combination with the limitations of claims 1, 9, or 19.”

Pe. 40. Petition contends

Claims 2, 12, and 23 require that each “dosing cycle” is “one day”— that is, a day-by-day dose ramp-up. Example 2 and Figures 2-3 do not describe daily ramp-up doses but rather weekly dosing cycles. *See* Ex. 1001, 25:66-26:5, Figs. 2-3; Ex. 1007, [0116]-[0121], Figs. 2-3. Claims 11 and 22, requiring a “different dose ... once daily,” suffer the same nondisclosure problem, as do claim 8 (requiring a specific day-by-day ramp-up from 100 to 200 to 400 mg) and claim 18 (requiring daily ramp-up).

Pet. 40. Petitioner contends “[c]laim 21 requires that 100 mg be the ‘starting dose’ among ‘three differing doses,’ but Example 2 and Figures 2-3 depict no such starting dose. *See* Ex. 1001, 25:66-26:5, Figs. 2-3.” Pet. 41.

Petitioner contends “[c]laim 26 requires co-administration ‘with cytarabine,’ but no such example exists. But cytarabine is merely listed among a laundry list of ‘other’ agents that ‘may be used in’ the “combination treatment.” Ex. 1001, 18:13-62; Ex. 1007, [0078]-[0079].” Pet. 41.

2. *Patent Owner’s position*

Patent Owner contends

The '087 specification repeatedly discloses the administration of GDC-0199 alone for the treatment of lymphoma and leukemia. For example, the '087 specification states that “GDC-0199 *alone* can be administered to the human in the absence of the GA101 antibody or the GA101 antibody alone can be administered to the patient in the absence of GDC-0199.” Ex. 1001 at 4:42-49 (emphasis added). The '087 specification further discloses that “methods are provided for the treatment of a cancer in a human [patient] in need thereof comprising administering to said human a GA101 antibody *and/or* GDC-0199 in multiple dosing cycles.” *Id.* at 4:10-13 (emphasis added). Moreover, the '087 specification teaches that “[i]n certain dosing cycles, one therapeutic agent *alone* is administered to the patient.” *Id.* at 23:39-40 (emphasis added). And the '087 specification discloses that “[i]n certain embodiments, escalating doses of GDC-0199 are administered to the patient *prior to* administration of the type II anti-CD20 antibody.” *Id.* at 24:11-13 (emphasis added).

Prelim. Resp. 18–19. Patent Owner contends the “'087 specification explains that ‘CD20 expressing cancer may be, for example, lymphomas[or] lymphocytic leukemias.’ *Id.* at 15:13-14. The '087 specification further states that ‘CD20 expressing cancer as used herein refers to lymphomas (e.g., B-Cell Non-Hodgkin’s lymphomas (NHL)) and lymphocytic leukemias.’ *Id.* at 15:37-39.” Prelim. Resp. 21–22.

Patent Owner contends

The '087 specification describes methods of treatment with GDC-0199 where “the amounts of GDC-0199 per dose administered to the patient are increased during a first dosing cycle.” Ex. 1001 at 24:3-6. The '087 specification provides “an exemplary dosing scheme,” as illustrated in Figure 2, where the daily GDC-0199 dose increases from 50 mg to 100 mg and then to 300 mg. *Id.* at 24:6-10.

Prelim. Resp. 23. Patent Owner contends “'087 specification further expressly discloses that 100 mg of GDC-0199 can be a dose within a dose escalation scheme as either an “initial dose” or a subsequent dose.” Prelim.

Resp. 25. Patent Owner notes the '087 specification teaches “the amount of GDC-0199 per dose administered to the patients begins with 50 mg or **100 mg**”; the ‘initial amounts’ can be ‘followed by dose amounts of **100 mg**, 200 mg, 300 mg or more of GDC-0199.’ *Id.* at 24:17-29.” Prelim. Resp. 25 (emphases in Prelim. Resp.).

Patent Owner contends that “because claim 19 uses the term ‘comprising,’ the 100 mg dose need only be administered at some point during the method of treatment.” Prelim. Resp. 26. Patent Owner contends that “because claim 9 uses the term “comprising,” the 100 mg and 200 mg doses do not need to be the first two doses or sequential doses. These two doses need only be administered at some point during the method of treatment.” Prelim. Resp. 27. Patent Owner contends that

The '087 specification discloses in column 24 that “the amount of GDC-0199 per dose administered to the patients begins with 50 mg or **100 mg**”; that the “initial amounts” can be “followed by dose amounts of 100 mg, **200 mg**, 300 mg or more of GDC-0199”; and that the “final amounts” can be “between 190 mg to **400 mg**.” *Id.* at 24:17-29 (emphases added). Moreover, because claim 1 uses the term comprising, the 100 mg, 200 mg, and 400 mg doses do not need to be the first or only doses or sequential doses. These three doses need to be administered at some point during the method of treatment, with the 400 mg dose following the 200 mg dose, and the 200 mg dose following the 100 mg dose.

Prelim. Resp. 29.

Patent Owner contends, regarding the dependent claims, that the '087 specification provides written description support for these claims. And the '087 specification discloses that the dosing cycle can be one day. *Id.* at 16:66-17:3 (“a dosing cycle is usually about 1, 2 . . . or 30 days”). From this disclosure, a POSA would have recognized that an effective method of treating leukemia

and lymphoma could include one-day dosing cycles as provided in claims 2, 12, and 23.

Prelim. Resp. 32. Patent Owner contends that Figure 2 shows “that as recited in claims 3, 13, and 24, Figure 2 and Example 2 teach a schedule in which the initial dose is administered for the first dosing cycle and the final dose amount is administered for multiple cycles.” Prelim. Resp. 33. Patent Owner contends that, as to “Dependent claims 4, 14, and 25 [that] recite administering the claimed dosing regimen ‘until disease progression.’” (Prelim. Resp. 35), a “POSA would understand that if a patient’s disease progressed while on the treatment, it would not make sense to continue the treatment. The ’087 specification discloses that the administration of GDC-0199 attempts to inhibit tumor growth. Accordingly, the ’087 specification supports administering the claimed dosing regimen ‘until disease progression.’” Prelim. Resp. 36.

Patent Owner contends

Claim 26 depends from claim 19 and recites administering GDC-0199 “in combination with cytarabine.” *Id.* at 37:1-2. . . . the ’087 specification states that . . . other cytotoxic, chemotherapeutic or anti-cancer agents, or compounds that enhance the effects of such agents (e.g. cytokines) may be used in the type II anti-CD20 antibody and Bcl-2 inhibitor combination treatment of CD20 expressing cancer.” *Id.* at 18:13-17. The ’087 specification states that “[s]uch agents include, for example: . . . cytarabine (Ara-C).” *Id.* at 18:24-32.

Prelim. Resp. 37.

3. '*087 Patent (Ex. 1001)*¹

The '*087 patent teaches “[t]he present invention is directed to a combination therapy involving a type II anti-CD20 antibody and a selective Bcl-2 inhibitor for the treatment of a patient suffering from cancer, particularly a CD20-expressing cancer.” Ex. 1001, 1:21–25. The '*087 patent teaches “[e]xemplary non-solid tumors that can be treated in the methods provided herein, include, for instance, a leukemia or a lymphoma.” Ex. 1001, 25:6–8.**

According to the '*087 patent:*

A dosing period as used herein is meant a period of time, during which each therapeutic agent has been administered at least once. A dosing cycle is usually about 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, or 30 days, and, in one embodiment, 6, 7, 8, 9, 10, 11, 12, 13, or 14 days, for example, 7 or 14 days.

In certain embodiments, a dosing period is a dosing cycle.

Ex. 1001, 16:64–17:4.

The '*087 patent teaches that in “certain embodiments, methods are provided for the treatment of a cancer in a human in need thereof comprising administering to said human a GA101 antibody and/or GDC-0199 in multiple dosing cycles. In an embodiment, each dosing cycle of the multiple dosing cycle is for at least 1 week.” Ex. 1001, 4:10–15. The '*087 patent teaches embodiments where “following the last dosing cycle of multiple**

¹ Because the '*087 patent is a direct continuation of priority documents including US Application 14/020,762, now US 9,539,251 with filing dates antedating the anticipation reference at Ex. 1011, we cite to the identical disclosure in the '*087 patent for convenience in analyzing priority support.**

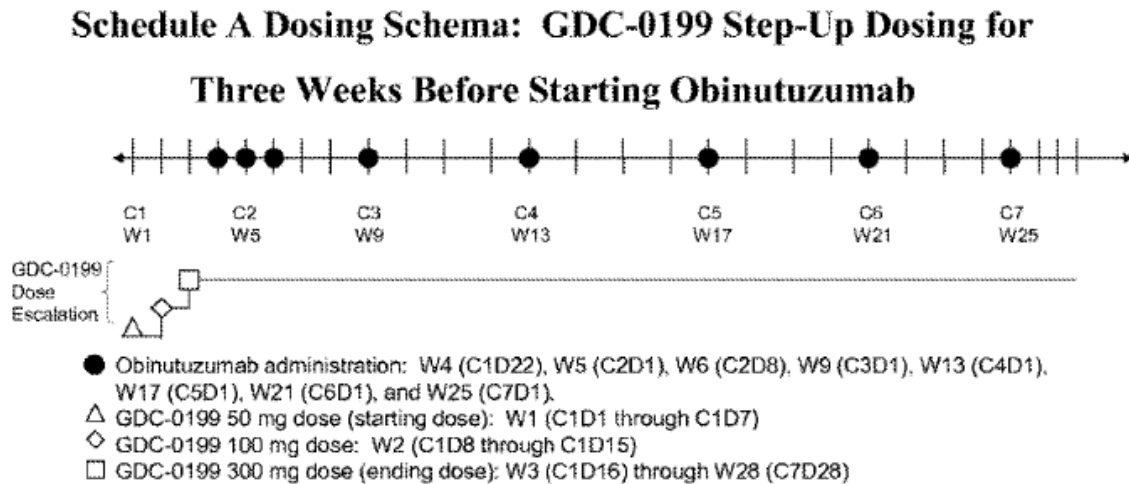
dosing cycles, GDC-0199 alone can be administered to the human in the absence of the GA101 antibody.” Ex. 1001, 4:45–48. The ’087 patent teaches that in

certain embodiments, escalating doses of GDC-0199 are administered to the patient prior to administration of the type II anti-CD20 antibody. In other embodiments, escalating doses of GDC-0199 are administered to the patient after the type II anti-CD20 antibody has been administered to the patient.

In some embodiments of the method of treatment provided herein, the amount of GDC-0199 administered to the patient per dose is increased during the first dosing cycle from initial amounts of between 10 mg to 80 mg to final amounts of between 190 mg to 400 mg. In certain embodiments, the amount of GDC-0199 per dose administered to the patients begins with 50 mg or 100 mg, and is increased to 300 mg per dose. In some embodiments, the amount of GDC-0199 in the initial doses administered to the patient can, for example, be between 20 mg to 60 mg (e.g., 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 55 mg or 60 mg doses), followed by dose amounts of 100 mg, 200 mg, 300 mg or more of GDC-0199.

Ex. 1001, 24:11–29.

Figure 2 of the ’087 patent is reproduced below:



C = cycle; D = day; W = week.

Figure 2 depicts a dosing schedule “consisting of GDC-0199 administered in escalating doses for 3 weeks prior to the first obinutuzumab² infusion.”

Ex. 1001, 25:67–26:1. In particular, Figure 2 describes administration of a 50 mg dose of GDC-0199 for the first week, a 100 mg dose for the second week, and a 300 mg dose for the third week alone and continuing through twenty-eight weeks. Ex. 1001, Figure 2.

The '087 patent teaches

GDC-0199 monotherapy may be continued in patients beyond 6-7 cycles of combination treatment described above (e.g., if they have acceptable toxicity and have not yet achieved maximal clinical response (i.e., are having continued improvement/reduction in tumor burden that has not yet stabilized for at least 2 months)). Such patients may continue GDC-0199 monotherapy until they have achieved maximal response or up to 1 year after the last patient is enrolled, whichever occurs first.

² Ex. 1001 teaches “a type II anti-CD20 antibody (GA101 antibody, in this case, obinutuzumab).” Ex. 1001, 4:65–67.

Ex. 1001, 26:25–33.

4. *Analysis*

a. Claims 1 and 9

We find that on the current record Petitioner has established a reasonable likelihood that claims 1 and 9 are not entitled benefit of priority to the '087 or earlier priority Specifications prior to the publication of the November 2018 Venclexta label. Claim 1, for example, recites a GDC-0199 dosing regimen “compris[ing] a dose of 100 mg of GDC-0199 per day, followed by orally administering to the patient a dose of 200 mg of GDC-0199 per day, followed by orally administering to the patient a dose of 400 mg of GDC-0199 per day.” This disclosure is not found in a single example, but must be selected from disparate parts of the Specification. “The written description requirement is not met when, as here, the specification provides at best disparate disclosures that an artisan might have been able to combine in order to make the claimed invention.” *Flash-Control, LLC v. Intel Corp.*, 2021 WL 2944592 4 (Fed Cir. 2021) (*citing Ariad*, 598 F.3d at 1352.)

We find the instant fact pattern similar to *Biogen Int'l GmbH v. Mylan Pharms. Inc.*, 18 F.4th 1333 (Fed. Cir. 2021). In *Biogen*, the Court found the issue was “whether the original specification describes ‘possession’ of the claimed therapeutically effective DMF480-dose limitation to treat MS.” *Id.* at 1342. The Court found the “specification’s sole reference to DMF480 constitutes a significant fact that cuts against Biogen’s case, particularly because it appears at the end of one range among a series of ranges.” *Id.* at 1343. The Court stated that unlike a different dose, DMF720, “the specification’s focus on basic research and broad DMF-dosage ranges show

that the inventors did not possess a therapeutically effective DMF480 dose at the time of filing.” *Id.* at 1343. The Court concluded that “the district court did not clearly err in finding that a skilled artisan would not have recognized, based on the single passing reference to a DMF480 dose in the disclosure, that DMF480 would have been efficacious in the treatment of MS, particularly because the specification's only reference to DMF480 was part of a wide DMF-dosage range and not listed as an independent therapeutically efficacious dose.” *Id.* at 1343.

As in *Biogen*, the '087 patent recited the invention in disparate portions of the Specification. In particular, the '087 patent recites a list including the particular cancers being treated (Ex. 1001, 15:63–65); lists of different dosing cycle lengths and treatment phases (Ex. 1001, 16:54–17:4, 22:52–23:5); a list reciting “GDC-0199 can, for example, be administered once a day, once every other day, once every three days, four, five or six days, or once a week, to the patient.” Ex. 1001, 23:61–64. And while the '087 patent does teach an “exemplary dosing scheme where amounts of GDC-0199 administered to patients in the first dosing cycle escalate from 50 mg doses the first week, to 100 mg doses the second week, to 300 mg doses the third week” (Ex. 1001, 24:6–10), the Specification merely lists alternate initial doses without demonstrating possession of specific dose escalation amounts that would have been therapeutically effective in “treating chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) in a patient” as recited in claims 1 and 9 of the '087 patent. *Cf. Biogen*, 18 F.4th at 1343. This understanding of treating is consistent with Patent Owner’s view, as Patent Owner explained that the method of treating is “a procedure or course of action that is designed to reduce or eliminate the number of

cancer cells in a patient, or to alleviate the symptoms of a cancer.” Prelim. Resp. 45.

At this stage of the proceeding, we are not persuaded that the sort of picking and choosing required to obtain the specific dose cycle length in days, the number of total cycles, and the particular dose amounts used in each cycle in claims 1 and 9 would “clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.” *Ariad*, 598 F.3d at 1351. “Although this case differs from *Ruschig* in that what was disclosed in *Ruschig* was a genus encompassing potentially half a million compounds, the rationale applies equally to this case, in which the disclosure of the . . . patent discloses a multitude of pharmacokinetic parameters.” *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1326 (Fed Cir. 2000) (citing *In re Ruschig*, 379 F.2d 990 (CCPA 1967)).

We note that selection of doses in claims 1 and 9 based on the example in Figure 2 of the '087 patent would require at least three changes to the disclosed dosing schema. Claim 1 does not mention a 50 mg and a 300 mg dose and requires addition of a 200 mg and 400 mg dose. Claim 9 does not mention a 50 mg dose and a 300 mg dose and requires addition of a 200 mg dose. Selection of only two additional different doses from a list of 13 creates a class of 169 different possibilities.

While the “envisage” test is ordinarily associated with anticipation, not benefit of priority (*see, e.g., In re Petering*, 301 F.2d 676, 681 (CCPA 1962)), *Schaumann* explains that an anticipation situation with separate elements that are selected and recombined

into different compounds than those named, we do not get a small recognizable class with common properties. We would apparently get from the French patent some 130 and from the

Swedish some 156 compounds. . . . We will not apply the Petering type of analysis to such a situation.

In re Schaumann, 572 F.2d 312, 316 (1978). This teaching in *Schaumann* is analogous to the instant situation, where multiple different selections of doses must be made, resulting in hundreds or thousands of different possibilities. Consistent with *Schaumann*, we do not find that the ordinary artisan would at once envisage hundreds of different dosing possibilities.

We therefore conclude that, based on the current record, there is a reasonable likelihood that claims 1 and 9 do not receive the benefit of priority to the '087 patent specification.

b. Claims 2–4, 8, 10–14, and 18

We find that on the current record Petitioner has established a reasonable likelihood that dependent claims 2–4, 8, 10–14, and 18 are not entitled to benefit of priority to the '087 or earlier priority Specifications prior to the publication of the November 2018 Venclexta label. We note that Patent Owner has not provided evidence such as a Declaration addressing these claims on the current record.

Claims 2–4, 8, 10–14, and 18 are also drawn to a selection from a multitude of dose parameters selected from within the specification of the '087 patent. As with independent claims 1 and 9, we do not presently read these claims as limited to specific combinations contemplated and defined by the '087 patent. *Novozymes* found such selection insufficient where the patent “provides formal textual support for each individual limitation recited in the claims . . . [but] nowhere describes the actual functioning [invention] . . . that those limitations together define.” *Novozymes A/S v. Dupont Nutrition Biosciences APS*, 723 F.3d 1336, 1349 (Fed. Cir. 2013). Instead,

these claims would appear to “to derive written description support from an amalgam of disclosures plucked selectively from the” ’087 patent. *Id.* at 1349.

At this stage of the proceeding, we agree with Patent Owner’s interpretation of “comprising” in the context of these claims (*see* Prelim. Resp. 13, 20–21) and therefore also agree with Patent Owner’s position on support for monotherapy. *See* Prelim. Resp. 18–19. We also do not rely upon either *Gentry Gallery* or *ICU Medical*. *See* Prelim. Resp. 38–39.

We are not, however on the current record, persuaded by Patent Owner’s argument that because Example 2 and Figure 2 provide the particular escalating dosage regimen recited in claim 1, that disclosure also provides sufficient description for a genus of possible dose configurations such as those recited in claims 2–4, 8, 10–14, and 18 simply because

The ’087 specification discloses in column 24 that “the amount of GDC-0199 per dose administered to the patients begins with 50 mg or **100 mg**”; that the “initial amounts” can be “followed by dose amounts of 100 mg, **200 mg**, 300 mg or more of GDC-0199”; and that the “final amounts” can be “between 190 mg to **400 mg**.” *Id.* at 24:17-29 (emphases added).

Prelim. Resp. 29. “A patent owner cannot show written description support by picking and choosing claim elements from different embodiments that are never linked together in the specification.” *Flash-Control*, 2021 WL 2944592 at *4. We also agree with Petitioner that

[t]he Federal Circuit has rejected that “a ‘laundry list’ disclosure” of every possible aspect of every possible limitation “would constitute a written description of every species in the genus, because “such a disclosure would not ‘reasonably lead’ those skilled in the art to any particular species.” *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571 (Fed. Cir. 1996).

Pet. 30. And to the extent that the specification of the '087 patent would have rendered the limitations of claims 2–4, 8, 10–14, and 18 obvious, “a description that merely renders the invention obvious does not satisfy the [written description] requirement.” *Ariad*, 598 F.3d at 1352.

c. Claim 19

We find that, on this record, Petitioner has not established a reasonable likelihood that claim 19 should not be entitled to benefit of priority to the '087 or earlier priority Specifications prior to the publication of the November 2018 Venclexta label. That is, claim 19 is entitled to priority. As noted above, the '087 patent teaches the requirements of claim 19 of treatment of leukemia or lymphoma, including chronic lymphocytic leukemia and small lymphocytic lymphoma (Ex. 1001, 15:63–64), by orally administering the Bcl-2 inhibitor (Ex. 1001, 16:49) GDC-0199 in escalating doses of 50 mg per day during a first week and 100 mg per day during a second week (Ex. 1001, Figure 2).

We find on the current record Petitioner's first argument relating to a lack of adequate guidance unpersuasive as Figure 2 of the '087 patent provides literal and express support for claim 19. We find the situation here comparable to *Capon v. Eshhar*, 418 F.3d 1349, 1357–58 (Fed. Cir. 2005). In *Capon*, claim 1 was drawn to a chimeric DNA and the disclosure provided “the nucleotide sequences of sixteen different receptor primers and four different scFv primers from which chimeric genes encoding scFvR may be obtained” as well as methods for “the production of chimeric genes encoding scFvR using primers.” *Id.* at 1356. *Capon* found this detailed disclosure sufficient. *Id.* This is also similar to *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 966 (Fed. Cir. 2002), where “reference in the

specification to deposits of nucleotide sequences describe those sequences sufficiently to the public for purposes of meeting the written description requirement.” Just as the literal description in *Enzo* was sufficient, here, the ’087 patent teaches a particular exemplary dosing schedule in Figure 2 of oral administration of 50 mg of GDC-0199 per day for one week followed by a dose of 100 mg of GDC-0199 per day for one week as required by claim 19. That literal support reasonably provides written descriptive support for claim 19.

We find on the current record Petitioner’s second argument purporting to limit the disclosure of the ’087 patent to combination therapies directly inconsistent with the plain text in the ’087 patent. The ’087 patent recognizes “GDC-0199 alone can be administered to the human in the absence of the GA101 antibody ,or the GA101 antibody alone can be administered to the patient in the absence of GDC - 0199.” Ex. 1001, 4:46–49. That the ’087 patent teaches alternatives of administering a GA101 antibody and/or GDC-0199 in multiple dosing cycles demonstrates possession by the ’087 patent of three alternative treatments: GA101 antibody and GDC-0199 together; GA101 antibody alone; and GDC-0199 alone. Ex. 1001, 4:10–17.

We agree with Patent Owner that claim 19 encompasses therapies with either GDC-0199 alone or in combination with the GA101 antibody because claim 1 uses the transitional term “comprising” that is “inclusive or open-ended and does not exclude additional, unrecited elements or method steps.” *Georgia-Pacific Corp. v. US. Gypsum Co.*, 195 F.3d 1322, 1327 (Fed. Cir. 1999); *see* Prelim. Resp. 26. Claim 19 therefore does not exclude

combination treatment with the GA101 antibody in addition to the recited dose escalation with GDC-0199.

Lastly, on the current record Petitioner does not persuade us that Figure 2 of the '087 patent alone fails to demonstrate benefit of priority for the invention of claim 19. Rather, Figure 2 of the '087 patent exemplifies administration of GDC-0199 alone to chronic lymphocytic leukemia patients in escalating doses with 50 mg per day during a first week and 100 mg per day during a second week as required by claim 19 of the '087 patent. Ex. 1001, Figure 2; Ex. 1001, 26:67–27:1. That further therapeutic interventions may be performed are irrelevant. Claim 19 need not include every embodiment in the disclosure of the '087 patent so long as there is clear benefit of priority of the claimed invention. “That claims are interpreted in light of the specification does not mean that everything expressed in the specification must be read into all the claims.” *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 957 (Fed. Cir.1983). We therefore do not read the combination therapy into claim 19 when the '087 patent suggests that GDC-0199 alone may be administered for some period of time. Ex. 1001, Figure 2.

Indeed, “[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using ‘words or expressions of manifest exclusion or restriction.’” *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (quoting *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1327 (Fed. Cir. 2002))). Here, Petitioner has identified no clear intention in the '087 patent or in the '087 patent prosecution that suggests limiting claim 19 to

combination therapy. As the evidence shows, the '087 patent expressly suggests “administering to said human a GA101 antibody and/or GDC-0199 in multiple dosing cycles.” Ex. 1001, 4:12–17. The '087 patent teaches “GDC-0199 alone can be administered to the human in the absence of the GA101 antibody.” Ex. 1001, 4:46–48.

We are not persuaded that Petitioner’s cited case law supports its written description position on claim 19 either. As Petitioner notes, the issue in *Gentry Gallery* was that “the specification itself only described sofas ‘having controls on the console.’” Pet. 37; citing *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1478–79 (Fed. Cir. 1998). However, the '087 patent does not limit the treatment method to a single embodiment, but expressly recognizes “GDC-0199 alone can be administered to the human in the absence of the GA101 antibody.” Ex. 1001, 4:45–49. Thus, the instant fact pattern differs from *Gentry Gallery* because here there is express disclosure of the claimed embodiment, and that embodiment is also disclosed in an example. Ex. 1001, Figure 2; Ex. 1001, 26:25–35.

We also find Petitioner’s reliance on *ICU Medical* unavailing as there “the specification describes only medical valves with spikes.” *ICU Medical, Inc. v. Alaris Medical Systems, Inc.*, 558 F.3d 1368, 1378 (Fed. Cir. 2009). In the present case, the '087 patent expressly describes that “GDC-0199 alone can be administered to the human in the absence of the GA101 antibody.” Ex. 1001, 4:45–49. Moreover, the '087 patent exemplifies a situation where for three weeks GDC-0199 is administered alone. Ex. 1001, Figure 2; Ex. 1001, 26:25–33.

We have considered the Declaration of Dr. Jeffrey Gordon, but we do not find Dr. Gordon's opinions with respect to claim 19 persuasive on this record.

Accordingly, we find that on the current record Petitioner has not successfully shown that a reasonable likelihood that independent claim 19 fails to comply with the written description requirement.

d. Claims 20–26

We find that on the current record Petitioner has established a reasonable likelihood that claims 20–26 should not be entitled to benefit of priority to the '087 or earlier priority Specifications prior to the publication of the November 2018 Venclexta label.

Also on the current record, we find that claims 20 and 22–24 are drawn to further dosing schedules that require selection from a multitude of dose parameters selected from within the specification of the '087 patent without specific evidence that any of these doses would have been effective in treating lymphoma or leukemia. For claim 21, drawn to 100 mg of Venclexta as an initial dose, Patent Owner does not point to a specific exemplary basis for this limitation in the '087 specification as effective in treating lymphoma or leukemia. These claims appear to lack express descriptive support in the '087 patent consistent with *Biogen*, which finds the “district court did not clearly err in finding that a skilled artisan would not have recognized, based on the single passing reference to a DMF480 dose in the disclosure, that DMF480 would have been efficacious in the treatment of MS.” *Biogen*, 18 F.4th at 1343.

For claim 25, we agree with Petitioner on the current record that the “priority documents do not discuss any ‘disease progression’ endpoint or

provide sufficient guidance on the subject. Ex. 1020 ¶¶ 209, 211. The complete lack of guidance on ‘disease progress’ is further exacerbated by the lack of discussion on TLS, either. Ex. 1020 ¶¶ 210-11.” Pet. 51. We are not persuaded by Patent Owner’s argument that a “POSA would understand that if a patient’s disease progressed while on the treatment, it would not make sense to continue the treatment.” Prelim. Resp. 36. While it may well be obvious to discontinue treatment if there is disease progression, “while the description requirement does not demand any particular form of disclosure, . . . or that the specification recite the claimed invention *in haec verba*, a description that merely renders the invention obvious does not satisfy the requirement” *Ariad*, 598 F.3d at 1352.

For claim 26 that recites combination therapy with cytarabine, Petitioner contends that

cytarabine is merely listed among a laundry list of “other” agents that “may be used in” the “combination treatment.” Ex. 1001, 18:13-62; Ex. 1007, [0078]-[0079]. And the specification requires *three* agents: a Bcl-2 inhibitor (e.g., GDC-0199), an antibody, and something among a laundry list of “other” agents. But the full scope of claim 26 includes administering just two: GDC-0199 and cytarabine. Yet it provides no description, much less guidance, on how one would administer a GDC-0199-and-cytarabine treatment omitting the antibody component. Ex. 1020 ¶¶ 136-41, 166-69.

Pet. 41. We are not persuaded by the contention that “even though Patent Owners do not believe that a blaze mark analysis is necessary, that test is met because this disclosure from the ’087 specification would provide blaze marks for the ‘cytarabine’ limitation.” Prelim. Resp. 37.

We agree with Petitioner, on the current record, as there are no specific blaze marks leading to selection of combination therapy with GDC-

0199 and cytarabine. This is particularly significant as there is no disclosure that this combination will effectively treat lymphoma or leukemia. “We are looking for blaze marks which single out particular trees. We see none.”

Ruschig, 379 F.2d at 995. That a laundry list is not sufficient to describe combination cancer therapy is consistent with *OSI*, which notes that

between 1990 and 2005 . . . there were 1,630 other new drug compounds that . . . targeted [a particular cancer] and were studied in Phase II trials. The failure rate for these compounds was 99.5%. . . . given a 99.5% failure rate and no efficacy data or any other reliable indicator of success, the only reasonable expectation at the time of the invention was failure.

OSI Pharm., LLC. V. Apotex, Inc., 939 F.3d 1375, (Fed. Cir. 2019).

C. Anticipation

1. *Venclexta Label November 2018 (Ex. 1006)*

Venclexta Label is a product label for venetoclax oral tablets including prescribing information for “the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), with or without 17p deletion, who have received at least one prior therapy.” Ex. 1006, 2. Table 1 of the Venclexta Label is reproduced below:

Table 1. Dosing Schedule for Ramp-Up Phase in Patients with CLL/SLL

	VENCLEXTA Daily Dose
Week 1	20 mg
Week 2	50 mg
Week 3	100 mg
Week 4	200 mg
Week 5 and beyond	400 mg

Table 1 explains how to “[a]dminister the VENCLEXTA dose according to a weekly ramp-up schedule over 5 weeks to the recommended daily dose of 400 mg The 5-week ramp-up dosing schedule is designed to gradually

reduce tumor burden (debulk) and decrease the risk of TLS.” Ex. 1006, 2.

Venclexta Label teaches “VENCLEXTA in Combination with Low-Dose Cytarabine.” Ex. 1006, 20 (underlining omitted).

2. *Petitioner’s position*

Petitioner contends “claims 1, 9 and 19 are the only independent claims of the ’087 patent and recite methods of treating lymphoma or leukemia by administering ‘escalating doses’ of GDC-0199. *Supra* Sections VI.D.4.” Pet. 53. Petitioner contends that

the 2018 Label disclosed treating “human patients” suffering from specific types of lymphoma and leukemia by orally administering venetoclax (i.e., “GDC-0199”) to patients using specific dosing cycles requiring escalating dose regimens. Ex. 1006, 1-4; *see also* Ex. 1020 ¶¶ 248, 250-51, 255, 257-58; *see also* Ex. 1006, 1 . . . For example, a patient being treated for CLL or SLL would follow a five-week dose ramp-up schedule in Table 1. Ex. 1006, 3; *see also Supra* Section VI.C.1; Ex. 1020 ¶¶ 250, 257. This “ramp-up” schedule required administering doses of 100 mg, 200 mg, and 400 mg per day, just as the independent claims of the ’087 patent require. Ex. 1006, 3; *see also* Ex. 1020 ¶¶ 250, 257.

Pet. 54–55. Petitioner contends that “like claim 1 of the ’087 patent, each of the ‘ramp-up’ dosing schedules disclosed in the 2018 Label could be part of a larger dosing cycle. Ex. 1006, 2-4, 8, 11-12; *see also* Ex. 1020 ¶ 256.” Pet. 55.

Petitioner contends, regarding claims 2–4 and 8 of the ’087 patent, that

the 2018 Label contemplated an escalating dosing regimen wherein “each dosing cycle is one day” and “a starting dose of the escalating doses is administered for one dosing cycle” (i.e., 100 mg is administered on day 1 only) and “an ending dose of the escalating doses is administered in multiple dosing cycles”

(i.e., either 400 mg or 600 mg is administered on days 4 *and beyond*). Ex. 1006, 3; *see also* Ex. 1020 ¶¶ 251, 258, 263-64. For the same reasons, the 2018 Label disclosed the administration of “GDC-0199” in the amounts and intervals recited in claim 8. Finally, the 2018 Label also explained that the AML dosing cycle and regimen should be continued “until disease progression ... is observed.” Ex. 1006, 3; *see also* Ex. 1020 ¶¶ 251, 258, 263-64.

Pet. 57.

Petitioner contends with regard to claims 10–14 and 18 of the ’087 patent that “like claim 10, the 2018 Label disclosed the administration of ‘three differing doses of GDC-0199.’ Ex. 1006, 1-3; *see also* Ex. 1020 ¶¶ 250-51, 257-58, 260.” Pet. 58. Petitioner contends “just like claim 11, the 2018 Label disclosed that each of the ‘ramp-up’ dosing schedules disclosed in the 2018 Label could be part of a larger dosing cycle. Ex. 1006, 3; *see also* Ex. 1020 ¶¶ 256, 261.” Pet. 58. Petitioner contends “claims 12–14 are identical to claims 2-4, setting aside the differences in their dependencies. Accordingly, for the reasons set forth above, claims 12-14 are anticipated by the 2018 Label.” Pet. 58. Petitioner contends that “claim 18, like claim 8, recites that ‘the patient is administered 100 mg of GDC-0199 per day for one day, followed by 200 mg of GDC-0199 per day for one day.’ . . . the 2018 Label disclosed every element of claim 18 for the same reasons set forth above.” Pet. 59.

Petitioner contends with regard to claims 20–26 of the ’087 patent that claims 20 and 22 mirror claims 10 and 11, while claims 23-25 are identical to dependent claims 2-4 and 12-14. For the same reasons discussed above, the 2018 Label disclosed the additional claim limitations in dependent claims 20 and 22. *Supra* Section VIII.A.3. Similarly, as described above, the 2018 Label disclosed all claim limitations recited in claims 23-25. *Supra* Sections VIII.A.1-3; *see also* Ex. 1020 ¶¶ 260-65.

Pet. 59–60. Petitioner contends, as to claim 21, that the “2018 Label disclosed that the ‘100 mg’ dose of venetoclax was the “starting dose” in the larger “ramp-up” dosing schedule. Ex. 1006, 2-4; *see also* Ex. 1020 ¶¶ 251, 258, 263-64.” Pet. 60. Petitioner contends, as to claim 26, that “the 2018 Label disclosed that when used to treat AML, venetoclax may be “administered in combination with cytarabine.” Ex. 1006, 3; *see also* Ex. 1020 ¶ 267.” Pet. 60.

3. *Patent Owner’s position*

Patent Owner does not specifically dispute that the disclosures of the November 2018 Venclexta Label anticipate claims 1–4, 8–14, and 18–26 of the ’087 patent. *See, generally*, Prelim. Resp. Patent Owner contends that

because the 2013 priority application and the other documents in the chain of continuations in this patent family contain identical disclosures to the ’087 specification and provide ample written description support for and enable the challenged claims. Therefore, the November 2018 Venclexta Label—Petitioner’s sole alleged anticipatory reference—does not qualify as prior art. Prelim. Resp. 15.

4. *Analysis*

We have already analyzed whether Petitioner has provided a reasonable likelihood that claims 1–4, 8–14, and 18–26 of the ’087 patent receive benefit of priority prior to the publication of the November 2018 Venclexta label. As discussed above, we find that on the current record there is a reasonable likelihood that claim 19 is entitled to benefit of priority. Therefore, the November 2018 Venclexta label does not qualify as prior art to claim 19 and we find there is not a reasonable likelihood that claim 19 is anticipated.

We do find that on the current record there is a reasonable likelihood that claims 1–4, 8–14, 18, and 20–26 of the '087 patent are not entitled to a benefit of priority prior to the November 2018 Venclexta label. Accordingly, Petitioner has demonstrated a reasonable likelihood that these claims are anticipated by the disclosures in the November 2018 Venclexta label.

XII. CONCLUSION

After reviewing the information presented in the Petition and the Preliminary Response, as well as the evidence of record, we determine that Petitioner has not established that it is more likely than not that claim 19 of the '087 patent is unpatentable. We determine that based on the evidence of record, Petitioner has established that it is more likely than not that claims 1–4, 8–14, 18, and 20–26 of the '087 patent are unpatentable.

XIII. ORDER

Accordingly, it is

ORDERED that, pursuant to 35 U.S.C. § 324(a), institution of an *inter partes* review of all challenged claims on all grounds presented in the Petition is granted; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 324(a) and 37 C.F.R. § 42.4(b), notice is hereby given of the institution of a trial, which commences on the entry date of this Decision.

IPR2023-00052
Patent 11,110,087 B2

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