

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CONCERT PHARMACEUTICALS, INC.,
Petitioner,

v.

INCYTE CORPORATION,
Patent Owner.

Case PGR2017-00034
Patent 9,662,335 B2

Before SHERIDAN K. SNEDDEN, CHRISTOPHER G. PAULRAJ, and
KRISTI L. R. SAWERT *Administrative Patent Judges*.

SNEDDEN, *Administrative Patent Judge*.

DECISION
Denying Institution of Post-Grant Review
37 C.F.R. § 42.208

I. INTRODUCTION

Concert Pharmaceuticals, Inc. (“Petitioner”) filed a Petition to institute a post-grant review of claims 1–6 of U.S. Patent 9,662,335 B2 (Ex. 1001; “the ’335 patent”). Paper 3 (“Pet.”). Incyte Corporation (“Patent Owner”) filed a Patent Owner Preliminary Response. Paper 8 (“Prelim. Resp.”).

We have authority to determine whether to institute a post-grant review. 35 U.S.C. § 324(c); 37 C.F.R. § 42.4(a). The standard for instituting a post-grant review is set forth in 35 U.S.C. § 324(a), which provides that a post-grant review may not be instituted “unless the Director determines . . . it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable.” Upon consideration of the Petition and Preliminary Response, as well as all supporting evidence, we determine that the Petition fails to demonstrate that it is more likely than not that the ’335 patent is eligible for post-grant review. Accordingly, we deny the Petition.

A. Related Proceedings

The parties inform us of no related pending litigations. Pet. 87; Paper 8.

B. The ’335 patent (Ex. 1001)

The ’335 patent claims recite compound 3-cyclopentyl-3-[4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-1H-pyrazol-1-yl]propanenitrile (“ruxolitinib”), including certain stereoisomers, that has been labeled with deuterium, and pharmaceutical compositions thereof. Ex. 1001, 366:14–34; Pet. 1; Prelim. Resp. 1 n.1. Ruxolitinib labeled with deuterium is referred to

as “deuterated ruxolitinib.” Pet. 1. The ’335 patent discloses that labeled compounds of the invention are useful in imaging techniques and “also in assays, both in vitro and in vivo, for localizing and quantitating JAK in tissue samples, including human, and for identifying JAK ligands by inhibition binding of a labeled compound.” Ex. 1001, 67:55–64. JAK stands for Janus kinase, the overexpression and/or abnormal activity of which is associated with various conditions and diseases. *See id.* at 61:44–63:30.

C. Challenged Claims

Challenged claims 1–6 of the ’335 patent are reproduced below:

1. A compound, which is 3-cyclopentyl-3-[4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-1H-pyrazol-1-yl]propanenitrile, wherein one or more hydrogen atoms are replaced by deuterium; or a pharmaceutically acceptable salt thereof.

2. A pharmaceutical composition comprising a compound of claim 1, or a pharmaceutically acceptable salt thereof, and a pharmaceutically acceptable carrier.

3. A compound, which is (3R)-3-cyclopentyl-3-[4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-1H-pyrazol-1-yl]propanenitrile, wherein one or more hydrogen atoms are replaced by deuterium; or a pharmaceutically acceptable salt thereof.

4. A pharmaceutical composition comprising a compound of claim 3, or a pharmaceutically acceptable salt thereof, and a pharmaceutically acceptable carrier.

5. A compound, which is (3S)-3-cyclopentyl-3-[4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-1H-pyrazol-1-yl]propanenitrile,

wherein one or more hydrogen atoms are replaced by deuterium;
or a pharmaceutically acceptable salt thereof.

6. A pharmaceutical composition comprising a compound of claim 5, or a pharmaceutically acceptable salt thereof, and a pharmaceutically acceptable carrier.

D. The Asserted Grounds

Petitioner challenges claims 1–6 of the '335 patent on the following grounds. Pet. 12–87.

Ground	Legal Basis¹	Challenged Claims
1	Lack of written description	1–6
2	Lack of enablement	1–6
3	Anticipation by Silverman ²	1–4

Petitioner supports its challenge with the Declaration of Dr. Michael Crimmins (Ex. 1002).

¹ The relevant post-grant review provisions of the America Invents Act (“AIA”), Pub. L. No. 112-29, 125 Stat. 284 (2011), took effect on March 16, 2013. 125 Stat. at 293, 311. Because the application from which the '335 patent issued was filed after that date, our citations to Title 35 are to its post-AIA version. Section 4(c) of the AIA re-designated 35 U.S.C. §§ 112(1), (2) as 35 U.S.C. §§ 112(a), (b), respectively, effective September 16, 2012. 125 Stat. at 296–297.

² Ex. 1004, Silverman, I., et al., WO 2013/188783 (filed on June 14, 2013; published on December 19, 2013)

II. ANALYSIS

A. *Post-Grant Review Eligibility*

Post grant review is available only for patents “described in section 3(n)(1)” of the Leahy-Smith America Invents Act (“AIA”), Pub L. No. 112-29, 125 Stat. 284 (2011). AIA § 6(f)(2)(A). Those are patents that issue from applications “that contain[] or contained at any time . . . a claim to a claimed invention that has an effective filing date in section 100(i) of title 35, United States Code, that is on or after” “the expiration of the 18-month period beginning on the date of the enactment of” the AIA. *Id.* § 3(n)(1).

Because the AIA was enacted on September 16, 2011, post grant review is available only for patents that issue from applications that, at one point, contained at least one claim with an “effective filing date,” as defined by 35 U.S.C. § 100(i), on or after March 16, 2013. Entitlement to the benefit of an earlier date under §§ 119, 120, 121, and 365 is premised on disclosure of the claimed invention in the manner provided by § 112(a) (other than the requirement to disclose the best mode) in the application for which the benefit of the earlier filing date is sought. *See* 35 U.S.C. §§ 119(e), 120. In the event that the application is not entitled to any earlier filing date or right of priority, the effective filing date is “the actual filing date of the . . . application for the patent containing a claim to the invention.” *Id.* § 100(i)(1)(A).

The ’335 patent issued from an application filed on June 3, 2016, which is after March 16, 2013. Ex. 1001, 1:9–24. But the ’335 patent claims priority to a series of continuation applications, the earliest of which was filed on December 12, 2006, which is before March 16, 2013. *Id.* Accordingly, if every claim of the ’335 patent is entitled to claim a priority

date before March 16, 2013, then the '335 patent is not eligible for post-grant review. In this regard, Petitioner asserts that none of the challenged claims were adequately enabled or described in any parent application, “each of which shares the same specification as the '335 patent,” or any provisional application. Pet. 12–20. Petitioner therefore asserts that each challenged claim has an effective filing date of June 3, 2016, which is the actual filing date of the '335 patent. *Id.*

Upon consideration of the Petition and Preliminary Response, as well as all supporting evidence, we are persuaded, for the reasons that follow, that the challenged claims are entitled to a priority date of at least December 12, 2006, the earliest filed non-provisional parent application. Therefore, based on the current record, the '335 patent is not eligible for post-grant review.

B. Claim Interpretation

We interpret claims using the “broadest reasonable construction in light of the specification of the patent in which [they] appear[.]” 37 C.F.R. § 42.200(b); *Cuozzo Speed Techs. LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under the broadest reasonable construction standard, claim terms are generally given 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) (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005)). Limitations, however, may not be read from the specification into the claims (*In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993)), nor may the Board “construe claims during [an *inter partes* review] so broadly that its constructions are *unreasonable* under general claim construction principles” (*Microsoft Corp.*

v. Proxyconn, Inc., 789 F.3d 1292, 1298 (Fed. Cir. 2015) (overruled on other grounds by *Aqua Products, Inc. v. Matal*, 872 F.3d 1290 (Fed. Cir. 2017)).

Petitioner construes “one or more hydrogen atoms” of ruxolitinib in the claims to mean that “any one or any combination of the 18 hydrogen atoms of ruxolitinib may be replaced with deuterium.” Pet. 11. In this regard, Patent Owner does not dispute Petitioner’s construction. Prelim. Resp. 12. We adopt Petitioner’s proposed construction of “one or more hydrogen atoms” for the purposes of this decision.

We determine that no explicit construction of any other claim term is necessary to determine whether to institute a trial in this case.

*C. No Post Grant Review Eligibility Based on Lack of Written Description Support*³

To satisfy the written description requirement under 35 U.S.C. § 112(a), the specification “must clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed.” *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1346 (Fed. Cir. 2013) (citing *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc)) (internal quotation marks and alterations omitted); *see also In re Driscoll*, 562 F.2d 1245 (CCPA 1977) (holding that the written description was sufficient where the disclosure listed a number of

³ As noted above, Petitioner asserts post-grant review eligibility based on the argument that each of the challenged claims lacks written description support in any parent non-provisional application or any provisional application. Pet. 12–20. Petitioner acknowledges that “each [non-provisional parent application] shares the same specification as the ’335 patent.” *Id.* at 20. Accordingly, we reference the ’335 patent specification in our analysis of whether the challenged claims have written description support in the parent applications.

possible structures that could be incorporated at the position in question, including one option that ultimately appeared in the claims).

Citing *Novozymes*, Petitioner contends that the '335 patent fails to provide any “blaze marks” to guide a person of ordinary skill in the art to the claimed deuterated ruxolitinib compounds. Pet. 74–80. Furthermore, citing *Ariad*, Petitioner contends that “written description requires a representative number of species that fall within the scope of the genus.” *Id.* at 80–82. Patent Owner opposes. Prelim. Resp. 14–23.

For the reasons set forth on pages 16–18 of the Preliminary Response, which we adopt, we agree with Patent Owner that Petitioner fails to establish that the challenged claims lack written description support. Briefly, the '335 patent specification describes the common structural features of the claimed compounds, and specifically discloses “3-cyclopentyl-3-[4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-1H-pyrazol-1-yl]propanenitrile” (i.e., ruxolitinib) as a “compound of the invention.” Ex. 1001, 109:1–111:46 (Example 67). The '335 patent specification (1) discloses the (3R)- and (3S)- structures of ruxolitinib; (2) provides a working example describing an exemplary chemical synthesis; (3) demonstrates separation of the (3R)- and (3S)- isomers, and (4) describes ruxolitinib’s biological activity. *Id.* Thus, the '335 patent describes ruxolitinib as a compound of the invention with great particularity, including by name, chemical structure, and exemplary synthesis.

Furthermore, the '335 patent specification discloses deuterium isotopes of the “compounds of the invention.” *Id.* at 32:60–64, 67:65–68:6. Specifically, the '335 patent discloses as follows:

Compounds of the invention can also include all isotopes of atoms occurring in the intermediates or final compounds. Isotopes include those atoms having the same atomic number but different mass numbers. For example, isotopes of hydrogen include tritium and deuterium.

Id. at 32:60–64. The '335 patent further discloses as follows:

The present invention further includes isotopically-labeled compounds of the invention. An “isotopically” or “radio-labeled” compound is a compound of the invention where one or more atoms are replaced or substituted by an atom having an atomic mass or mass number different from the atomic mass or mass number typically found in nature (i.e., naturally occurring). Suitable radionuclides that may be incorporated in compounds of the present invention include but are not limited to ^2H (also written as D for deuterium). . . .

The present invention can further include synthetic methods for incorporating radio-isotopes into compounds of the invention. Synthetic methods for incorporating radio-isotopes into organic compounds are well known in the art, and an ordinary skill in the art will readily recognize the methods applicable for the compounds of invention.

Id. at 67:65–68:28.

Given the disclosure of the chemical name and structure of ruxolitinib (Ex. 1001 at 109:1–111:46), a person of ordinary skill in the art would have known the location of each hydrogen atom that could potentially be replaced by deuterium. *See* Ex. 1002 ¶ 77 (depicting the hydrogen atoms in ruxolitinib’s chemical structure). Written description is fully satisfied where the disclosure includes “structural features common to the members of the genus so that one of skill in the art can ‘visualize or recognize’ the members of the genus.” *Ariad*, 598 F.3d at 1350. We conclude that the '335 patent disclosure fully satisfies this requirement. We find no merit in Petitioner’s arguments otherwise.

Accordingly, Petitioner's lack of written description argument fails, as does its argument that the alleged lack of written description limits the '335 patent claims to a PGR-eligible June 3, 2016 filing date.

D. No Post Grant Review Eligibility Based on Lack of Enablement

“[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without ‘undue experimentation.’” *Genentech Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993)). Nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples. *In re Marzocchi*, 439 F.2d 220, 223 (CCPA 1971). *See In re Howarth*, 654 F.2d 103, 105 (CCPA 1981) (“An inventor need not, however, explain every detail since he is speaking to those skilled in the art.”).

Petitioner contends that “[t]he '335 patent fails to enable a POSA to make the full scope of the claimed invention without undue experimentation.” Pet. 20 (citing *Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380, 1384 (Fed. Cir. 2013); *MagSil Corp. v. Hitachi Global Storage Techs., Inc.*, 687 F.3d 1377, 1380–81 (Fed. Cir. 2012)). Petitioner acknowledges that “the '335 patent provides a synthesis of ruxolitinib,” but contends that “none of [Patent Owner's] synthetic schemes teach or suggest how to make a *deuterated* ruxolitinib analog.” Pet. 65; *see also id.* at 16 (stating that “it would have required undue experimentation to *make* the vast majority of the claimed deuterated ruxolitinib analogs because the '335 patent specification, which is the same as the earlier-filed parent applications, does not describe or teach how to synthesize and/or isolate

even a single embodiment within the scope of the claims”); *id.* at 23 (“The genus is vast because the claims do not specify substitution of any particular hydrogen atom . . . , but instead, include every possible combination of one to 18 deuterium replacements.” (citing Ex. 1002 ¶¶ 75–79, 82–84, 91, 150)).

Petitioner further contends as follows:

[T]he replacement of hydrogen atoms by deuterium atoms on ruxolitinib is synthetically difficult for the vast majority of the deuterated ruxolitinib analogs. [Ex. 1002, ¶¶ 15, 38–140, 154–156, 177, Appendices 1–3]. Most of the hydrogen atom replacements, or combinations thereof, cannot be made by known synthetic methods without also introducing deuterium in undesired locations. *Id.* Such non-specific replacement of hydrogen means that the desired deuterated ruxolitinib analog would be part of a mixture with other deuterated ruxolitinib analogs. *Id.* Deuterated ruxolitinib analogs in such mixtures that differ from each other by no more than a few deuterium atoms would have nearly identical physical properties, and are consequently extremely difficult, if not impossible, in almost all instances to *separate from each other*. *Id.* Because the individual ruxolitinib analogs *cannot be separated from each other, most mixtures of those analogs cannot be made*. This is because a POSA would need the individual analogs in order to adjust the relative amounts for the various mixtures. *Id.* The ’335 patent is silent on how to address any of these synthesis and separation challenges.

Id. at 28–29 (emphasis added); *see also* Ex. 1002 ¶¶ 45, 57, 61, 87, 95, 116, 119, 134, 136, 140 (testifying that replacement of the hydrogen atoms with a deuterium atom would lead to inseparable mixtures of deuterated analogs). Thus, according to Petitioner, “it would have required undue experimentation to make the full scope of the claimed invention.” *Id.* at 21.

For the reasons set forth on pages 26–43 of the Preliminary Response, which we adopt, we are not persuaded by Petitioner’s arguments and

evidence attempting to show that the challenged claims lack enablement. Briefly, we are persuaded that “Petitioner’s declarant, Dr. Crimmins, specifically demonstrates how a POSA could have used known techniques to synthesize, as individual compounds or as compounds in mixtures, all of the analogs discussed in his analysis.” Prelim. Resp. 45–46; *see also id.* at 27 (“Dr. Crimmins demonstrates in detail . . . how to make, at least in mixtures, *all* the deuterium-substituted building blocks he considers.” (citing Ex. 1002 ¶¶ 97–140)). That is, deuteration of compounds was a known process and the accompanying disclosure in the specification need only be sufficient to enable those skilled in the art to achieve deuterated ruxolitinib, a compound of the invention that is described with great particularity, including by name, chemical structure, and exemplary synthesis. Ex. 1001, 109:1–111:46 (Example 67). Thus, on this record, we are persuaded that a person of ordinary skill in the art would have been able to make or carry out the claimed invention without undue experimentation. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986) (“[A] patent need not teach, and preferably omits, what is well known in the art.”).

Furthermore, as noted by Patent Owner, “isolation” or “separation” of each individual compound is not required to enable “making” the claimed invention. Prelim. Resp. 39. The claims are directed to ruxolitinib compounds where one or more of the hydrogen atoms are replaced with deuterium, without further limitation. There is no requirement for “selectively” synthesizing one deuterated compound at a time to make specific mixtures; specific mixtures of deuterated compounds are not claimed.

Moreover, even if some deuterated ruxolitinib compounds were difficult or impossible to make, the claims do not necessarily fail the enablement requirement for that reason. *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1576–77, 224 USPQ 409, 414 (Fed. Cir. 1984) (“It is not a function of the claims to specifically exclude . . . possible inoperative substances” (citing *In re Dinh-Nguyen*, 492 F.2d 856, 858–59 (CCPA 1974)). The number of inoperative embodiments within the scope of a claim is relevant if it forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention. *Atlas*, 750 F.2d at 1576–77. Petitioner, however, has not shown that to be the case here.

Accordingly, Petitioner’s lack of enablement argument fails, as does its argument that the alleged lack of enablement limits the ’335 patent claims to a PGR-eligible June 3, 2016 filing date.

E. Anticipation by Silverman

Petitioner’s anticipation challenge is asserted based on the assumption that the challenged claims are not entitled to an effective filing date earlier than June 3, 2016. As discussed above, Petitioner fails to carry its burden to show lack of written description or non-enablement. As such, Petitioner failed to establish that the ’335 patent is eligible for post-grant review and that Silverman is prior art.

III. CONCLUSION

For the foregoing reasons, we determine that the Petitioner has not demonstrated that claims 1–6 lack § 112 support in any parent non-provisional application to which the ’335 patent claims priority. Thus,

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Petitioner has failed to show that the effective filing date of any one of claims 1–6 is after the effective date of the AIA.

IV. ORDER

It is

ORDERED that the Petition is *denied* and no trial is instituted.

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