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Paper 16
Entered: January 16, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NOVARTIS PHARMACEUTICALS CORPORATION,
Petitioner,

v.

PLEXXIKON INC.,
Patent Owner.

Case PGR2018-00069
Patent 9,844,539 B2

Before SHERIDAN K. SNEDDEN, JO-ANNE M. KOKOSKI, and KRISTI L. R. SAWERT, *Administrative Patent Judges*.

SNEDDEN, *Administrative Patent Judge*.

DECISION
Denying Institution of Post-Grant Review
35 U.S.C. § 324(a)

I. INTRODUCTION

Novartis Pharmaceutical Corporation ("Petitioner") filed a Petition ("Pet.") for post grant review of claims 1, 2, 4–9, 11, 12, and 14–19 of U.S. Patent No. 9,844,539 B2 ("the '539 patent") (Ex. 1001) pursuant to 35 U.S.C. §§ 321–329. Paper 2. Plexxikon Inc. ("Patent Owner") filed a Preliminary Response ("Prelim. Resp."). Paper 12.

We have authority, acting under the designation of the Director, to determine whether to institute a post-grant review. 35 U.S.C. § 324; 37 C.F.R. § 42.4(a). The standard for instituting post-grant review is set forth in 35 U.S.C. § 324(a), which provides that a post-grant review may be instituted only if "the information presented in the petition . . . demonstrate[s] that 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 '539 patent is eligible for post-grant review. Accordingly, we deny the Petition.

A. Related Matters

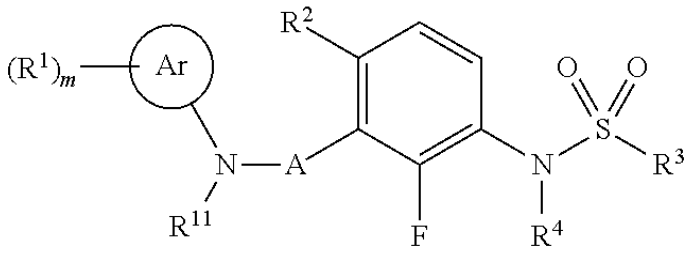
Petitioner identifies the following matter: *Plexxikon Inc. v. Novartis Pharmaceuticals Corporation*, Civil Action No. 4:17-cv-04405-HSG (EDL), filed August 3, 2017, in the United States District Court for the Northern District of California. Pet. 5; Paper 8, 2.

Patent Owner identifies IPR2018-01287 as involving U.S. Patent No. 9,469,640, which is related to the '539 patent. Paper 8, 2.

B. The '539 patent

The '539 patent relates generally to compounds which modulate kinases. Ex. 1001, 1:22–23. The '539 patent discloses compounds having the structure according to the following Formula Ib:

Formula Ib



wherein A is —C(O)— or —C($R^{12}R^{13}$)—; and

m is 0, 1, 2, 3, 4 or 5;

Ar is optionally substituted heteroaryl;

R^1 . . . is independently selected from the group consisting of halogen, *optionally substituted lower alkyl*, optionally substituted lower alkenyl, optionally substituted lower alkynyl, optionally substituted cycloalkyl, optionally substituted heterocycloalkyl, optionally substituted aryl, *optionally substituted heteroaryl*, —NO_2, —CN, —O—R^5, —N(R^5)—R^6, —C(X)—N(R^5)—R^6, —C(X)—R^7, —S(O)$_2$—N(R^5)—R^6, —S(O)$_n$—R^7, —O—C(X)—R^7, —C(X)—O—R^5, —C(NH)—N(R^8)—R^9, —N(R^5)—C(X)—R^7, —N(R^5)—S(O)$_2$—R^7, —N(R^5)—C(X)—N(R^5)—R^6, and —N(R^5)—S(O)$_2$—N(R^5)—R^6;[1]

R^2 is preferably fluoro or chloro;

R^3 is *optionally substituted lower alkyl*, optionally substituted $C_{3–6}$ cycloalkyl, optionally substituted heterocycloalkyl, *optionally substituted aryl* or optionally substituted heteroaryl;

R^4 is preferably H;

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[1] R^5, R^6, R^7, R^8, and R^9 are defined at column 2, lines 43–60 of the '539 patent.

R^{11} is preferably H;

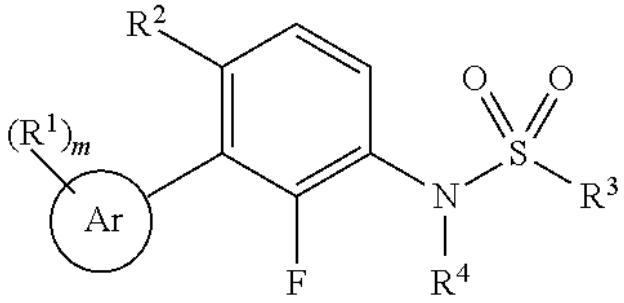
R^{12} is preferably H; and

R^{13} is preferably H.

Id. at 2:2–15, 5:36–6:11 (emphases added).

The '539 patent discloses compounds having the structure according to the following Formula Ic:

Formula Ic



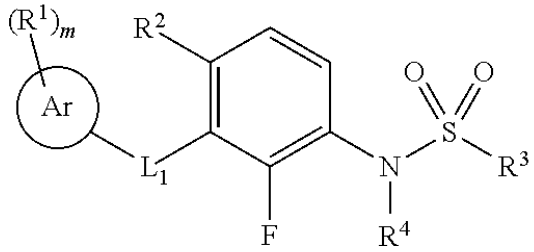
wherein m, Ar, R^1, R^2, R^3, and R^4, are defined similarly as for Formula Ib above. *Id.* at 6:36–64.

C. Illustrative Claim

Claims 1, 2, 4–9, 11, 12, and 14–19 are pending and challenged, of which claims 1 and 11 are independent. Independent claims 1 and 11 are representative of the challenged claims and are reproduced below:

1. A compound of formula (Ia):

(Ia)



or a pharmaceutically acceptable salt thereof, wherein:

L_1 is a bond or —N(H)C(O)—;

each R^1 is optionally substituted lower alkyl or optionally substituted heteroaryl;

R^2 is hydrogen or halogen;

R^4 is hydrogen;

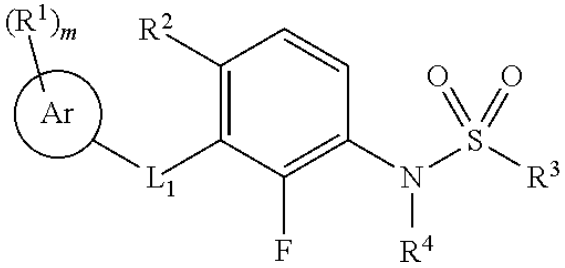
R^3 is optionally substituted lower alkyl or optionally substituted aryl;

m is 0, 1, 2, or 3; and

Ar is a monocyclic heteroaryl containing 5 to 6 atoms wherein at least one atom is nitrogen.

11. A compound of formula (Ia):

(Ia)



or a pharmaceutically acceptable salt thereof, wherein:

L_1 is a bond;

each R^1 is optionally substituted lower alkyl or optionally substituted heteroaryl;

R^2 is hydrogen or halogen;

R^4 is hydrogen;

R^3 is optionally substituted lower alkyl or optionally substituted aryl;

m is 0, 1, 2, 3, 4, or 5; and

Ar is a monocyclic heteroaryl containing 5 to 6 atoms wherein at least one atom is nitrogen.

D. The Alleged Grounds of Unpatentability

Petitioner challenges claims 1, 2, 4–9, 11, 12, and 14–19 of the '539 patent on the following grounds. Pet. 7–8.

Ground	Legal Basis[2]	Challenged Claims
1	Lack of written description	1, 2, 4–9, 11, 12, and 14–19
2	Lack of enablement	1, 2, 4–9, 11, 12, and 14–19
3	Anticipation by Rheault[3]	1, 2, 4–9, 11, 12, and 14–19

Petitioner supports its challenge with the Declaration of Dr. Phil S. Baran (Ex. 1002 or "Baran Dec.").

II. 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

[2] 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.

[3] Ex. 1026, Tara R. Rheault, U.S. Patent No. 7,994,185, granted Aug. 9, 2011 ("Rheault").

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.* at § 3(n)(1).

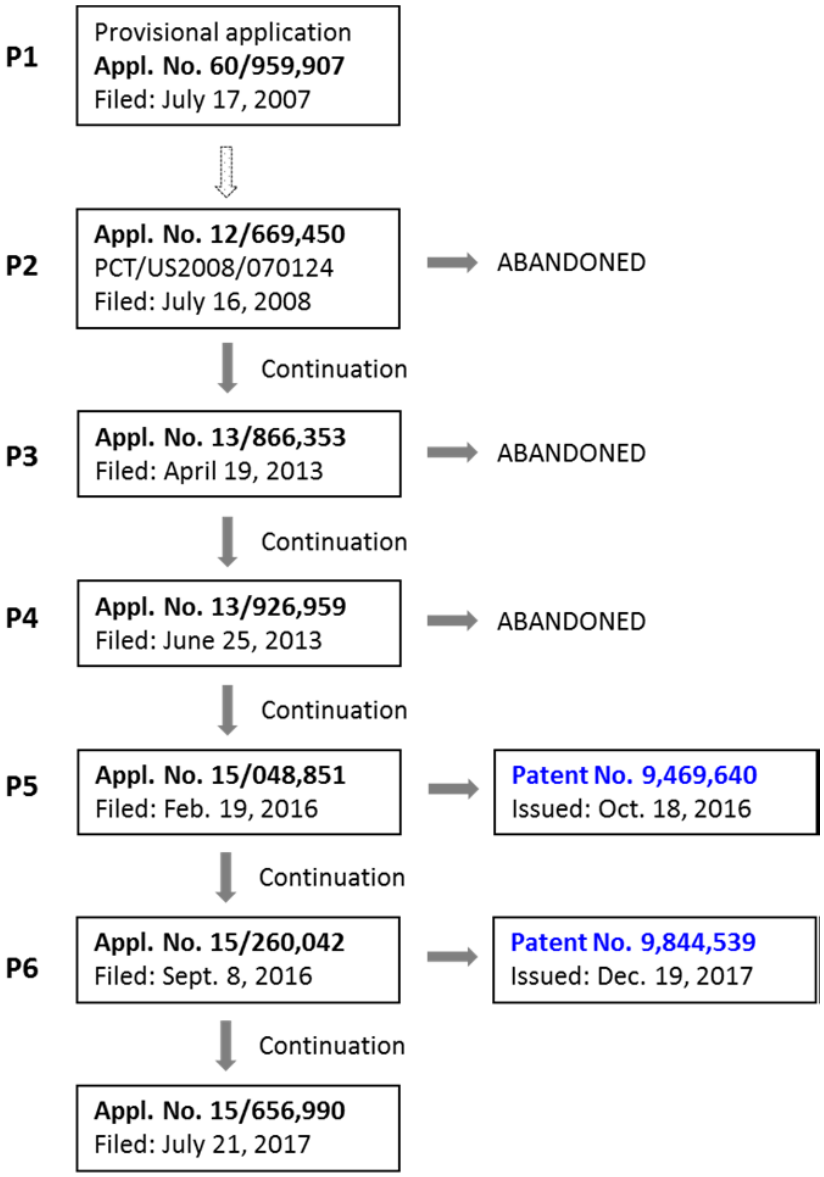
Post grant review is available only for patents that issue from applications that, at one point, contained at least one claim with an "effective filing date," as defined by 35 U.S.C. § 100(i), on or after March 16, 2013. Entitlement to the benefit of an earlier date under §§ 119, 120, 121, and 365 is 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 '539 patent issued from an application filed on September 8, 2016, which is after March 16, 2013. Ex. 1001. But the '539 patent claims priority to a series of continuation applications, the earliest of which was filed on July 14, 2007, which is before March 16, 2013. Ex. 1001, 1:7–18. Specifically, the priority claim of the '539 patent states as follows:

> This application is a continuation application of U.S. application Ser. No. 15/048,851, filed Feb. 19, 2016, which is a continuation of U.S. application Ser. No. 13/926,959, filed Jun. 25, 2013, which is a continuation of U.S. application Ser. No. 13/866,353 [("**P3**")], filed **Apr. 19, 2013**, which is a continuation application of Ser. No. 12/669,450 [("**P2**")], filed Jan. 15, 2010, which application is a National Phase application under 35 U.S.C. §371 of PCT/US2008/070124, filed **Jul. 16, 2008**, which claims the benefit under 35 U.S.C. §119(e) from U.S. Application No.

> 60/959,907 [("**P1**")], filed **Jul. 17, 2007**, which applications are hereby incorporated by reference in their entirety

Id. (emphases added). Petitioner provides the following schematic for the patent family of the '539 patent:



Pet. 12.

Accordingly, if every claim of the '539 patent is entitled to claim a priority date before March 16, 2013, then the '539 patent is not eligible for post-grant review. In this regard, Petitioner asserts that none of the

challenged claims were adequately described or enabled in any parent application filed before March 16, 2013. Pet. 12–67. Petitioner contends that the earliest effective filing date of the '539 patent is April 19, 2013, the filing date of the P3 application. *Id.* at 12–13.

Upon consideration of the Petition and Preliminary Response, as well as all supporting evidence, we are persuaded, for the reasons that follow, that Petitioner has not established, on this record, that the challenged claims are not entitled to a priority date of at least July 16, 2008. Therefore, based on the current record, the '539 patent is not eligible for post-grant review.

A. Claim Construction

As of the filing date of the instant Petition, 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. § 42.200(b); *Cuozzo Speed Techs. v. Lee*, 136 S. Ct. 2131, 2142–46 (2016). Under that standard, and absent any special definitions, we generally give claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire patent disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1993, 1257 (Fed. Cir. 2007). Any special definitions for claim terms must be set forth with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994). In the absence of such a definition, limitations are not to be read from the specification into the claims. *See In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993).

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

B. No Post Grant Review Eligibility Based on Lack of Written Description Support[4]

1. Petitioner's Contentions

Petitioner relies on the "blazemarks" test of *In re Ruschig*, 392 F.2d 990, 994–95 (CCPA 1967), to support its position that the specification of P2 application (Ex. 1004) fails to provide adequate description of the subgenus of compounds recited in the challenged claims. Pet. 18 (citing Baran Dec. ¶ 32). In particular, Petitioner contends that,

> . . . P2 does not guide one of ordinary skill to pick and choose the particular claimed options for each of the variables L_1, R^1, R^2, R^3, R^4, *m*, and Ar, or the combination of those variables, from the broad genera disclosed in P2 to arrive at the subject matter of the Challenged Claims. Baran Dec. ¶ 34. Nor does P2 set forth a representative number of species to support the full scope of the formulas of the Challenged Claims. Baran Dec. ¶ 35.

Id. at 19.

More specifically, Petitioner argues that there "are no blaze marks in P2 that point one of ordinary skill to the specific combination of claimed L_1 and R^1 substituents." Pet. at 32. Petitioner contends that, while "[c]ertain of the Challenged Claims provide that L_1 is either (i) 'a bond or -N(H)C(O)-' (claims 1, 2, 4-9) . . . [,] P2 does not guide one of ordinary skill to focus on either of these two options for L_1, particularly in combination with each of

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[4] 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. 12–67. Petitioner acknowledges that "[t]he specification of the '539 patent is the same as the specification of P2 and is deficient for the same reasons." *Id.* at 4. Accordingly, we reference the '539 patent specification in our analysis of whether the challenged claims have written description support in the parent applications.

the other specific substituents in the Challenged Claims, including R^1." *Id.* at 32. "For example, P2 provides that in Formula I, L_1 is selected from a group consisting of 21 options (many of which contain sub-options)." *Id.* at 32 (citing Ex. 1004, 2).

Regarding R^1 substituents, Petitioner contends that "P2 provides lists of options for R^1 that include 'optionally substituted lower alkyl,' 'optionally substituted heteroaryl,' as two of many options; however P2 does not describe a subgenus that has this specific combination of substituents." Pet. 41 (citing Baran Dec. ¶ 91). Petitioner further contends that "P2 encompasses an enormous number of possible R^1 groups that meet the definition of 'optionally substituted lower alkyl' and 'optionally substituted heteroaryl.'" *Id.* at 26 (citing Baran Dec. ¶¶ 38–40). Thus, according to Petitioner, "P2 does not guide one of ordinary skill to focus on any of these three options for R^1, particularly in combination with the other specific substituents in the Challenged Claims, including L_1." *Id.* at 41.

Regarding the examples provided in the specification, Petitioner contends that while P2 discloses 120 different compounds, only three compounds fall within the scope of the formulas recited in the challenged claims. *Id.* at 29–30. In particular, Petitioner contends that

> P2 also fails to disclose a sufficient number of representative species to support the claimed R^1 groups. Baran Dec. ¶ 102. Although the Challenged Claims encompass trillions of compounds, P2 describes only three species that have an R^1 that is "optionally substituted lower alkyl" (P-0007, P-0012, and P-0019), and only two of those examples (P-0007 and P-0012) fall within the scope of any of the Challenged Compound Claims (claims 1 and 7). Not a single example falls within the scope of the remaining Challenged Compound Claims. *Id.* And not a single example has an R^1 that is "optionally substituted

> heteroaryl." *Id.* at 45. Additionally, only one of the compounds that were reported to have activity in the assays disclosed in P2 has an R^1 that includes an optionally substituted lower alkyl or optionally substituted heteroaryl. *Id*.

Pet. 45–46. Petitioner further contends that

> although P-0001, P-0007 and P-0012 fall within the scope of certain Challenged Claims, they do not have many of the variables that are included within the scope of the Challenged Claims. Baran Dec. ¶ 52. For example, none has L_1 as a bond; R^1 as heteroalkyl or substituted heteroalkyl; R^2 as hydrogen, R^3 as substituted lower alkyl, aryl or substituted aryl; or *m* as 3, 4, or 5. *Id*. Thus, there are no representative species that fall within the scope of the Challenged Claims and have any of these structural features of the claims. *Id*. These examples, therefore, do not constitute a sufficient number of representative species to show possession of the breadth of the Challenged Claims. Baran Dec. ¶ 53.

Id. at 31.

2. Patent Owner's Contentions

Patent Owner contends that "almost all of Petitioner's arguments are ultimately based on two variables of the disclosed and claimed compounds," namely L_1 and R^1 substituents. Prelim. Resp. 17, 21. Patent Owner responds with the contention that formula Ib and Ic disclosed in P2 include the exact core structure set forth in the claims (*id.* at 19), and that "formulae Ib and Ic are set forth not in functional terms, but as unambiguous chemical structures with clear boundaries, thus demonstrating as a matter of law that the inventors necessarily envisioned and possessed the chemical compounds within their scope, including all of the claimed compounds" (*id.* at 22). Specifically, Patent Owner contends that: i) formula Ib provides –N(H)C(O)– as a preferred substituent for L_1 and formula Ic provides L_1 as a

bond (*id.* at 20 (citing Ex. 1001, 5:45, 5:53–54));[5] ii) both formula Ib and Ic provide, as options for R^1, "optionally substituted lower alkyl" and "optionally substituted heteroaryl" from a Markush group of well-known chemical substituents (*id.* (citing Ex. 1001, 2:3-14, 5:46-47, 6:50-51)); iii) R^2 is "hydrogen, fluoro or chloro" (*id.* (citing Ex. 1001, 5:54–55)); iv) R^4 as preferably H (*id.* (citing Ex. 1001, 6:10–11)); v) m=0, 1, 2, 3, 4, or 5 (*id.* at 21 (citing 2:15, 5:46-47, 6:50-51)); and vi) Ar is an "optionally substituted heteroaryl" (*id.* (citing Ex. 1001, 2:2, 5:46–47; 6:50–51)).[6] Thus, according to Patent Owner, "[b]ecause the specification here discloses well-defined genera through formulae Ib and Ic, the written description requirement is satisfied for the genus claims that are commensurate with these formulae." *Id.* at 25. Patent Owner acknowledges that the combination of formula Ib and Ic is somewhat broader than the claims, but contends that "any such differences are modest and do not indicate a lack of written description, as confirmed by governing law regarding chemical compound patents." *Id.* at 22.

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[5] While Patent Owner references the'539 patent (Ex. 1001) rather than P2 (Ex. 1004), we recognize that the disclosures of the two documents are substantially identical.

[6] The term "heteroaryl" is expressly defined in P2 as "a monocyclic aromatic ring structure containing 5 or 6 ring atoms." Ex. 1004 ¶ 90; Ex. 1001, 49:25–26. The term "optionally substituted heteroaryl" is expressly defined in P2 as "a heteroaryl that is optionally independently substituted, unless indicated otherwise, with one or more, preferably 1, 2, 3, 4 or 5, also 1, 2, or 3 substituents, attached at any available atom to produce a stable compound, wherein the substituents are selected from the group consisting of [a Markush group containing countless substituents]." Ex. 1004 ¶ 90; Ex. 1001, 49:25–26.

3. Analysis

In order to satisfy the written description requirement, the disclosure does not have to provide *ipsis verbis* support for the claimed subject matter. *Fujikawa v. Wattansin*, 93 F.3d 1559, 1570 (Fed. Cir. 1996). Instead, the disclosure need only reasonably convey to persons skilled in the art that the inventor had possession of the subject matter in question. *In re Edwards*, 568 F.2d 1349, 1351–52, 196 USPQ 465, 467 (CCPA 1978). Precisely how close the original description must come to comply with the description requirement of § 112 must be determined on a case-by-case basis. *Purdue Pharma. L.P. v. Faulding, Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000), *citing Vas- Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1561 (Fed. Cir. 1991).

The "blaze marks" do not need to identify what species among disclosed species are preferred; it is only necessary that the species or sub-species is identified. *In re Ruschig*, 392 F.2d at 994–95; *see also Novozymes A/S v. DuPont Nutrition Bioscis. APS*, 723 F.3d 1336, 1348 (Fed. Cir. 2013) (specification "contained no disclosure of any variant that actually satisfies the claims, nor is there anything to suggest that [the patentee] actually possessed such a variant at the time of filing"); *Boston Sci. Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1367 (Fed. Cir. 2011) (finding lack of written description where patent claimed "rapamycin or a macrocyclic triene analog thereof" but specification "fail[ed] to disclose even a single member of either the genus of 'analogs' of rapamycin, or the more specific genus of 'macrocyclic triene analogs' of rapamycin"); *Fujikawa*, 93 F.3d at 1570–71 (it was not clear error to hold that substitution of isopropyl for cyclopropyl in a chemical formula was not supported in the disclosure despite the two substituents being isosteric); *In re Driscoll*, 562 F.2d 1245, 1250 (CCPA

1977) ("*Ruschig* is readily distinguishable from the present case where the exact subgenus claimed is clearly discernible in the generalized formula of the [compound] set forth in the earlier filed application.").

We begin our analysis by stating that, on the current record, we are persuaded by Patent Owner that formula Ib and formula Ic, as disclosed in P2, support the recited options for L_1. Prelim. Resp. 20. In particular, formula Ib describes a genus in which –N(H)C(O)– is a preferred substituent for L_1 and formula Ic describes L_1 as a bond. *Id.* ("Formula Ib is limited to L_1 as -NR^{11}A-, with A having just two general options, one of which is -C(O)-, and further explains that R^{11} is 'preferably H.' This corresponds to -N(H)C(O)-. *See* Ex. 1001 at 5:45, 5:53–54. And formula Ic is limited to L_1 as a bond. *See id*. at 6:40–49."). Accordingly, we are not persuaded by Petitioner's argument that "P2 does not guide one of ordinary skill to focus on either of these two options for L_1. . . ." Pet. 32.

We also agree with Petitioner that, when assessing written description, it is necessary to consider the entire claimed subject matter in view of the disclosure. Pet. 40 (citing *Novozymes*, 723 F.3d at 1349 (explaining that the written description analysis requires "[t]aking each claim . . . as an integrated whole rather than as a collection of independent limitations")). In this regard, we note that the combination of formula Ib and Ic is broader than the formula recited in the claims with regard to R^1. Prelim. Resp. 22. In particular, we note the following difference between R^1 as described in the specification[7] in both formula Ib and formula Ic, and R^1 recited in independent claims 1 and 11.

[7] Petitioner acknowledges that "[t]he specification of the '539 patent is the same as the specification of P2 and is deficient for the same reasons." *Id.* at

Independent Claims 1 and 11	The ’539 patent specification
each R^1 is optionally substituted lower alkyl or optionally substituted heteroaryl	R^1 at each occurrence is independently selected from the group consisting of halogen, *optionally substituted lower alkyl*, optionally substituted lower alkenyl, optionally substituted lower alkynyl, optionally substituted cycloalkyl, optionally substituted heterocycloalkyl, optionally substituted aryl, *optionally substituted heteroaryl*, —NO_2, —CN, —O—R^5, —N(R^5)—R^6, —C(X)—N(R^5)—R^6, —C(X)—R^7, —$S(O)_2$—N(R^5)—R^6, —$S(O)_n$—R^7, —O—C(X)—R^7, —C(X)—O—R^5, —C(NH)—N(R^8)—R^9, —N(R^5)—C(X)—R^7, —N(R^5)—$S(O)_2$—R^7, —N(R^5)—C(X)—N(R^5)—R^6, and —N(R^5)—$S(O)_2$—N(R^5)—R^6 (Ex. 1001, 2:3–14, 5:46–47, 6:50–51).

Thus, as argued by Patent Owner, out of the 23 total possible substituents disclosed as a Markush group for R^1, two are claimed. Prelim. Resp. 22–23; *Driscoll*, 562 F.2d at 1249 (each member of a Markush group is “alternatively usable for the purposes of the invention.”); *see also* Pet. 41 (noting that R^1 is selected from a group consisting of 23 options). Considering that the claims define a sub-species where formula Ib and Ic support the recited options for L_1, and where the recited R^1 was selected from a Markush group of 23 substituents disclosed for R^1 in both formula Ib and Ic, we are not persuaded by Petitioner’s arguments that a person of ordinary skill in the art would not be able to clearly discern the sub-genus

4. Accordingly, we reference the ’539 patent specification in our analysis of whether the challenged claims have written description support in the parent applications.

now claimed from the generalized formula Ib or Ic disclosed in P2. Pet. 40–45.

Furthermore, we note that an original application containing "a broad and complete generic disclosure, coupled with extensive examples fully supportive of the limited genus now claimed" can provide written descriptive support for a later claimed subgenus that excludes some species from the original genus. *In re Johnson*, 558 F.2d 1008, 1018 (CCPA 1977). In this regard, Patent Owner directs our attention "numerous examples in the specification exemplifying a breadth of options for R^1." Prelim. Resp. 32 (citing Ex. 1001, 76:34–53 (P-0011, where R^1 is a substituted heteroaryl linked to a NH group); *id.* at 79:19–29 (P-0005, where R^1 is a substituted lower alkyl linked to a NH group); *id*. at 80:19–39 (P-0009, and P-0015 where R^1 for both compounds is a cycloalkyl linked to a NH group); *id*. at 80:51–60 , P-0017, where R^1 is an aryl linked to a NH group); *id*. at 80:40–50 (P-0016, where R^1 is a heteroaryl linked to a NH group); *id*. at 81:35–45 (P-0004, where R^1 is an acetyl linked to a NH group); *id*. at 94:15–25 (P-0003, where R^1 is a lower alkoxy); *id*. at 94:25–35 (P-0007, where both R^1 groups are lower alkyl); *id*. at 94:51–67 (P-0012, where R^1 is a substituted aryl); *id.* at 95:1–11 (P-0014, where R^1 is a substituted lower alkenyl). Moreover, Petitioner identifies 3 compounds disclosed in the specification (i.e., P-0001, P-0007 and P-0012) that fall within the scope of the claims. Pet. 29–30. We find such examples to adequately support the selection of R^1 as recited in the sub-genus now claimed.

Accordingly, on the current record, we are not persuaded by Petitioner's lack of written description argument, nor its argument that the lack of written description renders the '539 patent claims PGR-eligible.

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

1. Petitioner's Contentions

Petitioner contends that "P2 provides virtually no direction or guidance to teach a skilled person how to make the trillions of claimed compounds wherein L_1 is a bond." Pet. 49 (citing Baran Dec. ¶ 107). Petitioner contends that, while "Example 2 provides a prophetic general scheme for making theoretical compounds according to Formulae Ic and Ie, for which L_1 is a bond[,] . . . no compounds were actually synthesized according to this scheme, and the specification provides no indication that the scheme would be feasible across the full scope of the claimed genera where L_1 is a bond." *Id.* (citing Baran Dec. ¶ 108). Petitioner directs our attention to Step 4 of the general reaction scheme of Example 2, and contends that a "Suzuki-coupling" is required in order to form the L_1 bond. *Id.* at 50. Petitioner contends, however, that, while "Suzuki reactions are widely used in the pharmaceutical industry[,]" . . . it would be extremely difficult or even impossible to use a Suzuki reaction—especially as taught in Step 4 of P2—to form compounds comprising large portions of the claimed genera where L1 is a bond. *Id.* (citing Baran Dec. ¶ 111); *see also id.* at 50–62 (detailing the difficulty and unpredictability of Suzuki coupling reactions). Due to the difficulty and unpredictability of Suzuki coupling reactions, Petitioner concludes that "P2 fails to enable the person of ordinary skill to make the full scope of the Challenged Claims without undue experimentation." *Id.* at 61.

Additionally, Petitioner contends that P2 does not enable a person of ordinary skill to use the full scope of claimed compounds for which L_1 is a bond. Pet. 62–67. In particular, Petitioner contends that "P2 contains no

working examples and no direction or guidance to show a person of ordinary skill reading the specification that compounds in which L_1 is a bond might work as kinase inhibitors." *Id.* at 63; *see also id.* ("Nor is activity data (in any assay) for such compounds presented anywhere in P2.").

Petitioner also contends as follows:

> [A]lthough the Challenged Claims embrace a large genus of substituents at the R^3 position ('539 patent, claim 1 ("R^3 is optionally substituted lower alkyl or optionally substituted aryl"), each of the compounds disclosed as having activity has a propyl group at the R^3 position. Baran Dec. ¶ 148. The type and substitution pattern of the group at the R^3 position may affect the solubility of the claimed compounds as well as their interaction with the kinase. *Id.* Because P2 does not provide any disclosure of activity for compounds with, *e.g.*, aryl groups or groups having hydrophilic substituents at R^3 and also fails to disclose a structure-function relationship for substituents at that position, P2 does not enable a person of ordinary skill to use the full scope of the Challenged Claims.

Id. at 66.

2. Patent Owner's Contentions

Patent Owner contends that "Petitioner cannot dispute that P2 discloses, in Example 2, a reaction scheme for synthesizing the claimed genera of compounds in which L_1 is a bond . . . , P2 describes and illustrates a Suzuki coupling for this very purpose." Prelim. Resp. 43 (citing Pet. 50–51); *see also id.* at 44 ("Petitioner's articles recognize the Suzuki coupling as 'one of the most efficient methods for the construction of biaryl or substituted aromatic moieties' and a highly flexible reaction mechanism . . . ."). Patent Owner contends that "Petitioner has advanced no evidence showing that optimization of the Suzuki coupling in this case is anything other than routine." *Id.* at 55.

Patent Owner contends that "the structural similarity of compounds in which L_1 is a bond to the compounds disclosed in Tables 2a–2p of P2 further support the utility of the claimed genus." *Id.* at 64. In this regard, Patent Owner emphasizes that

> ***all*** of the compounds within the scope of Formula Ia have as a key "blaze mark" the core structure of a fluorinated phenyl bonded to a sulfonamide. This similarity would have provided a POSITA with additional reason to believe that all of the compounds within the scope of Formula Ia have, to some degree, the same kinase modulation utility as the compounds listed in Tables 2a-2p. This would have been further confirmed by publications in the art prior to July 16, 2008, disclosing that PLX4720, a compound featuring a sulfonamide group attached to a fluorinated phenyl group with the sulfonamide adjacent to the fluorine, exhibiting targeted binding to the kinase BRAF V600E due to the interaction of the sulfonamide moiety with the BRAF V600E kinase. Ex. 2005.

Id. at 64–65.

3. Analysis

"[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 also 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."). "To prove that a claim is invalid for lack of enablement, a challenger must show by clear and convincing evidence that a

person of ordinary skill in the art would not be able to practice the claimed invention without "undue experimentation." *Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1189 (Fed. Cir. 2014).

For the reasons set forth on pages 58–60 and 63–65 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, while difficult under certain conditions, Suzuki coupling was a well-known reaction scheme used in the pharmaceutical industry (Ex. 1025, 6; Ex. 1017, 2), and that P2 provides an example of how to use the reaction scheme to make compounds of claimed genera of compounds in which L_1 is a bond (Ex. 1001, 71:13–72:59). Moreover, even if some compounds falling within the scope of the claims 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)).

Furthermore, P2 discloses a generic class of compounds having a common core structure, discloses a common utility (modulation of protein kinases) for the entire generic class of compounds, and discloses representative assay results substantiating this utility. Ex. 1001, 1:20–54, 129:60–132:60. 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. On the current record, we are not persuaded that Petitioner has shown that to be the case here.

Thus, on this record, we are persuaded that a person of ordinary skill in the art would have been able to make or use the claimed invention without undue experimentation. Accordingly, we are persuaded that Petitioner's lack of enablement argument fails, as does its argument that the alleged lack of enablement limits the '539 patent claims to a PGR-eligible filing date.

III. CONCLUSION

For the foregoing reasons, Petitioner fails to carry its burden to show lack of written description or non-enablement. Consequently, Petitioner failed to establish that the '539 patent is eligible for post-grant review.

IV. ORDER

It is

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

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