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Paper No. 10
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HYBRIGENICS SA.
Petitioner,

v.

FORMA THERAPEUTICS, INC.
Patent Owner.

Case PGR2018-00098
Patent 9,840,491 B2

Before SHERIDAN K. SNEDDEN, ROBERT A. POLLOCK, and DAVID COTTA, *Administrative Patent Judges*.

COTTA, *Administrative Patent Judge*.

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

I. INTRODUCTION

Hybrigenics SA ("Petitioner" or "Hybrigenics") filed a Petition requesting a post grant review of claims 1–17 of U.S. Patent No. 9,840,491 B2 (Ex. 1001, "the '491 patent").[1] Paper 4 ("Pet."). Forma Therapeutics, Inc. ("Patent Owner" or "Forma") filed a Preliminary Response to the Petition. Paper 9 (Prelim. Resp.).[2]

Institution of post grant review is authorized by statute only when "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." 35 U.S.C. § 324; *see* 37 C.F.R. § 42.4. Upon considering the Petition, the Preliminary Response, and the cited evidence, we conclude that Petitioner has satisfied the burden under 35 U.S.C. § 324 to show that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable.

A. Related Proceedings

Petitioner represents that it is unaware of any other matters related to the '491 patent. Pet. 1. Patent Owner identifies several patent applications as related to the '491 patent, including Patent Cooperation Treaty Application No. PCT/US2016/016542, US Patent Application No. 62/112,487, and US Patent Application No. 15/837,393. Paper 6, 2.

B. The '491 Patent (Ex. 1001)

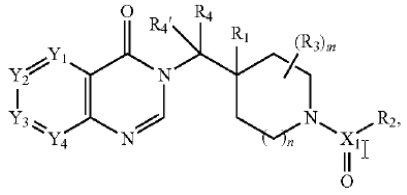
The '491 patent issued December 12, 2017, identifying Stephanos Ioannidis, Adam Charles Talbot, Bruce Follows, Alexandre Joseph Buckmelter, Minghua Wang, Ann-Marie Campbell, and David R. Lancia Jr.

[1] Petitioner identifies Hybrigenics SA as the real party in interest. Pet. 1.
[2] Patent Owner identifies Forma Therapeutics, Inc. as the real party in interest. Paper 6, 2.

as joint inventors. Ex. 1001. The patent "relates to inhibitors of USP7 [ubiquitin-specific protease 7]." *Id.* at Abstract.

The '491 patent teaches that "USP7 deubiquitinates a variety of cellular targets involved in different processes related to cancer and metastasis, neurodegenerative diseases, immunological disorders, osteoporosis, arthritis inflammatory disorders, cardiovascular diseases, ischemic diseases, viral infections and diseases, and bacterial infections and diseases." Ex. 1001, 1:62–2:2. The '491 patent also teaches that "[i]nhibition of USP7 with small molecule inhibitors . . . has the potential to be a treatment for cancers and other disorders." *Id.* at 3:1–2.

The '491 patent discloses "compounds of Formula (I):



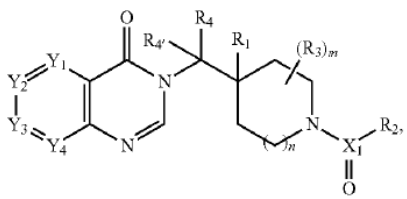
(I)

and pharmaceutically acceptable salts, hydrates, solvates, prodrugs, stereoisomers, and tautomers thereof." *Id.* at 3:7–23.

C. Challenged Claims

Petitioner challenges claims 1–17 of the '491 patent. Claims 1 and 16 are representative and are reproduced below.

1. A compound of Formula (I):



(I)

or a pharmaceutically acceptable salt, stereoisomer, and tautomer thereof,
wherein:
X_1 is C, S, or S(O);

Y_1 is N or CH;
Y_2 is N or CR_5;
Y_3 is N or CR_6;
Y_4 is N or CR_7;

. . . R_2 is (C_1-C_6) alkyl, (C_6-C_{14}) aryl, 5- or 6- membered heteroaryl comprising 1 to 3 heteroatoms selected from O, N, and S, (C_5-C_8) cycloalkyl, 3- to 7-membered heterocycloalkyl comprising 1 to 3 heteroatoms selected from O, N, and S, or —$NR_{10}R_{11}$, wherein the alkyl, aryl, heteroaryl, cycloalkyl, and heterocycloalkyl are optionally substituted with one to three R_8;

. . . wherein R_5, R_6, and R_7 and not all simultaneously H;

. . . provided that when R_2 is optionally substituted alkyl, R_5 is H, and R_7 is H, then R_6 is not chloro.[3]

16. A compound selected from:
3-((4-hydroxy-1-(3-phenylbutanoyl)piperidin-4-yl) methyl)-7-methoxyquinazolin-4(3H)-one;
3-((4-hydroxy-1-(3-phenylbutanoyl)piperidin-4-yl) methyl)-8-methylquinazolin-4(3H)-one;
7-amino-3-((4-hydroxy-1-(3-phenylbutanoyl)piperidin-4–yl)methyl)quinazolin-4(3H)-one;
N-(3-((4-hydroxy-1-(3-phenylbutanoyl)piperidin-4-yl)methyl)-4-oxo-3,4-dihydroquinazolin-7-yl)acetamide;
(R)-3-((4-hydroxy-1-(3-phenylbutanoyl)piperidin-4-yl)methyl)-7-methoxyquinazolin-4(3H)-one;
(R)-3-((4-hydroxy-1-(3-phenylbutanoyl)piperidin-4-yl)methyl)-8-methylquinazolin-4(3H)-one;
3-((1-(1-benzylindoline-5-carbonyl)-4-hydroxypiperidin-4-yl)methyl)-7- methylquinazolin-4(3H)-one;
3-((1-benzoyl-4-hydroxypiperidin-4-yl)methyl)-7-phenylquinazolin-4(3H)-one;
3-((1-benzoyl-4-hydroxypiperidin-4-yl)methyl)-8-phenylquinazolin-4(3H)-one;

[3] Claim 1 also includes limitations further limiting R substituents, and further limiting m, n, and q, but those limitations are not relevant to the dispositive issues in this Petition and so are not reproduced herein.

3-((1-(4-fluorobenzoyl)-4-hydroxypiperidin-4-yl)methyl)-8-(4-fluorophenoxy)quinazolin-4(3H)-one;
3-((4-hydroxy-1-(3-phenylbutanoyl)piperidin-4-yl)methyl) pyrido[2,3-d]pyrimidin-4(3H)-one;
3-((4-hydroxy-1-(3-phenylbutanoyl)piperidin-4-yl)methyl) pyrido[3,4-d]pyrimidin-4(3H)-one; or
3-((4-hydroxy-1-(3-phenylbutanoyl)piperidin-4-yl)methyl) pyrido[3,2-d]pyrimidin-4(3H)-one.

D. The Prosecution History

We discuss the prosecution history of the '491 patent for context because one of the prior art references asserted in this proceeding, the '150 patent,[4] was cited by the Examiner during prosecution and because Petitioner challenges material added by amendment as lacking written description support.

The application that issued as the '491 patent (Application No. 15/015,571), was filed on February 4, 2016. Ex. 1001. In an Office Action dated September 29, 2016, the Examiner rejected claims corresponding to the claims at issue under 35 U.S.C. § 112(a) as indefinite because the claims "defined variables (where applicable) as heterocycle, heteroaryl, heterocyclic, and or aryl" but the "specification does not define the ring size, heteroatom, number and nature of substituents, and the exact point of contact with the atom(s) for the substituents." Ex. 1002, 186. The Examiner also rejected these claims under 35 U.S.C. § 112(a) for failure to comply with the enablement requirement. *Id.* at 187. The pending claims were drawn to compounds of Formula I "or a pharmaceutically acceptable salt, hydrate, solvate, prodrug, stereoisomer, and tautomer thereof." *Id.* at

[4] Colland et al., US Patent No. 9,546,150 B2, issued Jan. 17, 2017 (Ex. 1003, "the '150 patent").

243. The Examiner found that "the specification, while being enabling for specific compounds disclosed in the specification, does not reasonably provide enablement for **hydrates, solvates and prodrugs** of those compounds and composition[s] containing same." *Id.* at 187.

In response to the September 29, 2016, Office Action, Patent Owner amended the claims by deleting the terms "hydrate," "solvate," and "prodrug." *Id.* at 142, 178. Patent Owner also amended the limitations relating to the R_2, R_3, R_6–R_{11}, R_{13}, R_{14}, R_{17}, R_{21}–R_{24}, R_{26}, and R_{27} substituents by narrowing the recited heteroaryl and heterocycle to a "5- or 6- membered heteroaryl comprising 1 to 3 heteroatoms selected from O, N, and S" and a "3- to 7- membered hetercycloalkyl comprising 1 to 3 heteroatoms selected from O, N, and S." *Id.* at 142–148. The portion of the claim relating to the R_2 substituent, as amended, is representative and reads as follows:

> R_2 is (C_1-C_6) alkyl, (C_6-C_{14}) aryl, 5- or 6-membered heteroaryl comprising 1 to 3 heteroatoms selected from O, N, and S, (C_5-C_8) cycloalkyl, 3- to 7-membered heterocycloalkyl comprising 1 to 3 heteroatoms selected from O, N, and S, -$NR_{10}R_{11}$, or –OR_{10}, wherein the alkyl, aryl, heteroaryl, cycloalkyl, and heterocycloalkyl are optionally substituted with one to three ~~or more~~ R_8;

Ex. 1002, 142 (underlined text reflects material added by amendment, strikeout text reflects material deleted by amendment). Patent Owner asserted that this amendment was supported by paragraphs 32, 33, and 41 of the Specification, was well as by pages 54–63. *Id.* at 177.

In an April 19, 2017 Office Action, the Examiner found that the pending enablement and indefiniteness rejections had "been obviated by Applicant's Amendment." *Id.* at 127. However, the Examiner entered six

new rejections over the prior art. Of particular relevance here, the Examiner rejected the pending claims as anticipated by and as obvious over the '150 patent. With respect to the obviousness rejection over the '150 patent, the Examiner stated:

> The claims differ from the reference by reciting specific species and a more limited genus than the reference. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties, and thus, the same use as taught for the genus as a whole. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. A prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus. Thus, Applicant's claims are obvious, and therefore, rejected under 35 U.S.C. 103.

Id. at 135.

In response to the April 17, 2017, Office action, Patent Owner argued that the '150 patent did not anticipate the claimed compounds because the '150 patent teaches a "4-quinazolinone compound . . . that is substituted by an alkoxy group at the 6-carbon corresponding to R_5 in Formula I" while the definition of R_5 in the claims "does not contemplate an alkoxy group." *Id.* at 87. In addition, Patent Owner argued that claim 1 specifies that "R_6 is not **chloro**" and that "R_5, R_6, and R_7 are not all simultaneously H" and, thus, the compounds disclosed in the '150 patent did not fall within the scope of the pending claims. *Id.* at 88–91.

Patent Owner similarly argued that the compounds of the '150 patent did not render the claimed compounds obvious because the phenyl portion of

the quinazolinone ring system in the fourteen exemplified compounds of the '150 patent exhibited only three substitution patterns "(i) no substitution; (ii) chloro substitution at C7; or (iii) alkoxy substitution at C6 and C7." *Id.* at 96. According to the Patent Owner, the ordinary artisan "motivated by a desire to arrive at an effective inhibitor of USP7, would have likely selected a compound with one of those three substitution patterns as a lead compound for further modification along with a substituted alkyl amide." *Id.* Accordingly, rather than modify one of the three quinazolinone ring systems exemplified in the '150 patent, the skilled artisan would "modify the substituted alkyl group bound to the piperidine amide." *Id.* Patent Owner also asserted that Examples 13 and 14 of the '150 patent "demonstrated the lowest inhibitory concentration of USP7, and would therefor likely be selected as lead compounds." *Id.* at 96–97. Since these compounds do not have quinazolinone rings that fall within the scope of the claims, and, according to the Patent Owner, the ordinary artisan would modify the piperidine amide in the compounds of the '150 patent rather than the quinazolinone ring, the claimed compounds would not have been obvious. *Id.* at 97.

The Examiner evidently found these arguments persuasive, allowing the claims because the "prior art does not teach or suggest the compositions and compounds substituted in the manner claimed by the Applicant." *Id.* at 37.

E. The Asserted Ground of Unpatentability

Petitioner challenges the patentability of claims 1–17 of the '491 patent on the following grounds:

Ground	Basis	Claims Challenged
1	35 U.S.C. § 103(a) – obvious over the '150 patent	1–17
2	35 U.S.C. § 112(a) – failure to comply with the enablement requirement	1–17
3	35 U.S.C. § 112(a) – failure to comply with the written description requirement	1–15 and 17

Petitioner submits the Declaration of Dr. Rémi Delansorne (Ex. 1004) in support of institution of post grant review.[5]

F. Person of Ordinary Skill in the Art

Factual indicators of the level of ordinary skill in the art include "the various prior art approaches employed, the types of problems encountered in the art, the rapidity with which innovations are made, the sophistication of the technology involved, and the educational background of those actively working in the field." *Jacobson Bros., Inc. v. U.S.*, 512 F.2d 1065, 1071 (Ct. Cl. 1975); *see also Orthopedic Equip. Co., v. U.S.*, 702 F.2d 1005, 1011 (Fed. Cir. 1983) (quoting with approval *Jacobson Bros.*).

Petitioner contends that the person of ordinary skill would have "the equivalent of at least a Ph.D. in biochemistry, organic chemistry, pharmacology or related science and has post-Ph.D. work in the field for at least three years including either as a post-doc or in industry." Pet. 4.

[5] Dr. Delansorne is Petitioner's Chief Executive Officer and Chairman of its Board of Directors (Ex. 1004, 1) and thus has an interest in this proceeding, which may diminish the persuasiveness of his testimony. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 294 (Fed. Cir. 1985) ("While the opinion testimony of a party having a direct interest in the pending litigation is less persuasive than opinion testimony by a disinterested party, it cannot be disregarded for that reason alone and may be relied upon when sufficiently convincing.")

At this stage in the proceeding, Patent Owner does not challenge Petitioner's definition. Accordingly, for purposes of this Decision and based on the present record, we accept Petitioner's definition, which is consistent with the level of skill reflected in the asserted prior art references. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (the prior art itself can reflect the appropriate level of ordinary skill in the art).

G. Claim Construction

We interpret claims of an unexpired patent using the "broadest reasonable construction in light of the specification of the patent in which [they] appear[]." 37 C.F.R. § 42.100(b); *see also Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016).[6] 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). "Absent claim language carrying a narrow meaning, the PTO should only limit the claim based on the specification . . . when [it] expressly disclaim[s] the broader definition." *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004).

Neither Petitioner nor Patent Owner proposes any specific constructions for any of the terms in the claims at issue. *See*, Pet. 12–13; Prelim. Resp. 21–26. Accordingly, at this stage of the proceeding, we

[6] The broadest reasonable interpretation ("BRI") construction standard applies to post grant reviews filed before November 13, 2018. 77 Fed. Reg. 48727 (Aug. 14, 2012) (codified at 37 C.F.R. § 42.100(b)), as amended at 81 Fed. Reg. 18766 (Apr. 1, 2016); *see also* 83 Fed. Reg. 51340 (Oct. 11, 2018) (changing the standard for interpreting claims in *inter partes* reviews filed on or after November 13, 2018). Because the Petition was filed prior to this date, on September 12, 2018, the BRI construction standard applies.

determine that no explicit construction of any claim term is necessary to determine whether to institute a trial in this case. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) ("[W]e need only construe terms 'that are in controversy, and only 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))); *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'").

II. REAL PARTY IN INTEREST

35 U.S.C. § 322(a)(2) requires that a petition for post grant review "may be considered only if . . . the petition identifies all real parties in interest." The Petition identifies only Hybrigenics SA as a real party in interest ("RPI"). Pet. 1. Patent Owner contends that Petitioner should also have named as real parties in interest Servier Laboratories ("Servier"), a third party with whom Hybrigenics has collaborated on USP inhibitors, as well as Hybrigenics Corp. and Hybrigenics Pharma Inc., two U.S. subsidiaries of Hybrigenics. Prelim. Resp. 10–19. Patent Owner introduces various publicly available documents to support its position. We have reviewed Patent Owner's assertions, as well as the evidence of record, and, for the reasons discussed below, we conclude that the present record does not support Patent Owner's assertion that Servier, Hybrigenics Corp, and/or Hybrigenics Pharma Inc. should have been named as real parties in interest.

"Determining whether a non-party is a 'real party in interest' demands a flexible approach that takes into account both equitable and practical considerations, with an eye toward determining whether the non-party is a

clear beneficiary that has a preexisting, established relationship with the petitioner." *Applications in Internet Time v. RPX Corp.*, 897 F.3d 1336, 1351 (Fed. Cir. 2018). Whether an entity that is not named as a participant in a given proceeding constitutes a "real party in interest" is a highly fact-dependent question that takes into consideration how courts generally have used that term to "describe relationships and considerations sufficient to justify applying conventional principles of estoppel and preclusion." Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,759 (Aug. 14, 2012) ("Trial Practice Guide"). According to the Trial Practice Guide,

> the spirit of that formulation as to . . . PGR proceedings means that, at a general level, the "real party-in-interest" is the party that desires review of the patent. Thus, the "real party-in-interest" may be the petitioner itself, and/or it may be the party or parties at whose behest the petition has been filed.

Id.

As stated in the Trial Practice Guide, there are "multiple factors relevant to the question of whether a non-party may be recognized as" a real party in interest. *Id.* (citing *Taylor v. Sturgell*, 553 U.S. 880, 893–895, 893 n.6 (2008)). There is no "bright line test." *Id.* Considerations may include, for example, whether a non-party exercises control over a petitioner's participation in a proceeding, or whether a non-party is funding the proceeding or directing the proceeding. *Id.* at 48,759–60. "[T]he two questions lying at [the] heart" of the RPI inquiry are "whether a non-party 'desires review of the patent' and whether a petition has been filed at a non-party's 'behest.'" *Applications in Internet Time*, 897 F.3d at 1351 (quoting Trial Practice Guide, 77 Fed. Reg. at 48,759). In assessing a petitioner's alleged failure to identify an RPI, "[t]he point is . . . to probe the extent to which [the non-party] has an interest in and will benefit from [the

petitioner's] actions, and inquire whether [the petitioner] can be said to be representing that interest after examining its relationship with [the non-party]." *Id.* at 1353.

A. Analysis of Servier Laboratories as a Potential Real Party in Interest

Patent Owner contends that Servier is "a clear beneficiary that has a preexisting, established relationship with" Hybrigenics and that Servier has an "actual measure of control or opportunity to control that might reasonably be expected between two formal coparties." Prelim. Resp. 11. Patent Owner cites a number of publicly available press releases, corporate presentations and financial reports that collectively show that Hybrigenics collaborates with Servier on "DUB[7] identification and validation, screening and profiling of development candidates in oncology, neurology, psychiatry, rheumatology, ophthalmology, diabetes and cardiovascular diseases." *See*, Ex. 2006 at 25, 29; *see also*, Ex. 2009, 4. These sources also show that Hybrigenics collaborated with Servier to develop a ubiquitin specific protease and received a milestone payment of €1.5 million as a part of that collaboration. *See*, Ex. 2002, 1; *see also*, Ex. 2006, 3, 25; Ex. 2007, 3, 27; Ex. 2008, 1, 4, 6, and 20; and Ex. 2009, 4. The publicly available documents also show that Servier has taken responsibility for future development of the USP that is the subject of the Servier/Hybrigenics collaboration, and that Hybrigenics stands to receive an additional €12 million if the USP achieves certain unidentified additional milestones. *Id.*

[7] USPs, including USP7, are a family of deubiquitinating ("DUB") enzymes. *See, e.g.*, Ex. 1001, at 1:41–42; Ex. 2001 ("The class of USPs is part of the wider family of DUBs").

Patent Owner contends that this evidence shows that Servier "stands to benefit from Petitioner's attempt to invalidate the '491 patent through this Petition" because, "[i]f a jointly developed USP inhibitor product were found to infringe the '491 patent, then Servier's substantial investment in milestone payments and product development would be in jeopardy." Prelim. Resp. 15.

At this stage of the proceeding, and based on the current record, we are persuaded that Petitioner has carried its burden of complying with 35 U.S.C. § 322 by identifying Hybrigenics SA as a real party in interest. The current record is not sufficient to support Patent Owner's contention that Servier should have been named as a real party in interest. Patent Owner has not directed us to persuasive evidence suggesting that Servier controlled, directed, financed, or participated in any way in the filing of this Petition. Patent Owner contends that "[b]y controlling and funding the development of Petitioner's USP inhibitors, it is evident that Servier 'exercised or could have exercised control over the proceeding.'" Prelim. Resp. 15. While we acknowledge the evidence reflecting that "Servier will take charge of" a "R&D program" "focused on one USP especially relevant to oncology" (Ex. 2002, 1), Patent Owner has not identified persuasive evidence suggesting that future control of an R&D program includes control over the present legal proceedings directed against a third party patent. Nor has Patent Owner directed us to evidence specifically identifying the USP inhibitor whose R&D program Servier controls, making it unclear to what extent Servier benefits from the filing of this Petition.

Even if we were to assume that the '491 patent would cover the USP that was the subject of the Servier/Hybrigenics collaboration, Patent

Owner's contention that Servier is a real party in interest amounts to little more than an assertion that Servier had a preexisting, established relationship with Petitioner and is a beneficiary of the Petition. This is insufficient to establish that Servier should have been named as a real party in interest. *See Unified Patents, Inc. v. Realtime Adaptive Streaming, LLC*, IPR2018-00883 (PTAB Nov. 27, 2018 (Public Version)) (Paper 36, 14–15) ("We agree with Petitioner that Patent Owner is overextending the reasoning of *AIT [Applications in Internet Time]*. The RPI analysis set out in *AIT* and the common law require more than simply confining the analysis to determining whether a party benefits generally from the filing of this Petition and also has a relationship with the Petitioner."). If the sole requirement for being named a real party in interest were that a party might benefit from the filing of a petition, as suggested by Patent Owner, it would ensnare third parties, such as suppliers and contract research organizations, with no connection to the Petition.

In sum, the current record does not tend to support that Servier exercised, or could have exercised, control over Petitioner's participation in this proceeding. Nor does the current record tend to support that the Petition was filed at the behest of Servier or that Servier "desires review" of the '491 patent. Accordingly, based on the record before us at this stage of the proceeding, we do not find Petitioner's identification of the real party in interest deficient for failing to identify Servier.

B. Analysis of Hybrigenics Corp. and Hybrigenics Pharma Inc. as Potential Real Parties in Interest

Patent Owner asserts that "Hybrigenics Corp. and/or Hybrigenics Pharma Inc., control U.S. activities of Petitioner." Prelim. Resp. 15. According to Patent Owner, "[b]ecause Petitioner's U.S. entities potentially

benefit from the Petition, it is also critical to 'assure proper application of the statutory estoppel provisions' to these entities with respect to Petitioner's decision to file the Petition." *Id*. at 15–16.

Patent Owner cites a number of publicly available documents that show that Hybrigenics Corp. "is the American subsidiary of [Petitioner]" (Ex. 2001, 2), "represent[s Petitioner] for R&D, regulatory and business development matters" "[i]n the American territory," and may "*facilitate future R&D interactions with the U.S. Food and Drug Administration*." Ex. 2003, 1. The documents also show that Hybrigenics Pharma Inc., is a U.S. subsidiary of Petitioner. Ex. 2004, 2.

Patent Owner argues that Hybrigenics' U.S. subsidiaries should have been named as real parties in interest because they would hold the New Drug Application ("NDA") should Hybrigenics seek to commercialize a drug product containing a USP inhibitor compound that infringes the '491 patent. Prelim. Resp. 16–17. According to Patent Owner, Hybrigenics' U.S. subsidiaries would thus have the ability to sell an infringing product. *Id*.

The current record is not sufficient to support Patent Owner's contention that Hybrigenics' U.S. subsidiaries should have been named as real parties in interest. Patent Owner has not directed us to persuasive evidence suggesting that Hybrigenics' U.S. subsidiaries controlled, directed, financed, or participated in any way in the filing of this Petition. Patent Owner's contention that Hybrigenics' U.S. subsidiaries are real parties in interest rests on little more than speculation that the subsidiaries would stand to benefit in the event that Hybrigenics seeks to commercialize a drug falling within the scope of the '491 patent. For the reasons discussed in connection

with Servier, mere status as a potential beneficiary of a Petition is not enough to establish an unnamed party as a real party in interest.

The cases cited by Patent Owner, *Cisco Sys., Inc. v. Hewlett Packard Enter. Co.*, IPR2017-01933, (PTAB Mar. 16, 2018) (Paper No. 9) and *Amazon.com, Inc. v. Appistry, Inc.*, IPR2015-00480, at 4–6 (PTAB July 13, 2015) (Paper 18) are not to the contrary. Prelim. Resp. 16. In *Cisco*, Cisco Systems, Inc. ("Cisco") filed a request for *inter partes* review. One week before the request was filed, Cisco invested $34 million into another company, Springpath, and attained "board-level representation" at Springpath. *Cisco*, Paper 9, 14. The record showed that Springpath had been accused of infringement in district court litigation, but that none of Cisco's products were accused of infringement. *Id.* at 15. After the request for *inter partes* review was filed, Cisco acquired Springpath as a wholly-owned subsidiary of Cisco. *Id.* Based on these facts, the Board determined that Springpath should have been named as a real party in interest because "Cisco [was] representing Springpath's interest, rather than its own and, thus, . . . pursuing its Petition as a proxy for Springpath." *Id.* at 14. Unlike the record in *Cisco*, the current record does not include evidence suggesting that Petitioner lacks an independent interest in these proceedings or that Petitioner was acting as a proxy for its U.S. subsidiaries.

In *Amazon*, the evidence showed that "Petitioner AWS [was] a wholly-owned subsidiary of AWSHC, which in turn [was] a wholly-owned subsidiary of ADS, [which in turn was] a wholly-owned subsidiary of Petitioner Amazon.com." *Amazon*, Paper 18, 5. The Petition named Amazon.com, the ultimate parent, and AWS, the ultimate subsidiary, as real parties in interest but failed to name the two intervening wholly owned

subsidiaries, AWSC and ADS. *Id.* at 4. The Board accepted Patent Owner's argument that the only way the ultimate parent, Amazon.com, could control its ultimate subsidiary, AWS, was by indirectly exercising its control over the two unnamed intervening subsidiaries. *Id.* at 4–6. The Board thus concluded that the intervening subsidiaries should have been identified as real parties in interest. *Id.* Unlike *Amazon*, the current record does not suggest that Hybrigenics' unnamed subsidiaries were intermediaries through which a parent that had been identified as a real party in interest exercised control over a subsidiary that was also named as a real party in interest.

III. WRITTEN DESCRIPTION

Petitioner challenges written description on two bases. First, Petitioner argues that during prosecution, Patent Owner narrowed the genus of substituents recited in claim 1, and that this narrowing amendment is not supported by the Specification. Pet. 55–58. Second, Petitioner argues that the Specification does not disclose sufficient species to adequately describe the broad genus recited in claim 1, and in the claims depending therefrom. *Id.* at 58–59. Patent Owner contends that these arguments have already been considered by the Examiner and thus we should exercise our discretion under 35 U.S.C. § 325(d) to deny institution on this ground. Prelim. Resp. 40–43. Patent Owner also disputes that the claims are not supported by the Specification. *Id.* at 51–56. We have reviewed Petitioner's and Patent Owner's assertions, as well as the evidence of record, and, for the reasons discussed below, we decline to exercise our discretion under 35 U.S.C. § 325(d) and conclude that Petitioner has demonstrated it is more likely than not that at least 1 of claims 1–15 and 17 do not comply with the written description requirement.

A. 35 U.S.C. § 325(d)

We have discretion to deny review when "the same or substantially the same prior art or arguments previously were presented to the Office." 35 C.F.R. § 325(d). When evaluating whether the same or substantially the same prior art or arguments were previously presented to the Office under § 325(d), the Board has considered a number of non-exclusive factors, including, for example: (1) the similarity of the asserted art and the prior art involved during the examination; (2) the extent to which the asserted art was considered during examination, including whether the prior art was the basis for rejection; (3) the cumulative nature of the asserted art and the prior art considered during examination; (4) whether Petitioner has pointed out sufficiently how the Examiner erred in its consideration of the asserted prior art; (5) the extent of the overlap between the arguments made during examination, and the manner in which Petitioner relies on the prior art or the applicant's arguments during examination; and (6) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the asserted prior art. *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, Case IPR2017-01586, slip op. at 17–28 (PTAB Dec. 15, 2017) (Paper 8) (informative).

Patent Owner invites us to enter a discretionary denial under 35 C.F.R. § 325(d) because "the Office considered – *and agreed with* – arguments presented during prosecution that substituents of Formula (I) were supported by the specification as filed." Prelim. Resp. 40. Patent Owner contends that it "presented arguments during prosecution showing support within the specification for [the] exact language" challenged by Petitioner as not supported by the Specification. *Id.* at 40–41. According to

the Patent Owner, "the Office, upon consideration of these arguments, did not levy a rejection for lack of written description." *Id.*

After considering the factors outlined in *Becton, Dickinson & Co.*, we are persuaded that the written description arguments presented in the Petition warrant reconsideration of the patentability of the claimed compounds. As discussed above, Patent Owner amended claim 1 in response to rejections under 35 U.S.C. § 112 for failure to comply with the enablement requirement and for indefiniteness. *See, supra p.* 6. In connection with this amendment, Patent Owner identified portions of the Specification that it believed supported the claimed amendment. Ex. 1002, 177–178. However, we find no indication in the record that the Examiner considered the written description arguments presented by the Petitioner. Nor do we find significant overlap between the arguments supporting the enablement and indefiniteness rejections entered by the Examiner and the written description arguments presented in the Petition. Indeed, the only overlap we identify is that it was apparently these rejections that prompted Patent Owner to add the claim language that Petitioner alleges is unsupported. Prelim. Resp. 41–42.

We acknowledge that after Patent Owner pointed to support for the amended claims in the Specification, the Examiner allowed the claims without entering a written description rejection. However, the mere absence of a written description rejection does not establish that the Examiner considered the arguments presented in the Petition. To find otherwise would potentially suggest that we should apply our discretion under 325(d) to deny review in every post grant review where written description is challenged because, before allowing a claim, an Examiner must always consider

whether the claims are supported by the Specification. *See* MPEP 2013(IV)(B).

Applying the factors identified in *Becton, Dickinson & Co.*, to the case at hand, we find that the circumstances favor institution because the arguments presented in the Petition were not specifically considered by the Examiner. Accordingly, we decline to exercise our discretion to deny review under 35 U.S.C. § 325(d).

B. Written Description Support for the Narrowing Amendment to Claim 1 Entered During Prosecution

A description adequate to satisfy 35 U.S.C. § 112, first paragraph, must '"clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.'" *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (enbanc) (citation omitted, alteration in original). "[T]he test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Id.*

Where the specification "does not use precisely the same terms used in a claim, the question then is whether the specification directs or guides one skilled in the art to the subject matter claimed." *Union Oil Co. of California v. Atlantic Richfield Co.*, 208 F.3d 989, 1003 (Fed. Cir. 2000). To support a claim directed to a species or subgenus within a broad generic disclosure, there must be "specific direction," expressed in "'full, clear, concise, and exact' language," to the narrower subject matter within the genus. *Id.* This requirement that the specification direct one to the claimed subject matter has been analogized to "'blaze marks' on specific trees that mark a trail through a forest." *Id.* (*citing In re Ruschig*, 379 F.2d 990, 994–

95 (CCPA 1967); *see also Fujikawa v. Wattanasin* 93 F.3d 1559, 1571 (Fed. Cir. 1996) ("In the absence of . . . blazemarks, simply describing a large genus of compounds is not sufficient to satisfy the written description requirement as to particular species or sub-genuses.").

As discussed above (*supra* p. 6), during prosecution, Patent Owner narrowed the scope of the R_2, R_3, R_6–R_{11}, R_{13}, R_{14}, R_{17}, R_{21}–R_{24}, R_{26} and R_{27} substituents by limiting the heteroaryl and heterocycloalkyl to a "5- or 6-membered heteroaryl comprising 1 to 3 heteroatoms selected from O, N, and S" and a "3- to 7- membered heterocycloalkyl comprising 1 to 3 heteroatoms selected from O, N, and S." Ex. 1002, 142–148.[8] Petitioner argues that the Specification of the '491 patent does not support this amendment. Pet. 55–58. During prosecution, Patent Owner cited to paragraphs 32, 33, and 41 and pages 54–63 of Application No. 15/015,571 as supporting the amendment at issue. Ex. 1002, 177–178. Petitioner contends that these paragraphs "merely list some possible heteroaryl and heterocycloalkyls corresponding to R_2." Pet. 57. According to Petitioner, the "limited number of specific examples of possible heteroaryls and heterocycloalkyls provided [in these paragraphs] is not sufficient to indicate to a person of ordinary skill in the art that the inventors, at the time of filing, were in possession of all of the heteroaryls and heterocycloalkyls included in [the amended claims]." Pet. 57. We agree with Petitioner.

Paragraph 33 of the Specification of Application No. 15/015,571 defines the term "heteroaryl." It reads:

[8] For convenience, going forward, we focus our analysis on the amendment to the R_2 substituent with the understanding that our analysis also applies to the R_3, R_6–R_{11}, R_{13}, R_{14}, R_{17}, R_{21}–R_{24}, R_{26} and R_{27} substituents, each of which was identically amended.

Unless otherwise specifically defined, "heteroaryl" means a monovalent monocyclic aromatic radical of 5 to 24 ring atoms or a polycyclic aromatic radical, containing one or more ring heteroatoms selected from N, O, or S, the remaining ring atoms being C. Heteroaryl as herein defined also means a bicyclic heteroaromatic group wherein the heteroatom is selected from N, O, or S. The aromatic radical is optionally substituted independently with one or more substituents described herein. Examples include, but are not limited to, furyl, thienyl, pyrrolyl, pyridyl, pyrazolyl, pyrimidinyl, imidazolyl, isoxazolyl, oxazolyl, oxadiazolyl, pyrazinyl, indolyl, thiophen-2-yl, quinolyl, benzopyranyl, isothiazolyl, thiazolyl, thiadiazole, indazole, benzimidazolyl, thieno[3,2-b]thiophene, triazolyl, triazinyl, imidazo[1,2-b]pyrazolyl, furo[2,3-c]pyridinyl, imidazo[1,2-a]pyridinyl, indazolyl, pyrrolo[2,3-c]pyridinyl, pyrrolo[3,2-c]pyridinyl, pyrazolo[3,4-c]pyridinyl, thieno [3 ,2-c]pyridinyl, thieno[2,3-c]pyridinyl, thieno[2,3-b]pyridinyl, benzothiazolyl, indolyl, indolinyl, indolinonyl, dihydrobenzothiophenyl, dihydrobenzofuranyl, benzofuran, chromanyl, thiochromanyl, tetrahydroquinolinyl, dihydrobenzothiazine, dihydrobenzoxanyl, quinolinyl, isoquinolinyl, 1,6-naphthyridinyl, benzo[de]isoquinolinyl, pyrido[4,3-b][1,6]naphthyridinyl, thieno[2,3-b]pyrazinyl, quinazolinyl, tetrazolo[1,5-a]pyridinyl, [1,2,4]triazolo[4,3-a]pyridinyl, isoindolyl, pyrrolo[2,3-b]pyridinyl, pyrrolo[3,4-b]pyridinyl, pyrrolo[3,2-b]pyridinyl, imidazo[5,4-b]pyridinyl, pyrrolo[1,2-a]pyrimidinyl, tetrahydro pyrrolo[1,2-a]pyrimidinyl, 3 ,4-dihydro-2H-1 X2-pyrrolo[2, 1-b]pyrimidine, dibenzo[b,d] thiophene, pyridin-2-one, furo[3,2-c]pyridinyl, furo[2,3-c]pyridinyl, 1H-pyrido[3,4-b][1,4] thiazinyl, benzooxazolyl, benzoisoxazolyl, furo[2,3-b]pyridinyl, benzothiophenyl, 1,5-naphthyridinyl, furo[3,2-b]pyridine, [1,2,4]triazolo[1,5-a]pyridinyl, benzo [1,2,3]triazolyl, imidazo[1,2-a]pyrimidinyl, [1,2,4]triazolo[4,3-b]pyridazinyl, benzo[c] [1,2,5]thiadiazolyl, benzo[c][1,2,5]oxadiazole, 1,3-dihydro-2H-benzo[d]imidazol-2-one, 3,4-dihydro-2H-pyrazolo [1,5-b][1,2]oxazinyl, 4,5,6,7-tetrahydropyrazolo[1,5-a]pyridinyl, thiazolo[5,4-d]thiazolyl, imidazo[2,1-b][1,3,4]thiadiazolyl, thieno[2,3-b]pyrrolyl, 3H-indolyl, and

> derivatives thereof. Furthermore when containing two fused rings the aryl groups herein defined may have an unsaturated or partially saturated ring fused with a fully saturated ring. Exemplary ring systems of these heteroaryl groups include indolinyl, indolinonyl, dihydrobenzothiophenyl, dihydrobenzofuran, chromanyl, thiochromanyl, tetrahydroquinolinyl, dihydrobenzothiazine, 3,4-dihydro-1H-isoquinolinyl, 2,3-dihydrobenzofuran, indolinyl, indolyl, and dihydrobenzoxanyl.

Ex. 1002, 313–314. This paragraph broadly defines "heteroaryl" as encompassing monocyclic and bicyclic aromatic rings of 5 to 24 ring atoms and discloses numerous exemplary heteroaryls. However, we do not find in paragraph 33 blazemarks to guide the ordinary artisan to a R_2 substituent comprising a "5- or 6- membered heteroaryl" as recited in claim 1.

Paragraph 41 of Application No. 15/015,571, which defines the term "heterocycloalkyl" presents similar written description issues. It reads:

> "Heterocyclyl" or "heterocycloalkyl" monocyclic or polycyclic rings containing carbon and heteroatoms taken from oxygen, nitrogen, or sulfur and wherein there is not delocalized π electrons (aromaticity) shared among the ring carbon or heteroatoms. The heterocycloalkyl ring structure may be substituted by one or more substituents. The substituents can themselves be optionally substituted. Examples of heterocyclyl rings include, but are not limited to, oxetanyl, azetadinyl, tetrahydrofuranyl, tetrahydropyranyl, pyrrolidinyl, oxazolinyl, oxazolidinyl, thiazolinyl, thiazolidinyl, pyranyl, thiopyranyl, tetrahydropyranyl, dioxalinyl, piperidinyl, morpholinyl, thiomorpholinyl, thiomorpholinyl S-oxide, thiomorpholinyl S-dioxide, piperazinyl, azepinyl, oxepinyl, diazepinyl, tropanyl, oxazolidinonyl, and homotropanyl.

Ex. 1002, 314. This paragraph broadly defines "heterocycloalkyl" as encompassing monocyclic or polycyclic rings "wherein there is not delocalized π electrons (aromaticity) shared among the ring carbon or heteroatoms." *Id.* It also discloses numerous exemplary heterocycloalkyls.

However, we do not find in paragraph 41 blazemarks to guide the ordinary artisan to a R_2 substituent comprising a "3- to 7- membered heterocycloalkyl" as recited in claim 1.

Nor do we find such blazemarks in the other passages identified by Patent Owner during prosecution as supporting this language.[9] Paragraph 32 defines the term "aryl" and provides examples of aryl compounds. Pages 54–63 describe various additional embodiments. We do not find in paragraph 32 or pages 54–63, blazemarks to guide the ordinary artisan to a R_2 substituent comprising a "5- or 6- membered heteroaryl" or a "3- to 7-membered heterocycloalkyl" as recited in claim 1. At this stage in the proceeding, we do not discern how the disclosures identified during prosecution – i.e. paragraphs 32, 33, and 41 and pages 54–63 of the Specification – would have provided blazemarks directing the ordinary artisan to the amended claim language. Absent such evidence, the current record tends to support Petitioner's position that the Specification does not provide written description support for the claim language reciting a "5- or 6- membered heteroaryl" and a "3- 7- membered heterocycloalkyl." Accordingly, based on the current record, we find that Petitioner has demonstrated that it is more likely than not that at least one claim of the '491 patent is unpatentable for failure to comply with the written description requirement.

[9] Patent Owner's Preliminary Response references the support for the September 26, 2016, Amendment identified during prosecution, but does not otherwise address Petitioner's argument that the amended claim language does not find written description support in the Specification. *See*, Prelim. Resp. 51–56.

Having determined that Petitioner has demonstrated that it is more likely than not that at least one claim of the '491 patent is unpatentable for failure to comply with the written description requirement, we institute a review as to all of challenged claims contained in the Petition. USPTO, Guidance on the Impact of *SAS* on AIA Trial Proceedings (April 26, 2018).

We offer the following views on Petitioner's additional written description argument and on the remaining claims and grounds for the parties' consideration, to the extent they wish to address them in any further briefing.

C. Written Description Support for the Broad Genus of Compounds Encompassed by Claim 1

Petitioner contends that claim 1 of the '491 patent includes millions of different compounds while the Specification exemplifies only thirteen specific compounds. Pet. 58. Petitioner argues that "[e]ven if all thirteen compounds are considered to be adequately described in the specification, this is clearly not a sufficient number of species to support the millions of different compound included in the broad genus recited in claim 1." *Id.* at 59.

Patent Owner argues that Petitioner's analysis is inadequate in that it does not discuss whether the '491 patent provides structural features common to the genus and does not discuss the state of the art. Prelim. Resp. 55. Patent Owner explains:

> Instead of providing evidence and evaluating, e.g., the teachings of the specification, the technology at issue, and the relevant state of the art in 2015 for the claims of the '491 patent, Petitioner merely makes broad and conclusory statements that the disclosure of a certain number of compounds is not a sufficient number of representative species to support the compounds of the challenged claims.

Id. Patent Owner thus contends that Petitioner has not met the burden to establish that it is more likely than not that the disclosure of the '491 patent does support claim 1. *Id.* at 55–56.

"Sufficient description of a genus . . . requires the disclosure of either a representative number of species falling within the scope of the genus or 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. The Federal Circuit has identified a number of factors to be considered in evaluating the adequacy of disclosures supporting generic claims, including "the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue." *Id.* at 1351.

While, at a superficial level, we tend to agree with the Petitioner that 13 exemplified compounds is a small number to be representative of a genus encompassing millions, the Petition does not include persuasive evidence or argument regarding the commonality of structural features within the genus of claim 1, the state of the art, or the predictability of the technology. *See*, Pet. 58–59. Nor does the Petition discuss the representativeness of the 13 exemplified compounds beyond pointing out that, quantitatively, they represent a small portion of the claimed genus. *Id.* The Federal Circuit has expressly declined to establish "bright-line rules governing . . . the number of species that must be disclosed to describe a genus claim, as this number necessarily changes with each invention, and it changes with progress in [the] field." *Ariad,* 598 F.3d 1351–52. Accordingly, it is not clear that the Petition has sufficiently established that it is more likely than not that the

Specification provides insufficient disclosure to support the genus of claim 1.

D. Written Description Support for Claims 2–15 and 17

Petitioner argues that claims 2–15 and 17 lack written description support because they "depend from claim 1 and include at least one or more of the definitions of the amended heteroaryl or heterocycloalkyl introduced in the amendment of claim 1." Pet. 59. Patent Owner does not separately address Petitioner's written description arguments for claims 2–15 and 17. Prelim. Resp. 51–56. For the reasons discussed in connection with claim 1, we find that the current record tends to support Petitioner's contention that claims 2–15 and 17 lack written description support for the amended claim language.

IV. ENABLEMENT

Petitioner argues that the Specification does not enable the ordinary artisan to make and use the full scope of the invention as claimed. Pet. 46–53. Petitioner's arguments focus on the relatively limited number of examples provided as compared to the broad scope of the claims. Patent Owner contends that Petitioner's arguments are conclusory and that the Specification provides guidance on synthetic methods as well as methods for analyzing the USP7 inhibitory capabilities of the claimed compounds. Prelim. Resp. 49–51. Patent Owner also argues that the Board should exercise its discretion under 35 U.S.C. § 325(d) to deny institution on this ground because it "merely repackages what was considered by the Office during prosecution."[10] We have reviewed Petitioner's and Patent Owner's

[10] We do not specifically address Patent Owner's 35 U.S.C. § 325(d) arguments as they relate to enablement because, as discussed above,

assertions, as well as the evidence of record. We offer the following views for the parties' consideration, to the extent they wish to address them in any further briefing.

"[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.'" *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993).

> The enablement requirement ensures that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims. The scope of the claims must be less than or equal to the scope of the enablement. The scope of enablement, in turn, is that which is disclosed in the specification plus the scope of what would be known to one of ordinary skill in the art without undue experimentation.

National Recovery Techs. Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1195–96 (Fed Cir. 1999).

Some experimentation, even a considerable amount, is not "undue" if, e.g., it is merely routine, or if the Specification provides a reasonable amount of guidance as to the direction in which the experimentation should proceed. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

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on this record, we are persuaded that Petitioner has demonstrated that it is more likely than not that at least one of claims 1–15 and 17 do not comply with the written description requirement. *See supra p.* 21–26. On this record, we also are persuaded that these arguments were not specifically considered by the Examiner. *See supra p.* 18–21. Under the current guidance, "if the PTAB institutes a trial, the PTAB will institute on all challenges raised in the petition." *See SAS* Guidance. Moreover, for the reasons discussed herein, we are inclined to agree with Patent Owner on the merits that Petitioner has not established that claims 1–17 fail to comply with the enablement requirement.

> Factors to be considered in determining whether a disclosure would require undue experimentation . . . . include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Id.

A. Enablement of Claim 1

Petitioner asserts that "[t]he specification only describes, discloses or lists thirteen specific compounds of Formula I and provides examples for synthesizing only four different illustrative compounds." Pet. 48. Petitioner argues that the four disclosed syntheses "are insufficient for one of ordinary skill in the art to know how to synthesize the remaining millions of compounds purportedly covered by Formula (I)." *Id.* In addition, Petitioner argues that the ordinary artisan "would not know which specific compounds of the millions of total compounds of Formula I would have the specification's disclosed exclusive use of its compounds (i.e., as an inhibitor of USP7)." *Id.*

Patent Owner argues that Petitioner has not met the burden to establish by a preponderance of the evidence that it is more likely than not that the claims are not enabled. Patent Owner explains:

> Petitioner presents no evidence of even a single compound within the scope of the claims that the person of ordinary skill in the art (e.g., synthetic organic chemist seeking to synthesize chemical compounds) would be unable to make and use without undue experimentation. Instead, Petitioner makes broad and conclusory statements that the disclosure of a limited number of compounds sharing a common structure somehow renders the

> person of ordinary skill in the art unable to make and use other compounds within the scope of the claim.

Prelim. Resp. 50. Patent Owner also argues that "[t]he specification provides both synthetic methods to make compounds of formula (I), as well as detailed instructions for analyzing USP7 inhibitory capabilities." *Id.* at 51 (citing Ex. 1001, 56:42–65:30).

While, at a superficial level, we tend to agree with the Petitioner that the number of exemplary synthesized compounds seems small as compared to the scope of the genus encompassed by claim 1, the Specification explains that "[t]he compounds of Formula (I) may be prepared by methods known in the art of organic synthesis as set forth in part by the following synthetic schemes." Ex. 1001, 48:8–10. The Specification then proceeds to describe general synthesis methods (*id.* at 48:10–38) and to provide specific examples in which compounds were synthesized using these methods. *Id.* at 48:38–50:60; 56:42–65:30.

Petitioner presents the testimony of Dr. Delansorne that the examples provided in the Specification "are insufficient for one of ordinary skill in the art to know how to synthesize the remaining millions of compounds purportedly covered by Formula (I)." Ex. 1004, 42–43. However, in support of this proposition, Dr. Delansorne relies entirely on the variance between the number of exemplary compounds synthesized in the Specification and the number of compounds encompassed in the claims. *Id.* at 41–43. Dr. Delansorne dismisses the guidance in the Specification as "very general and insufficient" (*id.* at 42), but neither Dr. Delansorne nor Petitioner explains why the general methods and specific examples disclosed in the Specification would have been insufficient to enable a skilled artisan to synthesize any particular compounds encompassed by the claimed genus.

Nor do they discuss the degree of experimentation that would have been required to synthesize any particular compound.

Similarly, Petitioner presents the testimony of Dr. Delansorne that the ordinary artisan "would not know which specific compounds of the millions of total compounds of Formula (I) would have the specification's disclosed exclusive use of its compounds (i.e. inhibitor of USP7)." *Id.* at 43. However, the Specification discloses two assays that can be used to assess USP7 inhibition. Ex. 1001, 65:30–66:68. Dr. Delansorne discusses these assays in connection with his analysis of the obviousness of the claimed compounds, concluding that the assays disclosed in the '491 patent are "less stringent" than those disclosed in a prior art patent. Ex. 1004, 29. However, neither Dr. Delansorne nor Petitioner explains why the skilled artisan would have been unable to use the disclosed assays to assess USP7 activity. Accordingly, it is not clear that the Petition has sufficiently established that it is more likely than not that the Specification provides insufficient disclosure to support the genus of claim 1.

Under the current guidance, "if the PTAB institutes a trial, the PTAB will institute on all challenges raised in the petition." *See SAS* Guidance. Because we are instituting a trial as to whether claim 1 is unpatentable for failure to comply with the written description requirement, we also institute trial as to whether Patent Owner complied with the enablement requirement with respect to claim 1.

B. Enablement of Claims 2–15 and 17

Claims 2–15 and 17 depend from claim 1. Petitioner argues that claims 2–15 and 17 "fail the enablement requirement for the reasons

provided above with respect to claim 1." Pet. 52. Our views with respect to enablement of claim 1 are discussed above.

C. Enablement of Claim 16

Claim 16 recites a compound selected from the thirteen listed compounds. Petitioner argues that claim 16 is not enabled because "only four of those thirteen compounds were synthesized and reported in the specification." Pet. 52. This argument is similar to the arguments Petitioner made with respect to claim 1, the only difference being that the variance between the number of compounds exemplified in the Specification and the number recited in the claims is smaller. Our views with respect to this argument are the same as discussed with respect to claim 1.

V. OBVIOUSNESS

Petitioner argues that claims 1–17 would have been obvious in view of the disclosure of the '150 patent. Pet. 13–46. Patent Owner contends that it would not have been obvious to modify the compounds disclosed in the '150 patent to arrive at the claimed compounds. Patent Owner also argues that the Board should exercise its discretion under 35 U.S.C. § 325(d) to deny institution on this ground because it "merely repackages certain prior art references and arguments discussed in detail with the Office during the second Office Action and subsequent response."[11] Prelim. Resp. 27. We

[11] We do not specifically address Patent Owner's 35 U.S.C. § 325(d) arguments as they relate to obviousness because, as discussed above, we have already concluded that Petitioner has demonstrated that it is more likely than not that at least one of claims 1–15 and 17 do not comply with the written description requirement and that these arguments were not specifically considered by the Examiner. *See supra p.* 21–26. Under the current guidance, "if the PTAB institutes a trial, the PTAB will institute on all challenges raised in the petition." *See SAS* Guidance. Moreover, for the

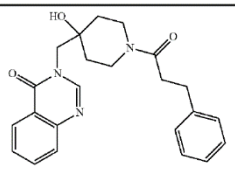
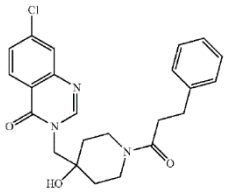
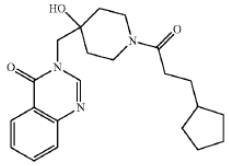
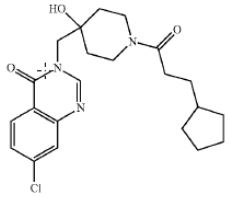
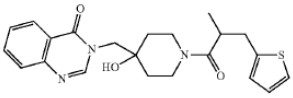
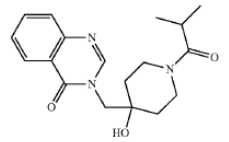
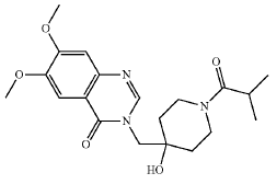
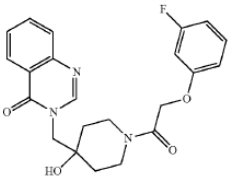
have reviewed Petitioner's and Patent Owner's assertions, as well as the evidence of record. We offer the following views for the parties' consideration, to the extent they wish to address them in any further briefing.

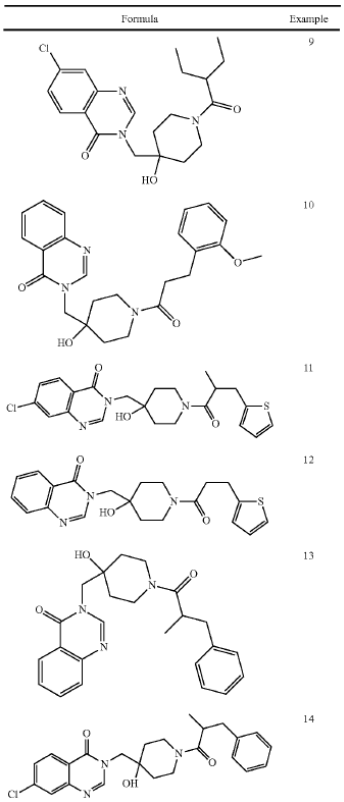
A. Disclosure of the '150 Patent

The '150 patent discloses "selective and reversible inhibitors of ubiquitin specific proteases, their process of preparation and their

reasons discussed herein, we tend to agree with Patent Owner on the merits that Petitioner has not established that claims 1–17 would have been obvious in view of the disclosure of the '150 patent.

therapeutic use. Ex. 1004, 1:7–10. The '150 patent discloses fourteen "representative compounds" each of which is reproduced below.

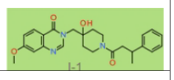
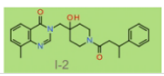
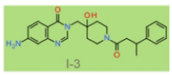
Formula	Example
	1
	2
	3
	4
	5
	6
	7
	8

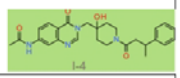
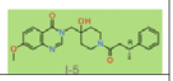
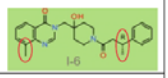
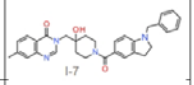
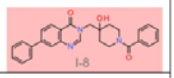
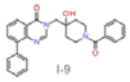


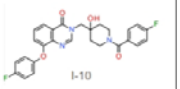
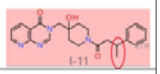
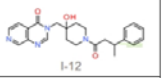
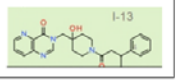
Ex. 1004, 20:38–22:55. The '150 patent describes the chemical synthesis of 14 examples, their inhibition of USP7 in two different types of assays, the reversibility of their inhibition of USP7, and their cytotoxicity towards cancerous cells.

B. Compounds of Claim 16

Claim 16 recites thirteen specific compounds. Petitioner provides the following table illustrating the structure of the compounds recited in claim 16.

Compound from claim 16 (I-1 – I-13)	Chemical Name	Chemical Structure
I-1	3-((4-hydroxy-1-(3-phenylbutanoyl)piperidin-4-yl)methyl)-7-methoxyquinazo- lin-4(3H)-one	
I-2	3-((4-hydroxy-1-(3-phenylbutanoyl)piperidin-4-yl)methyl)-8-methylquinazol- in-4(3H)-one	
I-3	7-amino-3-((4-hydroxy-1-(3-phenylbutanoyl)piperidin-4-yl)methyl)quinazoli- n-4(3H)-one	

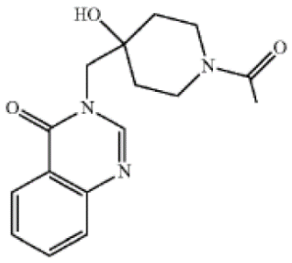
Compound from claim 16 (I-1 – I-13)	Chemical Name	Chemical Structure
I-4	N-(3-((4-hydroxy-1-(3-phenylbutanoyl)piperidin-4-yl)methyl)-4-oxo-3,4-dih- ydroquinazolin-7-yl)acetamide	
I-5	(R)-3-((4-hydroxy-1-(3-phenylbutanoyl)piperidin-4-yl)methyl)-7-methoxyqui- nazolin-4(3H)-one	
I-6	(R)-3-((4-hydroxy-1-(3-phenylbutanoyl)piperidin-4-yl)methyl)-8-methylquin- azolin-4(3H)-one	
I-7	3-((1-(1-benzylindoline-5-carbonyl)-4-hydroxypiperidin-4-yl)methyl)-7-met-hylquinazolin-4(3H)-one	
I-8	3-((1-benzoyl-4-hydroxypiperidin-4-yl)methyl)-7-phenylquinazolin-4(3H)-on- e	
I-9	3-((1-benzoyl-4-hydroxypiperidin-4-yl)methyl)-8-phenylquinazolin-4(3H)--one	

Compound from claim 16 (I-1 – I-13)	Chemical Name	Chemical Structure
I-10	3-((1-(4-fluorobenzoyl)-4-hydroxypiperidin-4-yl)methyl)-8-(4-fluoroph-enoxy)quinazolin-4(3H)-one	
I-11	3-((4-hydroxy-1-(3-phenylbutanoyl)piperidin-4-yl)methyl)pyrido[2,3-d]pyri- midin-4(3H)-one	
I-12	3-((4-hydroxy-1-(3-phenylbutanoyl)piperidin-4-yl)methyl)pyrido[3,4-d]pyri- midin-4(3H)-one	
I-13	3-((4-hydroxy-1-(3-phenylbutanoyl)piperidin-4-yl)methyl)pyrido[3,2-d]pyri- midin-4(3H)-one	

Pet. 17–19. The above table, reproduced from the Petition, depicts the structure of the compounds recited in claim 16. Petitioner has color coded the table for USP7 inhibition. Green highlighting reflects ++++ inhibition (compounds I-4, I-5, I-6), light green reflects +++ inhibition (compound I-13), white reflects ++ inhibition (compounds I-7, I-9, I-12), and pink reflects + inhibition (compounds I-8, I-11). *See*, Ex. 1004, 45 (Delansorne Decl., reproducing and describing the above table).

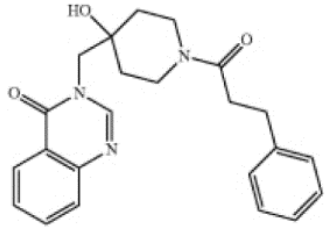
C. Analysis

Petitioner contends that the '150 patent discloses the following "base core structure" which is present in all fourteen exemplified USP7 inhibitor compounds of the '150 patent. Pet. 25–26.



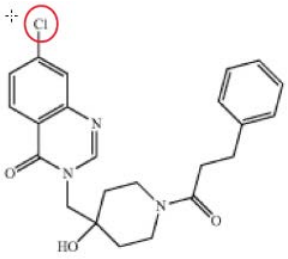
Petitioner asserts that "[u]sing the 14 examples in the '150 patent, one would predict that modifications including combinations and permutations of the variable substituents to the base core scaffold structure . . . can be made to the base core scaffolding while preserving the USP7 inhibition properties." Pet. 23.

Petitioner contends that the ordinary artisan would have started with the compound of Example 1 of the '150 patent as a lead compounds. Pet. 30. For reference Example 1 of the '150 patent is reproduced below.



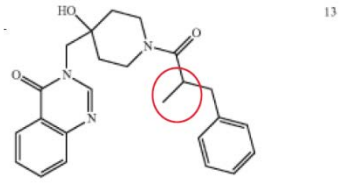
Ex. 1004, 20:45–55. Petitioner suggests that the following modifications to the compound of Example 1 would have been obvious.

First, Petitioner contends that it would have been obvious that one could "improve the activity of the compound of Example 1 of the '150 patent . . . by adding a chloride atom on the quinazoline-4-one ring as done in . . . Example 2 [of the '150 patent]." Pet. 30. Example 2 of the '150 patent is reproduced below with the added chloride circled.

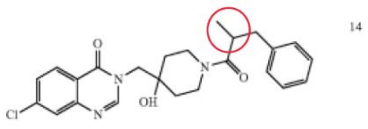


Ex. 1004, 20:55–68.

Second, Petitioner contends that the ordinary artisan would have known to "improve USP7 inhibition by adding a methyl group on the phenyl-propanoyl carboxylic acid side chain." Pet. 30–31. Petitioner points out that this modification occurs in Examples 13 and 14 of the '150 patent and that these are the most active compounds disclosed in that reference. *Id.* at 30–32. Examples 13 and 14 are reproduced below with the modified methyl group circled.



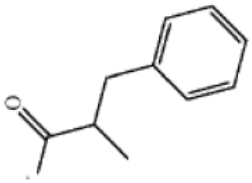
13

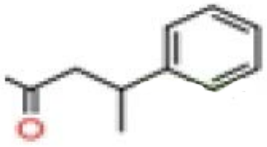


14

See, Ex. 1004, 22:35–55.

Third, Petitioner argues that it would have been obvious to replace the modified side chain of Examples 13 and 14 with a "very close isomer." *Id.* at 32. Specifically, Petitioner suggests replacing the 2-methyl-3-phenyl propanoyl (depicted below left) of Examples 13 and 14 with 3-phenyl-butanoyl (depicted below right).





Pet. 31–32. The difference between the two isomers is that the methyl is in the beta position rather than the alpha position with respect to the amide. *Id.* at 31. Petitioner contends that the skilled artisan would have expected that such a very close isomer "would be a good USP7 inhibitor." *Id.* at 32.

Fourth, Petitioner argues that in a compound in which R_5, R_6, and R_7 are all simultaneously hydrogen, it would have been obvious to replace at least one of R_5, R_6, and R_7 with an alternative, non-hydrogen substituent, such as a C_1–C_6 alkyl or a halogen. *Id.* Petitioner reasons that the skilled artisan would have expected a compound so modified to "be a[s] good [a] USP7 inhibitor as those in the '150 patent." *Id.* at 32–33.

Fifth, Petitioner argues that in a compound in which the quinazoline ring includes a chlorine substituent – such as in Example 2 of the '150 patent – it would have been obvious to substitute fluorine for the chlorine substituent. Petitioner reasons that fluorine is "a halogen having similar properties to chlorine" and thus the ordinary artisan would have expected it to "function in a very similar way as chlorine." *Id.* at 33. Thus, according to Petitioner, the ordinary artisan would have expected a compound in which

fluorine was substituted for chlorine to be "similarly reactive as a USP7 inhibitor." *Id.*

Having summarized the substituent modifications that Petitioner contends would have been obvious, we turn now to Petitioner's explanation of how these modifications would have rendered the claimed compounds obvious. Petitioner does this in two ways. First, Petitioner provides a broad, high-level summary as to why various substituents of the compounds recited in claim 16 would have been obvious. Petitioner explains:[12]

> Compounds I-1, I-3, I-4 and I-5 are obvious as they combine a substitution in position **7** of the quinazolinone and the position isomer (3-phenylbutanoyl) of the favorable "East side" chain (2-methyl-3-phenylpropanoyl), exactly like in Example 14, one of the two most active examples of the '150 patent. (Delansorne Dec. (Ex. 1005) at pages 15-16).
>
> Compounds I-2 and I-6 are obvious as they combine, on one hand, a substitution in position **8** of the quinazolinone and, on the other hand, the position isomer (3-phenylbutanoyl) of the favorable East side chain (2-methyl-3-phenylpropanoyl) which is found in examples 13 and 14, the two most active examples of the '150 patent. (Delansorne Dec. (Ex. 1005) at page 16).
>
> Compounds I-11, I-12 and I-13 are obvious as they are non-substituted azaquinolinones with the position isomer (3-phenylbutanoyl) of the favorable East side chain (2-methyl-3-phenyl-propanoyl) which is found in example 13, a nonsubstituted quinazolinone and one of the two most active examples of patent '150. (Delansorne Dec. (Ex. 1005) at page 16).

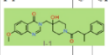
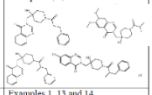
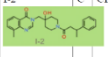
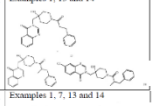
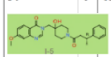
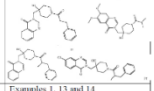
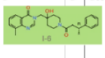
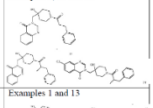
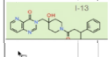
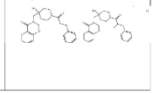
Pet. 20–21.

This is not persuasive because it employs impermissible hindsight. Rather than providing reasoning as to why it would have been obvious to

[12] In the below quote, the reference numbers I-# are those used in the table reproduced *supra p.* 36–37. They identify individual compounds recited in claim 16 of the '491 patent.

modify a known compound, it starts with the claimed compounds and provides reasons why its substituents would have been obvious. *Amerigen Pharmaceuticals Limited v. UCB Pharma GMBH*, 913 F.3d 1076, 1089 (Fed. Cir. 2019) ("Any compound may look obvious once someone has made it and found it to be useful, but working backwards from that compound, with the benefit of hindsight, once one is aware of it does not render it obvious."); *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1357 (Fed. Cir. 2007) ("[I]n cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound."); *Otsuka Pharmaceutical Co., Ltd. v. Sandoz, Inc.*, 678 F.3d 1280, 1292 (Fed. Cir. 2012).

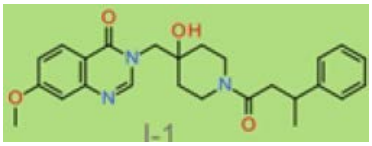
The second way that Petitioner explains how the modifications it proposes would have rendered the claimed compounds obvious is by providing a table comparing selected exemplary compounds from the '150 patent to five of the compounds recited in claim 16 of the '491 patent. This table is reproduced below.

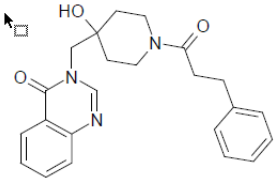
Compound From claim 16/substituents of Formula (I) ('491 Patent)	X_1	Y_1	Y_2	Y_3	Y_4	R_1	R_2	$R_{4'}$, $R_{4''}$	R_6	R_7	m	n	'150 Compounds that make Claim 1 ('491 Patent) Elements obvious
I-1 	C	CH	CH	CR_6	CR_7	OH	Alkyl substituted with R_8=phenyl	H,H	OMe	H	0	1	Examples 1, 7, 13 and 14 
I-2 	C	CH	CH	CR_6	CR_7	OH	Alkyl substituted with R_8=phenyl	H,H	H	Me	0	1	Examples 1, 13 and 14 
I-5 	C	CH	CH	CR_6	CR_7	OH	Alkyl substituted with R_8=phenyl	H,H	OMe	H	0	1	Examples 1, 7, 13 and 14 
I-6 	C	CH	CH	CR_6	CR_7	OH	Alkyl substituted with R_8=phenyl	H,H	H	Me	0	1	Examples 1, 13 and 14 
I-13 	C	N	CH	CR_6	CR_7	OH	Alkyl substituted with R_8=phenyl	H,H	H	H	0	1	Examples 1 and 13 

Pet. 36–38.

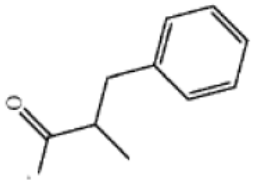
In the above table, Petitioner asserts that compounds I-1, I-2, I-5, I-6, and I-13 would have been obvious over various combinations of the example compounds of the '150 patent. Petitioner does not clearly articulate why any individual compound, including compounds I-1, I-2, I-5, I-6, and I-13 would have been obvious over the cited art. However, applying the general analysis set forth in the Petition to the specific compounds at issue, we understand Petitioner's argument, with respect to compound I-1, to be as follows.[13]

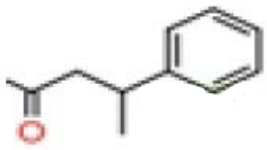
Petitioner alleges that compound I-1 would have been obvious in view of example compounds 1, 7, 13, and 14. Compound I of claim 16 and Example 1 of the '150 patent are reproduced below (with compound I-1 at left).





To arrive at the claimed compound I-1, Petitioner contends, first, that the ordinary artisan would start with the compound of Example 1 of the '150 patent. Pet 30 (identifying Example 1 as the lead compound). Second, the

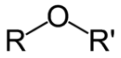




[13] We provide herein our comments on Petitioner's obviousness argument with respect to compound I-1. As Petitioner's obviousness argument, and the evidence offered in support of the same, is very similar for compounds I-2, I-5, I-6, and I-13, we do not separately analyze those compounds. Our comments on the obviousness of compound I-1 can reasonably be extended to compounds I-2, I-5, I-6 and I-13.

ordinary artisan would have added a methyl group to the phenyl-propanoyl carboxylic acid side chain as disclosed in Examples 13 and 14. Pet. 32. Third, the ordinary artisan would have changed the position of the methyl group, replacing the 2-methyl-3-phenyl propanoyl (depicted below left) of Examples 13 and 14 with 3-phenyl-butanoyl (depicted below right). Fourth, the person of ordinary skill in the art would have added an alkoxy group (depicted below) to the position corresponding to R_6 in Formula (I).

With respect to the first step in the above analysis of the obviousness of compound I-1, Petitioner relies on the testimony of Dr. Delansorne (Ex. 1004, 18) and the identification of Example 1 as one of seven lead



compounds in an article by Benedikt M. Kessler.[14] Patent Owner does not provide testimony contradicting the selection of Example 1 as a lead compound, but argues that Kessler identifies "five compounds that display better inhibition of USP7" than Example 1. Prelim. Resp. 44. Patent Owner also argues that the '150 patent discloses "at least six compounds with better USP7 inhibitory activity than Example 1" including Examples 13 and 14. *Id.* at 46. We are persuaded that the evidence of record tends to support the identification of Example 1 as a lead compound. In this regard, we note that Petitioner proposes modifying Example 1 in a manner consistent with Examples 13 and 14 and that the law does not require a single lead compound. *See, Altana Pharma AG v. Teva Pharmaceuticals USA, Inc.*, 566 F.3d 999, 1008 (Fed. Cir. 2009) ("[T]o the extent Altana suggests that the

[14] Kessler, *Selective and Reversible Inhibitors of Ubiquitin-Specific Protease 7: A Patent Evaluation (WO2013030218),* Expert Opin. Ther. Patents (2014) 24(5):597–602 (Ex. 1004, 65–70, "Kessler").

prior art must point to only a single lead compound for further development efforts, that restrictive view of the lead compound test would present a rigid test similar to the teaching-suggestion-motivation test that the Supreme Court explicitly rejected in *KSR*.").

With respect to the second step in the above analysis of the obviousness of compound I-1, Petitioner relies on the testimony of Dr. Delansorne, who notes that Examples 13 and 14 are the two most active of the representative compounds disclosed in the '150 patent. Ex. 1004, 19–20. At this stage in the proceeding, and absent testimony to the contrary, the evidence tends to support Petitioner's position that it would have been obvious to modify the compound of Example 1 to include a methyl group like that included in the compounds of Examples 13 and 14.

With respect to the third step in the above analysis of the obviousness of compound I-1, Petitioner relies on the solely on the testimony of Dr. Delansorne regarding the structural similarity of the claimed and prior art compounds. In *Takeda,* the Federal Circuit provided the following guidance on analyzing the obviousness based on structural similarity compounds.

> Our case law concerning prima facie obviousness of structurally similar compounds is well-established. We have held that "structural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions, creates a prima facie case of obviousness." *Dillon,* 919 F.2d [688,] 692 [(Fed. Cir. 1990)]. In addition to structural similarity between the compounds, a prima facie case of obviousness also requires a showing of "adequate support in the prior art" for the change in structure. *In re Grabiak,* 769 F.2d 729, 731–32 (Fed. Cir. 1985).

> We elaborated on this requirement in the case of *In re Deuel*, 51 F.3d 1552, 1558 (Fed. Cir. 1995), where we stated that "[n]ormally a prima facie case of obviousness is based upon structural similarity, *i.e.*, an established structural relationship between a prior art compound and the claimed compound." That is so because close or established "[s]tructural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds." *Id.* A known compound may suggest its homolog, analog, or isomer because such compounds "often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties." *Id.* We clarified, however, *that in order to find a prima facie case of unpatentability in such instances, a showing that the "prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention" was also required*. *Id.* (citing *In re Jones*, 958 F.2d 347 (Fed. Cir. 1992); *Dillon*, 919 F.2d 688; *Grabiak*, 769 F.2d 729; *In re Lalu*, 747 F.2d 703 (Fed. Cir. 1984)).

Takeda, 492 F.3d at 1356 (emphasis added).

Dr. Delansorne does not cite to any sources to support his testimony that it would have been obvious to replace the 2-methyl-3-phenyl propanoyl of Examples 13 and 14 with 3-phenyl-butanoyl. This tends to diminish the weight of his testimony. *See In re Acad. of Sci. Tech Ctr.*, 367 F.3d 1359, 1368 (Fed. Cir. 2004) ("[T]he Board is entitled to weigh the declarations and conclude that the lack of factual corroboration warrants discounting the opinions expressed in the declarations."); *see also* 37 C.F.R. § 42.65(a) ("Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight."). It also makes it unclear how the "prior art would have suggested making the specific molecular modification[]" of replacing the 2-methyl-3-phenyl propanoyl of Examples 13 and 14 with 3-phenyl-butanoyl.

With respect to the fourth step in the above analysis of the obviousness of compound I-1, Petitioner again relies on the solely on the testimony of Dr. Delansorne. Dr. Delansorne's analysis, in its entirety is as follows:

> [A]lthough claim 1 excludes R_5, R_6, and R_7 as all simultaneously being H, the compounds having alternative definitions of R_5, R_6, and R_7, e.g. an C_1–C_6 alkyl or a halogen, would be expected to be good USP7 inhibitors as those in the '150 patent.

Ex. 1004, 20. As discussed above with respect to the third step, the lack of citation diminishes the weight of Dr. Delansorne's testimony and makes it unclear how the "prior art would have suggested making the specific molecular modification[]" of adding an ether group to the position corresponding to R_6 in Formula (I).

We turn now to Patent Owner's arguments against obviousness. Patent Owner contends that non-obviousness is demonstrated by Kessler's disclosure with respect to a different compound, which taught that the chlorine substituent was critical to USP7 inhibitory capacity. Prelim. Resp. 47. Based on this disclosure, Patent Owner argues that the ordinary artisan would have lacked motivation and a reasonable expectation of success in removingthe chlorine atom, resulting in a compound that retained USP7 inhibitory activity. *Id.* Patent Owner contends that Kessler's disclosure regarding the importance of chlorine is consistent with the disclosure of the '150 patent that two of the most effective compounds contained a chlorine atom at the position corresponding to R_6 of the claimed compounds. *Id.* At this stage in the proceeding, and absent testimonial evidence explaining how Kessler's teachings would apply to compounds like Example 1 of the '150 patent, it is difficult to evaluate the persuasiveness of this argument.

Under the current guidance, "if the PTAB institutes a trial, the PTAB will institute on all challenges raised in the petition." *See SAS* Guidance. Because we are instituting a trial as to whether claim 1 is unpatentable for failure to comply with the written description requirement, we also institute trial as to whether claims 1–17 would have been obvious over the disclosure of the '150 patent.

VI. CONCLUSION

For the foregoing reasons, we conclude that the information presented in the Petition establishes that it is more likely than not that Petitioner will prevail in showing that at least claim 1 of the '491 patent is unpatentable. Accordingly, we institute an *inter partes* review of all challenged claims and all grounds presented in the Petition. Guidance on the Impact of *SAS* on AIA Trial Proceedings (April 26, 2018).

VII. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that pursuant to 35 U.S.C. § 324(a), a post grant review is instituted as to claims 1–15 and 17 of the '491 Patent under 35 U.S.C. § 112 for failure to comply with the written description requirement.

ORDERED that pursuant to 35 U.S.C. § 324(a), a post grant review is instituted as to claims 1–17 of the '491 Patent under 35 U.S.C. § 112 for failure to comply with the enablement requirement.

ORDERED that pursuant to 35 U.S.C. § 324(a), a post grant review is instituted as to claims 1–17 of the '491 Patent under 35 U.S.C. § 103 as obvious over the '150 patent.

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