Trials@uspto.gov
571-272-7822

Paper 68
Entered: May 11, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INCYTE CORPORATION,
Petitioner,

v.

CONCERT PHARMACEUTICALS, INC.,
Patent Owner.

PGR2021-00006
Patent 10,561,659 B2

Before CHRISTOPHER G. PAULRAJ, ROBERT A. POLLOCK, and DEVON ZASTROW NEWMAN, *Administrative Patent Judges.*

NEWMAN, *Administrative Patent Judge*.

JUDGMENT

Final Written Decision
Determining No Challenged Claims Unpatentable
35 U.S.C. § 328(a)

Denying in Part and Dismissing in Part
Patent Owner's Motion to Exclude Evidence

Dismissing Petitioner's Motion to Exclude Evidence
37 C.F.R. § 42.64

I. INTRODUCTION

This is a Final Written Decision in a post-grant review challenging the patentability of claims 1–21 (the "challenged claims") of U.S. Patent No. 10,561,659 B2 (Ex. 1001, "the '659 patent"). We have jurisdiction under 35 U.S.C. § 6.

Having reviewed the arguments of the parties and the supporting evidence, we find that Petitioner has not demonstrated by a preponderance of the evidence that each of the challenged claims is unpatentable.

A. Summary of Procedural History

Incyte Corporation ("Petitioner") filed a Petition (Paper 1, "Pet.") requesting a post-grant review of claims 1–21 of the '659 patent. Concert Pharmaceuticals, Inc., ("Patent Owner") filed a Preliminary Response (Paper 11, "Prelim. Resp."). Petitioner filed a Reply to Patent Owner's Preliminary Response (Paper 17, "Prelim. Reply") and Patent Owner filed a Preliminary Sur-Reply (Paper 19, "Prelim. Sur-Reply"). Based on the record then before us, we instituted trial with respect to all challenged claims 1–7 and 9–21[1]. Paper 20, 49 ("Dec.").

After institution of trial, Patent Owner filed a Request for Rehearing (Paper 23), which was denied (Paper 25). Patent Owner filed a Response (Paper 37, "Resp."), Petitioner filed a Reply to Patent Owner's Response (Paper 44, "Reply"), and Patent Owner filed a Sur-reply to Petitioner's Reply (Paper 51, "Sur-reply").

[1] Patent Owner disclaimed claim 8 subsequent to filing. *See* Ex. 2020. Hence, claim 8 and the Petition's Ground 3 challenging only claim 8 are no longer at issue in this case.

Both parties filed motions to exclude evidence and replies in support of those motions (Patent Owner: Papers 55, 61; Petitioner: Papers 56, 62). Both parties opposed each other's motions to exclude (Patent Owner: Paper 59; Petitioner: Paper 60).

We heard oral argument on February 10, 2022. A transcript of that hearing is entered as Paper 67 ("Tr."). Petitioner bears the burden of proving unpatentability of each claim it has challenged by a preponderance of the evidence, and the burden of persuasion never shifts to Patent Owner. *See* 35 U.S.C. § 326(e) (2018); 37 C.F.R. § 42.1(d); *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc*., 800 F.3d 1375, 1378 (Fed. Cir. 2015). This Final Written Decision is issued pursuant to 35 U.S.C. § 328(a) and 37 C.F.R. § 42.73.

B. Real Parties in Interest

Petitioner identifies itself as the real party-in-interest for Petitioner. Pet. 91. Patent Owner identifies itself as the real party-in-interest for Patent Owner. Paper 50, 1.

C. Related Matters

As related matters, Petitioner identifies pending U.S. Application No. 16/704,402, which claims the benefit of priority to U.S. Application No. 16/098,338, and IPR2017-01256 against Patent Owner's U.S. Patent No. 9,249,149. Pet. 91. Patent Owner also identifies U.S. Patent Application No. 16/704,402 as a related matter. Paper 50, 1.

D. The '659 Patent

The '659 patent is entitled "Treatment of Hair Loss Disorders with Deuterated JAK Inhibitors" and issued on February 18, 2020. Ex. 1001, codes (54), (45). According to the '659 patent, many current medicines

suffer from poor adsorption, distribution, metabolism, and/or excretion ("ADME") properties that limit their use for certain indications. *Id*. at 1:20–23. For example, rapid metabolism can cause drugs to be cleared too rapidly from the body, decreasing the drugs' efficacy in treating a disease. *Id*. at 1:29–32. Another ADME limitation is the formation of toxic or biologically reactive metabolites. *Id*. at 1:40–41.

The cytochrome P450 enzyme ("CYP") is typically responsible for the metabolism of drugs. *Id*. at 1:52–54. As such, the '659 patent identifies deuterium modification as a "potentially attractive strategy for improving a drug's metabolic properties." *Id*. at 2:7–8. Deuterium modification involves replacing one or more hydrogen atoms of a drug with deuterium atoms in an attempt to slow the CYP-mediated metabolism of a drug or to reduce the formation of undesirable metabolites. *Id*. at 2:8–12. Because deuterium forms stronger bonds with carbon than hydrogen, in certain cases, that stronger bond strength can positively impact the ADME properties of a drug, resulting in the potential for improved drug efficacy, safety, and/or tolerability. *Id*. at 2:13–19.

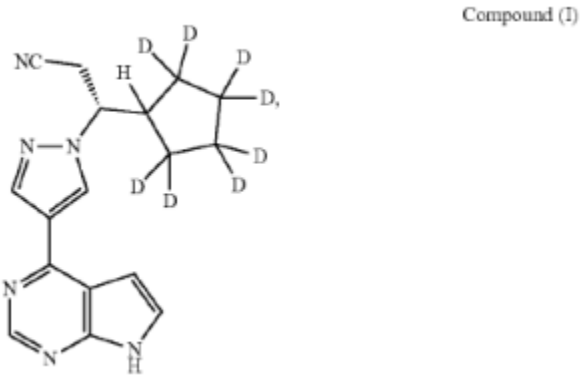
Ruxolitinib phosphate, a heteroaryl-substituted pyrrolo [2,3-d]pyrimidine, is an FDA-approved drug for treating patients with intermediate or high-risk myelofibrosis. *Id*. at 2:51–66. Ruxolitinib also has other potential applications, including the treatment of essential thrombocytopenia and is currently in clinical trials for the treatment of additional conditions. *Id*. at 2:66–3:5. Thus, according to the Specification, "[d]espite the beneficial activities of ruxolitinib, there is a continuing need for new compounds to treat the aforementioned diseases and conditions." *Id*. at 3:3–5.

The '659 patent discloses "a method for treating hair loss disorders that can be treated by compounds that modulate the activity of Janus Associated Kinase 1 (JAKl) and/or Janus Associated Kinase 2 (JAK2)." *Id*. at 3:43–46. The method comprises administering an effective amount of a deuterated compound (Compound (I)), or its pharmaceutically acceptable salt, once or twice a day, in specific dose ranges. *Id*. at 3:46–66. The method is disclosed as for use in treating the hair loss disorder alopecia areata or for generally "inducing hair growth in a subject." *Id*. at 3:66–67, 4:18–20. The level of deuterium incorporation into the drug is disclosed as between 52.5% to upwards of 99.5%. *Id*. at 6:42–52.

E. Illustrative Claim

Petitioner challenges claims 1–7, 9–21 of the '659 patent. Claim 1 is illustrative and recites:

1. A method of treating a hair loss disorder in a mammalian subject, the method comprising administering to the subject 16 mg/day or 24 mg/day of a compound represented by the following structural formula:



or a pharmaceutically acceptable salt thereof, wherein each position in Compound (I) designated specifically as deuterium has at least 95% incorporation of deuterium. Ex. 1001, 24:30–53.

F. Evidence

The parties rely on the following references and declarations that we refer to in this Decision:

Reference or Declaration	Date	Exhibit No.
Declaration of Dr. Steven Patterson, Ph. D.	Oct. 27, 2020	1007
Declaration of Frederick Peter Guengerich, Ph. D.	Nov. 5, 2021	1120
Declaration of William Damsky, M.D., Ph. D.	Nov. 12, 2021	1161
Declaration of Justin Ko, M.D., M.B.A.	Aug. 12, 2021	2059
Silverman et al., U.S. Patent No. 9,249,149 B2 ("Silverman")	Feb. 16, 2016	1002
Xing et al., *Alopecia areata is driven by cytotoxic T lymphocytes and is reversed by JAK inhibition*, NAT. MED. 20(9):043–1049 ("Xing")	Aug. 17, 2014	1003
Jakafi® (ruxolitinib) Prescribing Information, Physicians' Desk Reference 1281–1287 (69th ed. 2015) ("Ruxolitinib Prescribing Information").	Jan. 6, 2015	1004
Christiano et al., U.S. Patent No. 9,198,911 B2 ("Christiano").	Dec, 1, 2015	1005
Ni et al., U.S. Patent Pub. 2014/0135350 A1 ("Ni").	May 15, 2014	1006

G. Weight to Give Expert Testimony

Patent Owner argues that Dr. Patterson lacks the requisite experience and we should give little weight to his testimony. Patent Owner Motion to Exclude, Paper 55 ("PO MTE"); Paper 61, PO Reply to Petitioner's Opposition to Patent Owner's Motion to Exclude ("PO MTE Reply"). Patent Owner argues that Dr. Patterson's testimony should be excluded "because he is not an expert in deuteration, Janus kinase ('JAK') inhibitors,

or alopecia areata ('AA')," "has no prior experience with JAK inhibitors," and has never "dosed humans or done dosing studies in humans." PO MTE, 2–3. Patent Owner argues that Dr. Patterson "stated repeatedly that he is just a medicinal chemist and that he had to study AA and JAK inhibitors specifically for purposes of this case." *Id*. at 3 (citing Dr. Patterson's deposition testimony at Ex. 2055 at 26:4–14, 28:19–23, 29:8–13, 30:1–4, 31:4–7, 79:6–18, 56:25–57:7, 119:9–22).

Petitioner opposes exclusion, arguing that "Dr. Patterson has a Ph.D. in chemistry with over thirty years of experience in drug development, including designing and synthesizing thousands of compounds and serving as a primary investigator in drug dosing studies." Petitioner Opposition to Patent Owner Motion to Exclude, Paper 59 (citing Ex. 1008, 1; Ex. 2055, 40:4–41:22, 43:4–22, 48:22–50:2).

It is not necessary for an expert's experience or expertise to precisely match the art at issue. *SEB S.A. v. Montgomery Ward & Co*., 594 F.3d 1360, 1373 (Fed. Cir. 2010). However, one offering expert testimony must at least have ordinary skill in the art to provide relevant and reliable testimony that is helpful to the factfinder. *Kyocera Senco Indus. Tools, Inc. v. ITC*, 22 F.4th 1369, 1376–77 (Fed. Cir. 2022). "The Board has broad discretion to assign weight to be accorded expert testimony." Consolidated Trial Practice Guide 35 (available at https://www.uspto.gov/sites/default/files/documents/tpgnov.pdf?MURL=). Dr. Patterson has a Ph.D. in Chemistry and over 30 years of experience in drug design, drug administration, evaluation of drug effectiveness, and participated in drug design for over 20 years. Ex. 1007 ¶¶ 4–10; Ex. 1008, 1–2. He is author or co-author on over eight peer-reviewed journal articles involving medicinal chemistry. Ex. 1007 ¶ 5. We

find this level of skill to meet the qualifications for the level of skill in the art under the training and experience portion of the definition we have adopted for purposes of this opinion (*see* § II.B.), reproduced below:

> a Ph.D. in chemistry, pharmaceutical sciences, molecular biology, or a similar field, or an M.D. with similar background. A POSA would also have had at least several years of experience with drug design, drug development, clinical trials, or access to other individuals with that knowledge and experience. Likewise, a POSA would have had knowledge and experience in treating hair loss disorders, or access to a person with that knowledge and experience.

We note that Dr. Patterson himself also proposes this definition. *Id*. ¶ 102. However, Dr. Patterson does not have "knowledge and experience in treating hair loss disorders" and did not opine that, in regards to his testimony, he had access to a person with that knowledge and experience, as is proposed in the definition. *See generally*, Ex. 1007. Accordingly, we find Dr. Patterson qualified to opine on the level of ordinary skill with regard to issues of drug design, evaluation of effectiveness, and drug administration, but we find he is not adequately qualified to opine on the level of ordinary skill with regard to issues of treating hair loss disorders.

In reviewing Dr. Patterson's testimony, as well as the testimony provided by the other experts in this proceeding, Dr. Guengerich, Dr. Dansky, and Dr. Ko, we consider their opinions on the issues for which they are qualified to offer testimony, compare their opinions to the disclosures of the prior art references and the challenged patent, and the entirety of the evidence of record to weigh each part of their relative opinion testimony separately. *See Elbit Sys. of Am., LLC v. Thales Visionix, Inc*., 881 F.3d 1354, 1358 (Fed. Cir. 2018) ("The [Patent Trial and Appeal Board ('PTAB')] [i]s entitled to weigh the credibility of the witnesses." (citation

omitted)); *Icon Health & Fitness, Inc. v. Strava, Inc*., 849 F.3d 1034, 1041 (Fed. Cir. 2017) ("To the extent [a party] challenges the PTAB's factual findings, ... the PTAB is permitted to weigh expert testimony and other record evidence and, in so doing, rely on certain portions of an expert's declaration while disregarding others.").

H. Asserted Grounds

Petitioner asserts that claims 1–7 and 9–21 would have been unpatentable on the following grounds:

Claim(s) Challenged	35 U.S.C. §[2]	Reference(s)/Basis
1–7, 9–21	103	Silverman, Xing, Ruxolitinib Prescribing Information
1–7, 9–21	103	Silverman, Christiano, Ni

II. ANALYSIS

A. Legal Standards

Petitioner contends under both grounds that the challenged claims are unpatentable based on obviousness. Pet. 2. As set forth in 35 U.S.C. § 103(a),

> [a] patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art; (2) any

[2] As all of the filing dates at issue in this case are after March 16, 2013, we apply the current versions of 35 U.S.C. §§ 102, 103.

differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) when in evidence, objective evidence of nonobviousness. *Graham v. John Deere Co*., 383 U.S. 1, 17–18 (1966). An obviousness analysis "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398, 418 (2007). However, Petitioner cannot satisfy its burden of proving obviousness by employing "mere conclusory statements." *In re Magnum Oil Tools Int'l, Ltd*., 829 F.3d 1364, 1380 (Fed. Cir. 2016). Instead, Petitioner must articulate a reason why a person of ordinary skill in the art would have combined the prior art references. *In re NuVasive*, 842 F.3d 1376, 1382 (Fed. Cir. 2016); see also *Pers. Web Tech., LLC, v. Apple, Inc*., 848 F.3d 987, 993–94 (Fed. Cir. 2017) ("[O]bviousness concerns whether a skilled artisan not only could have made but would have been motivated to make the combinations or modifications of prior art to arrive at the claimed invention") (quoting *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015)).

B. Level of Ordinary Skill in the Art

The level of skill in the art is a factual determination that provides a primary guarantee of objectivity in an obviousness analysis. *Al-Site Corp. v. VSI Int'l Inc*., 174 F.3d 1308, 1324 (Fed. Cir. 1999) (citing *Graham v. John Deere Co*., 383 U.S. 1, 17–18 (1966); *Ryko Mfg. Co. v. Nu-Star, Inc*., 950 F.2d 714, 718 (Fed. Cir. 1991)). In determining the level of ordinary skill in the art, various factors may be considered, including the "type of problems encountered in the art; prior art solutions to those problems; rapidity with

which innovations are made; sophistication of the technology; and educational level of active workers in the field." *In re GPAC Inc*., 57 F.3d 1573, 1579 (Fed. Cir. 1995) (citation omitted).

We consider the asserted grounds of unpatentability in view of the understanding of a person of ordinary skill in the art. *KSR*, 550 U.S. at 399 (stating that obviousness is determined against the backdrop of the scope and content of the prior art, the differences between the prior art and the claims at issue, and the level 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 a person of ordinary skill in the art would have had

> a Ph.D. in chemistry, pharmaceutical sciences, molecular biology, or a similar field, or an M.D. with similar background. A POSA would also have had at least several years of experience with drug design, drug development, clinical trials, or access to other individuals with that knowledge and experience. Likewise, a POSA would have had knowledge and experience in treating hair loss disorders, or access to a person with that knowledge and experience.

Pet. 19–20.

Patent Owner proposes the same definition as Petitioner, but adds that the skilled artisan "would also have had experience in JAK inhibition, deuteration, and AA [alopecia areata] formulations, or access to a person

with that knowledge and experience." Resp. 15 (citing Ex. 2059 ¶ 14). Patent Owner's expert Dr. Ko critiques Petitioner's proposed definition as "incomplete, because it lacks any requirement for experience, or access to individuals with experience, in JAK inhibition, deuteration, and AA formulations." Ex. 2059 ¶ 16. However, neither Dr. Ko nor Patent Owner explains what difference this additional direct experience would have provided to an artisan with the skill level proposed by Petitioner, particularly when Petitioner's definition includes "experience in treating hair loss disorders," and for which the record contains evidence that existing JAK inhibitors such as ruxolitinib had been identified as causing reversal of hair loss caused by AA. Ex. 1003, 1043. Accordingly, we adopt Petitioner's proposed definition as consistent with the level of skill apparent in the cited prior art. In any event, as Patent Owner does not explain why its alternative definition would have any bearing on the outcome of the present case, and as we discern no appreciable difference in the parties' definitions, we note our findings and conclusions would be the same regardless of which definition were adopted.

We further note that the prior art itself demonstrates the level of skill in the art at the time of the invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required "where the prior art itself reflects an appropriate level and a need for testimony is not shown") (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp*., 755 F.2d 158, 163 (Fed. Cir. 1985)).

C. Claim Construction

We construe claims using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b). 37 C.F.R. § 42.100. Therefore, we construe the challenged claims under the framework set forth in *Phillips v. AWH Corp*., 415 F.3d 1303, 1312–19 (Fed. Cir. 2005) (en banc). Under this framework, claim terms are given their ordinary and customary meaning, as would have been understood by a person of ordinary skill in the art ("POSA"), at the time of the invention, in light of the language of the claims, the specification, and the prosecution history of record. *Id*. Only those terms that are in controversy need be construed and only to the extent necessary to resolve the controversy. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Matal*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (citing *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc*., 200 F.3d 795, 803 (Fed. Cir. 1999)).

We have considered Petitioner's claim construction proposals (*see* Pet. 21–23), which are uncontested (*see generally* Resp., not addressing construction), and find that it is not necessary to expressly construe any claim term for purposes of rendering this Decision.

D. Whether Silverman is Prior Art under 35 U.S.C. § 102(a)(1)

As a preliminary matter, the parties disagree about whether certain disclosures in Silverman are prior art under 35 U.S.C. § 102(a)(1) to the '659 patent.[3] Grounds 1 and 2 of the Petition allege obviousness using

[3] Petitioner previously argued that Silverman was also prior art under 35 U.S.C. § 102(a)(2), but did not pursue this argument after Patent Owner presented evidence that Silverman falls under the common-owner exception of § 102(b)(2)(C). *See* Reply 6–13; Dec. 18; Resp. 17–19; Tr. 45:23–46:9. Petitioner now contends only that Silverman is prior art under 35 U.S.C.

Silverman as the primary reference. Pet. 1–84. Silverman is owned by Patent Owner. Ex. 1002 code (71).

In its arguments for obviousness, Petitioner relies upon a declaration of Dr. Vinita Uttamsingh ("the 2015 Uttamsingh Declaration") and an accompanying applicant response, which were submitted during prosecution of the Silverman patent. In particular, Petitioner cites statements made by Dr. Uttamsingh as providing motivation for why a skilled artisan would have specifically identified Compound (I) (as recited in claim 1 of the '659 patent) from among the large number of compounds disclosed within the genus of Formula A recited in Silverman. *See, e.g.*, Pet. 15 (citing Ex. 1045, 407), 34 (citing Ex. 1045, 377, 416), 40 (citing Ex. 1045, 407, 416).

In our Decision, we found that Silverman is § 102(a) prior art on its face because it issued on February 2, 2016 (Ex. 1002, code (45)), before the earliest filing date of any provisional application to which the '659 patent claims priority (Ex. 1001, code (60)). Dec. 14. We concluded Petitioner had satisfied its initial burden of production of evidence on this issue, shifting the burden of production to Patent Owner to argue or produce evidence that Silverman is not prior art. *Dynamic Drinkware*, 800 F.3d at 1379. Notably, the burden of persuasion on the ultimate issue of the status of Silverman as prior art remains with Petitioner. *Id*. at 1378–80.

§ 102(a)(1). Reply 6–13. Accordingly, we confine our discussion to this issue.

> As the Federal Circuit stated in *Dynamic Drinkware,*
>
> the burden of persuasion is on the petitioner to prove "unpatentability by a preponderance of the evidence," 35 U.S.C. § 316(e), and that burden never shifts to the patentee.
>
> * * *
>
> A second and distinct burden, the burden of production, or the burden of going forward with evidence, is a shifting burden, "the allocation of which depends on where in the process of trial the issue arises." The burden of production may entail "producing additional evidence and presenting persuasive argument based on new evidence or evidence already of record."

Id. (citations omitted).

Patent Owner argues that key disclosures in Silverman and its prosecution history are not prior art under § 102(a)(1) because they fall within the exceptions set forth in § 102(b)(1)(A) and § 102(b)(1)(B). Resp. 16–28; Reply 1–10. Petitioner responds that the exceptions under § 102(b)(1) apply only to disclosures made 1 year or less before the effective filing date from an inventor of a claimed invention. Reply 6. Petitioner contends that Patent Owner's Response did not proffer, and therefore Patent Owner has waived, the bases for a § 102(b)(1) exception for Silverman. *Id.* For the reasons that follow, we find, based on our review of the record, that certain disclosures of Silverman are not prior art because they fall within the exceptions set forth in § 102(b)(1). We disagree with Petitioner's contention that Patent Owner waived any such argument by not identifying appropriate support in its post-institution Response.

1. Legal Background

35 U.S.C. § 102(a)(1) defines the prior art that will preclude the grant of a patent on a claimed invention and states:

> [a] person shall be entitled to a patent unless—
>
> (1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

35 U.S.C. § 102(b) sets out exceptions to AIA 35 U.S.C. § 102(a). Section 102(b)(1) provides two exceptions to § 102(a)(1) for disclosures made within one year of the effective filing date. Specifically, 35 U.S.C. § 102(b)(1) provides that a disclosure made one year or less before the effective filing date of a claimed invention shall not be prior art under 35 U.S.C. § 102(a)(1) with respect to the claimed invention if: (A) the disclosure was made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or (B) the subject matter disclosed had, before such disclosure, been publicly disclosed by the inventor or a joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor. 35 U.S.C. § 102(b)(1).

With regard to establishing unpatentability, a petitioner retains the burden of persuasion throughout the proceeding. *See Dynamic Drinkware,* 800 F.3d at 1378. However, with regard to specific evidence supporting the unpatentability challenge, such as the priority date of a reference used to establish obviousness, a petitioner shifts the burden of production to dispute the effective priority date of a prior art reference to the patent owner by alleging obviousness based upon a reference that appears to be prior art on its face. *Id.* at 1379–1380 (burden of production satisfied by assertion of anticipation, shifting burden to patent owner); *see also Pfizer, Inc. v. Genentech, Inc.*, IPR2017-01488, Paper 27 at 13 (PTAB Dec. 1, 2017)

(initial burden met where prior-art patents "predate the earliest possible priority date shown on the face of the" challenged patent).

2. Patent Owner's Arguments Regarding Exceptions to § 102(a)(1)

Patent Owner contends "the central disclosures of Silverman are not prior art under §102(a)(1) because they satisfy the inventor-disclosure exceptions in either §102(b)(1)(A) or (B)." Resp. 16. Citing the Manual of Patent Examining Procedure ("MPEP") § 717.01(b)(2), Patent Owner argues that the disclosures "apply on a disclosure-by-disclosure basis, and a particular disclosure is not considered prior art if it falls under *either* exception." *Id*. at 19. Patent Owner argues that three essential disclosures of Silverman should be excluded from Silverman as exceptions under § 102(b)(1)(A) and (B): 1) the structure of Compound (I); 2) metabolic stability data for Compound (I); and 3) metabolic stability date for other deuterated compounds disclosed in Silverman. *Id*.

Patent Owner alleges that the structure of Compound (I) was disclosed in the 2015 Uttamsingh Declaration by an inventor of the '659 patent. *Id*. at 20. As described in our Decision on Institution, the 2015 Uttamsingh Declaration was filed during the prosecution of Silverman as evidence of nonobviousness. Dec. 15–16. In that Declaration, Compound (I) was identified as Compound 111. Ex. 1045, 404.

Patent Owner argues that Dr. Uttamsingh's disclosure of Compound (I) satisfies § 102(b)(1)(B) because Silverman's disclosure of Compound (I) was 1) made on February 2, 2016, which was less than a year before the May 4, 2016 filing date of the earliest priority application of the '659 patent; and 2) Exhibit B of the 2015 Uttamsingh Declaration disclosed the structure of Compound (I). *Id*. at 21. Patent Owner argues that this disclosure also

satisfies § 102(b)(1)(A) because the disclosure was made less than a year before the May 4, 2016, filing date of the earliest priority application of the '659 patent by Dr. Uttamsingh. *Id*. at 23.

Patent Owner argues a similar analysis (e.g., the disclosure fits both § 102(b)(1)(A) and § 102 (b)(1)(B)) applies to the data disclosing the metabolic stability of Compound (I), as presented in the 2015 Uttamsingh Declaration: Silverman's disclosure of Compound (I) was 1) also made on February 2, 2016, less than a year before the filing date of the earliest priority application of the '659 patent; and 2) paragraphs 4–8 and Exhibit E of the 2015 Uttamsingh Declaration disclosed assay results indicating that Compound 111 (a.k.a. Compound (I) as recited in claim 1 of the '659 patent) had improved metabolic stability of 75–80% compared to non-deuterated ruxolitinib. *Id*. at 23 (citing Ex. 1045, 407, 415–416). Both allegedly exempted disclosures became public with the publication of the Silverman prosecution history on August 27, 2015, prior to the February 2, 2016, publication date of Silverman. *Id*. at 21 (citing Ex. 1046, 1).

Finally, Patent Owner alleges that the metabolic stability data reported in Silverman's Example 4 and Table 3 regarding deuterated Compounds 103, 107, and 127 over non-deuterated ruxolitinib, was exempt under both § 102(b)(1)(A) and § 102 (b)(1)(B) because 1) the data was disclosed in Silverman on February 2, 2016, less than a year before May 4, 2016, the filing date of the earliest priority application of the '659 patent; and 2) was obtained by three inventors of Silverman directly or indirectly from Dr. Uttamsingh's group. *Id*. at 24–27 (citing various paragraphs of the declarations of three inventors of Silverman and Dr. Uttamsingh regarding intra-company communications, Exs. 2069–2072). In essence, Patent

Owner argues Dr. Uttamsingh's group was the sole source of metabolic assays of the type used to create the data of Example 4 and Table 3, and because she directed and controlled this research, disclosure to the Silverman inventors of the structure and metabolic stability data of Compound (I) flowed directly or indirectly from Dr. Uttamsingh. *Id*. at 26–27.

3. Petitioner's Reply

Petitioner responds that Patent Owner has failed to meet its burden of production to establish the two prerequisites of § 102(b)(1), namely to show that the alleged disclosures were made 1 year or less before the effective filing date, and that the disclosure was made by an inventor of the claimed invention. Reply 6.

Petitioner argues that because Silverman and the 2015 Uttamsingh Declaration were made public more than a year before the '659 patent's actual filing date of November 1, 2018, the § 102(b)(1) exceptions could only apply if Patent Owner showed that each challenged claim was entitled to claim priority to the provisional patent application filed on May 6, 2016, as stated in Patent Owner's Response (Resp. 13). *Id*. at 7. Petitioner argues that Patent Owner's claim to priority is ineffective without a demonstration of entitlement, citing *Nat. Alternatives Int'l, Inc. v. Iancu*, 904 F.3d 1375, 1380 (Fed. Cir. 2018). *Id*. at 7–8.

Petitioner further argues that Patent Owner has not shown that Dr. Uttamsingh is an inventor of any challenged claim. *Id*. at 8. Petitioner argues that Dr. Uttamsingh's deposition testimony confirms that she did not invent or conceive any limitation of independent claims 1, 9, and 11, and that a different person "conceived all claims in the '758 provisional, which

include the limitations of the challenged dependent claims." *Id*. at 9 (citing Ex. 1172, 25:7–15). Petitioner also argues that Dr. Uttamsingh testified she did not invent Compound (I) and could not state whether the structure of the compound identified in the 2015 Uttamsingh Declaration was drafted by her as opposed to counsel. *Id*. at 10 (citing Ex. 1172, 13:15–19, 50:18–52:7).

Petitioner argues that Patent Owner's claim of exclusion is too broad in seeking to exclude Compound (I) entirely because that compound was previously disclosed in published PCT/US2013/045919 ("PCT application") as well as in Silverman. *Id*. (citing Ex. 1002, 1:6–16; Ex. 1173, 11). Moreover, Petitioner argues, even if the compound itself were excluded, more specific disclosures such as the 95% deuterated Compound (I) of claim 1 and other associated concepts including salt forms, timed dosages, and effective doses would not be excluded. *Id*. at 11–12 (citing 78 Fed. Reg. 11,059, 11,061 (Examination Guidelines for Implementing the First Inventor to File Provisions of the Leahy-Smith America Invents Act[4]) (regarding the example that where a genus is disclosed, individual species are not per se excluded).

Petitioner also argues that the evidence of record demonstrates that the metabolic stability data in Example 4 relating to Compound (I) and two other compounds was not generated by Dr. Uttamsingh, but by Patent Owner's staff member Richard Gallegos, who worked under Dr. Uttamsingh's direction. *Id*. at 12. Petitioner argues that Dr. Uttamsingh's status as director of the laboratory and its metabolic testing does not support exemption under § 102(b)(1)(A) because the Silverman inventors testified that Mr. Gallegos, not Dr. Uttamsingh, was the source of

[4] This has now been codified as MPEP § 2153.02.

the data's generation and dissemination. *Id*. at 12–13 (citing Ex. 2073, 12; Ex. 2069 ¶¶ 9–10; Ex. 2072 ¶ 9).

4. Patent Owner's Sur-reply

With regard to the effective filing date of the '659 patent, Patent Owner argues that it was Petitioner's burden as the party with the ultimate burden of persuasion to challenge the priority date of the challenged claims in its Petition rather than Patent Owner's burden to establish support in the absence of priority being an issue. PO Sur-reply 2–5 (citing, e.g., *Dynamic Drinkware,* 800 F.3d at 1380). Patent Owner argues that its burden was to provide a "chain of priority," which it did by listing a priority claim on the face of the patent. *Id*. at 4 (citing Ex. 1001, code (60)). Patent Owner argues that the cases cited by Petitioner are inapplicable because they regard circumstances where the petitioner had already shifted the burden to the patent owner. *Id*. at 4–5. Patent Owner argues that even if Petitioner's belated challenge were considered, Petitioner has not identified the information necessary for the challenge, including the claims and features allegedly lacking written description support in the priority applications. *Id*. at 5. Patent Owner argues the burden was never shifted to Patent Owner and that even if it were shifted, "the claims of the '659 patent are supported by U.S. Provisional Application No. 62/331,827. *Compare* Ex. 1001 claims 1-21 with Ex. 2004 at [11]-[20], [31]-[34], [48], [54], [75]." *Id*. (citing PO Prelim. Resp. 8 n2). Patent Owner argues that this citation comparing paragraph numbers in the provisional application to the '659 patent was sufficient to provide written description support to the extent the burden was shifted to it. *Id*. at 5–6.

With regard to inventorship, Patent Owner argues that Petitioner waived this argument by not challenging inventorship in its Petition. *Id*. at 6. Patent Owner further argues that, in the event inventorship is considered, Petitioner retains the burden of persuasion and Patent Owner only has a burden of production to provide evidence showing Dr. Uttamsingh is not an inventor. *Id*. at 6. Patent Owner argues that Dr. Uttamsingh's work satisfies the legal standard for inventorship, which is that a joint inventor needs to "generally contribute" by "perform[ing] only a part of the task which produces the invention." *Id*. (citing *Trovan, Ltd. v. Sokymat SA, Irori*, 299 F.3d 1292, 1301–1302 (Fed. Cir. 2002)). Patent Owner argues that Dr. Uttamsingh's inventorship oath and other evidence reflecting her contributions to the assay used to assess metabolic stability of the compounds at issue discharges its burden of production on inventorship. *Id*. (citing Ex. 1001 ¶ 72; Ex. 1047 ¶ 22; Ex. 2069 ¶¶ 6–12; Ex. 1047, 635–40; Ex. 1172, 28:14–29:6, 41:9–14, 42:4–6, 48:17–22, 49:12–17). Patent Owner argues that Dr. Uttamsingh's testimony in her deposition did not address the correct standard of inventorship and that Dr. Uttamsingh's omission from the list of inventors of the provisional application is harmless error. *Id*. at 7–8 (citing *E.I. du Pont de Nemours & Co. v. MacDermid Printing Solutions*, 525 F.3d 1353, 1360 (Fed. Cir. 2008)).

Patent Owner argues that Petitioner should not be permitted to rely upon disclosure of Compound (I)'s structure in the PCT application because Petitioner confined its allegations in the Petition to Silverman. *Id*. at 9. Patent Owner further argues that if Compound (I) is properly excluded, "there is no compound to have uses, doses, or salt forms." *Id*. Patent Owner further argues that Dr. Uttamsingh's reliance on Mr. Gallegos to physically

perform assays does not prevent her from being the inventor on the patent and that "information that was gathered and communicated at Dr. Uttamsingh's direction and under her control" should be excluded under § 102(b)(1)(A). *Id*. at 10 (citing *Trovan*, 299 F.3d at 1302). Patent Owner argues that the declaratory evidence of Dr. Uttamsingh and other Silverman inventors attesting that Dr. Uttamsingh was at least an indirect source of the metabolic data discharged its burden of production, and that Petitioner failed to demonstrate that Dr. Uttamsingh did not provide the relevant data. *Id*.

5. Analysis

a) Priority of the Challenged Claims

Petitioner asserts that Patent Owner's Response failed to prove that the '659 patent is entitled to rely on the May 4, 2016, filing date of the '827 provisional, and therefore Patent Owner has waived this argument, which is a necessary prerequisite for the exceptions under § 102(b)(1) to apply. Reply 6. We analyze below the arguments pertaining to Patent Owner's entitlement to rely on the '827 provisional filing date.[5]

The Petition stated that May 4, 2016, the filing date of the '827 provisional, was "the filing date of the '659 Patent's earliest priority application." Pet. 3. Because Silverman is § 102(a) prior art on its face,

[5] We decline to consider Petitioner's argument that the disclosure of Compound (I) in the published PCT/US2013/045919 provides any basis for denying Patent Owner's claim of exclusion. Reply 10. Petitioner did not include this publication in its asserted grounds of unpatentability (Pet. 2) and cannot now expand its basis for asserted unpatentability by relying upon an altogether different prior art reference. *See Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1370 (Fed. Cir. 2016) (determining that a petitioner exceeded the proper scope of a reply by relying upon new prior art references to support its unpatentability contentions).

having issued on February 2, 2016 (Ex. 1002, code (45)), Patent Owner's claim to the May 4, 2016, priority date became relevant with Patent Owner's assertion of the § 102(b) defenses in its Patent Owner Preliminary Response ("Prelim. Resp."). Along with raising § 102(b) defenses, Patent Owner confirmed its entitlement to this priority claim in the Preliminary Response and identified where the '827 provisional application (Ex. 2004) provided written description support for the claims of the '659 patent:

> [T]he claims of the '659 patent are supported by U.S. Provisional Application No. 62/331,827 (Ex. 2004), the earliest provisional application to which the '659 patent claims priority. *Compare* Ex. 1001 claims 1, 5, 6, *with* Ex. 2004 at [11], [13], [18], [54]; *compare* Ex. 1001 claims 2, 9, 15, 18, *with* Ex. 2004 at [20]; *compare* Ex. 1001 claims 3, 4, 16, 19, *with* Ex. 2004 at [19]; *compare* Ex. 1001 claim 7, *with* Ex. 2004 at [31]; *compare* Ex. 1001 claims 8, 9, 11, 14, *with* Ex. 2004 at [11], [13], [18], [34], [54]; compare Ex. 1001 claim 10, with Ex. 2004 at [12], [48], [75]; *compare* Ex. 1001 claim 12, *with* Ex. 2004 at [12], [18]; *compare* Ex. 1001 claims 13, 17, 20, *with* Ex. 2004 at [54]; *compare* Ex. 1001 claim 21, *with* Ex. 2004 at [13].

Prelim. Resp. 8 n.2 (citation omitted). *See also* Tr. 43:3–11 (Patent Owner's counsel arguing filing the '827 provisional was evidence establishing written description support).

Petitioner then requested a conference with the panel to request additional briefing "to address Patent Owner's arguments regarding the prior art status of the *Silverman* reference," stating the arguments of exclusion under § 102(b) "raise[d] issues that Petitioner could not have reasonably anticipated and warrants a Reply." Ex. 3001. We authorized Petitioner to file a Preliminary Reply to Patent Owner's Preliminary Response and Patent Owner to file a Preliminary Sur-Reply. Paper 17.

In its Preliminary Reply Petitioner did not challenge Patent Owner's argument that the provisional application provided written description support for the claims of the '659 patent or otherwise challenge Patent Owner's priority claim to the '827 provisional filed May 2016. *See generally* Prelim. Reply.

Petitioner's first argument on this issue was its assertion in its *post-institution* Reply that, because Patent Owner "has not argued—much less established—that any challenged claim is entitled to an earlier filing date" (e.g., the May 2016 filing date of the provisional application), the "effective filing date [] therefore defaults to the November 1, 2018, 'actual' filing date, precluding any §102(b)(a) exception." Reply 7. In this respect, Petitioner argues that Patent Owner should not be permitted to rely on its statement of support in the priority application made in the Patent Owner Preliminary Response because Patent Owner did not include this or another statement of support in its post-institution Response. *Id.* at 6.

We recognize that our Trial Practice Guide and Scheduling Order caution "that any arguments for patentability not raised in the response may be deemed waived." Consolidated Trial Practice Guide 94; Paper 21 (Scheduling Order), 7. But in this case Petitioner sought—and was granted—additional pre-institution briefing on the issue of Patent Owner's § 102(b) defenses, which provided sufficient opportunity to address Patent Owner's priority claim and the written description support identified in the Preliminary Response. Petitioner did not do so in its Preliminary Reply. *See generally* Prelim. Reply. Our Decision on Institution identified issues regarding § 102(b) defenses to be addressed at trial based what was presented to the Board at the time as disputed issues, which did not include

the claim for priority to the '827 provisional application. Dec. 19. Under these circumstances, we do not find waiver occurred.

Petitioner also cites *Natural Alternatives* for the proposition that a patent owner is required to prove entitlement to the priority date. *Id.* (citing *Nat. Alternatives,* 904 F.3d at 1380). We are not persuaded that the facts of *Natural Alternatives* apply here. In *Natural Alternatives*, the patent challenger first raised the issue that the patent owner's claim to priority was defective in its request for an *inter partes* reexamination, thereby squarely placing the issue under examination. *Nat. Alternatives*, 904 F.3d at 1378 (noting that "[t]he request alleged that 'the asserted claim to priority of the '381 Patent is defective'"). The patent owner claimed entitlement to rely on its priority claim under § 120. *Id*. at 1379. The court found that patent claims are not entitled without proof of priority simply because of the patent owner's claim of such. *Id*.

The facts differ here, where the issue of priority was not relevant until Patent Owner first asserted the § 102(b)(1) exceptions in its Preliminary Response. In that same paper, however, Patent Owner also stated it intended to rely on its claim to priority and provided some information regarding its written descriptive support in the provisional application. Prelim. Resp., 8 n.2. At that point, the burden of production to show that the challenged claims were not entitled to the asserted priority date shifted back to Petitioner to prove that Patent Owner is not entitled to the benefit of the earlier provisional application. *See Dynamic Drinkware*, 800 F. 3d at 1379–90 (explaining burden-shifting framework in AIA trial proceedings).

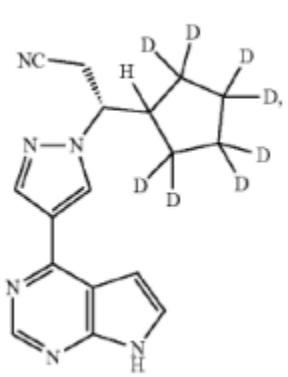
Petitioner did not produce evidence, through expert testimony or otherwise, showing any specific defect in written descriptive support from

the perspective of a person of skill in the art in the '827 provisional, and merely relies on a general statement that Patent Owner failed in its duty to establish the same. Reply 7. In such circumstances, we do not fault Patent Owner for failing to repeat arguments in its PO Response that Petitioner did not challenge in its Preliminary Reply. For at least the reasons set forth above, Petitioner has not established that the challenged claims are not entitled to claim priority to the '827 provisional.

In addition, regardless of who bears the burden, we independently conclude, based on the record before us, that the '827 provisional provides sufficient written descriptive support for the challenged claims. *See Rovalma, S.A. v. Bohler-Edelstahl GmbH & Co. KG*, 856 F.3d 1019, 1027 (Fed. Cir. 2017) (holding that the Board is not precluded "from relying on arguments made by a party and doing its job, as adjudicator, of drawing its own inferences and conclusions from those arguments . . . subject, of course, to the provision of adequate notice and opportunity to be heard").

Independent claim 1 of the '659 patent recites:

> 1. A method of treating a hair loss disorder in a mammalian subject, the method comprising administering to the subject 16 mg/day or 24 mg/day of a compound represented by the following structural formula:

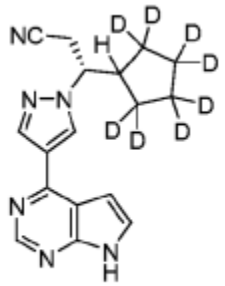


Compound (I)

> or a pharmaceutically acceptable salt thereof, wherein each position in Compound (I) designated specifically as deuterium has at least 95% incorporation of deuterium. Ex. 1001, 24:30–53.

Claims 5 and 6 recite administration of the compound of claim 1 once and twice a day, respectively. Paragraphs 11, 13, and 18 of the '827 application, reproduced below, provide:

> [11] It has now been found that deuterated analogs of ruxolitinib (including Compound (I), also referred to as D8-mxolitinib), are useful for the treatment of hair-loss disorders, including alopecia areata. Compound (I) is represented by the following structural formula:



Compound (I)

> [13] A first aspect of the invention is a method for treating hair loss disorders that can be treated by compounds that modulate the activity of Janus Associated Kinase 1 (JAK1) and/or Janus Associated Kinase 2 (JAK2). The method comprises administering to a subject (e.g., a mammalian subject) an effective amount of Compound (I), or a pharmaceutically acceptable salt thereof, once or twice per day, wherein the amount of Compound (I), or a pharmaceutically acceptable salt thereof, is in the range of about 4 mg/day to about 50 mg/day, for example, about 5 mg/day, about 10 mg/day, about 20 mg/day, about 30 mg/day, about 40 mg/day, or about 50 mg/day. In certain embodiments, the amount is about 4 mg/day, 8 mg/day, 16 mg/day, 32 mg/day or 48 mg/day. In certain embodiments, the hair loss disorder is alopecia areata. In certain embodiments, the subject is a human. Preferably, Compound (I), or a

> pharmaceutically acceptable salt thereof, is administered orally at any of the foregoing dosages. Preferably, the Compound (I), or a pharmaceutically acceptable salt thereof, is administered orally at any of the foregoing dosages in a pharmaceutical formulation which is a tablet.
>
> [18] A fourth aspect of the invention is a pharmaceutical composition comprising Compound (I), in the range of about 4 mg to about 50 mg (for example, about 5 mg, about 10 mg, about 20 mg, about 30 mg, about 40 mg, or about 50 mg), or an equivalent amount of a pharmaceutically acceptable salt thereof, together with a pharmaceutically acceptable carrier or diluent. In certain embodiments, the amount of Compound (I), or a pharmaceutically acceptable salt thereof, is about 4 mg, 8 mg, 16 mg, 24 mg, 32 mg or 48 mg. In certain embodiments, the pharmaceutical composition is a tablet.
>
> [54] In other embodiments, a compound of this invention has an isotopic enrichment factor for each designated deuterium atom of at least 3500 (52.5% deuterium incorporation at each designated deuterium atom), at least 4000 (60% deuterium incorporation), at least 4500 (67.5% deuterium incorporation), at least 5000 (75% deuterium), at least 5500 (82.5% deuterium incorporation), at least 6000 (90% deuterium incorporation), at least 6333.3 (95% deuterium incorporation), at least 6466. 7 (97% deuterium incorporation), at least 6600 (99% deuterium incorporation), or at least 6633.3 (99.5% deuterium incorporation).

Ex. 2004 ¶¶ 11, 13, 18, and 54. On their face, the above paragraphs provide written descriptive support for a method of treating hair-loss disorders by administering a compound of the structure of Compound (I), where the deuterium incorporation of each deuterium position is at least 95%, and the compound is administered once or twice daily in the ranges of the recited treatment amounts.

Claims 2, 9, 15, and 18 recite that the hair loss disorder sought to be treated with the method is alopecia areata. Ex. 1001, 24:54–26:39. We find

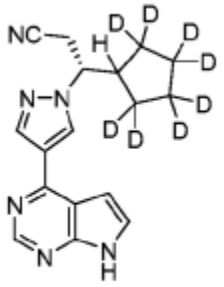
support for use of Compound (I) in treating alopecia areata in paragraph 20 of the '827 provisional: "[20] Hair loss disorders include, without limitation, androgenetic alopecia, alopecia areata, telogen effluvium, alopecia totalis, and alopecia universalis."

Claims 3, 4, 16, and 19 recite the method of claim 1 wherein administration of the compound of claim 1 is by oral administration or in tablet form. Ex. 1001, 24:56–60; 26:34–41. We find support for administration of Compound (I) orally and in tablet format in paragraph 19 of the '827 provisional: " . . . Preferably, the Compound (I), or a pharmaceutically acceptable salt thereof, is administered orally at any of the foregoing dosages in a pharmaceutical formulation which is a tablet."

Claim 7 recites the method of claim 1 in which any atom of Compound (I) "not designated as deuterium is present at its natural isotopic abundance." Ex. 1001, 24:65–66. We find support for the subject matter of claim 1, in addition to the previously mentioned paragraphs, in paragraph 31 of the '827 provisional: "In one embodiment, any atom not designated as deuterium is present at its natural isotopic abundance in Compound (I), or a pharmaceutically acceptable salt thereof."

Claim 8 recites:

> 8. A pharmaceutical composition comprising a pharmaceutically acceptable carrier or diluent and 8 mg or 12 mg of a compound represented by the following structural formula:



Compound (I)

> or a pharmaceutically acceptable salt thereof, wherein each position in Compound (I) designated specifically as deuterium has at least 95% incorporation of deuterium.

Ex. 1001, 25:1–22. Claim 9 recites a method of treating a hair loss disorder comprising administering 8 mg of Compound (I) to a subject twice a day, wherein each position designated as deuterium (D) has at least 95% incorporation of deuterium. *Id*. at 25:23–46. Claim 11 is identical except that the dosage is 12 mg twice a day. *Id*. at 26:1–23. Claim 14 recites the method of claim 1 "wherein the step of administering comprises administering to the subject 8 mg twice per day or 12 mg twice per day of Compound (I)." *Id*. at 26:29–31. We find written descriptive support for using Compound (I) in the recited amounts in paragraphs 11, 13, 18, and 54 of the '827 provisional (copied above), as well as paragraph 34 below:

> [34] The invention also provides pharmaceutical compositions comprising an effective amount of Compound (I), or a pharmaceutically acceptable salt thereof; and a pharmaceutically acceptable carrier. The carrier(s) are "acceptable" in the sense of being compatible with the other ingredients of the formulation and, in the case of a pharmaceutically acceptable carrier, not deleterious to the recipient thereof in an amount used in the medicament.

Ex. 2004 ¶ 34.

Claim 10 recites the method of claim 9, "wherein Compound (I) is administered as 10.5 mg of the phosphate salt twice per day" and claim 12 recites the same limitations using 15.8 mg of the phosphate salt twice a day. Ex. 1001, 25:47–48; 26:24–25. We find written descriptive support for the administration of Compound (I) as a phosphate salt in the claimed ranges in paragraph 12 of the '827 provisional below:

> [12] In certain embodiments, Compound (I) is administered as a pharmaceutically acceptable salt, such as the phosphate salt.

> Compound (I) can be administered in doses in the range of about 4 mg to about 50 mg per day (or the equivalent weight based on a salt, such as Compound (I) phosphate salt), administered as a single daily dose or in divided doses (e.g., twice per day). Based on these discoveries, novel therapies using Compound (I) or a pharmaceutically acceptable salt thereof, for treating a hair loss disorder in a mammalian subject are disclosed herein.

Ex. 2004 at ¶ 12 (*see also* ¶ 18, reciting administration of salt " . . . in a pharmaceutical composition comprising Compound (I), in the range of about 4 mg to about 50 mg (for example, about 5 mg, about 10 mg, about 20 mg, about 30 mg, about 40 mg, or about 50 mg), or an equivalent amount of a pharmaceutically acceptable salt thereof." *See also* ¶ 48 (effective amounts of about 10 mg/day administered in divided doses, twice a day).

Claims 13, 17, and 20 recite the method of use of Compound (I) in respective dosage amounts of 16 mg/day or 24 mg/day (claim 13), 8 mg twice a day (claim 17), and 12 mg twice a day (claim 20) wherein each deuterated position in Compound (I) has at least 97% deuterium. Ex. 1001 26:26–44. We find written descriptive support for these claims in paragraph 54, copied above (reciting an "isotopic enrichment factor for each designated deuterium atom of at least . . . at least 6466. 7 (97% deuterium incorporation)." Ex. 2004 ¶ 54.

Claim 21 recites the use of the method of claim 1, where administration is of 8 or 12 mg twice a day to a human subject. Ex. 1001, 26: 45–46. We find support for this claim in paragraph 13 of the '827 provisional:

> [13] A first aspect of the invention is a method for treating hair loss disorders that can be treated by compounds that modulate the activity of Janus Associated Kinase 1 (JAK1) and/or Janus Associated Kinase 2 (JAK2). The method comprises

> administering to a subject (e.g., a mammalian subject) an effective amount of Compound (I), or a pharmaceutically acceptable salt thereof, once or twice per day, wherein the amount of Compound (I), or a pharmaceutically acceptable salt thereof, is in the range of about 4 mg/day to about 50 mg/day, for example, about 5 mg/day, about 10 mg/day, about 20 mg/day, about 30 mg/day, about 40 mg/day, or about 50 mg/day. In certain embodiments, the amount is about 4 mg/day, 8 mg/day, 16 mg/day, 32 mg/day or 48 mg/day. In certain embodiments, the hair loss disorder is alopecia areata. In certain embodiments, the subject is a human. Preferably, Compound (I), or a pharmaceutically acceptable salt thereof, is administered orally at any of the foregoing dosages. Preferably, the Compound (I), or a pharmaceutically acceptable salt thereof, is administered orally at any of the foregoing dosages in a pharmaceutical formulation which is a tablet.

Ex. 2004 ¶ 13. *See also* Prelim. Resp. 8 n.2, providing statement of written descriptive support.

In sum, we have examined and are persuaded that, on this record, the challenged claims of the ’659 patent have written description support in the ’827 application. For this reason, we are not persuaded that the outcome of this proceeding would be any different had Patent Owner repeated the same assertions of written descriptive support in the provisional that it earlier stated in the Preliminary Response. Regardless of which party bears the burden on this issue, we find we find the challenged claims are entitled to the benefit of the May 4, 2016, provisional filing date. As a result, we are not persuaded by Petitioner’s argument that Patent Owner’s allegedly exempted disclosures under § 102(b) were not made within 1 year or less before the effective filing date of the ’659 patent.

b) Inventorship by Dr. Uttamsingh

As noted above, Petitioner asserts that Patent Owner has not shown Dr. Uttamsingh to be an inventor of any remaining challenged claim, and has therefore failed to meet its burden of production to establish a §102(b)(1) exception for Silverman. Reply 8–9. We disagree.

Patent law recognizes a "presumption that [a patent's] named inventors are the true and only inventors." *Acromed Corp. v. Sofamor Danek Grp., Inc*., 253 F.3d 1371, 1379 (Fed. Cir. 2001) (citing *Hess v. Advanced Cardiovascular Sys., Inc*., 106 F.3d 976, 980 (Fed. Cir. 1997)); *see also Drone Techs., Inc. v. Parrot S.A.,* 838 F.3d 1283, 1292 (Fed. Cir. 2016). "The determination of whether a person is a joint inventor is fact specific, and no bright-line standard will suffice in every case." *Fina Oil & Chem. Co. v. Ewen*, 123 F.3d 1466, 1473 (Fed. Cir. 1997). Inventorship requires that an individual "contribute in some significant manner to the conception or reduction to practice of the invention," "make a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention, and . . . [did] more than merely explain to the real inventors well-known concepts and/or the current state of the art." *Pannu v. Iolab Corp*., 155 F.3d 1344, 1351 (Fed. Cir. 1998); *Acromed,* 253 F.3d at 1379.

With regard to inventorship, we similarly find that when Patent Owner asserted the § 102(b)(1) exceptions, and identified evidence indicative of Dr. Uttamsingh's status as a named inventor, the burden of production shifted to Petitioner to prove that Dr. Uttamsingh was *not* an actual inventor of the '659 patent. *Cf. Dynamic Drinkware,* 800 F.3d at 1378–80. We find this burden-shifting to be appropriate given the

presumption that Dr. Uttamsingh is a properly named inventor on the '659 patent. *See Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1356–57 (Fed. Cir. 2015) ("A 'presumption' is a procedural tool that shifts the burden of proof on a substantive issue: if a basic fact is established, a court accepts a conclusion on the issue unless the presumption is rebutted with evidence that meets the presumption's associated standard of proof."). But again, regardless of the burden, we find that the evidence supports a conclusion that Dr. Uttamsingh is a joint inventor of the '659 patent.

The record contains presumptive evidence of Dr. Uttamsingh's inventorship, including her name being listed on the face of '659 patent as an inventor and her signed oath of inventorship. Ex. 1001, code (72); Ex. 1047, 22. Additionally, Dr. Uttamsingh testified regarding CYP3A4 Supersome assays, which she had helped develop and that were performed under her supervision to assess the metabolic stability of test compounds, and that generated the data for the 2015 Uttamsingh Declaration submitted during prosecution of the Silverman. Ex. 2069 ¶¶ 6–12. This data was submitted to overcome an obviousness rejection based on deuteration of ruxolitinib, and showed that, relative to ruxolitinib, the metabolic stability of Compound 111 was 75% greater than ruxolitinib in the CYP3A4 Supersome assay and 80% greater in the human liver microsome assay. Ex. 1045, 407. In response to the submission of this data, Silverman issued, claiming Compound 111 (Compound (I)) in dependent claim 7.[6] Ex. 1045, 459–467. *See also* PO Sur-reply at 7 (citing testimony of Dr. Uttamsingh regarding her

[6] The prosecution history reflects resolution of a provisional double patenting rejection through a subsequent amendment after final to address a double patenting issue. Ex. 1045, 449–457.

work on assays at Ex. 2069 ¶¶ 6–12; Ex. 1047 at 635–640; Ex. 1172 at 28:14–29:6, 41:9–14, 42:4–6, 48:17–22, 49:12–17).

The '659 patent pursued *only* Compound 111 of Silverman (as Compound (I)) for treatment of hair loss disorders, and lists Dr. Uttamsingh as an inventor. Ex. 1047, 20 (Dr. Uttamsingh listed as one of several inventors on 2017 Application Data Sheet). On this record, we find that Dr. Uttamsingh's contribution to the claimed subject matter of the '659 patent included her work in identifying the metabolic stability of Compound 111/(I) relative to other compounds disclosed in Silverman, thus singling this compound out for future development. *See* Ex. 2069 ¶¶ 6–12.

We have reviewed but find unpersuasive Petitioner's arguments that Dr. Uttamsingh is not an inventor because she testified that she did not invent any specific limitation of the '659 patent claims. *See* Reply 8–9 (citing Petitioner's deposition of Dr. Uttamsingh, Ex. 1172 at 13:15–19, 19:14–22, 21:3–23:10, 25:6–15, 75:7–11). As Patent Owner noted (PO Sur-reply 7–8), during the deposition, Petitioner did not question Dr. Uttamsingh about her overall contributions to the invention, but instead limited questions to expressly recited limitations of the provisional patent application claims and her knowledge of the contents of the application itself. *Id*. But patent inventorship is not as restrictive as the bounds of Petitioner's queries regarding conception of individual claim limitations. *Pannu*, 155 F.3d at 1351 (noting that "Inventors may apply for a patent jointly even though . . . each did not make a contribution to the subject matter of every claim of the patent.") (citing 35 U.S.C. § 116). We note that Dr. Uttamsingh is a scientist, not a patent attorney, and thus would not necessarily be qualified to testify about whether she met the legal standard for inventorship.

Furthermore, Petitioner's examination of Dr. Uttamsingh about the inventorship statements made within the '827 provisional do not evoke the nature of Dr. Uttamsingh's contribution to the utility of the compound and the claimed treatment method, particularly as they relate to narrowing down the field of compounds of the genus of Formula A of Silverman. Accordingly, we are not persuaded that Dr. Uttamsingh's deposition testimony undermines her status as an inventor.

On this record, we find that Dr. Uttamsingh's contributions in discerning metabolically superior compounds, as outlined by the work described in her declarations, were "not insignificant in quality, when that contribution is measured against the dimension of the full invention," and did "more than merely explain to the real inventors well-known concepts and/or the current state of the art." *Pannu*, 155 F.3d at 1351. We are not persuaded by Petitioner's argument (Reply 12–13) that Dr. Uttamsingh's use of Mr. Gallegos to perform the assays and communicate with colleagues on behalf of Dr. Uttamsingh undercuts the contributions she made that led to Patent Owner determining Dr. Uttamsingh is an inventor. Dr. Uttamsingh designed the assays that generated the information comprising the 2015 Uttamsingh Declaration. This declaration and its import in the Silverman prosecution is the crux of the disclosure at issue, and not whether it was shepherded in stages by or through a colleague or subordinate tasked to perform certain experiments or data collection.

Under these circumstances, we find it reasonable to accord the presumption that Dr. Uttamsingh is a properly named joint inventor, *Acromed,* 253 F.3d at 1379, as to *all* the claims of the '659 patent. While we acknowledge that there is some testimony in the record that Dr. Uttamsingh

did not invent or contribute to certain portions of the priority application as discussed above, the evidence of record does not support Petitioner's contention that Dr. Uttamsingh did not significantly contribute towards the subject matter of the challenged claims. Accordingly, we find that Petitioner has not carried its burden to overcome the presumption that Dr. Uttamsingh is a properly named inventor of the '659 patent.

c) Disclosure by Dr. Uttamsingh

As we determine that Dr. Uttamsingh is an inventor, we now review the evidence of record to determine if the statements made within the 2015 Uttamsingh Declaration are statements made by an inventor that fall within the scope of § 102(b)(1).

Petitioner contends that application of the § 102(b)(1) exceptions necessitates a claim-by-claim analysis for effective filing date and inventorship (Reply 6), meaning that Dr. Uttamsingh would have had to invent the subject matter of each specific claim she disclosed for the exception to apply. Petitioner has not pointed us to any authority for this proposition. While we recognize that "inventorship is determined on a claim-by-claim basis" (*Egenera, Inc. v. Cisco Sys., Inc.*, 972 F.3d 1367, 1376 (Fed. Cir. 2020), we do not agree that application of § 102(b)(1) is required to apply on a claim-by-claim basis in light of the plain language of the statute. In particular, § 102(a) includes an exception where "the disclosure was made by the inventor *or a joint inventor* or another who obtained the subject matter disclosed directly or indirectly from the inventor *or joint inventor*." In other words, under the circumstances presented here, § 102(b)(1) does not require Patent Owner to parse the subject matter recited in the 2015 Uttamsingh declaration and provide element-by-element

evidence of Dr. Uttamsingh's inventive contribution. Rather, it is sufficient that Dr. Uttamsingh is a joint inventor of the challenged patent and made the disclosures set forth in the 2015 Uttamsingh Declaration that later became public when the Silverman patent application published. However, because Dr. Uttamsingh's contribution to the patent appears to be elevating Compound (I) from the genus of Formula A of Silverman as the most promising candidate for future study, we conclude that even under the standard Petitioner proposes, Dr. Uttamsingh's disclosure was a material contribution to the invention. We conclude that Dr. Uttamsingh's participation in creating the 2015 Uttamsingh Declaration as a joint inventor is sufficient to invoke § 102(b)(1).

The evidence of record shows that the 2015 Uttamsingh Declaration was made public on August 27, 2015, via publication of Silverman's file history, US2015/0239896. Ex. 1002, 1. This date is less than a year prior to the '659 patent's earliest priority date, May 4, 2016. Ex. 1001, code (60). We therefore conclude that the subject matter recited in the 2015 Uttamsingh Declaration is a disclosure by an inventor or joint inventor that falls within the scope of § 102(b)(1).

Next, we determine the scope of the disclosure and the effect of exclusion of the disclosure on Silverman. The 2015 Uttamsingh Declaration conveyed that Dr. Uttamsingh assessed the metabolic stability of Compounds 103, 107, and 111 as part of her assessment of "over 250 different deuterated compounds and their non-deuterated counterparts" during her tenure as Patent Owner's employee. Ex. 1045, 415. Each of these three compounds was within the genus of Silverman's Formula A, disclosed for use in treating hair loss disorders. Ex. 1002, Abstract. The

structure of the three compounds was disclosed in Exhibit B of the 2015 Uttamsingh Declaration. Ex. 1045 at 404. Compound 111 is the same as Compound (I) recited in the '659 patent.

The results of the assay led Dr. Uttamsingh to conclude that Compounds 103, 107, and 111 are "are stabilized, metabolically, relative to ruxolitinib" as measured by the assays, with Compound 111 showing the highest relative stability. *Id*. at 414. Dr. Uttamsingh also opined that in her testing of the 250 compounds, "a number of the deuterated compounds tested showed a decrease in *in vitro* metabolic stability relative to their non-deuterated counterpart, even when deuteration was at a known site of metabolism." *Id*. at 416 (emphasis omitted).

The parties did not identify and we did not find any prior cases applying the inventor disclosure exceptions of § 102(b)(1). The parties reference MPEP § 717.01(b)(2), which provides:

> Where an exception pursuant to § 102(b) is found,
>
> [o]nly the portion of the third party's intervening disclosure that was previously in an inventor-originated disclosure (i.e., *the same subject matter*) is excepted as prior art under 35 U.S.C. 102(a). In other words, any portion of the third party's intervening disclosure that was not part of the previous inventor-originated disclosure is still available for use in a prior art rejection. Therefore, examiners should be aware that a declaration under 37 CFR 1.130(b) may only disqualify a portion of a disclosure that was applied in a rejection in an Office action, and that other portions of the disclosure may still be available as prior art. For example, if the inventor or a joint inventor had publicly disclosed elements A, B, and C, and a subsequent intervening U.S. patent, U.S. patent application publication, or WIPO published application discloses elements A, B, C, and D, then element D of the intervening U.S. patent, U.S. patent application publication, or WIPO published application is still available as prior art under 35 U.S.C. 102(a)(2).

MPEP § 717.01(b)(2). The example provided above conforms with our interpretation of § 102(b)(1), but does not contemplate the circumstances in this case where one of the elements disclosed is one of over 60 related molecules within a genus, defined in Silverman as Formula A, shown below:

A compound of Formula A:

Reproduced above is the chemical structure of a compound of the genus of Formula A from Silverman, which includes Compounds 103, 111, and 107 as individual species. *See* Ex. 1002, code (57).

Petitioner argues that "when an alleged §102(b)(1) disclosure includes a purported broad statement (e.g., genus), it cannot remove more specific disclosures (e.g., species) from the prior art." Reply 11.[7] We agree with Petitioner that application of § 102(b)(1) should not strike what was part of a broader genus from existence, nor should it entirely remove Silverman from consideration as § 102(a) art. Reply 11.

[7] As discussed in § II.D(3) above, Petitioner cites 78 Fed. Reg. 11,059, 11,077 (now codified as MPEP § 2153.02). However, we do not read this section to support Petitioner's argument, as the section pertains to whether an inventor's disclosure affects the ability of the species to function as prior art, not whether the species itself is separately patentable.

Applying this principle to the facts in this case, we find that, because the 2015 Uttamsingh Declaration is a disclosure from an inventor of the challenged '659 patent, application of § 102(b)(1) should result in exclusion of the teachings a person of ordinary skill in the art would have gleaned from reading Silverman. We find that the 2015 Uttamsingh Declaration elevated Compounds 103, 107, and 111 from the genus of compounds within Formula A of Silverman by disclosing that these compounds have enhanced metabolic stability as detected through the Supersome assays. For purposes of evaluating Silverman as prior art, we consider the 2015 Uttamsingh Declaration and its teachings calling attention to Compounds 103, 107, and 111 and their enhanced metabolic stability as disclosed in the declaration to be excluded from the knowledge of a person of ordinary skill in the art reading Silverman. However, all three compounds remain in the genus of compounds that fall within Formula A of Silverman.

E. Asserted Prior Art

1. Silverman (Ex. 1002)[8]

Silverman discloses the compound of formula A or "a pharmaceutically acceptable salt thereof; pharmaceutical compositions comprising the compound; and methods of treating the indications disclosed herein." Ex. 1002, Abstract. Formula A is "novel heteroaryl-substituted pyrrolo[2,3-d]pyrimidines, and pharmaceutically acceptable salts thereof." *Id*. at 3:25–27.

[8] Consistent with our determination in § II.D.5(c) above, we describe the teachings of Silverman absent the disclosures excluded under § 102(b)(1).

Formula A is reproduced below:

A compound of Formula A:

A compound of Formula A, above, or a pharmaceutically acceptable salt thereof, wherein:

Y^1 is selected from hydrogen and deuterium;

each Y^2 is independently selected from hydrogen and deuterium, provided that each Y^2 attached to a common carbon is the same;

each Y^3 is independently selected from hydrogen and deuterium, provided that each Y^3 attached to a common carbon is the same;

Y^4 is selected from hydrogen and deuterium; each Y^5 is the same and is selected from hydrogen and deuterium; and

Y^6, Y^7, Y^8, Y^9, and Y^{10} are each independently selected from hydrogen and deuterium; provided that when Y^1 is hydrogen, each Y^2 and each Y^3 are hydrogen, Y^4 is hydrogen, and each of Y^6, Y^7, Y^8, Y^9, and Y^{10} is hydrogen, then each Y^5 is deuterium.

Id. at 6:7–42.

Formula A depicts a chemical structure or a compound obtained by deuterium substitution of the drug ruxolitinib phosphate, an eteroaryl-

substituted pyrrolo[2,3-d]pyrimidine, which has been shown to inhibit Janus Associated Kinases (JAKs) and is an FDA-approved drug for treating patients with intermediate or high-risk myelofibrosis. *Id*. at 2:5–20, 2:53–65, 3:25–32. Ruxolitinib also has other potential applications, including the treatment of essential thrombocytopenia, psoriasis, and various forms of cancer. *Id*. at 3:3–6. However, "[d]espite the beneficial activities of ruxolitinib, there is a continuing need for new compounds to treat the aforementioned diseases and conditions." *Id*. at 3:19–21.

Deuterium substitution of a drug can be performed to enhance its metabolic properties by enriching the isotopes by replacing one or more hydrogen atoms of the drug with deuterium atoms in an attempt to slow the CYP-mediated metabolism of a drug or to reduce the formation of undesirable metabolites. *Id*. at 2:6–10. Because deuterium forms stronger bonds with carbon than hydrogen, in certain cases, that stronger bond strength can positively impact the ADME properties of a drug, resulting in the potential for improved drug efficacy, safety, and/or tolerability. *Id*. at 2:11–15.

Though not all embodiments are detailed, Silverman appears to disclose over 60 embodiments of Formula A[9] that depict deuterium substitutions at a number of specific positions within the structure of Formula A. *See id*. at Tables 1–2 (providing "Exemplary Embodiments of Formula 1"). As disclosed above, the 2015 Uttamsingh Declaration was disclosed to overcome an obviousness rejection based on deuteration of ruxolitinib, during prosecution of Silverman. Ex. 1045, 459–467. Data

[9] *See also* Tr. 15:16–17 (Petitioner's counsel stating Silverman discloses "63 or something like that species in Silverman of Silverman formula A.").

submitted with the declaration showed that, relative to ruxolitinib, the metabolic stability of Compound 111 was 75% larger than ruxolitinib in the CYP3A4 Supersome assay and 80% larger in the human liver microsome assay. *Id*. at 407. In response to the submission of this data, Silverman issued, claiming Compound 111 (Compound (I)) in dependent claim 7. Compound (I) is recited in the challenged claims.

Embodiments of Formula A have "an isotopic enrichment factor for each designated deuterium atom" ranging between deuterium incorporation of 52.5% to at least 99.5%. *Id*. at 4:7–17. Silverman discloses compositions including Formula A "and the use of such compositions in methods of treating diseases and conditions that are beneficially treated by administering an inhibitor of Janus-associated kinase with selectivity for subtypes 1 and 2 (JAK1/JAK2)." *Id*. at 3:27–32. Compositions can be made using a "pharmaceutically acceptable carrier" and may be "presented in unit dosage form, e.g., tables, sustained release capsules." *Id*. at 16:27, 17:4–5. Effective amounts can range from 5 g to 1 mg, and dosing can be daily or twice daily. *Id*. at 20:9–18. Silverman states that "guidance for selecting an effective dose can be determined by reference to the prescribing information for ruxolitinib." *Id*. at 20:25–27. Silverman also discloses that an embodiment can include a composition that "further comprises a second therapeutic agent . . . selected from any compound or therapeutic agent known to have or that demonstrates advantageous properties when administered with a compound having the same mechanism of action as ruxolitinib" and that the second agent is "useful in the treatment or prevention of a disease or condition selected from . . . alopecia areata." *Id*. at 19:42–50.

2. Xing (Ex. 1003)

Xing states "[a]lopecia areata (AA) is a common autoimmune disease that results from the damage of hair follicle by T cells." Ex. 1003, 1043. Xing further discloses that systemically administered pharmacological inhibitors of Janus Kinase family protein tyrosine kinases prevented the development of alopecia areata. *Id*. Xing states, "[n]otably three patients treated with oral ruxolitinib, an inhibitor of JAK1 and JAK2, achieved near complete hair regrowth within 5 months of treatment, suggesting the potential clinical utility of JAK inhibition in human AA." *Id*. To test whether inhibition of signal pathways would be therapeutically effective in vivo, the authors systemically administered ruxolitinib and tofacitinib. *Id*. at 1048. Ruxolitinib was administered to patients orally, 20 mg twice daily. *Id*. The drugs were found to prevent the development of alopecia areata on areas where grafting had occurred, signifying a lack of inflammation development. *Id*. Xing states "[t]he clinical response of a small number of patients with AA to treatment with the JAK1/2 inhibitor ruxolitinib suggests future clinical evaluation of this compound or other JAK protein tyrosine kinase inhibitors currently in clinical development is warranted in AA." *Id*.

3. Ruxolitinib Prescribing Information (Ex. 1004)

Ruxolitinib Prescribing Information ("RPI"), an excerpt from the 2015 Physician's Desk Reference, addresses the FDA approved uses of ruxolitinib phosphate (Jakafi) to treat myelofibrosis and polycythemia vera. Ex. 1004, 1281. RPI discloses the highlights of prescribing information for Jakafi or ruxolitinib. *Id*. RPI also discloses ruxolitinib formulation information, pharmacodynamic and pharmacokinetic data, clinical trial

results, and dosing recommendations, including the content of ruxolitinib in advised doses. *Id*. at 1282–1287.

4. Christiano (Ex. 1005)

Christiano discloses "methods for treating a hair loss disorder in a subject by administering a Janus Kinase/Signal Transducers and Activators of Transcription inhibitor." Ex. 1005, Abstract. According to Christiano, the inhibitor is a JAK1, JAK2, and/or a JAK3 inhibitor, a Stat1 and/or a Stat2 inhibitor, INCB018424 (ruxolitinib) or tofacitinib (CP690550). *Id*. at 1:67−2:4. Christiano discloses that alopecia areata is among the hair loss disorders targeted for treatment in the method. *Id*. at 2:4−6. Christiano also states, "the method further comprises determining whether the inhibitor administered induced hair growth in the subject afflicted with a hair loss disorder as compared to the subject's hair growth prior to treatment with the inhibitor." *Id*. at 2:9−12. Christiano discloses the treatment of mice with JAK3 inhibitors prevents alopecia areata. Ex. 1005, 6:36−37. Christiano reports treatment of dermal T cell infiltrates and inflammatory biomarkers by immunostaining and by flow cytometry. *Id*. at 6:38−40 (citing Figures 33A, 33B). The results showed an association between CD8+ T-cells, proinflammatory cytokines (IFN-γ), the JAK-STAT pathway in AA patients, and other data supporting the use of JAK inhibitors to treat AA. *Id*. at 4:21−12:39.

5. Ni (Ex. 1006)

Ni discloses "sustained-release formulations and dosage forms of ruxolitinib, or a pharmaceutically acceptable salt thereof, which are useful in the treatment of Janus kinase-associated diseases such as myeloproliferative disorders." Ex. 1006 ¶ 1. "Ruxolitinib . . . is the first FDA approved Janus

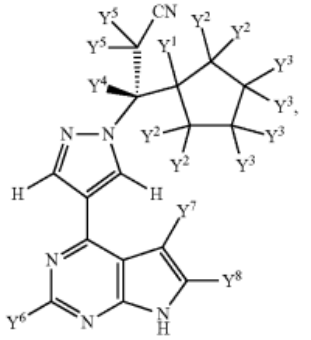
kinase (JAK) inhibitor and is the only drug currently approved for treatment of myelofibrosis." *Id*. ¶ 2. "To date, all published human clinical data for ruxolitinib relate to dosing of an immediate-release formulation." *Id*. ¶ 3. The "[i]mmediate-release dosage forms of ruxolitinib phosphate can be obtained commercially in 5, 10, 15, 20, and 25 mg doses as the drug product Jakafi® (ruxolitinib phosphate (tablets)) (NDA no. N202192)." *Id*. ¶ 124. Ni also discloses a bioavailability study "exploring the safety, tolerability, and efficacy of ruxolitinib, administered orally to patients with primary myelofibrosis (PMF) and post poly cythemia vera/essential thrombocythemia myelofibrosis (Post-PV/ET MF)." *Id*. ¶ 137. The study evaluated "two dose levels of 25 mg bid and 50 mg bid," "five dose regimens of 10 mg bid, 25 mg bid, 25 mg qd, 50 mg qd and 100 mg qd," and "six dose regimens of 10 mg bid, 15 mg bid, 25 mg bid, 50 mg qd, 100 mg qd and 200 mg qd." *Id*.

F. Ground I – Obviousness over Silverman, Xing, and Ruxolitinib Prescribing Information

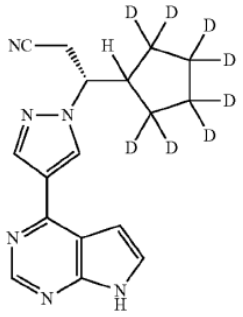
Petitioner challenges claims 1–7 and 9–21 under 35 U.S.C. § 103, contending the claimed subject matter would have been obvious in view of Silverman, Xing, and Ruxolitinib Prescribing Information. Pet. 23–86; Reply 13–27. Patent Owner argues these claims are patentable over the asserted references. PO Response 28–77; Sur-reply 11–24. We discuss the parties' contentions for each of the claims, but because certain disclosures of Silverman are excluded as described above in § II.D.5(c), we summarize only those allegations made by Petitioner relating to non-excluded portions of Silverman, and Patent Owner's responsive arguments.

In light of the exclusions and, given the definition of the ordinary level of skill in the art adopted in § II.B. above, we read Petitioner's

remaining argument regarding the person of skill in the art's identification of Compound (I) from Silverman to state "Compound (I) was disclosed and claimed in Patent Owner's prior-art *Silverman* patent . . . , which also recognized deuteration as '[a] potentially attractive strategy for improving a drug's metabolic properties….'" Pet. 12 (second and third alterations in original). We agree that the ordinarily skilled artisan would have found deuteration to provide potential metabolic stability vis-à-vis ruxolitinib, and would also have recognized that Formula A of Silverman, reproduced below, included the embodiment identified as Compound (I) of the '659 patent, also reproduced below to the right of Formula A:



Formula A



Compound (I)

The structures of Formula A of Silverman and Compound (I) of the '659 patent are reproduced above.

Petitioner contends that Xing discloses the treatment of AA with ruxolitinib, and Silverman disclosed that embodiments of Formula A, which would include Compound (I), were effective for "treating a disease that is beneficially treated by ruxolitinib." *Id*. at 27 (citing Ex. 1003, 1043, 1048; Ex. 1002, 20:57–59). Therefore, Petitioner argues, the skilled artisan would have found it obvious that Compound (I) could be used for treating a hair loss disorder. *Id*. at 26.

Patent Owner argues that Xing "and a handful of other anecdotal reports of hair regrowth in patients taking ruxolitinib" do not teach treatment with Compound (I) or at the doses claimed in the patent, and therefore do not teach a causal relationship between ruxolitinib administration and improvement in AA, which could be due to spontaneous remission. Resp. 37–38 (citing Ex. 2019 ¶¶ 64–68). Patent Owner also argues that potential side effects of JAK inhibitors taught away from their use. *Id*. at 31–32 (citing Ex. 2059 ¶ 57; Ex. 2037, 1).

Petitioner replies that JAK inhibitors like ruxolitinib were, at the time of the '659 patent application, established for treatment of hair loss, with limited, if any, side effects in the relevant population. Reply 14–16 (citing Ex. 1140, 4; Ex. 1161 ¶ 73).

Patent Owner's Sur-reply argues that Petitioner's data comes from anecdotal reports only without sufficient clinical data to support its statements of limited side effects. Sur-reply 11.

On this record, we find that the artisan would have found it obvious to use compounds of Formula A from Silverman to treat AA based on Silverman's teaching that deuterated Formula A compounds could be used to treat diseases beneficially treated by ruxolitinib and Xing's success in treating AA with ruxolitinib. However, without the benefit of the explicit identification of Compound 111 in Silverman based on the data from the 2015 Uttamsingh Declaration, Petitioner's argument for how the skilled artisan reading Silverman would have identified Compound (I) from the genus of Formula A is far different from what we considered at institution. Because this issue is potentially dispositive, we first examine the evidence remaining in Petitioner's case for the skilled artisan's identification of and

motivation to use Compound (I) and Patent Owner's arguments in opposition.

Petitioner's allegations related to obviousness of the challenged claims assert that Silverman teaches Compound (I) without explaining how Compound (I) was discerned from Formula A of Silverman. *See* Pet. 26–32, 69–84.[10] With regard to motivation to combine the teachings of Silverman, Xing, and RPI, Petitioner states that the skilled artisan

> would have been motivated to use Compound (I), the deuterated analog of ruxolitinib from *Silverman*, to treat AA, which *Xing* taught could be treated with ruxolitinib, to obtain at least the same efficacy as ruxolitinib and/or potentially improved pharmacokinetic properties in that treatment.

Id. at 33 (citing Ex. 1007 ¶¶ 126–135). The cited testimony by Dr. Patterson explains reasons for using a deuterated version of a drug, but does not provide reasoning for selecting Compound (I) itself. Ex. 1007 ¶¶ 126–135.

Petitioner alleges the artisan would have been motivated to orally administer tablets of Compound (I) to treat AA because Xing taught that orally administered ruxolitinib treated humans with AA. Pet. 33. Petitioner alleges Silverman's express teaching about the benefits of deuteration would have led the artisan to choose to use Compound (I) because the artisan would have expected equal or better efficacy and improved pharmacokinetics. *Id*. (citing Ex. 1007 ¶¶ 38–43, 126–135). None of these allegations, however, including the cited testimony of Dr. Patterson, is specific to Compound (I) *with regard to other embodiments of Formula A of Silverman*. Specifically, none of the evidence of record absent the excluded

[10] Petitioner discusses Compound (I) and its identification in Silverman, along with the 2015 Uttamsingh Declaration as background information at Pet. 11–15.

disclosures from the 2015 Uttamsingh Declaration explains why Compound (I) would have been selected from the genus of Formula A for further study in hair-loss treatment.

Petitioner's next allegations at Pet. 34 assert that Compound (I) was disclosed as useful in treating disease conditions that ruxolitinib is also used to treat, and that Compound (I) would have been selected as a natural candidate for further investigation in treating AA for reasons that are excluded under
§ 102(b)(1) because they arose from the 2015 Uttamsingh Declaration data. In a footnote, Petitioner states with relation to the Supersome assays performed by Dr. Uttamsingh, that: "Increased metabolic stability would have been expected since Compound (I) deuterated ruxolitinib's known 'metabolic hot spots.'" Pet. 34 (citing Ex. 1007 ¶¶ 151−158[11]).

The 2015 Uttamsingh Declaration did not address selection of Compound (I) due to deuteration at metabolic hot spots. However, the cited paragraphs of Dr. Patterson's declaration explaining the motivation for selecting Compound (I) largely rely on data from the 2015 Uttamsingh Declaration. These paragraphs are reproduced below, without footnotes:

Claimed Compound (I) (Claims 1−21)

> 151. A POSA would have been particularly motivated to use Compound (I), which had been disclosed and specifically claimed, was deuterated at ruxolitinib's metabolic hotspots, and was reported to have improved metabolic properties *in vitro*.
>
> 152. A POSA would have been motivated to use claimed Compound (I) as it was one of three compounds specifically called out in Claim 7 of *Silverman*, which points to two D_4-ruxolitinib species and D_8-ruxolitinib (i.e., claimed Compound

[11] Petitioner also cites "Paper 119" that is not of record in this proceeding.

(I)). As discussed, *Silverman* identifies the claimed Compound (I) as "Compound 111."

153. Compound (I) further stood out from the other deuterated analogs in *Silverman* as it was deuterated at ruxolitinib's primary sites of metabolism, i.e., its "metabolic hotspots." The motivation to select a compound deuterated at ruxolitinib's primary sites of metabolism was intuitive: placing deuterium at the sites of metabolism increases the impact of the KIE (whereas placing it at a location on the molecule that is not metabolized would not have been expected to have an effect). Indeed, Concert's marketing materials explicitly directed deuterating at hotspots "identified from literature reports of *in vivo* metabolism."

154. As shown by Shilling et al., metabolism on ruxolitinib's cyclopentyl ring accounted for the vast majority of the compound's metabolism. For this reason, a POSA would have been motivated to use Compound (I), which was deuterated exclusively at the cyclopentyl ring.

155. Data submitted by Concert (in a declaration from Dr. Vinita Uttamsingh) during prosecution of *Silverman* were consistent with the expectation of having deuterated ruxolitinib's metabolic hotspots and further pointed a POSA to Compound (I). The data showed that Compound (I) was among the compounds showing the greatest potential for improvement in metabolic stability. Indeed, of the three compounds addressed in Dr. Uttamsingh's declaration, Compound (I) showed the greatest potential for improvement in metabolic stability.

156. More specifically, in the supersome assays submitted by Concert, the D_4 compounds exhibited half-lives ($t_{1/2}$) 23% and 29% longer than ruxolitinib, while the D_8 Compound (I) had an 80% longer $t_{1/2}$. In the HLM assays, the D_4 compounds exhibited 30% and 25% longer half-livesthan ruxolitinib, while Compound (I) had a 75% longer $t_{1/2}$.

157. D_9-ruxolitinib "Compound 127" in *Silverman* showed numerically greater increase in *in vitro* stability, relative to ruxolitinib, than D_8-ruxolitinib (Compound (I)). This would not have directed a POSA away from Compound (I), however,

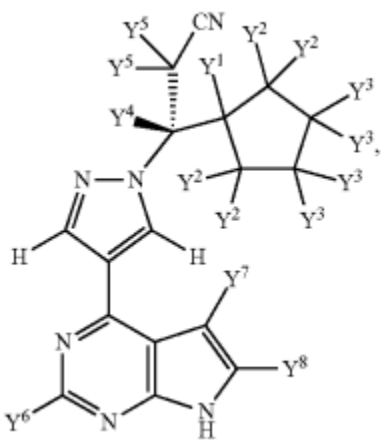
> since the 75−80% $t_{1/2}$ improvement for the D_8 "Compound 111" over ruxolitinib is substantial.
>
> 158. Thus, a POSA would have been motivated to use the claimed Compound (I) as it stood out from the other compounds in *Silverman* because it (1), was deuterated at ruxolitinib's metabolic hotspots, (2) showed superior *in vitro* data compared to other compounds specifically claimed and (3) was itself specifically claimed.

Ex. 1007 ¶¶ 151–158. As is evident in these paragraphs, the majority of the rationale used by Dr. Patterson to explain why a skilled artisan would have selected Compound (I) relies on data from the 2015 Uttamsingh Declaration. The sole rationale that could potentially be separated is that Compound (I) was deuterated at ruxolitinib's metabolic hotspots, and was reported to have improved metabolic properties *in vitro*. *Id*. ¶¶ 153, 154. However, the same is true for compound 127, as shown in Table 1 of Silverman, reproduced below, with relation to Formula A, also reproduced below:

TABLE 1

Exemplary Embodiments of Formula I

Cmpd	Y^1	Each Y^2	Each Y^3	Y^4	each Y^5
100	H	H	H	D	H
101	H	H	H	H	D
102	H	H	H	D	D
103	H	H	D	H	H
104	H	H	D	D	H
105	H	H	D	H	D
106	H	H	D	D	D
107	H	D	H	H	H
108	H	D	H	D	H
109	H	D	H	H	D
110	H	D	H	D	D
111	H	D	D	H	H
112	H	D	D	D	H
113	H	D	D	H	D
114	H	D	D	D	D
115	D	H	H	H	H
116	D	H	H	D	H
117	D	H	H	H	D
118	D	H	H	D	D
119	D	H	D	H	H
120	D	H	D	D	H
121	D	H	D	H	D
122	D	H	D	D	D
123	D	D	H	H	H
124	D	D	H	D	H
125	D	D	H	H	D
126	D	D	H	D	D
127	D	D	D	H	H
128	D	D	D	D	H
129	D	D	D	H	D
130	D	D	D	D	D



Formula A

Ex. 1002, 8:9–30. Table 1 above shows the location of chemical modifications of exemplary embodiments of Formula 1 (Ex. 1002, 7:10–24), shown above to the right of Table 1. Compound 127 contains a similar deuteration profile to Compound 111(I), with one additional deuteration location that is absent from Compound 127. With the logic presented about the benefits of deuterating the cyclopentyl ring, which "accounted for the vast majority of the compound's metabolism," the artisan would have been motivated to select Compound 127. Ex. 1007 ¶ 154; *see also* Ex. 1055, 8 ("The primary metabolic pathways for [ruxolitinib in humans . . . occur[s] on the cyclopentyl moiety.").

Yet, Dr. Patterson explains that the skilled artisan would instead have selected Compound 111 because it showed superior metabolic stability in Dr. Uttamsingh's Supersome assays, once again relying on data from the excluded disclosures from the 2015 Uttamsingh Declaration. Ex. 1007 ¶ 157 ("This would not have directed a POSA away from Compound (I), however, since the 75−80% $t_{1/2}$ improvement for the D_8 'Compound 111' over ruxolitinib is substantial."); *see also* Pet. at 40 (citing 2015 Uttamsingh Declaration as further evidence that "[a] POSA would have been further motivated to use Compound (I) in place of ruxolitinib based on the expectation that gains in metabolic stability were unlikely to be masked *in vivo* by metabolic switching, alternative routes of clearance, or the rate of blood flow relative to clearance" (Ex. 1007 ¶¶ 136−147; Ex. 1057, 1–2; Ex. 1058, 8; Ex. 1059, 10)). Accordingly, Dr. Patterson's testimony does not provide a sufficient evidentiary basis for a finding that the skilled artisan would have pursued use of Compound (I) independent of the information provided by the 2015 Uttamsingh Declaration.

At oral argument, we asked Petitioner why deuteration provided a basis for selecting Compound (I):

> MR. FELDSTEIN: . . . Silverman tells you where the metabolic hotspots are on formula A. It tells you that they're the 2 and 3 positions and what the art taught and what actually -- if I can actually go back to slide 30 for a second, what the art taught and it was basically the premise of the prior IPR[12] between the parties -- a finding was that you would know to deuterate Ruxolitinib's metabolic hotspots to achieve improved safety, tolerability, efficacy and that's confirmed here by Dr. Montellano in this case as well as Dr. Guengerich and Dr. Patterson . . . .
>
> * * *
>
> JUDGE NEWMAN: . . . Of the compounds disclosed in Silverman how many of them are deuterated at that 2 and 3 position?
>
> MR. FELDSTEIN: I think Compound 111 using the Silverman nomenclature is the only that's deuterated at all eight of those positions because there are four 2-positions and there are four 3-positions (indiscernible) and so there's only one compound that has those eight. There's another one, Compound 127 that has all nine, looking at our slide 31, there's a Y1- position that's not circled. Compound 127 has that ninth turning to deuterium and there are multiple versions where the Y2s are deuterated or the Y3s are deuterated but not both. Compound 111 is the only one where it's eight and just eight.
>
> JUDGE NEWMAN: So if I'm understanding your argument, you're saying that one of skill in the art would naturally be looking at those deuterated 2 and 3-positions and selecting which compounds to proceed with?
>
> MR. FELDSTEIN: Correct. It [sic] you deuterate at the 2 and 3-positions as suggested by the statement in Silverman there's one unique compound that you get out of that and that is in 4

[12] We confine the record to evidence presented in this matter and do not consider Petitioner's reference to data presented in a separate proceeding between the parties.

> Silverman nomenclature Compound 111, in the '659 nomenclature it's Compound (1). It brings you to a single compound.

Tr. 16:11–18:6.

When asked, Patent Owner responded to this point by noting that Petitioner had not included this argument in its Petition (*id*. at 49:23–50:1) and argued that Silverman did not teach what Petitioner argued:

> MR. CEDRONE: . . . As I understand their argument they rely on two sources to make that argument. They rely on a line from Silverman itself that talks about active metabolites at the 2- and 3-position. If you go back and read that paragraph it doesn't discuss deuteration at hotspots or anything that would motivate a POSA. It simply talks about the fact that there were active metabolites stemming from those 2- and 3-positions.
>
> The other point I would make is they cite in their slides the IPR decision discussing deuteration generally but the IPR was about synthesis of a compound. The question in this case is not synthesis of a compound, would there have been motivation to deuterate a compound because maybe it would have superior metabolic properties? The question in this case is would you select a particular compound from a genus of 60 plus compounds to treat a specific disease with specific side effects at specific doses and there's nothing in Silverman that gets you there once the compound is excluded and especially once the metabolic stability data is excluded.

Id. at 50:2–19.

The referenced paragraph of Silverman states:

> Three metabolites in humans have been identified as active, that resulting from hydroxylation at the 2-position on the cyclopentyl moiety, that resulting from hydroxylation at the 3-position on the cyclopentyl moiety and the ketone resulting from further oxidation at the 3-position on the cyclopentyl moiety.

Ex. 1002, 3:7–12.

We do not read this paragraph to provide sufficient motivation to a skilled artisan to have selected the disclosed compound with deuteration at only the 2- and 3-Y positions. We note that Silverman states in the "Background of the Invention" that a

> potentially attractive strategy for improving a drug's metabolic properties is deuterium modification. In this approach, one attempts to slow the CYP-mediated metabolism of a drug or to reduce the formation of undesirable metabolites by replacing one or more hydrogen atoms with deuterium atoms.

Id. at 2:5–10. However, Petitioner did not argue this as a basis for a skilled artisan's motivation in selecting Compound (I), but merely noted that the resultant metabolic stability "would have been expected." Pet. 34 n.8.

As Patent Owner argues, Petitioner's logic for selecting Compound (I) in the absence of data from the 2015 Uttamsingh Declaration is procedurally late, and even the declarants cited in Petitioner's Reply cite to the 2015 Uttamsingh Declaration as further evidence supporting their argument for selecting Compound (I). *See* Ex. 1120 ¶ 60; Ex. 1007 ¶¶ 157–158. Moreover, if deuteration results were entirely predictable, the data in the 2015 Uttamsingh Declaration would not have been necessary to generate to overcome obviousness or in general to assess the performance of the compounds. *See also, e.g.,* Ex. 1033, 14 (Discussing the imperfect science of deuteration: "[i]t is often falsely assumed that one simply replaces a C−H pair that is subject to oxidation with a C−D pair so that stability ensues. This naive view is surprisingly pernicious and not one by which practitioners of this approach are burdened.").

We are similarly unpersuaded by Petitioner's argument that motivation can be found where the skilled artisan would have been motivated to pursue one compound as one of several potential treatment

options. Pet. 35 (citing *Novartis Pharm. Corp. v. West-Ward Pharm. Int'l Ltd.*, 923 F.3d 1051, 1060 (Fed. Cir. 2019)). The *Novartis* court considered whether the district court applied the correct analysis of a skilled artisan's motivation to combine when considering whether the artisan would have been motivated to use a similar compound where a prior compound had been found effective in treating disease. 923 F.3d at 1060. Petitioner's argument makes the incorrect distinction as applied here: we agree that, on these facts, an ordinary artisan would have been motivated to pursue deuterated embodiments of ruxolitinib for use in AA, as supported by the reasoning in *Novartis*. *Id*. But here Petitioner alleged – and cannot sufficiently support without the 2015 Uttamsingh Declaration data – why Compound (I) is the only one of the similar compounds it selected. No other information or argument was presented in the Petition to support a motivation to use Compound (I) of the genus of Formula A of Silverman.

As explained above, Petitioner's rationale regarding deuteration at metabolic hotspots is insufficient alone, and Petitioner is precluded from relying on data from the 2015 Uttamsingh Declaration. Accordingly, we find that Petitioner has not met its burden to show by a preponderance of the evidence that a skilled artisan would have been motivated to select Compound (I) for use from among the genus of compounds falling within Formula A. For this reason, we find Petitioner has not shown that independent claim 1, which recites the use of Compound (I) for treating hair-loss, is obvious over Silverman, Xing, and RPI. Petitioner's additional arguments related to dependent claims 2–7 and 9–21 rely on the same teachings of Silverman. *See, e.g.*, Pet. 69, stating that the disclosures of the claims charts "for each dependent claim incorporate those of the

independent [claim]", and citing "EX1002, 7:7−8:43, 36:66−37:43 (disclosing Compound (I) ("compound 111") for claim 1)." Accordingly, we find Petitioner has not shown that claims 2–7 and 9–21, which all recite Compound (I), are obvious over Silverman, Xing, and RPI.

G. Ground 2 – Obviousness over Silverman, Christiano, and Ni

Petitioner relies on the same teachings from Silverman for its allegations of obviousness in Ground 2 as were applied to Ground 1 above. Pet. 62, 69–84; Reply 13. As these allegations include the same reasons for selecting Compound (I), we find that Petitioner has not met its burden to show by a preponderance of the evidence that a skilled artisan would have been motivated to select Compound (I) for use from among the embodiments of Formula A recited in Silverman. For this reason, we find Petitioner has not shown that claims 1–7 and 9–21, which all recite Compound (I), are obvious over Silverman, Christiano, and Ni.

III. MOTIONS

A. Petitioner's Motion to Exclude Evidence

Petitioner moves to exclude Exhibits 2073, 2083, 2084, and certain paragraphs from Patent Owner's expert declarations that rely upon those exhibits as unauthenticated hearsay and double hearsay. Papers 56, 62. Patent Owner opposes. Paper 59. As we have not relied on any of these objected-to exhibits or testimony in rendering this decision, we dismiss this motion as moot.

B. Patent Owner's Motion to Exclude Evidence

As discussed above in § I.G., we have restricted the weight we assign to Dr. Patterson's testimony to that addressing the level of ordinary skill with regard to issues of drug design, evaluation of effectiveness, and drug

administration. In rendering this decision, we considered Dr. Patterson's testimony for its support for Petitioner's allegations with regard to the alleged motivation to select Compound (I) for use, and assigned the testimony appropriate weight based on the developed record. We deny the motion.

Patent Owner also requests exclusion of Ex. 1039 as unauthenticated. We do not rely on Ex. 1039 in rendering our decision and dismiss the motion as moot with regard to this exhibit.

IV. CONCLUSION[13]

After considering Petitioner's and Patent Owner's arguments and evidence, we conclude that Petitioner has not shown, by a preponderance of the evidence, that claims 1–7 and 9–21 of the '659 patent would have been obvious over Silverman, Xing, and Ruxolitinib Prescribing Information, or over Silverman, Christiano, and Ni.

V. ORDER

In consideration of the foregoing, it is:

ORDERED that claims 1–7 and 9–21 of the '659 patent have not been shown to be unpatentable;

---

[13] Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this Decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. *See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. §§ 42.8(a)(3), 42.8(b)(2).

FURTHER ORDERED that Patent Owner's motion to exclude the testimony of Dr. Patterson is denied;

FURTHER ORDERED that Patent Owner's motion to exclude Exhibit 1039 is dismissed as moot; and

FURTHER ORDERED that Petitioner's motion to exclude Exhibits 2073, 2083, 2084 and certain paragraphs from Patent Owner's expert declarations that rely upon those exhibits is dismissed as moot; and

FURTHER ORDERED that, as this is a Final Written Decision, a party seeking judicial review of the Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

In summary:

Claims[14]	**35 U.S.C. §**	**Reference(s)/Basis**	**Claims Shown Unpatentable**	**Claims Not Shown Unpatentable**
1–7, 9–21	103	Silverman, Xing, Ruxolitinib Prescribing Information		1–7, 9–21
1–7, 9–21	103	Silverman, Christiano, Ni		1–7, 9–21
Overall Outcome				1–7, 9–21

[14] Ground 3 is no longer at issue in this case as Patent Owner filed a statutory disclaimer of claim 8 (*see* Ex. 2020). 37 C.F.R. § 42.207(e).

FOR PETITIONER:

Thomas Irving
Mark Feldstein
Trenton Ward
Drew Christie
Catherine Corser
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
Tom.irving@finnegan.com
Mark.feldstein@finnegan.com
Trenton.ward@finnegan.com
Drew.christie@finnegan.com
Collette.corser@finnegan.com

FOR PATENT OWNER:

Marta Delsignore
Gerard Cedrone
GOODWIN PROCTER LLP
mdelsignore@goodwinprocter.com
gcedrone@goodwinlaw.com