Paper No. 49
Filed: December 30, 2024

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FORTE BIOSCIENCES, INC.,
Petitioner,

v.

UNIVERSITY OF MASSACHUSETTS,
Patent Owner.

PGR2023-00014
Patent No. 11,278,505

PATENT OWNER'S NOTICE OF APPEAL

Pursuant to 35 U.S.C. §§ 141(c), 142, and 329, and 37 C.F.R. § 90.2(a), Patent Owner University of Massachusetts hereby provides notice of appeal to the United States Court of Appeals for the Federal Circuit from the Final Written Decision of the Patent Trial and Appeal Board ("Board") entered on June 24, 2024, (Paper No. 45) ("Final Written Decision") and from all underlying orders, decisions, rulings, and opinions relating to the post-grant review of U.S. Patent No. 11,278,505 ("the '505 patent") in PGR2023-00014, including the Decision Denying Patent Owner's Request for Rehearing entered on October 30, 2024 (Paper No. 48) ("Rehearing Denial"). This Notice is timely under 37 C.F.R. § 90.3(a)(1), having been filed no later than sixty-three (63) days after the issuance of the Rehearing Denial.

In accordance with 37 C.F.R. § 90.2(a)(3)(ii), Patent Owner states that the issues on appeal include, but are not limited to:

- The Board's determination that claims 1-5 of the '505 patent are unpatentable for lack of written description under 35 U.S.C. § 112(a);
- The Board's determination that claims 1-5 of the '505 patent are unpatentable for lack of enablement under 35 U.S.C. § 112(a);
- The Board's improper and erroneous reliance on the opinions of Petitioner's experts;
- The Board's improper and erroneous consideration or omission of evidence;

- The Board's application of incorrect legal standards for written description and enablement;
- Any Board finding decided adversely to Patent Owner unsupported by substantial evidence; and
- The Board's violation of the Administrative Procedure Act in rendering its Final Written Decision and Rehearing Denial.

Patent Owner further reserves the right to challenge any finding or determination supporting or relating to the issues above, and to challenge all other issues decided adversely to Patent Owner in any orders, decisions, rulings, or opinions underlying or supporting the Final Written Decision, including the Rehearing Denial. A copy of the Final Written Decision is attached to this Notice.

Pursuant to 35 U.S.C. § 142 and 37 C.F.R. § 90.2(a)(1), this Notice is being filed with the Director of the United States Patent and Trademark Office, and a copy of this Notice is being concurrently filed with the Board. In addition, a copy of this Notice and the required docketing fees are being filed with the Clerk's Office for the United States Court of Appeals for the Federal Circuit via CM/ECF in accordance with 37 C.F.R. § 90.2(a)(2), Federal Rule of Appellate Procedure 15, and Federal Circuit Rule 15.

Respectfully submitted,

Dated: December 30, 2024

/Mark J. Feldstein/
Mark J. Feldstein, Reg. No. 46,693
Lead Counsel for Patent Owner

CERTIFICATE OF SERVICE

I hereby certify that on December 30, 2024, in addition to being filed and served electronically through the Patent Trial and Appeal Board's P-TACTS System, this **PATENT OWNER'S NOTICE OF APPEAL** was filed with and served on the Director of the United States Patent and Trademark Office via email at the following:

Office of the General Counsel
U.S. Patent and Trademark Office
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I also hereby certify that on December 30, 2024, this **PATENT OWNER'S NOTICE OF APPEAL** and the requisite docketing fees were filed with the Clerk's Office of the United States Court of Appeals for the Federal Circuit via CM/ECF.

I further hereby certify that on December 30, 2024, this **PATENT OWENR'S NOTICE OF APPEAL** was served by electronic mail on the following counsel for Petitioner:

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Dated: December 30, 2024

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Paper 45
Date: June 24, 2024

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FORTE BIOSCIENCES, INC.,
Petitioner,

v.

UNIVERSITY OF MASSACHUSETTS,
Patent Owner.

PGR2023-00014
Patent 11,278,505 B2

Before GEORGIANNA W. BRADEN, ROBERT A. POLLOCK, and MICHAEL A. VALEK, *Administrative Patent Judges.*

BRADEN, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

Denying Petitioner's Motion to Exclude
37 C.F.R. § 42.64(c)

I. INTRODUCTION

A. Procedural Background

Forte Biosciences, Inc. ("Petitioner") filed a Petition requesting a post-grant review of claims 1–5 (the "challenged claims") of U.S. Patent No. 11,278,505 B2 (Ex. 1001, "the '505 patent"). Paper 2 ("Pet."). We instituted an *inter partes* review of claims 1–5. Paper 10 ("Dec. Inst."), 34.

After institution, University of Massachusetts ("Patent Owner") filed a Patent Owner Response to the Petition. Paper 19 ("Resp."). Petitioner filed a Reply to Patent Owner's Response (Paper 25, "Reply") and Patent Owner filed a Sur-reply (Paper 32, "Sur-reply"). Petitioner then filed a motion to exclude evidence (Paper 34, "Mot."), which Patent Owner opposed (Paper 37, "Opp. Mot."); and Petitioner filed a reply in support of its motion (Paper 39, "Reply Mot.). On March 20, 2024, the parties presented arguments at oral hearing, the transcript of which is of record. Paper 44 ("Tr.").

We have jurisdiction under 35 U.S.C. § 6, and issue this Final Written Decision pursuant to 35 U.S.C. § 328(a). We conclude that Petitioner has established by a preponderance of the evidence that claims 1–5 of the '505 patent are unpatentable under 35 U.S.C. § 112(a) for lack of written description and enablement.

B. Real Parties-in-Interest

Petitioner states that it "is the real party-in-interest." Pet. 21. Patent Owner lists itself, Villaris Therapeutics, Inc., and Incyte Corporation, as real parties-in-interest. Paper 4 (Patent Owner's Mandatory Notice), 1.

C. Related Proceedings

The parties do not list any related proceedings. *See* Pet. 21; Paper 4, 1. Patent Owner lists the following U.S. Patent Application Nos. as

"divisional" applications of the '505 patent: 17/667,699; 18/234,923; 18/451,160; and 18/607,636. Paper 43 (Patent Owner's Updated Mandatory Notices), 1.

D. Asserted Challenges to Patentability and Evidence of Record

Petitioner challenges the patentability of claims 1–5 of the '505 patent on the following bases:

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–5	112(a)	written description
1–5	112(a)	enablement
1–5	103	Harris[1], Xing[2]

In support of its patentability challenge, Petitioner relies on, *inter alia*, the Declarations of Abul Abbas, MBBS ("Dr. Abbas") (Ex. 1002) and R. Todd Plott, M.D. ("Dr. Plott") (Ex. 1004), as well as the Reply Declaration of Dr. Plott (Ex. 1047). Patent Owner relies on, inter alia, the Declaration of William Damsky, M.D., Ph.D. (Ex. 2005, "Dr. Damsky").

E. The '505 Patent (Ex. 1001)

The '505 patent is titled "Diagnosis and Treatment of Vitiligo," and issued on March 22, 2002. Ex. 1001, codes (45), (54). It is the U.S. National Stage Application of PCT/US2018/029185 and relies on provisional application No. 62/489,191, which was filed on April 24, 2017. *Id.* at codes (22), (60), (86).

[1] John E. Harris et al., *A Mouse Model of Vitiligo with Focused Epidermal Depigmentation Requires IFN-γ for Autoreactive CD8$^+$ T-Cell Accumulation in the Skin*, J. Investigative Dermatology, Vol. 132 (2012), 1869–1876 ("Harris," Ex. 1006).

[2] Luzhou Xing et al., *Alopecia areata is driven by cytotoxic T lymphocytes and is reversed by JAK inhibition*, Nature Medicine 20 (2014), 1043–1049 ("Xing," Ex. 1007).

1. Written Description

The '505 patent relates to methods for treating vitiligo. Ex. 1001, code (57); 6:31–33. The '505 patent explains that vitiligo "is a chronic, progressive autoimmune skin disease characterized by white or depigmented patches of skin." *Id.* at 6:34–35. The disease is caused $CD8^+$ T cells that target melanocytes (melanin-forming cells) for destruction. *Id.* at 1:29–31. The '505 patent explains that a specific class of $CD8^+$ T cells, tissue resident memory ("Trm") T cells "are present in both mouse and human vitiligo skin lesions." *Id.* at 1:49–50; *see id.* at 5:33–45 (citing Harris (Ex. 1006)). According to the '505 patent, "depleting Trm or inhibiting their function is a highly effective and durable treatment for vitiligo." *Id.* at 1:63–64. The '505 patent further explains that "others have shown" that interleukin-15 ("IL-15") "is required for the generation of CD8+ Trm in viral models in mice" and "is much more potent at generating CD8+ Trm pools than residual [interleukin-2 ('IL-2')] signaling in skin tissue." *Id.* at 6:3–9. According to the '505 patent "[t]he present data support targeting this cytokine as a strategy to clear autoreactive memory cells from the tissue, resulting in a long-lasting, durable response to treatment." *Id.* at 6:22–24.

The '505 patent describes methods for treating vitiligo as including "delivery of a therapeutically effective amount of an inhibitor of IL-15" and the IL-15 receptor,[3] to a vitiligo subject in need of treatment. *Id.* at 7:19–33. The '505 patent lists various diverse types of inhibitors of IL-15 and the IL-15 receptor, including small molecules, fusion proteins, peptides, antibodies, and nucleic acids. *See id.* at 7:34–8:37.

[3] IL-15 receptor may be abbreviated as "IL-15R."

In one embodiment, "mice with longstanding, stable vitiligo (>12 weeks after disease initiation) were treated with an anti-mouse IL-15Rβ antibody, which blocks IL-15 signaling." *Id.* at 33:17–22. The '505 patent reports "significant repigmentation in treated mice compared to controls (FIG. 6A–6C)" after 8 weeks of systemic treatment. *Id.* at 33:22–26. Mice treated with IL-15Rβ antibody for only 2 weeks also had significant repigmentation over a 10-week period, indicating a durable treatment option. *Id.* at 33:35–41 (citing Fig. 6F–I).

2. Illustrative Claims

As noted previously, Petitioner challenges claims 1–5 of the '505 patent, of which claim 1 is independent. Pet. 1; Ex. 1001, 44:13–27. Claims 2–5 depend directly or indirectly from claim 1. Claim 1 is illustrative of the challenged subject matter and is reproduced below.

> 1. A method of treating a subject who has a vitiligo lesion, the method comprising:
>
> identifying a subject in need of treatment; and
>
> administering a therapeutically effective amount of an inhibitor of IL-15 or the IL-15 receptor to the subject.

Ex. 1001, 44:12–17.

II. PRELIMINARY MATTERS

A. *Post-Grant Review Eligibility of the '505 Patent*

Post-grant reviews are available only for patents "described in section 3(n)(1)" of the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"). AIA § 6(f)(2)(A); *see Arkema Inc. v. Honeywell Int'l Inc.*, PGR2016-00011, Paper 13 at 15 (PTAB Sept. 2, 2016). These patents issue from applications "that contain[] or contained at any time . . . a claim to a claimed invention that has an effective filing date as

defined in section 100(i) of title 35, United States Code, that is on or after" "the expiration of the 18-month period beginning on the date of the enactment of" the AIA. AIA § 3(n)(1). Accordingly, post-grant reviews are available only for patents that issue from applications that at one point contained at least one claim with an effective filing date of March 16, 2013, or later. *See also* 37 C.F.R. § 42.204(a) (requiring that "petitioner . . . certify that the patent for which review is sought is available for post-grant review").

Petitioner asserts that the '505 patent claims earliest priority to April 24, 2017. Thus, Petitioner argues the '505 patent issued from applications having a filing date of March 16, 2013 or later. Petitioner filed the request for post-grant review on December 22, 2022, which is within nine months of the grant of the '505 patent on March 22, 2022. *See* Pet. 21; 35 U.S.C. § 321(c).

In our Decision on Institution, based on Petitioner's representations, we preliminarily found that the '505 patent was eligible for post-grant review. Dec. Inst. 6. Patent Owner did not dispute our finding nor otherwise argue that the '505 patent was ineligible for post-grant review in its Response. *See generally* PO Resp. Based on the entirety of the record presented at trial, we find that the '505 patent is eligible for post-grant review.

B. Level of Ordinary Skill in the Art

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)

(quotation marks omitted). Furthermore, the prior art itself can reflect the appropriate level of ordinary skill in the art. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

Petitioner contends that a person of ordinary skill in the art by April 24, 2017 "would have had an advanced degree (e.g., Ph.D., M.D., M.S., or equivalent), in a field related to medicine, immunology, molecular biology, cell biology, microbiology, pathology, biochemistry, peptide chemistry, or a related field." Pet. 18 (citing Ex. 1002 ¶¶ 39–40; Ex. 1004 ¶¶ 31–32). Petitioner asserts that the person of ordinary skill would also have had "at least 3–5 years of experience in treating autoimmune diseases or researching cytokine signaling pathways relevant to treating autoimmune diseases." *Id.*

Patent Owner does not contest Petitioner's proposed definition, except to modify the level such that an ordinarily skilled artisan "would have been familiar with well-known inhibitors of IL-15 and IL-15R as described in the '505 patent and recognized in the art as of April 2017." Resp. 26–27 (citing Ex. 2005 ¶ 94).

We adopt Petitioner's level of ordinary skill in the art with Patent Owner's proposed modification because it appears consistent with the problems addressed in the '505 patent and the prior art of record.

C. Claim Construction

A claim "shall be construed 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(b). Under that standard, the "words of a claim 'are generally given their ordinary and customary meaning.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc).

Both parties state that express claim construction is unnecessary at this stage of the proceeding and that all terms are to given their plain and ordinary meaning. Pet. 23; Resp. 38. We agree.

Construction is needed only for those terms "that are in controversy, and only to the extent necessary to resolve the controversy." *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)). Here, we determine that no claim construction is necessary.

III. ANALYSIS

A. Alleged Lack of Written Description

Petitioner argues claims 1–5 are unpatentable for lack of written description "because the specification fails to reasonably convey to a POSA that the applicant invented the broad invention that is claimed." Pet. 23–48; Reply 3–24. Patent Owner disagrees. Resp. 38–51; Sur-reply 11–26. For the reasons discussed below, we determine Petitioner has shown by a preponderance of the evidence that the challenged claims are unpatentable for lack of written description.

1. Legal Principles

35 U.S.C. § 112(a) requires that a patent's specification "contain a written description of the invention . . . in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). This provision ensures that as of the filing date "the inventor actually invented the invention claimed" (*id.* at 1350–51) and "the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art

as described in the patent specification" (*id.* at 1353–54). The specification therefore must demonstrate conception and at least constructive reduction to practice of "the complete and final invention with all its limitations." *Id.* at 1353. A specification that merely renders the invention obvious does not satisfy the written description requirement. *Id.* The determination "requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." *Id.* at 1351.

The level of detail required to satisfy the written description requirement "varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology." *Id.*; *see also Capon v. Eshhar*, 418 F.3d 1349, 1359 (Fed. Cir. 2005) ("[T]he determination of what is needed to support generic claims to biological subject matter depends on a variety of factors, such as the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, the predictability of the aspect at issue."). In the case of a claim to a genus, the en banc Federal Circuit has held that "a sufficient description of the genus . . . requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus." *Ariad*, 598 F.3d at 1350. "[F]unctional claim language can meet the written description requirement when the art has established a correlation between structure and function." *Id.*

2. Petitioner's position

Petitioner contends that "[t]he '505 patent claims lack written description support because they are overly broad and functionally defined and because the specification fails to disclose a representative number of

species commensurate with the scope of the claim." Pet. 24. Petitioner asserts that claim 1 is overly broad because it "encompasses *any method* of treating *any subject* who has a vitiligo lesion, if that method comprises (a) identifying a subject in need of treatment; and (b) administering to the subject a therapeutically effective amount of *any inhibitor* of IL-15 or the IL-15 receptor." *Id.* at 25. Petitioner further asserts the '505 patent "claims the use of any small molecule, antibody, peptide, or nucleic acid targeting IL-15 or the IL-15 receptor, among other inhibitors, for treating vitiligo." *Id.* (citing Ex. 1001, claim 2, 2:6–8). According to Petitioner, the claims (i) cover any type of interaction with IL-15 or the IL-15 reception (Reply 3), (ii) do not "even require physical or specific interaction with the claimed targets" (*id.*), (iii) encompass using molecules the inhibit IL-15 signaling even by 1% (*id.* at 4), and (iv) cover different signal pathways triggered by any version of IL-15 or any subunit of the IL-15 receptor so long as it "treats" vitiligo (*id.* at 5–6).

Petitioner then contends that, as compared to the broad functional language recited by the claims, the specification provides only one working example, "limited to using a specific, Fc-diminished rat/mouse chimeric antibody called ChMBC7 to target mouse CD122 (IL-2Rβ/IL-15Rβ), one half of the mouse βγ receptor complex that conveys both IL-2 and IL-15 signaling." Pet. 26 (citing Ex. 1002 ¶¶ 37, 66, 69, 71–72, 76, 86). Petitioner cites to Dr. Damsky's testimony that ChMBC7 was the only inhibitor tested, while noting that the '505 patent does not disclose its primary sequence, secondary structure, or binding epitope. Reply 14 (citing Ex. 1047 ¶ 43; Ex. 1046, 224:18–225:12, 225:25–226:8, 230:3–5, 230:6–13). Petitioner argues that the written description never discloses what type of inhibition ChMBC7 provides (*cis* only, *trans* only, or both; dimeric; IL-2 only, IL-15

only, both; etc.) and does not describe the extent of inhibition. *Id.* (citing Ex. 1047 ¶¶ 51–52; Ex. 1011, 2:35–48, 2:61–3:2, 9:27–38; Ex. 1012, 481–82). Petitioner argues that the '505 patent is merely "a black box that leaves 'the reader to guess though trial and error which molecules might operate similarly to ChMBC7 and which do not.'" *Id.* (citing Ex. 1047 ¶ 53). Petitioner contends that "[b]ased only on its experiments using ChMBC7 to deplete the CD8+ T cells in a CD8+ T cell-induced lesion mice model, the '505 patent would preempt the use of a very broad genus of inhibition pathways to treat vitiligo in any subject, including humans." Pet. 26 (citing Ex. 1002 ¶ 85; Ex. 1004 ¶¶ 24–27, 42–45).

Petitioner further argues that "unpredictability across the breadth of the massive claimed genera was significant." Reply 6–7.

> Because of the complicated interplay of the multiple receptor versions, molecules identified by the patent, PO, or Dr. Damsky ***as inhibitors*** also were capable of ***enhancing*** certain forms of IL-15 signaling. For example, HuMax-IL 15 inhibited IL-15 signaling in vitro but ***stimulated IL-15*** "reverse signaling" when used in vivo in humans. EX1047, ¶¶25-26 (EX2013, 2:10-18; EX2014, 2:12-20; EX2015, ¶[0003]; EX2025, 2:10-18; EX2078, 267). Soluble IL-15Rα molecules that can inhibit IL-15 signaling also form complexes with IL-15 and ***enhance IL- 15 signaling*** by improving half-life and *trans*-presenting IL-15 to βγ-receptors. EX1047, ¶30; EX1046, 256:15-258:4, 258:9-16; EX2005, ¶163; EX2079, 1, 5-6, 8. Additional anti-IL-15 antibodies inhibited IL-15 signaling in vitro but enhanced IL-15 signaling in vivo, including by *trans*-presenting IL-15 to βγ-receptors. EX1047, ¶¶29-30; EX1054, Abstract.

Id. According to Petitioner, it was known that the different IL-15 molecules and IL-15 receptor subunits have different effects depending on where the molecules bind. *Id.* at 7. Petitioner notes that whether a receptor is *cis*-

presenting[4] or *trans*-presenting can dictate if signaling is blocked or attenuated. *Id.* (citing Ex. 1047 ¶ 52). Therefore, Petitioner argues that the effects of the implicated molecules were complicated, unpredictable, and based on a "burdensome trial-and-error process." *Id.* at 9 (citing Ex. 1047 ¶ 11).

Petitioner further contends that IL-15 and IL-15 receptor inhibitors were not a "well-known" or discrete class of molecules with class-wide efficacy. Reply 11. According to Petitioner, "Dr. Damsky admitted he cannot recognize from the structure of a compound whether it is an inhibitor of IL-15 or the IL-15 receptor and he wasn't confident whether a pharmaceutical scientist could either." *Id.* (citing Ex. 1047 ¶ 85; Ex. 1046, 236:12–24; Ex. 1047 ¶¶ 56, 80–85). Petitioner, therefore, concludes that "the '505 patent merely draws 'a fence around the outer limits of a purported genus' of treating vitiligo by administering any inhibitor of either IL-15 or the IL-15 receptor, which is inadequate under § 112(a)." Pet. 28 (citing *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1350 (Fed. Cir. 2010) (en banc)); Reply 14.

3. Patent Owner's position

Patent Owner responds that the claims are directed to a "novel use of a known class of cytokine inhibitors" and that Petitioner "mischaracterizes the art as 'nascent.'" Resp. 1. Patent Owner makes several arguments against Petitioner's challenges.

[4] Presentation of the IL-2 or IL-15 cytokine on one cell to the βγ complex on another cell (common for IL-15, rare for IL-2) is called "trans-presentation," whereas presentation of the IL-2 or IL-15 cytokine to the βγ complex on the same cell (more common for IL-2 than for IL-15) is called "cis-presentation." *See* Ex. 1002 (citing Ex. 1015, 771).

First, Patent Owner contends the claims are narrowly drawn to novel methods of using IL-15 inhibitors and IL-15R inhibitors to treat a subject's vitiligo, not the discovery of new inhibitors themselves. *Id.* at 39. Patent Owner criticizes the Petition for wrongly focusing the inquiry on inhibitors and, therefore, failing "to show any written description deficiency for the claimed method of treating vitiligo." *Id.* (citing Ex. 2005 ¶¶ 111–140). According to Patent Owner, all the cases cited by Petitioner involve classes of novel compounds where making the compound itself was the claimed invention. *Id.* at 40–41 (citing *Ariad*, 598 F.3d at 1355 (addressing written description of an undeveloped class of compounds where the specification provided no working examples); *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330, 1336, 1339 n.3 (Fed. Cir. 2021) (finding inadequate written description for claims to a new class of antibodies), *cert. denied*, 143 S. Ct. 402 (2022); *Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1164 (Fed. Cir. 2019) (invalidating claims to a broad genus of largely undeveloped nucleosides), *cert. denied*, 141 S. Ct. 1234 (2021); *AbbVie Deutschland GmbH v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1301–02 (Fed. Cir. 2014) (inadequate written description for claims to undeveloped genus of "fully human IL-12 antibody" with a particular binding activity)).

Patent Owner attempts to distinguish *University of Rochester v G.D. Searle & Co., Inc.*, 358 F.3d 916, 925–926 (Fed. Cir. 2004). Resp. 41. Patent Owner explains that claims in the *Rochester* case were "directed to methods 'for selectively inhibiting' PGHS-2 activity in a human host," and "it was 'undisputed' that the specification failed to 'disclose any compounds that can be used in its claimed methods,' and there was even no evidence 'that such a compound was known.'" *Id.* (citing Rochester, 918, 926–27). Patent Owner argues that the claims here are directed to treating vitiligo

using a well-known class of compounds (IL-15/IL-15R inhibitors) in a novel method of treating vitiligo. *Id.* at 42. According to Patent Owner, the present claims:

> *do not* "depend[] upon finding a compound that" inhibits IL-15 or IL-15R. *Id*. And unlike *Rochester*, claim 2 narrows scope to particular classes of inhibitors exemplified in the specification—much more than a "vague functional description." *Id.* at 928. Moreover, the specification discloses 20 exemplary compounds that can be used to treat vitiligo with *hundreds more* known in the art. EX1001, 2:49–53, 7:33–8:37; EX2005, ¶¶ 114–125; EX2082, 1; EX2083, 1.

Id. Patent Owner also argues that "[t]here is also no evidence of any 'ineffective compounds.'" *Id.* (citing *Idenix*, 941 F.3d at 1164).

Second, Patent Owner contends the specification provides support for the claimed method because it "describes in extensive detail a range of inhibitors, pathways, and techniques for the treatment of vitiligo by inhibiting IL-15 signaling." Resp. 43–44 (citing Ex. 2005 ¶¶ 98–100; Ex. 1001, 1:66–2:17, 7:34–20:13). According to Patent Owner, the specification expressly incorporates by references over 300 prior art documents, and nearly all of which "are ignored by Petitioner." *Id.* at 44 (citing Ex. 1001, 2:49–52; Ex. 2005 ¶ 71). Then, Patent Owner takes issue with Petitioner's questions regarding *trans* or *cis* presentation by IL-15. *Id.* at 45. Patent Owner asserts that it was understood that "unlike other cytokines, IL-15 functions mainly through a *trans*-presentation such that antagonizing any one of IL-15, IL-15Rα, IL-15Rβ, or γc inhibits IL-15 signaling." *Id.* at 7 (citing Ex. 1016, 3–4, Fig. 2; Ex. 1015, 1, 2, (Fig. 1); Pet. 11–12 (*trans*-presentation common for IL-15, not IL-2); Ex. 2007, 69:9–70:9), 45. Patent Owner argues that this understanding is reflected in the '505 patent, including in Example 1, so that a person of ordinary skill in

the art at the critical time would have understood that the vitiligo treatment in Example 1 was representative of all the claims. *Id.* at 44–45.

Third, Patent Owner contends that Petitioner's "chemicals" argument (citing Pet. 36–39) and its "genus of subjects claimed" argument (citing *id.* at 39–41) are inapt because there are no chemicals claimed in the '505 patent and it was common practice to use preclinical mouse experiments to support human treatment. Resp. 45–48.

Finally, Patent Owner contends additional factors confirm sufficient written description support in the '505 patent for the challenged claims. *Id.* at 48–50 (citing Pet. 41 (quoting *Ariad*, 598 F.3d at 1351)). Specifically, Patent Owner argues that the state of the art was advanced and well-established with Petitioner's declarant admitting that the use of other cytokine signal inhibitors, had already been demonstrated clinically based on preclinical studies. *Id.* at 49 (citing Ex. 2007, 50:16–51:21; Ex. 1007). Yet, according to Patent Owner, Petitioner ignores the implications of this advance technology for its written description requirement challenge and that the art as it relates to the claimed method is not, in fact, unpredictable. *Id.* Patent Owner also asserts that the claims were allowed in prosecution because the cited prior art did not show that IL-15 inhibition would treat vitiligo, but that the '505 patent establishes the fact that "it was predictable that IL-15 or IL-15R inhibitors—hundreds of which were known—will inhibit IL-15 signaling." *Id.*

4. Analysis

To prevail in this post-grant review of the challenged claims, Petitioner must prove unpatentability by a preponderance of the evidence. 35 U.S.C. § 326(e); 37 C.F.R. § 42.1(d).

After considering the full record, we agree with Petitioner's

characterization of the operative facts. That is, the challenged claims are directed broadly to a method of treating vitiligo by administering an inhibitor of IL-15 or IL-15 receptor in a therapeutically effective amount. This is a functional description, requiring that the administered compound be both an inhibitor of IL-15 or IL-15 receptor and therapeutically effective. The specification, however, only provides a single working example a compound that meets these functional requirements, ChMBC7.

We understand Patent Owner's responsive argument to be that, given the nature of the claims, the proper inquiry under the written description requirement (1) should be whether the disclosure in the specification shows that the inventors possessed the recited method of administering a therapeutically effective amount of an IL-15 or IL-15 receptor inhibitor to treat vitiligo lesions, and (2) does not turn on whether the patentees were in possession of the entire genus of IL-15 or IL-15 receptor inhibitors. *See* Resp. 1–3, 38, 42; Sur-reply 12–13.

We do not agree. Despite Patent Owner's arguments, the present case is similar to *University of Rochester v G.D. Searle & Co., Inc.*, 358 F.3d 916, 925–926 (Fed. Cir. 2004) where the patentee argued that the holdings in precedential case law were limited to composition of matter claims, whereas the disputed claim was directed to a method. The Federal Circuit held that argument to be "a semantic distinction without a difference" and "[r]egardless whether a compound is claimed *per se* or a method is claimed that entails the use of the compound, the inventor cannot lay claim to that subject matter unless he can provide a description of the compound sufficient to distinguish infringing compounds from non-infringing compounds, or infringing methods from non-infringing methods." *Id.* at 926. The Court noted that "[t]he claimed method depends upon finding a

compound that selectively inhibits PGHS–2 activity. Without such a compound, it is impossible to practice the claimed method of treatment." *Id.* The Court in *Rochester* then explained that a "description of what a material does, rather than what it is, usually does not suffice" to meet the written description requirements of § 112(a) and "generalized language may not suffice if it does not convey the detailed identify of an invention." *Id.* at 923.

As noted previously, Patent Owner attempts to distinguish the *Rochester* case by arguing that:

> claim 1 of the '505 patent is directed to treating vitiligo using a well-known class of compounds (IL-15/IL-15R inhibitors) in a novel method of treating vitiligo and *do not* "depend[] upon finding a compound that" inhibits IL-15 or IL-15R. *Id*. And unlike *Rochester*, claim 2 narrows scope to particular classes of inhibitors exemplified in the specification—much more than a "vague functional description." *Id.* at 928. Moreover, the specification discloses 20 exemplary compounds that can be used to treat vitiligo with *hundreds more* known in the art. EX1001, 2:49–53, 7:33–8:37; EX2005, ¶¶114–125; EX2082, 1; EX2083, 1. There is also no evidence of any "ineffective compounds." *Idenix*, 941 F.3d at 1164.

PO Resp. 42. Patent Owner's arguments are unpersuasive. Rather, we credit Petitioner's evidence and Dr. Abbas's related testimony showing that the '505 patent lacks descriptive support for "a therapeutically effective amount of an inhibitor of IL-15 or the IL-15 receptor" as recited in claim 1 because of: (1) the ineffective IL-15/IL-15R inhibitors identified by Petitioner in Patent Owner's own documents; (2) the unidentified structural features of the broad categories of potential IL-15/IL-15R inhibitors listed in the specification (e.g., small molecules, peptides, antibodies, or nucleic acids) necessary or sufficient to perform the claimed method; (3) the lack of

information delineating how one of ordinary skill in the art would understand or determine whether any one of the cited individual inhibitors actually meets that functional requirement in the challenged claims; and (4) the unpredictability across the breadth of the claimed genera. *See* Ex. 2013, 2:10–18; Ex. 2014, 2:12–20; Ex. 2015 ¶ 3; Ex. 2025, 2:10–18; Ex. 2078, 267.

Petitioner demonstrates that several compounds identified by Patent Owner as inhibitors are actually ineffective and/or unpredictable in inhibiting IL-15/IL-15R signaling. *See* Pet. 27–39 (citing Ex. 1002 ¶¶ 64–80; Ex. 1014, Abstr., 6; Ex. 1013, Abstr.; Ex. 1004 ¶¶ 43–45; Ex. 1008, 786). For example, contrary to Patent Owner's contentions, soluble IL-15Rα molecules that can inhibit IL-15 signaling also can form complexes with IL-15, which induces a cellular response by *enhancing* IL-15 signaling (rather than inhibiting). Ex. 1047 ¶ 30; Ex. 1046, 256:15–258:4, 258:9–16; Ex. 2005 ¶ 163; Ex. 2079, 1, 5–6, 8. The enhanced IL-15 signaling limits the effectiveness of anti-IL-15 antibodies. *Id.*

Moreover, Petitioner has produced evidence that certain anti-IL-15 antibodies that inhibit IL-15 signaling *in vitro* have been shown to enhance IL-15 signaling, i.e., have the opposite effect, *in vivo*. Ex. 1047 ¶¶ 2–30; Ex. 1054, Abstr. (identifying an IL-15 antibody, DISCO280, with different responses and opposing cellular modes of actions depending on whether it was used *in vitro* or *in vivo*). Additionally, the various compounds identified in the '505 patent do not exhibit a consistent, class-wide effect for vitiligo treatment using IL-15/IL-15R antibodies. *See* Ex. 1001, 7:34–8:37; Ex. 1002 ¶¶ 67–69, 83–87, 91; Tr. 15:26–16:26. To the contrary, the evidence of record suggests that different compounds have widely-varying and unpredictable effects on the different aspects of the pertinent biological

pathways. *See e.g.*, Ex. 1046, 256:15–258:4, 258:9–16; Ex. 2005 ¶ 163; Ex. 2079, 1, 5–6, 8. For example, administration of a particular IL-15 antibody to rhesus macaques was reported to significantly reduce tissue effector memory T cell populations but not recirculating memory T cell populations. *See* Ex. 1013, Abstr.

Furthermore, the '505 patent asserts that the persistence of vitiligo depigmentation requires recirculating memory T cells and that ChMBC7 inhibition depleted human melanocyte antigen pre-melanosome protein (PMEL) T cells (not just memory-phenotype). *See* EX1001, 32:36–67, 33:24–30, 33:48–53, Figs. 6A–6D. As some IL-15/IL-15R antibodies were known to inhibit both tissue-resident memory T cell populations and recirculating memory T cells populations and others were not able to inhibit both, the evidence does not show that a person of ordinary skill in the art would have understood the ChMBC7 antibody as representative of all IL-15/IL15R inhibition pathways. In another example, antibodies to CD122 (a component of the IL-15 receptor within the scope of the claims) have been shown to bind to IL-15R but fail to inhibit trans-presentation of IL-15 or to inhibit IL-15 signaling in certain cell lines. *See* Ex. 1001, 35–48. Thus, if anything, the evidence of record suggests that a person of ordinary skill in the art would understand that different species of the functionally-recited inhibitors will produce widely-varying, sometimes counterintuitive, effects on the different biological pathways. *See* Tr. 14:3–17, 30:9–31:8, 34:12–35:12, 36:9–23; Ex. 1054, Abstr.; Ex. 2013, 2:10–18; Ex. 2079, 1, 5–6, 8.

This evidence of inconsistent and ineffective IL-15/IL-15R inhibitors is persuasive of the written description inquiry here where the '505 patent specification only provides a single working example using an Fc-diminished ChMBC7 mouse antibody to the beta subunit of the IL-15

receptor (i.e., IL-15Rβ) and fails to explain how, beyond ChMBC7, any of the "20 exemplary compounds across nine classes of inhibitors" identified in the specification function or otherwise relate to the recited method of treating vitiligo. *See* Ex. 1001, 7:34–8:37, 33:1–34:45; Resp. 9–10.

In this regard, the facts of this case are comparable to *Juno Therapeutics, Incl. v. Kite Pharma, Inc.*, 10F.4th 1330, 1338–139 (Fed. Cir. 2021) *cert. denied*, 143 S. Ct. 402 (2022), where the Court reversed a jury verdict finding written description where the claim was so broad as to encompass any a single-chain antibody variable fragment ("scFv") for binding any target, provided few details about which scFv could bind to which target antigens, provided only two example (one for each of two targets), and provided insufficient detail to permit an ordinarily skilled artisan to determine how or whether they were representative of the entire genus. Similarly, in the present case, it has not been shown that (1) the Fc-diminished ChMBC7 antibody would have been understood by an ordinarily skilled artisan at the critical time to be representative of the different inhibitor categories identified in the specification (*see* Ex. 1001, 7:34–8:37), and (2) that those categories would have been understood to be representative of the "*hundreds* of other IL-15/IL15R inhibitors . . . known in the art as of April 2017." *See* Resp. 11–12.

We also note Patent Owner's reliance on the *Merck PGR*'s holding and its underlying citation to the *UroPep* I case. Resp. 33. But these cases are distinguishable because in both cases there was persuasive evidence that the claims recited well-known classes of compounds, that were known to perform the function recited in the claimed methods, to target a specific biological pathway that either the petitioner failed to address (*Merck PGR*) or that presented a material issue of fact for resolution by the fact finder

(*UroPep* I). *See Merck*, PGR2021-00036, Paper 10 at 20; *Erfindergemeinschaft UroPep GbR*, 2016 WL 6138124, 15 (E.D. Tex. Oct. 21, 2016) ("*UroPep* I")[5]. As explained above, this is not the case here.

Finally, we are reminded that "a sufficient description of the genus . . . requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus." *Ariad*, 598 F.3d at 1350. "[F]unctional claim language can meet the written description requirement when the art has established a correlation between structure and function." *Id.*

Here, however, the challenged claims are directed to methods using a wide range of different types of compounds purported to be "IL-15/IL-15R inhibitors" that are not part of a known or readily identifiable class, do not target the same biological pathway, do not have any common structural features, and do not appear to always function as inhibitors. *See* Ex. 1018, Abstr., 1575–77, 1579; Ex. 1046, 189:4–19, 191:15–192:15, 193:18–196:22, 198:21–199:21, 197:12–198:19, 200:1–8, 207:11–14, 203:3–10, 207:15–21, 236:12–24; Ex. 1047 ¶¶ 19–23, 56, 63–64, 80–85. Therefore, we find there is neither a representative number of species disclosed, nor a sufficient

[5] *Erfindergemeinschaft UroPep GbR*, 2016 WL 6138124, 15 (E.D. Tex. Oct. 21, 2016) ("*UroPep* I") is a district court order denying defendants' summary judgment motions. *Erfindergemeinschaft UroPep GbR v. Eli Lilly & Co.*, 276 F. Supp. 3d 629 (E.D. Tex. 2017), *aff'd*, 739 F. App'x 643 (Fed. Cir. 2018) ("*UroPep* II") is a district court order denying defendants' motion for JMOL after a jury verdict. Patent Owner relies on both orders in its Response, so we define the cases as *UroPep* I and II in order to prevent confusion. *See* PO Resp. 33–34, 53–54

correlation between structure and function, to demonstrate possession of the functionally-defined genus of compounds administered in the broadly-recited method of treatment.

Accordingly, we determine Petitioner has shown by a preponderance of the evidence that the '505 patent does not provide sufficient written description of the compounds that can be used to carry out the claimed methods—an essential element of every claim.

B. Alleged Lack of Enablement

Petitioner argues claims 1–5 are unpatentable for lack of enablement because the '505 patent does not disclose how to make and use the full scope of treating vitiligo by inhibiting IL-15 or IL-15R across the genus claimed subjects. Pet. 48–63; Reply 3–22. Patent Owner disagrees. PO Resp. 51–73; Sur-reply 11–21. For the reasons discussed below, we find Petitioner has shown that at least one of the challenged claims is more likely than not unpatentable for lack of enablement.

1. Legal Principles

A patent's specification must describe the invention and "the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." 35 U.S.C. § 112(a). If a patent claims an entire class of processes, machines, manufactures, or compositions of matter, the patent's specification must enable a person skilled in the art to make and use the entire class. *Amgen v. Sanofi*, 598 U.S. 594 (May 18, 2023) (the "*Amgen* case") (citing *Holland Furniture Co.* v. *Perkins Glue Co.*, 277 U. S. 245 (1928)). "The more one claims, the more one must enable." *Id.* at 610.

Specifically, the specification must enable the full scope of the invention without undue experimentation. *Wyeth and Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380, 1384 (Fed. Cir. 2013); *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (The enablement requirement asks whether "the specification teach[es] those in the art to make and use the invention without undue experimentation."). In analyzing undue experimentation, we consider factors such as: "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *Wands*, 858 F.2d at 737.

A claim is not enabled where the specification discloses only a starting point for further iterative research in an unpredictable and poorly understood field. *Wyeth*, 720 F.3d at 1386; *Enzo Life Sciences v. Roche Molecular Sys.*, 928 F.3d 1340, 1345-46 (Fed. Cir. 2019) (where claims require both a particular structure and functionality, no enablement where specification fails to teach which of the many embodiments of the broad claims would exhibit that required functionality of being both hybridizable and detectable upon hybridization). This is true even for method claims that are directed to a new use of an existing class of compounds. *Wyeth*, 720 F.3d at 1385.

2. Petitioner's position

Petitioner applies the *Wands* factors to argue that the specification does not enable a person skilled in the art to make and use the claimed invention. *See* Pet. 53–63. First, Petitioner addresses the nature of the invention and state of the art. *Id.* at 53–54. Petitioner asserts that "[t]he

claims involve a complex invention of treating the autoimmune disease vitiligo across a broad genus of subjects . . . using inhibitors of complex and biologically unpredictable cytokine signaling pathways." *Id.* (citing Ex. 1002 ¶ 84; Ex. 1004 ¶ 59).

Second, Petitioner addresses the breadth of the claims. *Id.* at 54–58; Reply 3–4. Petitioner asserts that "claims are extremely broad at least with respect to the (1) multiple genera of inhibitory pathways; (2) multiple genera of structures used for each those inhibitory pathways; and (3) the broad and disparate genus of subjects implicated. Pet. 54–55 (citing Ex. 1002 ¶¶ 33, 85–87, 93; Ex. 1004 ¶¶ 35–36, 57). For example, Petitioner asserts that the claims recite the use of any inhibitor of IL-15 or the IL-15 receptor, including its various subunits. *Id.* at 55. Petitioner asserts that "each of these four sub-genera of inhibition is itself very broad, and inhibiting one subunit in a particular manner is not representative of the effects of inhibiting the other subunits or of inhibiting the same subunit in a different manner." *Id.* (citing Ex. 1002 ¶ 86).

Petitioner further asserts that the "claimed scope also is very broad because it encompasses using not only the few known compounds that are invoked (but never administered) in the specification, but also any other compounds that meet the claims' functional requirements." *Id.* at 56–57 (citing Ex. 1002 ¶¶ 31–33, 87). Petitioner notes that the claim have no limitations for the extent of IL-15/IL-15R inhibition. Reply 4 (citing Ex. 1047 ¶ 51). Petitioner argues that the claims encompass the use of molecules that inhibit IL-15 signaling by as little as 1%, even if such limited inhibition has not been shown to impact vitiligo expression or to meet the "therapeutically effective amount" required by the claims. *Id.* (citing Ex. 1046, 245:8–246:21). Thus, according to Petitioner, the claims

"encompass innumerable distinct inhibitory approaches, including many not yet conceived." *Id.* (citing Pet. 45–46, 56–57; Ex. 1002 ¶ 91).

Third, Petitioner addresses the amount of guidance and working examples in the specification. *Id.* at 59–61. Petitioner contends that the specification provides "sparse guidance" and a single example. *Id.* at 59 (citing Ex. 1002 ¶¶ 35, 62; Ex. 1004 ¶¶ 24–25, 33–34). Petitioner asserts that the single example discloses inhibiting CD122 (IL-2R/IL-15Rβ) with the ChMBC7 antibody, but does not disclose the sequence or structure of ChMBC7 nor the species of CD122 inhibition (IL-15 or IL-2). *Id.* at 59–60 (citing Ex. 1002 ¶¶ 37, 72, 89). According to Petitioner, the specification is a deficient "black box" with an unduly narrow working example directed to a single antibody. Reply 12. Petitioner further asserts that the 20 additional categories of molecules identified in the specification are insufficient, because they were never tested or evaluated to determine if they would produce the same effect as the disclosed antibody and it was not known in the art whether such molecules worked in the same manner. *Id.* at 12–13 (citing Ex. 2007, 93:16–97:25).

Fourth, Petitioner addresses the quantity of experimentation and the unpredictability of the art. Pet. 61–63. Petitioner asserts that "the only way to determine whether other forms of inhibition claimed by the '505 patent would achieve the desired result even in the mouse would be to individually test them" through an iterative, trial-and-error process. *Id.* at 61 (citing Ex. 1002 ¶¶ 79–81, 90–92). Furthermore, Petitioner asserts that "the number of compounds implicated by the claims is so large that it is truly incalculable." *Id.* at 62 (citing Ex. 1002 ¶¶ 83–87).

Petitioner further contends the claims also encompass inhibition of any one of the various types of IL-15 signaling and inhibition of any of the

various versions of the receptor, which provide different results. Reply 4 (citing Pet. 11–12, 26; Ex. 1002 ¶¶ 54–55, 37, 72–77, 86). According to Petitioner, the claims encompass more than a dozen different genera of inhibition, where one inhibitor alone is not representative of the entire genera. *Id.* (citing Ex. 1047 ¶ 61; Ex. 1046, 219:24–222:8). Petitioner relies on the Reply Declaration of Dr. Plott and the deposition testimony of Dr. Damsky to support its position to show that "[e]ven inhibitors of IL-15 or IL-15Rα encompass diverse forms of inhibition having differential effects." Reply 5 (citing Ex. 1047 ¶ 59, 21, 23, 25–26, 35–36, 40, 47; Ex. 1046, 58:5–60:13, 63:2–9, 91:25–93:10, 166:21–24, 168:25–169:5, 207:23–208:13, 208:15–209:22, 210:24–211:6, 212:17–213:3, 214:7–215:4, 216:18–217:3). Thus, Petitioner concludes that determining which compounds would inhibit IL-15/IL-15 was "so complicated and unpredictable, even *years after the critical date*, attempting to determine whether a particular molecule (e.g., an anti-CD122 antibody) was effective for treating vitiligo" was an uncertain and burdensome trial-and-error process. Reply 9 (citing Ex. 1047 ¶ 11).

3. Patent Owner's position

Patent Owner contends the challenged claims are directed to a new method of using of a well-known and well-developed class of inhibitors; a method that is enabled by the specification. Resp. 51. Patent Owner argues that "[w]here novelty is based on the *new use* of known elements, the analysis necessarily focuses on enablement of the *novel use* without regard to unclaimed structures or effects." *Id.* at 52 (citing *Genentech, Inc. v. Novo Nordisk, A/S* 108 F.3d 1361, 1366 (Fed. Cir. 1997) *(*explaining that "a specification need not disclose" what is well-known in the art since "[i]t is the specification, not the knowledge of one skilled in the art, that must

supply the novel aspects of an invention in order to constitute adequate enablement.")). Patent Owner argues that the enablement inquiry should focus on how much direction the patent provides and whether it provides working examples supporting the claimed method of treatment. *Id.* at 28, 52–53.

Patent Owner further likens the present facts to those in *Erfindergemeinschaft UroPep GbR v. Eli Lilly & Co.*, 276 F. Supp. 3d 629 (E.D. Tex. 2017), *aff'd*, 739 F. App'x 643 (Fed. Cir. 2018) ("*UroPep* II"). *Id.* According to Patent Owner, in *UroPep* II, the invention was directed to the use of a group of inhibitory compounds well known in the art . . . in a novel method of treating benign prostatic hyperplasia (BPH). PO Resp. 53–54 (citing 276 F. Supp. 3d at 648). And in *UroPep* II, the court held that the correct inquiry was not whether undue experimentation would be required of an ordinarily skill artisan to make all the members of the inhibitory compound genus, but the novel method of treating BPH. *Id.* Thus, Patent Owner argues that the claimed novel method is the proper focus for our enablement analysis. *Id.* Patent Owner then argues that the '505 patent does not claim novelty in any of the IL-15/IL-15 inhibitory compounds or inhibiting IL-15 signaling per se, but "in fact teaches, including via references incorporated therein, that both IL-15 signaling inhibitors and their various pathways were well-known in the art." *Id.* at 28, 57.

Patent Owner contends the recent Supreme Court decision in *Amgen* is distinguishable from the present case because the claims in *Amgen* were directed to "a novel and undeveloped genus of antibodies that (1) bind to specific amino acid residues on PCSK9, and (2) block PCSK9 from binding to LDL receptors." *Id.* at 54 (citing *Amgen*, 598 U.S. at 602, 610). Patent Owner then asserts that "*Amgen* applied the principle that 'the specification

must enable the full scope of the invention *as defined by its claims*' to hold claims to a novel and undeveloped genus of antibodies non-enabled." *Id.* Patent owner argues "[u]nlike the use of a well-known class as addressed in *UroPep* II, the *Amgen* antibodies themselves were both specifically claimed and the basis of novelty, making their enablement dispositive." *Id.* Patent Owner argues that, when the reasoning in *UroPep* II is applied to a proper analysis of the *Wands* factors, the Petition fails due to the advanced and fully developed state of the art regarding the well-known class of IL-15/IL-15R signaling inhibitors. *Id.* at 60–64.

Patent Owner asserts that only routine experimentation is required to practice the claimed method given the '505 patent specification, "the hundreds of IL-15 signaling inhibitors [that] were known in the art, and given the predictability of inhibiting the well-studied IL-15 signaling pathway known from the treatment of other autoimmune diseases." Resp. 65 (citing Ex. 2005 ¶¶ 161–163, 171–180). Patent Owner acknowledges the unpredictable state of the art, but argues that "the potential for unspecified disparate effects" noted by Petitioner "implicates balances of safety and efficacy, optimization, and FDA requirements—but not enablement." *Id.* at 66 (citing *United Therapeutics*, 74 F.4th at 1369); Tr. 38:9–39:21.

Patent Owner contends that the single working example of the '505 patent specification is sufficient because it was

> it was routine to rely on PoC models to expect common therapeutic effects among inhibitors of a common mechanism. §II.A.4. The *Harris* mouse model was (and remains) the primary model of vitiligo and has been recognized as representative of human disease pathology (§II.B.2), and Petitioner itself relied on the '505 patent's disclosure to project efficacy of a different inhibitor (FB-102) in treating vitiligo (§IV.C). EX2005, ¶ 168.

Id. at 68. Patent Owner asserts that "it is immaterial whether the effects of cytokine blocking could differ to some degree between mice and humans." *Id.* at 72 (citing Pet. 58). According to Patent Owner, its position is bolstered by "decades of research on cytokine inhibition and has led to therapeutic treatment of multiple autoimmune diseases." *Id.* Patent Owner then cites to the deposition testimony of Dr. Abbas, who testified as follows:

> Q. Was it common . . . as of April 2017 to expect that species that would antagonize IL-15 signaling would be useful in diseases -- autoimmune diseases that had been identified as having an IL-15 mechanism?
>
> THE WITNESS: It's reasonable, but it depends on how the mechanism was identified.

Ex. 2007, 74:19–75:10. Patent Owner, thus, concludes that the '505 patent's proof of concept studies with ChMBC7 is "representative" and enabling of treating vitiligo with inhibitors of IL-15 or IL-15R as claimed. PO Resp. 72.

4. Analysis

Claims 1 and 3–5 of the '505 patent recite methods for treating vitiligo using the entire class of IL-15 inhibitors or the entire class of IL-15 receptor inhibitors. *See* Ex. 1001, 44:12–26. Claim 2 limit the inhibitors of claim 1 to "a small molecule inhibitor, an antibody, a peptide inhibitor, or an inhibitory nucleic acid targeting IL-15 or the IL-15 receptor." *Id.* at 44:18–20. Thus, the inhibitor of claim 2 is purportedly narrower than that of claim 1, but still encompasses vast swaths of inhibitory molecules, *i.e.*, small molecules, antibodies, peptides, and nucleic acids. The enablement of such broad "genus claims" was addressed recently by the Supreme Court in the *Amgen* case. *See* 598 U.S. at 610.

In the *Amgen* case, the patents were directed to treating patients with high LDL cholesterol using antibodies that inhibit PCSK9—a naturally occurring protein that binds to and degrades LDL receptors responsible for extracting LDL cholesterol from the blood stream. *Id.* at 601. The patents claimed an "the entire genus" of antibodies that (1) "bind to specific amino acid residues on PCSK9," and (2) "block PCSK9 from binding to [LDL receptors]." *Id.* at 602. The patent specifications described the relevant antibody by its unique amino acid sequence and specifically identified the amino acid sequences of 26 antibodies that performed the two claimed functions. *Id.* at 602–603. The specification also described two methods for making other antibodies that performed the claimed binding and blocking functions. *Id.* at 603.

The Court found that the 26 specifically-identified antibodies were enabled, but that the broader scope of the claims beyond those specifically disclosed exemplary antibodies was not. *Id.* at 614–615.

The facts of the present case are similar to the *Amgen* case. Here, Patent Owner attempts to claim an entire class of treatment based on the function of two classes of inhibitors: inhibitors of IL-15 and inhibitors of the IL-15 receptor. As the Supreme Court in the *Amgen* case stated, "the more a party claims, the broader the monopoly it demands, the more it must enable." *Id.* at 613. Similarly, here the challenged claims encompass a large variety and number of species that could potentially be used to treat vitiligo.

Indeed, the inhibitors recited here are even broader than the genus of antibodies at issue in *Amgen* because neither the claims nor the specification provide any structural requirement for the claimed inhibitor. Indeed, claim 2 expressly states that the inhibitor is not limited to just antibodies, but also

encompasses small molecule, peptide, and nucleic acid inhibitors.[6] *See also* Ex. 1001, 7:34–8:37 (listing inhibitors such as antibodies, benzoic acid derivatives, and other small molecules). Nor does the '505 patent explain how these inhibitors may be related structurally so that such inhibitors could be identified without significant experimentation. For example, the specification here does not provide (1) the sequence or structure that corresponds to the exemplary inhibitor, (2) a purported binding site on the exemplary inhibitor that would correspond to other inhibitors that fall within the scope of the claims, or (3) how the exemplary inhibitor binding to/blocking of IL-15 receptor is representative of the binding/blocking by the 20 inhibitors listed in the specification. *See* Ex. 1001, 7:34–8:37.

To prove that a claim is invalid for lack of enablement, Petitioner "must show that a person of ordinary skill in the art at the critical time would not be able to practice the claimed invention without 'undue experimentation.'" *Alcon*, 745 F.3d at 1188 (quoting *In re Wands*, 858 F.2d 731, 736–37 (Fed. Cir. 1988)). That some experimentation is necessary does not mean that a claim is not enabled. *In re Wands*, 858 F.2d at 736–37. The "key word is 'undue,' not experimentation." *Id.*; *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1360 (Fed. Cir. 1998) (quoting *PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1564 (Fed. Cir. 1996); *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 959 F.3d 1091, 1100 (Fed. Cir. 2020)).

The Supreme Court, however, reiterated in *Amgen* that:

> If a patent claims an entire class of processes, machines, manufactures, or compositions of matter, the patent's

[6] Claim differentiation suggests that the inhibitor of claim 1 is even broader than the classes of molecules recited in dependent claim 2.

> specification must enable a person skilled in the art to make and use the entire class. In other words, the specification must enable the full scope of the invention as defined by its claims. The more one claims, the more one must enable.

598 U.S. at 610. A "specification may call for a reasonable amount of experimentation to make and use a patented invention. What is reasonable in any case will depend on the nature of the invention and the underlying art." *Id.* at 613. But the person of ordinary skill in the art cannot be left with merely "a hunting license" or obligated to engage in "painstaking experimentation" or "trial and error" to "see what works." *Id.* at 614.

Patent Owner argues that "the IL-15/IL-15R inhibitors disclosed in the specification were known in the art and "share the common 'general quality' of inhibiting a pathway known to be relevant to and having 'particular fitness for the particular purposes' of (*id.*) treating certain autoimmune diseases by blocking IL-15 signaling." Sur-reply 14 (citing Ex. 1011, 22; Ex. 2013, 3; Ex. 2017, Abstr.; Ex. 2024, 17; Ex. 2025, 2–3, 6; Ex. 2027, 4; Ex. 2028, 9; Ex. 2029, 4; Ex. 2031, 23; Ex. 2118, 53:22–54:9; Ex. 1018, 1; Ex. 2005, ¶¶ 52–63, 80–83, 130; Ex. 1046, 231:20–25). Patent Owner's argument is unavailing, however, because the record shows that different IL-15-specific inhibitors may operate in different ways that may result in differential effects, some of which may not include inhibition at all. *See* Ex. 1047 ¶¶21, 23, 40, 71; Ex. 1018, Abstr., 1576, 1579; Ex. 2013, 4:1–8; Ex. 2014, 4:9–15; Ex. 2015 ¶ 22; Ex. 2025, 4:34–5:2; Ex. 1046, 166:21–24, 168:25–169:5, 207:23–209:22, 210:4–17, 210:24–211:6; Ex. 1011, 1:67–2:4; Ex. 2005 ¶¶ 116, 134.

Thus, we find that the record supports Drs. Abbas and Plott's testimony, which we credit, that a person of ordinary skill in the art would be forced to hunt down and test every compound through painstaking

experimentation to determine if it works and falls within the claim scope. Ex. 1002 ¶¶ 85–90, 92; Ex. 1047 ¶ 53 (Dr. Plott's testimony that the "specification of the '505 patent is essentially a black box (so far as which aspects of IL-15 signaling it inhibits and how it operates), leaving the reader to guess through trial and error which molecules might operate similarly to ChMBC7 and which do not."); Ex. 1004 ¶ 61 (Dr. Plott's testimony that "from the perspective of a clinician, the amount of experimentation required would be extremely burdensome and success would be speculative."); Ex. 2007, 93:16–97:25, 38:208; Ex. 1046, 234:20–236:11. This is due to the fact that the claims (without limit) encompass any inhibition of any one of the various types of IL-15 signaling and various versions of the receptor, and even implicate other compounds that act on different targets but which inhibit the IL-15 signaling pathway. *See* Ex. 1047 ¶¶ 10, 53, 68; Ex. 2005 ¶ 71; Ex. 1046, 254:4–255:11, 158:12–160:20. The evidence has shown that IL-15/IL-15R inhibition is complicated and unpredictable, with some inhibitors also capable of *enhancing* forms of IL-15 signaling rather than preventing it. *See* Ex. 1047 ¶¶ 10, 25–26, 53; Ex. 2013, 2:10–18; Ex. 2014, 2:12–20; Ex. 2015 ¶ 3; Ex. 2025, 2:10–18; Ex. 2078, 267.

Additionally, unlike *Amgen* where the specification provided at least two purported methods for making the claimed antibodies, the '505 patent does not provide a single disclosure on how to make a claimed inhibitor. The specification's listing of nine classes and 20 individual compounds that could be used as an inhibitor of IL-15 or the IL-15 receptor (with references where information about each inhibitor may be located) is insufficient because these references do not explain fully how to make every inhibitor of IL-15 or the IL-15 receptor or whether every version of a compound falls within the scope of the limitless claims. *See* Ex. 1001, 7:34–8:4; Ex. 2016;

Ex. 2017; Ex. 2018; Ex. 2022, 28 ("There is also a knowledge gap in selecting the best approaches for finding inhibitors"); Ex. 2023 (directed to IL-2 signaling). We credit the testimony of Dr. Abbas, who explains that vitiligo treatment using cytokine inhibitors was nascent, complex, and unpredictable. Ex. 1002 ¶¶ 83–85. We also credit Dr. Plott's testimony that "[t]here was no consensus among practitioners that there was a class wide property of IL-15 and IL-15 receptor inhibitors for treating vitiligo" and "[t]he '505 patent merely identifies the result that is desired (treating vitiligo with IL-15 or IL-15 receptor inhibitors) but does not guide the POSA as to how to practice this invention." Ex. 1004 ¶¶ 57–58. Accordingly, the inhibitors recited here are both broader than the class of antibodies recited in *Amgen* and there is less disclosure as to how to make them. This runs contrary to the Supreme Court's instruction in *Amgen* that "[t]he more one claims, the more one must enable." 598 U.S. at 610.

Patent Owner attempts to avoid the "how to make" requirement by stating that the claims are directed towards a method of treatment with the specification providing one example of treatment in the specification. *See* Ex. 1001, 33:1–34:45. Patent Owner asserts that similar to *UroPep* II, here "the invention was to use a group of compounds well known in the art . . . in a novel method of treating" vitiligo. Sur-Reply 12 (citing *UroPep* II, 276 F. Supp. 3d at 648). According to Patent Owner, "[b]ecause the prior art disclosed hundreds of IL-15/IL-15R inhibitors . . . , § 112 support for the novel treatment method does not turn on the size of the inhibitor genus disclosed in the patent." *Id.* at 13 (citing *UroPep* II, 276 F. Supp. 3d at 649; *Merck Sharp & Dohme Corp. v. Genentech, Inc.*, PGR2021-00036, Paper 10

at 20 (PTAB July 24, 2021) (relevant inquiry is the challenged method claims and not the compounds themselves))[7].

Patent Owner's contentions are unavailing because the '505 patent claims methods that use an unlimited range of different types of compounds purported to be "IL-15/IL-15R inhibitors" that are not part of a known or readily identifiable class, do not target the same biological pathway, do not have any common structural features, and do not appear to always function as inhibitors. *See* Ex. 1018, Abstr., 1575–77, 1579; Ex. 1046, 189:4–19, 191:15–192:15, 193:18–196:22, 198:21–199:21, 197:12–198:19, 200:1–8, 207:11–14, 203:3–10, 207:15–21, 236:12–24; Ex. 1047 ¶¶ 19–23, 56, 63–64, 80–85. As noted previously regarding the written description challenge, Patent Owner relies on *UroPep* I. But *UroPep* I is inapplicable because in that case there was evidence of a well-known class of compounds, that were known to perform the function recited in the claimed methods, to target a specific biological pathway presented a material issue of fact for resolution by the fact finder. *See Erfindergemeinschaft UroPep GbR*, 2016 WL 6138124, 15 (E.D. Tex. Oct. 21, 2016) ("*UroPep* I"). Such facts are not supported on the record here.

Rather, this case is more similar to *Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380, 1384–85 (Fed. Cir. 2013). In *Wyeth*, the Court found method claims purporting to cover the new use of known compounds as well as "any structural analog" of those compounds to lack enablement. Specifically, the Court found that practicing the full scope of the claims

[7] Patent Owner's citation to a non-precedential Board decision in *Merck Sharp & Dohme Corp. v. Genentech, Inc.*, PGR2021-00036, Paper 10 at 20 (PTAB July 24, 2021) is unpersuasive because that decision issued prior to the Supreme Court's guidance in *Amgen*.

would require more than routine experimentation because a person of ordinary skill in the art could evaluate claimed function only by "synthesizing and screening each" compound. *Id.*

We also find that this case similar to *AstraZeneca v. Mylan* 2022. 2022 WL 16857400 (N.D. W.Va. Nov. 9, 2022). While that decision is not binding, the facts and the court's reasoning are apropos here. In *AstraZeneca*, the evidence showed that "[d]ue to the unpredictability of the art and lack of prior art to inform a POSA about the interactions between the ingredients, a POSA would have to test an astronomical number of formulations." 2022 WL 16857400, at *7. That was because the formulation ingredients "interact in interrelated and unpredictable ways." *Id.* at *13. As such, *AstraZeneca* demonstrates the same fatal flaw to practicing the full scope of the claims that was at issue in the Federal Circuit's *Idenix* case, the Supreme Court's *Amgen* case, and other precedent, i.e., a person of ordinary skill in the art at the critical time would have had to make and test a multitude of compounds or structures within structurally unlimited claims to determine whether it would work. *Amgen*, 598 U.S. at 615 (specification "leave[s] a person of ordinary skill in the art to 'random trial-and-error discovery' "); *Idenix Pharm. LLC v. Gilead Sci. Inc.*, 941 F.3d 1149, 1161 (Fed. Cir. 2019)(a person of ordinary skill in the art had to "make[ ] and test[ ]" "each" of unlimited set of structures); *Pharm. Res., Inc. v. Roxane Labs., Inc*., 253 F. App;x 26, 30 (Fed. Cir. 2007) ("a large part of the asserted claims' scope is directed toward inoperative embodiments," and experiments "evidence[d] numerous unsuccessful attempts . . . to practice subject matter within the scope of the claims").

Patent Owner assertions that because the claims are directed to a method of use, the '505 patent does not need to disclose information about

what inhibitors fall within the broad genera or how the inhibitors function are unavailing. The claims specifically recite "an inhibitor of IL-15 or the IL-15 receptor," and Patent Owner confirms the claims require the function of inhibiting IL-15. *See id.* at 44:15–16; Tr. 42:8–12. Therefore, because the challenged claims recite the administration of a functionally-defined genus of compounds, the specification must provide some guidance regarding structure for a recited element of the claim so that a person of ordinary skill is not left with "painstaking experimentation to see what works." *Amgen*, at 614.

Accordingly, we find Petitioner has shown by a preponderance of the evidence that claims 1–5 are unpatentable for lack of enablement.

C. Alleged Obviousness of Claims 1–5 in view of Harris and Xing

Petitioner argues claims 1–5 are unpatentable as obvious under 35 U.S.C. § 103 in view of Harris and Xing. Pet. 64–74. Patent Owner disagrees. PO Resp. 73–86. Because we find the challenged claims unpatentable for failing to provide the required written description and enablement under 35 U.S.C. § 112(a), we do not reach this challenged as proffered by Petitioner.

IV. MOTION TO EXCLUDE

Petitioner filed a Motion to Exclude Evidence. Paper 34 ("MTE"). Specifically, Petitioner moves to exclude the Declaration of Dr. Damsky (Ex. 2005), the expert testimony relied on in Patent Owner's Response. MTE 1–2. Petitioner, as the party moving to exclude evidence, bears the burden of proving that it is entitled to the relief requested, namely, that the material sought to be excluded is inadmissible under the Federal Rules of Evidence. *See* 37 C.F.R. §§ 42.20(c), 42.62(a). For the reasons explained below, Petitioner has not met that burden. Thus, Petitioner's MTE is denied.

Petitioner contends Dr. Damsky was not a person of ordinary skill in the art at the critical time, so his testimony is irrelevant and unreliable. MTE 1–2. According to Petitioner, Dr. Damsky's "study of 'basic immunology' during his fellowship completed in 2023 is all *post-critical date* experience. MTE 2 (citing Ex. 2005 ¶ 6; Ex. 2006, 1; Ex. 1046, 128:14–129:16). Petitioner further argues that Dr. Damsky "has no publications providing direct research on vitiligo and no pre-critical date publications doing direct research on IL-15 or IL-2." MTE 2–3 (citing Ex. 1046, 134:4–10, 136:20–137:2, 137:13–15).

Petitioner then contends Dr. Damsky is not reliable because he does not "fully disclosing his relationship to the inventors and the real parties-in-interest." MTE 3–4. According to Petitioner, Dr. Damsky's relationship with the inventors and real parties-in-interest means he may have a conflict of interest to the point where his "insider status" may have infected "his testimony with access to inside information that does not reflect the knowledge of a" person of ordinary skill in the art at the critical time. *Id.* at 4 (citing *Refac Int'l, Ltd. v. Lotus Dev. Corp.*, 81 F.3d 1576, 1582 (Fed. Cir. 1996); *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1188-89 (Fed. Cir. 2006); *Sanders v. Mosaic Co.*, 418 F. App'x 914, 919 (Fed. Cir. 2011).

Patent Owner opposes Petitioner's MTE. Paper 37 (Patent Owner's Opposition to MTE, "Opp."). Patent Owner contends that Dr. Damsky's Declaration is admissible because Dr. Damsky was person of ordinary skill in the art at the critical time, he began his research into cytokine signaling pathways prior to the critical date, and began treating patients with vitiligo prior to the critical date. Opp. 2, 6–10; *see* Tr. 49:4–50:10. According to Patent Owner, Dr. Damsky's substantive testimony rests on admissible evidence of record. *Id.* at 3.

Patent Owner further contends Dr. Damsky fully disclosed his prior relationship to the inventors and real parties-in-interest in his CV. Opp. 3. (citing Ex. 2006, 3), 10–13. Patent Owner argues that "the professional interactions on which Petitioner relies only confirm that he is a sought-after and credible expert, *not* an allegedly biased insider." *Id.* at 3. Patent Owner then argues that Petitioner's MTE is improper because it goes to the weight of the evidence, which should be found only in the briefs and not a motion to exclude. *Id.* at 4–5.

We agree with Patent Owner that Petitioner's position amounts to a disagreement with Dr. Damsky's reliability and goes to the weight that should be accorded his testimony and not the admissibility of that testimony. Regarding Petitioner's other arguments, we note first that we do not require a perfect match between an expert's experience and the relevant field. *See* Patent Trial & Appeal Board Consolidated Trial Practice Guide November 2019 at 34 (citing *SEB S.A. v. Montgomery Ward & Co.*, 594 F.3d 1360, 1373 (Fed. Cir. 2010)). Second, our reviewing court has held that a person need not be a person of ordinary skill in the art to testify as an expert under Federal Rule of Evidence 702, but rather must be "qualified in the pertinent art." *See Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1363–64 (Fed. Cir. 2008).

Accordingly, we deny Petitioner's motion to exclude the Declaration of Dr. Damsky (Ex. 2005).

V. CONCLUSION

After reviewing the entire record and weighing evidence offered by both parties, we determine that Petitioner has demonstrated by a preponderance of

the evidence that claims 1–5 of the '505 patent are unpatentable for lack of written description and enablement.[8]

In summary:

Claim(s)	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–5	112(a)	Written description	1–5	
1–5	112(a)	Enablement	1–5	
1–5	103	Harris, Xing[9]		
Overall Outcome			1–5	

VI. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner has demonstrated by a preponderance of the evidence that claims 1–5 of the '505 patent are unpatentable for lack of written description and lack of enablement under 35 U.S.C. § 112(a); and

FURTHER ORDERED that Patent Owner's Motion to Exclude Exhibit 2005 is denied;

[8] 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), (b)(2).

[9] We do not reach the challenge of claims 1–5 as allegedly being obvious over the combined teachings of Harris and Xing, because we have found the claims unpatentable for lack of written description and enablement.

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

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