

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NOVARTIS PHARMACEUTICALS CORPORATION,
Petitioner,

v.

THE REGENTS OF THE UNIVERSITY OF MICHIGAN and
UNIVERSITY OF SOUTH FLORIDA,
Patent Owners.

Case IPR2023-01346
U.S. Patent No. 10,633,344

PATENT OWNERS' SUR-REPLY

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LIST OF EXHIBITS

Exhibit Number	Description
2001	Declaration of Taylor Burgener in support of Motion for <i>Pro Hac Vice</i> Admission
2002	Declaration of Jacqueline T. Moran, Ph.D. in support of Motion for <i>Pro Hac Vice</i> Admission
2003	RESERVED
2004	RESERVED
2005	Margaret C. Etter, “ <i>Encoding and Decoding Hydrogen-Bond Patterns of Organic Compounds</i> ,” Acc. Chem. Res. 1990, 23, 120-126 (“Etter Rules”)
2006	Peterson et al., “ <i>Iterative High-Throughput Polymorphism Studies on Acetaminophen and an Experimentally Derived Structure for Form III</i> ,”” J. Am. Chem. Soc., 2002, 124, 10958-10959 (“Peterson”)
2007	Walsh et al., “ <i>Crystal Engineering of the Composition of Pharmaceutical Phases</i> ”, The Royal Society of Chemistry Chem. Commun., 2003, 186–187 (“Walsh”)
2008	Remenar et al., “ <i>Crystal Engineering of Novel Cocrystals of a Triazole Drug with 1,4-Dicarboxylic Acids</i> ”, J. Am. Chem. Soc., 2003, 125, 8456-8457 (“Remenar”)
2009	Yusov et al., “ <i>Hydrogen Bonded Frameworks: Smart Materials Used Smartly</i> ,” Mol. Syst. Des. Eng., 2021, 6, 756-778 (“Yusov”)
2010	Etter and MacDonald, et al., “ <i>Graph-Set Analysis of Hydrogen-Bond Patterns in Organic Crystals</i> ,”” Acta Cryst., . (1990,). B46, 256-262-266 (“Etter 1990”)
2011	Morissette et al., “ <i>High-Throughput Crystallization: Polymorphs, Salts, Co-Crystals and Solvates of Pharmaceutical Solids</i> , Advanced Drug Delivery Reviews, 2004, 56, 275-300 (“Morissette”)
2012	<i>Guidance for Industry Q3C—Tables and Lists</i> , Food and Drug Administration, November 2003 (“HHS Guidance 2003”)

2013	<i>Guidance for Industry Q3C Impurities: Residual Solvents</i> , Food and Drug Administration, December 1997 (“HHS Guidance 1997”)
2014	Declaration of Michael D. Ward, Ph.D.
2015	Deposition Transcript of Leah Appel, Ph.D. May 8, 2024
2016	Deposition Transcript of Robin D. Rogers, Ph.D. May 23, 2024
2017	Second Deposition Transcript of Robin D. Rogers, Ph.D. with Errata. October 2, 2024

The Regents of the University of Michigan and University of South Florida (“Patent Owners”) submit this Patent Owners’ Sur-Reply to Petitioner’s Reply to Patent Owners’ Response to Petition.

I. INTRODUCTION

Petitioner relies on a heightened standard to satisfy the written description and enablement requirements. Petitioner would require the specification to recite basic parameters and variables both parties agree a POSITA would have known in order to meet the Section 112 requirements. But that is not the law. As both the Patent Office and Federal Circuit recognize, what a POSITA already knows need not be disclosed in the patent’s specification. MPEP 2163 (“What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail.”); *see also Streck, Inc. v. Rsch. & Diagnostic Sys.*, 665 F.3d 1269, 1288 (Fed. Cir. 2012) (“It is well-established, however, that a specification need not disclose what is well-known in the art.”).

A POSITA would bring a high level of skill including knowledge of hydrogen bonding, pharmaceutical formulation, and high-throughput screening. With this high level of skill, a POSITA would readily ascertain that the inventors were in possession of the claimed invention. Similarly, the high level of skill in the art, the number of working examples, and the amount of direction and guidance provided in the ’956 Application/’344 Patent, demonstrate that a POSITA would be

able to make and use the full scope of the claimed invention without undue experimentation.

In short, Petitioner fails to prove that the '344 Patent is not entitled to the priority filing date of the '956 Application. Given that Petitioner focuses on an alleged 2014 priority date and only asserts prior art that was available after 2003, all grounds must fail. The patentability of the Challenged Claims should, therefore, be confirmed.

II. PETITIONER REQUIRES AN ENHANCED STANDARD OF WRITTEN DESCRIPTION AND ENABLEMENT

Petitioner requires an encyclopedic recitation of what a person of ordinary skill in the art would know in the specification – a requirement that is neither required nor preferred. A POSITA would bring their high level of education and training to the table in areas including hydrogen bonding, pharmaceutical formulation, and high-throughput screening. A POSITA would not need a treatise on these topics in the specification. Instead, a POSITA reading the specification would understand that the inventors were in possession of the claimed invention and would also understand how to make and use the claimed invention.

A. Hydrogen Bonding

Petitioner does not dispute that a POSITA would know Etter's rules for hydrogen bonding. Indeed, Dr. Rogers agrees that Etter's rules "were important in the early generation of the field called crystal engineering" which included the

1990s and early 2000s. EX2017 at 24:4-19. But Petitioner faults the inventors for not including the rules and their application in the specification. *See* Reply at 6 (“But the ’956 application nowhere discusses Etter’s ‘rules’ or how to apply them to predict co-crystal formation.”) The law does not require reciting what a POSITA would already know in the specification – to the contrary, it is *discouraged* to make a specification a treatise of what a POSITA would bring to the table already. As the MPEP states, “What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail.” MPEP 2163; *see also Streck*, 665 F.3d at 1288 (“It is well-established, however, that a specification need not disclose what is well-known in the art.”); *Koito Mfg. Co. v. Turn-Key Tech, LLC*, 381 F.3d 1142, 1156 (Fed. Cir. 2004) (“This Court has repeatedly explained that a patent applicant does not need to include in the specification that which is already known to and available to one of ordinary skill in the art.”); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986) (“Furthermore, a patent need not teach, and preferably omits, what is well known in the art.”).

Petitioner alleges that “numerous” examples do not follow Etter’s “rules.” Reply at 7. But Petitioner’s examples demonstrate that Etter’s rules do, in fact, work. Looking first at Vishweshwar (EX1082), while it discloses a single example that did not follow Etter’s rules, it also discloses five co-crystals in which

“[h]ydrogen bonding in these five structures obeys hierarchy rules.” Vishweshwar (EX1082) at 7. Similarly, Sharma (EX1081) states, “the crystal structure of 1:1 donor-acceptor complex of 3,5-dinitrobenzoic acid and 4-(*N,N*-dimethylamino) benzoic acid contains the uncommon O-H . . . O hydrogen-bonded carboxy homodimers rather than the heterodimers found in nine other related complexes.” Sharma (EX1081) at 1.

Dr. Rogers suggests that Dr. Etter’s rules are to be applied retrospectively, that they cannot be used to predict whether a crystal structure will form or not. EX2017 at 19:19-22:8. However, the very art that Dr. Rogers cites suggests that a POSITA would expect, i.e., have a strong belief that something will happen or be the case in the future, whether certain bonds will form. *See* Aakeroy (EX1025) at 6 (stating “A similar classification of the three polymorphs of 2 reveals that the *expected* intermolecular amine···nitro hydrogen bond is present in all three forms.”) (emphasis added); *see also* Vishweshwar (EX1068) at 2 (“These five acids afford the *expected* 1:2 complex of diacid and IN stabilized by acid-pyridine VI and amide-amide II hydrogen bonds (Scheme 2 a).”) (emphasis added); Sharma (EX1081) at 3 (“Inspection of the carboxy dimer motif in these ten structures shows that while complexes 2-10 contain the ‘expected’ heterodimer, the crystal structure of 1 contains dinitrobenzoic and dimethylaminobenzoic homodimers (Fig. 2).”); Vishweshwar (EX1082) at 7 (“Five cocrystals of diacid•IN with 1:2

stoichiometry are isolated and characterized by XRD. Hydrogen bonding in these five structures obeys hierarchy rules.”) Thus, contrary to Petitioner’s assertions otherwise, a POSITA would be able to use Etter’s rules to predict and expect the formation of the claimed co-crystals.

B. Pharmaceutical Formulation

Petitioner wrongly argues that Patent Owners’ formulation argument fails. Reply at 8. This argument ignores Figure 24 of the ’344 patent completely. The first step of Figure 24 is to “Evaluative Active Pharmaceutical Ingredient (API).” See EX1001 at Fig. 24. As Dr. Rogers repeatedly emphasized, see EX1002 at ¶126 and EX2016 at 31:2-8, the POSITA has a high level of education and training, including training in the “formulation of pharmaceutical compositions.” Contrary to Petitioner’s argument, a POSITA, as part of the pre-formulation work, “would have already tested and understood the solubility parameters of the API and any suitable co-formers, the types of available solvents and co-formers appropriate for pharmaceutical use, and the solvent(s) and co-former(s) in which the API and co-former prospects would or would not be soluble.” POR at 8-9. The ’344 patent need not, therefore, delineate each and every step of the “pre-formulation” work that the Petitioner identifies is missing – a POSITA would bring that education, training, and knowledge to the table.

C. High-Throughput Screening

Petitioner's first point is that "neither HTS nor its application to co-crystals is mentioned in the specification." Reply at 10. Nor does it have to be if it was within the POSITA's knowledge. *See* MPEP 2163; *see also Hybritech*, 802 F.2d at 1384; *Streck*, 665 F.3d at 1288. As Dr. Ward put forward, high-throughput screening for polymorphs was well-known as of the priority date, and a POSITA would apply the same principles for high-throughput screening of polymorphs to high-throughput screening for crystallization. *See* EX2014 at ¶¶48-49. Dr. Rogers agreed that high-throughput screen of polymorphs was known. EX2017 at 58:6-14.

Petitioner then suggests that "the use of HTS was far from straightforward," citing a laundry list of parameters to conduct these experiments. Reply at 10-11. Yet Petitioner again ignores the high level of skill in the art and its own definition of a POSITA that includes "experience preparing multiple-component crystalline solids *and evaluating their single crystal structures*." EX1002 at ¶19 (emphasis added). "Evaluating their single crystal structures" would include single-crystal X-ray diffraction, a technique known to a POSITA. EX2014 at ¶23 (reciting the definition of a POSITA, including that the skilled artisan has experience "experience preparing multiple-component crystalline solids and evaluating their single crystal structures"). Even if single-crystal X-ray diffraction would have

been a “time-intensive” tasks as Petitioner alleges, that does not equate to undue experimentation since a POSITA would know how to go about conducting the experiments.

Petitioner further strains reasonableness when they cite to Dr. Rogers’ opinion that “samples produced by HTS are unlikely to qualify” for single-crystal X-ray diffraction. Reply at 11. Dr. Rogers suggests that “in situations where a single crystal resulted but it was not suitable for single crystal X-ray diffraction analysis” – so a scenario where not only HTS failed but also SCXRD failed. EX1072 at ¶56. Then and only then, would a POSITA have to undergo the additional step of growing a suitable single crystal before conducting SCXRD. And Dr. Rogers again strains reasonableness when he relies on the “days, weeks, months, and, in some cases, even years to prepare for one API and co-former combination having a specific stoichiometric ratio.” EX1072 at ¶56. Not only does Dr. Rogers fail to cite any examples where it allegedly took years to create a co-crystal falling under the scope of the claims, but he fails to articulate any reason why a POSITA would continue down such a fruitless path.

III. THE ’956 APPLICATION HAS WRITTEN DESCRIPTION SUPPORT FOR THE FULL SCOPE OF THE CLAIMED CO-CRYSTALS

The ’956 Application has written description support for the full scope of the claimed co-crystals. Petitioner ignores the high level of education and training of a

POSITA when analyzing whether the inventors were in possession of the claimed invention. As discussed in Patent Owners' response, the "possession" inquiry of written description is not limited to the "four corners of the specification," rather, it is viewed objectively "from the perspective of a person of ordinary skill in the art." *Ariad Pharms. Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc); *see also Falkner v. Inglis*, 448 F.3d 1347, 1365 (Fed. Cir. 2006) (A "patent need not teach, and preferably omits, what is well known in the art"); *Capon v. Eshar*, 418 F.3d 1349, 1358 (Fed. Cir. 2005) ("The 'written description' requirement must be applied in the context of the particular invention and the state of the knowledge."); *see also Zoltek Corp. v. United States*, 815 F.3d 1302, 1308 (Fed. Cir. 2016) ("The written description 'need not include information that is already known and available to the experienced public.'") (citing *Space Sys./Loral, Inc. v. Lockheed Martin Corp.*, 405 F.3d 985, 987 (Fed. Cir. 2005)); *Bos. Sci. Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1366 (Fed. Cir. 2011) ("Because the specification is viewed from the perspective of one of skill, in some circumstances, a patentee may rely on information that is 'well-known in the art' for purposes of meeting the written description requirement.").

Petitioner's attempts to distinguish these cases are to no avail, given that Petitioner ignores a POSITA's extensive knowledge of hydrogen bonding and pharmaceutical formulation, *see supra* at Sections II.A-II.B, all of which were not

required to be articulated in detail in specification for the application to have sufficient written description support. *See Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049, 1064 (Fed. Cir. 2020) (finding that a POSITA's knowledge of an entire amino acid sequence from material outside the specification still supported the conclusion that the inventors were in possession of the claimed protein); *see also Biogen Int'l GmbH v. Mylan Pharms. Inc.*, 28 F.4th 1194, 1202 (Fed. Cir. 2022) (“[B]ecause the written description inquiry is conducted from the perspective of a person of ordinary skill in the art, extrinsic evidence regarding how a person of ordinary skill would understand what is disclosed in the patent specification can, at times, be relevant. *See, e.g., Forest Lab 'ys, LLC v. Sigmapharm Lab 'ys, LLC*, 918 F.3d 928, 937-38 (Fed. Cir. 2019) (affirming sufficient written description based on expert testimony about how a specification's disclosure would have been understood in view of what was known in the art); *Space Sys./Loral, Inc. v. Lockheed Martin Corp.*, 405 F.3d 985, 988-90 (Fed. Cir. 2005) (considering expert testimony regarding how the disclosure of the patent specification would have been interpreted by a skilled artisan).”).

Petitioner poses the rhetorical question “how does a POSA know which of the large genus of co-formers will form co-crystals with any given API(s) in the large genus of APIs?” Reply at 13. As supported by Patent Owners' expert, Dr. Ward, a POSITA in 2003 would have an understanding of hydrogen bonding and,

therefore, understand which APIs and co-formers were likely to form a co-crystal. For example, the POSITA would have: (1) an understanding of the likelihood of certain functional groups forming supramolecular synthons; (2) an understanding of a ranking of certain functional groups to form supramolecular synthons in the event multiple hydrogen bonding groups were present; and (3) sufficient working knowledge of whether hydrogen bonds between the API and some collection of co-formers were likely and, in the event of multiple potential synthons, the POSITA would have had a working knowledge of which ones would be preferred, even though other factors could impact synthon formation. *See* EX2014 at ¶¶54-55.

Petitioner further suggests that Patent Owners failed to identify any structural features common to APIs and co-formers that “enable a POSA to reasonably predict which ones would form a claimed synthon or co-crystal (and thus meet the functional limitation of forming a co-crystal).” Reply at 14. Not only is “enable[ment]” a separate legal inquiry from written description and, thus, the wrong analysis when analyzing whether the inventors were in “possession” of the claimed invention, but Petitioner is factually wrong. Patent Owners provided expert testimony that in 2003, “a POSA would have understood the likelihood of certain functional groups (e.g., carboxylic acids, amines, nitro, amides, pyridines, alcohols) to form supramolecular synthons and crystal packing motifs defined by

those synthons, based on numerous examples in single-component crystals and literature descriptions of hydrogen-bonding patterns.” EX2014 at ¶54.

IV. THE '956 APPLICATION HAS ENABLEMENT SUPPORT FOR THE FULL SCOPE OF THE CLAIMED CO-CRYSTALS

The examples, the framework Figure 24 provides, and the disclosure in the specification enables a POSITA to make and use the claimed invention. As shown below, the *Wands* factors support the enablement of the Challenged Claims.

A. Relative Skill in the Art

Petitioner argues that a POSITA’s skill level is neutral, citing *Enzo* and *Syngenta*. However, Petitioner ignores other decisions where a high level of skill in the art, even in an unpredictable art, was found in favor of enablement. In *Falkner v. Inglis*, 448 F.3d 1357 (Fed. Cir. 2006), the parties stipulated to a high-level of skill in the art. *Id.* at 1365. “The Board observed that ‘the mere fact that the experimentation may have been difficult and time consuming does not mandate a conclusion that such experimentation would have been considered to be ‘undue’ in this art. Indeed, great expenditures of time and effort were ordinary in the field of vaccine preparation.” *Id.* Similar to the field of vaccine preparation, “great expenditures of time and effort” were ordinary in the field of co-crystals. *See* EX2014 at ¶74 (citing a 20% success rate as being an acceptable benchmark for success, indicating that great expenses of time and effort were common in co-crystallization experimentation).

Petitioner charges Patent Owners with “[a]ttempting to rely on the knowledge of a POSA as a substitute for an enabling disclosure...[as] contrary to the law.” Reply at 20 (citing *Enzo Life Scis., Inc. v. Roche Molecular Sys., Inc.*, 928 F.3d 1340, 1347-48 (Fed. Cir. 2019)). Not so. Unlike *Enzo* where “serious doubts existed in the art as to whether the use of non-radioactive probes at non-Ward positions would be useful as probes,” here, hydrogen bonding was well-accepted by all POSITAs – a fact that even Dr. Rogers admits. See EX2014 at ¶38; EX2016 at 34:10-35:24, 39:4-40:5. Both experts – Petitioner’s and Patent Owners’ – appreciate that the POSITA would have been familiar with the hydrogen bonding work of Dr. Etter. EX2014 at ¶¶38-39; EX2016 at 39:4-9. Accounting for a POSITA’s understanding of the art, such as principles of hydrogen bonding and pharmaceutical formulation, is acceptable in an enablement analysis. *Falkner*, 448 F.3d at 1365 (finding enablement of the POSITA’s ability to “identify ‘essential’ poxvirus genes” where there was “undisputed testimony that as of the time of filing of the earliest Inglis application publications in professional journals had disclosed the DNA sequence of the poxvirus genome along with locations of the ‘essential regions’” and thus, “[t]he person of ordinary skill in the art would clearly have possessed such knowledge, and given the ready accessibility of the journals, the absence of incorporation by reference is not problematic”). This factor, thus, weighs in favor of enablement.

B. Nature of the Invention

As Petitioner acknowledges, the parties agree that “the nature of the invention is a pharmaceutical composition comprising a genus of co-crystals having certain properties.” Reply at 21. Petitioner, however, cites no legal authority for its proposition that because the field of pharmaceutical co-crystals was emerging and co-crystals were allegedly unpredictable, that this factor supports non-enablement. Reply at 21-22. Given the agreed-upon high level of skill in the art, this factor weighs in favor of enablement.

C. State of the Art, Predictability of the Art, and Quantity of Experimentation

As supported by Dr. Ward, a POSITA would bring their high level of education, skill, and training to the problem of pharmaceutical formulations comprising co-crystals and assess which compounds were likely to form the claimed co-crystals based on principles of hydrogen bonding, test those through high-throughput screening, and then assess the outcome through single crystal x-ray diffraction, as needed. EX2014 at ¶¶64-76.

Petitioner again ignores the high level of skill of a POSITA when it argues that the POSITA would “not know which APIs and co-formers will form co-crystals or, if formed, what stoichiometries they will have, whether solvent will be a component, and/or what bonds they will have.” Reply at 22. By making that broad assertion, Petitioner ignores all of the knowledge of hydrogen bonding a

POSITA would have, including its applicability to co-crystals, as well as knowledge of pharmaceutical formulation. EX2014 at ¶¶38-46.

Petitioner's reliance on Desiraju (EX1024) is further puzzling. As Petitioner accurately quotes, Desiraju states that "Even after identifying an important intermolecular interaction, failure to predict a crystal structure can arise because the same interaction can be used to make many different synthons . . . [T]he synthon concept tries to simplify what is essentially a very difficult problem. But even with apparently straightforward synthons, things can go wrong." EX1024 at 399. That may be true – but the Challenged Claims of the '344 patent are not directed to a method of *predicting* synthon formation. And in the same quote, Desiraju recognizes that "the same interaction can be used to make many different synthons" – exactly the point of using hydrogen bonding to create co-crystals. It does not matter which particular arrangement was formed as long as a co-crystal was formed.

These factors, therefore, weigh in favor of enablement.

D. The Amount of Direction or Guidance Presented and Presence of Working Examples

Petitioner selectively quotes the Patent Owners' response, suggesting that Patent Owners' position is that the '956 Application guides a POSITA on how to make a single claimed co-crystal. Reply at 24. Not so. The '956 Application

enables the *full scope* of the claimed co-crystals. As detailed in Dr. Ward's declaration, EX2014 at ¶¶77-79, there are nineteen examples in the specification that guide a POSITA on how to make and use the claimed co-crystals.

Furthermore, the specification provides ample descriptions of appropriate APIs, co-formers, and solvents to use. EX1001 at 3:12-26, 3:35-37, 9:27-40, Fig. 24.

Given this disclosure, this factor weighs in favor of enablement.

V. CONCLUSION

For the foregoing reasons, Patent Owners respectfully request a final written decision confirming patentability of the Challenged Claims.

Respectfully submitted,

Date: October 9, 2024

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CERTIFICATION UNDER 37 CFR § 42.24(d)

Under the provisions of 37 CFR § 42.24(d), the undersigned hereby certifies that the word count for the foregoing Patent Owner's Sur-Reply to the Petitioner's Reply totals 3,249, which is less than the 5,600 allowed under 37 CFR § 42.24.

Date: October 9, 2024

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e)(4), the undersigned certifies that on October 9, 2024, a complete and entire copy of this Patent Owners' Sur-Reply were provided via email, to the Petitioner by serving the email correspondence addresses of record as follows:

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