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Paper 13
Entered: October 26, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NOVARTIS PHARMACEUTICALS CORPORATION,
Petitioner,

v.

SHILPA PHARMA, INC.,
Patent Owner.

IPR2022-00886
Patent 9,266,816 B2

Before JOHN G. NEW, ZHENYU YANG, and ROBERT A. POLLOCK, *Administrative Patent Judges*.

NEW, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314, 37 C.F.R. § 42.4

I. INTRODUCTION

Petitioner Novartis Pharmaceuticals Corporation has filed a Petition (Paper 1, "Pet.") seeking *inter partes* review of claims 1–4 of US Patent 9,266,816 B2 (Ex. 1001, the "'816 patent"). Patent Owner Shilpa Pharma, Inc. ("Patent Owner") timely filed a Preliminary Response. Paper 8 ("Prelim. Resp."). With our authorization (Paper 9), Petitioner filed a corrected Reply to the Preliminary Response (Paper 11, "Reply") and Patent Owner filed a Sur-Reply (Paper 12, "Sur-Reply")

Under 35 U.S.C. § 314, the Board "may not authorize an *inter partes* review to be instituted unless … the information presented in the petition … and any response … shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." Upon consideration of the Petition, Preliminary Response, Reply, and Sur-Reply, and the evidence of record, we determine that the evidence presented demonstrates a reasonable likelihood that Petitioner would prevail in establishing the unpatentability of the challenged claims of the '816 patent.

II. BACKGROUND

A. Real Parties in Interest

Petitioner identifies Novartis Pharmaceuticals Corporation as the real party-in-interest. Pet. 45. Patent Owner identifies Shilpa Pharma, Inc. as the real party-in-interest. Paper 4, 1.

B. Related Matters

Petitioner and Patent Owner concur that '816 patent is the subject of pending litigation brought by Shilpa in *Shilpa Pharma, Inc. v. Novartis Pharmaceuticals Corporation,* Case No. 1:21-cv-00558- MN (D. Del.). Pet. 45, Paper 4, 1.

C. The Asserted Grounds of Unpatentability

Petitioner contends that claims 1–4 of the '816 patent are unpatentable, based upon the following grounds:

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1	1–4	102	Mutz[1]
2	1–4	103	Mutz, Gidwani[2]
3	1–4	102	Gidwani

Petitioner also relies upon, *inter alia*, the Declaration of Dr. Richard McClurg (the "McClurg Declaration," Ex. 1002). Patent Owner relies upon, *inter alia*, the Declarations of Dr. Craig Eckhardt (the "Eckhardt Declaration," Ex. 2008).

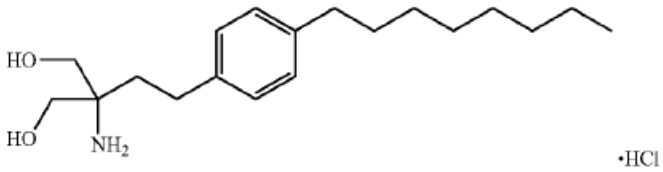
D. The '816 Patent

The '816 patent is entitled "Fingolimod Polymorphs and Their Processes." Ex. 1001, code (54). The '816 patent issued from US Ser. No. 13/635,207 (the "'207 application"). *Id.* at code (21).

[1] Mutz et al. (WO 2010/055028 A2, May 20, 2010 ("Mutz") Ex. 1004.

[2] Gidwani et al. (US 8,766,005 B2, July 1, 2014) ("Gidwani") Ex. 1005.

The ’816 patent discloses crystalline α, β, and μ polymorphic forms fingolimod hydrochloride (2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol hydrochloride) (“fingolimod HCl”), an immunosuppressant drug used in the treatment of multiple sclerosis, and processes for their preparation. Ex. 1001 col. 1, ll. 11–13, 44–46, 66–67. The structure of fingolimod HCl is depicted below:



Structure of fingolimod HCl

Ex. 1001 col. 1, ll. 17–23. Challenged claims 1–4 of the ’816 patent recite only the β form (“form- β”) of crystalline fingolimod. *See* Ex. 1001, claims 1–4.

The ’816 patent discloses x-ray powder diffraction (“XRPD”) spectra for the various crystalline isoforms, including that of form-β, which is reproduced below:

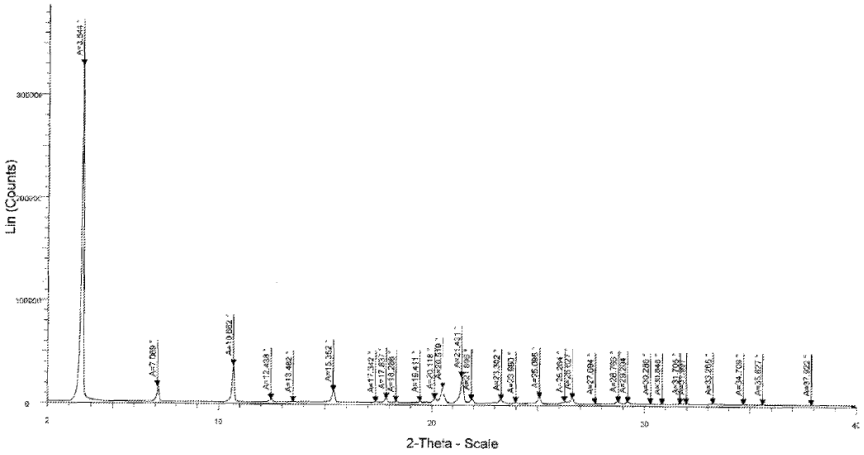


Figure 3 of the ’816 patent depicts an XRPD pattern of fingolimod HCl form-β

Figure 3 demonstrates that fingolimod HCl crystalline Form-β is characterized by an XRPD pattern comprising at least 4 characteristic 2θ° peaks selected from the XRPD peak set of 3.54, 7.07, 10.66, 15.35, 20.52, 21.43 and 25.10 ± 0.1 2θ°. Ex. 1001 col. 5, ll. 8–11.

The '816 patent also discloses, in Figure 4, a differential scanning calorimetry ("DSC") curve for crystalline fingolimod HCl form-β, as depicted below:

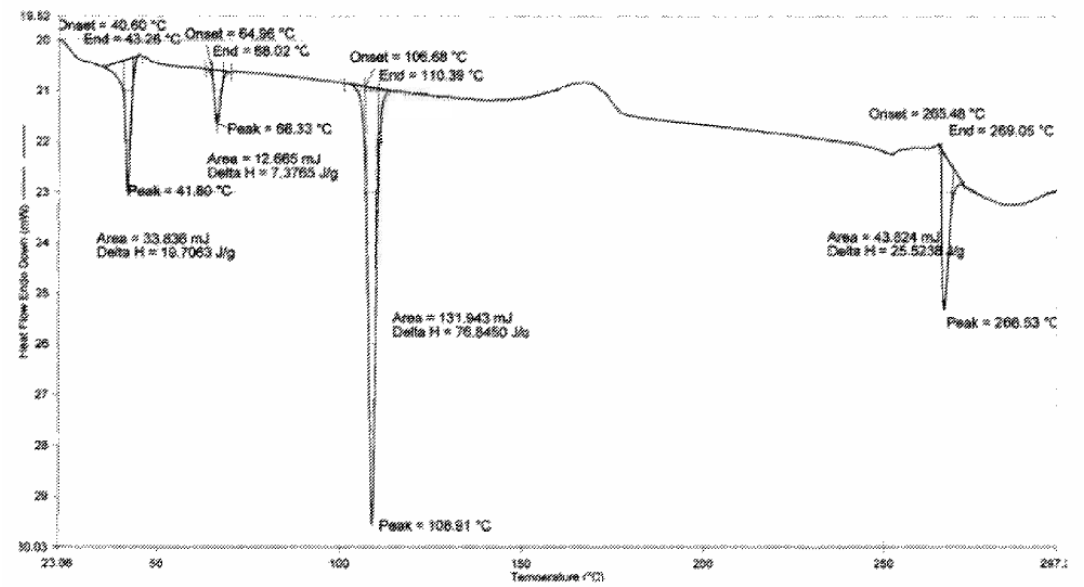


Figure 4 of the '816 patent depicts a DSC curve of crystalline fingolimod HCl form-β

As shown in Figure 4 of the '816 patent, crystalline form-β may be characterized by DSC isotherm comprising at least three endothermic peaks ranging between: (1) Peak-1, between 40 to 45°C; (b) Peak-2, between 65 to 70°C; (c) Peak-3, between 107 to 115°C; and (d) Peak-4, between 265 to 270°C. Ex. 1001 col. 5, ll. 1–7.

E. The Challenged Claims

Claims 1–4 are the challenged claims in this proceeding. *See* Section II.D. above. Claim 3 is representative, of the challenged claims, and recites:

> 3. Fingolimod hydrochloride crystalline Form-β characterized by X-ray powder diffraction pattern comprising characteristic 2θ° peaks selected from the XRPD peak set of 3.54, 7.07, 10.66, 15.35, 20.52, 21.43 and 25.10 ± 0.1 2θ° and DSC isotherm comprising the endothermic peaks ranging between 40 to 45° C. (Peak-1), 65 to 70°C. (Peak-2), 107 to 115°C. (Peak-3) and/or 265 to 270°C. (Peak-4).

Ex. 1001 col.10, ll. 1–7.

F. Prosecution History of the '816 Patent

The '816 patent matured from the '270 application which was filed on August 29, 2011, with original claims 1–15. Ex. 1001, codes (21), (22); Ex. 1014, 1–3. The Applicant filed a Preliminary Amendment on January 26, 2021, canceling original claims 1–6 and 13–15 and amending claims 7–12. *Id*.

On February 25, 2015. The Examiner entered a Non-Final Rejection of claims 7–12 for lack of enablement and indefiniteness under 35 U.S.C. § 112, first and second paragraphs, respectively, and under 35 U.S.C. § 102 as being anticipated by Kiuchi.[3] Ex. 1025, 3–6.

Pursuant to additional amendment of the claims, and submission of an affidavit distinguishing the claimed polymorph from the prior art, the

[3] M. Kiuchi et al., *Synthesis and Immunosuppressive Activity of 2-Substituted 2-Aminopropane-1,3-diols and 2-Aminoethanols*, 43 J. MED. CHEM. 2946-2961 (2000) ("Kiuchi") Ex. 1007.

Examiner issued a Notice of Allowance for claims 7–12 as claims 1–6 on November 23, 2021. Ex. 1027, 2.

III. ANALYSIS

A. Claim Construction

The Board applies the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b). *See* 37 C.F.R. § 100(b) (2020). Under that standard, claim terms "are generally given their ordinary and customary meaning" as understood by a person of ordinary skill in the art at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc). "In determining the meaning of the disputed claim limitation, we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence." *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1014 (Fed. Cir. 2006) (citing Phillips, 415 F.3d at 1312–17). Extrinsic evidence may also be considered, but is "less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" *Phillips*, 415 F.3d at 1317 (quoting *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004)).

Neither Petitioner nor Patent Owner proposes a construction for any claim terms apart from their plain and customary meaning. Pet. 16; *see generally* Prelim. Resp. Nor do we perceive, at this stage of the proceeding, a need to construe any claim term of the '816 patent for purposes of determining whether to institute trial. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 295, 803 (Fed. Cir. 1999) (holding that "only those

terms need to be construed that are in controversy, and only to the extent necessary to resolve the controversy"); *see also Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (applying *Vivid Techs* in the context of an *inter partes* review).

B. Person of Ordinary Skill in the Art

Petitioner asserts that a person of ordinary skill in the art would have at least a bachelor's degree in chemistry, chemical engineering, or related disciplines or equivalent experience, and at least five years of experience related to synthesis, crystallization, and/or detection and/or evaluation of solid-state forms in the pharmaceutical industry or an advanced degree in chemistry, chemical engineering, or related disciplines. Pet. 17. According to Petitioner, such a person would have a working knowledge of the preparation, characterization, and analysis of solid-state forms, including by XRPD and DSC. *Id.* Petitioner proposes that additional graduate education could substitute for experience, while significant experience in the field might be a substitute for formal education. *Id.*

Patent Owner contends that a person of ordinary skill in the art with respect to the claimed subject matter would include a person who possesses an advanced degree (e.g., a Master's degree or Ph.D., or foreign equivalent of either) in the fields of solid-state chemistry, chemical engineering, or a related discipline (i.e., organic chemistry) and several years of experience in crystal technology. Prelim. Resp. 32. Patent Owner asserts that a person of ordinary skill in the art could have a lower level of formal education, such as a bachelor's degree, if such a person had a higher degree of experience. *Id.* Patent Owner argues that such a person would understand that the process of developing pharmaceutical compositions requires a multi-disciplinary

approach, and would draw upon not only his or her own skills, but would also take advantage of certain specialized skills of others, to solve any given problem. *Id.* at 32–33 (citing Ex. 2008 ¶¶ 14–15).

Petitioner's and Patent Owner's respective definitions of a person of skill in the art are thus essentially consistent with each other. At this stage of the proceeding and for purposes of our analysis in this Decision, we therefore define a person of ordinary skill in the art as an individual with at least a bachelor's degree in solid-state chemistry, chemical engineering, or a related discipline (i.e., organic chemistry), and at least five years of post-degree experience in the field of experience related to synthesis, crystallization, and/or detection and/or evaluation of solid-state forms. Such a skilled artisan could have an advanced degree in the same or similar fields, with concurrently less experience. We find that this definition is consistent with the level of skill in the art, as reflected by the prior art. *See, e.g.*, Exs. 1004–1009, 2010; *see also Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required "where the prior art itself reflects an appropriate level and a need for testimony is not shown" (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985))).

C. Ground 1: Anticipation by Mutz

1. Overview of Mutz (Ex. 1004)

The Mutz reference, WO 2010/055028 A2, is entitled "Organic compounds," and was published on May 20, 2010 and is prior art to the '816 patent. Ex. 1004, codes (43), (54). Mutz is directed to crystalline forms and hydrates of 2-amino-2-[2-(4-octylphenyl)ethyl] propane-1,3-diol (fingolimod HCl), and to its uses. *Id.* at 2. Mutz discloses that fingolimod

HCl exists in a particular crystalline form (Form I) at room temperature, and undergoes change to an alternative crystalline form (Form II) at a transition temperature of approximately 40 °C. *Id.* Mutz further discloses that crystalline Form II undergoes a transition to a third crystalline form (Form III) at a temperature of approximately 66 °C, and at approximately 107 °C, fingolimod HCl forms a phase with lower crystalline order. *Id.*

Figure 1 of Mutz is an XRPD spectrum for crystalline Form I of fingolimod HCl, and is depicted below:

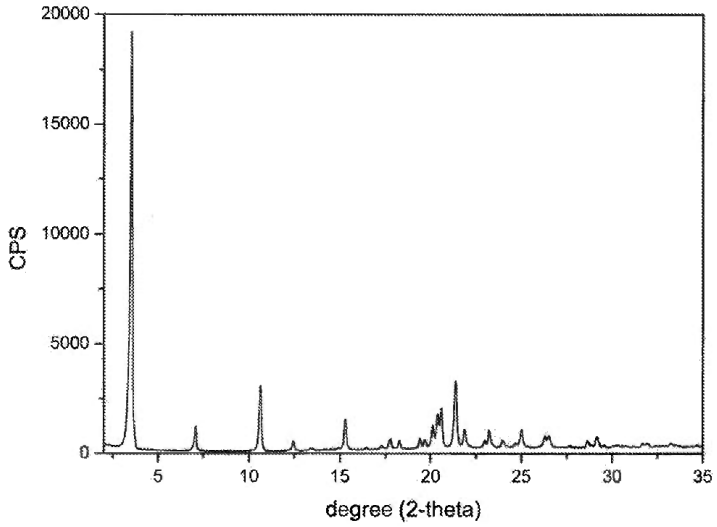


Figure 1 of Mutz is an XRPD spectrum of Form I of fingolimod HCl

Mutz also discloses tabular data describing the XRPD peaks and their relative intensity, which is reproduced below:

° deg 2 θ	d-space (Å)	Relative intensity
3.55	24.875	Strong
7.12	12.394	Weak
10.71	8.255	Weak
12.48	7.090	Weak
15.42	5.742	Medium
20.59	4.309	Medium

Ex. 1004, 16.

Mutz additionally describes differential scanning calorimetry ("DSC") curves for crystalline fingolimod HCl:

> DSC heating curves showed three characteristic transitions at approximately 40°C, 66°C and 107°C. The first endothermic peak at 40 °C is followed by a small exothermic peak which hints to melting of Form I followed by recrystallization into Form II. The second transition between Form II and Form III is a solid-solid transition. A third transition was observed at 107°C. Above 107°C, the X-ray powder pattern almost disappeared and only a single strong peak at 2.9° remained, suggesting formation of a phase with lower crystalline order above this temperature.

Ex. 1004, 15.

2. Petitioner's contentions with respect to Mutz

a. Claim 1

Claim 1 recites: "Fingolimod hydrochloride crystalline Form-β characterized by X-ray powder diffraction pattern comprising characteristic 2θ° peaks selected from the XRPD peak set of 3.54, 7.07, 10.66, 15.35, 20.52, 21.43 and 25.10 ± 0.1 2θ°."

Petitioner argues Mutz's crystalline Form I fingolimod HCl is the claimed Form-β, the room-temperature-stable form claimed in the '816 patent. Pet. 18–19 (citing Ex. 1002 ¶¶ 95–103). According to Petitioner, Mutz discloses each and every one of the peaks recited in claim 1 within the claimed range. *Id.* at 19 (citing Ex. 1004, Fig. 1; Ex. 1002 ¶¶ 104–106). Petitioner provides an annotated version of Figure 1 of Mutz, which is reproduced below:

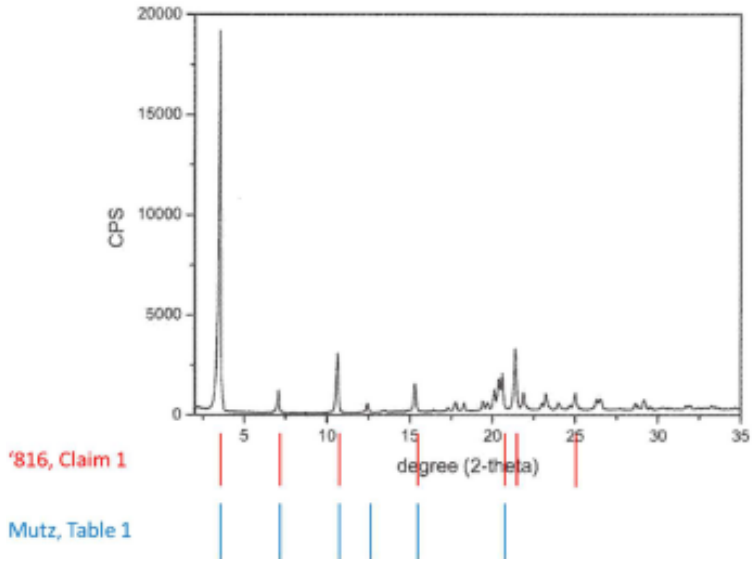


Figure 1 of Mutz, as annotated by Petitioner, depicting an XRPD spectrum of crystalline fingolimod HCl Form I, and indicating at bottom the location of the peaks recited in claim 1 of the '816 patent (red bars), and the location of the peaks described in Mutz's Table (blue bars, *see* Ex. 1004, 16)

Pet. 19.

Petitioner asserts that all seven peaks listed in the '816 patent's claims are shown in the XRPD pattern in Figure 1 of Mutz, as reflected by the red bars annotated in Mutz's Figure 1 above, and that five of the seven peaks recited in the '816 patent claims overlap with the peaks listed in the Mutz Table (i.e., 3.55, 7.12, 10.71, 15.42, and 20.59). Pet. 19 (citing Ex. 1004, 16). Petitioner's Declarant, Dr. McClurg, attests that disclosure of just these five peaks by the Mutz Table, let alone all seven disclosed in Mutz's Figure 1, would be sufficient to demonstrate to a skilled artisan that Mutz's Form I is the same crystalline form as Form-β, as recited in claim 1 of the '816 patent. *Id.* (citing Ex. 1002 ¶¶ 105–116).

b. Claim 2

Claim 2 recites: "Fingolimod hydrochloride crystalline Form-β according to claim 1, which is further characterized by DSC isotherm comprising endothermic peaks ranging between a. Peak-1—Between 40 to 45°C., b. Peak-2—Between 65 to 70°C., c. Peak-3—Between 107 to 115°C., d. Peak-4—Between 265 to 270°C."

Petitioner repeats its argument above that Mutz discloses fingolimod HCl with an XRPD pattern that includes all of the '816 patent claimed peaks, and further argues that Mutz also discloses DSC data that include all four claimed endothermic peaks, which lie within the recited ranges. Pet. 21 (citing Ex. 1002 ¶¶ 117–135). Specifically, Petitioner contends that Mutz discloses "DSC heating curves show[ing] three characteristic transitions at approximately 40°C, 66°C and 107°C." *Id.* at 23 (quoting Ex. 1004, 15.) Petitioner asserts that these three transitions fall within the ranges recited in claim 2. *Id.* (citing Ex. 1002 ¶¶ 119–125).

As further confirmation of this, Petitioner points to Wang[4], which also discloses endothermic DSC peaks for fingolimod matching those in Mutz. Pet. 23 (citing Ex. 1002 ¶¶ 135–137). Petitioner contends Mutz further discloses that the "onset of decomposition" for fingolimod HCl is "at ca. [circa] 260 °C," which, Petitioner asserts, a skilled artisan would have understood as corresponding to claim 1's Peak-4 "between 265 to 270° C." *Id.* (quoting Ex. 1004 at 15).

[4] J.-R. Wang et al., *Insight into the Conformational Polymorph Transformation of a Block-Buster Multiple Sclerosis Drug Fingolimod Hydrochloride (FTY 720)*, 109 J. PHARM. AND BIOMED. ANAL. 45–51 (2015) ("Wang") Ex. 1021.

Petitioner acknowledges the possibility that "ca. 260°C" as disclosed by Mutz may not constitute an express disclosure of the claimed endothermic peak at 265 to 270°C, however, Petitioner contends that this DSC peak is nevertheless inherently disclosed by Mutz. Pet. 23–24. Petitioner contends that a person of ordinary skill in the art would understand that, experimental parameters being equal, all fingolimod HCl will decompose at approximately the same temperature, regardless of what crystal form it was initially, and that this property will result in an endothermic peak in the claimed range. *Id.* at 24 (citing Ex. 1002 ¶ 128).

Furthermore, as Petitioner's Declarant, Dr. McClurg, points out, a skilled artisan would recognize that, because the details of decomposition are dependent upon the details of the experiment, and independent of the initial form of the material, the degradation temperature is not a useful transition to characterize a crystalline material. Pet. 24 (citing Ex. 1002 ¶¶ 133–134, 136). This is because, at that point in the DSC scan, fingolimod hydrochloride has undergone at least three phase transitions, including a transition to a "phase with lower crystalline order" (i.e., a liquid crystal), and so is not a crystal form at all. *Id.* Consequently, Dr. McClurg opines, Peak-4 between 265 to 270° C is not even a distinguishing characteristic of Form-β. *Id.*

c. Claim 3

Claim 1 recites "Fingolimod hydrochloride crystalline Form-β characterized by X-ray powder diffraction pattern comprising characteristic 2θ° peaks selected from the XRPD peak set of 3.54, 7.07, 10.66, 15.35, 20.52, 21.43 and 25.10 ± 0.1 2θ° and DSC isotherm comprising the

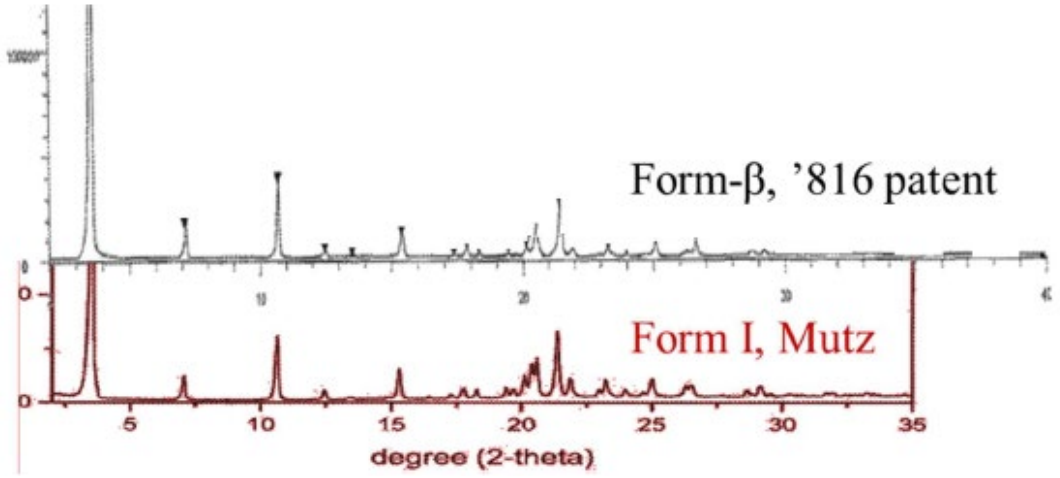
endothermic peaks ranging between 40 to 45°C. (Peak-1), 65 to 70°C. (Peak-2), 107 to 115°C. (Peak- 3) and/or 265 to 270°C. (Peak-4)."

Petitioner argues that claim 3 is substantially identical to claims 1 and 2 combined, with the exception of the use of "and/or", which requires only three or more DSC endothermic peaks from the recited set. Pet. 25.

d. Claim 4

Claim 4 recites: "Fingolimod hydrochloride crystalline Form-β according to claim 3, characterized by X-ray powder diffraction pattern as disclosed in FIG. 3 [of the '816 patent] and DSC isothermal pattern as disclosed in FIG. 4."

Figures 3 and 4 of the '816 patent are reproduced in Section II.D, above. Petitioner argues that, based on the XRPD date disclosed by Mutz, as discussed with respect to claim 1 above (*see* Section III.C.2.a), Mutz's crystalline fingolimod HCl Form I is identifiable as Shilpa's form-ß as disclosed by the XRPD pattern disclosed in Figure 3 of the '816 patent. Pet. 26 (citing e.g., *H. Lundbeck A/S v. Apotex Inc.*, No. CV 18-88-LPS, 2019 WL 3206016, at *4 (D. Del. July 16, 2019) (construing "characterized by an XRPD [pattern] as shown in [any of] FIG[S] . . ." as "identifiable by reference to an x-ray powder diffraction pattern as shown in [any of] FIG[S] . . . "). Petitioner provides a comparison between the XRPD spectra of Figure 3 of the '816 patent (form-β) and Figure 1 of Mutz (Form I):



Petitioner's annotated illustration depicting the XRPD spectra of Figure 3 of the '816 patent (top) and Mutz's Figure 1 (bottom)

Furthermore, argues Petitioner, as discussed above with respect to claim 2 (*see* Section III.C.2.b), the DSC information in Mutz demonstrates that Mutz's Form I is identifiable as form-β of the '816 patent by reference to the DSC isothermal pattern disclosed in Figure 4 of the '816 patent. Pet. 28.

Petitioner asserts that a person of skill in the art would understand that both XRPD spectra and DSC isothermal curves can demonstrate some slight variability depending upon various experimental factors. Pet. 27, 28–29 (citing Ex. 1002 ¶¶ 140–141, 146). Nevertheless, argues Petitioner, a person of ordinary skill in the art would have recognized that the XRPD and DSC information disclosed by Mutz is for the same crystal form as that depicted in Figures 3 and 4 of the '816 patent. *Id.*

3. Patent Owner's Preliminary Response

a. Preliminary Response

Patent Owner argues that Petitioner's argument fails because Mutz is not enabled for Forms I, II, or III of crystalline fingolimod HCl. Prelim Resp. 33. Specifically, Patent Owner contends that Mutz fails to disclose how to make Forms I, II, or III by chemical methods. *Id.* at 34. Patent Owner points out that Mutz fails to disclose the source of the material from which the XRPD and DSC measurements were allegedly obtained, and that, for Form I, there are no process steps recited, or starting materials disclosed. *Id.* Furthermore, Patent Owner asserts, Mutz fails to disclose any reaction or recrystallization conditions, drying conditions or times, solvents, reaction temperatures, or procedures for purifying the polymorphic forms are provided. *Id.* Patent Owner argues that, to be enabled, Mutz is required to disclose at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim. *Id.* (citing 35 U.S.C. § 112(a); *In re Fisher*, 427 F.2d 833, 839 (C.C.P.A. 1970)).

Patent Owner argues further that Form II is described by Mutz as a temperature-based polymorphic form that exists between 40ºC and 66ºC and that Form III is also a temperature-based form existing between 66ºC and 107ºC. Pet. 35 (citing Ex. 1004, 1). Patent Owner notes that Mutz teaches that crystalline Form I can be produced by cooling crystalline Forms II or III to a temperature of less than 40ºC, preferably to a temperature of 30ºC or less, and more preferably 20ºC or less, but argues that Mutz does not disclose how to prepare or synthesize Forms II or III as starting materials for Form I. *Id.* (citing Mutz, claim 12; Ex. 2008 ¶¶ 43–45).

Patent Owner further notes that there is no disclosure by Mutz that either of Forms II or III can be, or have been, isolated in a form suitable for

use in the compositions of Examples 1–13. Prelim. Resp. 36. Patent Owner observes that the existence of Forms II and III appear to have been premised on the observation of a DSC experiment beginning with Form I. *Id.* (citing Ex. 2008 ¶ 45). Patent Owner contends that Mutz's naming of fingolimod HCl Forms I, II and III, without providing "a person of ordinary skill in the art's ability to make the claimed compound" cannot constitute an enabling description under § 102. *Id.* at 36–37 (quoting *In re Gleave*, 560 F.3d 1331, 1337 (Fed. Cir. 2009); and citing, e.g., *In re Wiggins*, 488 F.2d 538, 543 (C.C.P.A. 1973)). Patent Owner asserts, furthermore, that the need for an enabling disclosure in the Mutz reference is especially acute because the Mutz applicants claim to be the first to discover polymorphic forms of fingolimod HCl. *Id.* at 38.

Patent Owner also notes that, when Petitioner submitted U.S. Appl. Ser. No. 13/128,825 (the "'825 application"), the U.S. counterpart to the Mutz application, the claims to Forms I-III were rejected by the Examiner as lacking adequate written descriptive support under 35 U.S.C. § 112, first paragraph. Prelim. Resp. 39 (citing Ex. 2012). The '825 application was then abandoned by Petitioner and a continuation, US Appl. Ser. No. 13/964,817 (the "'817 application"), was subsequently submitted. *Id.* (citing Exs. 2012, 2013). Claims 1–3 of the '817 application recited forms 1–III of fingolimod HCl as characterized by XRPD spectra. *Id.* (citing Ex. 2013). Patent Owner notes that, in similarly rejecting these claims as lacking written descriptive support, the Examiner found that "[t]he specification discloses that crystalline Form I of [fingolimod] hydrochloride comprises cooling crystalline Form II or Form III of FTY720 hydrochloride to a temperature of less than 40oC (page 3, specification). There is no

experimental procedure disclosed for the preparation of Form II and III." Pet. 40 (quoting Ex. 2014, 6).

Patent Owner argues that, although entered as a written description rejection, the Examiner's rejection sounds equally in lack of enablement as well, because the Examiner cites the '817 application's failure to disclose experimental procedures for the preparation of any of the forms, as well as its failure to specify the form used as the starting material. Prelim Resp. 40. Patent Owner notes that Petitioner subsequently abandoned the '817 application on December 18, 2015. Pet. 41 (citing Ex. 2015).

Patent Owner further points out that Mutz, or other applications by Petitioner corresponding to Mutz, have been rejected on similar written description grounds by the European Patent Office (Ex. 2016, 8), the Japanese Patent Office (Ex. 2019, 1–3; Ex. 2020, 2–3), and IP Australia[5] (Ex. 2034, 2). Prelim. Resp. 41–46. Patent Owner contends that the recognition by these foreign offices, as well as by the USPTO, that the failure of Mutz and its counterpart applications fail to adequately teach how to make fingolimod hydrochloride Forms I, II and III is strongly probative of a lack of enablement by Mutz in this proceeding.

b. Petitioner's Reply

Petitioner replies that, on its first page, Mutz expressly incorporates by reference Fujita.[6] Reply 1 (citing Ex. 1004, 1) (stating that "2-Amino-2-[2-4-C-(4-C_{2-20}-alkyl-phenyl)ethyl]propane-1,3-diol compounds are

[5] IP Australia is an agency of the Australian Government that administers intellectual property rights and legislation relating to, *inter alia*, patents. *See* https://www.ipaustralia.gov.au/

[6] Fujita et al. (EP 062406 B1, October 18, 1993) ("Fujita") Ex. 1048.

disclosed in EP-A-2-0627406 [Fujita], the relevant disclosure of which is incorporated herein by reference"). Petitioner asserts that Fujita discloses a method for making crystalline fingolimod HCl; specifically, Example 28 of Fujita teaches a method for synthesizing fingolimod and Example 29 describes the preparation of its hydrochloride salt, which is "recrystallized from ethanol to give 4.2 g of the subject compound." *Id.* at 2 (quoting Fujita 114–115).

Petitioner notes that, in the parallel district court litigation, Patent Owner's complaint states that Patent Owner carried out the Fujita method, reproducing Example 29 of US 5,604,229 (the "'229 patent)[7], which is identical to Example 29 of Fujita. Reply 2. Petitioner asserts that, in its district court complaint, Patent Owner reported analyzing the resulting crystalline fingolimod HCl. and stated that the resulting fingolimod HCl possessed all of the properties claimed in the '816 patent. *Id.* (citing Ex. 1028 ¶¶ 23, 31–32). Petitioner contends that Patent Owner expressly acknowledged that the '229 Patent describes a method for making fingolimod HCl. *Id.* (citing Ex. 1028 ¶ 24 ("Example 28 of the '229 patent describes the preparation of fingolimod (2-amino-2-[2-(4-octylphenyl) ethyl]-1,3-propanediol), and Example 29 describes the preparation of its hydrochloride salt.")). Petitioner alleges that, in the district court litigation, Patent Owner also relies on Mutz to establish infringement, which, Petitioner asserts, confirms that Mutz, which is prior art, anticipates the '816 patent. *Id.* at 2–3 (citing Pet. 20).

[7] Fujita et al. (US 5,604,229, February 18, 1997) (the '229 patent") Ex. 1003. The '229 patent is the equivalent of Fujita (*compare* Ex. 1048 *with* Ex. 1003).

Petitioner acknowledges that Fujita does not specify which crystal form is being made in Example 29, but contends that this is irrelevant, as shown by Patent Owner's own experiments as described in the district court complaint. Reply 3 (citing Ex. 1028 ¶¶ 31–32). Petitioner additionally points to Westheim[8], which is also prior art to the '816 patent, and which confirms that Fujita's Example 29 produces Mutz's Form I. *Id.* According to Petitioner, Westheim teaches fingolimod synthesis by the method disclosed in Example 29 of Fujita, and concludes that "[t]he crystalline fingolimod hydrochloride obtainable by processes of the prior art" (including Fujita) produces "a stable crystalline form . . . Form I." *Id.* (citing Ex. 1006 ¶¶ 2–5, 10–11, 13, 21, Figs. 1, 4).

Petitioner argues that it was therefore known in the prior art how to make crystalline fingolimod HCl, and that "a patent need not teach, and preferably omits, what is well known in the art." Reply 3–4 (quoting, e.g., *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986); *see also* Pet. 5 ("Methods for making crystalline fingolimod hydrochloride have also been published" (citing prior art references and the McClurg Declaration))).

Petitioner dismisses Patent Owner's arguments concerning the rejection of the claims of Mutz and its equivalent as being irrelevant, because they are based upon lack of written description and not enablement. Reply 4. Petitioner instead points to the rejection of Patent Owner's enablement argument by the European Patent Office ("EPO"). Reply 5. According to Petitioner, the EPO cited Mutz to reject similar claims recited in the European counterpart of the '816 patent, EP11842990 (the "'990

[8] Westheim (WO 2012/041358 A1, April 5, 2012) ("Westheim") Ex. 1006.

application"), stating that Mutz discloses "a crystalline Form I of [fingolimod] hydrochloride having the same [XRPD] as Form-β." *Id.* (citing Ex. 1029, 2).

Petitioner contends that Patent Owner, in response to the EPO's rejection, made the same enablement argument against Mutz that it presently makes in its Preliminary Response, but notes that the EPO rejected that argument, finding that "[f]or the preparation of Fingolimod hydrochloride, [Mutz] refers to the prior art document EP-A-0627 406 [Fujita]" and, further, "that Form I exists at room temperature . . . and [ ] that Form I is prepared by cooling Form II or Form III to a temperature below 40 °C." Reply 4 (quoting Ex. 1031, 4).

c. Patent Owner's Sur-Reply

Patent Owner responds that Fujita cannot be incorporated by reference under 37 C.F.R. § 1.57 because Fujita is neither a U.S. Patent or U.S. patent publication. Sur-Reply 1. Patent Owner contends that, because Petitioner argues that Mutz is enabled by its incorporation by reference of Fujita, Fujita is therefore essential to the enablement of Mutz. *Id.* (citing 35 U.S.C. § 112(a); 37 C.F.R. § 1.57(d)(1) (stating that "[e]ssential material "is material that is necessary to … provide a written description of the claimed invention, and of 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 [ ], to make and use the same"). Consequently, argues Patent Owner, the incorporation of Fujita is improper because it is neither a U.S. Patent or U.S. patent publication. *Id.* at 1–2 (citing 37 C.F.R. § 1.57(d); also citing *Pennwalt Corp. v. Akzona, Inc.*, 570 F.Supp. 1097, 1103 (D. Del.

1983); *Hulu, Inc. v. Sito Mobile R&D IP, LLC et al.*, 2022 Pat. App. LEXIS 2690 (PTAB May 17, 2022)).

Patent Owner next argues that Mutz's disclosure that "2-Amino-2-[2-(4-C_{2-20}-alkyl-phenyl)ethyl] propane-1,3-diol compounds are disclosed in EP-A-0627406, the relevant disclosure of which is incorporated herein by reference" is insufficiently specific to point the skilled artisan to the enabling disclosure for synthesizing fingolimod HCl. Sur-Reply 2. According to Patent Owner, to incorporate material by reference, "the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents." *Id.* at 3 (citing *Advanced Display Sys. Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282-83 (Fed. Cir. 2000).

Patent Owner contends, first, that Mutz fails to disclose with the requisite "detailed particularity" requirement of *Advanced Display* and its predecessors, because the sum total of its incorporation language states only that the relevant disclosure is incorporated by reference. Sur-Reply 3. However, argues Patent Owner, Mutz nowhere states what the relevant disclosure is in the 258-page Fujita application. *Id.* According to Patent Owner, the incorporation of all the C_{2-20}-alkyl-phenyl compounds requires an evaluation of which of the thousands of compounds generically and specifically disclosed are relevant and which disclosure(s) support those compounds. *Id.* (citing *Kyocera Wireless Corp. v. ITC*, 545 F.3d 1340 (Fed. Cir. 2008)).

Patent Owner next argues that Mutz also fails the requirement that the host document identify where in the relied-upon document the incorporated material can be found. Sur-Reply 3. Patent Owner asserts that Mutz does not specify the page number, line number, example number, or any other

descriptor, page number, line number, example number, or any other descriptor. *Id.* at 3–4. Consequently, argues Patent Owner, because Mutz states neither what material is being incorporated nor where in Fujita that material can be found, the incorporation fails as a matter of law. *Id*. at 4 (citing, e.g., *Advanced Display*, 212 F.3d at 1282).

Finally, Patent Owner argues that Mutz implicitly acknowledges that the product of Example 29 of Fujita is not any of Mutz Forms I-III by disclosing that it had discovered that fingolimod HCl exhibits polymorphism (Ex. 1004, p.1) and that "[a]ccordingly, the present invention provides novel crystalline forms of FTY720 hydrochloride." Sur-Reply 4 (quoting Ex. 1004, 1). Patent Owner argues that, if Mutz "discovered" that fingolimod HCl exhibits polymorphism, it was not disclosed in Fujita. *Id.* Similarly, contends Patent Owner, if Mutz disclosed "novel crystalline forms of FTY720 hydrochloride," none of them were disclosed in EP '406. *Id.* Patent Owner reasons that, in representing that Forms I-III were novel over the prior art – including Fujita's Example 29 – Mutz therefore acknowledges that whatever product Example 29 yielded, it was not Forms I-III. *Id.* Patent Owner notes that Fujita provides no XRPD data to confirm whether the visual observation of crystallinity in fact resulted in a polymorphic form, and provides no DSC data to indicate what form may have been obtained. *Id.*

4. Analysis

Having considered both parties' arguments, and the evidence of record as developed at this stage of the proceeding, we conclude that

Petitioner has established a reasonable likelihood of prevailing at trial on Ground 1.

It is undisputed by the parties that Mutz teaches all of the limitations of claims 1–4 of the '816 patent. Patent Owner argues, however, that Mutz cannot anticipate claims 1–4 because the reference is not enabled. *See Gleave*, 560 F.3d at 1334 (holding that, to anticipate, "the reference must "enable one of ordinary skill in the art to make the invention without undue experimentation." (citing *Impax Labs., Inc. v. Aventis Pharms. Inc.*, 545 F.3d 1312, 1314 (Fed. Cir. 2008))). Specifically, Patent Owner contends that, because Mutz does not disclose a method for making fingolimod HCl, it is not enabled and therefore cannot anticipate the claims of the '816 patent. We disagree.

As an initial matter, we reject Patent Owner's argument that Mutz's incorporation of Fujita by reference is improper under 37 C.F.R § 1.57(d). *See* Sur-Reply 1–2. Section 1.57 relates generally to the validity of *U.S.* patents and their applications. Specifically, Section 1.57 addresses the incorporation of a reference in the application data sheet of a continuation of a previous application for reasons of preserving for the continuing application the priority date of the previous application. Section 1.57 states that:

> Subject to the conditions and requirements of this paragraph, a reference made in the English language *in an application data sheet* in accordance with § 1.76 upon the filing of an application under 35 U.S.C. 111(a) *to a previously filed application*, indicating that the specification and any drawings of the application under 35 U.S.C. 111(a) are replaced by the reference to the previously filed application, and *specifying the previously filed application by application number, filing date*, and the intellectual property authority or country in which the previously filed application was filed, *shall constitute the specification and*

> *any drawings of the application under 35 U.S.C. 111(a) for purposes of a filing date under § 1.53(b)*.

37. C.F.R. § 1.57 (emphases added). Section 1.57(d) of the same chapter, states that "essential material," i.e., material that is necessary to "provide a written description of the claimed invention, and of the manner and process of making and using it" can only be incorporated by reference from a US patent or patent publication. 37 C.F.R. §§ 1.57(d)–d(1).

That is emphatically not the context in which Mutz is relied upon by Petitioner. Mutz, a foreign application, is cited as prior art to challenge the validity of the '816 patent on the grounds that it anticipates claims 1–4. We are not concerned with the validity of Mutz as a U.S. patent or patent application, of which it is neither. Rather, we look to Mutz to determine whether a person of ordinary skill in the art would understand that it discloses "all limitations of the claim," and is enabled. *Kalman v. Kimberly–Clark Corp.*, 713 F.2d 760, 772 (Fed. Cir. 1983), *Gleave*, 560 F.3d at 1334. Because there is no dispute at this stage that Mutz teaches the limitations of claims 1–4, the question directly before us, then, is whether a person of skill in the art, comprehending Mutz, and the Fujita reference it expressly incorporates, would understand that Mutz is enabled in that it discloses "how to make and use the full scope of the claimed invention without 'undue experimentation.'" *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997). Patent Owner's argument based upon Section 1.57(d) is thus inapposite.

Mutz expressly incorporates the teachings of Fujita on its first page. *See* Ex. 1004, 1. Example 28 of Fujita discloses the synthesis of 2-amino-2-[2-(4-octylphenyl)ethyl]-1,3-propanediols. Ex. 1048, 114–115. Fujita's Example 29 teaches the fairly straightforward synthesis of crystalline 2-

amino-2-[2-(4-octylphenyl)ethyl]-1,3-propanediol hydrochloride, i.e., fingolimod HCl. *Id.* at 115. Specifically Example 29 discloses that "2-Amino-2-[2-(4-octylphenyl)ethyl]-1,3-propanediol (7 g) was dissolved in ethanol (50 ml) and a 1N hydrochloric 45 acid/ether solution (50 ml) was added thereto. The solvent was distilled away and the resultant crystals were recrystallized from ethanol to give 4.2 g of the subject compound." *Id.* Furthermore, Westheim teaches that using the synthetic method of Fujita's Example 29 provides Form I of fingolimod HCl:

> The crystalline fingolimod hydrochloride obtainable by processes of the prior art documents disclosed above is characterized by a distinctive XRPD pattern and IR spectrum, which allow to conclude that each of these processes provides a stable crystalline form, which is denoted for purpose of the present invention as Form I.

Ex. 1006 ¶ 10. Indeed, in the parallel district court litigation, Patent Owner expressly admitted that Fujita discloses synthesis of fingolimod HCl. *See* 1028 ¶ 24 ("Example 28 of the '229 patent describes the preparation of fingolimod (2-amino-2-[2-(4-octylphenyl)ethyl]-1,3-propanediol), and Example 29 describes the preparation of its hydrochloride salt.")).

Patent Owner argues that, when Petitioner prosecuted the '817 application (the U.S. application corresponding to Mutz), the Examiner rejected the claims for the same reason that it argues disqualifies Mutz as anticipatory prior art, *viz.*, that Mutz failed to disclose the material that were used as the starting points for the synthesis of fingolimod Form I. *See* Ex. 2014, 6–7 (in which the Examiner finds that "There is no experimental procedure disclosed for the preparation of Form II and III" and that "the applicant did not specify the precise form that is employed as the starting

material in said formulations"). We do not find Patent Owner's argument persuasive for several reasons.

First, the basis for the Examiner's rejection was the alleged failure to comply with the written description requirement and not for lack of enablement. *See* Ex. 2014, 6. Although both requirements are contained within Section 112(a), our reviewing court has made it abundantly clear that these are two separate and distinct requirements. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed Cir. 1991) (holding that that "35 U.S.C. § 112, first paragraph, requires a 'written description of the invention' which is separate and distinct from the enablement requirement"). We certainly acknowledge that both the written description and enablement requirements both demand that the Specification teach the skilled artisan how to "make and use" the invention, but the former requires that the Specification must also convey with reasonable clarity that the inventor was in possession of the invention as of the filing date. *Id.* at 1563–64.

More importantly, there is no evidence of record that the Examiner, in rejecting Mutz's U.S. counterpart '817 application, considered the incorporation by reference of Fujita's teachings concerning synthesis of fingolimod HCl, or whether Petitioner (the then-Applicant) argued that the incorporation of Fujita enabled the '817 application. Indeed, the complete prosecution history of the '817 application is not part of the record of this proceeding.

However, the European Patent Office's consideration of Mutz in Patent Owner's prosecution of its European counterpart to the '816 patent (the '990 application) is instructive. As Petitioner points out, Patent Owner made the same argument then as it makes now, *viz.*, that Mutz is not anticipatory because it is not enabled. *See* Reply 4. The EPO rejected that

argument, expressly finding that "[f]or the preparation of Fingolimod hydrochloride, [Mutz] refers to the prior art document EP-A-0627 406 [Fujita]" and, further, "that Form I exists at room temperature . . . and [ ] that Form I is prepared by cooling Form II or Form III to a temperature below 40°C." Ex. 1031, 4. In short, the EPO found that the incorporation by reference of Fujita was enabling of Mutz.

Based upon the record as currently developed, we agree with the EPO. Fujita's Example 28 expressly teaches the synthesis of 2-Amino-2-[2-(4-octylphenyl)ethyl]-1,3-propanediol, and Example 29 teaches the synthesis of crystalline 2-Amino-2-[2-(4-octylphenyl)ethyl]-1,3-propanediol hydrochloride, i.e., crystalline fingolimod HCl. Moreover, the prior art Westheim reference expressly teaches that this method synthesizes fingolimod HCl Form I, which is the same as the '816 patent's form-β. *See* Ex. 1006 ¶¶ 2–5, 10–11, 13, 21, Figs. 1, 4).

Nor are we persuaded by Patent Owner's argument that Mutz would not direct a skilled artisan to the relevant portions of Fujita with sufficient specificity. *See* Sur-Reply 3–4. We agree with Patent Owner that Fujita discloses a large genus of 2-amino-2-[2-(4-C_{2-20}-alkyl-phenyl)ethyl] propane-1,3-diol compounds. *See generally* Ex. 1048. But Patent Owner's argument that a person of skill in the art would require "an evaluation of which of the thousands of compounds generically and specifically disclosed are relevant and which disclosure(s) support those compounds" (*see* Sur-Reply 3), would seem to have the argument precisely backward. At this point in the proceeding, it is reasonable to assume that a person of skill in the art, having understood that Mutz incorporates by reference the teachings of Fujita would then look to Fujita for the method of synthesizing the sole compound disclosed by Mutz: 2-amino-2-[2-(4-octylphenyl)ethyl]-1 ,3-

propanediol hydrochloride, i.e., crystalline fingolimod HCl. Fujita expressly teaches the synthesis of Form I in Examples 28 and 29, and Westheim confirms this. *See* Ex. 1048, Ex. 29; Ex. 1006 ¶ 10. We see few difficulties posed for the person of skill in the art in locating these relevant teachings among the disclosures of Fujita.

Similarly, we are not persuaded by Patent Owner's reliance upon *Advanced Display* in arguing that Mutz fails to describe with particularity what parts of Fujita are incorporated by reference. *See* Sur-Reply 3–4. We agree with Patent Owner that, to incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents. *See In re Seversky*, 474 F.2d 671, 674, 177 USPQ 144, 146 (C.C.P.A. 1973) (holding that incorporation by reference requires a statement "clearly identifying the subject matter which is incorporated and where it is to be found"). *Advanced Display* adds little to that definition, other than to hold that whether a document properly incorporates another by reference is a question of law. *See Advanced Display*, 212 F.3d 1272 at 1283.

More to the point, Mutz discloses that "2-Amino-2[2-(4-$_{C2-20}$-alkyl-phenyl)ethyl]propane-1,3-diol compounds are disclosed in EP-A-0627406, the relevant disclosure of which is incorporated herein by reference" Ex. 1004, 1. At this point in the proceeding, we agree with Petitioner that a person of ordinary skill in the art would understand that the relevant disclosures of Fujita with respect to Muz, therefore, are those teachings that relate to 2-amino-2[2-(4-octylpheny(ethyl] propane-1,3-diol, i.e., fingolimod, and its hydrochloride crystalline salt, fingolimod HCl. These teachings are in Examples 28 and 29, which, as we have explained, would be

within the competence of a skilled artisan to ferret out amongst the genus of compounds disclosed by Fujita.

5. Conclusion

We conclude, therefore, that Petitioner has demonstrated a reasonable likelihood of prevailing at trial in showing that claims 1–4 are anticipated by Mutz. We consequently institute *inter partes* review of all of the challenged claims with respect to Ground 1. Furthermore, because we institute *inter partes* review with respect to at least one claim, we institute trial of all challenged claims of the '816 patent based on all of the grounds identified in the Petition. *See SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018); *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (interpreting the statute to require "a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition"). We address the remaining grounds briefly, for the guidance of the parties.

D. Ground 2: Obviousness over Mutz

Because we conclude that Petitioner has established a reasonable likelihood of demonstrating at trial that claims 1–4 of the '816 patent are anticipated by Mutz (Ground 1), we similarly conclude, for the same reasons, that Petitioner has established a reasonable likelihood of prevailing in demonstrating that the challenged claims are obvious over Mutz. *See In re McDaniel*, 293 F.3d 1379, 1385 (Fed. Cir. 2002) (holding that "[i]t is well settled that 'anticipation is the epitome of obviousness'").

Patent Owner argues that, in its Petition, Petitioner fails to address secondary considerations of nonobviousness, e.g., long-felt but unsolved need, failure of others, copying by the industry, unexpected results and

commercial success. Prelim. Resp. 53. Patent Owner asks, rhetorically, "[h]ow could Petitioner ignore multiple billions of dollars of sales of the Gilenya product at issue?" *Id.* (citing in a footnote Matej Mikulic, *Novartis AG's top 10 drugs based on revenue in 2021(in million U.S. dollars)*, (2021) *available at*: https://www.statista.com/statistics/278114/novartis-top-drugs-based-on-revenue/ (last visited October 7, 2022) (not of record). However, Patent Owner makes no argument other than this rhetorical question, and adduces no evidence of record in support of secondary considerations of nonobviousness. We encourage the parties to develop these arguments further at trial.

E. Ground 3: Anticipation by Gidwani

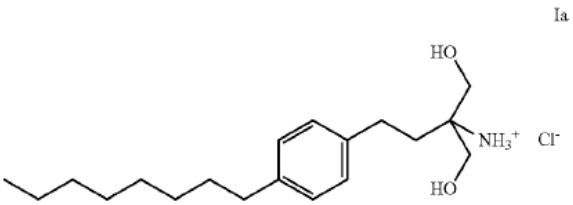
1. Overview of Gidwani (Ex. 1005)

Gidwani, US 8,766,005 B2, issued on July 1, 2014, and is prior art to the '816 patent. Ex, 1005 code (45). Gidwani is entitled "Process For Producing Fingolimod Salts" and is directed to "a process for producing pharmaceutically acceptable salts of fingolimod" and discloses "different pharmaceutically acceptable salts of fingolimod and a polymorphic form of fingolimod hydrochloride." *Id.* at Abstr.

Specifically, Gidwani discloses:

> Usually, pharmaceutically acceptable salts of fingolimod (I) (=I-i or I-i) are obtained in crystalline form. Depending on the acidic compound, pharmaceutically acceptable salts of fingolimod (I) (=I-i or I-i) may be obtained in different polymorphic forms. If the acidic compound is hydrochloric acid, then fingolimod in form of the hydrochloride salt as illustrated in the above formula Ia is obtained.

Ex. 1005 col. 8, ll. 17–22. Formula Ia of fingolimod hydrochloride is reproduced below:



Formula Ia depicts fingolimod HCl obtained by the method of Gidwani

Gidwani further discloses:

> Usually, the fingolimod hydrochloride (Ia) as obtained by the process of the present invention shows (when subjected to differential scanning calorimetry, commonly abbreviated as DSC) endothermic peaks between 66° C. to 69° C. and between 100° C. to 110° C., preferably between 67° C. to 68° C. and between 107° C. to 108° C. Further, it has been verified that none of the two peaks is related to residual solvents or other impurities. Hence, it is assumed that the fingolimod hydrochloride (Ia) as obtained by the process of the present invention crystallizes in a mixture of two polymorphic forms (referred to as mixture of polymorphic forms A and B).

Id. at col. 8, ll. 23–34. Gidwani also discloses:

> It further has been found that the mixture of polymorphic forms A and B can be converted into pure polymorphic form B. Polymorphic Form B of fingolimod hydrochloride (Ia) unexpectedly shows desirable properties. For example, polymorphic form B shows a constant dissolution profile before and after storage, i.e. the dissolution profile essentially remains constant during shelf life. Furthermore, polymorphic form B shows an advantageous processability in the preparation of pharmaceutical formulations. In particular, the flowability of polymorphic form B is superior when compared to form A or mixtures of forms A and B.

Id. at col. 8, ll. 52–62.

With respect to Form B, Gidwani discloses:

> Polymorphic Form B of fingolimod hydrochloride (Ia) shows (when subjected to differential scanning calorimetry) an endothermic peak between 100° C. to 110° C., preferably

> between 107° C. to 108° C. Thus, a further subject of the present invention is a compound according to formula (Ia) in crystalline form, wherein the differential scanning calorimetry (DSC) shows an endothermic peak between 100° C. to 110° C. *but not an endothermic peak between 66° C. to 69° C.*

Ex. 1005 cols 8–9, ll. 62–2 (emphasis added). Figure 4 of Gidwani depicts aa corresponding DSC curve of fingolimod HCl form B, which is reproduced below:

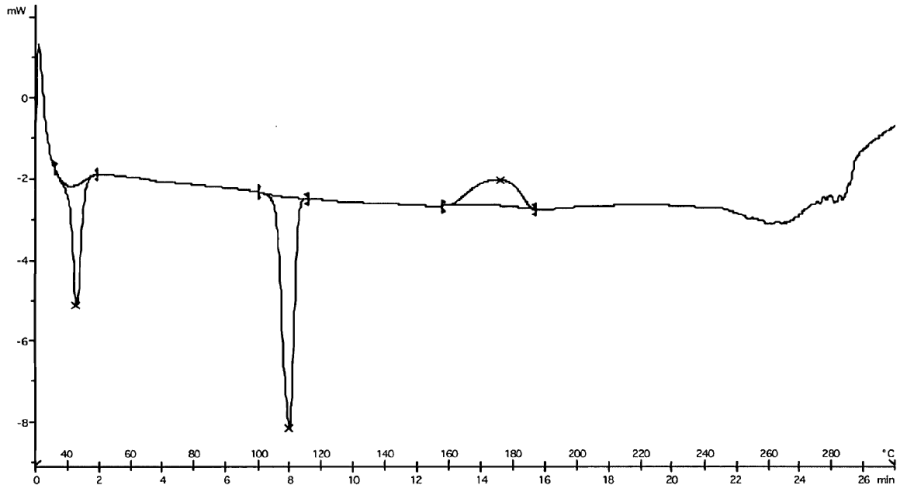
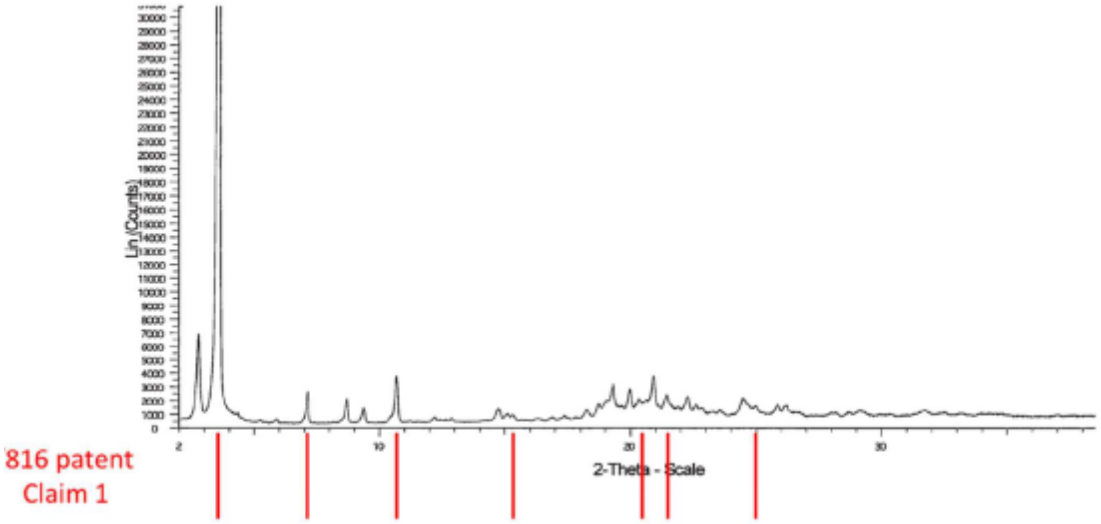


Figure 4 of Gidwani depicts a DSC curve obtained from fingolimod HCl Form B

2. Petitioner's contentions with respect to Gidwani

Petitioner argues that Example 2 of Gidwani discloses a process for the preparation of "crystalline fingolimod hydrochloride." Pet. 36 (citing Ex. 1005 col. 13, ll. 5–24). Petitioner notes that the XRPD pattern for the resulting fingolimod hydrochloride, which is a mixture of Mutz's Form I (Shilpa's Form-β) and Mutz's Form II, is shown in Figure 1 of Gidwani, and Petitioner's annotated version of Figure 1 is reproduced below:



Petitioner contends that, as shown above, Petitioner's annotated Figure 1 demonstrates that Gidwani discloses each and every one of the claimed peaks within the claimed range. Pet. 37 (citing Ex. 1002 ¶ 173). Petitioner adds that, although the XRPD pattern in Figure 1 contains peaks consistent with both Form I and Form II of Mutz, this does not prevent the identification of Form I as a component of the sample. The peaks indicative of Mutz's Form I/Shilpa's Form-β, including all claimed peaks recited in claim 1, are present, confirming that Mutz's Form I/Shilpa's Form-β is present in the sample. *Id.* (citing Ex. ¶ 174).

Petitioner next points to Figure 2 of Gidwani, which depicts a DSC curve taken from a mixture of fingolimod HCl Forms A and B, and which is reproduced below:

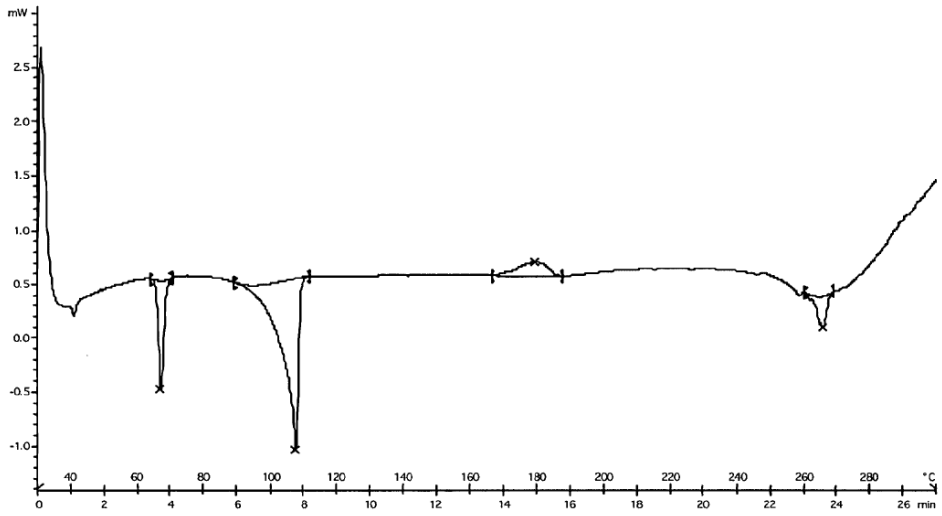


Figure 4 of Gidwani depicts a DSC curve obtained from fingolimod HCl Form B

Pet. 38. Therefore, argues Petitioner, Gidwani discloses endothermic peaks within each of the four claim ranges of claim 2. Pet. 39 (citing Ex. 1002 ¶ 177).

3. Patent Owner's Preliminary Response

Patent Owner contends that the sample in Gidwani's Example 2, from which the XRPD spectrum shown in Figure 1 above was produced, was expressly stated to be a mixture of two polymorphs, designated A and B. Prelim. Resp. 54 (citing Ex. 1005 col. 13, ll. 6–21). Patent Owner argues that, because there are no XRPD reference diffractograms provided for polymorphs A and B, no specific peaks in the Figure 1 diffraction pattern can be ascribed to either specific polymorph, and notes that Petitioner does not attempt to do so. *Id.* (citing Ex. 2008 ¶¶ 47, 49). Accordingly, Patent Owner argues, claims 1–4 of the '816 Patent cannot be anticipated because the Petition's mixing of data from two different polymorphs fails to establish that any specific polymorph yields the recited seven XRPD peaks. *Id.*

Similarly, Patent Owner notes that Gidwani discloses that its polymorphic Form B shows an endothermic peak between 100°C and 110°C (preferably between 107°C and 108°C), but not an endothermic peak between 66°C to 69°C. Prelim. Resp. 55 (citing Ex. 1005 col. 8, ll. 63–9, Figs 4 (reproduced above), 5). According to Patent Owner, Gidwani's disclosure of Form B as lacking a DSC endothermic peak between 66° C. to 69°C establishes that Form B cannot be the same as — and cannot anticipate —the claimed Form β of challenged claims 2–4, since Form β is repeatedly characterized by a DSC endothermic peak (Peak 2) between 65° C and 70°C.

4. Analysis

We find this analysis to be somewhat closer than that of Grounds 1 and 2. We agree with Patent Owner that the lack of an endothermic peak between 66°C to 69°C in Gidwani's crystalline fingolimod HCL Form B suggests that Form B is not the same as the '816 patents Form-β. However, we also note that such a peak *is* present in the DSC curve of Gidwani's Figure 2, which represents a mixture of Forms A and B. *See* Ex. 1005, Fig. 2. Petitioner's Declarant, Dr. McClurg, opines that "the DSC profile from Fig. 2 of [Gidwani] contains each of the claimed endothermic peaks of form-β." Ex. 1002 ¶ 183. Dr. McClurg similarly opines that, because all of the peaks in the XRPD of Gidwani's Figure 1, which depicts the XRPD spectrum of a mixture of Forms A and B, are present in the XRPD spectrum of the '816 patent's crystalline fingolimod HCl form-β, a person of skill in the art would understand that form-β is present in the mixture, presumably as Gidwani's Form A.

Patent Owner's Declarant, Dr. Eckhardt, disagrees, attesting that "[t]he Petitioner's mixture of data from to different polymorphs (A and B) in Fig. 1 fails to establish that any specific polymorph yields the seven XRPD peaks recited in claim 1 of the '816 patent." Ex. 2008 ¶ 49.

We agree with Patent Owner that fingolimod HCl Form B of Gidwani is unlikely to correspond to the '816 patent's form-β, because it lacks the recited Peak-3 "between 65 to 70°C." Nevertheless, that peak *is* present in Figure 2 of Gidwani, which represents a mixture of Forms A and B, as are the remaining claimed peaks (and not others). We find that it is reasonable to assume that a person of skill in the art, by a process of subtraction of the curves, could reasonably infer that Form A of Gidwani therefore represents the claimed form-β of the '816 patent, possessing the claimed peaks in the DSC curve. The same reasoning applies to the XRPD peaks of Gidwani's Figure 1, as compared to that presented in Figure 3 of the '816 patent, which shows the XRPD spectrum of the claimed fingolimod HCL form-β. We encourage the parties to develop these arguments further at trial.

F. Discretionary Denial of Institution of Inter Partes Review

Finally, Patent Owner urges us to exercise our discretion under both 35 U.S.C. §§ 314(a) and 325(d) to deny institution of trial. Prelim Resp. 4–22. Petitioner takes a contrary position, arguing that the Board should not deny institution. Pet. 40–45. We address the parties' arguments below.

1. Discretionary denial under 35 U.S.C. § 314(a)

a. Legal standard

Under our precedential decision in *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 15 at 12–17 (PTAB May 13, 2020), the Board, in deciding "whether efficiency, fairness, and the merits support the exercise of authority to deny institution in view of an earlier trial date in the parallel proceeding," should consider a variety of factors, and, in evaluating these factors, "takes a holistic view of whether efficiency and integrity of the system are best served." *Fintiv*, Paper 11 at 5–6; *see also Samsung Elecs. Am., Inc. v. Uniloc 2017 LLC*, IPR2020-00117, Paper 11 at 7–11 (PTAB May 28, 2020) (same). According to Patent Owner, granting the Petition for *inter partes* review would be an inefficient use of Board resources and is contrary to Congress's intent in establishing IPR proceedings. Prelim. Resp. 17.

In *Fintiv*, the Board set forth six factors relating to whether efficiency, fairness, and the merits support the exercise of authority to deny institution in view of an earlier trial date in the parallel proceeding:

1. whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted;

2. proximity of the court's trial date to the Board's projected statutory deadline for a final written decision;

3. investment in the parallel proceeding by the court and the parties;

4. overlap between issues raised in the petition and in the parallel proceeding;

5. whether the petitioner and the defendant in the parallel proceeding are the same party; and

6. other circumstances that impact the Board's exercise of *discretion, including the merits.*

Fintiv at 21.

In our analysis, we are also guided by the USPTO's recent *Interim Procedure for Discretionary Denials in AIA Postgrant Proceedings with Parallel District Court Litigation*, June 21, 2022 *available at*: https://www.uspto.gov/sites/default/files/documents/interim_proc_discretionary_denials_aia_parallel_district_court_litigation_memo_20220621_.pdf (last visited October 11, 222) (the "Guidance"). As stated by the Guidance, the Board will not rely on the *Fintiv* factors to discretionarily deny institution in view of parallel district court litigation when: (1) a petition presents compelling evidence of unpatentability; (2) a petitioner presents a stipulation (a "*Sotera* stipulation") not to pursue in a parallel proceeding the same grounds or any grounds that could have reasonably been raised before the PTAB[9]; and (3) if all other *Fintiv* factors weighing against exercising discretion to deny institution, or are neutral, the proximity to trial should not alone outweigh all of those other factors.[10] Guidance at 1–8.

We consider these interrelated factors, as they apply to the facts of the Petition, as follows.

i. *Fintiv* factor 1

With respect to *Fintiv* factor 1, Patent Owner argues that no motion to stay is currently pending, and neither party has indicated any intent to even

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[9] *See Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12 (PTAB Dec. 1, 2020) (precedential).

[10] The Guidance notes that the *Fintiv* factors do not apply to parallel litigation before the U.S. International Trade Commission (ITC). Guidance at 2–3, 5–7.

request a stay on these grounds. Prelim. Resp. 18. Petitioner does not dispute this. We find that, given the relatively early stage of the parallel district court litigation (*see Fintiv* factors 2 and 3 below) that this factor weighs slightly in favor of exercising our discretion to deny institution or is neutral.

ii. *Fintiv* factor 2

Patent Owner argues that trial in the parallel district court case is scheduled for October 10, 2023, which is roughly contemporaneous with the October 20, 2023 deadline for the final written decision, should *inter partes* review be instituted. Prelim. Rep. 18 (citing Ex. 2001, 4; Paper 3 (Notice of Filing Date); 35 U.S.C. § 316(a)(11)). Patent Owner notes that it filed its infringement action against Petitioner on April 21, 2021, and that the median interval between filing and trial is currently approximately 36 months. *Id.* at 18–19 (citing Ex. 2002). This latter figure predicts a trial date in April, 2024, well past the statutory date on which a final written decision would be due should we institute *inter partes* review.

We find that this factor weighs against exercising discretion to deny institution, given the current interval between statutory date for our Final Written Decision and trial in the District of Delaware.

iii. *Fintiv* factor 3

Patent Owner next argues that by the time the Board's institution decision is due, final non-infringement contentions will have been served (October 7, 2022) and final invalidity contentions will be due within a week (November 4, 2022). Prelim. Resp. 19. Patent Owner adds that document production will have been substantially completed (August 26, 2022), fact

discovery will cut off on November 11, 2022, and expert discovery will have begun. *Id.* (citing Ex. 2001). Patent Owner states that claim construction has been fully briefed and a *Markman* hearing is scheduled for November 23, 2022. *Id.* (citing Ex. 2001, 2).

We find that this factor weighs in against exercising discretion to deny institution, particularly in view of *Fintiv* factor 2, discussed above. The parties are in the early stages of discovery, and a *Markman* hearing has not yet been conducted. The parties are still a long way from a trial that will likely not begin before the Board renders its final written decision in the instituted *inter partes* review.

iv. *Fintiv* factor 4

With respect to the fourth *Fintiv* factor, Patent Owner contends that the parallel district court litigation will decide all of the issues raised in the Petition. Prelim Resp. Patent Owner notes that all three invalidity grounds raised in the Petition have been raised in Petitioner's invalidity contentions, which were served months ago. *Id.* (citing Ex. 2003).

Again, we find that this factor does not weigh in favor of the exercise of our discretion to deny institution of *inter partes* review. We acknowledge that the issues raised by the Petition appear to be the same as those raised before the district court by Petitioner. Normally, this factor weighs in favor of denial. Nevertheless, the Board can likely resolve those issues of patentability *via inter partes* review well before the matter goes to trial, which may be of some benefit to the district court. We consequently find that this factor weighs only slightly in favor of denial.

v. *Fintiv* factor 5

Patent Owner argues that the parties in this proceeding are the same as before the district court litigation, which should weigh in favor of denial of institution. Prelim. Resp. 21. Generally, however, this factor is weighed the same as factor 2 when the petitioner is the defendant in the litigation. If the Final Written Decision is anticipated to occur first, this factor typically weighs against exercising discretion to deny institution because of § 315(e) estoppel. In *Huawei Tech. Co. v. WSOU Inv.*, LLC, IPR2021-00225, for example, the panel agreed with the petitioner that "this factor favors denial if trial precedes the Board's Final Written Decision and favors institution if the opposite is true." Paper 11 at 14 (PTAB June 14, 2021) (internal quotation marks omitted). We consequently find that this factor weighs in favor of institution.

vi. *Fintiv* factor 6

With respect to the merits of the case, Patent Owner argues that Petitioner has failed to meet its burden under 37 C.F.R. § 42.108(c) of establishing a reasonable likelihood of success that any of the challenged claims are unpatentable. Prelim Resp. 22.

We disagree. We have explained, in Section II.C.4 above, why we conclude that Petitioner has established a reasonable likelihood of establishing at trial that claims 1–4 of the '816 patent are unpatentable. Indeed, with respect to Grounds 1 and 2 of the Petition, we find the evidence of unpatentability so strong as to be compelling. There is no dispute that Mutz teaches the claimed crystalline fingolimod HCl recited in the claims. The only remaining dispute with respect to these grounds is whether the disclosures of Mutz are enabled, which the incorporation by reference of

Fujita by Mutz appears to overcome by teaching the skilled artisan how to make Form I of crystalline fingolimod HCl. In view of the USPTO's Guidance with respect to compelling evidence of unpatentability, we find that, at this stage of the proceeding and on the record before us, this consideration outweighs all of the other *Fintiv* factors, none of which weigh strongly in favor of denial of institution.[11] *See* Guidance, n.6 ("The compelling evidence test affirms the PTAB's current approach of declining to deny institution under Fintiv where the evidence of record so far in the case would plain lead to a conclusion that one or more claims are unpatentable.") We accordingly do not exercise our discretion under 35 U.S.C. S 314(a) to deny institution of *inter partes* review. *See* Guidance, 3–5.

2. Discretionary denial under 35 U.S.C. § 325(d)

a. Legal standard

Under § 325(d), we have discretion to deny a petition that presents the same or substantially the same prior art or arguments as previously presented to the Office. *See* 35 U.S.C. § 325(d). In evaluating whether the factual predicate under § 325(d) is met, we consider a number of non-exclusive factors, as set forth in our decision in *Becton, Dickinson and Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 17–18 (PTAB Dec. 15, 2017) (precedential as to § III.C.5, first paragraph) ("the *Becton, Dickinson* factors"):

> (a) the similarities and material differences between the asserted art and the prior art involved during examination;

[11] We note that none of the other considerations cited in the Guidance apply in this case.

(b) the cumulative nature of the asserted art and the prior art evaluated during examination;

(c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection;

(d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art;

(e) whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and

(f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the prior art or arguments.

Becton, Dickinson, IPR2017-01586, Paper 8 at 17–18.

In performing an analysis under § 325(d):

> [T]he Board uses the following two-part framework: (1) whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.… If, after review of [*Becton, Dickinson*] factors (a), (b), and (d), it is determined that the same or substantially the same art or arguments previously were presented to the Office, then factors (c), (e), and (f) relate to whether the petitioner has demonstrated a material error by the Office.

Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH, IPR2019-01469, Paper 6 at 8 (PTAB Feb. 13, 2020) (precedential).

Consequently, we first turn to an analysis of *Becton, Dickinson* factors (a), (b), and (d) under this framework to determine whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office.

b. Part One of the *Advanced Bionic*s Analysis

Both parties agree that Mutz is listed as a reference on the face of the '816 patent and was submitted in an Information Disclosure Statement ("IDS") during prosecution. Pet. 41; Prelim. Resp. 8, 10. Similarly, Petitioner acknowledges that the PCT publication for Gidwani was cited in the Examiner's February 25, 2015 search results and Patent Owner contends that it submitted the Gidwani's application publication in the first IDS submitted with the filing of the '207 Application. Pet. 41; Prelim. Resp. 15 (citing Ex. 2005 (listing US 2012/0184617 to Gidwani et al ("'617 publication")). The extent to which the Examiner may have relied upon either reference is unclear, and neither reference formed the basis of, nor is mentioned in, the single Non-Final Office Action that preceded allowance of the claims of the '816 patent. *See* Ex. 1025, 6–8. Nevertheless, both references were indisputably before the Examiner during prosecution. We consequently turn to examine whether the Examiner materially erred in his consideration of the references.

c. Part Two of the *Advanced Bionics* Analysis

i. Mutz

The Specification of the '816 patent expressly discloses Mutz, stating that:

> Mutz et al in WO2010055028A2 reported various polymorphic forms of Fingolimod hydrochloride designated as Form-I (at room temperature), Form-II (however at a transition temperature of approximately 40°C.) and Form-III (however at a transition temperature of approximately 66°C.). Further, the patent application also mentions that approximately 107°C., Fingolimod hydrochloride forms a phase with lower crystalline order. However, *other than thermal transition based forms, no exact crystalline form have been reported in the literature*.
>
> In view of the existence of few known thermal transition based polymorphic forms of Fingolimod hydrochloride, there stills [sic] appears to be a need of novel crystalline forms, which are not only stable as well as convenient to scale up but also their processes provides improved yields & quality.

Ex. 1001 col.1, ll. 47–61 (emphasis added).

Petitioner contends that this characterization of Mutz is incorrect, and may have misled the Examiner away from conducting a substantive review of Mutz. Pet. 42. Petitioner contends that, as described above, Mutz discloses exact crystalline forms (Forms I, II, and III) and, for each form, Mutz reports XRPD and DSC data, as in the '816 patent, as well as data from other laboratory techniques. *Id.* Petitioner argues that Mutz, in fact, characterizes its crystal forms by more techniques than does the '816 patent. *Id.* Petitioner asserts that, by mischaracterizing Mutz and the prior literature as not reporting an "exact crystalline form" and suggesting that there "still appears to be a need of novel crystalline forms," Patent Owner directed the Examiner away from properly reviewing the disclosure of crystalline forms in Mutz and incorrectly suggested that the subject matter of the '816 patent was novel. *Id.* at 42–43.

Petitioner argues further that the '816 patent misleadingly and confusingly distinguishes the forms described by Mutz and other literature as "thermal transition based forms." Pet. 43 (citing Ex. 1001 col. 1, ll. 54–56). Petitioner contends that, to the contrary, Mutz describes the same thermal transitions between forms that are reported in the '816 patent. *Id.* According to Petitioner, both Mutz and the '816 patent, disclose DSC isotherms showing thermal transitions at approximately 40, 66 and 107°C. *Id.* (comparing Ex. 1004, 15 with Ex. 1001, col. 2, ll. 35–43). Petitioner contends that the Examiner erred in a manner material to the patentability of challenged claims in its consideration of Mutz. *Id.*

Patent Owner responds that, contrary to Petitioner's position, the passage from the '816 patent's Specification quoted above drew the Examiner's attention directly toward the most relevant portions of the Mutz reference and did not lead the Examiner away. Prelim. Resp. 9. Patent Owner notes that Mutz used nearly identical language to describe the polymorphic forms disclosed in the '816 patent's Specification. *Id.* (citing Ex. 1004, 1). According to Patent Owner, the '816 Specification then concluded its description of Mutz by stating that "other than thermal transition based forms, no exact crystalline form[s] have been reported in the literature." *Id.* at 10 (quoting Ex. 1001 col. 1, ll. 54–56). Patent Owner contends that the '816 Patent accurately told the Examiner that, beyond those forms disclosed in the Mutz reference, there were no literature reports of exact, i.e., characterized crystalline forms of crystalline fingolimod hydrochloride. *Id.*

Furthermore, argues Patent Owner, the '816 Patent listed the Mutz reference as the first Foreign Patent Document on the initial IDS filed September 14, 2012, and indicate "ALL" as the relevant portions of the

reference, again drawing the Examiner's attention to the entirety of the Mutz reference. Prelim. Resp. 10 (citing Ex. 2005, 1). Patent Owner argues that, during prosecution, it took every step to place the Mutz reference and its teachings directly before the Examiner. *Id.*

We are not persuaded by Patent Owner's argument. The passage of the '816 patent's Specification describing Mutz, quoted above, is at best incomplete. The '816 patent concludes its description of Mutz by expressly stating that "[h]owever, other than thermal transition based forms, no exact crystalline form have been reported in the literature." Ex. 1001 col. 1, ll. 54–56. In fact, Mutz expressly discloses XRPD spectra that indicate the crystalline structure. *See* Mutz, 2:

> Crystalline Form I of [fingolimod] hydrochloride is characterised by an X-ray powder diffraction pattern having peaks at least two, preferably at least four, and more preferably all, of the following 2-theta values: 3.6, 7.1, 10.7, 12.5, 15.4 and 20.6 degrees 2-theta. The peaks at said 2-theta values may have the following relative intensities: 3.6 (strong), 7.1 (weak), 10.7 (weak), 12.5 (weak), 15.4 (medium) and 20.6 (medium).

See also Mutz Fig. 1, Example 14. As we presently understand the methodology, X-ray powder diffraction is not a calorimetric method and XRPD spectra cannot reasonably be understood as revealing thermal-based transition forms. Rather, X-ray powder diffraction is a rapid analytical technique primarily used for phase identification of a crystalline material and can provide information on unit cell dimensions. *See* B.L. Dutrow, *X-ray Powder Diffraction (XRD)*, available at: https://serc.carleton.edu/research_education/geochemsheets/techniques/XRD

.html (last visited October 21, 2022).[12] *See* Ex. 3002. Or, in short, XRPD provides "exact crystalline form," as both the Specification of the '816 and Mutz disclose.

We consequently conclude that the Examiner materially erred in failing to address the disclosures of Mutz with respect to the XRPD spectra and DSC curve of crystalline fingolimod HCl which, on the record before us, we find could be reasonably understood to anticipate the claims of the '816 patent. Because we find the Examiner committed material error in this respect, we decline to exercise our discretion to deny institution under § 325(d).

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[12] Specifically:

> X-ray diffraction is based on constructive interference of monochromatic X-rays and a crystalline sample. These X-rays are generated by a cathode ray tube, filtered to produce monochromatic radiation, collimated to concentrate, and directed toward the sample. The interaction of the incident rays with the sample produces constructive interference (and a diffracted ray) when conditions satisfy Bragg's Law ($n\lambda=2d \sin \theta$). This law relates the wavelength of electromagnetic radiation to the diffraction angle and the lattice spacing in a crystalline sample. These diffracted X-rays are then detected, processed and counted. By scanning the sample through a range of 2θ angles, all possible diffraction directions of the lattice should be attained due to the random orientation of the powdered material. Conversion of the diffraction peaks to d-spacings allows identification of the mineral because each mineral has a set of unique d-spacings. Typically, this is achieved by comparison of d-spacings with standard reference patterns.

Id.

3. Conclusion

For the reasons we have explained, we decline to exercise our discretion under either 35 U.S.C. §§ 314(a) or 325(d). Accordingly, because we have determined that Petitioner has established at least a reasonable likelihood of prevailing at trial, we institute *inter partes* review of challenged claims 1–4 of the '816 patent. *See SAS*, 138 S.Ct. at 1359–60; *PGS*, 891 F.3d at 1360.

IV. CONCLUSION

For the forgoing reasons, we conclude that Petitioner has demonstrated a reasonable likelihood that at least one challenged claim of the '816 patent would have been obvious over the prior art of record. Accordingly, we institute an *inter partes* review of all challenged claims of the '816 patent, based on all of the grounds identified in the Petition. *See SAS*, 138 S.Ct. at 1359–60; *PGS*, 891 F.3d at 1360.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314, *inter partes* review is instituted on all claims and all Grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, *inter partes* review of the '816 patent shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

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