IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EISAI CO., LTD., EISAI INC., and NOVARTIS PHARMA AG,	:	
Plaintiffs,	:	
v.	:	C.A. No. 13-1279-LPS (Consolidated)
GLENMARK PHARMACEUTICALS, LTD. et al.,	:	
Defendants.	:	

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MEMORANDUM OPINION

March 17, 2015
Wilmington, Delaware

STARK, U.S. District Judge:

On July 24, 2013, Plaintiffs Eisai Co., Ltd., Eisai Inc. (collectively, "Eisai"), and Novartis Pharma AG ("Novartis") (collectively, "Plaintiffs") filed suit against Glenmark Pharmaceuticals, Ltd., Glenmark Generics Limited, and Glenmark Generics Inc. USA (collectively, "Glenmark") (C.A. No. 13-1279-LPS D.I. 1); Hetero Labs Ltd. and Hetero USA Inc. (collectively, "Hetero") (C.A. No. 13-1280-LPS D.I. 1); Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, "Lupin") (C.A. No. 13-1281-LPS D.I. 1); Mylan Pharmaceuticals Inc. ("Mylan") (C.A. No. 13-1282-LPS D.I. 1); and Roxane Laboratories, Inc. ("Roxane") (C.A. No. 13-1284-LPS D.I. 1), alleging infringement of U.S. Patent Nos. 6,740,669 ("the '669 patent"), 7,750,028 ("the '028 patent"), and 8,076,362 ("the '362 patent") (collectively, "the patents-in-suit"). Defendants are alleged to infringe the patents-in-suit pursuant to 35 U.S.C. § 271(e)(2) by having filed their respective Abbreviated New Drug Applications ("ANDA") seeking approval to market a generic version of Eisai's anti-epileptic drug product Banzel®. The patents-in-suit relate to crystal modification A of the compound 1-(2,6-difluorobenzyl)-1H-1,2,3-triazole-4-carboxamide, which is the active ingredient in Banzel®, and its use as a pharmaceutical product.

Pending before the Court is the issue of claim construction of various disputed terms of the patents-in-suit. The parties completed briefing on claim construction on November 14, 2014. (C.A. No. 13-1279-LPS D.I. 90, 97, 118, 120[1]) The parties also submitted technology tutorials (D.I. 87, 89) and provided expert reports (D.I. 92-96, 97 Ex. 1, 120 Ex. 5). The Court held a *Markman* hearing on December 8, 2014. (*See* D.I. 139) (Transcript) ("Tr.")

[1]On April 9, 2014, the actions were consolidated, with C.A. No. 13-1279-LPS as the lead case. The remainder of this Opinion will refer to the "D.I." number therein, unless otherwise indicated.

I. PROSECUTION HISTORY

A. '669 Patent

On June 8, 1998, Novartis filed PCT Application No. PCT/EP98/03427 ("the '427 application"). The national stage entry of the '427 application was U.S. Serial No. 09/125,329 ("the '329 application"), which ultimately issued on May 25, 2004 as the '669 patent. The '329 application was filed with independent claims directed to crystal modification A of the compound 1-(2,6-difluorobenzyl)-1H-1,2,3-triazole-4-carboxamide (hereinafter, "rufinamide") characterized by peaks determined by the patterns from different experimental techniques (e.g., X-Ray Powder Diffraction ("XRPD"), Fourier-Transform Infrared Spectroscopy ("FT-IR"), Fourier-Transform Raman Spectroscopy ("FT-Raman"), and Differential Scanning Calorimetry ("DSC")). (*See* D.I. 79 ("JCCC") Exs. R, S, T)

On June 1, 2000, the examiner rejected all pending claims (claims 1-25) on four separate bases.[2] (JCCC Ex. F) (May 30, 2000 Office Action) First, the examiner rejected the pending claims under § 102(a), (b), (e), and/or (f) as anticipated by European Patent No. 199,262 ("Meier I") and U.S. Patent No. 4,789,680 ("Meier II"), which disclosed "the crystal form of the instant compound obtained by recrystallization from ethanol" and therefore gave rise to anticipation under the "Petering doctrine"[3] and related genus case law. (*Id.* at 3) Second, the claims were

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[2]Claims 11, 12, 23, and 24 were also rejected under 35 U.S.C. § 101.

[3]*See In re Petering*, 301 F.2d 676, 681 (C.C.P.A. 1962) (affirming rejection under § 102(b) where prior art did not expressly name claimed compounds but "one skilled in this art would . . . at once envisage each member of this limited class, even though this skilled person might not at once define in his mind the formal boundaries of the class as we have done here").

rejected under § 103(a) as obvious in light of the combined teachings of Meier I and Meier II, which "teach the crystal forms of the instant known compound" (although not the "the lines with interplanar spacings of the X-ray powder pattern of said form") in view of two articles written by K. Munzel ("Munzel I" and "Munzel II"), which "teach that compounds exist as polymorphs and retain pharmaceutical activity." (*Id.* at 4) Third, all claims were also rejected under § 112, ¶ 2 as indefinite, as the examiner found (among other things) that "modification" in claims 1-9, 11-14, 16-21, 23, and 24 was indefinite "since a modification refers not only to crystal forms but also to undefined possible modifications of the chemical structure." (*Id.* at 5) The examiner also stated that Claim 1 "fails to clearly claim what is intended by applicants" with regard to crystal modifications A and A'." (*Id.* at 6) ("How can 'modification A" be identical to 'modification A'? Claim 1 does not permit any defects in 'modification A.' Yet the dependent claims recite that modification A has defects.") Finally, all claims were also rejected for obviousness-type double patenting. (*See id.* at 6-7)

In response to the § 102 prior art rejections, applicants stated:

> Although Applicants agree with the propositions set forth in the case law relied upon by the Examiner, it is Applicants' belief that they are inapplicable to the present fact situation. Quite simply, the Meier I and Meier II references are devoid of any mention that the compound 1-(2,6-difluorobenzyl)-1H-1,2,3-triazole-4-carboxamide ***can exist in different crystalline forms***, let alone the specific crystalline forms to which the instant claims are limited. Moreover, the instantly claimed crystalline forms are ***characterized by characteristic lines at interplanar spacings as determined by means of an X-ray powder pattern***. Accordingly, neither the teachings of Meier I nor the teachings of Meier II anticipate any of the instant claims since each and every element of the instantly claimed invention is not disclosed by either the Meier I or Meier II references . . . .

(JCCC Ex. G (Sept. 1, 2000 Amendment) at 5) (emphasis added) Similarly, with regard to the § 103 obviousness rejection, the applicants stated that "no more than a cursory review of the Meier references reveals the fact that they are silent with regard to even a hint of a recognition that the specific compound alluded to above can exist in different crystalline forms, let alone contains any suggestion that different crystalline forms could or should be made or how any of the crystalline forms can be obtained." (*Id.* at 6)

In an effort to overcome the § 112 indefiniteness rejection, the applicants either amended or canceled and replaced claims 1-9, 11-14, 16-21, 23, and 24 to recite either "crystal modification" or "crystal modification A." (*Id.* at 1-2) For example, amended claim 1 began: "Crystal modification A of the compound . . . ." (*Id.* Ex. J (Appendix of April 19, 2001 Appeal Brief) at A-1 (reciting claims as last amended, canceled, and replaced before Final Office Action)) On October 13, 2000, the rejections were maintained in the Final Office Action. (*See id.* Ex. H) In a response to the examiner's comment under § 112 that Claims 1-9, 13, 14, 16-21, 26, 28, 30, and 31 are substantial duplicates, the applicants stated: "Claim 1 is intended to claim a specific crystalline form of the compound 1-(2,6-difluorobenzyl)-1H-1,2,3-triazole-4-carboxamide, viz., crystal modification A, and characterizes said crystalline form with sufficient particularity. As to the other crystalline form, viz., crystal modification A', it is ***identical*** to crystal modification A, save for smaller line spacings as detected by X-ray analysis." (*Id.* Ex. I at 6) (emphasis in original)

After the Final Office Action rejected all pending claims, applicants filed an appeal with the USPTO Board of Patent Appeals and Interferences ("the Board"). Applicants re-stated their prior arguments for § 103 and obviousness-type double patenting. (*See id.* Ex. J (April 19, 2001

Appeal Brief) at 5-7) As for the § 102 and § 112 rejections, they were eventually withdrawn by the examiner. (*See id.* Ex. K (Examiner's Answer) at 3)

The Board reversed the examiner's rejections with regard to both remaining grounds. In terms of the § 103 obviousness rejection, the Board held that after "[h]aving carefully reviewed each Meier reference and the discussion of polymorphism in each Muenzel [sic] reference, we disagree that the cited prior art would have led a person having ordinary skill to the specific crystal modifications A and A' recited in the claims on appeal." (*Id.* Ex. V (Nov. 17, 2003 Board Decision) at 6)

2. '028 Patent

On January 11, 2006, Novartis filed U.S. Serial No. 11/329,945 ("the '945 application"), which is a continuation of the '329 application and ultimately issued on July 6, 2010 as the '028 patent. The '945 application included claims directed to methods of treating epilepsy using crystal modification A of rufinamide characterized by characteristic XRPD values.

On November 13, 2007, the examiner rejected all pending claims under § 102(b) as being anticipated by Meier II supplemented "with Palhagen et al." and under § 103 as unpatentable "over Palhagen et al. and Meier II in view of Rowland and Tozer, and Tasso et al." (JCCC Ex. X (Nov. 7, 2007 Office Action) at 2) In response to the § 102(b) rejection, the applicant stated:

> Applicant respectfully submits that, contrary to the Examiner's statement, Meier does not teach each and every element of Applicant's claims. More specifically, Meier, at col 20, example 35, discloses 1-(2,6-difluorobenzyl)-1H-1,2,3-triazole-4-carboxamide with a melting point of 237-240° C. This does not anticipate Applicant's claimed invention because it does not disclose crystal modification form A or form A'.
>
> Applicant claims 1-(2,6-difluorobenzyl)-1H-1,2,3-triazole-

> 4-carboxamide – form A – which is not taught by Meier. Moreover, ***crystal modification A is a significant limitation because crystal modification A is defined on page 2 of the specification as "melting at 242° C"***, which is outside of the range taught by Meier. Furthermore, Applicant teaches "a therapeutically effective amount of crystal modification A . . ." which is nowhere disclosed or discussed in Meier.

(*Id.* Ex. Y (Feb. 19, 2008 Amendment and Reply) at 7) (emphasis added) With regard to the reference to "page 2" in the specification, the disclosure states: "The novel crystal modification A of 1-(2,6-difluorobenzyl)-1H-1,2,3-triazole-4-carboxamide melts at 242° C (239-245° C)." (*See id.* Ex. EE (U.S. Serial No. 10/294,408) at 2 (continuation of '329 application containing common specification for all three patents-in-suit); *see also* '028 patent at 2:8-9)

3. '362 Patent

On April 26, 2010, Novartis filed U.S. Serial No. 12/767,003 ("the '003 application"), which is a continuation of the '329 application and ultimately issued on December 13, 2011 as the '362 patent. The '003 application was filed with independent claims directed to a solid dosage/tablet containing crystal modification A of rufinamide.

II. LEGAL STANDARDS

The ultimate question of the proper construction of a patent is a question of law. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837 (2015) (citing *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388-91 (1996)). "It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks omitted). "[T]here is no magic formula or catechism for conducting claim construction." *Phillips*, 415 F.3d at 1324. Instead, the court is free to attach the appropriate weight to appropriate sources "in

light of the statutes and policies that inform patent law." *Id.*

"[T]he words of a claim are generally given their ordinary and customary meaning . . . [which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.* at 1312-13 (internal citations and quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted). The patent specification "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

While "the claims themselves provide substantial guidance as to the meaning of particular claim terms," the context of the surrounding words of the claim also must be considered. *Phillips*, 415 F.3d at 1314. Furthermore, "[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment . . . [b]ecause claim terms are normally used consistently throughout the patent . . . ." *Id.* (internal citation omitted).

It is likewise true that "[d]ifferences among claims can also be a useful guide . . . . For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Id.* at 1314-15 (internal citation omitted). This "presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim." *SunRace Roots Enter. Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003).

It is also possible that "the specification may reveal a special definition given to a claim

term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316. It bears emphasis that "[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (internal quotation marks omitted), *aff'd*, 481 F.3d 1371 (Fed. Cir. 2007).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). The prosecution history, which is "intrinsic evidence," "consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

In some cases, "the district court will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Teva*, 135 S. Ct. at 841. Extrinsic evidence "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. For instance, technical dictionaries can assist the court in determining the meaning of a

term to those of skill in the relevant art because such dictionaries "endeavor to collect the accepted meanings of terms used in various fields of science and technology." *Phillips*, 415 F.3d at 1318. In addition, expert testimony can be useful "to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of ordinary skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Id.* Nonetheless, courts must not lose sight of the fact that "expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Id.* Overall, while extrinsic evidence "may be useful" to the court, it is "less reliable" than intrinsic evidence, and its consideration "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1318-19. Where the intrinsic record unambiguously describes the scope of the claimed invention, reliance on extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

Finally, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." *Osram GmbH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007).

III. CONSTRUCTION OF DISPUTED TERMS[4]

1. "crystal modification A" ['669 patent, claims 1, 6, 10, 11, and 18; '028 patent, claims 1, 3, 5, 6, and 8; '362 patent, claims 1, 5, and 8-16][5]

Plaintiffs' Proposed Construction: No construction is necessary. In the alternative: "a crystal modification of the compound 1-(2,6-difluorobenzyl)-1H -1,2,3-triazole-4-carboxamide (as opposed to a method of use or a method of manufacturing), referenced as 'A,' and having the characteristics specifically set forth in each respective claim or the claim from which it depends"
Defendant Roxane's Proposed Construction: "the crystal modification melting at 242° C and characterized by characteristic lines at interplanar spacings ('669 patent at 2:23-26) as determined by means of an X-ray powder pattern"
Defendant Lupin's Proposed Construction: "a crystal modification of 1-(2,6-difluorobenzyl)-1H-1,2,3-triazole-4-carboxamide that can be distinguished from other crystal modifications by reference to characteristics listed in the patent, such as x-ray powder pattern lines, FT-IR bands, FT-Raman bands, differential scanning calorimetry thermogram, or melting temperature"
Defendants Mylan and Glenmark's Proposed Construction: No construction is necessary. In the alternative: "a polymorphic crystal modification that can be distinguished from other crystal modifications"
Defendant Hetero's Proposed Construction: "a polymorphic crystal modification that can be distinguished from other crystal modifications, including by having interplanar spacings (d values) of 3.68 Å, 3.64 Å, 3.51 Å, 3.48 Å, 3.19 Å and 3.15 Å" Alternatively, the claim is indefinite.

[4]The parties have jointly proposed constructions for three terms. Finding the parties' constructions for "modification A" ('669 patent at claim 9) and "crystal modification" ('669 patent at claim 3) consistent with the intrinsic evidence, the Court construes both terms to mean "crystal modification A." (*See* JCCC Ex. A) Likewise, the Court construes the term "the compound 1-(2,6-difluorobenzyl)-1H-1,2,3-triazole-4-carboxamide" as "rufinamide insofar as it is a reference to the chemical compound 1-(2,6-difluorobenzyl)-1H-1,2,3-triazole-4 -carboxamide." (*See* D.I. 132)

[5]As the patents-in-suit are of the same family and share a continuous chain of prosecution, their specifications are nearly identical, except that the '028 specification includes additional examples concerning polymorphic forms referred to as crystal modifications B and C.

Court's Construction: "a crystal modification of the compound 1-(2,6-difluorobenzyl)-1H -1,2,3-triazole-4-carboxamide, referenced as 'A,' and having the characteristics specifically set forth in each respective claim or the claim from which it depends"

As an initial matter, the parties dispute whether the preamble is limiting.[6] The Court finds "crystal modification A" here is a limitation. Contrary to Plaintiffs' position, "crystal modification A" is more than a mere "term of convenience," *see Pfizer Inc. v. Dr. Reddy's Labs. Ltd.*, 2011 WL 767849, at *4 (D. Del. Feb. 28, 2011), but rather is a limitation arising from amendments made during prosecution of the '669 patent. In response to rejections by the examiner under § 112, made on the basis that "modification" alone could refer not only to modifications of the crystal forms but perhaps to undefined modifications of the chemical structure as well, the claims were amended to "***crystal*** modification" or "***crystal*** modification A."[7] (JCCC Ex. F at 5 (emphasis added); *id.* Ex. G at 1-2; *see also id.* Ex. I at 6 ("Claim 1 is intended to claim a specific crystalline form of the compound . . . .") Because the preamble is a limitation, the Court will construe the term.

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[6]The parties are in agreement, however, that the Court's construction should be the same across all of the patents-in-suit. Hence, for example, the Court will make a single determination as to whether the preamble is a claim limitation, and will not decide whether it may only be a limitation in one patent while not also being a limitation in another patent.

[7]*See also* JCCC Ex. G at 6 (responding to § 103 rejection over Meier: "Applicants readily acknowledge that Example 4 of Meier I and Example 35 of Meier II have the same chemical formula as the compound of Claims 1 and 7, the scopes of which are directed to ***two different crystalline forms of said compound*** . . . .") (emphasis added); *id.* at 8 (responding to obviousness-type double patenting rejection: "copending U.S. Application No. 09/129,330 . . . mentions the existence of ***crystal modifications A and A'***, i.e., the two crystalline forms to which the instant claims are directed . . . .") (emphasis added); *id.* at 4 (responding to rejection of "crystal modification A" in claim 1 as indefinite: "Claim 1 is intended to claim a specific crystalline form of [rufinamide], viz., ***crystal modification A***, and characterizes said crystalline form with sufficient particularity.") (emphasis added)

The Court construes the term "crystal modification A" to mean: "a crystal modification of the compound 1-(2,6-difluorobenzyl)-1H-1,2,3-triazole-4 -carboxamide, referenced as 'A,' and having the characteristics specifically set forth in each respective claim or the claim from which it depends" – which is an amended version of Plaintiffs' alternative proposed construction. This construction reflects the preamble's limitation that "crystal modification A" claims a specific crystal modification of the compound, while refraining from reading in limitations recited elsewhere in the body of claim 1 or only in one of the dependent claims.

The Court rejects Roxane's position that the preamble imposes a limitation that "crystal modification A" must be characterized by characteristic lines at interplanar spacings specifically recited in the '669 patent specification at column 2, lines 23-26. The purported prosecution history disclaimer cited by Roxane distinguishes the Meier reference on the basis that it is "devoid of any mention that the compound . . . can exist in different crystalline forms, let alone the specific crystalline forms to which the instant claims are limited." (*Id.* Ex. G at 5) The applicant then stated: "Moreover, the instantly claimed crystalline forms are characterized by characteristic lines at interplanar spacings as determined by means of an X-ray powder pattern." Thus, the applicant sought to overcome the § 102(b) rejection by explaining that the Meier reference fails to disclose even ***the possibility*** that the rufinamide compound can exist in different ***crystal forms***. The applicant then emphasized that the claimed invention provided a way of measuring such polymorphisms: i.e., characteristic lines at interplanar spacings of an X-ray powder pattern. This statement makes no reference to the specific d-values recited in the specification and in the body of Claim 1 (10.5 Å, 5.14 Å, 4.84 Å, 4.55 Å, 4.34 Å, 4.07 Å, 3.51 Å, 3.48 Å, 3.25 Å, 3.19 Å, 3.15 Å, 3.07 Å, 2.81 Å); to the extent the above statement may be read to

allude to those values, such a vague, implicit reference does not rise to the level of a clear and unambiguous disavowal. Therefore, the Court will not import the proposed limitation into the claim.

Likewise, the Court rejects Roxane's position that the preamble includes the limitation that crystal modification A "must melt at 242° C." Roxane endeavors to read a statement made by the applicant during the prosecution of the '028 patent, years after the '669 patent had already issued, back into the preamble of claim 1 of the '669 patent. More specifically, Roxane contends that because the applicants expressly stated during the '028 patent's prosecution that the claimed modification A is "defined on page 2 of the specification as 'melting at 242° C'" (*id.* Ex. Y at 7), the patentee's statements to the examiner apply equally to the earlier '669 patent, as the '669 patent's specification also has the same "melting at 242° C" phrase on page 2.

Roxane's argument fails for several reasons. First, the phrase Roxane references as appearing in the specifications of both the '669 and '028 patents actually reads in full: "crystal modification A of 1-(2,6-difluorobenzyl)-1H-1,2,3-triazole-4-carboxamide ***melts at 242° C. (239-245° C)***." ('669 patent at 1:63-65 (emphasis added); '028 patent at 2:8-9 (emphasis added); *see also* JCCC Ex. EE at 2) Roxane provides no basis for concluding a person of ordinary skill would understand the plain and ordinary meaning of the preamble term "crystal modification A" as limited to melting at 242° C when the reference to that melting point is immediately followed by a range "(239-245° C)." Roxane's arguments of lexicography and disclaimer based on the '028 prosecution history are also unavailing. Although the '669 and '028 patents share the same specification, the Court finds the statements relied on by Roxane have only weak probative value. Without explanation, Roxane asks the Court to read a statement made about (i) a term

concerning a therapeutically effective amount of "crystal modification A" (ii) appearing in the body of claims on a method of treating epilepsy (iii) in February 13, 2008 (iv) in response to a § 102(b) rejection of those distinct pending method claims as being anticipated by Meier, as somehow definitional to (i) a separate instance of the term "crystal modification A" (ii) appearing in the preamble of claims on the crystal form itself (iii) from a patent that issued on May 25, 2004. (*See* JCCC Ex. Y at 2-5) (showing "crystal modification A" appearing after "comprising" in all claims) Beyond the timing discrepancy, when the selectively quoted portions of the '028 patent prosecution history are considered in context, it is clear that the patentee was only addressing the specific Office Action rejections that were pending at the time, and not narrowly redefining the term "crystal modification A." In short, while "the prosecution history of one patent is relevant to an understanding of the scope of a common term in a second patent stemming from the same parent application," *Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340, 1349 (Fed. Cir. 2004), the different nature of the claims and rejections involved reduces the weight the Court will accord to the prosecution history here.

Separately, Hetero contends that its construction must be adopted to avoid rendering the term indefinite in claims 10 and 11. (*See* D.I. 90 at 17) (arguing Plaintiffs' construction makes claims 10 and 11, which claim modification A as characterized by "bands at 3412 cm^{-1} and 3092 cm^{-1} in the FT-IR spectrum," meaningless since the specification discloses that A' also has these bands) The Court disagrees. Hetero's argument relies on the mistaken assumption that crystal modification A and A' must have a different crystal structure that is ***detectable in the FT-IR spectrum***. The plain language of the claims makes clear crystal modification A and A' share the same crystal structure, and that A' is a particular type of A that has defects in the crystal lattice.

('669 patent at claim 7) ("The crystal modification A' of the compound 1-(2,6-difluorobenzyl)-1H-1,2,3-triazole-4-carboxamide, characterized in that it is identical to the modification A according to claim 1 but has defects in the crystal lattice."); *see also id.* at claims 12-16, 20, 21) Indeed, as written, most of the claims directed to crystal modification A' (claims 7, 12-16, 20, and 21) make no mention of different ***measurements*** as a basis for differentiating A' from A. Instead, crystal modification A' is claimed based on the physical differences – ***actual physical defects*** – in the crystal lattice.

As for manifesting those physical defects, the specification and claim 8 – the only other claim that mentions crystal modification A' – disclose and claim one possible way of detecting them. More precisely, during XRPD analysis, a characteristic measurement can be used to identify modification A': "smaller" spacings between certain pairs of lines at particular interplanar spacings in comparison to those found for modification A generally. (*Id.* at 6:28-31; *id.* at claim 8 (A' is "characterized by line spacings, smaller compared to modification A, between the pairs of lines at interplanar spacings 3.68 Å and 3.64 Å, 3.51 Å and 3.48 Å and 3.19 Å and 3.15 Å.")) Other measurements resulting from other analysis may not necessarily manifest the physical difference. Hetero insists that FT-IR spectrum measurements in claims 10 and 11 must allow a person of ordinary skill to distinguish between A and A'. However, Hetero has not pointed to any proof in the intrinsic record – or proffered extrinsic evidence – that confirms that these defects must be evident in measurements taken using FT-IR spectrum analysis involved in these claims. Hetero has failed to prove indefiniteness.

In short, crystal modification A' is a subtype of modification A. Claims 10 and 11 do not require this subtype to be identified, but rather claim the broader category (crystal modification

A), as detected using bands in the FT-IR spectrum. Claims 7, 12-16, 20, and 21 make clear A' can be identified from within the more general A population because A' has physical defects in the lattice, and claim 8 claims one particular method (XRPD) whose measurements will manifest that physical difference if examined as specified in the claim. Hence, in light of the intrinsic evidence, the Court concludes that its adopted construction for "crystal modification A" informs a person of ordinary skill with "reasonable certainty" about the difference between crystal modification A and crystal modification A' across the asserted claims. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124, 189 L. Ed. 2d 37 (2014) (holding "a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention").

2. "characterized by characteristic lines at [with] interplanar spacings (d values) of 10.5 Å, 5.14 Å, 4.84 Å, 4.55 Å, 4.34 Å, 4.07 Å, 3.51 Å, 3.48 Å, 3.25 Å, 3.19 Å, 3.15 Å, 3.07 Å, 2.81 Å, [as] determined by means of an X-ray powder pattern" ['669 patent, claim 1; '028 patent, claim 1; '362 patent, claims 1, 10, and 12]

Plaintiffs' Proposed Construction: "identifiable by reference to an X-ray powder pattern that includes characteristic lines at interplanar spacings (d values) of 10.5 Å, 5.14 Å, 4.84 Å, 4.55 Å, 4.34 Å, 4.07 Å, 3.51 Å, 3.48 Å, 3.25 Å, 3.19 Å, 3.15 Å, 3.07 Å, 2.81 Å"
Defendant Roxane's Proposed Construction: "having the exact interplanar spacings (d values) and relative intensities for the specified pattern of lines at 10.5 Å, 5.14 Å, 4.84 Å, 4.55 Å, 4.34 Å, 4.07 Å, 3.51 Å, 3.48 Å, 3.25 Å, 3.19 Å, 3.15 Å, 3.07 Å, 2.81 Å, as determined by means of an X-ray powder pattern"
Defendants Lupin, Mylan, and Glenmark's Proposed Construction: "distinguishable from all other forms of rufinamide by selected lines at [with] interplanar spacings (d values) of 10.5 Å, 5.14 Å, 4.84 Å, 4.55 Å, 4.34 Å, 4.07 Å, 3.51 Å, 3.48 Å, 3.25 Å, 3.19 Å, 3.15 Å, 3.07 Å, 2.81 Å ± measurement error, [as] determined by means of an X-ray powder pattern"

Defendant Hetero's Proposed Construction: "with selected lines at interplanar spacings (d values) of 10.5 Å, 5.14 Å, 4.84 Å, 4.55 Å, 4.34 Å, 4.07 Å, 3.51 Å, 3.48 Å, 3.25 Å, 3.19 Å, 3.15 Å, 3.07 Å, 2.81 Å ± measurement error, determined by means of an X-ray powder pattern"
Court's Construction: "identifiable by reference to an X-ray powder pattern that includes characteristic lines at interplanar spacings (d values) of 10.5 Å, 5.14 Å, 4.84 Å, 4.55 Å, 4.34 Å, 4.07 Å, 3.51 Å, 3.48 Å, 3.25 Å, 3.19 Å, 3.15 Å, 3.07 Å, 2.81 Å"

As an initial matter, Plaintiffs and Defendants Hetero and Roxane dispute whether (i) the plain meaning of the term "characterized by" accounts for experimental error and (ii) whether the term requires every single recited d-value to be present in every experimental run.

With regard to the first dispute, the claims and specification are silent on the matter of measurement error. However, the experts who have opined on the issue for both Plaintiffs and Defendants agree that XRPD – which the claims themselves state is used to determine "characteristic lines at [with] interplanar spacings (d values)" – was universally known at the pertinent time to be subject to measurement error. (*See* D.I. 97 (Declaration of Allan S. Myerson) ("Myerson Decl.") at ¶ 41; Declaration of Arnold L. Rheingold ("Rheingold Decl.") at ¶¶ 29-31 (minuscule unit of measurement for "d values" (Angstroms) introduces measurement error); *see also id.* Ex. C (U.S. Pharmacopeia (1995)) at 1844 ("2θ values should typically be reproducible to ±0.10 or 0.20 degrees")) It follows that a person of ordinary skill's understanding of the term XRPD would include the expected error associated with the measurement being used. *See Takeda Pharm. Co. v. Handa Pharm., LLC*, 2012 WL 1243109, at *12 (N.D. Cal. Apr. 11, 2012) (concluding in light of expert deposition that "person skilled in the art would not have required any discussion of the experimental error associated with XRPD diffraction, either in the specification or in the claims, to understand that the references to

'characteristic peaks at interplanar spacings (d)' allowed for such experimental error").

As for the second issue, the plain and ordinary meaning of "characterized by" does not require all of the recited d-values to be present in every experimental run (i.e., an exact one-to-one match). Rather, as the broad claim language (drafted by the applicants and approved by the PTO) sets out, the claim limitation is satisfied as long as the crystal form can be "characterized by" – that is, ***identified by*** – reference to ***the characteristic lines*** set forth in the claim.[8] (*See also* '669 patent at Table 1 (listing d-values measured for crystal modification A); Myerson Decl. at ¶ 23 ("POSA would compare the d-values obtained experimentally on that sample with that of the reference polymorphic forms of the compound and would look for the presence of ***unique characteristic peaks*** which would signify a given crystalline form.") (emphasis added))

The remaining dispute among the parties concerns whether a certain measurement, "relative intensities," is necessary to characterize the claimed crystal modifications. With regard to Roxane's proposed construction, the plain language of the claims does not require inclusion of "relative intensities," and Roxane has failed to demonstrate that the prosecution history evidences a clear and unambiguous disavowal of claim scope such that the issued claims' reference to "XRPD" necessarily requires relative intensity values. (*See* JCCC Ex. G, (September 1, 2000 Office Action Response) at 5 (no discussion of relative intensities); *id.* Ex. I at 2; *id.* Ex. J at 4-5) Therefore, having rejected the proposed limitations Hetero and Roxane would have the Court

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[8]It will be for the factfinder to determine whether any accused crystal forms are the claimed "crystal modification A," but these infringement questions do not bear on the proper claim construction. *See PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1355 (Fed. Cir. 1998) (stating once claim term is defined with "whatever ***specificity and precision is warranted*** by the language of the claim and the evidence . . . the task of determining whether the construed claim reads on the accused product is for the finder of fact.") (emphasis added).

read into the claim language, and because Lupin, Mylan, and Glenmark largely view their construction as concordant with Plaintiff's proposal (*see* Tr. at 69-70),[9] the Court adopts Plaintiff's proposed construction.

3. A. **"characterized by the following absorptions in the FT-IR spectrum (KBr pellet-transmission method) at 3092 cm^{-1} and 3412 cm^{-1}" ['669 patent, claim 3]**

B. **"characterized by bands at 3412 cm^{-1} and 3092 cm^{-1} in the FT-IR spectrum" ['669 patent, claim 10]**

C. **"characterized by absorption bands at 3412 cm^{-1} and 3092 cm^{-1} in the FT-IR spectrum (KBr pellet-transmission method)" ['028 patent, claim 3]**

Plaintiffs' Proposed Construction: "identifiable by reference to a FT-IR spectrum (KBr pellet-transmission method) that includes bands at 3412 cm^{-1} and 3092 cm^{-1}"
Defendant Roxane's Proposed Construction: "having absorption bands in the FT-IR spectrum (KBr pellet-transmission method) with peaks at 3412 cm^{-1} and 3092 cm^{-1}"
Defendants Lupin, Mylan, and Glenmark's Proposed Construction: "distinguishable from all other forms of rufinamide by the following absorptions in the FT-IR spectrum (KBr pellet-transmission method) 3412 cm^{-1} and 3092 cm^{-1} ± measurement error"
Defendant Hetero's Proposed Construction: "with the following absorptions in the FT-IR spectrum (KBr pellet-transmission method) 3412 cm^{-1} and 3092 cm^{-1} ± measurement error"
Court's Construction: "identifiable by reference to a FT-IR spectrum (KBr pellet-transmission method) that includes bands at 3412 cm^{-1} and 3092 cm^{-1}"

4. A. **"characterized by bands at 1080 cm^{-1} in the FT-[Raman] spectrum" ['669 patent, claim 11 (pending certificate of correction)]**

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[9]To the extent there is a dispute, Lupin, Mylan, and Glenmark's proposed construction includes the requirement that the crystal modification is "distinguishable from all other forms of rufinamide by selected lines at interplanar spacings." The claim language as understood by a person of ordinary skill at the time of invention imposes no such requirement that these 13 XRPD measurements must enable one to distinguish "all other forms of rufinamide" – especially given the vagueness of what Defendants mean by "forms."

B. "characterized by an absorption band at 1080 cm^{-1} in the FT-Raman spectrum" ['028 patent, claim 6]

Plaintiffs' Proposed Construction: "identifiable by reference to a FT-Raman spectrum that includes a band at 1080 cm^{-1}"
Defendant Roxane's Proposed Construction: "with absorption bands in the FT-IR spectrum (KBr pellet-transmission method) with peaks at 1080 cm^{-1}"
Defendants Lupin, Mylan, and Glenmark's Proposed Construction: "distinguishable from all other forms of rufinamide by a band at 1080 cm^{-1} ± measurement error in the FT-Raman spectrum"
Defendant Hetero's Proposed Construction: "with an absorption band at 1080 cm^{-1} ± measurement error in the FT-Raman spectrum"
Court's Construction: "identifiable by reference to a FT-Raman spectrum that includes a band at 1080 cm^{-1}"

5. "characterized by an endothermic peak in the range from 230° C. to 260° C., the peak temperature being 239-245° C., and the endothermic signal being 209 J/g+/-10 J/g" ['669 patent, claim 6; '028 patent, claim 5]

Plaintiffs' Proposed Construction: "identifiable by reference to a thermogram in differential scanning calorimetry that includes an endothermic peak in the range from 230° C. to 260° C., the peak temperature being 239-245° C., and the endothermic signal being 209° J/g +/-10 J/g"
Defendant Roxane's Proposed Construction: "having an endothermic peak in the range from 230° C. to 260° C., the peak temperature being 239-245 ° C., and the endothermic signal being 209 J/g +/-10 J/g"
Defendants Lupin, Mylan, and Glenmark's Proposed Construction: "distinguishable from all other forms of rufinamide by differential scanning calorimetry by an endothermic peak in the range from 230° C. to 260° C., the peak temperature being 239-245° C., and the endothermic signal being 209 J/g +/-10 J/g"
Defendant Hetero's Proposed Construction: "with an endothermic peak in the range from 230° C. to 260° C., the peak temperature being 239-245° C., and the endothermic signal being 209 J/g +/-10 J/g"
Court's Construction: "identifiable by reference to a thermogram in differential scanning calorimetry that includes an endothermic peak in the range from 230° C. to 260° C., the peak temperature being 239-245° C., and the endothermic signal being 209° J/g +/-10 J/g"

The proposed constructions for terms characterizing the claimed crystal modification on

the basis of (i) absorptions/bands in the FT-IR spectrum, (ii) absorptions/bands in the FT-Raman spectrum,[10] and (iii) endothermic measurements largely involve the same disputes as discussed above. In light of the Court's construction of "characterized by characteristic lines," and because the Court finds the additional intrinsic evidence presented for these terms provides no basis for reading in additional limitations, the Court adopts Plaintiffs' proposed constructions.

6. "sodium carboxymethylcellulose" ['362 patent, claims 18 and 21]

Plaintiffs' Proposed Construction: No construction is necessary. Plain and ordinary meaning.
Defendant Roxane's Proposed Construction: "sodium carboxymethylcellulose that is not cross-linked"
Court's Construction: No construction is necessary. Plain and ordinary meaning.

Defendant Roxane contends that the term "sodium carboxymethylcellulose" is limited to versions of the compound that are not cross-linked. "Sodium carboxymethylcellulose" appears only once in the specification as a "Core material" in "Formulation I." (*See* '362 patent at 8:33-59) (Example 1) Nothing in the patent or the prosecution history expressly or implicitly

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[10]Roxane also challenges this term as indefinite, due to its use of the phrase "FT-IR" rather than "FT-Raman." Only Roxane contends that the Certificate of Correction does not control, notwithstanding suggestions in the caselaw to the contrary. *See Pfizer Inc. v. Teva Pharm. U.S.A., Inc.*, 882 F. Supp. 2d 643, 699 (D. Del. 2012), *aff'd sub nom. Pfizer Inc. v. Teva Pharm. USA, Inc.*, 555 F. App'x 961 (Fed. Cir. 2014) ("[B]ecause infringement under § 271(e)(2) is hypothetical and, therefore, cannot occur prior to the filing of a complaint, a certificate of correction can be applied where the defendants' ANDA products will prospectively infringe the patents-in-suit."). Even if the certificate does not apply in this case, a person of ordinary skill would have readily understood that the claim contains a small typographical error; given that the intended phrase would be easily inferred from the claims and specification, the term informs a person or ordinary skill with reasonable certainty of the scope of the claim such that the claim is not indefinite. *See Nautilus*, 134 S. Ct. at 2129. Relatedly, the word "bands" is an obvious grammatical mistake that does not affect the scope of the claim since it is referring in the claim itself to ***a single band***.

limits that material to sodium carboxymethylcellulose that is "not cross-linked." Furthermore, Roxane relies on expert testimony that unpersuasively characterizes the relevant entry in the *Handbook of Pharmaceutical Excipients* (*see* D.I. 93 (Declaration of Kinam Park) ("Park Decl.") at ¶ 22), and is at odds with testimony proffered by formulation expert Professor Gregory Amidon, to the effect that a person of ordinary skill would have understood from the single reference to sodium carboxymethylcellulose in Table 1 of the specification that the compound was to be used as a disintegrant, which could employ both the cross-linked or non-cross-linked forms. (D.I. 120 Ex. 5 (Declaration of Gregory Amidon) ("Amidon Decl.") at ¶ 23)

7. "in essentially pure form" ['669 patent, claim 9; '028 patent, claim 8]

Plaintiffs' Proposed Construction: "where the compound 1-(2,6-difluorobenzyl)-1H -1,2,3-triazole-4 carboxamide has purity of greater than 95% of crystal modification A"
Defendants' Proposed Construction: "in greater than 95% purity"
Court's Construction: "purity of greater than 95% based on modification A or A'"

In order to remain faithful to the definitional statement expressly provided by the patentee in the specification, the Court rejects both parties' constructions and construes the term to mean "purity of greater than 95% based on modification A or A'." ('669 patent at 6:32-36) ("The invention relates to the essentially pure form of the modification A or A' of [rufinamide]. The term 'essentially pure form' means purity of >95%, in particular >98%, primarily >99%, based on the modification A or A'.")

IV. CONCLUSION

The Court construes the disputed terms as explained above. An appropriate Order follows.