IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, LLC, FOREST LABORATORIES HOLDINGS, LTD., MERCK KGaA and MERCK PATENT GESELLSCHAFT MIT BESCHRÄNKTER HAFTUNG, Plaintiffs, v. ACCORD HEALTHCARE INC., et al., Defendants.	Civil Action No. 15-272-GMS CONSOLIDATED

ORDER CONSTRUING THE TERMS OF U.S. PATENT NOS. 7,834,020, 8,193,195, 8,236,804, AND 8,673,921

After having considered the submissions of the parties, and hearing oral argument on the matter, IT IS HEREBY ORDERED, ADJUDGED, and DECREED that, as used in the asserted claims of U.S. Patent Nos. 7,834,020 ("the '020 patent"), 8,193,195 ("the '195 patent"), 8,236,804 ("the '804 patent"), and 8,673,921 ("the '921 patent"):

1. The terms "**administer,**" "**administered,**" and "**administering**" are construed to mean "deliver[ed/ing] into the body."[1]

2. The term "**corresponding to**" is construed to mean "matching the values recited in the claims, including error ranges stated therein."[2]

[1] Prior to the *Markman* hearing, the parties agreed on this construction. The parties submitted a stipulation to that effect on October 19, 2016.

[2] Prior to the *Markman* hearing, the parties agreed on this construction. The parties submitted a stipulation to that effect on October 19, 2016.

3. The term "**exhibits the following XRD data**" is construed to mean "show all the following peaks and intensities, including an error range of +/- 0.1θ for the two-theta values."[3]

4. The entire preamble "**[a] method of treating a patient suffering from a depressive disorder, an anxiety disorder, a bipolar disorder, mania, dementia, a substance-related disorder, a sexual dysfunction, an eating disorder, obesity, fibromyalgia, a sleeping disorder, a psychiatric disorder, cerebral infarct, tension, side-effects in the treatment of hypertension, a cerebral disorder, chronic pain, acromegaly, hypogonadism, secondary amenorrhea, premenstrual syndrome, undesired puerperal lactation, or combinations thereof . . .**" is construed as limiting.[4]

5. The term "**effective amount**" is construed as "an amount sufficient to promote a therapeutic effect."[5]

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[3] Prior to the *Markman* hearing, the parties agreed on this construction. The parties submitted a stipulation to that effect on October 19, 2016.

[4] Prior to the *Markman* hearing, the parties agreed on this construction. The parties submitted a stipulation to that effect on October 19, 2016.

[5] Defendants' proposed construction for "effective amount" was "[a]n amount of the specified crystalline modification of vilazodone HCL sufficient to produce the desired effect." (D.I. 86 at 4). Plaintiffs requested that the court construe "effective amount" as an "amount sufficient to promote a therapeutic effect." *Id.* The court adopts Plaintiffs' proposed construction. We do, however, wish to emphasize that there must be an effective amount of whatever compound follows the term "effective amount" in the claims. The court notes that there does not seem to be a genuine dispute between the parties over this issue. Plaintiffs state that "the phrase 'the specified crystalline modification of vilazodone HCL' in [D]efendants' proposed construction of 'effective amount' should be rejected because it is redundant: each of the claims at issue identifies what substance must be present in an 'effective amount.'" (D.I. 96 at 15). The court agrees with Plaintiffs' characterization of Defendants' construction as redundant. We will not say that a specific crystalline form of 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine hydrochloride must be present in an amount that is effective because that would lead to either a nonsensical or redundant reading of the claims.

Claim 1 of the '195 patent discloses "an effective amount of a compound which is a crystalline hydrochloride salt of 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine." '195 patent, col. 26 ll. 61–64. Claim 1 does not recite an effective amount of a specified crystalline modification. Therefore, it would be nonsensical to construe "effective amount" to demand that an effective amount of a specific crystalline modification be present in the final compound.

Claim 1 of the '804 patent states that there must be "an effective amount of a compound which is 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine hydrochloride anhydrate in crystalline modification IV (Form IV)." '804 patent, col. 27 ll.17–col. 28 ll.1. In this case, to construe "effective amount" to mean an amount of the specified crystalline modification of vilazodone HCL would be redundant because the claim term plainly tells us that there must be an effective amount of vilazodone HCL anhydrate Form IV. Therefore, the court does not find it necessary to construe "effective amount" to mean an amount of the specific crystalline form of vilazodone disclosed in some of the claims.

The parties also dispute whether an "effective amount" must "produce" or "promote" a desired or therapeutic effect. Plaintiffs contend that an "effective amount" is one "sufficient to promote a therapeutic effect," whereas Defendants declare that it must be an amount "sufficient to produce the desired effect." (D.I. 87 at 15). First, the court notes that the parties do not dispute the meaning of "desired effect" versus "therapeutic effect." When Defendants were asked during the *Markman* hearing if they believed there was a difference between therapeutic and desired effect, they responded that "the

6. The term "**crystalline modification**" is construed to mean "crystalline form" and the term "**crystalline**" is construed in accordance with its plain and ordinary meaning.[6]

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therapeutic effect here would be the desired effect." *Markman* Hr'g, 76:4–5. Second, the court will adopt Plaintiffs' proposed construction of "promoting a therapeutic effect" because the parties entered into a stipulation that supports such a construction.

The parties stipulated that the term "treating" should be construed to mean "attempting to cause a therapeutic effect on," and the phrase "is treated in the patient" should be construed to mean "an attempt is made to cause a therapeutic effect in the patient." (D.I. 101 at 2). The preamble to claim 1 of the '804 patent discloses "[a] method of treating a major depressive disorder." '804 patent, col. 27 l. 15. The end of that same claim states "wherein the major depressive disorder is treated in the patient." *Id.* col. 28 l. 7. The plain language of the claim is clear that the effective amount is an amount sufficient to treat a patient with a major depressive disorder. When the court substitutes the parties' stipulation for the term "treat" and the phrase "is treated in the patient," it is left with an understanding that the effective amount must be one that is sufficient to attempt to cause a therapeutic effect on. Had the stipulation for the term "treating" been "to cause a therapeutic effect on," it is possible that the court would have come out the other way. Because the word "attempt" is inserted into the stipulated construction, however, the word "promote" in Plaintiffs' proposed construction is more appropriate than "produce."

Defendants state that a clinician would consider an "effective amount" to be an amount necessary to "cause the desired effect." (D.I. 93 at 5). While that may be true, the parties explicitly stipulated that "treating" meant "attempting to cause." (D.I. 101 at 2). If the court does not adopt Plaintiffs' proposed construction it is left with a nonsensical claim that effectively requires "a method of [attempting to cause a therapeutic effect on] a major depressive disorder . . . [by] administering . . . a pharmaceutical composition comprising an [amount of vilazodone sufficient to produce the therapeutic effect]." '804 patent, col. 27 ll. 15–18. The court does not see how you can *attempt* to have a therapeutic effect on a patient when administering an amount of a drug *sufficient to produce* the therapeutic effect. It makes more sense, given the structure of the claim and the stipulation, to say that a physician would attempt to cause a therapeutic effect on a patient by giving him an amount sufficient to promote that effect. Therefore, the court adopts Plaintiffs' proposed construction.

[6] Defendants request that both "crystalline" and "crystalline modification" be construed to mean "entirely in crystalline form comprising only Form I to XVI, and combinations thereof (as appropriate)." (D.I. 86 at 6). Plaintiffs contend that the term "crystalline" does not need construction and should be construed in accordance with its plain and ordinary meaning. (D.I. 87 at 4). It seems that both Defendants' and Plaintiffs' experts agree on the plain and ordinary meaning of "crystalline" to a person having ordinary skill in the art—a solid morphological form where "atoms or molecules are arranged with a three-dimensional long-range order." (D.I. 88 ¶¶ 19, 35); *see* (D.I. 94 ¶ 23) (Defendants' expert agreeing with Plaintiffs' expert that "crystalline" means "the arrangement of atoms or molecules with a 3D long-range order"). Though the court does find some of Defendants' argument persuasive, they are not convincing enough to warrant a departure from the plain and ordinary meaning of "crystalline" when the claim language, specification, and prosecution history are analyzed as a coherent whole. *See Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) (there is a presumption that words of a claim will generally be given their "ordinary and customary meaning" absent clear intention from the patentees to act as their own lexicographers); *see also See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 389 (1996) ("a term can be defined only in a way that comports with the instrument as a whole.").

Defendants state that because claim 1 of U.S. Patent No. 7,834,020, claim 1 of U.S. Patent No. 8,236,804, and claims 5, 11, and 13 of U.S. Patent No. 8,673,921 all use "crystalline modification" followed by "IV" or "(V)" or a parenthetical further stating "(Form IV)," "crystalline modification" and

"crystalline" must refer to only forms of crystalline vilazodone disclosed in the patent. '020 patent, col. 27 ll.42–43; '804 patent, col. 28, l. 1; '921 patent, col. 27 ll. 15–26, col. 28 ll. 8, 33. It is not clear why referring specifically to certain forms of vilazodone in certain claims would mean that the terms "crystalline" and "crystalline modification" could only refer to the specific polymorphs identified as Forms I–XVI. Plaintiffs never try to argue that "crystalline" vilazodone or a "crystalline modification" of vilazodone refers to a form of vilazodone that is not crystalline. *See Markman* Hr'g 37:8 ("crystalline vilazodone is crystalline). Instead, Plaintiffs contend that there is no support in the specification or the claims for limiting "crystalline" or "crystalline modification" to only Forms I through XVI. The court agrees.

The language in claim 1 of the '921 patent supports Plaintiffs' argument. Claim 1 discloses "a compound which is 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine hydrochloride in its crystalline modification." '921 patent col. 27 ll.13–15. Dependent claims 2, 3, and 4 then claim the compound of claim 1 in a specific crystalline modification. *Id.* at col. 27 ll. 17–22. If the court adopted Defendants' proposed construction, it would be redundant to have independent claim 1 and then dependent claims 2 through 4—there would be no need to further disclose specific modifications in the dependent claims if they were already encompassed by claim 1. Additionally, construing claim 1 as directed to only crystalline modifications I–XVI would violate the well-known doctrine of claim differentiation. *See Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, 438 F.3d 1374, 1380 (Fed. Cir. 2006) (referring "to the presumption that an independent claim should not be construed as requiring a limitation added by a dependent claim").

The language in claim 1 of the '195 patent is similar to the language in claim 1 of the '921 patent in that it does not specify a form, I through XVI, that 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine must take. '195 patent, col. 26 ll. 60–65. Instead, claim 1 discloses "a compound which is a crystalline hydrochloride salt of 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine." *Id.* col. 26 ll. 62–64. Claims 3, 4, 5, and 6 then disclose a compound that is a hydrate, monohydrate, and hemihydrate, respectively, of the compound in claim 1. *Id.* col. 27 ll. 4, 7, 9–12. Claims 7–15 then go on to disclose the compound of claim 1 in the different crystalline forms, specifically forms III, IV, V, and VIII. *Id.* col. 27 ll. 13–24, col. ll. 281–21. Under Defendants' proposed construction, claims 7–15 of the '195 patent would be redundant because claims 1–6 would cover all of the specific crystalline forms. Again, such redundancy would violate the doctrine of claim differentiation and fail to comport with the structure and plain meaning of the claims

One of Defendants' most persuasive arguments for why "crystalline" should not have its plain and ordinary meaning is that Forms I–XVI are characterized as "products of the invention" in the specification shared by all the patents in suit. '195 patent, col. 14, ll. 47–48. Defendants contend that the use of "crystalline" and "crystalline modification" in the specification is analogous to the use of "injectable, aqueous pharmaceutical composition" in the specification of the patent at issue in *Baxter Healthcare Corp. V. Mylan Laboratories, Ltd.*, because in both cases the specification clearly limited the term in ways not inherently obvious from the claim language. Nos. 14-cv-7094, 2016 WL 1337279, at *14–15 (D.N.J. Apr. 5, 2016). In *Baxter*, the court explains that in rare situations when the specification contains clear and unambiguous limiting statements, such as "the present invention includes" or "all embodiments of the present invention are," the court will limit the claims to what the invention includes or the preferred embodiments. *Id.* at *14 (quoting *Pacing Techs., LLC v. Garmin Int'l, Inc.*, 778 F.3d 1021, 1024 (Fed. Cir. 2015)).

The *Baxter* court found that the terms "stable" and "ready to use" should be included in the claim phrase "injectable, aqueous pharmaceutical composition" because the specification stated that the prior art left open a need for a ready-to-use, stable form of the claimed compound. *Id.* Additionally, the Summary of the Invention stated that the invention related to a ready-to-use, injectable form of the composition. *Id.* Here, the specifications for the patents at issue state that the prior art was directed to mixtures of amorphous, crystalline and free-base forms of vilazodone, creating a need in the art for pure crystal or crystalline forms of the compound. '202 patent, col. 1 ll. 60–67, col. 2 ll. 1–6. The first sentence of the

Summary of the Invention makes clear that the invention is "[m]ethods for preparing pure crystals of 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine hydrochloride." '020 patent, col. 2 ll. 20–22. The Summary of the Invention section then goes on to state that "[f]urthermore, surprisingly" new forms of 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine were found, along with processes for their preparation. As Plaintiffs point out, this implies that the patent is directed generally to methods for preparing pure crystals of 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine hydrochloride. *Markman* Hr'g, 27:3–7. Then, in addition to that general method, the patent also discloses new crystalline forms that fall into four general classes: hydrochloride hydrates, hydrochloride anhydrates, solvates, and pure amorphous. '020 patent, col. 2 ll. 29–67, col. 3 ll. 1–20. Thus, the patent is directed to a method for preparing pure crystals of 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine hydrochloride, a method for preparing the specific polymorphs of that general compound, and the polymorphs themselves. The specification here, unlike in *Baxter*, does not clearly limit the scope of "crystalline" or "crystalline modification."

The specification routinely describes crystalline forms of 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine generally, and when the patentees wanted to refer to specific "preferred forms" within a broader class of a crystalline modification, they did so explicitly. In the section of the specification that describes solvates of 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine hydrochloride, a number of different solvents and the molar ratios of those solvents and the main compound are disclosed. '020, col. 4 ll. 9–40. Only after that introductory paragraph does the specification explain the specific "preferred forms of solvates." *Id.* ll. 41–43. These preferred forms are forms I, II, XV, X, XI, and XIV. *Id.* ll. 44–64. Each "preferred form[]" has a specific molar ratio of solvent to the main compound, a "characteristic IR absorption spectra," and a "characteristic X-ray diffraction pattern." *Id.* col. 5 l. 21–col. 9 l. 12. Despite the fact that the specification shared by all the patents in suit refers to Forms I–XVI as the "products of the invention," the specification as a whole makes clear that Forms I–XVI are preferred embodiments, not the entirety of the invention. '020 patent, col. 4 ll. 47–49. Therefore, limitations from the specification will not be read into the claim terms. *See Williamson v. Citrix Online, LLC*, 770 F.3d 1371, 1377 (Fed. Cir. 2014) (explaining the court's presumption against limiting the claims to specific examples or embodiments in the specification), *vacated*, 603 F. App'x 1010 (Fed. Cir. 2015).

Additionally, the prosecution histories of the patents in suit do not contain a clear disavowal of the argument that "crystalline" is broader than just forms I through XVI. In the '020 patent prosecution history, applicants amended claim 1 to include "1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine hydrochloride anhydrate in crystalline modification IV." (D.I. 97, Ex. 10 at 2). Defendants argue that, because this amendment was in response to a rejection of that claim under 35 U.S.C § 102(b), in light of the '241 patent, Plaintiffs are estopped from asserting that "crystalline" is broader than the specific forms identified in the specification and some of the claims. (D.I. 86 at 9). The rejection by the Examiner, however, states that "the '241 patent discloses amorphous 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine hydrochloride." (D.I. 97, Ex. 11 at 5). Prior to amendment by the applicants, claim 1 of the '020 patent disclosed the amorphous form of 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine hydrochloride. (D.I. 97, Ex. 12 at 2). Therefore, it is not clear why applicants amended claim 1 to delete a number of forms originally disclosed in the patent application along with the amorphous form, only leaving Form IV of the compound. *Omega Eng'g, Inc, v. Raytek Corp.*, 334 F.3d 1314, 1324 (Fed. Cir. 2003) (holding that the doctrine of prosecution disclaimer will not apply to situations where the supposed disavowal of claim scope is ambiguous).

The prosecution histories of the '195 and '921 patents only lend further support to Plaintiffs' proposed construction. In a non-final rejection of claims in the '195 patent, the Examiner noted that the closest prior art was the '241 patent, and that patent failed "to teach or suggest a crystalline form of 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine hydrochloride. (D.I 97, Ex. 13 at

13–14). Therefore, the '241 patent "fail[ed] to anticipate or render obvious claims reciting specific crystalline forms of 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine hydrochloride." (D.I. 97, Ex. 13 at 13–14). The Notice of Allowability for the '921 makes a very similar finding with regard to the '241 patent, stating that it "does not teach the claimed crystalline forms." (D.I. 97, Ex. 19 at 2). It is worth noting that claim 1 of the '921 is a claim broadly directed to "1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine hydrochloride in its crystalline modification." '921 patent, col. 27 ll. 13–15. This broad claim was allowed over the compound disclosed in the '241 patent, further demonstrating that naming a specific crystalline form was not necessary to overcome the prior art.

Oddly, during prosecution of the '804 patent the Examiner rejected claim 1 of the patent application as being anticipated by the '241 patent. (D.I. 97, Ex. 18 at 6). The examiner stated that the '241 patent did teach a method of using 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine in its crystalline hydrochloride salt form. *Id.* In the applicants' response, they specifically state that they are not acquiescing to the characterization of the claims, but they amended claim 1 to recite polymorphic form IV. (D.I. 97, Ex. 17 at 4). Additionally, during prosecution of the '921, the '195, and the '020 patents the Examiner said that the '241 patent did not disclose crystalline forms of 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine hydrochloride. For those two reasons, the court does not find that the amendment to the '804 patent demonstrates a clear disavowal of the argument that "crystalline" is broader than just Forms I-XVI.

Defendants also ask the court to construe the term "crystalline modification" to mean "entirely in crystalline form comprising only Form I to XVI, and combinations thereof (as appropriate)." (D.I. 86 at 6). This is the same construction they requested for "crystalline." *Id.* The court declines to adopt Defendants' proposed construction because the patentees have defined what they mean by "crystalline modification" in the specification shared by all the patents in suit. The '020 patent specification states "[t]hroughout the specification, the term 'Form' is generally used as a synonym for the term "modification" or "crystalline modification." '020 patent, col. 2 ll. 26–29. The specification then states that the "present invention furthermore provides 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine hydrochloride hydrates in crystalline modifications." *Id.* ll. 41–43. Analyzed as a whole, the specification indicates that "crystalline modification" means a crystalline morphological form that 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine hydrochloride is capable of taking.

Claim 1 of the '921 patent is further evidence of the patentees intention to use "crystalline modification" to broadly define the relevant crystalline forms—crystalline anhydrates, crystalline hydrates, crystalline solvates, and crystalline dihydrichlorides. *See* '921 patent, col. 27 ll. 13–16 ("[a] compound which is 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine hydrochloride in its crystalline modification, wherein the compound is an anhydrate, hydrate, solvate, or dihydrochloride). Therefore, the court agrees with Plaintiffs' proposed construction. "Crystalline modification" will be construed as crystalline form, referring broadly to the categories of crystalline forms that 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine hydrochloride can take.

The court does not believe that there is support in the claim language, specification or prosecution histories for Defendants' proposition that "crystalline" and "crystalline modification" must be interpreted to mean that the resulting compound is "entirely crystalline." (D.I. 86 at 6). When a patent recites a compound comprising a specific polymorphic form, that does not foreclose the possibility that other active ingredients are also present. *See In re Armodafinil Patent Litig. Inc.*, 939 F. Supp. 2d 456, 474 (D. Del. 2013) (explaining that the claim term "comprising" allows for other forms of armodafinil to be present in the recited composition). Additionally, the prosecution history does not present a reason why crystalline must be interpreted to mean entirely crystalline. As previously noted, the prosecution history repeatedly characterized the '241 patent as disclosing an amorphous form of 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine hydrochloride. (D.I. 97, Ex. 11 at 5); (D.I. 97, Ex.

7. The term "**characteristic peak**" is construed to mean "peak representative of a crystalline form's X-ray diffraction pattern."[7]

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13 at 12–13). There is no clear reason why a prior art patent disclosing an amorphous form of vilazodone hydrochloride would necessitate that the terms at issue be construed to mean "entirely crystalline." Defendants' arguments that the terms at issue, if not entirely crystalline, are anticipated or rendered obvious by the '241 prior art patent are invalidity arguments, not appropriate at this stage of litigation. Therefore, the court will not limit the construction of "crystalline" or "crystalline modification" to "entirely crystalline" when nothing in the claim language, specification or prosecution history warrant such a limitation.

[7] Defendants maintain that "characteristic peak" should be construed as "a powder XRD peak having intensity ≥ 3*noise, which serves to identify the crystalline modification." (D.I. 86 at 17). Defendants explain that "Table III of the '804 patent lists data for powder X-ray diffraction patterns for sixteen polymorphic forms." *Id.* Defendants then point out that Form XIV shows data for only seven characteristic peaks, whereas all the other polymorphic forms have data for ten characteristic peaks. *Id.* at 17–18; *see* '804 patent, col. 26 ll. 47–49. Defendants declare that, because the specification says "[f]urther peaks exhibit intensities <3* noise," '804 patent, col. 27 l. 11, the patentees do not consider a peak less than three times the noise level a "characteristic peak." (D.I. 86 at 17–18). The claim language, specification, and prosecution history, however, do not support Defendants' construction. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996) (explaining that to ascertain the meaning of the claims, the court looks to the claims, the specification, and the prosecution history).

Table III is titled "[d]ata of powder-XRD-pattern of polymorphic Forms. (10 characteristic peaks of each polymorph have been taken for evaluation. The XRD instrument is controlled for 2Theta +/-0.1)." '804 patent, col. 24 ll. 30–35. The titles indicates that "10 characteristic peaks of each polymorph have been taken for evaluation," which implies that there could be other characteristic peaks for each polymorph—the peaks shown in Table III were just those taken for evaluation. *See id.*

While Form XIV has an asterisk for peaks 8, 9, and 10, stating that "further peaks exhibit intensities <3*noise," that does not appear to contradict or undermine the title of Table III. *See* '804 patent, col. 26 ll. 47–29. Table III explicitly states the peaks it includes are "characteristic peaks." '804 patent, col. 24 l. 32. Though applicants may have decided not to include the peaks exhibiting intensities <3*noise in Table III, the plain language does nothing to suggest that those peaks do not qualify as characteristic peaks. If anything, the fact that the statement next to the asterisk says "further peaks" implies that there are possibly many more peaks that the applicants chose not to include in Table III. *See* '804 patent, col. 27 l. 11. The patent does not explicitly say that characteristic peaks are only those that exhibit intensities <3*noise. The court declines to read that limitation into the term.