**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| ACERTA PHARMA B.V., et al.,<br><br>Plaintiffs,<br><br>v.<br><br>CIPLA LIMITED, et al.,<br><br>Defendants. | C.A. No. 24-587-GBW<br>(LEAD CASE) |
| ACERTA PHARMA B.V., et al.,<br><br>Plaintiffs,<br><br>v.<br><br>MSN PHARMACEUTICALS, INC., et al.,<br><br>Defendants. | C.A. No. 25-43-GBW |

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**MEMORANDUM OPINION**

November 25, 2025
Wilmington, Delaware

GREGORY B. WILLIAMS
U.S. DISTRICT JUDGE

This action was filed by Plaintiffs AstraZeneca Pharma B.V., AstraZeneca UK Limited, AstraZeneca Pharmaceuticals LP, and AstraZeneca AB ("AstraZeneca") against Defendants Cipla Limited and Cipla USA, Inc. ("Cipla") and MSN Pharmaceuticals Inc. and MSN Laboratories Pvt. Ltd. ("MSN") alleging infringement of U.S. Patent Nos. 10,272,083 ("the '083 Patent") and 11,059,829 ("the '829 Patent").[1] Before the Court is the issue of claim construction for multiple disputed terms in these patents. The Court has considered the parties' briefing [2], accompanying exhibits, expert declarations, and the arguments presented during the *Markman* hearing held on October 28, 2025. D.I. 56, D.I. 57, D.I. 67. Upon consideration of the full record, the Court issues the following constructions.

## I. LEGAL STANDARDS

### A. Claim Construction

"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) (en banc) (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)); *see also Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989) ("A claim in a patent provides the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using,

[1] AstraZeneca sued Cipla and MSN in separate actions, however the cases were consolidated on April 16, 2024. *See* D.I. 28.

[2] MSN did not participate in the briefing and has taken no position on the constructions of the disputed or agreed upon claims. *See* D.I. 56 at 4 (MSN "anticipates taking no position on the construction of the terms Plaintiff and Cipla are disputing going forward.").

or selling the protected invention."). "[T]here is no magic formula or catechism for conducting claim construction." *Phillips*, 415 F.3d at 1324. The Court is free to attach the appropriate weight to appropriate sources "in light of the statutes and policies that inform patent law." *Id.* The ultimate question of the proper construction of a patent is a question of law, although subsidiary fact-finding is sometimes necessary. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 326 (2015); *see also Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 378, 388-91 (1996).

"The words of a claim are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art when read in the context of the specification and prosecution history." *Thorner v. Sony Comput. Ent. Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (citing *Phillips*, 415 F.3d at 1313). A person of ordinary skill in the art "is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Phillips*, 415 F.3d at 1313.

"When construing claim terms, [the court] first look[s] to, and primarily rel[ies] on, the intrinsic evidence, including the claims themselves, the specification, and the prosecution history of the patent, which is usually dispositive." *Sunovion Pharms., Inc. v. Teva Pharms. USA, Inc.*, 731 F.3d 1271, 1276 (Fed. Cir. 2013). "Other claims of the patent in question, both asserted and unasserted, can . . . be valuable" in discerning the meaning of a disputed claim term, because "claim terms are normally used consistently throughout the patent" and so "the usage of a term in one claim can often illuminate the meaning of the same term in other claims." *Phillips*, 415 F.3d at 1314 (citing *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342 (Fed. Cir. 2001)). In addition, "[d]ifferences among claims can also be a useful guide in understanding the meaning of particular claim terms." *Id.* (citing *Laitram Corp. v. Rexnord, Inc.*, 939 F.2d 1533, 1538 (Fed. Cir. 1991)). "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 (citing *Liebel–Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 910 (Fed. Cir. 2004)).

In addition to the claims, the court should analyze the specification, which "is always highly relevant to the claim construction analysis . . . [as] 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). 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 (citing *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)). "[E]ven when the specification describes only a single embodiment, [however,] 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.'" *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (quoting *Liebel-Flarsheim*, 358 F.3d at 906). Furthermore, the specification "is not a substitute for, nor can it be used to rewrite, the chosen claim language." *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004).

The 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), (citing *Graham v. John Deere Co.*, 383 U.S. 1, 33 (1966)), *aff'd*, 517 U.S. 370 (1996). The 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 . . . ." *Phillips*, 415 F.3d at 1317.

In some cases, the 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*, 574 U.S. at 331 (citing *Seymour v. Osborne*, 20 L.Ed. 33 (1871)). 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. Overall, while extrinsic evidence may be useful, it is "less significant than the intrinsic record in determining the legally operative meaning of claim language." *Phillips*, 415 F.3d at 1317 (cleaned up).

**B. Indefiniteness**

Section 112 of the Patent Act requires that the claims of a patent "particularly point[] out and distinctly claim[] the subject matter which the inventor or a joint inventor regards as the invention." 35 U.S.C. § 112(b). The "primary purpose of the definiteness requirement" that § 112(b) contains "is to ensure that the claims are written in such a way that they give notice to the public of the extent of the legal protection afforded by the patent, so that interested members of the public, e.g., competitors of the patent owner, can determine whether or not they infringe." *All Dental Prodx, LLC v. Advantage Dental Prods., Inc.*, 309 F.3d 774, 779-80 (Fed. Cir. 2002) (citation omitted).

"[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." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). While a "potential infringer" need not "be able to determine *ex ante* if a particular act infringes the claims," the patentee must "apprise the public of what is still open to them[]" such that "a person of ordinary skill in the art could determine whether or not an accused product or method infringes the claim." *Niazi Licensing Corp. v. St. Jude Med. S.C., Inc.*, 30 F.4th 1339, 1346-47 (Fed. Cir. 2022) (quotation marks and citations omitted).

Like claim construction, definiteness is a question of law, but courts must sometimes render factual findings based on extrinsic evidence to resolve the ultimate issue of definiteness. *See Sonix Tech. Co. v. Publications Int'l, Ltd.*, 844 F.3d 1370, 1376 (Fed. Cir. 2017). "Patent claims are presumed to be valid and definite." *B.E. Tech., LLC v. Twitter Inc.*, No. 20-621, 2024 WL 579076, at *1 (D. Del. Feb. 13, 2024) (citing 35 U.S.C. § 282). Thus, the challenger must prove indefiniteness by clear and convincing evidence. *See Nippon Shinyaku Co. v. Sarepta Therapeutics, Inc.*, No. 21-1015, 2023 WL 4314485, at *6 (D. Del. July 3, 2023).

## II. AGREED-UPON TERMS

The parties agreed upon the construction of the below claim terms as follows:

| Claim Term | Agreed-Upon Construction |
|---|---|
| "A method of treating chronic lymphocytic leukemia (CLL) or small lymphocytic leukemia (SLL) in a human subject suffering therefrom"<br><br>('083 Patent, Claims 1-7) | The quoted preamble language is limiting as to the intentional purpose for which the method must be performed, i.e., treating chronic lymphocytic leukemia (CLL) or small lymphocytic leukemia (SLL) in a human subject suffering therefrom, which requires treating CLL or SLL in a human subject, but does not require a particular level of efficacy. |
| "A method of treating a mantle cell lymphoma (MCL) in a human subject suffering therefrom"<br><br>('083 Patent, Claims 8-20) | The quoted preamble language is limiting as to the intentional purpose for which the method must be performed, i.e., treating Mantle Cell Lymphoma (MCL) in a human subject suffering therefrom, which requires treating MCL in a human subject suffering therefrom, but does not require a particular level of efficacy. |

The Court will adopt these agreed-upon constructions.

## III. DISPUTED TERMS

### A. The '083 Patent

#### 1. "a compound of Formula (II) . . . or a pharmaceutically acceptable salt thereof"

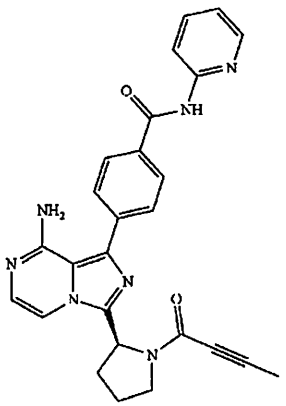
| Disputed Term | Plaintiffs AstraZeneca Construction | Defendants Cipla Construction | The Court's Construction |
|---|---|---|---|
| "a compound of Formula (II) . . . or a pharmaceutically acceptable salt thereof"<br><br>('083 Patent, Claims 2-4, 9-11, 15-16, 18, 20) | Plain and ordinary meaning where "pharmaceutically acceptable salt" does not exclude salts that are solvates and/or hydrates. | a compound of Formula (II) or a pharmaceutically acceptable salt thereof, but not a hydrate or a solvate thereof | Plain and ordinary meaning where "pharmaceutically acceptable salt" does not exclude salts that are solvates and/or hydrates |

The parties dispute whether the claim term "pharmaceutically acceptable salt" includes salts that are also solvates or hydrates. D.I. 56 at 9-20.

The term appears in independent claim 1 and dependent claims 2, 9, 18 and 20 of the '083 Patent. Claim 1 recites:

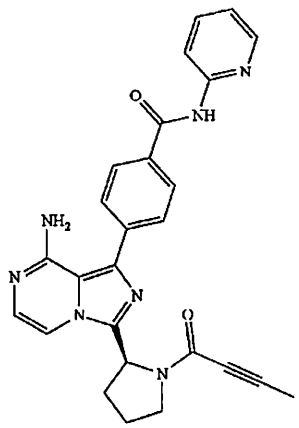
> A method of treating chronic lymphocytic leukemia (CLL) or small lymphocytic leukemia (SLL) in a human subject suffering therefrom, comprising the step of orally administering, to the human subject, a dose of 100 mg twice daily of a Bruton's tyrosine kinase (BTK) inhibitor, wherein the BTK inhibitor is **a compound of Formula (II):**

(II)



**or a pharmaceutically acceptable salt**, solvate, or hydrate thereof.

'083 Patent at cl. 1 (emphasis added). Claim 2 recites:

> The method of claim 1, wherein the BTK inhibitor is **a compound of Formula (II):**
>
> (II)
>
> 
>
> **or a pharmaceutically acceptable salt thereof.**

'083 Patent at cl. 2 (emphasis added).

Starting with the claims, nothing therein suggests that salts which are also hydrates or solvates are excluded. The recitation of "a pharmaceutically acceptable salt, solvate, or hydrate thereof" in claim 1 does not indicate the exclusion of a salt-solvate or salt-hydrate in claims 2, 9, 18 and 20. The plain language of the term "pharmaceutically acceptable salt" would include all pharmaceutically acceptable salts, such as salt-hydrates and salt-solvates. Therefore, claim 1 encompasses pharmaceutically acceptable salts, solvates, or hydrates. Claim 2, however, narrows the scope by including only pharmaceutically acceptable salts, salt-solvates or salt-hydrates, thereby expressly excluding hydrates or solvates without a salt.[3]

[3] The term "pharmaceutically acceptable salt" refers to salts derived from a variety of organic and inorganic counter ions known in the art. *See* '083 Patent at 10:51-53.

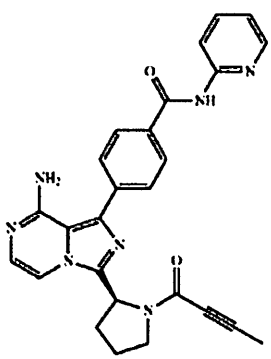
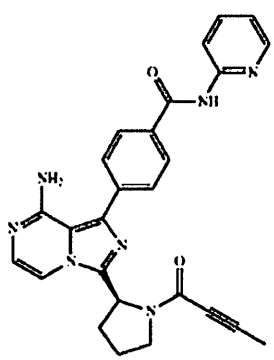
Both parties contend that their construction is consistent with the specification. The specification defines "pharmaceutically acceptable salt" as "salts derived from a variety of organic and inorganic counter ions known in the art." '083 Patent at 10:51-53. Cipla contends that its construction is correct because the specification excludes hydrates from the definition of "pharmaceutically acceptable salt" and that the definition of "solvate" omits any reference to salt. D.I. 56 at 13; *see also* '083 Patent at 22:16-18 ("Solvate refers to a compound in physical association with one or more molecules of a pharmaceutically acceptable solvent."). Therefore, "a POSA would understand that the patentee did not intend . . . to include salt-hydrates and/or salt-solvates." D.I. 56 at 13. The Court is not persuaded by Cipla's argument that the absence of explicit reference to hydrates or solvates in the definitions of salt and solvate constitutes clear exclusion of salt-hydrates or salt-solvates. The Court agrees with AstraZeneca and finds that the specification supports the conclusion that a compound containing a counter ion qualifies as a salt; irrespective of whether water molecules or other solvents are present. *Id.* at 10-11. The specification reflects that a salt formation involves the presence of a counter ion. '083 Patent at 10:51-53. Therefore, the presence of water or solvent molecules does not alter the compound's classification as a salt.

Furthermore, the experts retained by both parties concur that a salt-hydrate qualifies as a salt. *See* D.I. 56 at 17; Trout Decl. ¶ 45; Reibenspies Decl. ¶ 87; Reibenspies Tr. at 50:3-9. This consensus supports the Court's conclusion and impression that a person of ordinary skill in the art[4] would likewise understand that salt-hydrates and salt-solvates fall within the category of salts.

[4] The parties appear to agree that, for the purpose of the '083 patent, a person of ordinary skill in the art ("POSA") at the filing date would have possessed a doctoral degree in chemistry, chemical engineering or pharmacokinetics, or a medical degree with experience with pharmaceutics. *See* D.I. 56 at 7-9.

Accordingly, the Court will construe "a compound of Formula (II) . . . or a pharmaceutically acceptable salt thereof" to be the plain and ordinary meaning, where "pharmaceutically acceptable salt" does not exclude salts that are solvates or hydrates.

**2. "a dose of 100 mg twice daily of a BTK inhibitor . . . or a pharmaceutically acceptable salt, solvate, or hydrate thereof"**

<table>
<tr><th>Disputed Term</th><th>Plaintiffs AstraZeneca Construction</th><th>Defendants Cipla Construction</th><th>The Court's Construction</th></tr>
<tr><td>a dose of 100 mg twice daily of a BTK inhibitor . . . or a pharmaceutically acceptable salt, solvate, or hydrate thereof<br><br>('083 Patent, Claims 1, 8)</td><td rowspan="3">Plain and ordinary meaning where "100 mg" refers to 100 mg of the compound of Formula (II) in its free base form:<br>  </td><td>a dose of 100 mg twice daily of a BTK inhibitor or a pharmaceutically acceptable salt, solvate, or hydrate thereof</td><td rowspan="3">Plain and ordinary meaning where "100 mg" refers to 100 mg of the compound of Formula (II) in its free base form:<br>  </td></tr>
<tr><td>a dose of 100 mg twice daily of a BTK inhibitor . . . or a pharmaceutically acceptable salt thereof<br><br>('083 Patent, Claims 2-4, 9-11, 15-16)</td><td>a dose of 100 mg twice daily of a BTK inhibitor or a pharmaceutically acceptable salt thereof</td></tr>
<tr><td>a dose of 100 mg twice daily of a BTK inhibitor . . . or a pharmaceutically acceptable salt thereof . . . wherein the pharmaceutically</td><td>a dose of 100 mg twice daily of a pharmaceutically acceptable salt of a BTK inhibitor</td></tr>
</table>

| | | | |
|---|---|---|---|
| acceptable salt . . . is administered to the human subject<br><br>('083 Patent, Claims 18, 20) | | | |

The central issue in the parties' dispute of this claim term concerns the interpretation and application of the term "100 mg" as used in claims 1-4, 8-11, 15-16, 18 and 20 of the '083 Patent. Claim 1, which the Court finds exemplar, recites: "a dose of 100 mg twice daily of a Bruton's tyrosine kinase (BTK) inhibitor, wherein the BTK inhibitor is a compound of Formula II or a pharmaceutically acceptable salt, solvate, or hydrate thereof." '083 Patent, claim 1. The plain language of claim 1 can be interpreted two ways: 1) 100 mg . . . of . . . a compound of Formula (II) or 100 mg of a pharmaceutically acceptable salt, or 100 mg of a solvate, or 100 mg of hydrate thereof (Cipla's construction) or 2) 100 mg . . . of . . . a compound of Formula (II) [,] or a pharmaceutically acceptable salt, solvate, or hydrate thereof (AstraZeneca's construction). Cipla allegedly construes the claim term as written, according to its plain language. *See* D.I. 56 at 24, 36 ("claims require administering 100 mg to any one of the [] four types of BTK inhibitors."). Under AstraZeneca's proposed construction, the phrase refers to 100 mg of acalabrutinib, a BTK inhibitor, in its free base form. *Id.* at 21. Upon consideration of the evidence, the Court agrees with AstraZeneca and adopts the plain and ordinary meaning where "100 mg" refers to 100 mg of the compound of Formula (II) in its free base form.

"[A] plain and simple reading of the claim terms cannot deviate from the objective base line from which to begin claim interpretation; that is, how a person of ordinary skill in the art understands a claim term." *Celgene Corp. v. Hetero Labs Ltd.*, No. 17-03387, 2020 WL 3249117, at *9 (D.N.J. June 16, 2020) (internal citations omitted). "[A]n ordinary meaning of a claim term is merely a short-hand for the appropriate connotation under the law: the meaning, to a person of

ordinary skill in the art." *Id.* (internal citations omitted). Here, Cipla fails to provide sufficient evidence that its construction would be understood by a person of ordinary skill in the art, and Cipla's expert was silent on this issue. Accordingly, the Court relies on AstraZeneca's expert, Dr. Bernhardt Trout, who opined that, consistent with industry practice, drug dosage is described in terms of the amount of active moiety administered and that the dose of the active moiety corresponds to the therapeutically effective dose of the drug. Trout Decl. ¶¶ 49-50.

Dr. Trout explains that the United States Food and Drug Administration ("FDA") applies the United States Pharmacopeia ("USP") salt policy, which states that "[w]hen an active ingredient in a drug product is a salt, the drug product monograph title will contain the name of the active moiety (or neutral form), and not the name of the salt (e.g., 'newdrug tablets' instead of 'newdrug hydrochloride tablets')" and "[t]he strength also be expressed in terms of the active moiety (e.g., '100 mg newdrug') rather than the salt strength equivalent (e.g., '123.7 mg newdrug hydrochloride')." *Id.*; *see also In re Fetzima*, No. 17-10230, 2021 WL 2349981, at *4–6 (D.N.J. June 8, 2021); *Mars, Inc. v. H.J. Heinz Co., L.P.*, 377 F.3d 1369, 1374 n.3 (Fed. Cir. 2004) ("We agree with the parties that regulations issued by regulatory agencies can be helpful to a claim construction analysis if they are probative of an industry-specific meaning for a disputed claim term."). Thus, in accordance with industry standards, a person of ordinary skill in the art would understand that the same amount of active moiety would be administered regardless of whether the drug is in the form of a free base or a salt.

The specification does not support a basis for deviating from industry standards. The '083 Patent defines the invention broadly to encompass the compound of Formula (II) or a pharmaceutically acceptable salt, solvate, hydrate, cocrystal or prodrug thereof. '083 Patent at 2:10-17. The grouping of salts, solvates, and hydrates together as alternative embodiments of a

single chemical entity signals that these forms are pharmaceutically acceptable interchangeable carriers of the same active molecule. For example, the specification describes a clinical study where the patients were administered 100 mg of acalabrutinib in its free base form. *Id.* at 59:5-15, 65:4-24.

Furthermore, the parties' dispute is identical to the dispute in *In re Fetzima*, 2021 WL 2349981. After considering the language of the claim term, the specification, the prosecution history and the extrinsic evidence presented in the written submission and the *Markman* hearing, the court held that "the dosage limitation, 120 mg/day, refers to the active moiety of the levomilnacipran salt, rather than the overall drug compound." *Id.* at *6.

Therefore, consistent with the specification, industry standards, and *In re Fetzima*, the Court construes "a dose of 100 mg twice daily of a BTK inhibitor . . . or a pharmaceutically acceptable salt, solvate, or hydrate thereof" consistent with its plain and ordinary meaning where "100 mg" refers to 100 mg of the compound of Formula (II) in its free base form.

**B. The '829 Patent**

**1. "characterized by a reflection X-ray powder diffraction pattern comprising of at least five peaks"**

| Claim Term | Plaintiffs AstraZeneca Construction | Defendants Cipla Construction | Proposed Construction |
|---|---|---|---|
| characterized by a reflection X-ray powder diffraction pattern comprising at least five peaks<br><br>('829 Patent, Claims 1-2, 5-25, 28-37, 39-42) | Not indefinite.<br><br>characterized by a reflection X-ray powder diffraction pattern that includes, but is not limited to, at least five peaks<br><br>The peaks identified in the specification, including the claims, of the '829 Patent were measured using Cu-Kα radiation. The source of | Indefinite. | Not indefinite.<br><br>characterized by a reflection X-ray powder diffraction pattern that includes, but is not limited to, at least five peaks<br><br>The peaks identified in the specification, |

| | | | |
|---|---|---|---|
| | radiation, Cu-Kα, is not a limitation of these claims, and the use of Cu-Kα radiation is not required to prove infringement of these claims. | | including the claims, of the '829 Patent were measured using Cu-Kα radiation. The source of radiation, Cu-Kα, is not a limitation of these claims, and the use of Cu-Kα radiation is not required to prove infringement of these claims. |

As depicted above, AstraZeneca contends that the claim term "characterized by a reflection X-ray powder diffraction pattern comprising at least five peaks" is not indefinite and should be construed as "characterized by a reflection X-ray powder diffraction pattern that includes, but is not limited to, at least five peaks . . .." D.I. 56 at 41. Cipla contends that the claim term is indefinite. *Id.* at 45. For the reasons discussed below, the claim term "characterized by a reflection X-ray powder diffraction pattern comprising at least five peaks" is not indefinite.

Claim 1 of the '829 Patent recites:

> A crystal form of (S)-4-(8-amino-3-(1-(but-2-ynoyl)pyrrolidin-2-yl)imidazo[1,5-a]pyrazin-1-yl)-N-(pyridin-2-yl)benzamide maleate, or hydrate thereof, characterized by a reflection X-ray powder diffraction pattern comprising at least five peaks selected from the group consisting of 5.3°±0.2° 2θ, 9.8°±0.2° 2θ, 10.6°±0.2° 2θ, 11.6°±0.2° 2θ, 13.5°±0.2° 2θ, 13.8°±0.2° 2θ, 13.9°±0.2° 2θ, 14.3°±0.2° 2θ, 15.3°±0.2° 2θ, 15.6°±0.2° 2θ, 15.8°±0.2° 2θ, 15.9°±0.2° 2θ, 16.6°±0.2° 2θ, 17.4°±0.2° 2θ, 17.5°±0.2° 2θ, 18.7°±0.2° 2θ, 19.3°±0.2° 2θ, 19.6°±0.2° 2θ, 19.8°±0.2° 2θ, 20.0°±0.2° 2θ, 20.9°±0.2° 2θ, 21.3°±0.2° 2θ, 22.1°±0.2° 2θ, 22.3°±0.2° 2θ, 22.7°±0.2° 2θ, 23.2°±0.2° 2θ, 23.4°±0.2° 2θ, 23.7°±0.2° 2θ, 23.9°±0.2° 2θ, 24.5°±0.2° 2θ, 24.8°±0.2° 2θ, 25.2°±0.2° 2θ, 25.6°±0.2° 2θ, 26.1°±0.2° 2θ, 26.4°±0.2° 2θ, 26.7°±0.2° 2θ, 26.9°±0.2° 2θ, 27.1°±0.2° 2θ, 27.6°±0.2° 2θ, 28.8°±0.2° 2θ, 29.5°±0.2° 2θ, 30.0°±0.2° 2θ, 30.3°±0.2° 2θ, 30.9°±0.2° 2θ, 31.5°±0.2° 2θ, 31.9°±0.2° 2θ, 32.5°±0.2° 2θ, 34.0°±0.2° 2θ, and 35.1°±0.2° 2θ.

'829 Patent at cl. 1. Cipla contends that the claim term is indefinite because a person of ordinary

skill in the art would not know which types of X-ray Powder Diffraction ("XRPD" or "PRXRD") radiation were intended because the claims fail to identify the source of radiation used to collect the XRPD pattern and multiple forms of the compound would fall within the claim's scope with no way to distinguish them from "the crystal form" claimed. D.I. 56 at 45.

A patent is presumed valid, and indefiniteness must be proven by clear and convincing evidence. *See* 35 U.S.C. § 282 (2006); *see also Nautilus*, 572 U.S. at 901; *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 789 F. 3d 1335, 1344-45 (Fed. Cir. 2015) (applying clear and convincing standard to indefiniteness analysis). Thus, the Court may conclude that this term is indefinite only if the record contains clear and convincing evidence that the claim term would not inform a POSA with "reasonable certainty" as to the claim's meaning. *See Nautilus*, 572 U.S. at 909. Cipla has not met this burden.

The Court is persuaded that a person of ordinary skill in the art[5] would be able to assess the crystalline form and exemplary XRPD patterns provided in the patent and discern with reasonable certainty whether a particular crystalline form is characterized by a particular XRPD pattern. This is supported by both parties' experts. For example, Cipla's expert, Dr. Reibenspies, stated at his deposition that he could determine whether any compound fell within claim 1. *See* Reibenspies Tr. at 121:4-123:21. Dr. Trout, AstraZeneca's expert, also opines, "any source of radiation could be used to assess whether a particular compound falls within the scope of claim 1". Trout Decl. ¶ 79. Therefore, a person of ordinary skill in the art would understand that the claimed compound can be identified using a range of reflection XRPD methodologies, including

[5] The parties appear to agree that, for the purpose of '829 Patent, a POSA at the time of filing would have possessed a doctoral degree in chemistry, chemical engineering or related field with experience working with pharmaceutics, or a master's or bachelor's degree in a similar field with significant experience. D.I. 56 at 7-8.

but not limited to, Cu-Kα. *Id.*

In light of the specification, it is evident that the peaks recited in claim 1 were measured using Cu-Kα radiation. The parties agree that FIG. 42 of the '829 Patent illustrates the peaks found in claim 1. Trout Decl. ¶ 80; Reibenspies Tr. 113:2-113:4. Also, each of the twenty-six XRPD diffractograms disclosed in the patent identify Cu-Kα as the radiation source. *See* '829 Patent FIGs 1-2, 12, 21, 26-27, 29, 31, 33, 36, 41-44, 49, 54, 57-58, 60-66, 72. Additionally, as of the priority date, Cu-Kα was (and still is) the prevalent radiation source used in the industry. Trout Decl. ¶ 81; Reibenspies Decl. ¶ 38. While Cipla is correct that the claims do not expressly identify a radiation source, this omission appears to reflect the inventors' intent rather than a deficiency in the disclosure. The specification consistently reports peak positions in 2θ without specifying the wavelength and does so in a manner consistent with established conventions in the field. Therefore, in the Court's view, a person of ordinary skill in the art would understand that the reported diffraction data was obtained using the standard Cu-Kα radiation customarily employed.

The Court turns next to Cipla's second argument that the claims describe two (or more) crystalline forms employing the same 49 peaks. D.I. 56 at 49. Cipla contends that claims 1-2, 4-25, 27-37, and 39-42 do not distinguish the claimed form from any other forms "characterized by a reflection X-ray powder diffraction pattern comprising at least five peaks". *Id.* Cipla argues that despite hydrates of a crystal form having different crystal structures than anhydrate, and crystals differing among various hydrates, both an anhydrate and one or more hydrates are covered by the same XRPD pattern specified in the claims. *Id.* Cipla's argument is unpersuasive. The claims encompass a crystal form of acalabrutinib maleate, or hydrate thereof that has the characteristic XRPD pattern comprising at least five peaks. *See* '829 patent cls. 1-2, 4-25, 27-37, and 39-42. Accordingly, a compound will only fall within the scope of the claim if it meets all the

limitations of the claim. *See* D.I. 56 at 62 ("If an acalabrutinib maleate hydrate form has five of the 49 peaks, but that same acalabrutinib maleate in anhydrate form does not have five of the 49 peaks, the POSA would understand that the latter does not fall within the scope of claim 1").

In the absence of clear and convincing evidence, the Court finds the claim term not indefinite. When the only dispute over a claim term concerns indefiniteness, and not its substantive construction, "there is no further material dispute to be resolved." *Align Tech., Inc. v. 3Shape A/S*, No. 18-1949, 2020 WL 7695927, at *10 (D. Del. Dec. 28, 2020); *see, e.g.*, *SentriLock, LLC v. Carrier Fire & Sec. Americas LLC*, No. 20-520, 2024 WL 3328495, at *4 n.2 (D. Del. July 8, 2024). Here, the Court observes that Cipla repeatedly refers to the claim language as "characterized **by** five of the peaks," although the claim language states, "characterized by a . . . pattern **comprising at least** five peaks." It is unclear whether this misstatement was intentional. To avoid ambiguity, the Court construes "characterized by a reflection X-ray powder diffraction pattern comprising at least five peaks" as "characterized by a reflection X-ray powder diffraction pattern that includes, but is not limited to, at least five peaks". *See Bioverativ Inc. v. CSL Behring LLC*, No. 17-914, 2019 WL 1276030, at *8 (D. Del. Mar. 20, 2019) ("I will construe 'comprising' to mean 'including but not limited to').

Lastly, AstraZeneca contends that the Court should construe the term to clarify how the peaks were formed. AstraZeneca's construction is consistent with the Court's analysis above. Accordingly, the Court construes the disputed term to mean "characterized by a reflection X-ray powder diffraction pattern that includes, but is not limited to, at least five peaks" and "[t]he peaks identified in the specification, including the claims, of the '829 Patent were measured using Cu-Kα radiation. The source of radiation, Cu-Kα, is not a limitation of these claims, and the use of Cu-Kα radiation is not required to prove infringement of these claims."

2. **"characterized by a reflection X-ray powder diffraction pattern comprising at least five peaks selected from the group consisting of [49 recited peak values]"**

| Claim Term | Plaintiffs AstraZeneca Construction | Defendants Cipla Construction | Proposed Construction |
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| characterized by a reflection X-ray powder diffraction pattern comprising at least five peaks selected from the group consisting of 5.3°±0.2° 2θ, 9.8°±0.2° 2θ, 10.6°±0.2° 2θ, 11.6°±0.2° 2θ, 13.5°±0.2° 2θ, 13.8°±0.2° 2θ, 13.9°±0.2° 2θ, 14.3°±0.2° 2θ, 15.3°±0.2° 2θ, 15.6°±0.2° 2θ, 15.8°±0.2° 2θ, 15.9°±0.2° 2θ, 16.6°±0.2° 2θ, 17.4°±0.2° 2θ, 17.5°±0.2° 2θ, 18.7°±0.2° 2θ, 19.3°±0.2° 2θ, 19.6°±0.2° 2θ, 19.8°±0.2° 2θ, 20.0°±0.2° 2θ, 20.9°±0.2° 2θ, 21.3°±0.2° 2θ, 22.1°±0.2° 2θ, 22.3°±0.2° 2θ, 22.7°±0.2° 2θ, 23.2°±0.2° 2θ, 23.4°±0.2° 2θ, 23.7°±0.2° 2θ, | Not indefinite.<br><br>characterized by a reflection X-ray powder diffraction pattern that includes, but is not limited to, at least five peaks selected from the group consisting of 5.3°±0.2° 2θ, 9.8°±0.2° 2θ, 10.6°±0.2° 2θ, 11.6°±0.2° 2θ, 13.5°±0.2° 2θ, 13.8°±0.2° 2θ, 13.9°±0.2° 2θ, 14.3°±0.2° 2θ, 15.3°±0.2° 2θ, 15.6°±0.2° 2θ, 15.8°±0.2° 2θ, 15.9°±0.2° 2θ, 16.6°±0.2° 2θ, 17.4°±0.2° 2θ, 17.5°±0.2° 2θ, 18.7°±0.2° 2θ, 19.3°±0.2° 2θ, 19.6°±0.2° 2θ, 19.8°±0.2° 2θ, 20.0°±0.2° 2θ, 20.9°±0.2° 2θ, 21.3°±0.2° 2θ, 22.1°±0.2° 2θ, 22.3°±0.2° 2θ, 22.7°±0.2° 2θ, 23.2°±0.2° 2θ, 23.4°±0.2° 2θ, 23.7°±0.2° 2θ, 24.5°±0.2° 2θ, | Indefinite. | Not indefinite.<br><br>characterized by a reflection X-ray powder diffraction pattern that includes, but is not limited to, at least five peaks selected from the group consisting of 5.3°±0.2° 2θ, 9.8°±0.2° 2θ, 10.6°±0.2° 2θ, 11.6°±0.2° 2θ, 13.5°±0.2° 2θ, 13.8°±0.2° 2θ, 13.9°±0.2° 2θ, 14.3°±0.2° 2θ, 15.3°±0.2° 2θ, 15.6°±0.2° 2θ, 15.8°±0.2° 2θ, 15.9°±0.2° 2θ, 16.6°±0.2° 2θ, 17.4°±0.2° 2θ, 17.5°±0.2° 2θ, 18.7°±0.2° 2θ, 19.3°±0.2° 2θ, 19.6°±0.2° 2θ, 19.8°±0.2° 2θ, 20.0°±0.2° 2θ, 20.9°±0.2° 2θ, 21.3°±0.2° 2θ, 22.1°±0.2° 2θ, 22.3°±0.2° 2θ, 22.7°±0.2° 2θ, 23.2°±0.2° 2θ, 23.4°±0.2° 2θ, 23.7°±0.2° 2θ, |

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| 23.9°±0.2° 2θ, 24.5°±0.2° 2θ, 24.8°±0.2° 2θ, 25.2°±0.2° 2θ, 25.6°±0.2° 2θ, 26.1°±0.2° 2θ, 26.4°±0.2° 2θ, 26.7°±0.2° 2θ, 26.9°±0.2° 2θ, 27.1°±0.2° 2θ, 27.6°±0.2° 2θ, 28.8°±0.2° 2θ, 29.5°±0.2° 2θ, 30.0°±0.2° 2θ, 30.3°±0.2° 2θ, 30.9°±0.2° 2θ, 31.5°±0.2° 2θ, 31.9°±0.2° 2θ, 32.5°±0.2° 2θ, 34.0°±0.2° 2θ, and 35.1°±0.2° 2θ<br><br>('829 Patent, Claims 1, 14-21, 35) | 24.8°±0.2° 2θ, 25.2°±0.2° 2θ, 25.6°±0.2° 2θ, 26.1°±0.2° 2θ, 26.4°±0.2° 2θ, 26.7°±0.2° 2θ, 26.9°±0.2° 2θ, 27.1°±0.2° 2θ, 27.6°±0.2° 2θ, 28.8°±0.2° 2θ, 29.5°±0.2° 2θ, 30.0°±0.2° 2θ, 30.3°±0.2° 2θ, 30.9°±0.2° 2θ, 31.5°±0.2° 2θ, 31.9°±0.2° 2θ, 32.5°±0.2° 2θ, 34.0°±0.2° 2θ, and 35.1°±0.2° 2θ.<br><br>The peaks identified in the specification, including the claims, of the '829 Patent were measured using Cu-Kα radiation. The source of radiation, Cu-Kα, is not a limitation of these claims, and the use of Cu-Kα radiation is not required to prove infringement of these claims. | | 23.9°±0.2° 2θ, 24.5°±0.2° 2θ, 24.8°±0.2° 2θ, 25.2°±0.2° 2θ, 25.6°±0.2° 2θ, 26.1°±0.2° 2θ, 26.4°±0.2° 2θ, 26.7°±0.2° 2θ, 26.9°±0.2° 2θ, 27.1°±0.2° 2θ, 27.6°±0.2° 2θ, 28.8°±0.2° 2θ, 29.5°±0.2° 2θ, 30.0°±0.2° 2θ, 30.3°±0.2° 2θ, 30.9°±0.2° 2θ, 31.5°±0.2° 2θ, 31.9°±0.2° 2θ, 32.5°±0.2° 2θ, 34.0°±0.2° 2θ, and 35.1°±0.2° 2θ.<br><br>The peaks identified in the specification, including the claims, of the '829 Patent were measured using Cu-Kα radiation. The source of radiation, Cu-Kα, is not a limitation of these claims, and the use of Cu-Kα radiation is not required to prove infringement of these claims. |

The parties dispute whether the claim term "characterized by a reflection X-ray powder diffraction pattern comprising at least five peaks selected from the group consisting of [49 recited

peak values]" is indefinite. For reasons similar to those discussed above, Cipla again fails to prove with clear and convincing evidence that the claim term is indefinite.

Cipla contends that "characterizing acalabrutinib maleate by 5 of the 49 peaks recited in the [49-Peak claims[6]] fails to distinguish the claimed form from any other form of acalabrutinib maleate." D.I. 56 at 55. To support its argument, Cipla argues that the broad range of the XRPD values and 2θ values would encompass nearly any form of crystalline acalabrutinib maleate, thereby failing to inform a person of ordinary skill in the art with reasonable certainty which specific form of acalabrutinib maleate is claimed. *Id.* at 56-57. The Court disagrees. A wide range of XRPD and 2θ values does not, by itself, render a claim indefinite, because "[b]readth is not indefiniteness." *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1341 (Fed. Cir. 2005) (citing *In re Gardner*, 57 C.C.P.A. 1207, 427 F.2d 786, 788 (C.C.P.A. 1970)). Here, "this claim is neither broad nor narrow, but definite of this particular chemical structure." *Id.* Cipla also repeats its assertion that the claims are indefinite on the ground that they describe two (or more) crystalline forms employing the same 49 peak positions. For the reasons already discussed in the preceding section, the Court finds this argument unpersuasive.

Accordingly, and for the same reasons discussed above, the Court will construe "characterized by a reflection X-ray powder diffraction pattern comprising at least five peaks selected from the group consisting of 5.3°±0.2° 2θ, 9.8°±0.2° 2θ, 10.6°±0.2° 2θ, 11.6°±0.2° 2θ, 13.5°±0.2° 2θ, 13.8°±0.2° 2θ, 13.9°±0.2° 2θ, 14.3°±0.2° 2θ, 15.3°±0.2° 2θ, 15.6°±0.2° 2θ, 15.8°±0.2° 2θ, 15.9°±0.2° 2θ, 16.6°±0.2° 2θ, 17.4°±0.2° 2θ, 17.5°±0.2° 2θ, 18.7°±0.2° 2θ, 19.3°±0.2° 2θ, 19.6°±0.2° 2θ, 19.8°±0.2° 2θ, 20.0°±0.2° 2θ, 20.9°±0.2° 2θ, 21.3°±0.2° 2θ,

[6] Cipla defines the 49-Peak Claims as claims 1, 14-21 and 35 of the '829 Patent. *See* D.I. 56 at 55.

22.1°±0.2° 2θ, 22.3°±0.2° 2θ, 22.7°±0.2° 2θ, 23.2°±0.2° 2θ, 23.4°±0.2° 2θ, 23.7°±0.2° 2θ, 23.9°±0.2° 2θ, 24.5°±0.2° 2θ, 24.8°±0.2° 2θ, 25.2°±0.2° 2θ, 25.6°±0.2° 2θ, 26.1°±0.2° 2θ, 26.4°±0.2° 2θ, 26.7°±0.2° 2θ, 26.9°±0.2° 2θ, 27.1°±0.2° 2θ, 27.6°±0.2° 2θ, 28.8°±0.2° 2θ, 29.5°±0.2° 2θ, 30.0°±0.2° 2θ, 30.3°±0.2° 2θ, 30.9°±0.2° 2θ, 31.5°±0.2° 2θ, 31.9°±0.2° 2θ, 32.5°±0.2° 2θ, 34.0°±0.2° 2θ, and 35.1°±0.2° 2θ" as "characterized by a reflection X-ray powder diffraction pattern that includes, but is not limited to, at least five peaks selected from the group consisting of 5.3°±0.2° 2θ, 9.8°±0.2° 2θ, 10.6°±0.2° 2θ, 11.6°±0.2° 2θ, 13.5°±0.2° 2θ, 13.8°±0.2° 2θ, 13.9°±0.2° 2θ, 14.3°±0.2° 2θ, 15.3°±0.2° 2θ, 15.6°±0.2° 2θ, 15.8°±0.2° 2θ, 15.9°±0.2° 2θ, 16.6°±0.2° 2θ, 17.4°±0.2° 2θ, 17.5°±0.2° 2θ, 18.7°±0.2° 2θ, 19.3°±0.2° 2θ, 19.6°±0.2° 2θ, 19.8°±0.2° 2θ, 20.0°±0.2° 2θ, 20.9°±0.2° 2θ, 21.3°±0.2° 2θ, 22.1°±0.2° 2θ, 22.3°±0.2° 2θ, 22.7°±0.2° 2θ, 23.2°±0.2° 2θ, 23.4°±0.2° 2θ, 23.7°±0.2° 2θ, 23.9°±0.2° 2θ, 24.5°±0.2° 2θ, 24.8°±0.2° 2θ, 25.2°±0.2° 2θ, 25.6°±0.2° 2θ, 26.1°±0.2° 2θ, 26.4°±0.2° 2θ, 26.7°±0.2° 2θ, 26.9°±0.2° 2θ, 27.1°±0.2° 2θ, 27.6°±0.2° 2θ, 28.8°±0.2° 2θ, 29.5°±0.2° 2θ, 30.0°±0.2° 2θ, 30.3°±0.2° 2θ, 30.9°±0.2° 2θ, 31.5°±0.2° 2θ, 31.9°±0.2° 2θ, 32.5°±0.2° 2θ, 34.0°±0.2° 2θ, and 35.1°±0.2° 2θ. The peaks identified in the specification, including the claims, of the '829 Patent were measured using Cu-Kα radiation. The source of radiation, Cu-Kα, is not a limitation of these claims, and the use of Cu-Kα radiation is not required to prove infringement of these claims."

## IV. CONCLUSION

The Court will adopt the parties' agreed-upon constructions and construe the disputed claim terms as described above. The Court will issue an Order consistent with this Memorandum Opinion.

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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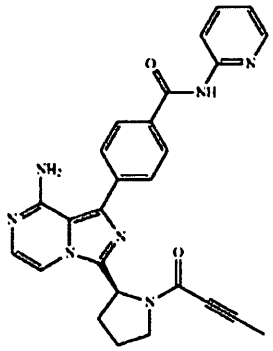
| ACERTA PHARMA B.V., et al.,<br><br>Plaintiffs,<br><br>v.<br><br>CIPLA LIMITED, et al.,<br><br>Defendants. | C.A. No. 24-587-GBW<br>(LEAD CASE) |
| ACERTA PHARMA B.V., et al.,<br><br>Plaintiffs,<br><br>v.<br><br>MSN PHARMACEUTICALS, INC., et al.,<br><br>Defendants. | C.A. No. 25-43-GBW |

**ORDER**

At Wilmington this 25th day of November 2025 and consistent with the Memorandum Opinion issued this day, **IT IS HEREBY ORDERED** that the Court construes the following claim terms of U.S. Patent Nos. 10,272,083 ("the '083 Patent") and 11,059,829 ("the '829 Patent") as follows:

| Claim Term | Court's Construction |
|---|---|
| **Agreed-Upon Constructions** | |
| "A method of treating chronic lymphocytic leukemia (CLL) or small lymphocytic leukemia (SLL) in a human subject suffering therefrom"<br><br>('083 Patent, Claims 1-7) | The quoted preamble language is limiting as to the intentional purpose for which the method must be performed, i.e., treating chronic lymphocytic leukemia (CLL) or small lymphocytic leukemia (SLL) in a human subject suffering therefrom, which requires |

| Claim Term | Court's Construction |
|---|---|
| | treating CLL or SLL in a human subject, but does not require a particular level of efficacy. |
| "A method of treating a mantle cell lymphoma (MCL) in a human subject suffering therefrom"<br><br>('083 Patent, Claims 8-20) | The quoted preamble language is limiting as to the intentional purpose for which the method must be performed, i.e., treating Mantle Cell Lymphoma (MCL) in a human subject suffering therefrom, which requires treating MCL in a human subject suffering therefrom, but does not require a particular level of efficacy. |
| **Disputed Constructions** | |
| "a compound of Formula (II) . . . or a pharmaceutically acceptable salt thereof"<br><br>('083 Patent, Claims 2-4, 9-11, 15-16, 18, 20) | Plain and ordinary meaning where "pharmaceutically acceptable salt" does not exclude salts that are solvates and/or hydrates |
| "a dose of 100 mg twice daily of a BTK inhibitor . . . or a pharmaceutically acceptable salt, solvate, or hydrate thereof"<br><br>('083 Patent, Claims 1, 8) | Plain and ordinary meaning where "100 mg" refers to 100 mg of the compound of Formula (II) in its free base form:<br><br>  |
| "a dose of 100 mg twice daily of a BTK inhibitor . . . or a pharmaceutically acceptable salt thereof"<br><br>('083 Patent, Claims 2-4, 9-11, 15-16) | |
| "a dose of 100 mg twice daily of a BTK inhibitor . . . or a pharmaceutically acceptable salt thereof . . . wherein the pharmaceutically acceptable salt . . . is administered to the human subject"<br><br>('083 Patent, Claims 18, 20) | |

| Claim Term | Court's Construction |
|---|---|
| "characterized by a reflection X-ray powder diffraction pattern comprising at least five peaks"<br><br>('829 Patent, Claims 1-2, 5-25, 28-37, 39-42) | Not indefinite.<br><br>characterized by a reflection X-ray powder diffraction pattern that includes, but is not limited to, at least five peaks<br><br>The peaks identified in the specification, including the claims, of the '829 Patent were measured using Cu-Kα radiation. The source of radiation, Cu-Kα, is not a limitation of these claims, and the use of Cu-Kα radiation is not required to prove infringement of these claims. |
| "characterized by a reflection X-ray powder diffraction pattern comprising at least five peaks selected from the group consisting of 5.3°±0.2° 2θ, 9.8°±0.2° 2θ, 10.6°±0.2° 2θ, 11.6°±0.2° 2θ, 13.5°±0.2° 2θ, 13.8°±0.2° 2θ, 13.9°±0.2° 2θ, 14.3°±0.2° 2θ, 15.3°±0.2° 2θ, 15.6°±0.2° 2θ, 15.8°±0.2° 2θ, 15.9°±0.2° 2θ, 16.6°±0.2° 2θ, 17.4°±0.2° 2θ, 17.5°±0.2° 2θ, 18.7°±0.2° 2θ, 19.3°±0.2° 2θ, 19.6°±0.2° 2θ, 19.8°±0.2° 2θ, 20.0°±0.2° 2θ, 20.9°±0.2° 2θ, 21.3°±0.2° 2θ, 22.1°±0.2° 2θ, 22.3°±0.2° 2θ, 22.7°±0.2° 2θ, 23.2°±0.2° 2θ, 23.4°±0.2° 2θ, 23.7°±0.2° 2θ, 23.9°±0.2° 2θ, 24.5°±0.2° 2θ, 24.8°±0.2° 2θ, 25.2°±0.2° 2θ, 25.6°±0.2° 2θ, 26.1°±0.2° 2θ, 26.4°±0.2° 2θ, 26.7°±0.2° 2θ, 26.9°±0.2° 2θ, 27.1°±0.2° 2θ, 27.6°±0.2° 2θ, 28.8°±0.2° 2θ, 29.5°±0.2° 2θ, 30.0°±0.2° 2θ, 30.3°±0.2° 2θ, 30.9°±0.2° 2θ, 31.5°±0.2° 2θ, 31.9°±0.2° 2θ, 32.5°±0.2° 2θ, 34.0°±0.2° 2θ, and 35.1°±0.2° 2θ"<br><br>('829 Patent, Claims 1, 14-21, 35) | Not indefinite.<br><br>characterized by a reflection X-ray powder diffraction pattern that includes, but is not limited to, at least five peaks selected from the group consisting of 5.3°±0.2° 2θ, 9.8°±0.2° 2θ, 10.6°±0.2° 2θ, 11.6°±0.2° 2θ, 13.5°±0.2° 2θ, 13.8°±0.2° 2θ, 13.9°±0.2° 2θ, 14.3°±0.2° 2θ, 15.3°±0.2° 2θ, 15.6°±0.2° 2θ, 15.8°±0.2° 2θ, 15.9°±0.2° 2θ, 16.6°±0.2° 2θ, 17.4°±0.2° 2θ, 17.5°±0.2° 2θ, 18.7°±0.2° 2θ, 19.3°±0.2° 2θ, 19.6°±0.2° 2θ, 19.8°±0.2° 2θ, 20.0°±0.2° 2θ, 20.9°±0.2° 2θ, 21.3°±0.2° 2θ, 22.1°±0.2° 2θ, 22.3°±0.2° 2θ, 22.7°±0.2° 2θ, 23.2°±0.2° 2θ, 23.4°±0.2° 2θ, 23.7°±0.2° 2θ, 23.9°±0.2° 2θ, 24.5°±0.2° 2θ, 24.8°±0.2° 2θ, 25.2°±0.2° 2θ, 25.6°±0.2° 2θ, 26.1°±0.2° 2θ, 26.4°±0.2° 2θ, 26.7°±0.2° 2θ, 26.9°±0.2° 2θ, 27.1°±0.2° 2θ, 27.6°±0.2° 2θ, 28.8°±0.2° 2θ, 29.5°±0.2° 2θ, 30.0°±0.2° 2θ, 30.3°±0.2° 2θ, 30.9°±0.2° 2θ, 31.5°±0.2° 2θ, 31.9°±0.2° 2θ, 32.5°±0.2° 2θ, 34.0°±0.2° 2θ, and 35.1°±0.2° 2θ.<br><br>The peaks identified in the specification, including the claims, of the '829 Patent were measured using Cu-Kα radiation. The source |

| Claim Term | Court's Construction |
| --- | --- |
| | of radiation, Cu-Kα, is not a limitation of these claims, and the use of Cu-Kα radiation is not required to prove infringement of these claims. |

GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE