IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VIIV HEALTHCARE COMPANY, SHIONOGI & CO., LTD, and VIIV HEALTHCARE UK (NO. 3) LIMITED,	:	**CIVIL ACTION**
	:	**17-1576**
Plaintiffs,	:	**CONSOLIDATED**
v.	:	
LUPIN LIMITED et al.,	:	
Defendants.	:	

MEMORANDUM OPINION

Goldberg, J. **September 26, 2019**

This patent litigation dispute involves seven consolidated patent infringement and invalidity lawsuits, all arising under the Hatch-Waxman Act. Plaintiffs—the owner, assignee, and licensee of U.S. Patent No. 9,246,986 ("the '986 Patent")—filed each of these actions for patent infringement alleging violation of 35 U.S.C. § 271, based upon Defendants' submissions of Abbreviated New Drug Applications ("ANDAs") with the Federal Drug Administration ("FDA").[1] Those ANDAs seek FDA approval of generic versions of one or both of two brand-name drugs, "TIVICAY®" and "TRIUMEQ®." Defendants responded with counterclaims for non-infringement and invalidity. Currently before me is the claim construction of two terms contained in the '986 Patent.

[1] The Defendants are: Lupin Limited; Lupin Pharmaceuticals, Inc.; Apotex Corp.; Cipla Limited; Cipla USA, Inc.: Sandoz Inc.; Lek Pharmaceuticals d.d.; and Laurus Labs Limited.

I. FACTUAL AND PROCEDURAL BACKGROUND[2]

Plaintiff ViiV Healthcare Company sells and distributes TIVICAY® and TRIUMEQ®, both of which are tablets taken orally to treat HIV. TIVICAY® contains the active ingredient dolutegravir sodium. TRIUMEQ® contains three active ingredients including dolutegravir sodium.

The '986 Patent, entitled "synthesis of carbamoylpyridone HIV integrase inhibitors and intermediates," issued on January 26, 2016. Plaintiff Shionogi & Co., Ltd. is the assignee of the '986 Patent, and Plaintiff ViiV Healthcare UK (No. 3) Limited is the exclusive licensee of the '986 Patent. Pursuant to 21 U.S.C. § 255, the '986 Patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") in connection with TIVICAY® and TRIUMEQ®.

Each of the Defendants in these cases filed ANDAs with the FDA, seeking approval to sell generic versions of TIVICAY® or TRIUMEQ® before the expiration of the '986 Patent.[3] Thereafter, Plaintiffs filed these lawsuits for patent infringement.

Plaintiffs and Defendants dispute the appropriate construction of two claim terms: (1) "A crystal form of a sodium salt of a compound of formula AA," contained in Claims 1 through 6 of the '986 Patent; and (2) "A crystal form of a hydrate of a sodium salt of a compound of formula AA," contained in Claims 7 through 12 of the '986 Patent.

[2] On May 18, 2017, Chief Judge D. Brooks Smith of the United States Court of Appeals for the Third Circuit designated me as a visiting judge for the District of Delaware, pursuant to 28 U.S.C. § 292(b), to handle this and other Delaware cases.

[3] The following facts are derived from Plaintiffs' Complaints and the parties' claim construction briefs.

II. LEGAL PRINCIPLES GOVERNING CLAIM CONSTRUCTION

Claim construction is the first step in the infringement analysis. At claim construction, the court defines the meaning and scope of the disputed claim terms. See Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995), aff'd, 517 U.S. 370 (1996). Claim construction is an issue of law for the court to decide. Id. Following claim construction, the court's interpretations are used by the factfinder to determine whether there has been infringement, by comparing the asserted claims with the accused device or prior art. Id.

"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) (internal quotation marks omitted). Thus, the focus of a court's analysis must therefore begin and remain on the language of the claims, "for it is that language that the patentee chose to use to 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.'" Interactive Gift Express, Inc. v. Compuserve, Inc., 256 F.3d 1323, 1331 (Fed. Cir. 2001) (quoting 35 U.S.C. ' 112, & 2). There is a "heavy presumption" that the terms of a claim mean what they say and have their ordinary and customary meaning. Texas Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1202 (Fed. Cir. 2002). That ordinary meaning "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." Phillips, 415 F.3d at 1313.

Generally, a person of ordinary skill in the art would not understand the ordinary and customary meaning of a claim term in isolation. As such, the ordinary meaning may be derived from a variety of sources including intrinsic evidence, such as the claim language, the written description, drawings, and the prosecution history; as well as extrinsic evidence, such as

dictionaries, treatises, or expert testimony. Dow Chem. Co. v. Sumitomo Chem. Co., Ltd., 257 F.3d 1364, 1373 (Fed. Cir. 2001).

The "most significant source" of authority is "the intrinsic evidence of record, i.e., the patent itself, including the claims, the patent specification[4] and, if in evidence, the prosecution history." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996); see also Phillips, 415 F.3d at 1313 (holding that a person of ordinary skill in the art is deemed to read the claim terms in the context of the entire patent, including the specification). The specification "is the single best guide to the meaning of a disputed term" and is usually dispositive as to the meaning of words. Vitronics, 90 F.3d at 1582. Although it is improper to import limitations from the specification into the claims, "one may look to the written description to define a term already in a claim limitation, for a claim must be read in view of the specification of which it is a part." Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1248 (Fed. Cir. 1998). On occasion, "the specification may reveal a special definition given to a claim term . . . that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." Phillips, 415 F.3d at 1316. The specification may also reveal an intentional disclaimer, or disavowal, of claim scope by the inventor . . . [, which] is regarded as dispositive." Id. "The 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, 158 F.3d at 1250.

The court "should also consider the patent's prosecution history, if it is in evidence." Markman, 52 F.3d at 980. This consists of "the complete record of proceedings before the Patent

[4] The specification is "that part of a patent application which precedes the claim and in which the inventor specifies, describes, and discloses the invention in detail." McCarthy's Desk Encyclopedia of Intellectual Property 408 (2d ed. 1995).

Office and includes the prior art cited during examination." Phillips, 415 F.3d at 1317. "Like the specification, the prosecution history provides evidence of how the [Patent and Trademark Office ('PTO')] and the inventor understood the patent." Id. at 1317. Nonetheless, it is the least probative form of intrinsic evidence because it "represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation." Id.

If ambiguity still exists after considering all the intrinsic evidence, the court may rely on extrinsic evidence, which is "all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." Markman, 52 F.3d at 980. "[D]ictionaries, and especially technical dictionaries, . . . have been properly recognized as among the many tools that can assist the court in determining the meaning of particular terminology." Phillips, 415 F.3d at 1318. Additionally, expert testimony can provide background on the technology at issue, explain how it works, speak to what a person of ordinary skill in the art would understand, and establish that a particular term has a particular meaning in the pertinent field. Id. Notably, however, extrinsic evidence is "less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" C.R. Bard, Inc. v. U.S. Surgical Corp., 388 F.3d 858, 862 (Fed. Cir. 2004) (quoting Vanderlande Indus. Nederland BV v. Int'l Trade Comm'n, 366 F.3d 1311, 1318 (Fed. Cir. 2004)).

Ultimately, during claim construction, "[t]he sequence of steps used by the judge in consulting various sources is not important; what matters is for the court to attach the appropriate weight to be assigned to those sources in light of the statutes and policies that inform patent law." Phillips, 415 F.3d at 303.

III. DISCUSSION

Plaintiffs and Defendants dispute the appropriate construction of two claim terms, focusing specifically on the following italicized language: (1) "*A crystal form* of a sodium salt of a compound of formula AA" (contained in Claims 1 through 6 of the '986 Patent); and (2) "*A crystal form of a hydrate* of a sodium salt of a compound of formula AA," (contained in Claims 7 through 12 of the '986 Patent). Plaintiffs maintian that both of these terms need no further construction and should be read in light of their plain and ordinary meaning. Defendants contend that the terms should be construed as, respectively, "an *anhydrate* crystalline form of dolutegravir sodium" and "a *monohydrate* crystalline form of dolutegravir sodium in which one molecule of water is in the crystal lattice for every one molecule of dolutegravir sodium." (Joint Claim Construction Chart). Understanding these positions requires some background regarding the chemistry of crystalline compounds like those covered by the '986 Patent.

A. Scientific Background

A chemical compound can take either an "amorphous" form or a "crystalline" form. When a compound is in a crystalline form, its molecules appear in regular arrangements that are repeated in three dimensions (forming a "lattice" structure). By contrast, and as the name suggests, an "amorphous" compound does not have molecules that are arranged in a regular order. The '986 Patent covers certain crystalline forms of the compound dolutegravir sodium. (See Pl.'s Br. 4; Defs.' Br. 4.)

A crystalline compound can sometimes crystallize in different arrangements or forms. These different crystal forms are called "polymorphs." Distinguishing between different polymorphs is important, because different polymorphs of the same compound can exhibit different chemical and physical properties, such as different melting points or dissolution rates. Thus, different polymorphs can have different clinical effects. (See Pl.'s Br. 4.)

A crystalline compound becomes a "solvate" when it incorporates a solvent into its crystalline structure. When that solvent is water, the solvate is a known as a "hydrate." But when the crystalline compound does not incorporate any solvent into its structure, it is referred to as an "anhydrate." (See Pl.'s Br. 5; Defs.' Br. 4.)

Solvates and hydrates can be either "stoichiometric," meaning the ratio of compound to solvent remains constant, or "non-stoichiometric," meaning that the ratio does not stay constant but, rather, changes depending on certain conditions like humidity. The different ratios of compound to water are referred to as "hydration states." A few examples of hydration states are "monohydrate" (a 1:1 ratio of compound molecules to water molecules) and "dihydrate" (a 1:2 ratio of compound molecules to water molecules). (See Pl.'s Br. 5–6; Defs.' Br. 4–5.)

The extent to which a crystalline compound's *hydration state* impacts its *structure* is somewhat disputed by the parties. Plaintiffs maintain that while structure may be impacted by hydration state, that is not always the case. (See Pl.'s Br. 6; Tr. of Oral Argument 14:22–15:7.) Specifically, Plaintiffs' expert posits that non-stoichiometric solvates can go through changes in hydration state without changing structure. (Pl.'s Br. 6 (citing Myerson Decl. ¶¶ 34, 36).) Defendants have not addressed this point directly, but did note at oral argument their disagreement with the general proposition that "hydration or solvation doesn't identify a crystal form." (Tr. of Oral Argument 16:6–9.)

Importantly, the parties do agree that a compound's crystalline structure can be identified using a number of different measurement techniques, including "X-ray powder diffraction ("XRPD"), infrared absorption spectroscopy ("IR"), and solid-state NMR spectroscopy ("ssNMR"). Thus, the data yielded by using one or more of these techniques provide a unique "signature" useful for identifying the particular crystal structure being examined. (Defs.' Br. 5.)

B. The Parties' Proposed Constructions and Supporting Arguments

Each of the twelve claims of the '986 Patent refer to a "crystal form" of dolutegravir sodium, identifying that form by reference to data from one of the measurement techniques discussed above. Specifically, the twelve claims are as follows:

> 1. A crystal form of a sodium salt of a compound of formula AA having characteristic diffraction peaks at 6.4°±0.2°, 9.2°±0.2°, 13.8°±0.2°, 19.2°±0.2°, and 21.8°±0.2° degrees two-theta in an X-ray powder diffraction pattern.
>
> 2. The crystal form according to claim 1, having characteristic diffraction peaks at 6.4°±0.2°, 9.2°±0.2°, 13.8°±0.2°, 14.6°±0.2°, 15.2°±0.2°, 17.6°±0.2°, 19.2°±0.2°, 21.8°±0.2°, 24.1°±0.2°, and 28.7°±0.2° degrees two-theta in an X-ray powder diffraction pattern.
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> 3. The crystal form according to claim 1, having characteristic infrared absorption spectra at 1641 cm-1±2 cm-1, 1536 cm-1±2 cm-1, 1503 cm-1±2 cm-1, and 1424 cm-1±2 cm-1.
>
> 4. A crystal form of a sodium salt of a compound of formula AA having characteristic infrared absorption spectra at 1641 cm-1±2 cm-1, 1536 cm-1±2 cm-1, 1503 cm-1±2 cm-1, and 1424 cm-1±2 cm-1.
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> 5. The crystal form according to claim 4, having characteristic infrared absorption spectra at 1641 cm-1±2 cm-1, 1536 cm-1±2 cm-1, 1503 cm-1±2 cm-1, 1424 cm-1±2 cm-1, 1282 cm-1±2 cm-1, 1258 cm-1±2 cm-1, 1093 cm-1±2 cm-1, and 1069 cm-1±2 cm-1.
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> 6. A crystal form of a sodium salt of a compound of formula AA having one or more spectra selected from the group consisting of (a) to (c):
> (a) X-ray diffraction pattern substantially as shown in FIG. 1;
> (b) Infrared absorption spectra substantially as shown in FIG. 2; and
> (c) Solid state 13C-NMR spectra substantially as shown in FIG. 3.
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> 7. A crystal form of a hydrate of a sodium salt of a compound of formula AA having characteristic diffraction peaks at 8.0°±0.2°, 9.3°±0.2°, 11.3°±0.2°, 16.0°±0.2°, and 22.8°±0.2° degrees two-theta in an X-ray powder diffraction pattern.
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> 8. The crystal form according to claim 7, having characteristic diffraction peaks at 8.0°±0.2°, 9.3°±0.2°, 11.3°±0.2°, 15.4°±0.2°, 16.0°±0.2°,

18.7°±0.2°, 19.1°±0.2°, 19.8°±0.2°, 22.8°±0.2°, and 26.8°±0.2° degrees two-theta in an X-ray powder diffraction pattern.

9. The crystal form according to claim 7, having characteristic infrared absorption spectra at 1637 cm-1±2 cm-1, 1536 cm-1±2 cm-1. 1501 cm-1±2 cm-1, and 1422 cm-1±2 cm-1. 15

10. A crystal form of a hydrate of a sodium salt of a compound of formula AA having characteristic infrared absorption spectra at 1637 cm-1±2 cm-1, 1536 cm-1±2 cm-1, 1501 cm-1±2 cm-1, and 1422 cm-1±2 cm-1.

11. The crystal form according to claim 10, having one or more spectra selected from the group consisting of (d) and (e):
(d) X-ray powder diffraction pattern substantially as shown in FIG. 4; and
(e) Infrared absorption spectra substantially as shown in FIG. 5.

12. A crystal form of a hydrate of a sodium salt of a compound of formula AA having one or more spectra selected from the group consisting of (d) and (e):
(d) X-ray powder diffraction pattern substantially as shown in FIG. 4; and
(e) Infrared absorption spectra substantially as shown in FIG. 5.

The parties seem to agree that the term "sodium salt of a compound of formula AA"—which appears in each claim either directly or by reference to another claim—refers to the compound dolutegravir sodium. What the parties dispute is whether the term "crystal form" in each of the claims should be further construed to identify the particular *hydration state* of the claimed crystal forms—in light of the specific measurement data set out in both of the claims and the specification. Thus, for Claims 1 through 6, Defendants contend that the term "a crystal form" of dolutegravir sodium should be construed as "an *anhydrate* crystalline form of dolutegravir sodium"—because the measurement data shows that the crystal form is an anhydrate. Likewise, for Claims 7 through 12, Defendants argue that the term "a crystal form of a hydrate of" dolutegravir sodium should be further construed as "a *monohydrate* crystalline form of dolutegravir sodium in which one molecule of water is in the crystal lattice for every one molecule

of dolutegravir sodium." Defendants press this construction because the measurement data shows that the crystal form is a monohydrate.

Defendants' position relies on the specification, which identifies, as examples of the invention, two crystal forms of dolutegravir sodium: Compound 13, which is an anhydrate, and Compound 13b, which is a monohydrate.[5] Defendants contend that these two crystal forms of dolutegravir sodium are, in fact, the *entirety* of the invention, because—as the specification itself reveals—these two crystal forms yield the same measurement data that is listed in the twelve claims. Specifically, Compound 13 yields the same measurement data listed in Claims 1 thorough 6; and Compound 13b yields the same measurement data listed in Claims 7 through 12. Because these two sets of data create two unique "signatures" for the two crystal forms, Defendants argue, Compounds 13 and 13b are the entirety of the invention claimed by the the '986 Patent, and the claims should be construed accordingly.

Plaintiffs respond that Defendants' proposed construction impermissibly imports limitations from the specification into the claims. Plaintiffs stress that the specification makes clear that Compounds 13 and 13b are merely embodiments of the invention claimed by the '986 Patent, and that it is improper to construe the claims as limited to those embodiments.

For the reasons set forth below, I agree with Plaintiffs and conclude that the claim language, specification, and prosecution history of the '986 Patent do not clearly indicate that Compounds 13 and 13b are the entirety of the invention. Accordingly, I will decline to adopt Defendants' proposed construction, which seeks to limit the claims to those two embodiments.

[5] Plaintiffs do not appear to dispute that Compound 13 is an anhydrate and Compound 13b a monohydrate. The specification refers to Compound 13b as a "monohydrate form of compound 13." ('986 Patent, Col. 18, ll. 65–68.)

C. Analysis

The United States Court of Appeals for the Federal Circuit has recognized that there is a "fine line" between the permissible practice of reading a patent's claims in light of the specification, and the prohibited practice of importing limitations from the specification into the claims. See Abbott Labs. v. Sandoz, Inc., 566 F.3d 1282, 1288 (Fed. Cir. 2009). As the Federal Circuit explained:

> This court has recognized the fine line between the encouraged and the prohibited use of the specification. When the specification describes a single embodiment to enable the invention, this court will not limit broader claim language to that single application unless the patentee has demonstrated *a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction.* By the same token, the claims cannot enlarge what is patented beyond what the inventor has described as the invention. *Thus this court may reach a narrower construction, limited to the embodiment(s) disclosed in the specification, when the claims themselves, the specification, or the prosecution history clearly indicate that the invention encompasses no more than that confined structure or method.*

Id. (emphasis added) (citations and internal quotation marks omitted).

Here, applying Abbott Laboratories, in order to determine whether Defendants' proposed construction is appropriate, I must decide whether the claim language, the specification, and the prosecution history of the '986 Patent "clearly indicate that the invention encompasses no more" than Compounds 13 and 13b. Id.[6]

[6] This standard is not inconsistent with a case cited by Defendants for the proposition that they need not show "a clear and unambiguous disclaimer of claim scope" for their construction to prevail. (See Def.'s Surreply Br. 1–2 (citing Phillips v. AWH Corp., 415 F.3d 1303, 1320–21 (Fed. Cir. 2005)).) The Federal Circuit in Phillips merely rejected an approach that required a court to consult the specification "only after a determination is made . . . as to the ordinary meaning or meanings of the claim term in dispute." 415 F.3d at 1320. But the Federal Circuit in Phillips acknowledged the need "to avoid the danger of reading limitations from the specification into the claim," and noted that doing so is often at odds with the patentee's intent because "persons of ordinary skill in the art rarely would confine their definitions of terms to the exact representations depicted in the embodiments." Id. at 1323. In rejecting Defendants' proposed construction, I do not, as Phillips cautions against, decline to consult the specification in light of the plain meaning of the claim language. Rather, as discussed below, I find that the specification does not clearly indicate that the invention is limited to the embodiments, Compounds 13 and 13b.

In arguing that the claim language, specification and prosecution history limits the claims scope, Defendants attempt to analogize this case to the Federal Circuit's decision in Abbott Laboratories. Like the '986 Patent, the patent-in-suit in Abbott Laboratories claimed a crystal form of a compound (there, a compound called "cefdinir"), "defining [the particular form's] unique characteristics" by reference to data yielded from XRPD measurements. 566 F.3d at 1286 (noting that the patent-in-suit "use[ed] [XRPD] as a way to claim the structure and characteristics of the unique crystalline form"). But unlike the '986 Patent, the patent-in-suit in Abbott Laboratories claimed priority to the patent holder's previous Japanese patent application, which described two crystal forms of the compound—termed "Crystal A" and "Crystal B." Id. at 1287. Importantly, the patent-in-suit "jettisoned the Crystal B disclosure found in the [Japanese application]." Id. Accordingly, at the claim construction phase, the district court construed the claim term "crystalline" as being limited to "Crystal A as outlined in the specification." Id.

On appeal, the Federal Circuit noted that the plain meaning of the term "crystalline" broadly refers to *any* crystal form, but nevertheless held that the district court had properly construed that term as being limited to the crystal form described in the specification, Crystal A. Abbott Labs., 566 F.3d at 1290–91. As discussed in greater detail below, the Federal Circuit concluded that the district court's construction was supported by both the patent-in-suit's specification and its prosecution history. See id.

The district court in Abbott Laboratories noted that Crystal A was referred to throughout the specification of the patent-in-suit, and that the XRPD data for Crystal A that was set out in the specification exactly matched the data in the claim language. Abbott Labs., 566 F.3d at 1289. The district court explained, "if [the patent holder] intended . . . to distinguish Crystal A from other forms of crystalline cefdinir" that fell within the patent-in-suit's claims, it would have provided

additional XRPD data showing how Crystal A differed from those other forms. Id. Instead, "by listing in [the specification] only the same [XRPD data] featured in [the claim language], [the patent holder] confirmed that Crystal A was synonymous with the invention listed in [the claim language]." Id.

Defendants correctly point out that, here, as in Abbott Laboratories, the specification of the '986 Patent discusses only two specific crystal forms of dolutegravir sodium that Plaintiffs created, Compounds 13 and 13b. And like Crystal A in Abbott Laboratories, the measurement data for Compounds 13 and 13b, set out in the specification, exactly match the measurement data included in the language of the twelve claims of the '986 Patent. Thus, Defendants argue, those claims are properly construed as being limited to Compounds 13 (an anhydrate) and 13b (a monohydrate).

Importantly, however, neither the district court's nor the Federal Circuit's analysis in Abbott Laboratories ended there. Instead, both courts looked beyond the matching measurement data, noting that the "specification's recitation of Crystal A as its sole embodiment *does not alone justify the . . . limitation of claim scope to that single disclosed embodiment*." Abbott Labs., 566 F.3d at 1290 (emphasis added). The Federal Circuit stressed that the limiting construction was further supported by the patent-in-suit's prosecution history. Id. at 1290-1291. Specifically, the fact that the previous Japanese patent application listed Crystal B, while the later patent-in-suit did not, "establishe[d] unequivocally that [the patent holder] knew and could describe both Crystal A and Crystal B" and chose to "disclose[] and claim[] [Crystal] A alone." Id. at 1290. The Federal Circuit concluded that the prosecution history showed "a clear and intentional disavowal of claim scope beyond Crystal A," and, accordingly, construing the patent's claims as limited to Crystal A was appropriate. Id.

Plaintiffs persuasively argue that Abbott Laboratories is distinguishable on this basis. Unlike in Abbott Laboratories, here, there is no evidence that Plaintiffs knew of other crystal forms of dolutegravir sodium and deliberately chose not to claim them, as the patent holder in Abbott Laboratories knew of the unclaimed Crystal B. Nor is there other evidence in the specification or prosecution history that Plaintiffs intended to limit the claims of the '986 Patent to Compounds 13 and 13b. And, importantly, the specification itself states that Compounds 13 and 13b are merely "examples . . . intended for illustration only and are not intended to limit the scope of the invention in any way." (See '986 Patent, col. 13 ll. 1–3.)[7] Thus, unlike in Abbott Laboratories, the evidence does not "clearly indicate that the invention encompasses no more" than the two embodiments described in the specification, Compounds 13 and 13b, and it would be inappropriate to construe the claims as such. Abbott Labs., 566 F.3d at 1288.

Defendants are correct that the claims of the '986 Patent are limited to *specific* crystal forms of dolutegravir sodium, and do not broadly encompass *any* crystal form of the compound. Indeed, the parties agree that the measurement data in the claims of the '986 Patent create two unique "signatures" that identify two specific crystal structures.[8]

[7] Defendants argue that the specification's use of the term "Compound 13" in connection with the phrase "the present invention," indicates an intent to limit Claims 1 through 6 to Compound 13. (See '986 Patent, col. 9, ll. 38–40 (providing that "[t]he present invention also features crystalline forms of a compound of formula AA (*Compound 13*, *Example 1*) salt and a hydrate thereof." (emphasis added)).) But this language tellingly includes the term "example," indicating an intent merely to identify Compound 13 as an embodiment of the invention and not the entirety of the invention, consistent with the more explicit language later in the specification. (See id. at col. 13 ll. 1–3 ("The following examples are intended for illustration only and are not intended to limit the scope of the invention in any way.").)

[8] The '986 Patent's prosecution history further supports the fact that Plaintiffs claimed *specific* crystal forms. Before it was amended, the application that eventually became the '986 Patent contained a claim that read "a crystal form of a sodium salt or a hydrate thereof of a compound of formula AA," but did not recite any measurement data for that crystal form. (See Joint Claim Construction Chart, Ex. C at 2.) The PTO rejected this claim as indefinite "because the phrase 'crystal form' is not clear." (Id., Ex. D. at 2–3.) To overcome this deficiency, the PTO recommended that the claim be amended to recite specific measurement data, resulting in the current claim language specifying that data. (Id.)

But while it is true that the ’986 Patent claims specific crystal forms by way of certain measurement data, and that Compounds 13 and 13b exhibit that exact same data, it does not follow that Plaintiffs intended Compounds 13 and 13b to constitute the *entirety* of the invention. As Plaintiffs note, a crystalline form of dolutegravir sodium may exist that exhibits the same crystal structure as Compound 13 or Compounds 13b—and thus exhibits the measurement data set out in the ’986 Patent’s claims—but yet differs in *hydration state*. Specifically, Plaintiffs point out that non-stoichiometric crystalline compounds can lose water (thus changing hydration state) without changing the crystal structure. It therefore makes sense that a patent applicant—like Plaintiffs here—seeking to claim a particular crystalline structure as the invention, would define the invention by reference to the measurement data, rather than by reference to the hydration state.

Finally, Defendants argue that I should adopt their proposed construction, because if I do not, the ’986 Patent’s claims would be invalid for lack of written description or enablement.[9] It could be that the ’986 Patent’s claims are invalid for lack of enablement, as the enablement requirement requires a patent’s specification to “teach those skilled in the art how to make and use the *full scope* of the claimed invention without undue experimentation.” Trs. of Bos Univ., 896 F.3d at 1362. And here, Defendants have pointed to expert testimony that the specification of the ’986 Patent would not teach a skilled artisan how to make any crystal form of dolutegravir sodium apart from Compounds 13 and 13b. (See Defs.’ Surreply Br. 9–10.) But the Federal Circuit has made clear that a court should only construe claims to avoid invalidity where “the court concludes,

[9] “A patent’s specification must contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains to make and use the same.” Trustees of Bos. Univ. v. Everlight Elecs. Co., 896 F.3d 1357, 1362 (Fed. Cir. 2018) (internal quotation marks and alterations omitted). Similarly, “to be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.” Id. (internal quotation marks and alterations omitted).

after applying all the [other] available tools of claim construction, that the claim is still ambiguous." Liebel–Flarsheim, 358 F.3d 898, 911 (Fed. Cir. 2004); see also Elekta Instrument S.A. v. O.U.R. Scientific Int'l, Inc., 214 F.3d 1302, 1309 (Fed. Cir. 2000) (holding that where a "claim is susceptible of only one reasonable construction, [a court] cannot construe the claim differently from its plain meaning in order to preserve its validity").

For the reasons set out above, I conclude that the claim language, the specification, and the prosecution history are not ambiguous. Rather, they indicate an intent to claim specific crystal forms by reference to the measurement data yielded by those forms.[10] And they do not "clearly indicate that the invention encompasses no more" than Compounds 13 and 13b such that Defendants' construction is appropriate. Abbott Labs., 566 F.3d at 1288. Accordingly, I decline to adopt Defendants' proposed construction and construe the claims, as Plaintiffs suggest, in light of their plain and ordinary meaning.

IV. CONCLUSION

The claims shall be construed as set forth above and in the Claim Construction Order that follows.

[10] In this way, this case differs from one that Defendants rely on for the proposition that a claim can be construed as limited to an embodiment when "necessary to tether the claims to what the specification indicates the inventor actually invented." Medicines Co. v. Mylan, Inc., 853 F.3d 1296, 1309 (Fed. Cir. 2017). In Medicines, the court was faced with construing the claim term "efficient mixing." Id. While the description in the specification provided only "open-ended and vague teachings" regarding the meaning of the disputed claim term, the sole embodiment of the invention—"Example 5"—provided "a clear objective standard by which to measure the scope of the term." Id. Here, the specification and the claim language both provide a clear standard by which to measure the scope of the claims—namely, the measurement data.