

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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TAIHO PHARMACEUTICAL CO., LTD,))
and TAIHO ONCOLOGY, INC.,))
))
Plaintiffs,))
))
v.)	C.A. No. 19-2342-JLH
))
MSN LABORATORIES PRIVATE LTD.,))
and MSN PHARMACEUTICALS INC.,))
))
Defendants.))
_____)

MEMORANDUM OPINION

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Wilmington, Delaware



JENNIFER L. HALL, U.S. DISTRICT JUDGE

This is a patent case. Plaintiffs Taiho Pharmaceutical Co., Ltd. and Taiho Oncology, Inc. (collectively, “Taiho”) filed this action on December 23, 2019, against Defendants MSN Laboratories Private Ltd. and MSN Pharmaceuticals Inc. (collectively, “MSN”). The Amended Complaint alleges that MSN’s submission of an Abbreviated New Drug Application (ANDA) for approval of a generic version of Lonsurf® infringed certain Taiho patents, including U.S. Patent Nos. RE46,284 E (“’284 patent”) and 10,457,666 (“’666 patent”) under 35 U.S.C. § 271(e)(2)(A). (D.I. 18.) After the Court resolved the parties’ disputes regarding the ’284 Patent (*see* D.I. 175), the case was reassigned to me.

In April 2024, I presided over a two-day bench trial concerning the ’666 patent. (*See* D.I. 255, 256 (trial transcripts).) This Memorandum Opinion addresses a claim construction issue with respect to the ’666 patent that is dispositive of Taiho’s claim of infringement.

I. BACKGROUND

One of the active ingredients in Lonsurf® is tipiracil. The ’666 patent is entitled “Stable Crystal Form of Tipiracil Hydrochloride and Crystallization Method for the Same.” The specification provides that “[t]he present invention relates to a stable crystal form of tipiracil hydrochloride having excellent preservation stability and being useful as an active ingredient of medicaments, and a crystallization method for the same.” (’666 patent at 1:19–22.) The patent describes three crystal forms of tipiracil hydrochloride—termed Crystal Form I, Crystal Form II, and Crystal Form III—and it sets forth a powder X-ray diffraction chart for each form. (*Id.* at Figs. 1–3.) The specification goes on to describe certain advantages of Crystal Form I for use in medicaments.

Taiho only asserts claim 3. It provides:

3. Crystal Form I of 5-chloro-6-(2-iminopyrrolidin-1-yl)methyl-2,4(1H,3H)-pyrimidinedione hydrochloride exhibiting peaks at angles of 11.6°, 17.2°, 17.8°, 23.3°, 27.1°, and 29.3° as a diffraction angle ($2\theta \pm 0.2^\circ$), and having a purity of at least 90% by mass.

On September 14, 2020, the parties stipulated to the Court that there are “no [] claim terms that require construction.” (D.I. 46.) But as the case progressed, it became clear to the parties and the Court that the parties disputed the meaning of the term “purity” in claim 3: Taiho now contends that the term refers to chemical purity, while MSN says it refers to crystal form purity. On September 17, 2021, the Court ordered that “the parties’ experts should opine on the competing definitions of the disputed claim term and the Court can resolve the claim construction issue during or after trial.” (Sept. 17, 2021 Oral Order; *see also* D.I. 133 at 23–25.)

The case was reassigned to me on November 17, 2023, and I presided over a two-day bench trial in April 2024. At the conclusion of the trial, the parties agreed that the resolution of the claim construction dispute was potentially dispositive of Taiho’s claim of infringement of the ’666 patent.¹ In the interest of efficiency, I ordered the parties to file briefs directed solely to the claim construction dispute. The Court now resolves that dispute in favor of MSN.

II. LEGAL STANDARD

The purpose of the claim construction process is to “determine[e] the meaning and scope of the patent claims asserted to be infringed.” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff’d*, 517 U.S. 370 (1996). When the parties have an actual dispute regarding the proper scope of claim terms, their dispute must be resolved by the judge. *Id.*

¹ **Court:** Is it correct that if the Court adopts Defendants’ construction of the purity limitation, that there is no infringement under [35 U.S.C. §] 271(e)(2)?
Taiho’s counsel: That is true, Your Honor.
(D.I. 256 at 162.)

at 979. The Court only needs to construe a claim term if there is a dispute over its meaning, and it only needs to be construed to the extent necessary to resolve the dispute. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

“[T]here is no magic formula or catechism for conducting claim construction.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1324 (Fed. Cir. 2005). But there are guiding principles. *Id.*

“The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation.” *Id.* at 1313. In some cases, the ordinary meaning of a claim term, as understood by a person of ordinary skill in the art, is readily apparent even to a lay person and requires “little more than the application of the widely accepted meaning of commonly understood words.” *Id.* at 1314. Where the meaning is not readily apparent, however, the court may look to “those sources available to the public that show what a person of skill in the art would have understood [the] disputed claim language to mean.” *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004). Those sources include “the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.” *Id.*

“The claims themselves provide substantial guidance as to the meaning of particular claim terms.” *Phillips*, 415 F.3d at 1314. For example, “the context in which a term is used in the asserted claim can be highly instructive.” *Id.* Considering other, unasserted, claims can also be helpful. *Id.* “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.

In addition, the “claims ‘must be read in view of the specification, of which they are a part.’” *Id.* at 1315 (quoting *Markman*, 52 F.3d at 979). The specification “is always highly relevant to the claim construction analysis.” *Id.* (quoting *Vitronics Corp. v. Conceptronic, Inc.* 90 F.3d 1576, 1582 (Fed. Cir. 1996)). The specification may contain a special definition given to a claim term by a patentee, in which case, the patentee’s lexicography governs. *Id.* at 1316. The specification may also reveal an intentional disclaimer or disavowal of claim scope. *Id.* However, “even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction.” *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (internal marks omitted).

Courts should also consider the patent’s prosecution history. *Phillips*, 415 F.3d at 1317. It may inform “the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.” *Id.* Statements made by a patentee or patent owner during inter partes review may also be considered. *Aylus Networks, Inc. v. Apple Inc.*, 856 F.3d 1353, 1362 (Fed. Cir. 2017).

In appropriate cases, courts may also consider extrinsic evidence, which “consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Markman*, 52 F.3d at 980. For example, dictionaries, especially technical dictionaries, can be helpful resources during claim construction by providing insight into commonly accepted meanings of a term to those of skill in the art. *Phillips*, 415 F.3d at 1318. Expert testimony can also be useful “to ensure that the court’s understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish

that a particular term in the patent or the prior art has a particular meaning in the pertinent field.” *Id.*; see also *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 331–32 (2015).

III. DISCUSSION

Claim 3 requires, among other things, a “Crystal Form I” of tipiracil hydrochloride “having a purity of at least 90% by mass.” The parties dispute the meaning of the term “purity.” Taiho asserts that “purity” refers to “chemical purity.” (D.I. 253, 257.) In other words, Taiho says that the 90% figure refers to the percent of the mass that is tipiracil hydrochloride, as opposed to chemical impurities. MSN asserts that “purity” refers to “polymorphic purity.” (D.I. 254, 258.) In other words, MSN says that the 90% figure refers to the percent of the mass that is in Crystal Form I, as opposed to other forms.

Taiho contends that the term “purity” is ordinarily understood by those of skill in the art to mean chemical purity. But the question here is whether a skilled artisan would ascribe that meaning in the context of claim 3 of the ’666 patent. Having carefully considered all the intrinsic and extrinsic evidence of record, I agree with MSN that the term refers to polymorphic purity.

Starting with the words of claim 3, they don’t shed much light on the proper resolution of this dispute. The other claims in the patent aren’t much help either.

The remainder of the specification strongly supports MSN’s contention that a skilled artisan would understand that “purity,” as used in the context of claim 3 of the ’666 patent, refers to polymorphic purity. The specification acknowledges that methods for producing tipiracil hydrochloride were known in the art, but it explains that prior art methods resulted in mixtures of different crystal forms. (*See, e.g.*, ’666 patent at 2:9–33 (“[I]t has turned out later that the white crystals obtained by these [prior art] methods were mixed crystals containing Crystal III described below.”).) And the specification explains that “[a]t present, there is no known method by which a

stable crystal form of highly-pure anhydrous tipiracil hydrochloride can be obtained with high reproducibility.” (*Id.* at 2:33–35.) Then, under the heading “Technical Problem,” the specification provides that “[a]n objective of the present invention is to provide a stable crystal form of tipiracil hydrochloride useful as an active ingredient of medicaments.” (*Id.* at 2:54–56.) It goes on to describe the inventors’ characterization of three different crystal forms of tipiracil hydrochloride, and the inventors’ conclusion that the properties of Crystal Form I, including its stability, make it advantageous for use as a medicament. (*Id.* at 2:60–3:8.) Under the heading, “Solution to Problem,” the specification states that the inventors had, “through trial and error, found a production method for advantageously obtaining a highly-pure Crystal I under specific conditions.” (*Id.*)

The specification goes on to describe how to make “Crystal I of high purity.” (*Id.* at 4:54–6:21.) And it expressly defines “high purity” as polymorphic purity: “[h]igh purity’ used in the present invention means that at least 90% by mass, preferably 95% by mass, and more preferably 99% by mass of the crystals of [tipiracil hydrochloride] are the crystals of the present invention.” (*Id.* at 6:5–9; 4:55–57.) The specification discloses that, in order to make “high purity” crystals of Crystal Form I, it is important to control the crystallization temperature, which prevents the formation of Crystal Form II during the crystallization step. (*See, e.g., id.* at 5:28–29 (“When the [crystallization] temperature is 40°C or lower, Crystal [Form] II, which is poor in long-term storage stability, is precipitated.”); *id.* at 11:7–11 (“The results show that Crystal [Form] II, which is poor in storage stability, was obtained when the crystallization temperature was below 35[°C]. When the crystallization temperature was maintained at 44°C or higher, Crystal [Form] I, which has high storage stability, was efficiently obtained with high purity.”).)

Notably, claim 3 requires “purity of at least 90%,” and the only mention in the specification of a “90%” figure is the specification’s reference to polymorphic purity. (*Id.* at 6:4–9.) In contrast, the specification does not refer to any chemical impurities by percentage (of mass or otherwise).

When the disclosure is considered as a whole, it strongly supports MSN’s position that a person of skill in the art would understand that claim 3 is referring to polymorphic purity. That conclusion is supported by the testimony of MSN’s expert, Dr. Sneed, who explained why the above quoted passages (and others) would lead a person of skill in the art to understand that “purity,” as used in claim 3, refers to polymorphic purity. (D.I. 256 at 71–82, 89; *see, e.g., id.* at 76 (explaining, among other things, that a person of skill in the art would understand that “the problem [the inventors] were trying to solve was to come up with a method that doesn’t give a mixture of crystals; it gives polymorphically pure Form I”).) I find Dr. Sneed’s opinion credible and consistent with the intrinsic evidence.

To be sure, there are passages in the specification that relate to the concept of chemical purity. (D.I. 255 at 133–35; D.I. 256 at 77–80, 156–58.) For example, the patent teaches that performing the crystallization step at temperatures above 63°C results in a “large” amount of “decomposition products”—*i.e.*, chemical impurities—and “that a temperature of lower than 63°C is preferred for efficiently producing Crystal [I] containing less impurities.” (’666 patent at 5:29–33.) But Dr. Sneed persuasively explained that, while that particular sentence refers to chemical purity, the paragraph as a whole instructs how to make crystals with high polymorphic purity. According to Dr. Sneed, the passage explains that you should conduct the crystallization step above 40°C to make polymorphically pure Crystal Form I—because lower temperatures will result in some Crystal Form II appearing—but that you should conduct the crystallization step below 63°C because otherwise you will decompose your tipiracil hydrochloride. (D.I. 256 at 78–80.) Dr.

Sneed also explained that the patent’s disclosure that “Crystal I and Crystal III hardly contain analogous substances” (*i.e.*, chemical impurities) after long-term storage (*see* ’666 patent at 7:7–13) would be understood by a person of skill as highlighting “the property of the crystals once you’ve made them in a pure form” and shows that “the crystals have the advantage of having long-term storage stability and they don’t decompose, they don’t produce analogous substances when you store them.” (D.I. 256 at 76–82.) In Dr. Sneed’s view, those passages would not cause a person of skill in the art to conclude that “purity” in claim 3 refers to chemical purity, particularly since the specification says that “[h]igh purity’ used in the present invention means that at least 90% by mass, preferably 95% by mass, and more preferably 99% by mass of the crystals of [tipiracil hydrochloride] of the present invention” (’666 patent at 6:5–9), which is clearly referring to polymorphic purity. (*Id.* at 74.) I agree.

MSN’s construction is also supported by the prosecution history of the ’666 patent. Although the examiner appears to have initially understood “purity” in the pending claims to refer to chemical purity (*see* JTX-0009.1153–54), the examiner and the patentee later treated “purity” synonymously with polymorphic purity. For example, the patentee argued that amended claims reciting “Crystal Form I . . . having a purity of at least [90%/99%] by mass” should be allowed because there was no prior art that “teaches/suggests the crystal form having such a high purity^[2] or any specific processes for making the claimed crystal form.” (JTX-0009.1168–70; *see also id.* (patentee arguing that “[t]he [prior art] reference discloses no process for making crystal form I or any other crystal form. . . . There is no publically [sic] available information or document that

² Recall that the specification says that “[h]igh purity’ used in the present invention means that at least 90% by mass, preferably 95% by mass, and more preferably 99% by mass of the crystals of [tipiracil hydrochloride] are the crystals of the present invention.” (’666 patent at 6:5–9.)

disclosed or enabled one of ordinary skill in the art to make the claimed crystal form. The first disclosure of the existence of *impure crystal* form III is found in the present disclosure, which is not prior art.” (emphasis added).) Then, later in the prosecution, the examiner expressed the understanding that a claim requiring “having a purity of at least 90% by mass” meant “having a crystal Form 1 purity of at least 90%.”³ (JTX-0009.1199 (referring to pending claims at JTX-0009.1178–79).)

IV. CONCLUSION

The Court has carefully reviewed the parties’ remaining arguments concerning the intrinsic and extrinsic evidence and has determined that they do not warrant extended discussion. For the reasons stated above, the Court construes “purity” as used in claim 3 of the ’666 patent as “polymorphic purity.” In view of Taiho’s acknowledgement that MSN does not infringe under this construction (D.I. 256 at 162), the Court will enter judgment of non-infringement. The parties shall meet and confer and file a proposed judgment within 7 days.

³ Taiho points out that the claims in the related ’833 patent were amended during reexamination to expressly refer to “crystal Form I purity,” *i.e.*, polymorphic purity. According to Taiho, the fact that claim 3 of the ’666 patent refers to “purity” instead of “crystal Form I purity” means that it must refer to something different. I disagree. It is clear from the prosecution history of the ’666 patent that the examiner and the patentee understood “purity” as used in the claims to refer to polymorphic purity, which is consistent with the disclosure of the specification. *Cf. Baran v. Med. Device Techs., Inc.*, 616 F.3d 1309, 1316 (Fed. Cir. 2010) (explaining that the presumption that different terms have different meanings “is overcome where, as here the evidence indicates that the patentee used the two terms interchangeably”). My conclusion about how a person of skill in the art would interpret “purity” in claim 3 of the ’666 patent is not changed by the fact that a different examiner (in an *ex parte* reexamination in which the patent claims were given their “broadest reasonable interpretation” (*see* JTX-0008.0532)), looked at a different patent and only allowed certain claims after they were amended to specify polymorphic purity.