

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

RIGEL PHARMACEUTICALS INC.,

Plaintiff,

v.

ANNORA PHARMA PRIVATE LTD.,
HETERO LABS LTD., and HETERO
USA, INC.,

Defendants.

Civil Action No. 22-4732 (SRC)

OPINION & ORDER

CHESLER, U.S.D.J.

This matter comes before the Court on the application for claim construction by Plaintiff Rigel Pharmaceuticals Inc. (“Rigel”) and Defendants Annora Pharma Private Ltd., Hetero Labs Ltd., and Hetero USA, Inc., (collectively, “Defendants”). These cases arise from patent infringement litigation involving two patents generally directed to compositions and methods related to the drug fostamatinib: United States Patent Nos. 8,263,122 (“the ’122 patent”) and 8,652,492 (“the ’492 patent”). Plaintiff Rigel owns these patents and has sued the Defendants for patent infringement. The parties seek claim construction of two terms in these patents.

ANALYSIS

I. The law of claim construction

A court’s determination “of patent infringement requires a two-step process: first, the court determines the meaning of the disputed claim terms, then the accused device is compared to the claims as construed to determine infringement.” Acumed LLC v. Stryker Corp., 483 F.3d

800, 804 (Fed. Cir. 2007). “[W]hen the district court reviews only evidence intrinsic to the patent (the patent claims and specifications, along with the patent’s prosecution history), the judge’s determination will amount solely to a determination of law.” Teva Pharms. USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831, 841 (2015).

The focus of claim construction is the claim language itself:

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. Attending this principle, a claim construction analysis must begin and remain centered on the claim language itself, for that is the language the patentee has chosen to ‘particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.’

Innova/Pure Water, Inc. v. Safari Water Filtration Sys., 381 F.3d 1111, 1115-1116 (Fed. Cir. 2004) (citations omitted).

The Federal Circuit has established this framework for the construction of claim language:

We have frequently stated that the words of a claim ‘are generally given their ordinary and customary meaning.’ We have made clear, moreover, that the ordinary and customary meaning of a claim term 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. 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. . .

In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words. In such circumstances, general purpose dictionaries may be helpful. In many cases that give rise to litigation, however, determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art. Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to those sources available to the public that show what a person of skill in the art would have understood disputed claim language to

mean. 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.

Phillips v. AWH Corp., 415 F.3d 1303, 1312-1314 (Fed. Cir. 2005) (citations omitted).

II. Claim construction of the disputed terms

A. “Starch”

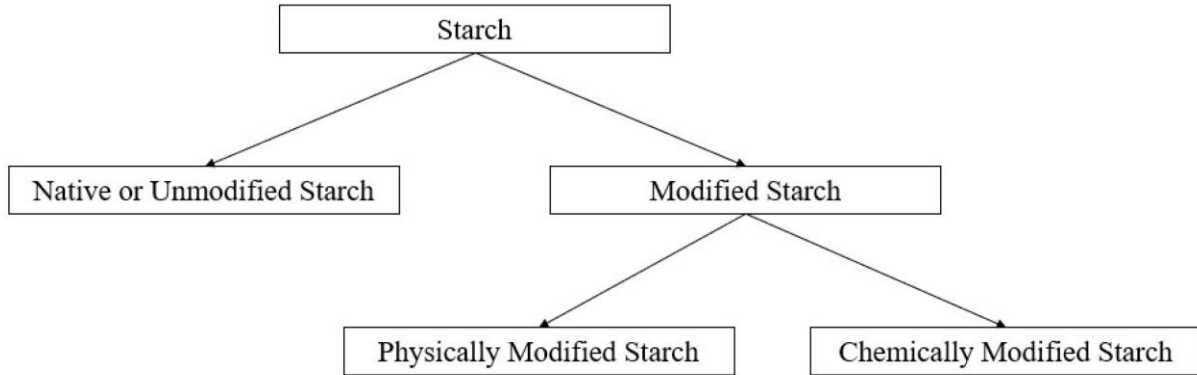
The term “starch” appears in claims three through six in both the ’122 and ’422 patents.

Claims three through six are identical in the two patents at issue:

3. The formulation of claim 1, wherein the water sequestering agent is selected from the group consisting of starch, magnesium sulfate, calcium chloride, silica gel, and kaolin.
4. The formulation of claim 3, wherein the water sequestering agent is starch.
5. The formulation of claim 4, wherein the starch is partially pregelatinized.
6. The formulation of claim 5, wherein the starch is derived from Maize.

Plaintiff proposes that “starch” means “a substance containing the polysaccharides amylose and/or amylopectin in modified or unmodified form.” Defendants propose this construction: “plain and ordinary meaning, i.e., ‘excipient having the formula $(C_6H_{10}O_5)_n$ and consisting of the polysaccharides amylose and amylopectin.’”

Although it is not obvious from a quick read of the proposed constructions, the main dispute between the parties concerns the question of whether “starch” includes or excludes chemically modified starches. Plaintiff offers a diagram (the “Starch Diagram”) expressing its understanding of the relationship between “starch” and “chemically modified starch:”



(Pl.’s Br. at 16.) Thus, Plaintiff proposes that “chemically modified starch” falls within the scope of “starch.” Defendants contend that “chemically modified starch” does not fall within the scope of “starch” but, rather, is excluded from that scope.

Defendants contend that “starch” here has its plain and ordinary meaning,¹ which their proposed construction reflects. Defendants’ opening brief begins by looking at extrinsic evidence of the ordinary meaning of “starch” (texts, dictionaries, their expert’s opinion), then gives a nod to the intrinsic evidence with the conclusory assertion that it fits Defendants’ proposed construction, and, last, challenges Plaintiff’s proposed construction. The Court begins by considering the intrinsic evidence: “while extrinsic evidence can shed useful light on the relevant art, we have explained that it is less significant than the intrinsic record in determining the legally operative meaning of claim language.” Phillips, 415 at 1317. In Phillips, the Federal

¹ Plaintiff does not clearly state a position on whether “starch” carries its plain and ordinary meaning, but does not propose any theory of meaning based on lexicography or disclaimer. Plaintiff’s reply brief only indirectly indicates agreement with “starch” having its ordinary meaning by citing Thorner v. Sony Comput. Entm’t Am. LLC, 669 F.3d 1362, 1367 (Fed. Cir. 2012) (“The patentee is free to choose a broad term and expect to obtain the full scope of its plain and ordinary meaning unless the patentee explicitly redefines the term or disavows its full scope.”) The Court infers that there is no dispute between the parties that “starch” must be construed so that it has the full scope of its plain and ordinary meaning.

Circuit explained at length why this is so. Id. at 1317-19; see also Personalized Media Communs., LLC v. Apple Inc., 952 F.3d 1336, 1340 (Fed. Cir. 2020) (“When construing claim terms, we first look to, and primarily rely on, the intrinsic evidence, including the claims themselves, the specification, and the prosecution history of the patent, which is usually dispositive”).

As to the intrinsic evidence, Defendants attempt to make an argument based on the fact that the specification discloses sodium starch glycolate as an example of a disintegrant: “In another embodiment, the formulation further comprises [various ingredients] and/or one or more disintegrants (e.g., Sodium Starch Glycolate . . .” ‘122 patent, col. 3 ll.27-34. Defendants contend that: 1) sodium starch glycolate is a chemically modified starch;² and 2) “[t]he specification treats sodium starch glycolate as a disintegrant, not as a type of starch” (Defs.’ Br. at 8.) The Court does not understand the logic of the second proposition. The cited part of the specification does offer sodium starch glycolate as an example of a disintegrant, but the Court sees no basis for the inference that a compound cannot be both a starch and a disintegrant at the same time; Defendants offer no rationale for concluding that the two categories are mutually exclusive. The Court finds nothing in the intrinsic evidence that supports the inference that chemically modified starches are excluded from the scope of “starch.” What is the evidence that a POSA would view sodium starch glycolate as not a starch?

Defendants’ opening brief argues very quickly that Plaintiff’s construction does not fit with the specification’s use of sodium starch glycolate as an example of a disintegrant. It is only in their responsive brief that Defendants develop this idea into the argument that “the intrinsic

² Plaintiff does not dispute this assertion.

evidence supports a construction that includes physical modification of starch, but not chemical modification.” (Defs.’ Resp. Br. at 2.)

Even if the Court overlooked the problem of this being pretty much a new argument in a reply brief, and even if the Court overlooked the fact that Defendants never connect this argument to specific words in their proposed construction, the argument still fails to persuade that the specification’s use of sodium starch glycolate as an example of a disintegrant is useful, relevant intrinsic evidence of the meaning of “starch.” The logic of the argument does not work, because it rests on the unacknowledged and unproven presumption that “disintegrant” and “starch” are mutually exclusive categories. Absent some proof of that hidden presumption, the argument can go nowhere.³

The parties agree that “starch” has its plain and ordinary meaning here, and that the patentees did not clearly set forth a definition. “Claim terms are generally given their plain and ordinary meaning, i.e., the meaning the terms would have to a person of ordinary skill in the art when read in the context of the specification and prosecution history.” Guardant Health, Inc. v. Vidal, 2023 U.S. App. LEXIS 11037, at *5 (Fed. Cir. May 5, 2023). Neither party has persuaded the Court that a POSA would find that the specification or prosecution history has spoken to the

³ The Court notes that Dr. Moreton, in his 2008 book chapter on disintegrants, wrote pages about the use of starches – in all their native, physically modified, and chemically modified forms – as disintegrants in tablet formulations. (Pl.’s Ex. 20 at 230-234.) Dr. Moreton, at his deposition, admitted that, in his book chapter, he included chemically-modified starches in the category of starches. (Pl.’s Ex. 19 at 108:19-22.) Dr. Moreton’s book chapter notes that the National Formulary 19 “has a monograph for Modified Starch that states that starch ‘may be modified by chemical means.’” (Pl.’s Ex. 20 at 234.) It appears that, in 2008, Dr. Moreton did not see “starch” and “disintegrants” as mutually exclusive categories. Rather, he treated starches as a class of potential disintegrants, and he treated chemically modified starches as a category of starch.

question of whether chemically modified starches are or are not starches. The Court thus turns to the extrinsic record to understand the plain meaning of “starch” to the ordinary artisan skilled in the art of pharmaceutical tablet formulation. The Court finds significant extrinsic evidence that weighs against Defendants’ understanding of the scope of “starch.” As already noted, Dr. Moreton’s 2008 book chapter included chemically modified starches in the category of starches, which he admitted at his deposition.

Defendants’ contention that the ordinary meaning of “starch” to a POSA excludes chemically modified starches is contradicted as well by a text Defendants rely on, “Handbook of Pharmaceutical Excipients.” (Defs.’ Ex. 6.) Defendants include the Handbook’s section on pregelatinized starch, which states: “Pregelatinized starch is a starch that has been chemically or mechanically processed to rupture all or part of the starch granules. . .” (Defs.’ Ex. 6 at HET_FOS_0024098.) Claim 5 requires that “the starch is partially pregelatinized.” Thus, based on Defendants’ own reference, claim 5 requires a starch that has been either chemically or mechanically processed. This weighs against Defendant’s proposition that a POSA would believe that starch excludes chemically modified starch. Two of Plaintiff’s references also say that pregelatinized starch may be chemically or mechanically processed. (“Handbook of Pharmaceutical Granulation Technology,” Pl.’s Ex. 9 at 111; “Excipient Selection Can Significantly Affect Solid-State Phase Transformation in Formulation During Wet Granulation,” Pl.’s Ex. 12 at E319.)

Plaintiff takes the position that “starch” includes both native and modified starches, and that modified starch includes both physically and chemically modified forms, as expressed in Plaintiff’s Starch Diagram. The Court finds that Plaintiff has correctly outlined the

understanding of the word “starch” that a POSA would have after reading the intrinsic evidence, and that Defendants are incorrect in their contention that “starch” excludes chemically modified starches.

This resolves a key dispute between the parties about the meaning of “starch.” The disputes that remain are: 1) should the construction invoke the formula $(C_6H_{10}O_5)_n$; and 2) does “starch” require both polysaccharides⁴ amylose and amylopectin (Defendants’ position), or amylose and/or amylopectin (Plaintiff’s position)?

Defendants propose a construction that includes the formula $(C_6H_{10}O_5)_n$, but Defendants cite no place in the patents at issue where the formula appears. Defendants first quote the entry for “starch” in the Handbook of Pharmaceutical excipients, which gives that formula, accompanied by “where $n = 300 - 1000$.” (Defs.’ Ex. 6 at HET_FOS_0024092.) Thus, Defendants did not incorporate the Handbook’s complete expression of the formula, having omitted the numerical range for “ n ,” and neither party has addressed the significance of that omission. Defendants also cite Merriam-Webster’s Collegiate Dictionary, which gives that formula without placing any limits on “ n .” (Defs.’ Ex. 11 at 1143.) Because Defendants also contend that sodium starch glycolate is a chemically modified starch which does not have the same “chemical makeup” as starch, there is reason to suspect that the proffered chemical formula is simply another means to accomplish Defendants’ goal of excluding chemically modified starches from the scope of “starch.” (Defs.’ Br. at 8.) The Court has already ruled against Defendants on that issue. The formula will not be incorporated into the construction.

The last area of dispute concerns the question of whether starch requires both of the

⁴ The parties appear to agree that amylopectin and amylose are both polysaccharides.

polysaccharides amylose and amylopectin. Plaintiff first cites the definition of starch in the 2004 edition of “A Dictionary of Chemistry:” “a polysaccharide consisting of various proportions of two glucose polymers, amylose and amylopectin.” (Pl.’s Ex. 11 at 529.) Plaintiff’s opening brief does not explain why the proposed construction says “amylose *and/or* amylopectin.” Defendants’ opening brief argues that Plaintiff’s proposed “and/or” construction is incorrect, because a POSA would understand that starch contains both polymers. Plaintiff, in response, points out that Defendants’ own reference, “Handbook of Pharmaceutical Excipients,” states:

Starches from different plant sources differ in their amylose/amylopectin ratio. For example, corn starch contains about 27% amylose, potato starch about 22%, and tapioca starch about 17%. In contrast, waxy corn starch contains almost entirely amylopectin, with no amylose.

(Defs.’ Ex. 6 at 730.) Plaintiff points out, as well, that both Plaintiff’s expert, Dr. Little, and Defendants’ expert, Dr. Moreton, stated at their depositions that a starch may contain no amylose. (Little Dep. at 16:18-17:3; Moreton Dep. at 112:19-113:1.) Given that the experts agree that a starch may contain no amylose, the construction of “starch” will reflect that fact.

The Court finds that neither party’s proposed construction is entirely correct and will modify Plaintiff’s proposed construction as explained above. “Starch” means “a substance which contains the polysaccharide amylopectin and may also contain the polysaccharide amylose; the term includes native starches which have been modified by physical or chemical means.”

B. “Water”

Claims 1, 8, and 14 of the '122 patent and claim 1 of the '492 patent disclose formulations which include water as one component. Claim 8 of the '492 patent discloses a process in which water is used. Plaintiff proposes that “water” means “H₂O that is not associated

with any other excipient or API.” Defendants propose that “water” has its ordinary meaning, “bound or unbound water.” In short, the key dispute here is about whether there can be H₂O that is not water, because it is “associated” with another excipient or API.

Plaintiff first argues that only its construction “makes sense in the context of claim 8 of the ’492 patent,” the process claim. (Pl.’s Br. at 7.) This claim states:

8. A wet granulating process, comprising:

a) . . . ;

b) granulating the blended mixture of a) while adding water to form wet granules; . . .

Plaintiff argues: “In this context, a POSA would have understood that the ‘water’ recited in the claim cannot be associated with the other formulation components.” (Pl.’s Br. at 7.) The Court agrees, but for a different reason: this result does not show that the claim term “water” lacks its ordinary scope; it is the result of the word “adding.” When water is added to something, the “added water” was not part of the mixture prior to the water being added. Claim 8 does not suggest that “water” has a more limited scope to its meaning; the interpretation suggested by Plaintiff comes from the word “adding,” rather than an atypical meaning of “water.”

Plaintiff next contends that the claim term “water sequestering agent” only makes sense when its proposed construction is used. In opposition, Defendants point out that Plaintiff’s argument has the nonsensical effect of relabeling H₂O bound to an excipient as not water. What is the H₂O bound to excipients in the blended composition of claim 8(a) if it is not water? What other name would a POSA give it? Similarly, Defendants point out that, if Plaintiff’s construction is used, when water is added to the blended composition, as required by claim 8(b), any water that becomes associated with any excipient is no longer water. Defendants also point

out that, under Plaintiff's construction, once the "water sequestering agent" binds/sequesters the unbound water, it is no longer water.⁵ This makes no sense. The Court rejects Plaintiff's proposed construction of water. Water means "H₂O."

In conclusion, the Court construes the terms at issue as follows. Water means "H₂O." "Starch" means "a substance which contains the polysaccharide amylopectin and may also contain the polysaccharide amylose; the term includes native starches which have been modified by physical or chemical means."

SO ORDERED.

s/ Stanley R. Chesler
STANLEY R. CHESLER, U.S.D.J.

Dated: February 7, 2024

⁵ The parties did not explore the meaning of the claim term, "water sequestering agent," but the Court observes that the ordinary meaning of "sequester" is "to set apart." (<https://www.merriam-webster.com/dictionary/sequester> (last accessed 2/7/2024)). If "sequestering" has its ordinary meaning here, then, the sequestering agent sets the water apart. This suggests that the water, which has been set apart, remains water.