IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INTERCEPT PHARMACEUTICALS, INC., and INTERCEPT PHARMA EUROPE LTD.,	)	
Plaintiff,	)	
	)	C.A. No. 20-1105
v.	)	CONSOLIDATED
APOTEX INC., and APOTEX CORP., LLC,	)	
Defendants.	)	

MEMORANDUM ORDER

At Wilmington this 23rd day of March 2022:

IT IS HEREBY ORDERED that the claim terms of U.S. Patent Nos. 9,238,673 ("the '673 Patent"), 10,047,117 ("the '117 Patent"), 10,174,073 ("the '073 Patent"), 10,052,337 ("the '337 Patent"), 10,751,349 ("the '349 Patent"), and 10,758,549 ("the '549 Patent") with agreed-upon constructions are construed as follows (*see* D.I. 115 § II):

1. "pharmaceutical composition" means "formulation containing obeticholic acid in a form suitable for administration to a subject" ('673 Patent, claims 1–23; '073 Patent, claims 1–2, 6–27, 36–37, 39–42, 44–61);

2. "pharmaceutical formulation" means "formulation containing obeticholic acid in a form suitable for administration to a subject" ('117 Patent, claim 1);

3. "cholestatic liver disease" means "disease or condition in which bile excretion from the liver is impaired or blocked" ('117 Patent, claims 2 and 3);

4. "chronic liver disease" means "disorder of the liver that persists over time" ('117 Patent, claims 2 and 4)

5. "primary biliary cirrhosis" is "also known as primary biliary cholangitis" ('117 Patent, claims 2 and 6);

6. "jet-milling" means "milling that jets compressed gas and raw material particles from a nozzle into a chamber to reduce particle size through collisions" ('337 Patent, claim 13);

7. "jet-milled" means "reduced in size using jet-milling" ('337 Patent, claim 14);

8. "jet-milled particles" means "particles that have been reduced in size using jet-milling" ('349 Patent, claims 1 and 19; '549 Patent, claims 12 and 23).

As announced at the hearing on March 4, 2022, IT IS HEREBY ORDERED that the disputed claim terms of claim terms of the '673 Patent, the '117 Patent, the '337 Patent, the '349 Patent, and the '549 Patent are construed as follows:

1. "obethicholic acid Form 1" / "obethicholic is Form 1" means "non-crystalline obeticholic acid" ('673 Patent, claims 1–23; '117 Patent, claim 8);

2. "substantially pure solid form of obeticholic acid" means "solid form obeticholic acid that has a potency of greater than about 95%, taking into account impurities, including solvents and water" ('117 Patent, claim 1);

3. "particles" has its plain and ordinary meaning, which is "minute portions of matter" ('337 Patent, claims 1–8; '349 Patent, claims 1, 19; '549 Patent, claims 12, 23);

4. "intra-granular portion comprising obeticholic acid" / "intra-granular portion comprises said obeticholic acid" / "intra-granular portion comprises obeticholic acid" shall have its plain and ordinary meaning ('337 patent, claim 11; '349 patent, claim 4; '549 patent, claims 12, 23).

The parties briefed the issues (*see* D.I. 115) and submitted an appendix containing intrinsic and extrinsic evidence (*see* D.I. 116–18), and the Intercept Plaintiffs provided a tutorial describing the relevant technology (D.I. 121). The Court carefully reviewed all submissions in connection with the parties' contentions regarding the disputed claim terms, heard oral argument (*see* D.I. 141) and applied the following legal standards in reaching its decision.

I. LEGAL STANDARDS

A. Claim Construction

"[T]he ultimate question of the proper construction of the patent [is] a question of law," although subsidiary fact-finding is sometimes necessary. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837-38 (2015). "[T]he words of a claim are generally given their ordinary and customary meaning [which 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 v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc) (internal citations and quotation marks omitted). Although "the claims themselves provide substantial guidance as to the meaning of particular claim terms," the context of the surrounding words of the claim also must be considered. *Id.* at 1314. "[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted).

The patent specification "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. "Even 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) (internal quotation marks omitted) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)).

In addition to the specification, a 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) (en banc), *aff'd*, 517 U.S. 370 (1996). The prosecution history, which is "intrinsic evidence, . . . consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. "[T]he 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, making the claim scope narrower than it would otherwise be." *Id.*

In some cases, courts "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*, 135 S. Ct. at 841. 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. Expert testimony can 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." *Phillips*, 415 F.3d at 1318. Nonetheless, courts must not lose sight of the fact that "expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Id.* Overall, although extrinsic evidence "may be useful to the court," it is "less reliable" than intrinsic evidence, and its consideration "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1318-19. Where the intrinsic record unambiguously describes the scope

of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

II. THE COURT'S RULING

The Court's rulings regarding the disputed claim terms of the '673, '117, '337, '349, and '549 Patents were announced from the bench at the conclusion of the hearing as follows:

> . . . At issue we have six patents in two patent families and four terms that are the subject of dispute between Plaintiffs and the Apotex defendants.[1]
>
> I am prepared to rule on each of the disputes. I will not be issuing a written opinion, but I will issue an order stating my rulings. I want to emphasize before I announce my decisions that although I am not issuing a written opinion, we have followed a full and thorough process before making the decisions I am about to state. I have reviewed the patents in dispute. I have also reviewed the portions of the prosecution history, the expert declaration and the other references submitted. There was full briefing on each of the disputed terms and Intercept submitted a technology tutorial. We have also had argument here today. All of that has been carefully considered.
>
> As to my rulings, I am not going to read into the record my understanding of claim construction law. I have a legal standard section that I have included in earlier opinions, including somewhat recently in *Roche Diabetes Care, Inc. v. Insulet Corp.*, C.A. No. 20-825. I incorporate that law and adopt it into my ruling today and will also set it out in the order that I issue.
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> Neither party has suggested any differences in the definitions of a person of ordinary skill in the art that are relevant to the issues currently before me.
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> Now the disputed terms.
>
> The first term is "obeticholic acid Form 1"/ "obeticholic acid is Form 1" in claims 1-23 of the '673 Patent and claim 8 of the '117 Patent. Plaintiff proposes the construction "non-crystalline obeticholic acid." The Apotex Defendants propose "non-crystalline obeticholic acid made using a process in which crystalline

[1] There are no terms in dispute for RE 48,286, in another patent family.

> obeticholic acid is produced as a synthetic intermediate in the penultimate step of the synthesis." And the other Defendants assert[ed] that no construction is necessary but today at the hearing they represented that if pressed to tell me what the meaning is they agreed with Apotex.
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> The crux of the dispute is whether to read the process aspects Apotex advocates into the term. And as to that issue, I agree with Plaintiffs that the answer should be no. And I will adopt Plaintiffs' proposed construction and construe the term as "non-crystalline obeticholic acid."
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> I think that this construction is supported by Federal Circuit case law. In *Phillips v. AWH Corp.*, the Federal Circuit made clear that when "the specification [] reveal[s] a definition given to a claim term . . . the inventor's lexicography governs."[2] Here, the specification defines the term, stating: "As used herein, the term "obeticholic acid Form 1 "refers to income obeticholic acid."[3]
>
> Defendant Apotex argues that "Intercept's alleged description of 'obeticholic acid form 1' does not follow any standardized format and thus 'does not purport to be definitional.'"[4] I disagree. The patentee's definitional syntax referred to the term "as used herein" alongside the defined term. The term is in a section of the specification entitled "Definitions." In the patents, the phrase "as used herein" is put alongside a defined term 15 times. Moreover, the phrase "as used herein" has been recognized as definitional in a wide host of Federal Circuit and district court cases.[5]

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2 415 F.3d 1303, 1316 (Fed. Cir. 2005).

3 ('673 Patent, 40:49–50; '117 Patent, 41:6–7).

4 (D.I. 115 at 17).

5 Apotex argues that, even if the Court were to find the phrase in question to be definitional, the "so-called 'express definition' cannot be read at the exclusion of the remainder of the patent and prosecution history." (D.I. 115 at 28). None of the case law Apotex cites, however, requires the Court to define the term differently. In *Chiesi*, footnote 10 rejects the notion that the phrase in question was explicitly defined, and therefore the lexicographer rule was not implicated in that case. *Chiesi USA Inc. v. MSN Pharms. Inc.*, No. CV 19-18564, 2021 WL 4843806, at *8 n.10 (D.N.J. Oct. 18, 2021). Apotex's other case, *Trading Techs.*, is not helpful because the "express definition" in that case included the parenthetical "(discussed in detail later)," and the Federal Circuit affirmed the district court construing the definition in light of the referenced discussion. *Trading Techs. Int'l,*

> Second, product claims are typically not limited by a method of manufacture, and process limitations will only be "treated as part of a product claim if the patentee has made clear that the process steps are an essential part of the claimed invention."[6] And contrary to Apotex's arguments, the patents here do not clearly treat the process as an essential part of the claimed invention. As I already discussed, the patentee defined the term in question and did not define it in terms of the process by which is it made. And further, the specification contains some discussion of the compound as a compound, and not the product of a process, including a statement that the "present invention relates to a obeticholic acid, or a pharmaceutically acceptable salt, solvate or amino acid conjugate thereof, having a potency of greater than about 98% . . . ."[7] That portion of the patent does not refer to Form 1, but at least one other portion does. At column 31, line 49 of the '673 Patent, it says "[t]he present application provides compositions comprising obeticholic acid Form 1 and processes for the synthesis of highly pure acid Form 1 . . ."
>
> Additionally, the prosecution history shows that although the patentee originally included product and process claims, a restriction requirement was imposed because the Examiner regarded the product and the process as being distinct inventions. And the applicants elected to proceed with the product claims, not the process claims.[8] In light of all of this, I do not conclude that the process is "an essential part of the claimed invention." And I will, as I have already said, construe obeticholic acid Form 1 and obeticholic acid is Form 1 as "non-crystalline obeticholic acid."
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> The second term is "substantially pure solid form of obeticholic acid" in claim 1 of the '117 Patent. Plaintiffs propose the construction "obeticholic acid that has a potency of greater than about 95%, taking into account impurities, including solvents and water." The Apotex Defendants propose the construction "non-crystalline obeticholic acid made using a process in which crystalline obeticholic acid is produced as a synthetic intermediate in the penultimate step of synthesis." And the remaining Defendants

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Inc. v. eSpeed, Inc., 595 F.3d 1340, 1353 (Fed. Cir. 2010). Unlike *Trading Techs.*, the definition here is exclusive and conclusive.

6 *Anderson Corp. v. Fiber Composites, LLC,* 474 F.3d 1361, 1375 (Fed. Cir. 2007).

7 ('673 Patent, 3:29–31).

8 (D.I. 117, Exhibits F and E).

again said no construction is necessary but today said that if pressed, they agree with Apotex.

The dispute for this term is essentially the same as just discussed for the first term. So I will just go ahead and say that I find that the specification's defining "substantially pure obeticholic acid" to be controlling for the reasons I stated in construing the preceding term. The specification, at column 40, lines 40-42, states: "As used herein, the term 'substantially pure obeticholic acid' refers to obeticholic acid that has a potency of greater than about 95%. The potency of the obeticholic acid takes into account impurities including e.g., water, solvents, and other organic and inorganic impurities that are in a sample of obeticholic acid." I think what I expressed in my discussion of the previous term about lexicography and the process not being essential to the claimed invention is equally true here. I understand that the term in the specification is "substantially pure obeticholic acid" and not "substantially pure solid form of obeticholic acid," but I agree with Plaintiffs that the slight difference does not detract from the lexicography. The dispute here is not about what solid means. Both sides said that that term is not disputed and I don't need to address it. Instead, the dispute – and what the parties are construing – is the part of the term "substantially pure obeticholic acid." So I do think that lexicography applies and because of that and the additional reasons I stated for term 1, I will not import a process limitation into this claim. And I will construe "substantially pure solid form of obeticholic acid" as "solid form obeticholic acid that has a potency of greater than about 95%, taking into account impurities, including solvents and water."

The third term is "particles" in claims 1-8, 13 and 15 of the '337 Patent, claims 1 and 19 of the '349 Patent, and claims 12 and 23 of the '549 Patent. Plaintiffs say that no construction is necessary whereas the Apotex Defendants propose the construction "obeticholic acid that has been subjected to jet milling." The remaining Defendants agreed today with Apotex.

As I've already noted, process limitations will only be "treated as part of a product claim if the patentee has made clear that the process steps are an essential part of the claimed invention."[9] And again, I do not think the necessary clarity exists here.

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9 *Anderson Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1375 (Fed. Cir. 2007).

First, the patentee never referred to the jet-milling process as required. The specification discusses jet-milling extensively, but never as an essential process for the claimed product. Instead, the specification discusses jet-milling in the context of embodiments[10] and in discussing the importance of particle size. With respect to particle size and distribution, the specification is clear that micronizing is what is important, and the patent states explicitly that "[i]n one embodiment, the micronizing is carried out using a jet-mill." So I don't find anything in the specification saying jet-milling is required.[11]

As Defendants point out, in their remarks to the patent examiner the applicants described jet-milling as "a preferred process for making the claimed product particles."[12] In those remarks, the applicants disparaged three other processes, saying that "the claimed product cannot be made by another process such as ball milling, high pressure homogenization, or a cryogenic spray process because these processes may not provide the desired product size and particle size distribution."[13] Nothing in these statements that refer to a preferred process and say others may not work, however, indicate that jet-milling is required. Moreover, read in context, the applicants were responding to the Examiner's suggestion that "[i]n the instant case the product can be made by another and materially [sic] process such as ball milling, high pressure homogenization or a cryogenic spray process."[14] So, I don't see that as a clear statement that applicants were disparaging every other micronizing process. They were, rather, responding to the Examiner's suggestion that the three specific micronizing processes cited could create the claimed product.

Additionally, claim differentiation weighs against importing this limitation. The Federal Circuit counsels that "claim differentiation takes on relevance in the context of a claim

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10 (*See, e.g.*, '337 Patent, 16:15–16, 26:16–17).

11 The specification makes clear that micronizing is required, and that "[i]n one embodiment, the micronizing is carried out using a jet-mill." (*See, e.g.*, '337 Patent, 26:4–5).

12 (D.I. 118, Exhibit R at Appx 1349).

13 (*Id.*)

14 (*Id.*, Exhibit Q at Appx 1335).

construction that would render additional, or different, language in another independent claim superfluous."[15]

Here, claim 14 of the '337 Patent which depends from claim 11 explicitly refers to jet-milling but independent claim 11 of the same patent does not. In fact the only thing that claim 14 adds is that the obeticholic acid is jet-milled. Reading in a process limitation to "particles" would render claim 14's additional language superfluous. Of course, claim differentiation creates a rebuttable presumption, not a total obstacle, but for the reasons stated above, I do not think Defendant Apotex has overcome that presumption. Therefore, I will construe "particles" to have its plain meaning, which is minute portions of matter.

Finally, the fourth term, which is three similar phrases: "intra-granular portion comprising obeticholic acid" / "intra-granular portion comprises said obeticholic acid" / "intra-granular portion comprises obeticholic acid" in claim 11 of the '337 Patent, claim 4 of the '349 Patent, and claims 12 and 23 of the '549 Patent. Plaintiffs propose that no construction is necessary. And the Apotex and other Defendants propose the construction "intra-granular portion comprising obeticholic acid that has been subjected to jet-milling."

The parties' arguments for this term are nearly identical to that of the last term. Actually, it seems to me that there is less support for importing the jet-milling limitation here than the last term. So I will refrain from importing them and give the term its plain and ordinary meaning. And in doing that I am understanding that the parties agree what intra-granular means and is not in dispute. Indeed, the Apotex Defendants used that term in its construction and the only issue they raised is whether the obeticholic acid had to be jet-milled.

Maryellen Noreika

The Honorable Maryellen Noreika
United States District Judge

15 *Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, 484 F.3d 1374, 1381 (Fed. Cir. 2006).