IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIAL - PORTELA & CA S.A., BIAL - HOLDING, S.A., and SUNOVION PHARMACEUTICALS INC.,	:	
Plaintiffs,	:	
v.	:	Civil Action No. 18-279-CFC
TORRENT PHARMACEUTICALS LTD. and TORRENT PHARMA INC.,	:	
Defendants.	:	
BIAL - PORTELA & CA S.A., BIAL - HOLDING, S.A., and SUNOVION PHARMACEUTICALS INC.,	:	
Plaintiffs,	:	
v.	:	Civil Action No. 18-304-CFC
ALKEM LABORATORIES LIMITED and S&B PHARMA, INC.,	:	
Defendants.	:	
BIAL - PORTELA & CA S.A., BIAL - HOLDING, S.A., and SUNOVION PHARMACEUTICALS INC.,	:	
Plaintiffs,	:	
v.	:	Civil Action No. 18-312-CFC
LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC.,	:	
Defendants.	:	

BIAL - PORTELA & CA S.A., BIAL - HOLDING, S.A., and SUNOVION PHARMACEUTICALS INC., Plaintiffs, v. JUBILANT LIFE SCIENCES LIMITED, JUBILANT PHARMA LIMITED, JUBILANT GENERICS LIMITED, JUBILANT LIFE SCIENCES (USA) INC., and JUBILANT CADISTA PHARMACEUTICALS INC., Defendants.	:	Civil Action No. 18-336-CFC
BIAL - PORTELA & CA S.A., BIAL - HOLDING, S.A., and SUNOVION PHARMACEUTICALS INC., Plaintiffs, v. DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC., Defendants.	:	Civil Action No. 18-341-CFC

BIAL - PORTELA & CA S.A., BIAL - HOLDING, S.A., and SUNOVION PHARMACEUTICALS INC., Plaintiffs, v. HETERO LABS LIMITED, HETERO LABS LIMITED UNIT-V, and HETERO USA INC., Defendants.	:	Civil Action No. 18-342-CFC
BIAL - PORTELA & CA S.A., BIAL - HOLDING, S.A., and SUNOVION PHARMACEUTICALS INC., Plaintiffs, v. APOTEX INC. and APOTEX CORP., Defendants.	:	Civil Action No. 18-382-CFC
BIAL - PORTELA & CA S.A., BIAL - HOLDING, S.A., and SUNOVION PHARMACEUTICALS INC., Plaintiffs, v. SPH SHANGHAI ZHONGXI PHARMACEUTICAL CO., LTD., Defendant.	:	Civil Action No. 18-775-CFC

MEMORANDUM ORDER

Before me is the matter of claim construction of terms found in six patents asserted in this case: U.S. Patent Nos. 5,753,646 ("the #646 patent"), 8,372,431 ("the #431 patent"), 9,206,135 ("the #135 patent"), 9,566,244 ("the #244 patent"), 9,643,929 ("the #929 patent"), and 9,750,747 ("the #747 patent). Oral argument regarding claim construction was held on October 11, 2019.

At the heart of this Hatch-Waxman case is Aptiom®, an anti-epileptic drug approved by the Food and Drug Administration (FDA) for the treatment of partial-onset seizures. Plaintiffs Bial-Portela & CA S.A. and Bial-Holding, S.A. developed Aptiom® and own the asserted patents. Plaintiff Sunovion Pharmaceuticals is the holder of the Aptiom® New Drug Application and the exclusive licensee of the asserted patents, all of which Sunovion listed in the FDA's Orange Book. The asserted patents cover the active pharmaceutical ingredient in Aptiom®, eslicarbazepine acetate; pharmaceutical compositions and formulations containing eslicarbazepine acetate; and methods of treatment in certain patient subpopulations using eslicarbazepine acetate.

Defendants are eight manufacturers that filed Abbreviated New Drug Applications (ANDAs) seeking FDA approval to market generic eslicarbazepine acetate tablets prior to the expiration of the asserted patents. Plaintiffs allege that Defendants' filing of their respective ANDAs constitute infringement under 35

U.S.C. § 271(e).

TERM A: "stereoisomer" in claim 1 of the #646 patent

1. Plaintiffs' proposed construction: "the compound having the same molecular formula, but being arranged differently in space"
2. Defendants' proposed construction: "either S(–) or R(+) enantiomer of the recited compounds in the genus"
3. **Court's Construction: "the compound having the same molecular formula, but being arranged differently in space"**

Claim 1 of the #646 patent recites: "A compound of general formula I, *or stereoisomer thereof*, wherein: . . . R is hydrogen, alkyl, aminoalkyl, halogenalkyl, aralkyl, cycloalkyl, cycloalkylalkyl, alkoxy, aryl or pyridyl . . . ." #646 patent at claim 1 (8:50–66). I construe "stereoisomer" in claim 1 of the #646 patent as "a compound having the same molecular formula, but being arranged differently in space" because that is the term's plain and ordinary meaning to a person of ordinary skill in the art (POSITA) at the time of the invention and the intrinsic record does not otherwise define or limit the term.

A court should construe claim terms according to the plain and ordinary meaning that the term would have to a POSITA when read in the context of the specification and prosecution history. *Thorner v. Sony Comput. Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012). "There are only two exceptions to this general rule: 1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of the claim term either in the specification or during prosecution." *Id.* In either event, the

lexicography or disavowal must be clear and unmistakable. *See id.* at 1367–68. Here, the claims, written description, and prosecution history do not specifically define or limit the meaning of the term stereoisomer. Thus, the term must be construed according to its plain and ordinary meaning.

The plain and ordinary meaning of the term stereoisomer to a POSITA at the time of the invention was "a compound having the same molecular formula, but being arranged differently in space." According to *Organic Chemistry*, isomers are "different compounds that have the same molecular formula" and stereoisomers are "[t]he particular kind of isomers that are different from each other *only* in the way the atoms are oriented in space (but are like one another with respect to which atoms are joined to which other atoms)." Robert Thornton Morrison & Robert Neilson Boyd, *Organic Chemistry*, 125 (6th ed. 1992). (The parties agree that it is appropriate for me to rely on this definition set forth in *Organic Chemistry*. *See* D.I. 58[1] at 6; Markman Hr'g Tr. 24:2–9.)

Instead of using the plain and ordinary meaning, Defendants seek to limit the term stereoisomer to only the S(–) or R(+) enantiomers of the recited compounds. D.I. 58 at 5. Nothing in the specification or prosecution history, however, limits or specially defines the term to include only the S(–) and R(+) enantiomers of the compound. Instead, the written description supports a broader reading of the term.

[1] All citations are to the docket for C.A. No. 18-0279 unless stated otherwise.

It states: "The invention . . . relates to new compounds of general formula I, including *all possible* stereoisomers . . . ." #646 patent at 1:36–39 (emphasis added). Moreover, Defendants' proposed construction would exclude embodiments of claim 1: specifically, compounds 16 and 31 of claim 2. D.I. 58 at 8 (citing #646 patent at 9:41–42, 10:12–13). An interpretation that excludes a preferred embodiment "is rarely, if ever, correct and would require highly persuasive evidentiary support" that does not exist here. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996).

Defendants' argument relies, in part, on the figure in claim 1 that follows the word "thereof." *See* #646 patent at claim 1 (8:53–63). Defendants claim that the wavy line in the figure identifies the location of the chiral center of the stereoisomers. D.I. 58 at 10. In Defendants' view, the patentees "limited themselves to [the] set of stereoisomers located at the chiral center, not all possible stereoisomers." *Id.* Nothing in the text of the written description or claims, however, states that the wavy line is the only potential location of the chiral center.

Finally, Defendants assert that the prosecution history supports its construction. Claim 1 of the #646 patent originally recited "[c]ompounds of general formula I, including all possible stereoisomers." D.I. 58 at 10 (citing D.I. 59 at Appx131). That claim language was rejected by the patent examiner, and the patentees amended the claim to recite "[a] compound of general formula I, or

stereoisomer thereof." *Id.* (citing D.I. 59 at Appx138).

The prosecution history can inform the claim construction analysis. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005). "Yet because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Id.* at 1317. Thus, "it is inappropriate to limit a broad definition of a claim based on prosecution history that is itself ambiguous." *Inverness Med. Switz. GmbH v. Warner Lambert Co.*, 309 F.3d 1373, 1382 (Fed. Cir. 2002).

Here, the prosecution history is too ambiguous to justify reliance on it in construing the disputed term. It is not clear if the change to "a compound, or stereoisomer thereof" was made for grammatical reasons (as Plaintiffs contend), to limit the types of stereoisomers claimed for validity purposes (as Defendants contend), or for some other reason. Without a clear explanation of the amendment, the change does not limit the plain meaning of the term.

Furthermore, the new language of the amended (and final) claim—"a compound . . . or stereoisomer thereof"—does not limit the term stereoisomers to two kinds of enantiomers. The language "a compound, or stereoisomer thereof" would cover multiple types of stereoisomers based on the plain meaning of those words.

Because the written description and prosecution history do not unmistakably limit the scope of the term "stereoisomers," I construe the term according to its plain and ordinary meaning to a POSITA at the time of the invention. That plain and ordinary meaning is "the compound having the same molecular formula, but being arranged differently in space."

TERM B **"10-acetoxy-10, 11-dihydro-5H-dibenz/b,f/azepine-5-carboxamide" in claim 2 of the #646 patent**

1. Plaintiffs' proposed construction: "licarbazepine acetate, including R-licarbazepine acetate, S-licarbazepine acetate, or a mixture of R-licarbazepine acetate and S-licarbazepine acetate in any proportion"
2. Defendants' proposed construction: "licarbazepine acetate, i.e. a racemic mixture consisting of the S(–)-10-acetoxy-10, 11-dihydro-5H-dibenz/b,f/azepine-5-carboxamide and R(+)-10-acetoxy-10, 11-dihydro-5H-dibenz/b,f/azepine-5-carboxamide individual enantiomers"
3. **Court's Construction: "licarbazepine acetate, including R-licarbazepine acetate, S-licarbazepine acetate, or a mixture of R-licarbazepine acetate and S-licarbazepine acetate in any proportion"**

The parties agree that 10-acetoxy-10, 11-dihydro-5H-dibenz/b,f/azepine-5-carboxamide is the compound licarbazepine acetate. They dispute, however, whether the claimed compounds include the R-enantiomer, the S-enantiomer, and mixtures thereof in any proportion (as Plaintiffs contend) or only racemic mixtures of the R- and S-enantiomers (as Defendants contend).

I construe "10-acetoxy-10, 11-dihydro-5H-dibenz/b,f/azepine-5-carboxamide" as "licarbazepine acetate, including R-licarbazepine acetate, S-

licarbazepine acetate, or a mixture of R-licarbazepine acetate and S-licarbazepine acetate in any proportion." Nothing in the intrinsic record limits 10-acetoxy-10, 11-dihydro-5H-dibenz/b,f/azepine-5-carboxamide to a specific form. Thus, I construe the term to include all stereoisomeric forms in accordance with its plain and ordinary meaning in the context of the written description and prosecution history.

The language of claim 2 and the written description of the #646 patent show that the claimed licarbazepine acetate in claim 2 includes all of its stereoisomers, not just its racemic stereoisomer. Claim 2 recites: "A compound as defined in claim 1 which is: (1) 10-acetoxy-10, 11-dihydro-5H-dibenz/b,f/azepine-5-carboxamide . . . ." #646 patent at claim 2 (9:7–9). And claim 1 recites: "A compound of general formula I, or stereoisomer thereof . . . ." *Id.* at claim 1 (8:50–51). Thus, claim 1 recites a compound and all of its stereoisomeric forms and claim 2 lists preferred compounds of the compound defined in claim 1. Furthermore, the written description of the #646 patent states: "The invention . . . relates to new compounds of general formula I, including *all* possible stereoisomers . . . ." *Id.* at 1:36–39 (emphasis added). Finally, Example 4 describes a method of preparing (+)-10-acetoxy-10, 11-dihydro-5H-dibenz/b,f/azepine-5-carboxamide, and (+)-10-acetoxy-10, 11-dihydro-5H-dibenz/b,f/azepine-5-carboxamide is not a racemic mixture. *Id.* at 6:52–54; D.I. 58

at 20, 22. Claim terms are normally not interpreted "in a way that excludes disclosed examples in the specification." *Verizon Servs. Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1305 (2007).

Defendants assert that the prosecution history shows that the patentee disclaimed the S- and R-enantiomers because, in a declaration submitted to the United Stated Patent and Trademark Office, the patentee identified the S- and R-enantiomers with the nomenclature "S(–)" and "R(+)" and that nomenclature does not appear in the disputed term in claim 2. D.I. 58 at 22–23. I disagree. The prosecution history cannot be used to limit the scope of a claim unless it shows that the patentee "clearly disavowed" the claim scope during prosecution. *IMS Tech., Inc. v. Haas Automation, Inc.*, 206 F.3d 1422, 1439 (Fed. Cir. 2000). Denoting the S- and R-enantiomers during prosecution and not in the claim language is not a clear disavowal of claim scope that limits the compound to the S- and R-enantiomers. The patentee's failure to use the S(–) and R(+) nomenclature could also be interpreted as showing that the patentee intended the claimed compound to include *more* than just the S- and R-enantiomers instead of excluding those stereoisomeric forms. Furthermore, Defendants' own reasoning would exclude Defendants' construction. Defendants insist that I construe the disputed compound term as racemic only, but in the same declaration Defendants cite, the patentee also identified racemic licarbazepine acetate with the term "racemic" in front of the

compound name, *see* D.I. 59 at Appx 147, and the term racemic does not appear in the disputed term in claim 2, *see* #646 patent at claim 2. Thus, using Defendants' logic, because the term racemic does not appear before the compound term in dispute, the compound cannot include the racemic form.

The Federal Circuit has required "convincing intrinsic evidence [to confine] otherwise-unrestricted claims to racemic mixtures." *Sumitomo Dainippon Pharma Co. v. Emcure Pharms. Ltd.*, 887 F.3d 1153, 1158 (Fed. Cir. 2018). Yet here, nothing in the intrinsic record supports limiting the claim to racemic mixtures. The term "racemic" does not appear in the #646 patent. *See* #646 patent. And the prosecution history does not show that the compound is limited to racemic mixtures. Because the patent does not limit the licarbazepine acetate compound to particular stereoisomeric forms, I construe the disputed term to include the S-and R-enantiomers and mixtures of those two enantiomers in any proportion.

TERM C **"licarbazepine acetate" in claims 8, 12, and 13 of the #431 patent and claims 1 and 2 of the #244 patent**

1. Plaintiffs' proposed construction: "R-licarbazepine acetate, S-licarbazepine acetate, or a mixture of R-licarbazepine acetate and S-licarbazepine acetate in any proportion"
2. Defendants' proposed construction: "the individual R- and S-isomers, the racemic mixture of the isomers, and also non-racemic mixtures of the R- and S-isomers in any proportion, where 'R-licarbazepine acetate' means the R-isomer in substantially pure form, i.e., at least about 90% pure, preferably at least about 95% pure, more preferably at least about 98% pure, and most preferably at least about 99% pure; and 'eslicarbazepine acetate' or 'S-licarbazepine acetate' means S-isomer in substantially pure form,

i.e., at least about 90% pure, preferably at least about 95% pure, more preferably at least about 98% pure, and most preferably at least about 99% pure"

3. **Court's Construction: "the individual R- and S-isomers, the racemic mixture of the isomers, and also non-racemic mixtures of the R- and S-isomers in any proportion"**

I construe the term "licarbazepine acetate" as "the individual R- and S-isomers, the racemic mixture of the isomers, and also non-racemic mixtures of the R- and S-isomers in any proportion" because the common written description of the #431 patent and the #244 patent expressly defines the term licarbazepine acetate using that definition.

A patent applicant "may choose to be his own lexicographer . . . as long as the special definition of the term is clearly stated in the patent specification or file history." *Vitronics*, 90 F.3d at 1582. Here, the patentee clearly defined licarbazepine acetate in the written description of the relevant patents. The common written description of the #431 and #244 patents states: "In this specification the expression 'licarbazepine acetate' encompasses the individual R- and S-isomers, the racemic mixture of the isomers, and also non-racemic mixtures of the R- and S-isomers in any proportion." #431 patent at 4:49–52; #244 patent at 4:57–61.

Defendants ask me to add to the term's construction additional text from the paragraph in the written description containing the definition just quoted. That paragraph reads as follows:

> Licarbazepine acetate is optically active, existing in two enantiomeric forms. In this specification the expression 'licarbazepine acetate' encompasses the individual R-and S-isomers, the racemic mixture of the isomers, and also non-racemic mixtures of the R- and S- isomers in any proportion. In this specification "R-licarbazepine acetate" means the R-isomer in substantially pure form, i.e. at least about 90% pure, preferably at least about 95% pure, more preferably at least about 98% pure, and most preferably at least about 99% pure. In this specification "eslicarbazepine acetate" or "S-licarbazepine acetate" means S-isomer in substantially pure form, i.e., at least about 90% pure, preferably at least about 95% pure, more preferably at least about 98% pure, and most preferably at least about 99% pure."

#431 patent at 4:48–61; #244 patent at 4:56–5:3. Defendants ask me to construe "licarbazepine acetate" as including the last two sentences of this paragraph.

While the claims should be construed in the context of the entire patent and prosecution history, the last two sentences in the paragraph do not narrow the definition of licarbazepine acetate but instead provide definitions for two different terms—"R-licarbazepine acetate" and "eslicarbazepine acetate." The structure of the paragraph shows that each of these sentences sets forth an individual definition, not a further limitation on the original term licarbazepine acetate. The additional sentences define two embodiments of licarbazepine acetate—R-licarbazepine acetate and S-licarbazepine acetate—with purity limitations. The parties only dispute the construction of licarbazepine acetate, not R-licarbazepine acetate and

eslicarbazepine acetate. Thus, the definitions of those embodiments are not relevant here.

In short, I construe licarbazepine acetate as "the individual R- and S-isomers, the racemic mixture of the isomers, and also non-racemic mixtures of the R- and S-isomers in any proportion" because that is how the written description of the patents defines the term.

TERM D **"(S)-(–)-10-acetoxy-10, 11-dihydro-5H-dibenz/b,f/azepine-5-carboxamide having a chemical purity of at least about 99.96%" and "having a chemical purity of (S)-(–)-10-acetoxy-10, 11-dihydro-5H-dibenz/b,f/azepine-5-carboxamide of about 99.96%" in claims 1 and 2 of the #929 patent and claims 2 and 9 of the #135 patent**

1. Plaintiffs' proposed construction: "eslicarbazepine acetate having a chemical purity of at least about 99.96%" and "having a chemical purity of the eslicarbazepine acetate of about 99.96%"
2. Defendants' proposed construction: "eslicarbazepine acetate obtained by a process of reduction of oxcarbazepine using a ruthenium catalyst and having a chemical purity of at least about 99.96%" and "eslicarbazepine acetate obtained by a process of reduction of oxcarbazepine using a ruthenium catalyst and having a chemical purity of about 99.96%"
3. **Court's Construction: "eslicarbazepine acetate obtained by a process of reduction of oxcarbazepine using a catalyst and having a chemical purity of at least about 99.96%" and "eslicarbazepine acetate obtained by a process of reduction of oxcarbazepine using a catalyst and having a chemical purity of about 99.96%"**

The parties agree that (S)-(–)-10-acetoxy-10,11-dihydro-5H-dibenx/b,f/azepine-5-carboxamide is eslicarbazepine acetate. Defendants argue,

however, that the disputed term contains a process limitation—i.e., that the eslicarbazepine acetate must be "obtained by a process of reduction of oxcarbazepine using a ruthenium catalyst." Plaintiffs argue that the disputed claims recite compounds and compositions only.[2]

I construe "(S)-(–)-10-acetoxy-10, 11-dihydro-5H-dibenz/b,f/azepine-5-carboxamide having a chemical purity of at least about 99.96%" as "eslicarbazepine acetate obtained by a process of reduction of oxcarbazepine using a catalyst and having a chemical purity of at least about 99.96%" because the written description makes clear that the claims include process limitations.

Generally, words of a claim are given their "ordinary and customary meaning as understood by a [POSITA] when read in the context of the specification and prosecution history." *Thorner*, 669 F.3d at 1365. "There are only two exceptions to this general rule: 1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of the claim term either in the specification or during prosecution." *Id.*

Here, although the claims cover compounds on their face, the patentee has disavowed the full scope of the claim because the written description

[2] Although claims 2 and 9 of the #135 patent claim compounds and claims 1 and 2 of the #929 patent claim compositions, the parties have agreed that there is no difference between the terms compound and composition in the pharmaceutical context. Tr. 57:16–19. Thus, I will use those terms interchangeably.

unambiguously shows that the claimed invention is a process, not a compound. Although product claims are generally not limited to their methods of manufacture, "process steps can 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" and thus has disavowed the full scope of the product claim. *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1375 (Fed. Cir. 2007). Here, throughout the written description of the asserted patents, the invention is exclusively described as a method or process for the preparation of eslicarbazepine acetate. "When a patent . . . describes the features of the 'present invention' as a whole, this description limits the scope of the invention." *Verizon Servs. Corp.*, 503 F.3d at 1308. The patents' shared Field of the Invention states that "[t]he present invention relates to a process for the asymmetric catalytic reduction of oxcarbazepine." #135 patent at 1:18–22; #929 patent at 1:20–24. The title of both patents is "Asymmetric Catalytic Reduction of Oxcarbazepine." #135 patent at Title; #929 patent at Title. The shared Abstract states: "A process for preparing [eslicarbazepine acetate or R-licarbazepine acetate] by reduction of oxcarbazepine in the presence of a catalyst and a hydride source is disclosed." #135 patent at Abstract; #929 patent at Abstract. And finally, the shared Summary and Detailed Description of the Invention describes exclusively a process or method for preparing eslicarbazepine acetate through reduction of oxcarbazepine in the presence of a catalyst and a

hydride source. *See* #135 patent at Summary of the Invention, Detailed Description of the Invention; #929 patent at Summary of the Invention, Detailed Description of the Invention.

The intrinsic evidence here is similar to that in *Forest Laboratories, LLC v. Sigmapharm Laboratories, LLC*, 918 F.3d 928, 933 (Fed. Cir. 2019). In *Forest Labs.*, the Federal Circuit read a method into a claim that was a composition claim on its face. *Id.* The Court cited language in the written description describing the invention as a whole and the title of the patent as proof that the claims included the method. *Id.*

Plaintiffs rely on *AstraZeneca LP v. Breath Ltd.*, 542 F. App'x 971 (Fed. Cir. 2013) in support of their argument that process limitations should not be read into the compound claims at issue here. D.I. 58 at 37, 53. In *AstraZeneca*, however, the written description of the patent disclosed three separate concepts: a process, products, and methods of use. 542 F. App'x at 976. Here, the written description only discloses a process.

Additionally, the written description of the patents describes the prior art problem as a problematic process not a problematic compound, further showing that the claimed invention is a process, not a compound. *See Honeywell Int'l, Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1318 (Fed. Cir. 2006) ("The written description's detailed discussion of the prior art problem addressed by the patented

invention, *viz.*, leakage of non-metal fuel filters in EFI systems, further supports the conclusion that the fuel filter is not a preferred embodiment, but an only embodiment."). The written description characterizes the claimed invention as an *improved method* for the preparation of eslicarbazepine acetate. *See, e.g.*, #135 patent at 2:60–64. The Background of the Invention criticizes a prior art process for using high amounts of a ruthenium catalyst that resulted in a high residual level of ruthenium. #135 patent at 2:9–27; #929 patent at 2:11–30. It further criticizes the prior art process as not "economically viable for large-scale manufacturing purposes." #135 patent at 2:27–32; #929 patent at 2:10–35. The patent's solution to the prior art problem is an "improved method" that results in low residual ruthenium in the resulting product and is "conveniently operable on a large-scale." #135 patent at 4:5–10; #929 patent at 4:10–16. Thus, the prior art problem addressed by the patented invention was the disparaged process, not the high ruthenium content or low purity of the resulting eslicarbazepine.

Plaintiffs argue that because other claims in the #135 patent expressly recite product-by-process claims and claims 2 and 9 of the same patent do not, claims 2 and 9 must not claim a process. (They also assert that this argument applies to claims 1 and 2 of the #929 patent even though the #929 patent has no product-by-process claims.) In other words, Plaintiffs assert the doctrine of claim differentiation. That doctrine holds that "different words or phrases used in

separate claims are presumed to indicate that the claims have different meanings and scope." *Andersen*, 474 F.3d at 1369. If "the absence of such difference in meaning and scope would make a claim superfluous, [then] the difference between claims is significant." *Id.* at 1369. Plaintiffs argue that because the word "process" is used in certain claims of the #135 patent and not in claims 2 and 9 of the same patent, claims 2 and 9 must have a different meaning.

A presumption arising from the doctrine of claim differentiation can be overcome by "powerful evidence to the contrary" in the written description. *Id.* at 1370. For example, in *Forest Labs.*, the Federal Circuit read an administration method into a claim even though another claim in the patent expressly claimed that same method, because of strong evidence in the written description showing that the claim included the method. 918 F.3d at 932. In this case, the written description is replete with descriptions of the invention as a process and devoid of any description of the invention as a compound. It thus constitutes powerful evidence that the claimed invention is a process as opposed to a compound, and it overcomes any presumption arising from the doctrine of claim differentiation. Furthermore, the claims that use process language—claims 4, 7, and 10 of the #135 patent—describe processes that are more limited than the process implied in claims 2 and 9. Thus, construing claims 2 and 9 as having a process limitation would not render claims 4, 7, and 10 superfluous.

The written description's repeated and unequivocal descriptions of the invention as a method and process also defeat Plaintiffs' argument that the applicant's cancellation of product-by-process claims and addition of purity claims during the prosecution history shows that the inventors intended to remove the process limitations and end up with purely composition claims.

While cancelling of the product-by-process claims might suggest that the inventors intended to change the claims to compound claims, the prosecution history does not clearly indicate their intentions, whereas the written description unambiguously states that the "present invention" is a process. An unclear prosecution history "cannot contradict . . . clear statements in the specification describing the invention more narrowly." *Honeywell*, 452 F.3d at 138–39.

Finally, Defendants' proposed construction includes the use of a ruthenium catalyst. The parties did not address in their briefing whether the catalyst in the claimed process must be ruthenium. At oral argument, Plaintiffs could only point to one non-ruthenium catalyst in the patents' written description, tr. at 83:13–84:8, and the Defendants questioned whether the portion of the written description Plaintiffs cited actually recites use of a ruthenium catalyst in the oxcarbazepine reduction process, *id.* at 86:4–7. At this time, I will not construe the term as requiring the use of a ruthenium catalyst because the written description does not appear on its face to require that the catalyst that is essential to the invention be a

ruthenium catalyst. The written description describes use of a catalyst generally, *see, e.g.*, #135 patent at 1:19–21, 3:2–3, and the plain language of the "chemical purity" term construed here does not include ruthenium (as described below, another claim term that recites "ruthenium" is construed to require the use of ruthenium as a catalyst). If at trial it is established that the catalyst must be ruthenium, I will revise my construction.

Because the written description shows the claimed invention is a process, not a compound, I construe "(S)-(–)-10-acetoxy-10, 11-dihydro-5H-dibenz/b,f/azepine-5-carboxamide having a chemical purity of at least about 99.96%" as "eslicarbazepine acetate obtained by a process of reduction of oxcarbazepine using a catalyst and having a chemical purity of at least about 99.96%."

TERM E **"a compound being (S)-(–)-10-acetoxy-10, 11-dihydro-5H-dibenz/b,f/azepine-5-carboxamide and comprising about 2 ppm of ruthenium or less" and "less than 2 ppm of ruthenium" in claims 1, 3, and 6 of the #135 patent**

1. Plaintiffs' proposed construction: "eslicarbazepine acetate having an amount of ruthenium at about 2 ppm or less but more than zero" and "an amount of ruthenium less than 2 ppm but more than zero"
2. Defendants' proposed construction: "eslicarbazepine acetate obtained by a process of reduction of oxcarbazepine using a ruthenium catalyst and having an amount of residual ruthenium at about 2 ppm or less but more than zero" and "an amount of residual ruthenium less than 2 ppm but more than zero"
3. **Court's Construction: "eslicarbazepine acetate obtained by a process of reduction of oxcarbazepine using a ruthenium catalyst and having an amount of residual ruthenium at about**

2 ppm or less but more than zero" and "an amount of residual ruthenium less than 2 ppm but more than zero"

I construe "a compound being (S)-(–)-10-acetoxy-10, 11-dihydro-5H-dibenz/b,f/azepine-5-carboxamide and comprising about 2 ppm of ruthenium or less" as "eslicarbazepine acetate obtained by a process of reduction of oxcarbazepine using a ruthenium catalyst and having an amount of residual ruthenium at about 2 ppm or less but more than zero." And I construe "less than 2 ppm of ruthenium" as "an amount of residual ruthenium less than 2 ppm but more than zero."

The written description of the #135 patent makes clear that the claimed ruthenium in eslicarbazepine acetate is the residual ruthenium resulting from a process of reducing oxcarbazepine in the presence of a ruthenium catalyst. As described above, the written description shows that the claimed invention of the #135 patent is a process for preparing eslicarbazepine acetate by reduction of oxcarbazepine in the presence of a catalyst and a hydride source. Moreover, throughout the written description, ruthenium is referred to exclusively as residual. For example, Example 3 explains that the described process results in "[r]esidual ruthenium content . . . [of] less than 2 ppm. #135 patent at 16:15–17; *see also* #135 patent at 2:21–25, 6:3, 9:18, 12:36, 16:15. The written description never describes the ruthenium in the claimed compound as anything other than the residual ruthenium. Also, as described above, a part of the patent's solution to the prior art

problem is an improved method that results in low residual ruthenium. Thus, the use of a ruthenium catalyst that results in a low residual ruthenium content is essential to obtain the claimed ruthenium content of eslicarbazepine acetate.

The written description shows that the claimed ruthenium is the residual ruthenium resulting from the claimed process, not the ruthenium in the compound from any source. Thus, I construe "less than 2 ppm of ruthenium" as "an amount of residual ruthenium less than 2 ppm but more than zero."

TERM F **"the (R)-isomer of (S)-(–)-10-acetoxy-10, 11-dihydro-5H-dibenz/b,f/azepine-5-carboxamide being below the limit of detection" and "the amount of (R)-isomer of (S)-(–)-10-acetoxy-10, 11-dihydro-5H-dibenz/b,f/azepine-5-carboxamide is below the limit of detection" and "below the limit of detection" in claims 5, 8, and 11 of the #135 patent and claim 3 of the #929 patent**

1. Plaintiffs' proposed construction: "(R)-licarbazepine acetate is not detectable by HPLC"
2. Defendants' proposed construction: "Indefinite"
3. **Court's Construction: "(R)-licarbazepine acetate is not detectable by HPLC"**

Because Defendants have not offered a construction of "below the limit of detection," I adopt Plaintiffs' proposed construction. I will entertain Defendants' indefiniteness arguments at a later date.

TERM G **"A method of treating partial-onset seizures in a patient who is suffering from or susceptible to absence seizures, which method comprises:" in claims 1 and 16 of the #747 patent**

The parties agree that this preamble is limiting and that it does not require construction. I will entertain Defendants' arguments that the term is indefinite at a

later date.

TERM H **"absence seizures" in claims 1, 9, 16, and 18 of the #747 patent**

1. Plaintiffs' proposed construction: "brief, generalized epileptic seizures with two characteristic features: (1) impairment of consciousness (absence) and (2) particular spike-and-slow wave discharges as measured by electroencephalography (EEG)"
2. Defendants' proposed construction: "a variety of generalized seizure which, in contrast to partial-onset seizures, affect the whole of the brain, producing abnormal electrical activity throughout both hemispheres and, typically, loss of consciousness. Absence seizures are brief, generalized epileptic seizures with two characteristic features: (1) impairment of consciousness (absence) and (2) particular spike-and-slow wave discharges as measured by electroencephalography (EEG)"
3. **Court's Construction: "A variety of generalized seizure which, in contrast to partial-onset seizures, affect the whole of the brain, producing abnormal electrical activity throughout both hemispheres and, typically, loss of consciousness. Absence seizures are brief, generalized epileptic seizures with two characteristic features: (1) impairment of consciousness (absence) and (2) particular spike-and-slow wave discharges as measured by electroencephalography (EEG)"**

At oral argument, Plaintiffs agreed to the use of Defendants' construction of this term. Tr. 89:12–17. Thus, I will adopt Defendants' proposed construction.

TERM I **"a patient who is suffering from or susceptible to absence seizures" in claims 1, 16, and 18 of the #747 patent**

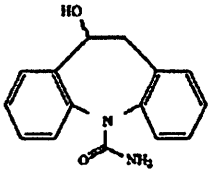
1. Plaintiffs' proposed construction: "a patient who is suffering from absence seizures, or who has particular spike-and-slow wave discharges characteristic of absence seizures and may have been diagnosed as suffering from absence seizures, may have previously experienced at least one seizure such as an absence seizure, myoclonic seizure or tonic-clonic seizure, or may have a family history of epilepsy"
2. Defendants' proposed construction: "Indefinite"

3. Court's Construction: **"a patient who is suffering from absence seizures, or who has particular spike-and-slow wave discharges characteristic of absence seizures and may have been diagnosed as suffering from absence seizures, may have previously experienced at least one seizure such as an absence seizure, myoclonic seizure or tonic-clonic seizure, or may have a family history of epilepsy"**

Because Defendants have failed to offer a construction of the term "a patient who is suffering from or susceptible to absence seizures," I will adopt Plaintiffs' proposed construction. I will entertain Defendants' indefiniteness arguments at a later date.

TERM J **Construction of claims 3 and 4 of the #646 patent**

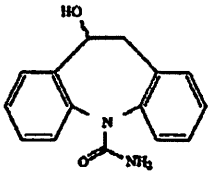
1. Plaintiffs' proposed construction:
   a. Claim 3: "a process for producing a compound having the general formula I of claim 1 comprising reacting compounds of formula II



II

with compounds of the general formula III A—CO—R III wherein: R is the same as defined above for general formula I; A is hydrogen, halo or —O—CO—R group or —O—CO—OR' group, wherein R' is lower alkyl"

   b. Claim 4: "the process covered by claim 3 wherein the reaction is conducted in the presence of at least one condensing agent or base"
2. Defendants' proposed construction: "Indefinite"
3. **Court's Construction:**
   a. **Claim 3: "a process for producing a compound having the general formula I of claim 1 comprising reacting compounds of formula II**



with compounds of the general formula III A—CO—R III wherein: R is the same as defined above for general formula I; A is hydrogen, halo or —O—CO—R group or —O—CO—OR' group, wherein R' is lower alkyl"

b. **Claim 4: "the process covered by claim 3 wherein the reaction is conducted in the presence of at least one condensing agent or base.**

Because Defendants have not offered a proposed construction of claims 3 and 4 of the #646 patent, I adopt Plaintiffs' proposed construction.

WHEREFORE, at Wilmington this 17th day of October 2019, the Court adopts the claim constructions set forth above.

COLM F. CONNOLLY,
UNITED STATES DISTRICT JUDGE