IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

In re Nexletol/Nexlizet ANDA Litigation	**Consol. Court No. 2:24-cv-05921-JCG-CF** **ANDA CASE**

OPINION AND ORDER

[Providing claim construction for the patents in suit.]

Dated: September 3, 2026

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Choe-Groves, Judge: This matter is before the Court for claim construction of terms in U.S. Patent Numbers 11,760,714 ("the '714 Patent"), 11,613,511 ("the '511 Patent"), 11,926,584 ("the '584 Patent"), 12,398,087 ("the '087 Patent"), and 12,404,227 ("the '227 Patent") (collectively, the "Asserted Patents" or "Patents"). See Joint Claim Construction Prehearing Statement ("Joint Claim Chart"); Decl. Liza M. Walsh, Ex. 1, U.S. Patent No. 11,760,714 ("'714 Patent"); Ex. 3, U.S. Patent No. 11,613,511 ("'511 Patent"); Ex. 4, U.S. Patent No. 11,926,584 ("'584 Patent"); Ex. 5, U.S. Patent No. 12,398,087 ("'087 Patent"); Ex. 6, U.S. Patent No. 12,404,227 ("'227 Patent") (collectively, ECF No. 210-1). The Parties seek construction of the following term: "pharmaceutical material." Joint Claim Chart at 3–4. Upon consideration of the Joint Claim Chart and arguments of counsel, the Court defines the disputed claim term as set forth below.

BACKGROUND

Esperion Therapeutics, Inc. ("Plaintiff" or "Esperion") filed suit against Defendants Renata Limited, Somerset Therapeutics, LLC, Somerset Pharma, LLC, MSN Pharmaceuticals Incorporated, MSN Laboratories Private Limited, Aurobindo Pharma Limited, Apitoria Pharma Private Limited, and Sandoz Incorporated (collectively, "Defendants"). Compl., Court No. 24-06017 (ECF No. 1); Compl., Court No. 24-06386 (ECF No. 1); Compl., Court No. 24-06348 (ECF No. 1); Compl., Court No. 24-09457 (ECF No. 1); Compl., Court No. 24-06387

(ECF No. 1); Compl., Court No. 24-05921 (ECF No. 1).[1] This Opinion concerns the first step of the two-step infringement analysis, the construction of claims in the '714, '511, '584, '087, and '227 Patents. The Asserted Patents share a common specification and claim priority to the same provisional application. '714 Patent at 1:6–13; '511 and '584 Patents at 1:6–14; and '087 and '227 Patents at 1:6–15. The Asserted Patents share a common title "Method of Making Bempedoic Acid and Compositions of the Same." '714, '511, '584, '087, and '227 Patents at [54]. The United States Patent and Trademark Office ("USPTO") issued the '714 Patent on September 19, 2023, the '511 Patent on March 28, 2023, the '584 Patent on March 12, 2024, the '087 Patent on August 26, 2025, and the '227 Patent on September 2, 2025. '714, '511, '584, '087, and '227 Patents at [45]. The Asserted Patents are directed to the development of bempedoic acid (8-hydroxy-2,2,14,14-tetramethylpentadecanedioic acid) with purity and impurity profiles of a "commercializable" drug product for the treatment of diseases

[1] The cases were consolidated into Court No. 24-05921. See Consent Order Consol. (ECF No. 39); Consol. Order (ECF No. 137). Amended Complaints were filed in each consolidated case. See Stipulation Order Third Am. Compl. Setting Deadline Answer Case Deadlines (ECF No. 166); Third Am. Compl., Court No. 24-06017 (ECF No. 40); Second Am. Compl., Court No. 24-06386 (ECF No. 35); Third Am. Compl., Court No. 24-06348 (ECF No. 32); Second Am. Compl., Court No. 24-06387 (ECF No. 42); Am. Compl., Court No. 24-09457 (ECF No. 14). All record documents cited infra are filed under Court No. 24-05921.

including liver disorders and cardiovascular disease. '714 Patent at 1:20–28; '511, '584, '087, and '227 Patents at 1:21–29.

The Parties filed a joint claim construction chart and briefs in support of their respective constructions. Joint Claim Chart; Pl.'s Opening Claim Construction Br. ("Pl.'s Br.") (ECF No. 208); Defs.' Opening Markman Br. ("Defs.' Br.") (ECF No. 211); Defs.' Resp. Markman Br. ("Defs.' Resp. Br.") (ECF No. 224); Pl.'s Resp. Claim Construction Br. ("Pl.'s Resp. Br.") (ECF No. 225). The Court held a claim construction hearing on July 7, 2026, and the Parties did not call expert witnesses. See Minutes of Proceeding (ECF No. 272).

CLAIM CONSTRUCTION STANDARD

When the meaning of a patent claim's language is disputed, the Court must construe the claim as a matter of law. Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). "[T]he construction of a patent, including terms of art within its claim, is exclusively within the province of the court." Markman, 517 U.S. at 372. "The purpose of claim construction is to 'determin[e] the meaning and scope of the patent claims asserted to be infringed.'" O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., 521 F.3d 1351, 1360 (Fed. Cir. 2008) (quoting Markman, 52 F.3d at 976).

"The patent is a fully integrated written instrument." Markman, 52 F.3d at 978. For claim construction, "[a] court should look first to the intrinsic evidence of

record, i.e., the patent itself, including the claims, the specification and, if in evidence, the prosecution history." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) (citing Markman, 52 F.3d at 979). "The words of a claim are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art when read in the context of the specification and prosecution history." Thorner v. Sony Comput. Ent. Am. LLC, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (citing Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc)).

Limitations from dependent claims, the specification, and embodiments will not be read into the claims. "The doctrine of claim differentiation [ ] creates a presumption that [ ] dependent claim limitations are not included in the independent claim." GE Lighting Sols., LLC v. AgiLight, Inc., 750 F.3d 1304, 1310 (Fed. Cir. 2014) (citation omitted). Limitations found in the specification are not imposed into the claims. Phillips, 415 F.3d at 1323–24. In the same vein, "[i]t is improper to read limitations from a preferred embodiment described in the specification—even if it is the only embodiment—into the claims absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited." GE Lighting Sols., LLC, 750 F.3d at 1309 (citation omitted) (discussing a figure as a "depicted embodiment").

DISCUSSION

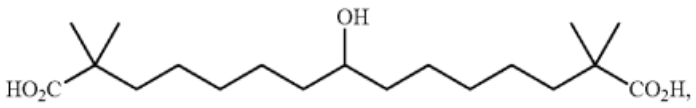
I. Disputed Term

The Parties disagree on one claim term, "pharmaceutical material," found in Claims 1–20 of the '714, '584, and '227 Patents, and Claims 1–17 of the '511 and '087 Patents. Joint Claim Chart at 3–4.

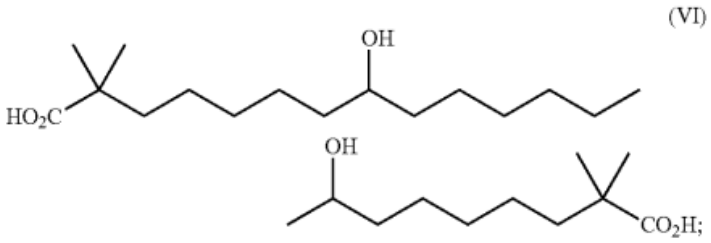
A. "[P]harmaceutical material"

Plaintiff asserts that the plain and ordinary meaning of the term "pharmaceutical material" should prevail in view of the claims, specification, and prosecution history, and thus should be defined as "[a] substance suitable for use as an active pharmaceutical ingredient." Pl.'s Br. at 12; Joint Claim Chart at 3–4. Defendants assert that the term "pharmaceutical material" should be construed to include the particular process disclosed by the claim language as the sole method of manufacture. Defs.' Br. at 17; Joint Claim Chart at 3–4.

Claim 1 of the '714 Patent claims:

> [a] pharmaceutical formulation comprising:
> a pharmaceutical material comprising a crystalline form of the compound of formula (V):
>
> (V)
>
> 
>
>
> or a pharmaceutically acceptable salt thereof;
> wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 98% by weight based on the total weight of the

pharmaceutical material, and the pharmaceutical material comprises 0.0001% to less than or equal to 0.15% of the compound of formula (VI):

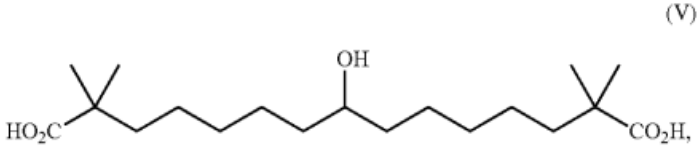


and
a pharmaceutically acceptable excipient.

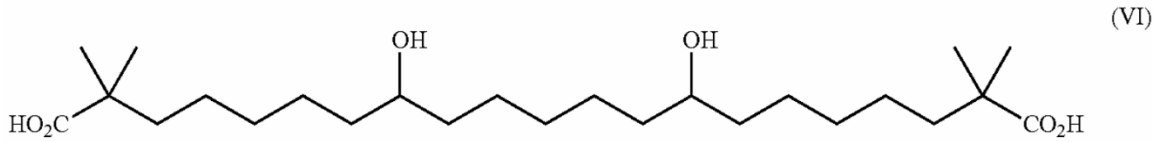
'714 Patent at 83:6–46.

Claim 1 of the '511 Patent claims:

[a] pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof;
wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% weight based on the total weight of the pharmaceutical material, the pharmaceutical material comprises 0.0001% to less than or equal to 0.15% of a compound of formula (VI):



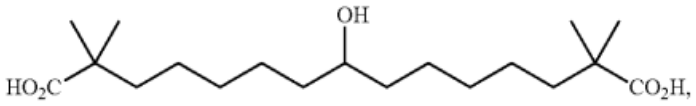
and the crystalline form of the compound of formula (V) exhibits an X-ray powder diffraction pattern comprising peaks at the following diffraction angles (2θ): 10.3±0.2, 10.4±0.2, 17.9±0.2, 18.8±0.2, 19.5±0.2, and 20.7±0.2.

'511 Patent at 81:31–82:4.

Claim 1 of the ’584 Patent claims:

[a] method of lowering low-density lipoprotein choles -terol (LDL-C) in a human in need thereof comprising administering to the human a therapeutically effective amount of a pharmaceutical material comprising a crystal-line form of the compound of formula (V):

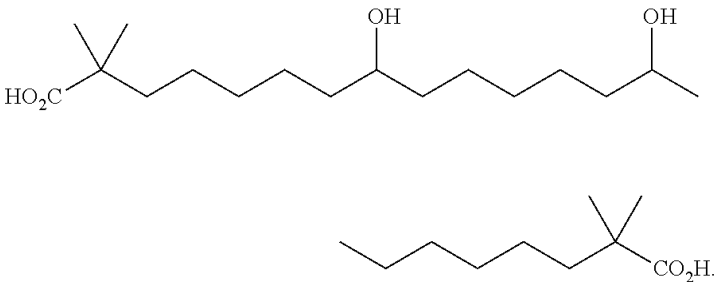
(V)



or a pharmaceutically acceptable salt thereof;

wherein the pharmaceutical material comprises the com-pound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical mate-rial, and the pharmaceutical material comprises 0.0001% to less than or equal to 0.15% of a compound of formula (VI):

(VI)

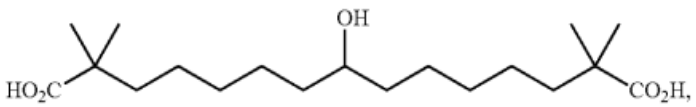


’584 Patent at 83:38–84:11.

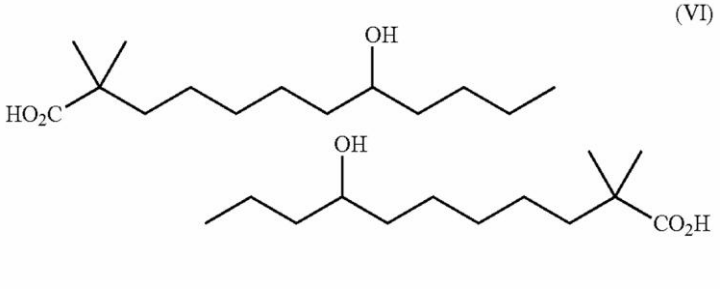
Claim 1 of the ’087 Patent claims:

[a] pharmaceutical material comprising a compound of formula (V):

(V)



wherein the pharmaceutical material comprises the com-pound of formula (V) in the amount greater than 98% by

> weight based on the total weight of the pharmaceutical material and the pharmaceutical material comprises 0.001% to 0.15% of a compound of formula (VI):
>
> (VI)
>
> 
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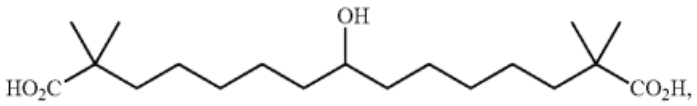
>
> or a pharmaceutically acceptable salt thereof, based on the total weight of the pharmaceutical material.

'087 Patent at 83:2–39.

> Lastly, Claim 1 of the '227 Patent claims:
>
> [a] pharmaceutical material comprising a crystalline form of the compound of formula (V):
>
> (V)
>
> 
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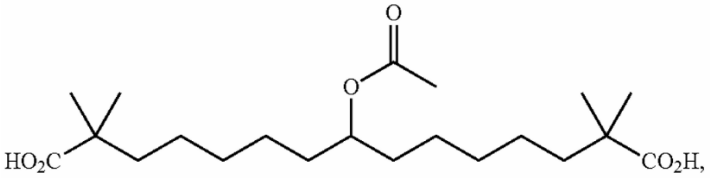
>
> or a pharmaceutically acceptable salt thereof;
>
> wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount great than 99.0% by weight based on the total weight of the pharmaceutical material; and the pharmaceutical material comprises 0.0001% to 0.15%
>
> (VIII)
>
> 
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>
> or a pharmaceutically acceptable salt thereof, based on the total weight of the pharmaceutical material.

'227 Patent at 83:40–84:2.

The Parties dispute whether the term "pharmaceutical material" contained in the Asserted Patents relates to a substance or a process. See Joint Claim Chart at 3–4; Pl.'s Br. at 2; Defs.' Br. at 16–17. Plaintiff argues that the term "pharmaceutical material," although not expressly defined in the specification, has a common-sense meaning of a "material (i.e., an ingredient or substance) that can be used in pharmaceutical products, including drugs for the treatment of medical conditions." Pl.'s Br. at 13–14 (citation omitted). Plaintiff claims that in the context of patents that concern the development of a chemical compound to exploit its potential therapeutic activity, the term "pharmaceutical material" is not just an ingredient that can be used in a drug product, "but a substance suitable for use as an active pharmaceutical ingredient." Id. at 14 (emphasis and citation omitted). Plaintiff emphasizes that the "summary" of the Asserted Patents describes the inventors' discovery of "highly pure, stable forms of bempedoic acid suitable for use as an active pharmaceutical ingredient." Id. (citing '714 Patent at 1:32–35) (emphasis omitted). Defendants contend that the term "pharmaceutical material" is the result of a particular process having specific steps that distinguished the claimed invention from the prior art. Defs.' Br. at 18. Defendants argue that the claimed invention is tied to a specific synthesis process and that the "definitions" section of the common specification supports construing "pharmaceutical material" to require process steps. Id.

"In construing terms used in patent claims, it is necessary to consider the specification as a whole, and to read all portions of the written description, if possible, in a manner that renders the patent internally consistent." Budde v. Harley-Davidson, Inc., 250 F.3d 1369, 1379–80 (Fed. Cir. 2001). "The best source for understanding a technical term is the specification from which it arose, informed, as needed, by the prosecution history." Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1478 (Fed. Cir. 1998). "When the specification explains and defines a term used in the claims, without ambiguity or incompleteness, there is no need to search further for the meaning of the term." Id.

Plaintiff argues that the language of the shared specification relating to exemplary processes is permissive. Pl.'s Br. at 23. Plaintiff focuses on language in the specification that describes the methods of preparing bempedoic acid as one aspect of the invention, and pharmaceutical materials comprising bempedoic acid as another aspect. Id. (citing '714 Patent at 21:50–57, 50:39–42). Plaintiff asserts that the claims of the Asserted Patents are directed to: "(1) a 'pharmaceutical material' with specific recited properties that render it suitable for use as an active pharmaceutical ingredient[;] (2) a 'pharmaceutical formulation' that contains the 'pharmaceutical material[;]' and (3) a 'method' of lowering cholesterol by administering the 'pharmaceutical material.'" Id. at 7 (internal citations omitted). In each of these claims, Plaintiff states that the "pharmaceutical material" is made

up of: (1) a stable "crystalline form" of bempedoic acid; (2) a level of purity within a specified range; and (3) a controlled amount of a specified diol impurity and/or a specified acetate impurity. Id. at 7–8. Plaintiff avers that the specification does not state that any specific process is a requirement of the claimed inventive compositions. Pl.'s Br. at 23. Plaintiff contends that the specification makes clear that "none of its language should be read to limit the scope of the claims[,]" rendering Defendants' attempt to limit the claims improper. Id. (citation omitted).

Throughout their proposed construction, Defendants reference the '714, '511, '584, and '087 Patents as the "Diol Patents." See Defs.' Br. at 1. Defendants rely on the specification to argue that the definition of "purified bempedoic acid" supports construing "pharmaceutical material" to require process steps, because the definition of "purified bempedoic acid" is "when isolated as a solid, a pharmaceutical material contains at least 99.0% weight of [bempedoic acid], based on the total weight of the pharmaceutical material[,]" which supports construing "pharmaceutical material" to require process steps. Id. at 19 (quoting '714 Patent at 9:60–10:1) (alteration in original). Defendants aver that the specification states that "[t]hese terms and phrases can be used interchangeably herein[,]" implying that "pharmaceutical material" must be "purified" or "isolated." Id. (quoting '714 Patent at 22:3–7). Defendants assert that the specification supports construing "pharmaceutical material" to require process steps because the specification states

that "[t]the development of robust, cost-effective and efficient manufacturing methods for the production of pharmaceutically active compounds with desired yield and purity remains a significant challenge[,]" and identifies that "a process for synthesizing bempedoic acid . . . is desired, whereby the product has purity and impurity profiles required by regulatory agencies for the production of a commercializable drug product." Id. (quoting '714 Patent at 1:16–27).

Defendants contend that the common specification "makes it clear that the claimed 'pharmaceutical material' must be bempedoic acid produced by a particular synthetic route that generates the 'fingerprint' diol and acetate impurities." Id. at 22 (citing '714 Patent at 1:56–3:13; 22:23–65; 3:16–18; 3:40–56; 9:60–10:1; 23:1–3; 35:23–50:30; 51:37–55; 51:55–52:50). Defendants aver that each claim of the '714, '511, '584, and '087 Patents states that the "pharmaceutical material" includes both bempedoic acid and the diol impurity, while each claim of the '227 Patent states that the "pharmaceutical material" includes both bempedoic acid and the acetate impurity. Id. at 18 (citations omitted). Defendants argue that during the prosecution of the '714, '511, '584, and '087 Patents, the Applicant characterized the claimed invention as being:

> a pharmaceutical material that includes at least two compounds, the predominant one being the compound of formula (V) or bempedoic acid, in crystalline form. The other compound is known as the 'diol impurity,' i.e., the compound of formula (VI), which is a 'fingerprint impurity' indicative of the synthetic process used to make the bempedoic acid[.]

Id. at 18 (emphasis and citation omitted). Defendants assert that because the combination of bempedoic acid and the diol impurity results from a synthetic process used to make the bempedoic acid, "pharmaceutical material" must be made by the process, otherwise the fingerprint impurity would not be generated. Id.

"Although the specification may aid the court in interpreting the meaning of disputed language in the claims, particular embodiments and examples appearing in the specification will not generally be read into the claims." Constant v. Advanced Micro-Devices, Inc., 848 F.2d 1560, 1571 (Fed. Cir. 1988). It is "not enough that the only embodiments, or all of the embodiments, contain a particular limitation. We do not read limitations from the specification into claims[.]" Thorner, 669 F.3d at 1366. The specification states that in certain embodiments, "the methods of preparing bempedoic acid result in purified bempedoic acid, which also can be described herein with respect to a pharmaceutical material, i.e., a pharmaceutical material comprising an amount of bempedoic acid or an amount of a compound of formula (V), or a pharmaceutically acceptable salt thereof." '714 Patent at 22:2–8. The specification further provides that, "in various embodiments, the methods [for preparing a pharmaceutical material comprising bempedoic acid] generally include" process steps. Id. at 22:24–23:3. The claim language similarly employs permissive language. Claim 1 of the '714 Patent recites "a pharmaceutical material comprising a crystalline form of the compound of formula

(V) . . . or a pharmaceutically acceptable salt thereof[.]" Id. at 83:2–17. Claim 1 continues that "the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 98% by weight based on the total weight of the pharmaceutical material[.]" Id. at 83:18–22. Claim 1 states that the pharmaceutical material "comprises 0.0001% to less than or equal to 0.15% of a compound of formula (VI) . . . and a pharmaceutically acceptable excipient." Id. at 83:22–46. The specification describes the process for preparing bempedoic acid as part of "certain embodiments" that "generally include" and "can" be used to create the pharmaceutical material of the claims. Id. at 22:2–23.

The claim language states that the "pharmaceutical material" must be highly pure with a high percentage of bempedoic acid by weight, and must also contain low, controlled levels (between 0.0001% and 0.15% by weight) of a specific diol impurity (*i.e.*, the compound of Formula VI) in the '714, '511, '584, and '087 Patents, and/or a specific acetate impurity (*i.e.*, the compound of Formula VIII) in the '227 Patent. See, e.g., '714 Patent at 83:18–24; '511 Patent at 81:50–56; '584 Patent at 83:52–58; '087 Patent at 83:12–16; '227 Patent at 84:35–41. The specification identifies multiple impurities that represent several different embodiments of the invention in Section IV, "High Purity Compositions of Bempedoic Acid," but the claims of the Asserted Patents identify only the diol

impurity of Formula VI and the acetate impurity of Formula VIII. See '714 Patent at 50:39–57:67; '511 Patent at 50:21–57:49; '584 Patent at 50:59–58:31; '087 Patent at 51:12–58:58; '227 Patent at 50:50–58:36.

It is not evident from the specification that there was an intention to read a process limitation into the claims. "It is well established that claims are not limited to preferred embodiments, unless the specification clearly indicates otherwise." WesternGeco LLC v. Geophysical Corp., 889 F.3d 1308, 1323–24 (Fed. Cir. 2018); see also Falana v. Kent State Univ., 669 F.3d 1349, 1355 (Fed. Cir. 2012) ("[T]his court has 'cautioned against limiting the claimed invention to preferred embodiments or specific examples in the specification.'"). The specification contains permissive language that describes the process for preparing bempedoic acid as part of certain embodiments used to create the pharmaceutical material of the claims. '714 Patent at 22:2–23. The specification of the Asserted Patents does not describe the process recited by Defendants' proposed construction as essential to the claimed invention. It is improper to read a process limitation into the claims when there is an absence of a clear indication in the intrinsic record that the patentee intended the claims to be so limited. GE Lighting Sols., LLC, 750 F.3d at 1309 (citation omitted); see Sanofi-Aventis U.S. LLC v. Sandoz, Inc., 345 F. App'x 594, 597–98 (Fed. Cir. 2009) (refusing to read a process limitation into the claims where the specification did not use language of requirement).

Defendants refer to the '714 Patent's prosecution history to support their construction and assert that the Applicant distinguished the claimed "pharmaceutical material" from bempedoic acid made by prior art processes. Defs.' Br. at 20. Defendants claim that during the prosecution of the '714 and '511 Patents, the U.S. Patent Applications Nos. 17/742,728 ("'511 Patent Prosecution") and 17/577,829 ("'714 Patent Prosecution") show that the claimed "pharmaceutical material" was distinguished from prior art bempedoic acid on the ground that the prior art bempedoic acid "does not include the diol impurity because it follows the synthesis in Dasseux et al., International Publication No. WO 2004/067489[.]" Defs.' Br. at 20 (emphasis omitted) (citing Ex. 4 (ECF No. 209-5); Ex. 9 (ECF No. 209-12)). The USPTO originally rejected the claims of the '714 Patent because the prior art already taught a high purity form of bempedoic acid. See Decl. Liza M. Walsh, Ex. 7, Office Action for U.S. Patent No. 17/577,829 at 10 (ECF No. 210-1). The USPTO stated that "only in those cases where the purified product is as a result of the purification so different in properties and uses as to be in effect a new compound has such a purified product been considered patentable." Id. at 9. "The instant case does not come under this exception." Id. In response, the Applicant stated that "although the discussion herein includes reference to the method of making bempedoic acid, the resulting compositions of matter and their purity profiles are different for Applicant's claimed invention of the cited references."

See Decl. Liza M. Walsh, Ex. 12, Office Action for U.S. Patent No. 17/742,728 at 9 (ECF No. 210-2). The Patent Application discussed a purified product to be patentable when the "result of the purification [is] so different in properties and uses as to be in effect a new compound[,]" but does not opine as to whether the "process" itself was the focus of the application. See Decl. Liza M. Walsh, Ex. 7, Office Action for U.S. Patent No. 17/577,829 at 9. In its response, the Applicant stated that the "claimed invention is a pharmaceutical material that contains primarily an [active pharmaceutical ingredient] with a fingerprint impurity that is indicative of a method used to make the pharmaceutical material on a commercial scale, in contrast to the laboratory scale synthetic processes of the cited references." See Decl. Liza M. Walsh, Ex. 12, Office Action for U.S. Patent No. 17/742,728 at 9.

The prosecution history further supports that there was no intention to read a process limitation into the claims of the Asserted Patents. The specification does not indicate that the claims require a certain process and, as informed by the prosecution history, the Applicant did not intend for a process limitation to be read into the claims. See Multiform Desiccants, Inc., 133 F.3d at1478 ("The best source for understanding a technical term is the specification from which it arose, informed, as needed, by the prosecution history."). The claimed invention in the Asserted Patents may consist of the bempedoic acid of Formula V, the diol

impurity of Formula VI, and the acetate impurity of Formula VIII, and the specification contains permissive language that describes the process for preparing bempedoic acid. See '714 Patent at 22:2–23, 83:6–46; '511 Patent at 81:31–82:4; '584 Patent at 83:38–84:11; '087 Patent at 83:2–39; '227 Patent at 83:40–84:2.

Defendants also offer extrinsic evidence in the form of the related European Patent Application No. 24194322.4, arguing that statements made during the prosecution of the foreign patent support Defendants' construction of the term "pharmaceutical material." Defs.' Br. at 23–24.

The use of "pharmaceutical material" in Plaintiff's proposal defines the claim term "pharmaceutical material" by physical characteristics, including its content, crystalline form, purity, and controlled impurities. Joint Claim Chart at 3–4. Defendants' proposed construction relies on portions of the specification detailing a process that describes "embodiments" of aspects of the claimed invention separate from the "pharmaceutical materials." Id. The specifications of the Asserted Patents state that "[n]o language in the specification should be construed as indicating any non-claimed element as essential to the practice of the present invention." '714 and '584 Patents at 6:49–51; '584, '087, and '227 Patents at 6:50–52. Defendants' proposed construction seeks to import process limitations from the specification into the claim term, while Plaintiff's proposal seeks to define the term "pharmaceutical material" by its ordinary meaning in light of a

problem and solution identified in the specification. Joint Claim Chart at 3–4. Plaintiff's proposal defines "pharmaceutical material" as a "highly pure, stable form[] of bempedoic acid suitable for use as an active pharmaceutical ingredient" where the "pharmaceutical material" is a "substance suitable for use as an active pharmaceutical ingredient." Pl.'s Br. at 2.

The Court must consider the specification as a whole and if possible, read all portions of the written description "in a manner that renders the patent internally consistent." Budde, 250 F.3d at 1379–80. Defendants' construction does not read all portions of the written description in a manner that renders the Asserted Patents internally consistent. Defendants' construction imports a specific process limitation contained in an embodiment of the specification based on the resulting diol and acetate impurities produced by that process. The process limitation proposed by Defendants is not internally consistent with all portions of the written description because the specification discloses multiple other impurities that represent several different embodiments of the invention. See '714 Patent at 50:39–57:67; '511 Patent at 50:21–57:49; '584 Patent at 50:59–58:31; '087 Patent at 51:12–58:58; '227 Patent at 50:50–58:36. Defendants' proposed construction seeks to import a process limitation absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited. See GE Lighting Sols., LLC, 750 F.3d at 1309.

Plaintiff's proposal that "pharmaceutical material" means "a substance suitable for use as an active pharmaceutical ingredient" is supported by the context of the specification and prosecution history. See Thorner, 669 F.3d at 1365. The "summary" of the Asserted Patents describes the inventors' discovery of "highly pure, stable forms of bempedoic acid suitable for use as an active pharmaceutical ingredient." '714 Patent at 1:32–35. The claim language states that the "pharmaceutical material" must be highly pure with a high percentage of bempedoic acid by weight and must also contain low levels of a specific diol impurity in the '714, '511, '584, and '087 Patents, and/or a specific acetate impurity in the '227 Patent. See, e.g., '714 Patent at 83:18–24; '511 Patent at 81:50–56; '584 Patent at 83:52–58; '087 Patent at 83:12–16; '227 Patent at 84:35–41. The Asserted Patents are directed to the development of bempedoic acid with purity and impurity profiles of a "commercializable" drug product for the treatment of diseases, and are not directed to the process used to produce bempedoic acid. '714 Patent at 1:20–28; '511, '584, '087, and '227 Patents at 1:21–29.

Throughout the prosecution history, the Applicant distinguished the claimed invention's purity profiles from laboratory scale synthetic processes of the cited references by stating that the diol and/or acetate impurity is indicative of a method used to make the pharmaceutical material on a commercial scale. See Decl. Liza M. Walsh, Ex. 12, Response Office Action for U.S. Patent Application No.

17/742,728 at 9. The Patent Application discussed a purified product to be patentable when the result of the purification is so different in properties and uses as to be in effect a new compound but does not opine as to whether the "process" itself was the focus of the application. See Decl. Liza M. Walsh, Ex. 7, Response Office Action for U.S. Patent Application No. 17/577,829 at 9.

The Court concludes that the term "pharmaceutical material" means "a substance suitable for use as an active pharmaceutical ingredient." Accordingly, the Court adopts Plaintiff's plain and ordinary meaning for the claim term "pharmaceutical material."

CONCLUSION

For the foregoing reasons, the Court adopts the plain and ordinary meaning of the disputed claim term from the Asserted Patents as follows:

1. "pharmaceutical material" as "a substance suitable for use as an active pharmaceutical ingredient."

IT IS SO ORDERED this 3rd day of September, 2026.

/s/ Jennifer Choe-Groves
Jennifer Choe-Groves
U.S. District Court Judge*

*Judge Jennifer Choe-Groves, of the United States Court of International Trade, sitting by designation.