

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

BRECKENRIDGE PHARMACEUTICAL,
INC.,

Plaintiff,
Counterclaim-Defendant,

v.

HETERO USA, INC., HETERO LABS
LIMITED UNIT-III, HETERO LABS
LIMITED, and CAMBER
PHARMACEUTICALS, INC.,

Defendants,
Counterclaim-Plaintiffs.

C.A. No. 24-0571-GBW

Kelly E. Farnan, Sara M. Metzler, RICHARDS, LAYTON & FINGER, P.A., Wilmington, DE;
Christopher J. Sorenson, MERCHANT & GOULD P.C., Minneapolis, MN.

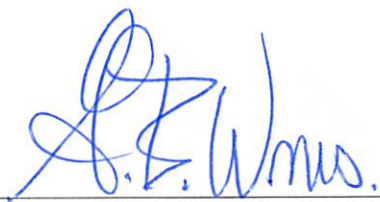
Counsel for Plaintiff / Counterclaim-Defendant

Kenneth L. Dorsney, Cortlan S. Hitch, MORRIS JAMES LLP, Wilmington, DE; Dennies
Varughese, Adam C. LaRock, Christopher Coleman, STERNE, KESSLER, GOLDSTEIN & FOX
PLLC, Washington, D.C.

Counsel for Defendants / Counterclaim-Plaintiff

MEMORANDUM OPINION

June 26, 2025
Wilmington, Delaware


GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE

Pending before the Court is the parties'¹ Joint Claim Construction Brief (D.I. 82). The Joint Claim Construction Brief includes five disputed terms from U.S. Patents Nos. 11,013,729 (“the ’729 patent”) and 11,752,142 (“the ’142 patent”) (together, the “Asserted Patents”). The Court held a claim construction hearing on May 15, 2025. Below, the Court describes whether, how, and why it will construe the disputed terms from the Asserted Patents. The Court writes for the benefit of the parties and assumes their familiarity with this action.

I. LEGAL STANDARDS

Below are the legal standards for (A) claim construction and (B) indefiniteness.

A. Claim Construction

“It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (internal quotation marks omitted); *see also Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989) (“A claim in a patent provides the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using, or selling the protected invention.”). “[T]here is no magic formula or catechism for conducting claim construction.” *Phillips*, 415 F.3d at 1324. The Court is free to attach the appropriate weight to appropriate sources “in light of the statutes and policies that inform patent law.” *Id.* The ultimate question of the proper construction of a patent is a question of law, although

¹ The Plaintiff / Counterclaim-Defendant is Breckenridge Pharmaceutical, Inc. (“Breckenridge”). The Defendants / Counterclaim-Plaintiffs are Hetero USA, Inc., Hetero Labs Limited Unit-III, Hetero Labs Limited, and Camber Pharmaceuticals, Inc. (collectively, “Hetero”).

subsidiary fact-finding is sometimes necessary. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318 (2015) (quoting *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996)).

“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*, 415 F.3d at 1312-13). A person of ordinary skill in the art “is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification.” *Phillips*, 415 F.3d at 1313.

“When construing claim terms, the court first looks to, and primarily relies on, the intrinsic evidence, including the claims themselves, the specification, and the prosecution history of the patent, which is usually dispositive.” *Sunovion Pharms., Inc. v. Teva Pharms. USA, Inc.*, 731 F.3d 1271, 1276 (Fed. Cir. 2013). “Other claims of the patent in question, both asserted and unasserted, can . . . be valuable” in discerning the meaning of a disputed claim term because “claim terms are normally used consistently throughout the patent,” and so, “the usage of a term in one claim can often illuminate the meaning of the same term in other claims.” *Phillips*, 415 F.3d at 1314. In addition, “[d]ifferences among claims can also be a useful guide[.]” *Id.* For example, “the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.” *Id.* at 1314-15.

In addition to the claim, the Court should analyze the specification, which “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. Conceptoronic, 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)). And, the specification “is not a substitute for, nor can it be used to rewrite, the chosen claim language.” *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004).

The Court “should also consider the patent’s prosecution history, if it is in evidence.” *Markman*, 52 F.3d at 980. The 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[.]” *Phillips*, 415 F.3d at 1317.

In some cases, the Court “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. Overall, while extrinsic evidence may be useful, it is “less significant than the intrinsic record in determining the legally operative meaning of claim language.” *Phillips*, 415 F.3d at 1317 (internal quotation marks and citations omitted).

B. Indefiniteness

Section 112 of the Patent Act requires that the claims of a patent “particularly point[] out and distinctly claim[] the subject matter which the inventor . . . regards as the invention.” 35 U.S.C. § 112(b). The “primary purpose of the definiteness requirement” that § 112(b) contains “is to ensure that the claims are written in such a way that they give notice to the public of the extent of the legal protection afforded by the patent, so that interested members of the public, e.g., competitors of the patent owner, can determine whether or not they infringe.” *All Dental Prodx, LLC v. Advantage Dental Prods., Inc.*, 309 F.3d 774, 779-80 (Fed. Cir. 2002) (citation omitted).

“[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 904 (2014). While a “potential infringer” need not “be able to determine *ex ante* if a particular act infringes the claims,” the patentee must “apprise the public of what is still open to them[]” such that “a person of ordinary skill in the art could determine whether or not an accused product or method infringes the claim.” *Niazi Licensing Corp. v. St. Jude Med. S.C., Inc.*, 30 F.4th 1339, 1346-47 (Fed. Cir. 2022) (quotation marks and citations omitted).

Like claim construction, definiteness is a question of law, but courts must sometimes render factual findings based on extrinsic evidence to resolve the ultimate issue of definiteness. *See Sonix Tech. Co. v. Publications Int’l, Ltd.*, 844 F.3d 1370, 1376 (Fed. Cir. 2017). “Patent claims are presumed to be valid and definite.” *B.E. Tech., LLC v. Twitter Inc.*, No. 20-cv-621-GBW, 2024 WL 579076, at *1 (D. Del. Feb. 13, 2024) (citing 35 U.S.C. § 282). Thus, the challenger must prove indefiniteness by clear and convincing evidence. *See Nippon Shinyaku Co. v. Sarepta Therapeutics, Inc.*, No. 21-cv-1015-GBW, 2023 WL 4314485, at *6 (D. Del. July 3, 2023).

II. DISCUSSION

The Court construes the following terms from the Asserted Patents: (A) “two distinct types of particles,” (B) “the first type of particles is free from,” / “and is free from dabigatran etexilate,” and (C) “mixing the first type of particles and the second type of particles with the at least one pharmaceutically acceptable excipient,” / “a mixture of [two distinct types of particles and at least one pharmaceutically acceptable excipient].”

A. “two distinct types of particles”

Claim Term	Breckenridge's Construction	Hetero's Construction	Court's Construction
“two distinct types of particles” '729 patent (claims 1, 11, 16) '142 patent (claims 1, 8, 16)	No construction required Alternatively, “two different types of particles”	“a first type of particles that is not in contact with a second type of particle” Alternatively, indefinite	Plain and ordinary meaning which is “two different types of particles”

Claim 1 of the '729 patent recites:

A composition comprising: a mixture of at least two distinct types of particles wherein

a) the first type of particles comprise dabigatran etexilate in the form of the free base or in the form of a pharmaceutically acceptable salt or polymorph thereof, wherein the first type of particles is free from organic acids and inorganic acids; and

b) the second type of particles comprise at least one pharmaceutically acceptable organic acid, wherein the second type of particles is coated with a protective coating layer and is free from dabigatran etexilate.

As depicted above, Breckenridge contends that the Court does not need to construe the phrase “two distinct types of particles.” D.I. 82 at 7. In the alternative, Breckenridge puts forth the construction of “two different types of particles.” *Id.* Hetero contends that the Court should construe the claim as “a first type of particles that is not in contact with a second type of particle.” *Id.* In the alternative, Hetero contends that the claim term is indefinite. D.I. 82 at 18. For the

reasons that follow, the Court adopts the plain and ordinary meaning of the phrase “two distinct types of particles” which is “two different types of particles.” The Court also holds that the claim is not indefinite.

1. The Court adopts the plain and ordinary meaning of “two distinct types of particles” as two different types of particles

Any claim construction analysis must “begin and remain centered on the language of the claims themselves, for it is that language that the patentee chose to use to ‘particularly point out and distinctly claim the subject matter which the patentee regards as his invention.’” *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001) (quoting 35 U.S.C. § 112, ¶ 2); *see also Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc). Moreover, there is a heavy presumption that claim terms are to be given their ordinary and customary meaning. *Aventis Pharm. Inc. v. Amino Chemicals Ltd.*, 715 F.3d 1363, 1373 (Fed. Cir. 2013).

Here, the court adopts the ordinary and plain meaning of “two distinct types of particles,” which is that the particles are different types. Where a claim “is comprised of commonly used terms,” meaning that “each is used in common parlance and has no special meaning in the art,” no construction is necessary. *Summit 6, LLC v. Samsung Elecs. Co.*, 802 F.3d 1283, 1291 (Fed. Cir. 2015); *accord Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc) (explaining that “readily apparent” terms require “little more than the application of the widely accepted meaning of commonly understood words”). Because the words of this term are commonly used, the Court does not have to construe the terms and uses the plain and ordinary meaning.

The remaining language in the relevant claims confirms this term’s meaning. For example, subpart “a)” of claim 1 of the ’729 patent recites the “first type of particles” as particles containing the active pharmaceutical ingredient (“API”) “free from” organic or inorganic acids. ’729 Patent,

cl. 1. Subpart “b)” of the same claim then recites the “second type of particles” as particles that contain at least one acceptable organic acid “free from” the API. *Id.* This claim language demonstrates that the types of particles are different.

Moreover, there are process claims that depend on claim 1 that explicitly recite one means for preparing a composition of claim 1 that involves preparing two distinct types of particles. For example, the first two steps of claim 8 (steps i through ii) involve preparing granules² with API that does not include acid. ’729 patent, cl. 8. The next three steps (steps iii through v) involve preparing coated granules with acid and no API. *Id.* The API and the coated acid granules are then blended together “to form a mixture of at least two types of granules,” followed by the optional addition of another excipient to the blend. *Id.* A lubricant is then also added to the blend, followed by “filling the lubricated mixture . . . into suitable hard capsules.” *Id.*

Hetero contends that the asserted claims, and patent specifications, support construing “two distinct types of particles” to mean “a first type of particle that is not in contact with a second type of particle.” D.I. 82 at 7. Hetero’s underlying reasoning, however, is strained.

First, Hetero attempts to undercut Breckenridge’s construction. Regarding the asserted claims, Hetero first takes issue with using the rest of the claim language to construe the meaning of “distinct.” *Id.* at 10. Because the remainder of the claim language already describes “the qualitative content of each type of particle,” Hetero contends that Breckenridge’s proposed construction therefore renders “distinct” superfluous. *Id.* at 10-11 (citing *Exxon Chem. Patents, Inc. v. Lubrizol Corp.*, 64 F.3d 1553, 1557 (Fed. Cir. 1995) (Courts “must give meaning to all the words in [patent] claims.”)).

² The specification defines a granule as a type of “particle.” ’729 Patent, 8:63–9:1.

This argument is unconvincing. Hetero provides no support for its position that Breckenridge's proposed construction is superfluous. Hetero merely states that Breckenridge's position does not give meaning to the term "distinct." In reality, the remainder of the claim language describes what the two distinctions are. One particle is distinct because it has dabigatran and is free from acid, and the second particle is distinct because it has acid and is free from dabigatran. *See Power Mosfet Techs., L.L.C. v. Siemens AG*, 378 F.3d 1396, 1410 (Fed. Cir. 2004) ("[W]here neither the plain meaning nor the patent itself commands a difference in scope between two terms, they may be construed identically.").

Hetero's next issue with Breckenridge's construction is that the claim language regarding the dabigatran particle being free from acid and the acid particle being free from dabigatran was added via amendments over two years after the "distinct" limitation. *Id.* at 11. Yet this argument misses the full context of those amendments. Examining the prosecution history, it's clear that when the patent first included the word "distinct," "distinct" referred to the content of the particles. The claim, as then amended, stated: "A composition comprising a mixture of at least two distinct types of particles wherein a) the first type of particles comprise dabigatran . . . and b) the second type of particles comprise at least one pharmaceutically acceptable organic acid." D.I. 82-1, Ex. E at PageID # 1417 (emphasis omitted).

Furthermore, Hetero claims that the "distinct" limitation was added in response to a matter unrelated to the types of the particles. However, the prosecution history shows that the opposite is true. The applicant added the word distinct because the phrase "two types of particles" recited in then-instant Claim 21 did "not make the distinction between the two particles being different." D.I. 82-1, Ex. E at PageID # 1411.

Second, Hetero's arguments for its own construction are unavailing. For instance, the full language of claim 1 requires a "composition comprising: a mixture of at least two distinct types of particles." '729 patent, cl. 1. Hetero's construction strains under this full language because it is hard to understand how "a first type of particle that is not in contact with a second type of particle" could be together in a mixture.

Hetero attempts to counter this argument by contending that the lubricant from claim 8 "ensures the two types of particles are not in contact. D.I. 82 at 12. Furthermore, Hetero cites the specification that states that "the presence of an organic acid in close contact with the active [i.e., dabigatran]" in a composition made "without any special steps taken to separate the two from each other, can make the active highly susceptible to hydrolysis in the presence of humidity." '729 Patent 2:50-54. Hetero asserts that the "special step" which separates the two types of particles is the addition of the lubricant. *Id.* Yet, Hetero provides zero support for its claim that the lubricant physically separates the two particles. The specification merely states that lubricants are "substances used in solid dosage formulations to reduce friction during compression of the solid dosage [form]." '729 Patent at 8:33-35. Likewise, there is nothing that connects the phrase "special step" to the addition of the lubricant. The "special step" could be any number of steps.

Also, Hetero claims that the prosecution history overwhelmingly supports its proposed construction. "The prosecution history, in particular, 'may be critical in interpreting disputed claims.'" *Univ. of Mass., Carmel Laby's., LLC v. L'Oreal S.A.*, 36 F.4th 1374, 1379 (Fed. Cir. 2022) (citations omitted). In particular, Hetero contends that the patent examiner continued to reject the '729 patent because the "claims [did] not make the distinction between the two types of particles being different" even after the patent claims added the word "distinct." D.I. 82 at 14. As a follow-up, the patent applicant articulated that the claimed formulations "comprise two distinct

types of particles” and “are physically separated when the dosage form is taken and both dissolve at the same time.” *Id.* at 15. Hetero highlights this quote in support of its contention that “distinct” means “a first type of particle that is not in contact with a second type of particle.”

Hetero, however, misinterprets this prosecution history in two ways. First, Hetero is incorrect in its reasoning for why the patent office rejected the ’729 patent application after it included the word “distinct.” The examiner rejected the claims on obviousness grounds, which the Board of Patent Appeals later overturned. D.I. 82 at 23 (citing D.I. 82-1, Ex. A). Second, Hetero misreads the phrase “physically separated.” In the patent application, the applicant is distinguishing the current composition from the composition in the patent application US Pat. App. 2006/183779 (“US ’779”), which the patent examiner identified as background to the ’729 patent. D.I. 82 at 13; *see also* ’729 Patent, 2:30–44 (discussing US ’779 as part of the background of the invention). As the Board of Patent Appeals explains, the composition in US ’779 was a single pellet of “an organic acid core surrounded by ‘a separating layer followed by a layer containing the active substance.’” D.I. 82-1, Ex. A at 4 (quoting US ’779). On the other hand, the ’729 patent composition was different because the active substance and acid are “physically separated” into two different particles instead of one pellet like in US ’779.

This same contrast explains the cherry-picked word “contiguous” that Breckenridge used in the oral argument before the Patent Trial and Appeal Board. D.I. 82 at 18. What is contiguous are the layers of the different substances in a single pellet of the US ’779 composition. In contrast, the ’729 patent composition “separated” the substances into separate particles. D.I. 82-1, Ex N at 9. Thus, it’s clear from this contrast that the phrases “physically separated” and “contiguous” refer to the number and types of particle/pellet used, not forbidding all contact between the two substances as Hetero suggests. D.I. 82 at 15.

For the foregoing reasons, the Court adopts the plain and ordinary meaning of “two distinct types of particles” which is two different types of particles.

2. The claim “two distinct types of particles” is not indefinite

Because a person of ordinary skill in the art would be reasonably certain as to the claim scope, the term “two distinct types of particles” is not indefinite. The intrinsic record and the remaining claim language provides enough context to the word “distinct” that would give a POSA enough reasonable certainty as to the claim scope. *See Nautilus*, 572 U.S. at 904. In its brief, Hetero’s indefiniteness argument rehashes many of the same arguments it made against Breckenridge’s claim construction. Namely, Hetero repeats that there are many definitions of distinct and that Breckenridge’s construction is superfluous. Having already addressed these arguments in construing the claim, Hetero’s indefiniteness argument likewise fails.

B. “the first type of particles is free from” / “and is free from dabigatran etexilate”

Claim Term	Breckenridge’s Construction	Hetero’s Construction	Court’s Construction
<p>“the first type of particles is free from organic acids and inorganic acids”</p> <p>’729 Patent (claim 1)</p> <p>’142 Patent (claims 1, 8)</p> <p>“the first type of particles is free from organic and inorganic acids”</p> <p>’729 Patent (claims 11, 16)</p> <p>“the first type of particles is free from tartaric acid”</p> <p>’142 Patent (claim 16)</p>	<p>No Construction Required.</p> <p>Alternatively, “the first type of particles does not contain organic acids and inorganic acids in contact with the dabigatran etexilate”</p>	<p>“the first type of particles does not contain any amount of organic acids and inorganic acids”</p>	<p>Plain and ordinary meaning of “free from” which is “does not contain any”</p>
<p>“and is free from dabigatran etexilate”</p> <p>’729 Patent (claims 1, 11, 16)</p> <p>’142 Patent (claims 1, 8, 16)</p>	<p>No Construction Required.</p> <p>Alternatively, “and does not contain dabigatran etexilate in contact with the organic acid.”</p>	<p>“and does not contain any amount of dabigatran etexilate”</p>	<p>Plain and ordinary meaning which is “and does not contain any dabigatran etexilate”</p>

Claim 1 of the ’729 patent recites:

A composition comprising: a mixture of at least two distinct types of particles wherein

- a) the first type of particles comprise dabigatran etexilate in the form of the free base or in the form of a pharmaceutically acceptable salt or polymorph thereof, wherein the first type of particles is free from organic acids and inorganic acids; and

b) the second type of particles comprise at least one pharmaceutically acceptable organic acid, wherein the second type of particles is coated with a protective coating layer and is free from dabigatran etexilate.

The parties have identified two claims that contain the term “free from” as needing construction. Because the parties group these claims and put forth the same reasoning for both in their briefs, the Court will address both claims at the same time. *See* D.I. 82 at 33-53.

As depicted above, Breckenridge contends that the Court does not need to construe the phrases “the first type of particles is free from” and “and is free from dabigatran etexilate.” D.I. 82 at 34, 37. As constructions, Breckenridge alternatively puts forth “the first type of particles does not contain organic acids and inorganic acids in contact with the dabigatran etexilate” and “and does not contain dabigatran etexilate in contact with the organic acid,” respectively. *Id.* Hetero contends that the Court should respectively construe the phrases as “the first type of particles does not contain any amount of organic acids and inorganic acids” and “and does not contain any amount of dabigatran etexilate.” *Id.* For the reasons that follow, the Court adopts the plain and ordinary meaning of the phrases. First, “the first type of particles is free from” means the first type of particles “does not contain any.” Second, “and is free from dabigatran etexilate” means “and does not contain any dabigatran etexilate.”

Because this claim “is comprised of commonly used terms,” no construction is necessary. *Summit 6*, 802 F.3d at 1291. This district has previously given meaning to the term “free from” as “does not contain.” In *Cumberland Pharm. Inc. v. Sagent Agila LLC*, No. CV 12–825–LPS, 2013 WL 5913742 (D. Del. Nov. 1, 2013), the representative claim of the patent-in-suit required a “stable aqueous pharmaceutical composition comprising between 200 and 250 mg/mL acetylcysteine, wherein the composition is *free from a chelating agent*” *Id.* at *2 (emphasis in original). The court held that claim construction was not necessary in order to determine that

“‘free from a chelating agent’ means that a claimed composition may not include a chelating agent.” *Id.*

Likewise, cases outside this district have interpreted “free from” in a similar manner as “does not contain.” See *King Pharms. Inc. v. Purdue Pharma L.P.*, 718 F. Supp. 2d 703 (W.D. Va. 2010) (emphasis in original) (construing the phrase “an opioid antagonist composition . . . *free from* an opioid agonist” as “the opioid antagonist composition does not contain an opioid agonist”); *Bioavail Laby’s Int’l SRL v. Impax Laby’s., Inc.*, 433 F. Supp. 2d 501, 519 (E.D. Pa. 2006) (“[T]here is no reason not to apply the ordinary English meaning of ‘free of’ when construing ‘free of stabilizer’: ‘not having or using’; ‘lacking.’”).

Breckenridge agrees with the conclusion that “free from” does not require construction. Its interpretation of the term, however, is strained. Breckenridge believes that the claim “the first type of particles is free from” means “the first type of particles does not contain organic acids and inorganic acids in contact with the dabigatran etexilate” and that the claim “and is free from dabigatran etexilate” means “and does not contain dabigatran etexilate in contact with the organic acid.” D.I. 82 at 34. In support of its “contactless” theory, Breckenridge cites the specification and the prosecution history. Neither of these sources, however, support Breckenridge’s theory.

First, the ’729 patent specification advises that “the presence of an organic acid in close contact with the active in a tablet composition without any special steps taken to separate the two from each other, can make the active highly susceptible to hydrolysis in the presence of humidity.” ’729 Patent at 2:50-54. Breckenridge cites this passage as evidence that “free from” means the particles are not in contact. D.I. 82 at 35.

Where “patents distinguish the prior art” on the basis of a particular structure and “point out the advantages of [that particular structure,] . . . the claims should not be read so broadly as to

encompass the distinguished prior art structure.” *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1343 (Fed. Cir. 2001); *see also Openwave Sys., Inc. v. Apple Inc.*, 808 F.3d 509, 513 (Fed. Cir. 2015) (where “the specification [] reveal[s] an intentional disclaimer, or disavowal, of claim scope by the inventor, . . . the inventor’s intention, as expressed in the specification, is regarded as dispositive”).

Breckenridge’s citation of the ’729 patent specification is without context, and it glances over text that contradicts its position. While it is true that the specification advises against contact between the active and the acid, that language is not directly connected to the “free from” claim. At the same time, the specification identifies the manufacturing process of US ’779 as “cumbersome, time consuming and uneconomical.” ’729 Patent 2:43-44. Meanwhile, the specification describes the claimed two particle composition as “stable” and “can be prepared by simple, non-tedious, and cost-effective process.” *Id.* at 3:4-6. This sort of “distinguish[ing of] the prior art” where the patent “point[s] out the advantages of” a two particle design means that “the claims should not be read so broadly as to encompass the distinguished prior art structure,” which, in this case, is a single particle containing both the acid and the active substance. *SciMed Life Sys.*, 242 F.3d at 1343.

Breckenridge disagrees with the conclusion that the specification disavowed the structure of the active and acid in the same particle. Breckenridge contends that if anything was disavowed in the patent specification, it was the single particle formulation. D.I. 82 at 49. Breckenridge further supports its position by claiming that absent “a clear disavowal,” a patentee is “free to choose a broad term and expect to obtain the full scope of its plain and ordinary meaning.” *Id.* (citing *Datacore Software Corp. v. Scale Computing, Inc.*, C.A. No. 22-535-GWB, 2023 WL 5207928, at *7-8 (D. Del. Aug. 14, 2023)).

However, Breckenridge's argument is a distinction without a difference. Yes, the patent specification disavows the single particle formulation, and it is that single particle formulation where both the active and the active are part of the same structure. Additionally, Breckenridge's citation to *Datacore* does not help its position. The Court has already determined it will use the plain and ordinary meaning. The plain and ordinary meaning, however, is different than what Breckenridge suggests.

Second, Breckenridge cites a declaration submitted during the '729 patent's prosecution in support of its position. D.I. 82 at 48. That declaration compared compositions with a protective coating on one type of particle (the acid particle) to compositions without a protective coating on either type of particle. The composition with a protective coating on one of the particles had significantly lower impurity levels in the experiment than the composition without the protective coating on the acid particles. D.I. 82-1, Ex. R at 1-4. Breckenridge suggests that the results of this experiment, where the less pure particles did not touch due to the protective coating, show that the two particles should not be contact with each other. D.I. 82 at 48.

"Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent." *Phillips*, 415 F.3d at 1317. "The prosecution history, in particular, 'may be critical in interpreting disputed claims,'" and "even where 'prosecution history statements do not rise to the level of unmistakable disavowal, they do inform the claim construction.'" *Univ. of Mass.*, 36 F.4th at 1379 (citations omitted).

Likewise, the doctrine of prosecution disclaimer "preclud[es] patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution" if a patentee "has unequivocally disavowed a certain meaning to obtain [a] patent" in a way that is "clear and unmistakable," and "narrows the ordinary meaning of the claim congruent with the scope of the

surrender.” *Omega Eng’g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1324-26 (Fed. Cir. 2003); *see also Traxcell Techs., LLC v. Nokia Sols. & Networks Oy*, 15 F.4th 1136, 1141 (Fed. Cir. 2021) (“The doctrine [of prosecution disclaimer] ensures that claims are not construed one way in order to obtain their allowance and in a different way against accused infringers.”). “Prosecution disclaimer can arise from both claim amendments and arguments.” *SpeedTrack, Inc. v. Amazon.com*, 998 F.3d 1373, 1379-80 (Fed. Cir. 2021) (“An applicant’s argument that a prior art reference is distinguishable on a particular ground can serve as a disclaimer of claim scope even if the applicant distinguishes the reference on other grounds as well.”).

Breckenridge’s citation to the submitted declaration is unavailing because Breckenridge never connects the conclusion of that experiment to the “free from” claims. In addition, other portions of the prosecution history work against Breckenridge’s position.

During prosecution, the ’729 patent applicant specifically disclaimed the US ’779 composition. In particular, the applicant disclaimed the structure of having acid core layer, an insulating layer, and an active substance layer all in one particle. D.I. 82-1 at PageID # 1403, # 1405 (“Having all three components in a single particle was necessary for the [US ’779 composition], and using two distinct particles as presently claimed would destroy the invention of [the US ’779].”). Here, the ’729 patent unmistakably disclaims the structure of the US ’779 and, thus, cannot claim a structure where the acid and active substance are in the same particle.

While the Court agrees with many of Hetero’s arguments against Breckenridge’s purported meaning of “free from,” Hetero’s own construction is a bridge too far. Hetero’s view of the meaning of the claim would take it one step further to “does not contain any amount of.” D.I. 82 at 34. Hetero cites *King Pharma* in support of its position, but the decision of *King Pharma* runs contrary to Hetero’s construction. In *King Pharma*, the Court construed “*free from* an opioid

agonist” as “does not contain an opioid agonist” while finding the construction “completely free of opioid agonist at all times” without merit. *King Pharma.*, 718 F. Supp. 2d at 714 (emphasis in original). The court held that there was no basis in the claim for “at all times” in the claims, the specification, or the prosecution history. *Id.*³ Likewise, for the phrase “free from” in the subject claim, there is no support in the claims, the specification, or the prosecution history for “amount of” to be added to “does not contain any.”

For its part, Hetero states that it could agree to the meaning of “free from” as “does not contain any” insofar as it does not provide Breckenridge “wiggle room.” D.I. 82 at 53. The Court is not providing any party wiggle room. Instead, the Court interprets the claim without “add[ing] a limitation not present in the claim itself.” *Nellcor Puritan Bennett v. Masimo Corp.*, 402 F.3d 1364, 1371 (Fed. Cir. 2005) (citation omitted).

For the foregoing reasons, the Court adopts the plain and ordinary meaning of “the first type of particles is free from” which is the first type of particles “does not contain any,” and the Court adopts the plain and ordinary meaning of “and is free from dabigatran etexilate” which is “and does not contain any dabigatran etexilate.”

³ The court also held that “completely” was redundant to “free from.” *King Pharma.*, 718 F. Supp. 2d at 714.

C. “mixing the first type of particles and the second type of particles with the at least one pharmaceutically acceptable excipient” / “a mixture of [two distinct types of particles and at least one pharmaceutically acceptable excipient]”

Claim Term	Breckenridge’s Construction	Hetero’s Construction	Court’s Construction
“mixing the first type of particles and the second type of particles with the at least one pharmaceutically acceptable excipient” ’729 patent (claim 6)	No construction necessary. Alternatively, “mixing two different types of particles and at least one pharmaceutically acceptable excipient.”	Plain and Ordinary meaning, i.e., mixing (1) the first type of particles and the second type of particles with (2) the at least one pharmaceutically acceptable excipient that is external to the two types of particles	Mixing the first type of particles and the second type of particles and the at least one pharmaceutically acceptable excipient where the at least one pharmaceutically acceptable excipient need not be external to the two types of particles prior to mixing
“a mixture of [two distinct types of particles and at least one pharmaceutically acceptable excipient]” ’729 patent (claims 11, 16)	No construction necessary. Alternatively, “a mixture of two different types of particles and at least one pharmaceutically acceptable excipient.”	Plain and Ordinary meaning, i.e., “a mixture consisting of (1) two distinct types of particles and (2) at least one pharmaceutically acceptable excipient that is external to the two types of particles.”	A mixture of the first type of particles and the second type of particles and the at least one pharmaceutically acceptable excipient where the at least one pharmaceutically acceptable excipient need not be external to the two types of particles prior to the mixing

As depicted above, Breckenridge contends that no construction is required to understand the meaning of either “mixing the first type of particles and the second type of particles with the at least one pharmaceutically acceptable excipient” from claim 1 of the ’729 patent or “a mixture of [two distinct types of particles and at least one pharmaceutically acceptable excipient]” from claims 11 and 16 of the ’729 patent. D.I. 82 at 54. Breckenridge alternatively contends that the

Court should construe (1) “mixing the first type of particles and the second type of particles with the at least one pharmaceutically acceptable excipient” to mean “mixing two different types of particles and at least one pharmaceutically acceptable excipient” and (2) “a mixture of [two distinct types of particles and at least one pharmaceutically acceptable excipient]” to mean “a mixture of two different types of particles and at least one pharmaceutically acceptable excipient.” D.I. 82 at 54.

Hetero, on the other hand, contends that the Court should adopt the plain and ordinary meaning of each term. D.I. 82 at 54. Hetero contends that the plain and ordinary meaning of each term means, respectively, “mixing (1) the first type of particles and the second type of particles with (2) the at least one pharmaceutically acceptable excipient that is external to the two types of particles” and “a mixture consisting of (1) two distinct types of particles and (2) at least one pharmaceutically acceptable excipient that is external to the two types of particles.” D.I. 82 at 54. The fundamental dispute between the parties is whether the at least one pharmaceutically acceptable excipient must be “external” to the first and second types of particles. For the reasons discussed below, the at least one pharmaceutically acceptable excipient need not be external to the two types of particles.

Claim 1 of the '729 patent recites “[a] composition comprising: a mixture of at least two distinct types of particles.” Claim 2 of the '729 patent, which depends on claim 1, recites “[t]he composition according to claim 1, further comprising at least one pharmaceutically acceptable excipient.” Claim 2 of the '729 patent therefore recites a composition comprising (1) “a mixture of at least two distinct types of particles” and (2) “at least one pharmaceutically acceptable excipient.” Notably, the *composition* of claim 2, and not necessarily the *mixture*, comprises the at least one pharmaceutically acceptable excipient. *See Renishaw PLC v. Marposs Societa' per*

Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998) (“The construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.”).

Claim 6 of the ’729 patent, which depends on claim 2, recites: “A process for the preparation of the composition according to claim 2, comprising the step of mixing the first type of particles and the second type of particles with the at least one pharmaceutically acceptable excipient.” (emphasis added).⁴ The parties debate whether “the at least one pharmaceutically acceptable excipient” from claim 6 must be external to the two types of particles. Breckenridge contends that the “plain language of” claim 6 encompasses an excipient “that is within (or part of) the particles.” D.I. 82 at 55. Hetero asserts that “if the excipient from claim 2 is already present in the two particles, there is nothing to mix with the two” types of particles. D.I. 82 at 58-59.

Breckenridge has the better approach. Critically, the term “mixing” does not mean “adding.” Compare claim 8 of the ’729 patent (reciting “adding a lubricant”) with claim 6 of the ’729 patent (reciting “mixing . . .”); *Starhome GmbH v. AT&T Mobility LLC*, 743 F.3d 849, 857-58 (Fed. Cir. 2014) (“The doctrine of claim differentiation is based on the common sense notion that different words or phrases used in separate claims are presumed to indicate that the claims

⁴ An isolated examination of claim 6 suggests different meanings that depend on the referent to which the preposition “with” applies, in that claim 6 could mean either (1) the step of mixing “the first type of particles and the second types of particles” with “the at least one pharmaceutically acceptable excipient,” or (2) the step of mixing “the first type of particles” and “the second types of particles with the at least one pharmaceutically acceptable excipient.” The former, upon which both parties base their proposed constructions, is the correct approach, including because there is no direct antecedent basis for “the second types of particles with the at least one pharmaceutically acceptable excipient.” See *In re Downing*, 754 F. App’x 988, 996 (Fed. Cir. 2018) (“A claim is indefinite when it contains words or phrases where the meaning is unclear, which may be the result of the lack of an antecedent basis.”); *B.E. Tech., LLC v. Twitter Inc.*, No. 20-cv-621-GBW, 2024 WL 579076, at *1 (D. Del. Feb. 13, 2024) (“Patent claims are presumed to be valid and definite.” (citing 35 U.S.C. § 282)).

have different meanings and scope.” (cleaned up)); *LIQWD, Inc. v. L'Oreal USA, Inc.*, No. 17-14-JFB-SRF, 2019 U.S. Dist. LEXIS 74203, at *8 (D. Del. May 2, 2019) (“Different words in a patent have different meanings and the same words have the same meaning.”).

If “the at least one pharmaceutically acceptable excipient” was already “added” to one or both of the two types of particles, that “addition” would not foreclose the “mixing” of the two types of particles with “the at least one pharmaceutically acceptable excipient.” This is because when the two particles are mixed together, “the at least one pharmaceutically acceptable excipient” is already included and, thus, satisfies the claim. Accordingly, the Court construes “mixing the first type of particles and the second type of particles with the at least one pharmaceutically acceptable excipient” to mean “mixing the first type of particles and the second type of particles and the at least one pharmaceutically acceptable excipient where the at least one pharmaceutically acceptable excipient need not be external to the two types of particles prior to mixing.”

A similar analysis extends to claims 11 and 16. Claim 11 recites “[a] composition consisting of a mixture of two distinct types of particles and at least one pharmaceutically acceptable excipient.” Claim 16 recites “[a] capsule containing a pharmaceutical composition consisting of a mixture of two distinct types of particles and at least one pharmaceutically acceptable excipient.”⁵ In each of these claims, if “the at least one pharmaceutically acceptable excipient” was already “added” to one or both of the two types of particles, that “addition” would not foreclose a “mixture” of the two distinct types of particles and the at least one pharmaceutically

⁵ Claim 11 is nearly identical to claim 2, except that claim 11 uses the word “consisting” and claim 2 uses the word “comprising.” See generally *Cias, Inc. v. All. Gaming Corp.*, 504 F.3d 1356, 1360-61 (Fed. Cir. 2007) (“In the patent claim context the term ‘comprising’ is well understood to mean ‘including but not limited to.’ . . . It is equally well understood in patent usage that ‘consisting of’ is closed-ended and conveys limitation and exclusion.”). Claim 16 is nearly identical to claim 11, except that claim 16 uses the word “capsule” while claim 11 uses the word “composition.”

acceptable excipient. Accordingly, the Court construes “a mixture of [two distinct types of particles and at least one pharmaceutically acceptable excipient]” to mean “a mixture of the first type of particles and the second type of particles and the at least one pharmaceutically acceptable excipient where the at least one pharmaceutically acceptable excipient need not be external to the two types of particles prior to the mixing.”

The Court’s constructions comport with various canons of claim construction. *See Nellcor Puritan Bennett*, 402 F.3d at 1371 (holding that claims “cannot” be construed “to add a limitation not present in the claim itself” (citation omitted)); *see also Phillips*, 415 F.3d at 1314 (“Because claim terms are normally used consistently throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims.”). The Court’s constructions are also consistent with the “most preferred embodiment,” in which “the said first type of particles comprising dabigatran etexilate mesylate . . . also comprise one or more excipients.” *See* ’729 patent 4:38-44.

Hetero’s case law does not help its construction. In particular, Hetero cites *Becton, Dickinson & Co. v. Tyco Healthcare Grp., LP*, 616 F.3d 1249 (Fed. Cir. 2010) for the proposition that where “a claim lists elements separately, the clear implication of the claim language is that those elements are distinct component[s] of the patented invention.” D.I. 82 at 58. The contemplated scenario where “the at least one pharmaceutically acceptable excipient” is added to one or both of the two types of particles, however, comports with, or at least does not violate, *Becton*, in that “the at least one pharmaceutically acceptable excipient” is still “distinct” from the other “component[s]” of the patented invention. *See Becton*, 616 F.3d at 1254. Hetero’s reliance on *Baxter Healthcare Corp. v. Nevakar Injectables, Inc.*, Nos. 12-1184-CJB, 21-1186-CJB, 2023 WL 4175261 (D. Del. Jun. 26, 2023) and *Purdue Pharm. Prods. L.P. v. Actavis Elizabeth LLC*,

No. 12-5311 (JLL)(JAD), 2015 WL 5032650 (D.N.J. Aug. 25, 2015) (D.I. 82 at 58) fails for the same reason.⁶

III. CONCLUSION

The Court will construe the disputed claim terms as described above. The Court will issue an Order consistent with this Memorandum Opinion.

⁶ The Court notes that the parties discuss the accused device in their briefing. *See, e.g.*, D.I. 82 at 62 (“According to Hetero, its product ‘contains only dabigatran and tartaric acid particles without any excipient that keeps those particles separate from one another.’” (citation omitted)). The Court did not, however, construe the claims with reference to the accused device. *See Wilson Sporting Goods Co. v. Hillerich & Bradsby Co.*, 442 F.3d 1322, 1330 (Fed. Cir. 2006) (explaining that “claims may not be construed with reference to the accused device” (quoting *NeoMagic Corp. v. Trident Microsystems, Inc.*, 287 F.3d 1062, 1074 (Fed. Cir. 2002))).