IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SCALE BIOSCIENCES, INC. and ROCHE SEQUENCING SOLUTIONS, INC.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 22-1597-CJB
PARSE BIOSCIENCES, INC.,	)	
Defendant.	)	
PARSE BIOSCIENCES, INC. and UNIVERSITY OF WASHINGTON,	)	
Counterclaim-Plaintiffs,	)	
v.	)	
SCALE BIOSCIENCES, INC.,	)	
Counterclaim-Defendant.	)	

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MEMORANDUM OPINION

October 8, 2025
Wilmington, Delaware

Christopher J. Burke

BURKE, United States Magistrate Judge

In this action filed by Plaintiff and Counterclaim-Defendant Scale Biosciences, Inc. (hereafter, "Scale" or "Plaintiff") against Defendant and Counterclaim-Plaintiff Parse Biosciences, Inc. (hereafter, "Parse" or "Defendant"), Plaintiff alleges infringement of United States Patent Nos. 10,626,442 (the "'442 patent"), 10,982,256 (the "'256 patent"), 11,512,341 (the "'341 patent"), and 11,634,752 (the "'752 patent," and collectively, the "asserted patents" or "patents-in-suit"). Presently before the Court[1] is Defendant's Motion for Summary Judgment of Invalidity under 35 U.S.C. § 112(a) ("Section 112(a)") with respect to the '752, '442, and '256 patents (collectively, the "patents at issue"), filed pursuant to Federal Rule of Civil Procedure 56 ("Motion"). (D.I. 314)

In this Memorandum Opinion, the Court will address the Motion as it relates to the '752 patent. For the reasons set forth below, the Motion is GRANTED as to that patent.

I. BACKGROUND

A. Procedural Background

Plaintiff commenced this action on December 14, 2022; its Complaint then asserted various claims for direct and indirect infringement of the '442 patent, the '256 patent, and the '341 patent. (D.I. 1)[2] Plaintiff filed a First Supplemental Complaint on August 30, 2023, which

[1] The parties have jointly consented to the Court's jurisdiction to conduct all proceedings in this case, including trial, the entry of final judgment, and all post-trial proceedings. (D.I. 12)

[2] When Scale filed the initial Complaint in December 2022, it initially also listed Roche Sequencing Solutions, Inc. ("Roche") as a Nominal Defendant. (D.I. 1 at ¶ 3; D.I. 325 at 3) The initial Complaint explained that Roche is the owner of the asserted patents (albeit one that, at that time, had not yet agreed to join as a party in the action); it also noted that Scale is the exclusive licensee of those patents. (D.I. 1 at ¶¶ 2-3) Subsequently, on May 3, 2023, Roche re-aligned as a Plaintiff in this case. (D.I. 53; D.I. 325 at 3) That said, because the relevant

is the operative complaint in this case; it there added claims of direct and indirect infringement of the '752 patent. (D.I. 70) With regard to the First Supplemental Complaint, on August 30, 2023, Parse filed an Answer and Parse, along with University of Washington, filed certain operative counterclaims against Scale. (D.I. 71)[3]

The Court held a *Markman* hearing on December 15, 2023. (D.I. 114) Between January 18, 2024 and September 5, 2024, the Court issued various orders regarding claim construction. (D.I. 118-19; D.I. 121; D.I. 126; D.I. 239; D.I. 241)

Defendant filed the instant Motion on February 24, 2025—the same date that the parties each filed various other summary judgment and *Daubert* motions. (D.I. 314) The Motion was fully briefed as of April 17, 2025. (D.I. 395) The Court heard oral argument on the portion of the Motion discussed herein on June 12, 2025. (D.I. 419 (hereinafter, "Tr."))

B. Factual Background

At present, Plaintiff is asserting infringement of claim 11 of the '442 patent, claims 1-2, 6-11, and 14 of the '752 patent, claims 1-2 and 5-6 of the '256 patent, and claim 13 of the '341 patent (collectively, the "asserted claims," and without claim 13 of the '341 patent, the "claims at issue"). (D.I. 325 at 1; D.I. 329, ex. 32; D.I. 439) The three patents at issue, which share a common specification, (D.I. 325 at 4), are generally directed to "methods, compositions, kits and devices for the detection of target molecules" in a sample of cells. (*See, e.g.*, '256 patent,

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answering brief here was filed solely by Scale, (*see, e.g.*, D.I. 366), because the Motion only relates to claims brought by Plaintiffs against Parse, and for ease of reference, herein when the Court refers to the non-movant, it has and will simply refer to "Scale" by name or as "Plaintiff."

[3] As a result, Parse and the University of Washington are Counterclaim-Plaintiffs in this case as well. That said, because the instant Motion only relates to claims brought against Parse, herein when the Court refers to the movant, it will simply refer to "Parse" by name or as "Defendant."

Abstract)[4] The inventions described therein are said to address the need for "accurate and sensitive detection, identification and quantification of target molecules in every cell of a complex population to retain specific information regarding that target molecule." (*Id*., col. 1:44-48)

Plaintiff asserts that Defendant infringes each of the asserted claims by making, selling, offering for sale, and using what at least Plaintiff describes as 19 different kits (and 19 other add-on products and services) for labeling target molecules within cells (the "accused products" or "accused kits"). (D.I. 307 at 3; *see also* D.I. 70 at ¶¶ 15-26, 34-156; *but see* D.I. 326, ex. 12 at ¶ 36, 38-40) The accused kits may be used to perform split pool combinatorial barcoding of a whole transcriptome. (D.I. 328, ex. 10 at ¶ 109; D.I. 326, ex. 12 at ¶ 338) Transcriptome sequencing allows researchers to analyze the mRNA, among other target molecules, within the cell, (D.I. 326, ex. 12 at ¶¶ 38, 337-38), and such a process is facilitated by labeling target molecules with barcodes, as described in the methods claimed in the asserted patents, (*id.* at ¶¶ 20-22).

Certain aspects of the Motion relate to the claim term "unique binding agent" ("UBA"). The Court previously construed "UBA" as used in the asserted patents to mean "a molecule or assembly that is designed to bind with at least one target molecule, at least one target molecule surrogate, or both[.]" (D.I. 118; *see also* '442 patent, col. 17:18-20)[5] Per the shared patent

[4] The asserted patents are found in various places on the docket, including at D.I. 328, Exhibits 1-4. Hereafter, the Court will cite to these patents simply by their number.

[5] Relatedly, the Court construed the term "target molecules" as used in the patents at issue to mean "molecules of interest . . . that are being detected or quantified." (D.I. 119; *see also id*. (noting both parties agreed that the term has this meaning, but that a remaining possibly disputed issue was whether target molecules are ones with a "known individual identity") (citing D.I. 114 at 93, 106-07))

specifications, a UBA can be, *inter alia*, an aptamer or an antibody. (*See, e.g.*, '442 patent, cols. 4:18-20, 5:42-44, 7:27-29, 11:42-44, 17:66, 19:18; D.I. 315 at ¶¶ 2, 4)

Additional facts relevant to resolution of the instant Motion will be discussed in Section III.

II. STANDARD OF REVIEW

A. Summary Judgment

Summary judgment is appropriate where "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party bears the burden of demonstrating the absence of a genuine issue of material fact. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 585 n.10 (1986). If the moving party has sufficiently demonstrated the absence of such a dispute, the nonmovant must then "come forward with specific facts showing that there is a genuine issue for trial." *Id*. at 587 (internal quotation marks, citation, and emphasis omitted). If the nonmoving party fails to make a sufficient showing in this regard, then the moving party is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). During this process, the Court will "draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence." *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000).

However, in order to defeat a motion for summary judgment, the nonmoving party must "do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co.*, 475 U.S. at 586. The "mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact." *Anderson v.*

Liberty Lobby, Inc., 477 U.S. 242, 247-48 (1986). Facts that could alter the outcome are "material," and a factual dispute is "genuine," only where "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id*. at 248. "If the evidence is merely colorable . . . or is not significantly probative . . . summary judgment may be granted." *Id*. at 249-50 (internal citations omitted).

A party asserting that a fact cannot be—or, alternatively, asserting that a fact is—genuinely disputed must support the assertion either by "citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials" or by "showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact." Fed. R. Civ. P. 56(c)(1)(A) & (B).

B. Claim Construction

The Court has often set out the relevant legal standards for claim construction, including in opinions addressing a motion for summary judgment; one such opinion was *Glaxo SmithKline LLC v. Glenmark Pharms. Inc., USA*, Civil Action No. 14-877-LPS-CJB, Civil Action No. 14-878-LPS-CJB, 2017 WL 8948972, at *3-4 (D. Del. May 24, 2017), *report and recommendation adopted,* 2017 WL 2493786 (D. Del. June 9, 2017). The Court hereby incorporates by reference its discussion in *Glaxo SmithKline LLC* of these legal standards and will follow them herein. To the extent consideration of the disputed terms here necessitates discussion of other, related legal principles, the Court will address those principles in Section III below.

C. Invalidity

A patent granted by the United States Patent and Trademark Office ("PTO") is presumed to be valid. 35 U.S.C. § 282(a); *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 100-03 (2011). The rationale underlying this presumption of validity is that "the PTO, in its expertise, has approved the claim[.]" *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 426 (2007). The burden of proving invalidity always rests with the patent challenger, who must establish a patent's invalidity by clear and convincing evidence in order to prevail. *Microsoft Corp.*, 564 U.S. at 95. Clear and convincing evidence places within the mind of the fact finder "an abiding conviction that the truth of [the] factual contentions are highly probable." *Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009) (quoting *Colorado v. New Mexico*, 467 U.S. 310, 316 (1984)).

III. DISCUSSION

As to the portion of its Motion at issue here, Defendant argues that the '752 patent is invalid for lack of written description and lack of enablement. (D.I. 325 at 4-19; D.I. 395 at 1-6) Below, the Court will first set out some general legal principles relating to an assessment of the written description and enablement requirements at the summary judgment stage. Thereafter, it will address the invalidity arguments that Defendant makes concerning the '752 patent.

A. Legal Standards Regarding Written Description and Enablement

Section 112(a) of the Patent Act mandates that every patent "shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same[.]" 35 U.S.C. § 112(a). This provision imposes two separate requirements—the "written description" requirement and the "enablement" requirement. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1344 (Fed.

Cir. 2010) (en banc); *Puma Biotechnology, Inc. v. AstraZeneca Pharms. LP*, 723 F. Supp. 3d 327, 341 (D. Del. 2024).

To satisfy Section 112(a)'s written description requirement, the patent's disclosure must "reasonably convey[] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharms.*, 598 F.3d at 1351; *see also Vasudevan Software, Inc. v. MicroStrategy, Inc.*, 782 F.3d 671, 682 (Fed. Cir. 2015). In other words, because the purpose of the written description requirement is "to ensure that inventors have actually invented the subject matter claimed[,]" *Ariad Pharms.*, 598 F.3d at 1342, the requirement relates to whether the specification "allow[s] a person[] of ordinary skill in the art [a 'POSITA'] to recognize that [the patent applicant] invented what is claimed[,]" *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991); *see also Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1163 (Fed. Cir. 2019); *Natera, Inc. v. CareDx, Inc.*, 767 F. Supp. 3d 144, 150 (D. Del. 2025) (setting forth various ways in which a patentee may satisfy the written description requirement). Whether a claim is supported by an adequate written description is a question of fact. *AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1297 (Fed. Cir. 2014).

To satisfy the enablement requirement of Section 112(a), "the specification must enable the full scope of the invention as defined by its claims." *Amgen Inc. v. Sanofi*, 598 U.S. 594, 610 (2023); *Spinal Generations, LLC v. Depuy Synthes, Inc.*, Civil Action No. 22-1368-CFC, 2025 WL 1100627, at *1 (D. Del. Apr. 11, 2025). That is, "the specification of a patent must teach those skilled in the art how to make and use the full scope of the patented invention without undue experimentation." *Baxalta Inc. v. Genentech, Inc.*, 81 F.4th 1362, 1365 (Fed. Cir. 2023) (internal quotation marks and citation omitted); *see also Genentech, Inc. v. Novo Nordisk A/S*,

108 F.3d 1361, 1365 (Fed. Cir. 1997). So "[i]f a patent claims an entire class of processes, machines, manufactures, or compositions of matter, the patent's specification must enable a person skilled in the art to make and use the entire class." *Amgen*, 598 U.S. at 610; *see also id*. at 613 ("[T]he more a party claims, the broader the monopoly it demands, the more it must enable"). "Enablement is a legal question based on underlying factual determinations." *Vasudevan Software*, 782 F.3d at 684.

B. Analysis

As was noted above, with regard to the '752 patent, Plaintiff asserts independent claim 1 and dependent claims 2, 6-11, and 14 (all of which depend from claim 1). Below, the Court will first set out the parties' arguments for and against invalidity. Thereafter, it will assess the merits.

1. The Parties' Arguments

As to this patent, Defendant's multi-step argument for invalidity goes as follows:

> (1) The asserted claims of the '752 patent encompass UBAs.;
>
> (2) The patent's specification together with the Court's prior claim construction explains that UBAs may be, among other things, antibodies and aptamers, and that they have the ability to specifically bind to target molecules.;
>
> (3) Therefore, UBAs that are antibodies and aptamers and that have the above-referenced functionality are within the full scope of the claims at issue.; but
>
> (4) The '752 patent "is fatally lacking written description for the full scope of UBAs that are capable of binding to the full scope of targets within or on the full scope of cells" and "fails to comport with the enablement requirement given the vast breadth of the asserted claims and their functional requirements."

(D.I. 325 at 4-5)

In response (and as is further noted below), Plaintiff does not challenge the assertion that the full scope of all antibodies and aptamers that could function as UBAs are not fully described or enabled in the '752 patent. (Tr. at 97, 102, 111; *see also* D.I. 395 at 1; *see generally* D.I. 366 at 1-16) Rather, Plaintiff asserts that UBAs are not encompassed within the scope of claim 1 (and similarly claims 2, 6-11, and 14)—and so the specification need not describe or enable them. (D.I. 366 at 1-2, 7-9; Tr. at 116-17)

The parties' dispute here particularly implicates the language of asserted claim 1 and unasserted claim 5 in the '752 patent. Those claims recite as follows (with relevant language set off in italics):

> **1**. A kit for split-pool barcoding target molecules that are in or on cells or cell organelles, comprising:
>
> (i) at least *two sets of assayable polymer subunit (APS) oligonucleotides*, wherein each set comprises at least 10 APS oligonucleotides that each comprise:
>
> a 5' end sequence that is common to the APS oligonucleotides in the set,
>
> a 3' end sequence that is common to the APS oligonucleotides in the set, and
>
> an internal sequence that distinguishes the APS oligonucleotides in the set from one another, and
>
> (ii) one or more linking oligonucleotides, wherein a linking oligonucleotide is complementary to the 5′ end sequence of the APS oligonucleotides of one set and the 3′ end sequence of the APS oligonucleotides of another set,
>
> wherein the *APS oligonucleotides* from different sets are configured to link together in an ordered fashion in the presence of the one or more linking oligonucleotides to form all or part of a cell or organelle origination barcode.

> **5**. The kit of claim **1**, wherein the *APS oligonucleotides of at least one of the sets of APS oligonucleotides comprise a unique binding agent (UBA)*.

('752 patent, cols. 57:50-58:3, 58:14-16 (emphasis added))

As can be seen above, the kit of claim 1 recites and includes at least two sets of "APS oligonucleotides," and claim 5 appears to further limit the kit of claim 1 by stating that the "APS oligonucleotides of at least one of the sets of APS oligonucleotides [described in claim 1] comprise a . . . UBA[.]" (*Id*.) The Court has not previously construed the term "APS oligonucleotides." Earlier in the case, the parties presented the term "assayable polymer subunit (APS)" for construction. There, Plaintiffs' proposed construction was "component(s) of a molecular complex that provide a package of information" and Defendant's was "detectable components such as polymer subunits or small molecules that can be linked to each other within a COB [(cell originating barcode)]." (D.I. 239) The Court rejected inclusion of certain aspects of Defendant's proposal in any construction (i.e., "such as polymer subunits or small molecules" and "can be linked to each other within a COB"); it otherwise ruled that the term should simply be afforded its plain and ordinary meaning. (*Id*.)

Plaintiff's argument against invalidity here is that, as to the asserted claims of the '752 patent: (1) it is only necessary for the patent to describe and enable what is claimed by the language of claim 1; and (2) because claim 1 only facially or expressly recites "APS oligonucleotides"—a term that does not encompass or include UBAs—this means that UBAs need not be fully described or enabled in the patent in order for the asserted claims to be valid (instead, only "APS oligonucleotides" need be fully described and enabled). (D.I. 366 at 1-9; *see also* Tr. at 115-19)

Above, the Court noted that in cases like *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (en banc), the United States Court of Appeals for the Federal Circuit has explained that in order to satisfy the written description requirement, the patent must "reasonably convey[] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date[,]" 598 F.3d at 1351, and that in *Amgen Inc. v. Sanofi*, 598 U.S. 594 (2023), the United States Supreme Court has explained that to satisfy the enablement requirement, "the specification must enable the full scope of the invention as defined by its claims[,]" 598 U.S. at 610. And so here, the dispute boils down to whether UBAs fall within the "claimed subject matter" and the "full scope" of claim 1 (and the other asserted claims)—such that they must be described pursuant to *Ariad* and enabled under *Amgen*.

2. The Merits

With the parties' positions now set out, the Court turns to the merits. In doing so, the Court will first explain why it concludes that the scope of what is claimed in claim 1 encompasses UBAs—such that the patent must describe and enable UBAs in order for the asserted claims to be valid. Next, the Court will analyze a key case that Plaintiff heavily relies on in making a contrary argument— *In re Entresto*, 125 F.4th 1090 (Fed. Cir. 2025)—and explain why the case does not help Plaintiff here. Lastly, the Court will then apply the appropriate written description and enablement analysis to the asserted claims, explaining why the Motion must be granted when doing so.

a. The scope of what is claimed in claim 1 encompasses UBAs, such that in order for the asserted claims to avoid invalidity pursuant to the written description and enablement doctrines, the patent must fully describe and enable UBAs.

As an initial matter, the Court observes that the parties' core dispute here is about the scope of claim 1. Therefore, the dispute implicates the need for claim construction. This is

because "[t]he words of the claims define the scope of the patented invention." *Computer Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366, 1373 (Fed. Cir. 2008); *see also Cont'l Paper Bag Co. v. E. Paper Bag Co.*, 210 U.S. 405, 419 (1908) ("[T]he claims measure the invention.") (*quoted in Amgen*, 598 U.S. at 610).[6] Therefore, the "scope of what is claimed (and what must be adequately described [and enabled]) is, in turn, determined through claim construction." *In re Entresto*, 125 F.4th 1090, 1098 (Fed. Cir. 2025) (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc)).[7]

Federal Circuit law on claim construction establishes that a court's clear presumption should be that "[b]y definition, an independent claim is broader than a claim that depends from it, so if a dependent claim reads on a particular embodiment of the claimed invention, the corresponding independent claim must cover that embodiment as well." *Littelfuse, Inc. v. Mersen USA EP Corp.*, 29 F.4th 1376, 1380 (Fed. Cir. 2022); *see also Alcon Rsch., Ltd. v. Apotex Inc.*, 687 F.3d 1362, 1367 (Fed. Cir. 2012) ("It is axiomatic that a dependent claim cannot

[6] Because the parties' dispute hinges on the meaning and scope of claim language, as opposed to adequacy of the patents' disclosures, the scope question must be resolved by the Court, not the jury. *See O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008) ("When the parties present a fundamental dispute regarding the scope of a claim term, it is the court's duty to resolve it."); *Puma Biotechnology*, 723 F. Supp. 3d at 347.

[7] *See also e.g.*, *Atl. Rsch. Mktg. Sys., Inc. v. Troy*, 659 F.3d 1345, 1354 (Fed. Cir. 2011) ("[C]laim construction is inherent in any written description analysis.") (internal quotation marks and citation omitted); *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 959 F.3d 1091, 1101 (Fed. Cir. 2020) (observing that "under the governing claim construction [] the claim term embraced [a specific element, and t]he enablement question, then, was a concrete one: whether the 'specification did not enable the full scope of the invention because it did not enable [that element]'") (citation omitted); *Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1194-95 (Fed. Cir. 1999) (reviewing a district court's claim construction, which in turn set out the scope of the relevant claim for purposes of an enablement determination).

be broader than the claim from which it depends.").[8] Relatedly, "where dependent claims have no meaningful difference [from the independent claim] other than an added limitation, . . . construing the independent claim to exclude material covered by the dependent claim would be inconsistent." *Trs. of Columbia Univ. in City of New York v. Symantec Corp.*, 811 F.3d 1359, 1370 (Fed. Cir. 2016). As a result, courts will at times look to dependent claims in articulating the scope of the independent claim from which the dependent claims depend. *See, e.g.*, *Alcon Rsch.*, 687 F.3d at 1367 (concluding that "the concentrations recited in the . . . patent's dependent claims must necessarily meet claim 1's limitations of therapeutically effective for treating allergic eye disease"); *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1242 (Fed. Cir. 2003) ("If the dependent claims expressly recite 'up to about 10%' silicon, then the independent claims, which must be at least as broad as the claims that depend from them, must include aluminum coatings with 'up to about 10%' silicon.").[9]

Here, again, dependent claim 5 of the '752 patent recites the "kit of claim 1, wherein the *APS oligonucleotides* of at least one of the *sets of APS oligonucleotides* [referenced in claim 1] *comprise a unique binding agent (UBA)*." ('752 patent, col. 58:14-16 (emphasis added)) And as articulated above, the parties currently have a dispute about claim 1's scope, in light of this language. Defendant's position is that because claim 5 depends on claim 1, and claim 5 defines

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[8] *See also, e.g.*, *Baxalta Inc. v. Genentech, Inc.*, 972 F.3d 1341, 1345-46 (Fed. Cir. 2020) (assessing the district court's claim construction of the term "antibody" in a patent's independent claim 1, and holding that the court's construction was faulty, as it excluded certain embodiments of what an antibody could be that were claimed in certain dependent claims, such that the "dependent claims confirm[ed] that 'antibody' [was] not so limited"); *Intamin Ltd. v. Magnetar Techs., Corp.*, 483 F.3d 1328, 1335 (Fed. Cir. 2007) ("An independent claim impliedly embraces more subject matter than its narrower dependent claim.").

[9] *See also Shire ViroPharma Inc. v. CSL Behring LLC*, Civil Action No. 17-414, 2019 WL 6118253, at *6-7 (D. Del. Nov. 18, 2019); *Merck Sharp & Dohme Corp. v. Hospira Inc.*, 221 F. Supp. 3d 497, 520 (D. Del. 2016).

"APS oligonucleotides" as "compris[ing]" a UBA, then the scope of claim 1 must encompass APS oligonucleotides comprising (i.e., including) UBAs. (D.I. 325 at 5 ("Claim 1's APSs therefore encompass APSs comprising UBAs.")) Conversely, Plaintiff's position is that claim 5's reference to a UBA recites an *additional*—i.e., an "optional" and "separate"—element of the invention; Plaintiff is thus arguing that "APS oligonucleotides and UBAs are separate things[,]" such that UBAs do not have to be enabled or described for the asserted claims to be valid. (Tr. at 132-34, 136-37, 148; D.I. 366 at 2; *see also* Tr. at 118-19)

The Court sides with Defendant here. It explains why below.

Pursuant to the claim construction principles set out above, claim 5 should be read to narrow what can make up the "APS oligonucleotides" referenced therein (i.e., of at least one of the sets of APS oligonucleotides recited in claim 1). It does so by specifying that these APS oligonucleotides "comprise a UBA[.]" ('752 patent, col. 58:15-16) In other words, the way someone typically reading a patent like this would understand claims 1 and 5, read together, is that: (1) claim 1's reference to a set of "APS oligonucleotides" is a reference to an item that can encompass within its scope a UBA; and (2) that claim 5 is now requiring that at least one set of such "APS oligonucleotides" *must* include a UBA. (Tr. at 99-100; D.I. 325 at 5)

This understanding comports with the reality that, in patent law, "'[c]omprising' is a term of art used in claim language which means that the named elements are essential, but other elements may be added[.]" *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501 (Fed. Cir. 1997); *see In re Crish*, 393 F.3d 1253, 1257 (Fed. Cir. 2004).[10] Claim 5's use of "comprise" tells us

[10] Plaintiff asserts to the contrary that the fact that claim 5 reads "APS oligonucleotides . . . comprise a . . . UBA[,]" '752 patent col 58:14-16, indicates that the word "comprise" is teaching that a UBA is an "additional component" that is now required to be "joined to" the "APS oligonucleotides"—i.e., that APS oligonucleotides and UBAs described here are separate things. (Tr. 135-37) The Court disagrees. Such a reading would contravene

that it is "essential" that the APS oligonucleotides referred to in that claim must include a UBA. If claim 5 teaches that at least one of the sets of APS oligonucleotides discussed in claim 1 must comprise (or include) a UBA, then claim 1 must encompass a set of APS oligonucleotides that includes a UBA. (Tr. at 100, 148; D.I. 325 at 5); *see also Littelfuse, Inc.*, 29 F.4th at 1380.

This conclusion also aligns with the claim construction principle that where a dependent claim is different from its independent claim because it adds a limitation, then the independent claim should not be construed to exclude the material covered by the dependent claim. *Trs. of Columbia Univ. in City of New York.*, 811 F.3d at 1370. Here, as the Court has construed them,

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traditional claim construction principles about what the use of the term "comprise" is meant to indicate in this context (i.e., that here, UBAs are within the scope of what at least one set of the APS oligonucleotides of claim 1 can include). *See, e.g.*, *Phillips Petroleum Co. v. Huntsman Polymers Corp.*, 157 F.3d 866, 874 (Fed. Cir. 1998) ("The use of 'comprising' and 'which comprises' in the composition . . . claims generally would mean that the claims require the presence of [the elements recited thereafter], but that additional elements . . . may be present."); *Curia IP Holdings, LLC v. Salix Pharms., Ltd.*, Civil Action No. 21-19293 (ES) (JRA), 2024 WL 4039583, at *13 (D.N.J. Sept. 4, 2024) (observing the term "comprises," as used in a claim before defining a chemical composition, was a "term of art in patent law that mean[s] 'including' or 'including but not limited to'") (quoting *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1319 (Fed. Cir. 2009)); *see also* Manual of Patent Examining Procedure ("MPEP") § 2111.03(I) ("The transitional term 'comprising' . . . is synonymous with 'including,' containing,' or 'characterized by[.]'") (collecting cases). Plaintiff's interpretation of "comprising" is more akin to the meaning of the phrase "*further* comprises" or "*further* comprising." *See, e.g.*, *Baxter Healthcare Corp. v. Nevakar Injectables, Inc.*, Civil Action No. 21-1184-CJB, Civil Action No. 21-1186-CJB, 2023 WL 4175261, at *4 (D. Del. June 26, 2023) ("Federal courts have noted that the addition of 'further comprises' before an additional term . . . can also signal that the additional term is something separate and apart from what came before it.") (collecting cases); *see also HTC Corp. v. IPCom GmbH & Co., KG*, 667 F.3d 1270, 1275 (Fed. Cir. 2012) ("[T]he drafter likely would have followed the recitation of the mobile station in paragraph 7 with 'further comprising' instead of 'comprising' to signal that *additional* modification would be attached to the mobile station."); (Tr. at 128 (Plaintiff's counsel asserting that claim 5 is the same as a dependent claim that makes reference to an independent claim to an invention comprising "A, B, and C" and then states "wherein the invention *further comprises* [element] D.") (emphasis added)). But claim 5 does not use the wording "further comprises." (*See* Tr. at 99-100) Nor does claim 5 claim "The kit of claim **1**, further comprising a UBA" or "The kit of claim **1**, additionally including a UBA" or language to that effect.

claims 1 and 5 follow this rule. Claim 5 requires that at least one of the sets of APS oligonucleotides referenced therein *must* include a UBA—whereas claim 1's scope encompasses sets of APS oligonucleotides that *can* include UBAs. *See Shire ViroPharma Inc. v. CSL Behring LLC*, Civil Action No. 17-414, 2019 WL 6118253, at *6-7 (D. Del. Nov. 18, 2019) (holding that where independent claim 1 recited a method of treatment and a dependent claim recited a specific type of result from the treatment (i.e., a reduction in the severity and/or number of HAE attacks), then since "a dependent claim cannot be broader [than] the independent claim from which it depends, it stands to reason the method of claim 1 . . . must include treatment that 'results in at least a reduction in the severity and/or number of HAE attacks'") (citations omitted). To find otherwise would result in an inconsistent reading of the claim language, as it is written. *See Trs. of Columbia Univ. in City of New York*, 811 F.3d at 1370. And nowhere in its briefing did Plaintiff demonstrate that there is a good reason to rebut or jettison the claim construction principles set out above or show that the Court's reading of the relevant claim language otherwise cannot be correct.

Instead, during oral argument, in opposing the conclusion discussed above, Plaintiff's counsel asserted that "APS oligonucleotides" could not include a "UBA" because the two terms have been construed to perform different functions. (Tr. at 137-38) That is, counsel stated that the function of APS oligonucleotides is to "convey information" or to "carr[y] a packet of information that helps you determine where a target molecule came from" while a UBA's function is to "bind[] to one or more target molecules." (*Id.* at 137) But so far as the Court can tell, even in light of this, there is no reason why a "UBA" couldn't fall within the scope of what a set of "APS oligonucleotides" can be understood to refer to in the asserted kit claims of the '752 patent. Both UBAs and APS oligonucleotides can be the same type of molecule. (*Compare* '752

patent, col. 19:25-27 ("In some embodiments, the UBA is an aptamer. Aptamers include nucleic acid aptamers (i.e., single-stranded DNA molecules[].") *with id*., col. 37:31 ("The APS can be specific strands of DNA[.]")) So, it could be the case that while "APS oligonucleotides" refers to an item that conveys or provides a package of information, that term—as the patentee used it in claim 1 and claim 5—is *also* broad enough to include within its scope a component (i.e., a UBA) that permits the execution of an *additional* function (i.e., binding).

Nor does it seem unreasonable to conclude that claim 1 was meant to claim a kit that can include a UBA. As Defendant persuasively points out, it makes sense that claim 1 could encompass UBAs because a UBA's defined function is to bind target molecules—i.e., making UBAs the thing contemplated by the patent that is supposed to associate or bind claim 1's "cell or organelle origination barcode[s]" to target molecules. (D.I. 395 at 4; *see also* '752 patent, col. 58:2-3; D.I. 108-1 at 3) Additionally, it is understandable to think that the patentee may have meant to include a UBA within the scope of claim 1's kit, because both sides agree that when it came to claim 5, the patentee surely claimed just that kind of kit (i.e., one that now requires a UBA).

With this all now established, opinions like the Federal Circuit's decision in *Alcon Rsch., Ltd. v. Apotex Inc.*, 687 F.3d 1362 (Fed. Cir. 2012) guide the remainder of the Court's analysis. In that case, independent claim 1 covered "[a] method for treating allergic eye disease in humans comprising stabilizing conjunctival mast cells by topically administering to the eye a composition comprising a therapeutically effective amount of [a pharmaceutical compound, olopatadine]." *Id*. at 1364. Dependent claim 2 was directed to the method of claim 1, wherein "the amount of [olopatadine] is from about 0.0001 w/v % to about 5% (w/v)." *Id*. at 1367. The Federal Circuit, noting that a dependent claim cannot be broader from the claim on which it

depends, found that if claim 2 covered the range from 0.0001 w/v % to 5% w/v, then claim 1 must cover at least that range. *Id*. And because a dependent claim typically narrows the claim from which it depends and must incorporate all of the limitations of the claim to which it refers, the *Alcon Rsch.* Court explained that that "the concentrations recited in the . . . patent's dependent claims must necessarily meet claim 1's limitations of being therapeutically effective for treating allergic eye disease by stabilizing conjunctival mast cells." *Id*. With this having been explained, the Federal Circuit then went on to assess enablement. *Id*. There, the patentee was arguing that some of the concentrations covered by claim 2 did not actually stabilize mast cells, such that the range recited in claim 2 was operative, but "just at a narrower concentration than the claimed range." *Id*. at 1368 (internal quotation marks and citation omitted). In rejecting this argument, the Federal Circuit explained:

> This is not how patent law works. When you claim a concentration range of 0.0001-5% w/v (as claim 2), you can't simply disavow the invalid portion and keep the valid portion of the claim. If everything up to 0.001% w/v is admittedly not enabled, then the entire claim is invalid. . . . Courts do not rewrite claims to narrow them for the patentee to cover only the valid portion. [The patentee] cannot have it both ways. Because claim 2 sets forth a concentration range, that range at a minimum must be included in claim 1, whatever its limitations. When analyzing the validity of claim 1 or claim 2, by the express claim language, the clinically relevant therapeutic amount must include 0.0001-5% w/v olopatadine.

Id.; *see also AK Steel Corp.*, 344 F.3d at 1242-44 (engaging in a similar claim construction analysis, and then going on to assess the evidence regarding enablement under the correct construction).

Applying *Alcon Rsch*. to the parties' dispute is straightforward in light of the content of the patent's claims and the Court's decisions above. That is, we know dependent claim 5 requires that "at least one of the sets of APS oligonucleotides comprise a [] UBA[.]" ('752

patent, col. 58:14-16) And above, the Court has concluded that claim 5's language means that that UBAs—and more specifically here, functional antibodies, aptamers, etc.—fall within the scope of the "APS oligonucleotides" described in claim 1. From there, *Alcon Rsch*. shows us that the '752 patent needs to disclose and teach a POSITA how to make and use such UBAs, in order to describe and enable the full scope of claim 1. (Tr. at 99, 133); *McRO, Inc.*, 959 F.3d at 1100 ("Once the precise scope of the claimed invention is defined, the question is whether undue experimentation is required to make and use the full scope of embodiments of the invention claimed."); *ABS Glob., Inc. v. Inguran, LLC*, 914 F.3d 1054, 1074 (7th Cir. 2019) (citing *Alcon Rsch*. and explaining that if a limitation in a dependent claim is not enabled, since this limitation necessarily would have fallen within the scope of the independent claim from which it depends, that means that the full scope of the independent claim is not enabled and that both claims are invalid).[11]

b. Plaintiff's reliance on *In re Entresto* is unavailing.

In arguing against the Court's conclusion above, Plaintiff relies heavily on *In re Entresto*. (D.I. 366 at 2-9) But for the reasons set out below, *In re Entresto* is not helpful to Plaintiff here.

In *In re Entresto*, the Federal Circuit assessed the adequacy of written description and enablement relating to a patent that claimed a pharmaceutical composition comprising the drug valsartan and the drug sacubitril, wherein the two drugs were "administered in combination[.]" *In re Entresto*, 125 F.4th at 1095. At the claim construction stage of the case, the parties' sole

[11] *See also Galderma Lab'ys, L.P. v. Amneal Pharms., LLC*, 337 F. Supp. 3d 371, 416-17 (D. Del. 2018) (agreeing with the defendant's argument that "because certain dependent claims . . . recite SR and once-daily formulations of [the pharmaceutical], the independent claims also encompass SR and once-daily formulations, and such formulations are part of the full scope the patents must enable"), *aff'd in part on other grounds, rev'd in part on other grounds,* 806 F. App'x 1007 (Fed. Cir. 2020).

dispute as to the relevant patent related to the phrase "in combination." *Id*. The defendants argued that term limited the claim to administration of valsartan and sacubitril "as two separate components . . . (i.e., in a non-complexed form, such as a physical mixture)[,]" while the plaintiff asserted that the term was broad enough to also include a "complex of non-covalently bonded valsartan and sacubitril[.]" *Id*. Because the specification was silent as to whether the compounds must be separate and not complexed, the district court gave "in combination" what it thought was the term's plain and ordinary meaning—meaning that it construed the term to encompass, *inter alia*, a complex of the drugs. *Id*. at 1095, 1098. Thereafter, the parties stipulated to infringement based on the court's construction covering complexes. *Id*. at 1099 & n.5.

The case then proceeded to a bench trial on certain validity-related issues, including lack of written description and enablement. *Id*. at 1095-96. As to those issues, the defendants argued that the patent must enable and describe valsartan and sacubitril as both a physical combination and as a complex, since the district court had construed the asserted claims to cover both, and since a patent must enable and describe the full scope of its claims. *Id*. at 1096. The plaintiff disagreed, arguing that a complex of the two drugs was an after-arising invention that need not be enabled or described, *id*. at 1097; in that regard, it was undisputed that the complexed form of valsartan and sacubitril was "not discovered until four years after the priority date" of the patent at issue, *id*. at 1098. The district court ultimately determined that: (1) because enablement is judged as of the priority date, later-existing state of the art may not be properly considered in the enablement analysis—and since complexes of the two drugs were unknown in the art as of the priority date, they need not have been enabled in the patent (and relatedly, that defendants had failed to sufficiently establish lack of enablement); and (2) as to written description, since it was

undisputed that the complexes were unknown to POSITA as of the relevant time period, they could not have been and were not disclosed in the patent—and that this meant that the claims were invalid for lack of written description. *Id*. at 1097.

On appeal, the Federal Circuit overturned the district court's finding of invalidity due to inadequate written description and affirmed the district court's finding of no invalidity on lack-of-enablement grounds. *Id*. at 1099. In discussing the written description issue (and the district court's related claim construction decision), the *In re Entresto* Court wrote as follows:

> The fact that the [] patent does not describe a complexed form of valsartan and sacubitril does not affect the validity of the patent. That complex—not discovered until four years after the priority date of the [] patent—is not what is claimed. By stating that the claims were "*construed to cover* complexes of valsartan and sacubitril," the district court erroneously conflated the distinct issues of patentability and infringement, which led it astray in evaluating written description. . . . Written description asks whether that which is claimed is adequately described. As we have explained:
>
> [C]laims are not construed "to cover" or "not to cover" the accused [product]. That procedure would make infringement a matter of judicial whim. It is only *after* the claims have been *construed without reference to the accused device* that the claims, as so construed, are applied to the accused device to determine infringement.
>
> *SRI Int'l v. Matsushita Elec. Corp. of America*, 775 F.2d 1107, 1118 (Fed. Cir. 1985).
>
> Here, after claim construction, [the defendants] stipulated to infringement of the as-construed claims.[] In light of that stipulation and the fact that the [] patent does not claim valsartan-sacubitril complexes, any further issue regarding such complexes is not before us.
>
> For those reasons, we hold that the district court clearly erred in finding that claims 1-4 of the [] patent are invalid for lack of written description. The patent has an adequate written description of what is claimed.

Id. at 1098-99 (emphasis in original). In a related footnote, the *In re Entresto* Court explained that to the extent that the defendants were maintaining that "the claims were construed to *claim* valsartan-sacubitril complexes (*i.e.*, to the extent [the defendants alleged] that [their] stipulation of infringement was made on that basis), that construction would have been error" because "[c]laim interpretation requires the court to ascertain the meaning of the claim to one of ordinary skill in the art *at the time of invention*." *Id*. at 1099 & n.5. Since "valsartan-sacubitril complexes were undisputedly unknown at the time of the invention [the patent] could not have been construed as claiming those complexes as a matter of law." *Id*.[12]

Following the same line of reasoning, the Federal Circuit upheld the district court's decision with regard to enablement, stating that "a specification must only enable the *claimed* invention." *Id*. at 1099. Because "the patent d[id] not claim as its invention valsartan-sacubitril complexes" and such complexes were "part of a later-existing state of art that may not be properly considered in the enablement analysis[,]" the *In re Entresto* Court agreed with the district court's holding that such later-discovered complexes need not be enabled (and thus that the claim was not invalid on lack-of-enablement grounds). *Id*. 1099-1100 (internal quotation marks omitted and citations omitted).

Having now set out the contours of the *In re Entresto* decision, the Court turns back to Plaintiff's argument about the opinion. That argument was difficult for the Court to

[12] At one point during the hearing on this portion of the Motion, Plaintiff's counsel suggested that the *In re Entresto* Court believed that the district court had construed the term at issue to include the complexed form of the drugs, and that the Federal Circuit had not taken issue with such a construction. (Tr. at 118) That appears to be incorrect, in light of the footnote from the Federal Circuit's opinion discussed above. *In re Entresto*, 125 F.4th at 1099 n.5; *see also* (Tr. at 106, 140).

understand—both after reading it in Plaintiff's briefing and after hearing it during oral argument on the Motion. But Plaintiff's argument appeared to include the following points:

- Plaintiff repeatedly asserted its view that the '752 patent does not need to fully describe and enable what the asserted claims "encompass" or "cover[]"; instead, it must fully describe and enable only the "invention defined by the limitation that those claims recite" or the "recited element[s]" of the asserted claims—i.e., "only what is 'claimed.'" (D.I. 366 at 3, 5-6, 8; Tr. at 120, 127, 129, 156-57)

- What does that distinction mean, in practice, to Plaintiff? Plaintiff's counsel further (somewhat confusingly, in the Court's view) described Plaintiff's position as meaning that "the invention claimed in [c]laim 1 must be enabled for its full scope, but the specification does not have to enable or describe everything that falls within the scope of [c]laim 1. In other words, everything that would infringe [c]laim 1." (Tr. at 116)

- As applied more specifically to the to the '752 patent, Plaintiff wrote in its briefing that "even if the [asserted claims of the '752 patent] cover a kit comprising a 'UBA,' as recited in unchallenged claim 5, UBAs are not part of the invention defined by [those asserted claims] and thus need not be described or enabled." (D.I. 366 at 8)

- The above understanding of what is and is not required by the written description and enablement doctrines, according to Plaintiff, is drawn from *In re Entresto*. Plaintiff notes that in that decision, the Federal Circuit stated that a patent must describe "whatever is now claimed[.]" (*Id*. at 3, 4 (emphasis omitted) (citing *In re Entresto*, 125 F. 4th at 1097)) And it asserts that *In re Entresto*'s conclusion was that "[b]ecause the 'complex' was not a recited element, it was not 'claimed,' so it did not need to be described or enabled, even if the claims covered a pharmaceutical composition comprising the complex[,]" (*id*. at 3 (citing *In re Entresto*, 125 F. 4th at 1097-1100)), or that "the lack of disclosure of the complexes '[did] not affect the validity of the patent' because '[t]hat complex . . . is not what is claimed[,]'" (*id.* at 4-5 citing *In re Entresto*, 125 F. 4th at 1097, 1098).

Again, the crux of Plaintiff's argument here was difficult for the Court to pin down. (*See, e.g.*, Tr. at 114-46, 155-57) It could be that all Plaintiff was trying to convey is that: (1) in a

claim (like claim 1) to a kit that is "comprising" certain listed required elements; (2) the patent need only describe and enable the full scope of kits that have the required elements set out in the claim; but (3) the patent does not need to describe or enable unlisted or "unclaimed" elements that might be found in an accused apparatus—i.e., characteristics that are not required to be in the apparatus in order for it to infringe, because they are not encompassed within any of the claim's elements. (D.I. 366 at 4 (citing *Lochner Techs., LLC v. Vizio, Inc.*, 567 F. App'x 931, 938-39 (Fed. Cir. 2014) for the premise that "there is no precedent requiring a patentee to disclose or enable unclaimed elements")) During oral argument on the Motion, at times Plaintiff's counsel suggested that this is what Plaintiff was driving at. There, counsel addressed a potential written description or enablement challenge: "[F]or a multi-element invention, a claim to an invention comprising A, B, and C will include within its scope an embodiment which is A, B, C, and D . . . [b]ut in order to [describe or] enable the claim to A, B, and C, you do not need to describe [or enable] that optional feature." (Tr. at 131; *see also id.* at 132) The Court certainly agrees with Plaintiff that this is the law. But in such a scenario, a party *would* need to describe and enable the invention as to the full scope of what *is* claimed—i.e., to the apparatus comprising A, B, and C. (Tr. at 110) And here, in light of the Court's claim construction analysis above, the UBA referenced in claim 5 is not something that was absent from claim 1 and was only separately added by the dependent claim. Instead, a UBA is a *part of* what *is encompassed* within the scope of the actual elements listed in claim 1 (i.e., a part of the "A, B, and C" of claim 1). And so the patent must describe and enable a kit that contains a set of APS oligonucleotides that include a UBA. (D.I. 395 at 1; Tr. at 148)

Otherwise, nothing about the decision in *In re Entresto* upsets the Court's conclusion here. Again, in that decision, the Federal Circuit noted that "[t]he scope of what is claimed (and

what must be adequately described) is, in turn, determined through claim construction." *In re Entresto*, 125 F.4th at 1098; *see also Idenix Pharms.*, 941 F.3d at 1156 n.3 ("We are tasked with deciding whether the claims, *as construed*, are enabled."). The Court reads *In re Entresto* as conveying that the scope of the key claim there did not include (i.e., that the patent did not "claim") complexes—and that this was demonstrated by the fact that the complex form of the claimed composition was an after-arising invention, which was "undisputedly unknown" at the time of the invention. *In re Entresto*, 125 F.4th at 1098-99 & n.5 (explaining that claim interpretation requires the Court to ascertain the meaning of a claim term to a POSITA "*at the time of the invention*"); (D.I. 395 at 4-6; Tr. at 103-04, 148, 153). In other words, the complex form was simply "not what [was] claimed" by the claims at issue, so the patent there did not need to enable or describe such complexes. *In re Entresto*, 125 F.4th at 1098; (D.I. 395 at 3). Nothing in *In re Entresto* suggests that if the scope of a required claim element includes a component, then a patent does not need to describe and enable that full scope of that claim—i.e., an embodiment that has such a component. (D.I. 395 at 1 (Defendant arguing that Plaintiff is wrong to suggest that "optional embodiments are excused from the written description and enablement requirements"))[13]

Here, in contrast, UBAs were known at the time of filing the '752 patent. More than that, UBAs were discussed in a significant portion of the patent's specification, and APS

[13] As was noted above, at one point in *In re Entresto*, the Federal Circuit faulted the district court for stating that the claims at issue were "construed to cover complexes of valsartan and sacubitril" and thus for "erroneously conflat[ing] the distinct issues of patentability and infringement[.]" 125 F.4th at 1098 (emphasis omitted, internal quotation marks and citation omitted); *see also* (D.I. 366 at 2, 7). The Court understands that portion of the *In re Entresto* decision simply to be stating that in assessing what must be enabled and described for validity purposes, the right focus is on what the claims *claim*—and not on the elements of an accused product.

oligonucleotides were *explicitly defined* in claim 5 as including UBAs. (Tr. at 107; '752 patent, cols. 17:23-20:33, 58:16) In all, *In re Entresto* is not contrary to the Court's conclusion that UBAs are encompassed within the full scope of claim 1 in the '752 patent and must be described and enabled by the patent.[14]

c. The asserted claims of the '752 patent are invalid for lack of written description and lack of enablement.

Now that it has been established that the '752 patent's specification must describe and enable UBAs for claim 1 to be valid, the remainder of the invalidity analysis can be summarized as follows:

> (1) UBAs include, *inter alia*, antibodies and aptamers designed to bind to at least one target molecule. ('752 patent, cols. 4:24-26, 5:48-50, 7:33-35, 9:49-52, 11:46-48, 17:24-34, 18:5-65; 19:25-20:14; D.I. 118);
>
> (2) Therefore, antibodies and aptamers that are capable of performing the requisite functionality must be described and enabled. (D.I. 395 at 1; *see* D.I. 366 at 9);
>
> (3) Defendant has provided ample evidence to support its argument that the asserted claims cover a vast number of antibodies and aptamers for targeting a vast number of target molecules, but that the patent's disclosure does not indicate how to determine or predict the full scope of which antibodies and aptamers will bind to which targets. ('752 patent, cols. 18:5-19:24, 19:28-35, 19:45-49; D.I. 328, ex. 11 at ¶¶ 88, 195; *id*., ex. 13 at ¶ 339; D.I. 329, ex. 18 at ¶¶ 48-49, 118, 129-30; *id*., ex. 19 at ¶¶ 68-71, 102, 124, 148-56;

[14] Plaintiff further relied on a few additional Federal Circuit opinions to support its arguments, (D.I. 366 at 4-9), but the cases are not helpful to Plaintiff's position. *See, e.g.*, *United Therapeutics Corp. v. Liquidia Techs., Inc.*, 74 F.4th 1360, 1369 (Fed. Cir. 2023) (holding that a method of treatment claim did not require enablement or description of "safety" and "efficacy" of the drug because "the claim language 'treating [a disease]' does not import additional safety and efficacy limitations"), *cert. denied,* 144 S. Ct. 873 (2024); *Lochner Techs., LLC*, 567 F. App'x at 938-39 (finding that unclaimed or unrecited elements need not be disclosed and enabled); *Allergan USA, Inc. v. MSN Lab'ys Priv. Ltd.*, 111 F.4th 1358, 1373 (Fed. Cir. 2024) (reversing a district court's finding of lack of written description, where an optional component of the claim was undisclosed).

> *id*. ex. 22 at 40-45, 47-48, 61, 67, 80-81, 84-86, 113-14, 122, 129, 134-36, 138-39, 145-48, 154; *id*., ex. 25 at 137-38); and
>
> (4) Plaintiff's sole evidence for enablement of the '752 patent are declarations of its expert, Dr. Peter Sims, which do not address enablement or description of UBAs, including antibodies or aptamers. (D.I. 383 at ¶¶ 33-35; *id*., ex. B at ¶¶ 263-90, 481-537; *see also* D.I. 366 at 9 (Plaintiff noting that its "evidence shows that the specification describes and enables the invention *defined by* the [claims at issue]") (emphasis added); Tr. at 97 (Defendant's counsel explaining that Plaintiff had not challenged Defendant's evidentiary basis for asserting invalidity here, and instead that Plaintiff's challenge was purely a legal one (i.e., as to whether UBAs are claimed in claim 1 and must be fully described and enabled)); D.I. 395 at 1, 4 (Defendant making the same point in its briefing))

As a result, there is no genuine dispute of material fact that the full scope of claim 1 is not sufficiently described or enabled. *See Amgen*, 598 U.S. at 613-15; *Baxalta Inc.*, 81 F.4th at 1366-67. And there is no question that the remaining asserted claims of the patent rise and fall with the decision as to claim 1. *See Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1377 (Fed. Cir. 1999) (explaining that with regard to an enablement inquiry like this one, the dependent claims "stand or fall together with" the independent claim from which they depend); *Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1198 (Fed. Cir. 1999) (same); (D.I. 395 at 2 (Defendant noting that there is "no dispute that the '752 patent's other claims rise and fall with claim 1" for purposes of this inquiry)).

IV. CONCLUSION

For the foregoing reasons, the Court concludes the claims at issue in the '752 patent are invalid for failing to satisfy the written description and enablement requirements of Section 112(a). It thus GRANTS Defendant's Motion as to that patent. An appropriate Order will issue.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SCALE BIOSCIENCES, INC. and ROCHE SEQUENCING SOLUTIONS, INC.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 22-1597-CJB
PARSE BIOSCIENCES, INC.,	)	
Defendant.	)	
PARSE BIOSCIENCES, INC. and UNIVERSITY OF WASHINGTON,	)	
Counterclaim-Plaintiffs,	)	
v.	)	
SCALE BIOSCIENCES, INC.,	)	
Counterclaim-Defendant.	)	

ORDER

At Wilmington, Delaware this **8th day of October, 2025**;

For the reasons stated in the Memorandum Opinion issued this same date, IT IS HEREBY ORDERED that Defendant Parse Biosciences, Inc.'s "Motion for Summary Judgment #1: The Asserted Claims of the '442, '752, and '256 Patents are Invalid for Lack of Written Description and Enablement[,]" (D.I. 314), filed pursuant to Federal Rule of Civil Procedure 56, is GRANTED as it relates to the '752 patent.

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE