

**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.	)	
	)	

Kelly E. Farnan and Sara M. Metzler, RICHARDS, LAYTON, & FINGER, PA, Wilmington, DE; Stephen S. Rabinowitz, WOLF, GREENFIELD, & SACKS, P.C., New York, NY; Chelsea A. Loughran, Stuart V.C. Duncan Smith, Emma L. Frank, and Arden E. Bonzo, WOLF, GREENFIELD, & SACKS, P.C., Boston, MA, Attorneys for Plaintiff and Counterclaim-Defendant Scale Biosciences, Inc.

Karen L Pascale and Robert M. Vrana, YOUNG CONAWAY STARGATT & TAYLOR LLP, Wilmington, DE; Byron L. Pickard, R. Wilson Powers III, Chandrika Vira (argued), Christopher M. Gallo, Brady P. Gleason, David Y. Wang, Louis P. Panzica, Jr., Ryan N. Kaiser, and Cristen A. Corry, STERNE, KESSLER, GOLDSTEIN & FOX, P.L.L.C., Washington, D.C., Attorneys for Defendant and Counterclaim-Plaintiff Parse Biosciences, Inc. and Counterclaim-Plaintiff University of Washington.

MEMORANDUM OPINION

November 4, 2025
Wilmington, Delaware

Christopher J. Burke
BURKE, United States Magistrate Judge

In this action originally filed by Plaintiff and Counterclaim-Defendant Scale Biosciences, Inc. (hereafter, “Scale”) against Defendant and Counterclaim-Plaintiff Parse Biosciences, Inc. (hereafter, “Parse”), Parse, along with Counterclaim-Plaintiff the University of Washington (“UW”), brought counterclaims of infringement of United States Patent Nos. 10,900,065 (the “065 patent”), 11,168,355 (the “355 patent”), and 11,427,856 (the “856 patent” and collectively, the “asserted patents” or “patents-in-suit”). Presently before the Court¹ is Scale’s “Motion for Summary Judgment of Non-Infringement of the Asserted Parse Claims[,]” filed pursuant to Federal Rule of Civil Procedure 56 (“Motion”). (D.I. 300) For the reasons set forth below, the Motion is GRANTED.²

I. BACKGROUND

The Court incorporates by reference (and will not repeat here) its discussion of the factual and procedural background of this case found in its Memorandum Opinion dated October 8, 2025 (“October 8 MO”), to the extent it is relevant to the instant Motion. (D.I. 466 at 2-5) Below it includes additional background information also relevant to the Motion.

A. Procedural Background

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 In line with the Court’s typical convention, the case caption on the previous page includes those attorneys whose names were listed on the relevant briefs regarding the instant dispositive Motion (with a notation being made as to the attorney who argued the Motion). The Court additionally notes that here, a later-admitted attorney not on the briefing, Paul T. Ehrlich of TENSEGRITY LAW GROUP, LLP, Redwood Shores, CA, argued the Motion for Scale.

After the filing of the operative First Supplemental Complaint in this case on August 30, 2023, (D.I. 70), on the same day, Parse filed an Answer and Parse and UW filed certain operative counterclaims, (D.I. 71).³ Among the counterclaims were those asserting that Scale literally infringes the '065 patent, the '355 patent, and the '856 patent. (*Id.* at 38-65)

Scale 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. 300) The Motion was fully briefed as of April 17, 2025. (D.I. 391) The Court heard very lengthy oral argument on the Motion on October 10, 2025. (D.I. 498 (hereafter “Tr.”))

B. Factual Background

At present, Parse is asserting infringement of claims 1, 12, and 20 of the '065 patent, claims 1, 5-6, and 22 of the '355 patent, and claims 1, 5-7, and 22 of the '856 patent (collectively, the “asserted claims”). (D.I. 439 at 1) Generally speaking, the asserted patents and asserted claims are directed to “[m]ethods of uniquely labeling or barcoding molecules within a cell, a plurality of cells, and/or a tissue[.]” (*See, e.g.*, '065 patent, Abstract)⁴ Such a method is further described in claim 1 of the '065 patent, which is representative of all of the asserted claims for our purposes here. Claim 1 recites as follows (with particularly relevant language to the Motion highlighted in italics):

1. *A method of uniquely cell-specifically labeling RNA molecules within a plurality of cells*, the method comprising:

³ Although they are not the only parties to this case, the briefs here are filed solely in the name of Scale and Parse; thus, hereafter, for sake of simplicity, the Court will simply refer to those two parties by name (and not to their other co-parties).

⁴ The asserted patents are found in various places on the docket, including at D.I. 308, Exhibits 5-7. Hereafter, the Court will cite to these patents simply by their number.

- (a) providing a plurality of permeabilized cells in admixture, wherein each of the plurality of cells comprises ribonucleic acid (RNA) molecules;
- (b) without lysing the cells, reverse transcribing the RNA molecules within the plurality of cells, thereby generating complementary deoxyribonucleic acid (cDNA) molecules within the plurality of cells, wherein primers used to reverse transcribe the RNA molecules comprise a poly(T) sequence, a mix of random sequences, or both a poly(T) sequence and a mix of random sequences;
- (c) dividing the plurality of cells comprising the cDNA molecules into a plurality of primary aliquots, wherein the plurality of primary aliquots comprises a first primary aliquot and a second primary aliquot;
- (d) providing primary nucleic acid tags to the plurality of primary aliquots, wherein the primary nucleic acid tags provided to the first primary aliquot are different in sequence from the primary nucleic acid tags provided to the second primary aliquot;
- (e) coupling the provided primary nucleic acid tags of (d) to the cDNA molecules from each of the plurality of primary aliquots, thereby tagging the cDNA molecules with the primary nucleic acid tags and producing primary nucleic acid-tagged cDNA molecules, whereby the primary nucleic acid-tagged cDNA molecules of the first primary aliquot are tagged with a different primary nucleic acid tag than the primary nucleic acid-tagged cDNA molecules of the second primary aliquot;
- (f) combining the plurality of primary aliquots;
- (g) dividing the combined primary aliquots of (f) into a plurality of secondary aliquots, wherein the plurality of secondary aliquots comprises a first secondary aliquot and a second secondary aliquot;
- (h) providing secondary nucleic acid tags to the plurality of secondary aliquots, wherein the secondary nucleic acid tags provided to the first secondary aliquot are different in sequence from the secondary nucleic acid tags provided to the second secondary aliquot; and
- (i) coupling the provided secondary nucleic acid tags of (h) to the primary nucleic acid-tagged cDNA molecules of (e) thereby tagging the primary nucleic acid-tagged cDNA molecules with the

secondary nucleic acid tags and producing secondary nucleic acid-tagged cDNA molecules, whereby the secondary nucleic acid-tagged cDNA molecules of the first secondary aliquot are tagged with a different secondary nucleic acid tag than the secondary nucleic-acid tagged cDNA molecules of the second secondary aliquot.

('065 patent, cols. 29:44-31:3 (emphasis added)) This process claimed in the '065 patent results in “tags that form a cell-specific label that identifies the cell from which the cDNA originated.”

(D.I. 313, ex. 22 at ¶ 575 (citing '065 patent, col. 4:20-25))

Parse asserts that Scale infringes the asserted claims by making, selling, offering for sale, and using certain of Scale’s single-cell RNA sequencing kits, among other related kits and products (the “accused products”). (D.I. 301 at C12; D.I. 313, ex. 22 at ¶ 36) Scale’s accused products undisputedly utilize at least three steps, or “splits,” where cells are divided up and reactions take place to generate tagged molecules: (1) Indexed Reverse Transcription, (2) Indexed Ligation, and (3) Indexed PCR. (D.I. 301 at C13, C16-C26) “Reverse transcription” is a process for synthesizing a (more stable) cDNA molecule that is complementary to the (less stable) mRNA that is produced in the cell. (D.I. 327 at ¶ 21; D.I. 313, ex. 23 at ¶¶ 59-60) It is this reverse transcription step that is most directly at issue in the present Motion.

Claim 1’s preamble will also be particularly relevant here too. Again, that preamble⁵ recites “[a] method of uniquely cell-specifically labeling RNA molecules within a plurality of cells[.]” ('065 patent, col. 29:44-45) At the *Markman* stage of the case, the parties had a dispute about the meaning of this preamble phrase. (D.I. 101 at 50-67) During prosecution, the patentee made a statement that disclaimed certain claim scope relating to the phrase—in that the patentee,

⁵ The preambles of all of the other asserted claims in the other asserted patents are the same as, or essentially similar to, claim 1’s preamble. When the Court discusses claim 1’s preamble herein, it should be understood to also be referring to the preambles relevant to all asserted claims.

in remarks to the Examiner, stated that “[t]he cell specific label is the product of multiple rounds of appending well-specific tags to cDNAs within each cell as the cells are pooled and split.”

(D.I. 309, ex. 20 at PARSE0000964) The patentee’s statement prompted the Court to find the preamble’s phraseology to be limiting—and to construe the preamble to mean “[a] method of generating labels that identify the cell of origin of RNA molecules, where the cell-specific labels are the product of *multiple rounds of appending well-specific tags to cDNAs within intact cells.*”

(D.I. 241 (emphasis added); *see also* D.I. 301 at C10).

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

II. STANDARD OF REVIEW

The Court incorporates by reference its discussion of the legal standards relating to summary judgment motions and to claim construction, which were also set out in its October 8 MO. (D.I. 466 at 5-6) Below, the Court will discuss some additional legal standards relevant to addressing a motion for summary judgment as to a claim of patent infringement.

The familiar patent infringement analysis consists of two steps. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995). First, the court must determine the meaning and scope of the patent claims asserted to be infringed. *Id.* Claim construction is generally a question of law, although subsidiary factfinding is sometimes necessary. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 326-27 (2015). Second, the trier of fact must compare the properly construed claims to the allegedly infringing product. *Markman*, 52 F.3d at 976. This second step is a question of fact. *ActiveVideo Networks, Inc. v. Verizon Commc’ns, Inc.*, 694 F.3d 1312, 1319 (Fed. Cir. 2012).

“Literal infringement of a claim exists when every limitation recited in the claim is found in the accused device.” *Kahn v. Gen. Motors Corp.*, 135 F.3d 1472, 1477 (Fed. Cir. 1998). “If any claim limitation is absent from the accused product, there is no literal infringement as a matter of law.” *Amgen Inc. v. F. Hoffman-La Roche Ltd*, 580 F.3d 1340, 1374 (Fed. Cir. 2009). The patent owner has the burden of proving infringement and must do so by a preponderance of the evidence. *SmithKline Diagnostics, Inc. v. Helena Lab’ys. Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988).

When an accused infringer moves for summary judgment of non-infringement, such relief may be granted only if at least one limitation of the asserted claim does not read on an element of the accused product. *See Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1376 (Fed. Cir. 2005); *see also TechSearch, L.L.C. v. Intel Corp.*, 286 F.3d 1360, 1369 (Fed. Cir. 2002) (“Summary judgment of non[-]infringement is [] appropriate where the patent owner’s proof is deficient in meeting an essential part of the legal standard for infringement, because such failure will render all other facts immaterial.”). Therefore, the court may grant summary judgment of non-infringement only if, after viewing the facts in the light most favorable to the non-movant, there is no genuine issue as to whether the accused product is covered by the claims, as construed by the Court. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1304 (Fed. Cir. 1999).

III. DISCUSSION

Scale raises three distinct arguments as to why its accused products do not infringe the asserted patents; any one of these arguments would be a sufficient ground for the Court to grant this Motion, should it agree with Scale. (D.I. 307 at 22; Tr. at 65, 99) Below, the Court need only address Scale’s second argument, which relates to why Scale’s accused products do not

meet the preamble’s requirements. (D.I. 307 at 27-30; D.I. 359 at 30-32; D.I. 391 at 12-14) In doing so, the Court will conclude that this argument is well taken—and that it requires that summary judgment of non-infringement be granted to Scale as to all asserted claims (in turn disposing of the entire Motion).

In advancing its infringement theories, Parse asserts that at least two of the steps in the workflow of the accused products involve “*appending well-specific tags to cDNAs* within intact cells” as required by the preamble: i.e., the Indexed Reverse Transcription step and the Indexed Ligation step. (*See, e.g.*, D.I. 313, ex. 22 at ¶¶ 601-09) And in its briefing on this Motion, Scale did not dispute that the Indexed Ligation step could count as one of the requisite “multiple rounds of appending well-specific tags to cDNAs[.]” (*See* D.I. 307 at 28; *see also* D.I. 359 at 21) Instead, the parties disagree about whether the Indexed Reverse Transcription step can amount to a second qualifying “round” in this regard. (D.I. 359 at 31-32)

Below, the Court will assess whether there exists a genuine disputed issue of material fact on this question. In doing so, it will first address whether claim construction is required as to any relevant terms in the preamble. Thereafter, the Court will analyze the record to determine whether there is a genuine dispute of material fact as to whether the accused products (and particularly the accused products’ use of the Indexed Reverse Transcription step) practice the key preamble-related limitation at issue.

A. Step One of the Infringement Analysis: Claim Construction

As an initial matter, before assessing whether Scale’s accused products can satisfy the preamble’s limitation as a factual matter, the Court must first determine whether further claim construction is required for any important preamble-related term. (D.I. 466 at 11-12); *see also* *Teva Pharms.*, 574 U.S. at 326-27. In particular, the Court will examine two words that it

included in its construction of the preamble: “cDNA[.]” (a term that also appears in the body of claim 1 and in other asserted claims, (*see, e.g.*, '065 patent, col. 29:51)), and “appending[.]” (D.I. 241)

The Court begins with “cDNA.” In its briefing on the Motion, Scale was uncertain as to whether the parties actually had a disagreement about this term’s meaning. To the extent they did, Scale suggested a few different (though functionally similar) proposed constructions for the term—in line with what it understands the plain and ordinary meaning of “cDNA” to be. (D.I. 307 at 28; D.I. 391 at 13) During argument on the Motion, Scale’s counsel focused on one of those proposals: i.e., “a biopolymer made of connected nucleotides, not any one separate nucleotide[.]” (D.I. 307 at 28 (citing D.I. 301 at C17 & D.I. 327 at ¶ 59 (citations omitted)); Tr. at 109-11, 132, 158, 161)

In its briefing, Parse did not offer an alternative construction of “cDNA.” (D.I. 359 at 30-32) That said, during the hearing, at first Parse’s counsel suggested that the parties might actually have a dispute about what “cDNA” is or can be in this regard. (Tr. at 132-33 (Parse’s counsel, when asked “If [Scale] think[s] that cDNA means a biopolymer made of connected nucleotides, not any one separate nucleotide, [do] you disagree with that?” responding “We do disagree with that, yes.”); *id.* at 146 (Parse’s counsel suggesting that the parties’ dispute “could be framed” as a claim construction dispute over the term “cDNA”—though also arguing that the parties may simply have a “factual dispute” about infringement regarding the term)) But eventually, Parse’s counsel agreed that for a biopolymer to be “cDNA” it is required to be made up of connected nucleotides (as opposed to amounting to one individual, single nucleotide)—a position that was consistent with Parse’s prior statement of record that “cDNA is formed once a nucleotide hybridizes to the RNA and attaches to the adjacent nucleotide through a

phosphodiester bond.” (D.I. 372 at C17; *see also* Tr. at 139-40 (Parse’s counsel confirming that Parse agrees that for something to be “cDNA” it must be a “collection of nucleotides, more than one” and that there must be “more than one nucleotide attached”); *id.* at 142-43; D.I. 313, ex. 23 at ¶ 44 (Parse’s infringement expert, Dr. Rahul Satija, noting that DNA is a “linear chain[] of individual building blocks known as ‘nucleotides.’”) (*cited in* D.I. 307 at 29))⁶

Therefore, in the end, there did not appear to be any real dispute as to what constitutes “cDNA[],” as that term appears in the Court’s construction of the preamble and in the asserted claims. (Tr. at 107-08) In line with the evidence put forward by Scale, (*see* D.I. 327 at ¶ 59), and the parties’ agreement as set out above, the Court concludes that the plain and ordinary meaning of “cDNA” is: “a biopolymer made of connected nucleotides, not any one separate nucleotide.”

Next, the Court turns to the term “appending.” At some points during the hearing, it seemed like the parties might have a disagreement about the meaning of this word—a word found in the Court’s construction of claim 1’s preamble (i.e., “*appending* . . . tags to cDNA”). (Tr. at 118-20, 124-28, 149, 151, 158-63; D.I. 359 at 30) To be sure, there seemed to be no real dispute about what it means to “append” one thing to another. That is, Scale and Parse both acknowledged that to “append[]” means to “attach” or “affix” the one thing to the other. (D.I.

⁶ At one point during the hearing, Parse’s counsel believed that Scale might dispute that “cDNA” could possibly be composed of one nucleotide drawn from the primer and one nucleotide that is attached to that primer-based nucleotide during the process of reverse transcription. (Tr. at 130-31, 137-44; *see also id.* at 109, 116) But later in the hearing, Scale’s counsel confirmed that, at least for purposes of the Motion, Scale would not contest that this type of a combination of nucleotides could possibly count as “cDNA.” (*Id.* at 158 (Scale’s counsel noting that he was “leaving aside whether [cDNA] can be the first nucleotide attached to a primer or whether it has to be the second or more[,]” and was simply asserting that to have cDNA “it takes connected nucleotides”))

327, ex. 30 at ¶¶ 233-34 (Scale’s infringement expert, Dr. Alex K. Shalek, citing dictionary definitions for the proposition that “appending” means “attaching, affixing, or adding one thing to another”) (citations omitted); *see also* D.I. 313, ex. 24 at ¶ 62 (Dr. Satija not disputing that appending means to attach, affix, or add one thing to another)) But at the hearing, it seemed possible that the parties might not agree about the *temporal* nature of what it means to be “appending” one item to another item. (Tr. at 118-20) For example, Scale’s position was that “appending,” as used in the Court’s construction (and relatedly, in the relevant disclaimer made by the patentee during prosecution) clearly connotes “the present tense” of that word—i.e., the act of “bringing two things together[.]” (Tr. at 118; *see also id.* at 121; D.I. 327, ex. 30 at ¶¶ 233-34; D.I. 241)

But ultimately, after hearing Parse’s counsel also discuss this issue during the hearing, the Court concludes that the parties were not having a dispute about this “temporal” issue either. (Tr. at 128) During argument, Parse’s counsel agreed that “appending” a tag to something is a concept that is assessed and satisfied at the moment when one item is “attaching to” another item—not at some time after that first connection between the two items occurs. (*Id.* at 145-46, 151) And this only makes sense, in light of the claim construction (and related disclaimer) at issue here. After all, the patentee used the phrase “*appending* . . . tags to cDNA”—and not language like “cDNA, which has been *appended* to a tag” or something like that. (*Id.*) Put differently, the use of the “-ing” in “appending” indicates that we are focused on the “moment in time” of “first connection” between the two existing items at issue. (*Id.* at 114-15, 119-20; D.I. 327, ex. 30 at ¶ 234)

In light of this, in the Court’s view, there is no need to adopt some further construction of the word “appending,” nor is there any need to consider extrinsic evidence about what the word

means in this context. (D.I. 359 at 30 (citing D.I. 307 at 28 (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc))))⁷ The Court and the parties know what it means. It is a reference to the “present tense” moment in which one item is attaching or affixing to another.

In the end, then, the parties were not really having a dispute about what “cDNA[]” or “appending” means.⁸ And with the meaning of those words now further clarified, the Court can turn to second step of the infringement analysis.

B. Step Two of the Infringement Analysis: Comparing the Properly Construed Claims to the Allegedly Infringing Products

The Court next addresses the parties’ arguments about whether there is a dispute of fact as to whether the accused products practice what claim 1’s preamble phrase requires.

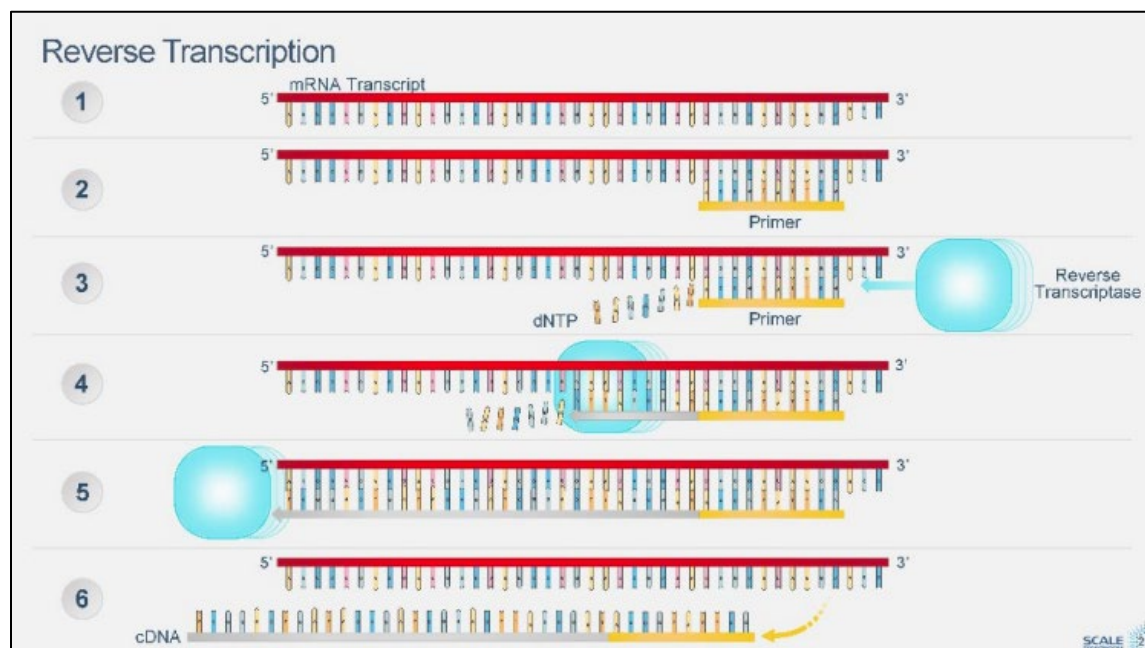
Here, as noted above, the key portion of this infringement analysis relates to the Indexed Reverse Transcription step. The Court will first summarize the sides’ positions as to why there is or is not a genuine dispute of fact regarding whether this step can amount to one of the “rounds of appending well-specific tags to cDNA[.]”

Scale argues that it cannot. To that end, Scale’s expert, Dr. Shalek, first explains that in this reverse transcription step, Scale’s products assist in creating cDNA from the mRNA found in cells; he notes that this process permits the study of RNA sequences while mitigating any

⁷ It would be somewhat unusual to provide a further “claim construction” of the word “appending”—in that this word itself does not appear at all in the asserted claims, (D.I. 101 at 53), but instead only in the Court’s construction of another disputed claim term (i.e., the preamble phrase). *Advanced Fiber Techs. (AFT) Tr. v. J & L Fiber Servs., Inc.*, 674 F.3d 1365, 1373 (Fed. Cir. 2012). That said, when “construction of a claim term necessitates a derivative construction of a non-claim term, a court may perform the derivative construction in order to elucidate the claim’s meaning.” *Id.*; see also *AlterWAN, Inc. v. Amazon.com, Inc.*, C.A. No. 19-1544 (MN), 2024 WL 4635380, at *2 (D. Del. Oct. 31, 2024); (Tr. at 117-18). Here though, as the Court notes above, it discerns that no further construction of “appending” is needed.

⁸ It is worth noting that this was Parse’s position all along in its briefing—i.e., that the parties did not have a claim construction dispute regarding the meaning of “cDNA” or “appending.” (D.I. 359 at 30)

concern about RNA degradation during the process of split pool synthesis (since RNA is relatively unstable as compared to DNA). (D.I. 327, ex. 30 at ¶¶ 52, 103-14) Reverse transcription makes use of one or more “primers” that have a “poly-T region” that binds or attaches to a “poly-A region” of mRNA; this, in turn, permits an enzyme called “reverse transcriptase” to extend the primer by adding nucleotides, one at a time, that are complementary to the mRNA sequence. (*Id.* at ¶¶ 53, 235; *see also* Tr. at 101-02) This process is depicted in steps 2-5 below, which are drawn from an image found in Dr. Shalek’s Rebuttal Expert Report (“Dr. Shalek’s Rebuttal Report”):



(D.I. 327, ex. 30 at ¶ 53) Reverse transcription results in single strands of cDNA whose nucleotide sequences are complementary to the sequence of the mRNA template. (*Id.*)

Scale’s argument regarding non-infringement as to the preamble’s “appending” limitation is then described by Dr. Shalek as follows:

[A]s the cDNA is synthesized, individual nucleotides are successively added so that the primer sequence becomes part of the growing cDNA. The primer’s sequence, which is complementary to the mRNA, is continuous with the complementary sequence that

is added through reverse transcription. The result is the cDNA, whose nucleotide sequences reflect the sequence of the mRNA template. *The cDNA does not exist separate from the primer used to synthesize the cDNA, so it cannot be said that cDNA is ever appended, attached, affixed, or added to the primer.*

(*Id.* at ¶ 235 (emphasis added)) In other words (as Scale’s counsel further explained during the Motion hearing), Scale’s position is as follows:

- (1) The asserted claims require “appending . . . tags to cDNA[.]”;
- (2) During Indexed Reverse Transcription, the moment at which the tag is “appending” to something, that “appending” occurs when “the first nucleotide [is] coming in and binding to the primer[.]” which contains the barcode (i.e., the “tag”); and
- (3) Therefore, in that scenario, the tag is not “appending” to already-existing “cDNA”—instead, at the moment where the tag is appending or attaching to something, it is attaching to *one individual nucleotide at a time*.

(D.I. 391 at 12-13 (Scale asserting that Parse’s infringement position appears to rely on “appending [to] one nucleotide at a time” rather than “to cDNA”); *see also* D.I. 307 at 28-30; Tr. at 101-04, 123-24, 158-62; D.I. 491-1 at 13)

In pushing back on this conclusion, Parse argues that in the Indexed Reverse Transcription step, when the first nucleotide is hybridized to its complementary nucleotide within the mRNA and then also linked to an adjacent nucleotide contained within the barcoded primer, this amounts to “appending” a tag to “cDNA.” (Tr. at 129-57; D.I. 359 at 31) In support, Parse makes two primary arguments about why the preamble’s “appending” limitation can be met in part via the Indexed Reverse Transcription step. The Court will address these below, explaining why both arguments are unavailing.

First, Parse relies heavily on the following statement drawn from paragraph 60 of the Reply Expert Report of its expert, Dr. Satija (“Dr. Satija’s Reply Report”):

As I explained in my Opening Report, once the nucleotides hybridize to the RNA and are attached to the adjacent nucleotide through a phosphodiester bond via the polymerase activity, they become cDNA. This means that, even if “appending” required the cDNA to exist independent of the barcoded RT primer—which it does not—then the first nucleotide that matches the RNA becomes cDNA, which is appended to the RT primer. And as I showed in my Opening Report, the ScaleBio Accused Products and Services synthesize cDNA that is appended (attached, affixed, or added as a supplement) to the barcoded RT oligo primers.

(D.I. 313, ex. 24 at ¶ 60; *see* Tr. at 134-48; *see also* D.I. 359 at 31)⁹ During the Motion hearing, Parse’s counsel further emphasized Dr. Satija’s position (set out above), in arguing that Dr. Satija’s “view is that . . . when that first nucleotide comes along, [and] hybridizes to the RNA into the primer” then “[c]DNA is formed[.]” (Tr. at 134)

However, as Scale notes, (Tr. at 164), paragraph 60 of Dr. Satija’s Reply Report cannot help Parse here. Instead, Dr. Satija’s statements actually confirm that there is *not* a genuine dispute of material fact. Again, in paragraph 60, Dr. Satija sets out his view that: (1) at the point at which “the nucleotides [utilized by the accused products] hybridize to the RNA and *are attached to the adjacent nucleotide* . . . [then] they *become cDNA*[.]”; and how (2) the accused products “synthesize cDNA that *is appended* (attached, affixed, or added as a supplement) to the barcoded RT oligo primers[.]” (D.I. 313, ex. 24 at ¶ 60 (emphasis added)) But these excerpts make clear that, even in Dr. Satija’s telling, “cDNA” is not formed until at least the moment when a “nucleotide[] hybridize[s] to the RNA and [is] *attached to the adjacent nucleotide*”—i.e., that *this* point in time is when these two nucleotides “*become cDNA*.” (*Id.* (emphasis added)); *see also* D.I. 391 at 12 (citing D.I. 372 at C17)) This is also brought home by Dr. Satija’s use of the past tense to describe the action that takes place with respect to the “cDNA” and the tags

⁹ Both the parties and their experts often use “RT” as a shorthand for the process that is reverse transcription.

(i.e., “the first nucleotide that matches the RNA becomes cDNA, which is *appended* to the RT primer” or “the ScaleBio Accused Products and Services synthesize cDNA that is *appended* (*attached, affixed, or added* as a supplement) to the barcoded RT oligo primers”). (D.I. 313, ex. 24 at ¶ 60 (emphasis added); *see also id.* at ¶ 67 (“[T]he synthesized cDNAs would be *appended* (*attached, affixed, or added* as a supplement) to the barcoded RT primers through a covalent interaction.”) (emphasis added))

The problem here for Parse is that the plain language of the Court’s construction of the preamble requires “*appending* well-specific tags *to cDNA*[.]” That is, it requires (first) the existence of cDNA and then (second) the process of appending a tag to that *already-existing* cDNA. (Tr. at 104-05, 108, 160, 164; D.I. 327, ex. 30 at ¶ 234 (Dr. Shalek noting that “[t]o attach, affix, or add a tag to the cDNA, a POS[IT]A would have understood there must be cDNA to which the tag is attached, affixed, or added”)) Dr. Satija’s opinion, in which he describes cDNA that does not exist until no earlier than the moment of appending, simply demonstrates why use of the accused products cannot meet this claim limitation.¹⁰ Put differently, Parse’s position—i.e., that cDNA can be *simultaneously* created *at the very moment that it is being*

¹⁰ In an earlier portion of paragraph 60, Dr. Satija writes that a person of ordinary skill in the art (“POSITA”) “would understand that cDNA does not need to exist separate from a barcoded RT oligo primer to append the cDNA to the barcoded RT oligo primer” and that “[a] POS[IT]A would understand that synthesizing cDNA from a barcoded RT oligo primer appends a barcoded RT oligo primer *to cDNA*.” (D.I. 313, ex. 24 at ¶ 60 (emphasis added); D.I. 359 at 31) But those portions of paragraph 60 simply articulate a conclusion—i.e., that the preamble’s limitation is met. Yet the remainder of paragraph 60 is where Dr. Satija is attempting to articulate why the facts about how the accused products work can support his previously-asserted conclusion. And as the Court has set out above, these remaining statements do *not* help support Parse’s position. Instead, the remainder of paragraph 60 makes clear, in fact, that the tagged primer at issue is *not* appending “*to cDNA*”; instead, the primer/tag is appending to individual nucleotides, one by one—i.e., nucleotides that are, prior to the moment of appending, *not* “*cDNA*” *at all*.

appended to a tag (connected to the primer)—is simply in conflict with the preamble’s requirement that cDNA *must already exist* prior to the moment of appending or attaching. (Tr. at 156-58 (Parse’s counsel confirming that Parse’s position here is that the accused products’ reverse transcription step can amount to a round of appending well-specific tags to cDNA in that there, “you’re appending cDNA [and] creating cDNA” and “that’s happening *at the same time*[,]” since “cDNA in this process *is not created until the nucleotide attaches* to a nucleotide . . . associated with a tag”) (emphasis added); *see also id.* at 153-54 (the Court questioning Parse’s counsel as to how, if something “doesn’t become cDNA until [the nucleotide] connects to the nucleotide that’s on the primer, how would we be appending the tag to cDNA” since “[w]ouldn’t you need to have cDNA already by the point in which [the cDNA is] touching the tag?”))¹¹

Second, Parse asserts that Scale’s position is weakened by a supposed contradiction found in Dr. Shalek’s Rebuttal Report. (Tr. at 148-50) More specifically, Parse and Dr. Satija note that in this report, Dr. Shalek describes reverse transcription by stating that “as the cDNA is synthesized, individual nucleotides are successively added so that the primer sequence *becomes* part of the growing cDNA.” (D.I. 313, ex. 24 at ¶ 61 (quoting D.I. 327, ex. 30 at ¶ 235))

¹¹ During oral argument, Scale’s counsel suggested that one reason that the prosecution disclaimer reads in this way (i.e., that “fully formed cDNA [must exist] before the appending moment”) is because the concept of “appending” does not describe the process of reverse transcription very well. (Tr. at 165-66) Scale’s counsel argued that the word “appending is not a good fit for” characterizing the reverse transcription step because it “really came from the world of coupling,” which “mean[s] bringing two things together”—and so this disclaimer was meant to match steps (e) and (i) of the claims “really well[.]” (*Id.* at 165; *see also id.* at 166 (noting that “bringing two fully formed molecules together is a different biological process [than] a polymerase systemic reaction” like reverse transcription)) That may well be correct. But the Court, in resolving this Motion, need not opine on what prompted the patentee to use the particular wording it did in making its disclaimer. Ultimately, because the patentee in fact made a clear and unmistakable disclaimer of certain claim scope, then the words the patentee chose to use in that disclaimer (as included in the Court’s construction of the preamble), (D.I. 309, ex. 20 at PARSE0000964; *see also* D.I. 241), must control the Court’s analysis of claim scope. *See Omega Eng’g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1324 (Fed. Cir. 2003).

(emphasis added)) It is Parse's view that with these words, Dr. Shalek is acknowledging that when one nucleotide attaches to the adjacent nucleotide contained within the primer during reverse transcription, this can amount to "cDNA." (Tr. at 150-51)

But in reality, there is no material dispute between Dr. Shalek and Dr. Satija (or, relatedly, between Scale and Parse) on the key facts that matter here. Indeed, the parties are in agreement about how the accused products work. The parties agree that adding complementary nucleotides one by one, via the reverse transcription process means that those nucleotides and the nucleotides from the primer *will* all "become[] part of the growing cDNA." (D.I. 327, ex. 30 at ¶ 235) Crucially, however, as Scale notes, Dr. Shalek does *not* agree with Dr. Satija that the accused products meet the preamble's claim limitation. (Tr. at 159-60; D.I. 327, ex. 30 at ¶ 249) That is because (as Dr. Shalek puts it), in the reverse transcription process, "[t]he cDNA *does not exist* separate from the primer used to synthesize the cDNA"—that is, it only comes into existence when the nucleotides at issue connect or attach to the primer, and so it cannot be said that existing cDNA is ever "appended, attached, affixed, or added to the primer." (D.I. 327, ex. 30 at ¶ 235 (emphasis added); *see also* Tr. at 159-60 (Scale's counsel noting that "the only evidence that you've heard is that one nucleotide comes in and becomes cDNA after it has been incorporated [such that] you never have a situation where you are bringing polymers together"))

In sum, on this record, there can be no genuine dispute of material fact as to whether Indexed Reverse Transcription may qualify as one of the "rounds of *appending* well-specific tags *to cDNA[]*." It cannot. Again, that is because, during reverse transcription, at the moment a tag (connected to the primer) is about to be appended to a single nucleotide, it is undisputed that no "cDNA" molecule has yet been formed. (Tr. at 137-38, 159; D.I. 313, ex. 24 at ¶ 60; D.I. 327, ex. 30 at ¶ 235) Therefore, there can be no genuine dispute of material fact as to whether Scale's

products literally infringe the asserted claims; they do not.¹² And so, as a matter of law, Scale is entitled to summary judgment of non-infringement of the asserted claims.

IV. CONCLUSION

For the foregoing reasons, the Court GRANTS Scale's Motion.¹³ An appropriate Order will issue.

¹² In the briefing on this Motion, Scale argued that Parse could not use a doctrine of equivalents ("DOE") theory to meet the limitation of the preamble requiring "multiple rounds of appending well-specific tags to cDNAs within intact cells." (D.I. 391 at 14) And during the hearing on the Motion, Parse's counsel confirmed that in Parse's briefing, it had not raised a DOE theory with respect to how Scale's products could infringe the limitation at issue in this opinion. (Tr. at 210; *see also* D.I. 359 at 30-32) Therefore, herein, the Court need only address the issue of literal infringement in order to grant summary judgment in full to Scale as to the asserted claims.

¹³ As such, the portions of this Motion relating to Scale's first and third non-infringement arguments are DENIED as moot.

SCALE BIOSCIENCES, INC. and
ROCHE SEQUENCING SOLUTIONS,
INC.,

Plaintiffs,

v.

PARSE BIOSCIENCES, INC.,

Defendant.

PARSE BIOSCIENCES, INC. and
UNIVERSITY OF WASHINGTON,

Counterclaim-Plaintiffs,

v.

SCALE BIOSCIENCES, INC.,

Counterclaim-Defendant.

ORDER

For the reasons stated in the Memorandum Opinion issued this same date, IT IS
HEREBY ORDERED that the motion for summary judgment of non-infringement of U.S. Patent
Nos. 10,900,065, 11,168,355, and 11,427,856 filed by Plaintiff Scale Biosciences, Inc. pursuant
to Federal Rule of Civil Procedure 56, (D.I. 300), is GRANTED.

Christopher J. Burke
Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE