

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TWINSTRAND BIOSCIENCES, INC., &
UNIVERSITY OF WASHINGTON,

Plaintiffs,

v.

GUARDANT HEALTH, INC.,

Defendant.

C. A. No. 21-01126-GBW
UNSEALED ON 6/10/24

MEMORANDUM ORDER

Pending before the Court is the parties' dispute of the proper construction of the ordering of steps in U.S. Patent Nos. 102,876,631 (the "'631 patent") and 107,601,127 (the "'127 patent"). Having considered the parties' briefing and after hearing oral argument, the Court construes the '127 patent to require that the steps of the claimed methods are performed in order and construes the '631 patent to require that some, but not all, of the steps of the claimed methods are performed in order. *See* D.I. 468; D.I. 471.

I. LEGAL STANDARDS

“‘[T]he claims of a patent define the invention to which the patentee is entitled the right to exclude.’” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (citation omitted); *Aventis Pharms. Inc. v. Amino Chemicals Ltd.*, 715 F.3d 1363, 1373 (Fed. Cir. 2013) (same). “[T]here is no magic formula or catechism for conducting claim construction.” *Phillips*, 415 F.3d at 1324. The Court is free to attach the appropriate weight to appropriate sources “in light of the statutes and policies that inform patent law.” *Id.* The ultimate question of the proper construction of a patent is a question of law, although “subsidiary factfinding is sometimes

necessary.” *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 326–27 (2015); see *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996) (“the construction of a patent . . . is exclusively within the province of the court.”).

“The words of a claim are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art when read in the context of the specification and prosecution history.” *Thorner v. Sony Comput. Entm’t Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (citing *Phillips*, 415 F.3d at 1313); *Unwired Planet, LLC v. Apple Inc.*, 829 F.3d 1353, 1358 (Fed. Cir. 2016) (similar). The “‘only two exceptions to this general rule’” are (1) when a patentee defines a term or (2) disavowal of “‘the full scope of a claim term either in the specification or during prosecution.’” *Thorner*, 669 F.3d at 1365 (citation omitted).

The Court “‘first look[s] to, and primarily rel[ies] on, the intrinsic evidence,’” which includes the claims, written description, and prosecution history and “‘is usually dispositive.’” *Personalized Media Commc’ns, LLC v. Apple Inc.*, 952 F.3d 1336, 1340 (Fed. Cir. 2020) (citation omitted). “[T]he specification ‘ . . . is the single best guide to the meaning of a disputed term.’” *Akzo Nobel Coatings, Inc. v. Dow Chem. Co.*, 811 F.3d 1334, 1340 (Fed. Cir. 2016) (citation omitted). “[T]he specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess.’ When the patentee acts as its own lexicographer, that definition governs.” *Cont’l Cirs. LLC v. Intel Corp.*, 915 F.3d 788, 796 (Fed. Cir. 2019) (quoting *Phillips*, 415 F.3d at 1316). However, “[the Court] do[es] not read limitations from the embodiments in the specification into the claims.” *MasterMine Software, Inc. v. Microsoft Corp.*, 874 F.3d 1307, 1310 (Fed. Cir. 2017) (citation omitted)). The “written description . . . is not a substitute for, nor can it be used to rewrite, the chosen claim language.” *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004).

The Court “should also consider the patent’s prosecution history, if it is in evidence.” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995), *aff’d*, 517 U.S. 370; *Cont’l Cirs.*, 915 F.3d at 796 (same). The prosecution history may “‘demonstrat[e] how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution” *SpeedTrack, Inc. v. Amazon.com*, 998 F.3d 1373, 1377 (Fed. Cir. 2021) (quoting *Phillips*, 415 F.3d at 1317).

The Court may “need to look beyond the patent’s intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period.” *Teva*, 574 U.S. at 331. “Extrinsic evidence consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Markman*, 52 F.3d at 980; *Phillips*, 415 F.3d at 1317 (same). Extrinsic evidence may be useful, but it is “less significant than the intrinsic record in determining the legally operative meaning of claim language.” *Cont’l Cirs.*, 915 F.3d at 799 (internal quotation marks and citations omitted). However, “[p]atent documents are written for persons familiar with the relevant field Thus resolution of any ambiguity arising from the claims and specification may be aided by extrinsic evidence of usage and meaning of a term in the context of the invention.” *Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116, 1119 (Fed. Cir. 2002); *see Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 899 (2014) (explaining that patents are addressed “to those skilled in the relevant art”).

II. DISCUSSION

The parties dispute whether every step of the asserted claims must be performed in order. The Court finds that the steps of the ’127 patent must be performed in order, that the steps of dependent claim 21 of the ’631 patent must be performed in order, and that some (but not all) of

the steps of claim 1 of the '631 patent must be performed in order. The Court also finds that simultaneous or iterative performance of the steps is within the scope of the claims.

“Unless the steps of a method actually recite an order, the steps are not ordinarily construed to require one.” *Interactive Gift Express, Inc. v. CompuServe Inc.*, 256 F.3d 1323, 1342 (Fed. Cir. 2001). The steps of a method recite an order if the claim language, read in light of the specification “directly or implicitly requires such a narrow construction.” *Id.* Antecedent basis is insufficient for a narrowing construction, at least where the specification teaches embodiments where certain steps could occur simultaneously and/or in a different order. *See id.*

A. The Plain Language of the '127 Patent Requires that the Steps of the Claimed Method are Performed in Order.

The Court construes claim 1 of the '127 patent to require that the steps of the claimed method are performed in order. Claim 1 of the '127 patent has four steps, labeled “a” through “d”. *See* '127 patent at claim 1. Step (d) has three substeps—“confirming,” “comparing,” and “analyzing.” *Id.* TwinStrand conceded that steps (a) through (d) must occur in order. Tr. TwinStrand also conceded that the “analyzing” and “comparing” substeps must occur after the “confirming” substep because the “analyzing” and “comparing” steps act on “at least one of the *confirmed* first and second strand sequence reads...” *Id.*; *see also* '127 patent at claim 1 (emphasis added). Thus, the parties’ only dispute is whether the “comparing” substep must occur prior to the “analyzing” substep.

The Court construes claim 1 of the '127 patent to require that the “comparing” substep must occur prior to the “analyzing” substep. The comparing substep recites “comparing at least one of the confirmed first and second strand sequence reads to a reference sequence.” '127 patent at claim 1. Then, the analyzing step “identifies a sequence variation” by analyzing

“correspondences” between the “confirmed” sequence reads. *Id.* The correspondences between the sequence reads and the reference sequence cannot be “analyzed” before the sequence reads and the reference sequence are “compared” because there is nothing to analyze until the comparison is made. Because the parties agree that all other steps in claim 1 of the ‘127 patent occur in order, the Court construes claim 1 of the ‘127 patent to require that the steps of the claimed method are performed in order. *See Tr.*

Similarly, the Court construes claim 22 of the ‘127 patent to require that the steps of the claimed method are performed in order. Claim 22 follows the same structure of claim 1; claim 22 has four steps labeled (a) through (d), with step (d) having four (4) substeps. ‘127 patent at claim 22. The Court construes claim 22 to require that each step must occur in order because the parties agree that steps (a) through (d) must occur in order, and each substep of step (d) provides the antecedent basis for the following substep. *See Tr.* In substep 1, the strand sequence reads generated by the prior steps are grouped into families. ‘127 patent at claim 22. In substep 2, a plurality of strand sequence reads within the families are collapsed to provide a consensus sequence. *Id.* In substep 3, the consensus sequence is compared to a reference sequence. *Id.* In substep four, the correspondences between the consensus sequence and the reference sequence are analyzed to identify a sequence variation. *Id.* Each of these steps must be performed in order because each step receives the sequence to be acted upon from the previous substep. *See id.* Thus, the only logical way to read the claims is to require that the steps of the claimed method are performed in order. *See Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1369 (Fed. Cir. 2003) (the Court should “look to the claim language to determine if, as a matter of logic or grammar, they must be performed in the order written.”)

B. The Plain Language of the '631 Patent Requires that Some, but not All, Steps of the Claimed Method are Performed in Order.

With respect to the '631 patent, the parties have agreed that the steps of dependent claim 21 must be performed in the listed order. Tr. With respect to claim 1, the parties have also agreed that, with respect to an individual molecule, (1) the wet-lab steps of claim 1 must precede the dry-lab steps, (2) the “confirming” step must precede the “comparing” step, (3) the “comparing” step must precede the “identifying” steps, and (4) the “identifying” steps must precede the “generating” step. *Id.* The parties further agree that the “identifying” steps may be performed in either order. *Id.* The Court agrees with the parties on those issues. Thus, the parties dispute only whether the “separating,” “grouping,” and “confirming” steps must be performed in the order recited in the patent. The Court finds that claim 1 of the '631 patent does not limit these steps to being performed in the recited order.

Guardant’s chief argument is that each and every step must be performed in order because at least some steps must be performed in the recited order, and there is no difference between how those steps and the rest of the patent is written. Tr. Guardant’s position, however, is contradicted by Federal Circuit precedent indicating that the order of steps is not all-or-nothing. *See Interactive Gift*, 256 F.3d 1323 at 1344 (holding that step one did not need to occur before step four, even though step three needed to occur before step four and all steps are written the same). Guardant’s position is further contradicted by Guardant’s concession that the two “identifying” steps do not have to be performed in order. Tr. These steps are not written in any “different” way than the other steps. *See* '631 patent at claim 1. Thus, if the “identifying” steps are not required to be performed in the order written, there is no reason for the Court to import a claim limitation of ordered performance into the other steps where the claim language does not “refer[] to the completed results of the prior step.” *See Kaneka*, 790 F.3d at 1306.

The plain text of the claims does not require performance of the “grouping,” “separating,” and “confirming” steps in a specific order. ’631 patent at claim 1. Each has the same antecedent basis: “the first and second strand sequence reads.” *Id.* Thus, the “prior step” to which these steps refer is the “sequencing step”. *Kaneka*, 790 F.3d at 1306; *see* ’631 patent at claim 1. The sequencing step is a wet-lab step which the parties agree must precede the “grouping,” “separating,” and “confirming” steps. Tr.

Further, logic does not require performance of the “grouping,” “separating,” and “confirming” in a specific order. *See Altiris*, 318 F.3d at 1369; *see* ’631 patent at claim 1. The “grouping” and “separating” steps are both sorting operations (on the DNA molecule and first and second strands of that molecule, respectively). *Id.* There is no logical reason why these steps must be performed in a specific order, as the result would be the same regardless of what step occurs first. *See id.* Similarly, one could “confirm” the presence of at least one first and second strand sequence read before sorting without loss of functionality. *See id.* Thus, the Court sees no logical requirement that these steps be in order.

Moreover, the specification does not require the steps to be performed in a specific order. Indeed, an embodiment of the patent appears to “confirm,” “group,” and then “separate” the sequence reads. *Id.* at 3:21-31. A different embodiment appears to “separate” before “grouping.” *Id.* at 26:24-50 (describing grouping and matching by partner tags after separating the reads). Construing the patent claims to exclude these embodiments would require “highly persuasive evidentiary support”. *Vitronics Corp v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996). Guardant provides no such support. Tr.

Because the claim language read in light of the specification and the factual considerations do not militate in favor of requiring a strict order, the Court finds that the “grouping,” “separating,” and “confirming” steps do not need to be performed in the recited order. *See* ‘631 patent.

C. The Steps of the Asserted Claims May Be Performed Iteratively/Simultaneously.

The parties also dispute whether each step of the claimed method must be completed before the next step begins. *Tr.* The Court finds that iterative or simultaneous performance is within the scope of the claims.

Federal Circuit precedent has recognized that it is possible “claims require order but do not require discrete steps.” *Kaneka Corp. v. Xiamen Kingdomway Grp. Co.*, 790 F.3d 1298, 1306 (Fed. Cir. 2015). Where the “claims do not exclude a process in which every claim step is occurring simultaneously,” then “a process step does not need to be complete before another step begins.” *Id.* Without plain language in the claims requiring discrete performance, or disclaimer in the specification, “it is not required that any one step be carried out separately or independently of any other step.” *Id.*

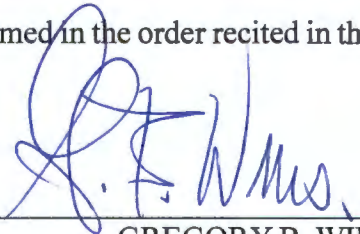
The plain language of the claims of the ‘127 and ‘631 patents does not require the steps to be carried out independently. *See* ‘127 patent; ‘631 patent. For example, one could “analyze” the correspondences between sequence reads while “comparing” those sequence reads to a reference sequence. *See* ‘127 patent at claim 1. Similarly, one could begin “identifying” nucleotide positions where the compared first and second strand sequence reads are non-complementary and “generating” a high accuracy consensus sequence read while still “comparing” the sequence reads. *See* ‘631 patent at claim 1. While not all steps can be logically performed at the same time as every other step (e.g. “confirming” the presence of first and second sequence reads probably must be completed before “generating” a consensus sequence

read, at least for an individual sequence read), the claims contemplate a generally continuous process. *See id.* Nothing in the plain language of the claims generally requires steps to be carried out separately or independently. *See id.*

The specification does not clearly disclaim simultaneous or iterative processing. *See id.* Instead, the specification appears to contemplate simultaneous and iterative processing. Figure 10 of both Asserted Patents contains code that iterates though a strand sequence read on a position-by-position basis, compares sequence reads, identifies complementary bases, and adds any consensus bases to a consensus sequence. '631 patent at Fig. 10. While the precise importance of this figure is disputed, Figure 10 at least weighs against a finding of disclaimer. *Compare* Pachter Decl., ¶¶ 31-33 *with* Quackenbush Decl. ¶¶ 27-44. Nothing else in the specification references iterative or simultaneous processing or operates as a disclaimer. *See* '631 patent. Accordingly, the Court construes the claims to include simultaneous or iterative performance.

III. CONCLUSION

At Wilmington this November 3, 2023, for the reasons set forth above, **IT IS HEREBY ORDERED** that the Court construes the '127 and '631 patents such that (1) the steps of claims 1 and 22 of the '127 patent must be performed in the order recited in the claims, (2) some, but not all of the steps of claim 1 of the '631 patent must be performed in the order recited in the claims, and (3) the steps of claim 21 of the '631 patent must be performed in the order recited in the claims.



GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE