UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

FATE THERAPEUTICS, INC.; and WHITEHEAD INSTITUTE FOR BIOMEDICAL RESEARCH, Plaintiffs, v. SHORELINE BIOSCIENCES, INC., Defendant.	Case No.: 22-cv-00676-H-MSB **ORDER:** **(1) GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT; AND** [Doc. No. 290.] **(2) DENYING PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT AS MOOT** [Doc. No. 289.]

On July 14, 2023, Defendant Shoreline Biosciences, Inc. ("Shoreline") filed a motion for summary judgment, and Plaintiffs Fate Therapeutics, Inc. ("Fate") and Whitehead Institute for Biomedical Research ("Whitehead") filed a motion for partial summary judgment. (Doc. Nos. 289, 290.) On July 28, 2023, the parties filed their respective responses in opposition. (Doc. Nos. 307, 312.) On August 4, 2023, the parties filed their respective replies. (Doc. Nos. 335, 340.)

The Court held a hearing on the matter on August 28, 2023. Jonathan D. Ball, Rose

C. Prey, Giancarlo L. Scaccia, Danielle M. Zapata, Joseph T. Ergastolo, Jeffrey R. Colin, Ben Witte, Aimee Housinger, and Wen Xue appeared for Plaintiffs. Eric M. Acker, Michael A. Jacobs, Drew A. Hillier, and Regan Rundio appeared for Defendant Shoreline. For the reasons below, the Court grants Shoreline's motion for summary judgment, and the Court denies Plaintiffs' motion for partial summary judgment as moot.

Background

In the present action, Plaintiffs assert claims for patent infringement under 35 U.S.C. §§ 271(a), (b), and (g) against Defendant Shoreline, alleging claims for infringement of U.S. Patent Nos. 8,071,369 ("the '369 Patent"), 8,932,856 ("the '856 Patent"), 8,951,797 ("the '797 Patent"), 8,940,536 ("the '536 Patent"), 9,169,490 ("the '490 Patent"), 10,457,917 ("the '917 Patent"), and 10,017,744 ("the '744 Patent") (collectively, "the asserted patents"). (Doc. No. 162, Supp. FAC ¶¶ 157-414.) Specifically, Plaintiffs allege that Shoreline makes, uses, sells, offers for sale, and/or imports induced pluripotent stem cells ("iPSCs") that infringe one or more claims of the asserted patents.[1, 2] (Id. ¶ 140; see, e.g., id. ¶¶ 162 ("Defendants' use of their 'iPSC-derived cell therapy manufacturing platform' infringed at least claim 1 of the '369 Patent."), 212 ("iPSCs used by Defendants to make at least the iPSC-derived natural kill (NK) cell platforms are made by a process

---

[1] Induced pluripotent stem cells ("iPSCs") "are pluripotent stem cells generated from somatic cells by reprogramming." (Doc. 162, Supp. FAC ¶ 31; see Doc. No. 184, Answer to Supp. FAC ¶ 31; see also Doc. No. 151-14, Plath Decl. ¶ 59; Doc. No. 152, Snyder Decl. ¶ 43.) "Four specific genes—cMYC, OCT3/4, SOX2 and KLF4—encoding transcription factors play a role in converting or reprogramming somatic cells into pluripotent stem cells." (Doc. 162, Supp. FAC ¶ 32; see Doc. No. 184, Answer to Supp. FAC ¶ 32; Doc. No. 199, Answer to Supp. FAC ¶ 32; see also Doc. No. 184, Counterclaims ¶ 43 ("iPSCs are generated in culture from somatic cells through the introduction of reprogramming factors that transform a somatic cell into a pluripotent state."); Doc. No. 152, Snyder Decl. ¶¶ 41, 43.)

[2] The asserted claims in this action are: claims 1-6, 8 and 9 of the '369 Patent; claims 1-7 of the '856 Patent; claims 1-6 and 8 of the '797 Patent; claims 1-10 and 12-17 of the '536 Patent; claims 1-6 and 8-10 of the '490 Patent; claims 1-18 of the '917 Patent; and claims 1-3 and 5-9 of the '744 Patent. (Doc. No. 354-7, Plath Decl. ¶ 1.)

that comprises at least each step of claim 1 of the '856 Patent.").)

Plaintiff Whitehead is the owner via assignment of the patents-in-suit. See U.S. Patent No. 8,071,369, at [73] (issued Dec. 6, 2011); U.S. Patent No. 8,932,856, at [73] (issued Jan. 13, 2015); U.S. Patent No. 8,951,797, at [73] (issued Feb. 10, 2015); U.S. Patent No. 8,940,536, at [73] (issued Jan. 27, 2015); U.S. Patent No. 9,169,490, at [73] (issued Oct. 27, 2015); U.S. Patent No. 10,017,744, at [73] (issued Jul. 10, 2018); U.S. Patent No. 10,457,917, at [73] (issued Oct. 29, 2019). Plaintiffs allege that Fate is the exclusive licensee of the asserted patents. (Doc. No. 162, Supp. FAC ¶¶ 16, 19.)

The '369 Patent is entitled "Compositions for reprogramming somatic cells" and was issued on December 6, 2011. '369 Patent at [45], [54]. The '856 Patent is entitled "Methods for reprogramming somatic cells" and was issued on January 13, 2015. '856 Patent at [45], [54]. The '797 Patent is entitled "Compositions for identifying reprogramming factors" and was issued on February 10, 2015. '797 Patent at [45], [54]. The '536 Patent is entitled "Methods for making somatic cells more susceptible to reprogramming" and was issued on January 27, 2015. '536 Patent at [45], [54]. The '490 Patent is entitled "Methods for reprogramming somatic cells" and was issued on October 27, 2015. '490 Patent at [45], [54]. The '744 Patent is entitled "Methods for reprogramming somatic cells" and was issued on Jul. 10, 2018. '744 Patent at [45], [54]. The '917 Patent is entitled "Methods for reprogramming somatic cells" and was issued on October 29, 2019. '917 Patent at [45], [54].

The asserted patents are all related and all share a common specification.[3] (See Doc. No. 149 at 5 & n.2; Doc. No. 151 at 2 & n.2 (the parties agreeing that the asserted patents all share the same specification); see also Doc. No. 162, Supp. FAC ¶ 132.) The shared specification states that the disclosed invention is directed to "methods for reprogramming somatic cells to a less differentiated state." '369 Patent col. 2 ll. 24-25; see also id. at [57]

[3] The Court will cite to the '369 Patent's specification as the "shared specification" of the asserted patents.

("The invention provides methods for reprogramming somatic cells to generate multipotent or pluripotent cells.").

The asserted composition patents are the '369 Patent, the '797 Patent, and the '490 Patent. Independent claim 1 of the '369 Patent claims:

> A composition comprising an isolated primary somatic cell that comprises an exogenously introduced nucleic acid encoding an Oct4 protein operably linked to at least one regulatory sequence.

'369 Patent col. 20 ll. 40-43.

Independent claim 1 of the '797 Patent claims:

> A composition comprising an isolated primary somatic cell that comprises an exogenously introduced nucleic acid encoding Oct 4, wherein the exogenously introduced nucleic acid increases Oct4 expression in the cell.

'797 Patent col. 20 ll. 40-43.

Independent claim 1 of the '490 Patent claims:

> A somatic cell comprising an exogenous nucleic acid encoding Oct4 and an amount of Oct4 expression comparable to the amount of Oct4 expression in an embryonic stem cell.

'490 Patent col. 20 ll. 39-41.

The asserted method patents are the '856 Patent, the '536 Patent, the '744 Patent, and the '917 Patent. Independent claim 1 of the '856 Patent claims:

> A method of making a somatic cell more susceptible to reprogramming to a pluripotent state comprising introducing at least one exogenous nucleic acid encoding Oct 4 operably linked to at least one regulatory sequence into the cell, thereby increasing expression of Oct4 protein in the somatic cell, wherein increased expression of Oct4 protein makes the cell more susceptible to reprogramming to a pluripotent state.

'856 Patent col. 20 ll. 38-44.

Independent claim 1 of the '536 Patent claims:

> A method of making a primary somatic cell more susceptible to reprogramming to a less differentiated state, comprising: introducing an exogenous nucleic acid encoding an Oct 4 protein operably linked to at least one regulatory sequence into the somatic cell, wherein expression of the exogenously introduced nucleic acid results in making the somatic cell more

susceptible to reprogramming to a less differentiated state.

'536 Patent col. 20 ll. 37-44.

Independent claim 1 of the '744 Patent claims:

> A method of making a somatic cell more susceptible to reprogramming to a cell having a less differentiated state, comprising:
>
> > obtaining a somatic cell that comprises an exogenously introduced polynucleic acid encoding Oct4 protein, and an exogenously introduced polynucleic acid encoding Sox2 or Nanog protein;
> >
> > wherein the exogenously introduced polynucleic acids result in making the somatic cell more susceptible to reprogramming to a less differentiated state.

'744 Patent col. 21 ll. 14-23.

Independent claim 1 of the '917 Patent claims:

> A method of making a somatic cell more susceptible to reprogramming to a less differentiated state, comprising: introducing an exogenous nucleic acid encoding an Oct 4 protein operably linked to at least one regulatory sequence into the somatic cell, thereby increasing expression of Oct4 protein in the somatic cell, wherein increased expression of Oct4 protein makes the cell more susceptible to reprogramming; and wherein the exogenous nucleic acid is transiently transfected into the somatic cell.

'917 Patent col. 21 ll. 16-24.

On May 13, 2022, Plaintiffs filed a complaint against Defendants Shoreline and Dan S. Kaufman, alleging claims for infringement of the '369 Patent, the '856 Patent, the '797 Patent, the '536 Patent, the '490 Patent, and the '917 Patent. (Doc. No. 1, Compl. ¶¶ 66-236.) On August 12, 2022, the Court issued a scheduling order. (Doc. No. 51.) On January 3, 2023, Plaintiffs filed a first amended complaint against Defendants, adding a claim for infringement of the '744 Patent. (Doc. No. 112, FAC ¶¶ 375-414.) On January 10, 2023, the Court issued an amended scheduling order. (Doc. No. 115.)

On February 14, 2023, Plaintiffs filed a supplemental first amended complaint – the operative complaint. (Doc. No. 162, Supp. FAC.) On February 17 and 23, 2023, Defendants filed answers and counterclaims to Plaintiffs' supplemental first amended complaint. (Doc. Nos. 184, 199.)

On February 28, 2023, the Court issued a claim construction order construing agreed up and disputed claim terms from the asserted patents.[4] (Doc. No. 208.) On March 27, 2023, the Court denied Shoreline's motion for partial summary judgment. (Doc. No. 226.) On March 30, 2023, the Court denied Defendants' partial motion to dismiss Plaintiffs' supplemental first amended complaint. (Doc. No. 234.) On June 9, 2023, the Court dismissed Defendant Kaufman from the action with prejudice pursuant to Plaintiffs' motion. (Doc. No. 273.)

By the present motions for summary judgment, Defendant Shorelines moves for summary judgment of all of Plaintiffs' claims for patent infringement – Plaintiffs' claims for direct infringement under 35 U.S.C. § 271(g); Plaintiffs' claims for induced infringement under § 271(b); and Plaintiffs' claims for direct infringement under § 271(a). (Doc. No. 354 at 1-2.) In addition, Plaintiffs move for partial summary judgment of: (1) the underlying direct infringement of the '369 Patent by ThermoFisher in support of their claim for induced infringement under § 271(b); and (2) of certain affirmative defenses and certain counterclaims that the asserted method claims are invalid under 35 U.S.C. §§ 101, 102, and 103. (Doc. No. 352-14 at 1-2, 7-15.)

Discussion

I. Legal Standards

A. Legal Standards Governing Summary Judgment

Summary judgment is appropriate under Federal Rule of Civil Procedure 56 if the moving party demonstrates "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); Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). Material facts are facts that, under the governing substantive law, may affect the outcome of the case. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A dispute as to a material fact is genuine if there is sufficient

[4] On April 19, 2023, the Court denied Plaintiffs' motion for reconsideration of the Court's claim construction order. (Doc. No. 255.)

evidence for a reasonable jury to return a verdict for the non-moving party. Id. "Disputes over irrelevant or unnecessary facts will not preclude a grant of summary judgment." T.W. Elec. Serv., Inc. v. Pac. Elec. Contractors Ass'n, 809 F.2d 626, 630 (9th Cir. 1987).

A party seeking summary judgment always bears the initial burden of demonstrating that there is no genuine dispute as to any material fact. Celotex, 477 U.S. at 323. A moving party without the ultimate burden of proof at trial can satisfy its burden in two ways: (1) by presenting "evidence negating an essential element of the nonmoving party's claim or defense;" or (2) by demonstrating "that the nonmoving party does not have enough evidence of an essential element to carry its ultimate burden of persuasion at trial." Nissan Fire & Marine Ins. Co. v. Fritz Companies, Inc., 210 F.3d 1099, 1102 (9th Cir. 2000). Once the moving party establishes the absence of a genuine dispute as to any material fact, the burden shifts to the nonmoving party to "set forth, by affidavit or as otherwise provided in Rule 56, 'specific facts showing that there is a genuine issue for trial.'" T.W. Elec. Serv., 809 F.2d at 630 (quoting former Fed. R. Civ. P. 56(e)); accord Horphag Research Ltd. v. Garcia, 475 F.3d 1029, 1035 (9th Cir. 2007). To carry this burden, the non-moving party "may not rest upon mere allegation or denials of his pleadings." Anderson, 477 U.S. at 256; see also Behrens v. Pelletier, 516 U.S. 299, 309 (1996) ("On summary judgment, . . . the plaintiff can no longer rest on the pleadings."). Rather, the nonmoving party "must present affirmative evidence . . . from which a jury might return a verdict in his favor." Anderson, 477 U.S. at 256.

When ruling on a summary judgment motion, the court must view the facts and draw all reasonable inferences in the light most favorable to the non-moving party. Scott v. Harris, 550 U.S. 372, 378 (2007). The court should not weigh the evidence or make credibility determinations. See Anderson, 477 U.S. at 255. "The evidence of the non-movant is to be believed." Id. Further, the court may consider other materials in the record not cited to by the parties, but it is not required to do so. See Fed. R. Civ. P. 56(c)(3); see also Simmons v. Navajo Cnty., 609 F.3d 1011, 1017 (9th Cir. 2010) ("[A] district court has no independent duty 'to scour the record in search of a genuine issue of triable fact.'").

B. Legal Standards Governing Patent Infringement

A patent infringement analysis proceeds in two steps. Niazi Licensing Corp. v. St. Jude Med. S.C., Inc., 30 F.4th 1339, 1350 (Fed. Cir. 2022); JVW Enterprises, Inc. v. Interact Accessories, Inc., 424 F.3d 1324, 1329 (Fed. Cir. 2005). In the first step, the court construes the asserted claims as a matter of law. See Niazi, 30 F.4th at 1351; JVW, 424 F.3d at 1329. In the second step, the factfinder compares the properly construed claims to the allegedly infringing device (for an apparatus claim) or the allegedly infringing act (for a method claim). See id.

"'The patentee bears the burden of proving infringement by a preponderance of the evidence.'" Creative Compounds, LLC v. Starmark Labs., 651 F.3d 1303, 1314 (Fed. Cir. 2011); see Medtronic, Inc. v. Mirowski Fam. Ventures, LLC, 571 U.S. 191, 193 (2014) ("A patentee ordinarily bears the burden of proving infringement."). "To prove infringement, the plaintiff bears the burden of proof to show the presence of every element or its equivalent in the accused device [or process]." Uniloc USA, Inc. v. Microsoft Corp., 632 F.3d 1292, 1301 (Fed. Cir. 2011); accord Star Sci., Inc. v. R.J. Reynolds Tobacco Co., 655 F.3d 1364, 1378 (Fed. Cir. 2011).

Under the doctrine of equivalents, "a product or process that does not literally infringe . . . the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." Warner–Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 21 (1997); accord Eagle Pharms. Inc. v. Slayback Pharma LLC, 958 F.3d 1171, 1175 (Fed. Cir. 2020). The Federal Circuit "applies two articulations of the test for equivalence." Voda v. Cordis Corp., 536 F.3d 1311, 1326 (Fed. Cir. 2008) (citing Warner–Jenkinson, 520 U.S. at 21); see UCB, Inc. v. Watson Lab'ys Inc., 927 F.3d 1272, 1284 (Fed. Cir. 2019). Under the insubstantial differences test, "'[a]n element in the accused device is equivalent to a claim limitation if the only differences between the two are insubstantial.'" UCB, 927 F.3d at 1284 (quoting Voda, 536 F.3d at 1326). "Alternatively, under the function-way-result test, an element in the accused device is

equivalent to a claim limitation if it 'performs substantially the same function in substantially the same way to obtain substantially the same result.'" Voda, 536 F.3d at 1326 (quoting Schoell v. Regal Marine Indus., Inc., 247 F.3d 1202, 1209–10 (Fed. Cir. 2001)); see Ajinomoto Co. v. Int'l Trade Comm'n, 932 F.3d 1342, 1356 (Fed. Cir. 2019). "Regardless how the equivalence test is articulated, 'the doctrine of equivalents must be applied to individual limitations of the claim, not to the invention as a whole.'" Mirror Worlds, LLC v. Apple Inc., 692 F.3d 1351, 1357 (Fed. Cir. 2012) (quoting Warner–Jenkinson, 520 U.S. at 29).

"'Infringement, whether literal or under the doctrine of equivalents, is a question of fact.'" Advanced Steel Recovery, LLC v. X-Body Equip., Inc., 808 F.3d 1313, 1317 (Fed. Cir. 2015) (quoting Absolute Software, Inc. v. Stealth Signal, Inc., 659 F.3d 1121, 1129–30 (Fed. Cir. 2011)). "Summary judgment of noninfringement is proper when no reasonable jury could find that every limitation recited in a properly construed claim is found in the accused device either literally or under the doctrine of equivalents." Advanced Steel, 808 F.3d at 1317; see EMD Millipore Corp. v. AllPure Techs., Inc., 768 F.3d 1196, 1201 (Fed. Cir. 2014).

II. Plaintiffs' Claims for Direct Infringement Under 35 U.S.C. § 271(g)

In the operative complaint, Plaintiffs allege that Shoreline infringes the asserted method patents – the '856 Patent, the '536 Patent, the '744 Patent, and the '917 Patent – under 35 U.S.C. § 271(g). (Doc. No. 162, Supp. FAC ¶¶ 211-14, 283-86, 356-59, 396-99.) Shoreline moves for summary judgment that it does not infringe the asserted method patents under § 271(g) by using the accused iPSCs. (Doc. No. 351 at 8-23.)

Section 271(g) of the Patent Act provides:

> Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for

> infringement on account of the importation or other use, offer to sell, or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after—
>
> (1) it is materially changed by subsequent processes; or
>
> (2) it becomes a trivial and nonessential component of another product.

35 U.S.C. § 271(g). By its terms, "Section 271(g) prohibits the unauthorized importation into the United States, or sale or use within the United States, of a 'product which is made by a process patented in the United States.'" Momenta Pharms., Inc. v. Teva Pharms. USA Inc., 809 F.3d 610, 615 (Fed. Cir. 2015) (quoting 35 U.S.C. § 271(g)) (emphasis removed); see Syngenta Crop Prot., LLC v. Willowood, LLC, 944 F.3d 1344, 1359 (Fed. Cir. 2019) (Section 271(g) "makes clear that the acts that give rise to liability under § 271(g) are the importation, offer for sale, sale, or use within this country of a product that was made by a process patented in the United States.").

Plaintiffs' claim for infringement under § 271(g) against Shoreline is based on Shoreline's purchase and use of certain iPSCs that were manufactured by third parties. (See Doc. No. 162, Supp. FAC ¶¶ 211-14, 283-86, 356-59, 396-99; Doc. No. 354-24, Plath Expert Report ¶¶ 56-566.) Shoreline argues that it does not infringe the asserted method claims because the accused iPSCs were not made using the required two-step "priming" process, and they were not made using somatic cell nuclear transfer ("SCNT"). (Doc. No. 351 at 8.) All of the asserted method claims include within the claimed method the step of "[makes/making/make] the [somatic] cell more susceptible to reprogramming." '856 Patent col. 20 ll. 43-44; '536 Patent col. 20 ll. 42-44, col. 20 ll. 61-63, col. 21 ll. 13-14; '744 Patent col. 21 ll. 22-23; '917 Patent col. 21 ll. 22-23, col. 22 ll. 12-13. In the claim construction order, the Court construed that claim term as "[primes/priming/prime] the [somatic] cell to improve the cloning efficiency of the subsequent reprogramming."[5] (Doc. No. 208 at 33.)

---

[5] The Court subsequently denied Plaintiffs' motion for reconsideration of this claim construction. (Doc. No. 255 at 11-28.)

The Court's claim construction for the claim term is two-part. First, as explained in the February 28, 2023 claim construction order and the April 19, 2023 order denying Plaintiffs' motion for reconsideration, the Court's claim construction requires a two-step process where there is an initial or antecedent "priming" step then a "subsequent reprogramming step." (See id. at 31-32; Doc. No. 255 at 18-23.) Second, the Court's claim construction requires that the "priming" step improve the "cloning efficiency" of the subsequent reprogramming step. (Doc. No. 208 at 22-26; Doc. No. 255 at 23-28.) Shoreline argues that the accused processes used to manufacture the iPSCs at issue do not satisfy either of these requirements contained in the Court's claim construction. (Doc. No. 351 at 8.) The Court addresses those two requirements in turn below.

A. The Two-Step Process of "Priming" and then "Reprogramming"

Shoreline argues that it does not infringe the asserted method claims under § 271(g) because no accused iPSC line was made using the two-step process required by the Court's claim construction. (Doc. No. 351 at 11.) In setting forth the relevant claim construction, the Court explained that the asserted method claims require a two-step process where there is an initial or antecedent "priming" step involving the induction of Oct4 expression and then a "subsequent reprogramming step." (See Doc. No. 208 at 31-32; Doc. No. 255 at 18-23.)

Shoreline argues that the reprogramming processes used by the iPSC manufacturers at issue do not satisfy the relevant two-step requirement because, in the processes at issue, Oct4 is added with other transcription factors in one step to initiate the reprogramming process. (Doc. No. 351 at 11-13.) In response, Plaintiffs argue that Shoreline's contention is merely semantic and without merit. (Doc. No. 354 at 10.) But in making this argument, Plaintiffs concede that Oct4 is used during the overall reprogramming processes at issue. (See Doc. No. 354 at 10 ("The reprogramming process still entails two steps: Oct4 first primes the somatic cell genome for subsequent reprogramming independent of the other transcription factors.").) Indeed, consistent with this, Plaintiffs' technical expert Dr. Plath describes the process of making iPSCs as a "two-step reprogramming process." (Doc. No.

354-7, Plath Decl. at pp. 23 ("1. Yamanaka's two-step reprogramming process"), 24 ("Dr. Kaufman's Articles Describe a Two-Step Reprogramming Process"), 26 ("Lonza's Infringing Two-Step Reprogramming Process"), 28 ("ThermoFisher's Infringing Two-Step Process").) Indeed, during her deposition, Dr. Plath explained that what she considered to be the "priming" step of the direct reprogramming process "is an essential step of the entire process" and "is the initial step of reprogramming." (Doc. No. 351-11, Plath Depo. at 430; see also Doc. No. 351-23, Plath Expert Report ¶¶ 223, 443, 490.)

In light of these concessions by Plaintiffs and their expert Dr. Plath, Plaintiffs cannot demonstrate that the iPSC reprogramming processes at issue satisfy the Court's claim construction for the relevant claim term. The Court's claim construction specifically requires that the induction of Oct4 expression occur prior to and be separate from the reprogramming process. (See Doc. No. 208 at 31-32; Doc. No. 255 at 18-23.) Plaintiffs and their expert concede that in the direct reprogramming processes at issue the induction of Oct4 occurs during the reprogramming process and is the initial step of the reprogramming process. As such, Plaintiffs cannot demonstrate infringement of the asserted method claims under § 271(g) as a matter of law. See Presidio Components, Inc. v. Am. Tech. Ceramics Corp., 702 F.3d 1351, 1358 (Fed. Cir. 2012) ("'If any claim limitation is absent from the accused device, there is no literal infringement as a matter of law.'"); see also Duncan Parking Techs., Inc. v. IPS Grp., Inc., 914 F.3d 1347, 1363 (Fed. Cir. 2019) (explaining that a district court need not "credit an expert's testimony" regarding infringement when it is "clearly foreclosed by the district court's claim construction").[6]

Plaintiffs assert that infringement can be demonstrated because the direct reprogramming process entails two steps. (Doc. No. 354 at 10.) Plaintiffs further argue that whether one refers to "priming" with Oct4 as part of an overall process of

---

[6] Plaintiffs do not assert a theory of infringement under the doctrine of equivalents as to the two-step requirement portion of the Court's claim construction. (See Doc. No. 354 at 18 ("Plaintiffs rely on DOE only for the 'cloning efficiency' portion of the Court's construction of 'makes a cell more susceptible to reprogramming.'").)

reprogramming or refers to only the step after "priming" with Oct4 as reprogramming is "trivial" and "merely semantic." (Id.; see also Doc. No. 354-7, Plath Decl. ¶ 45 ("Whether the entire two-step process or only the second step is styled 'reprogramming' is inconsequential . . . .").) The Court disagrees. A proper literal infringement analysis involves a comparison of the properly construes claims to the allegedly infringing process. See Niazi, 30 F.4th at 1351; JVW, 424 F.3d at 1329. Under that analysis, the precise meaning of words and the precise scope of the claims matter. Under the Court's claim construction for the relevant claim term, the precise scope of the asserted method claims is that the relevant "priming" step must occur "prior to" the reprogramming step. It does not matter that the direct reprogramming process overall can be described as a two-step process. If the purported "priming" step occurs during the reprogramming processes – as Plaintiffs and their expert concede –, then the processes do not satisfy the Court's claim construction of the relevant claim term, meaning there is no literal infringement as a matter of law.

In sum, the accused direct reprogramming processes at issue do not satisfy the Court's claim construction for the claim term "[makes/making/make] the [somatic] cell more susceptible to reprogramming," and, therefore, Plaintiffs cannot establish infringement of the asserted method claims under § 271(g) as a matter of law. As a result, Shoreline is entitled to summary judgment of Plaintiffs' § 271(g) claims for patent infringement. See Presidio, 702 F.3d at 1358.

B. "[primes/priming/prime] . . . to improve . . . cloning efficiency"

Shoreline also argues that it does not infringe the asserted method claims under § 271(g) because none of the accused cell lines were made by priming a somatic cell to improve "cloning efficiency." (Doc. No. 351 at 13-21.) In response, Plaintiffs argue that Defendants' motion for summary judgment on this ground should be denied because the "cloning efficiency" limitation contained in the Court's claim construction for the relevant claim term can be satisfied under the doctrine of equivalents. (Doc. No. 354 at 12-27.)

As an initial matter, the Court rejects Plaintiffs' attempt to isolate the phrase "cloning

efficiency" and analyze infringement under the doctrine of equivalents as to only that specific phrase. The Supreme Court and the Federal Circuit have explained that "'the doctrine of equivalents must be applied to individual limitations of the claim.'" Mirror Worlds, 692 F.3d at 1357 (quoting Warner–Jenkinson, 520 U.S. at 29). Here, the relevant limitation is "[primes/priming/prime] the [somatic] cell to improve the cloning efficiency of the subsequent reprogramming." (Doc. No. 208 at 33.) It is not simply the phrase "cloning efficiency." As such, the Court will apply the doctrine of equivalents to that limitation as a whole.[7]

i. Exclusion From Scope of the Claims

Shoreline argues that Plaintiffs' theory of infringement under the doctrine of equivalents fails as a matter of law because Plaintiffs cannot recapture subject matter that the Court has specifically held to be outside the scope of the claims. (Doc. No. 351 at 14-15.) The Court agrees.

The Federal Circuit has explained that the "the concept of equivalency cannot embrace a structure that is specifically excluded from the scope of the claims." Dolly, Inc. v. Spalding & Evenflo Companies, Inc., 16 F.3d 394, 400 (Fed. Cir. 1994); accord Enzo Biochem Inc v. Applera Corp., 702 F. App'x 971, 977 (Fed. Cir. 2017). At claim construction, the parties thoroughly litigated the issue of whether the claim limitation at issue encompasses direct reprogramming. Indeed, this issue was directly addressed not only at the claim construction hearing but also through Plaintiffs' subsequent motion for reconsideration.

In both the claim construction order and the order denying Plaintiffs' motion for reconsideration, the Court specifically held that direct reprogramming is excluded from the scope of the claim term "[makes/making/make] the [somatic] cell more susceptible to

---

[7] At the summary judgment hearing, Plaintiffs stated that they did not think that it would matter if the Court analyzed infringement under the doctrine of equivalents using the broader limitation. (Doc. No. 385 at 34-35.)

reprogramming." Indeed, in the April 19, 2023, order denying Plaintiffs' motion for reconsideration, the Court expressly held that the scope of the claims only encompassed "blastocyst formation and ES cell derivation" efficiency, "nuclear transfer cloning efficiency," and "cloning efficiency," which "are all specific to SCNT." (Doc. No. 255 at 27.) And the Court expressly rejected Plaintiffs' contention that the claims could encompass "the efficiency of ES cell generation generally," which would include direct reprogramming processes. (Id. at 23-26.) The Court explained: "That the efficiency at issue was consistently described in the intrinsic record within the specific context of SCNT is important because both the specification of the asserted patents and Plaintiffs' own presentation at the February 27, 2023 [claim construction] hearing make clear that SCNT is very different than direct reprogramming." (Id. at 25-26 (citing '369 Patent col. 1 ll. 46-55, col. 2 ll. 4-13, col. 3 ll. 60-67, col. 4 ll. 30-32; Doc. No. 218 at 3-6).) In other words, both the specification of the asserted patents and Plaintiffs' presentation at the claim construction hearing make clear that using Oct4 during the direct reprogramming process is not equivalent to using Oct4 to prime a cell for subsequent SCNT reprogramming. Because the Court specifically held that direct reprogramming processes are excluded from the scope of the claims at issue, Plaintiffs cannot rely on the doctrine of equivalents to recapture that claim scope as a matter of law. See Dolly, 16 F.3d at 400; Enzo, 702 F. App'x at 977.

Plaintiffs contend that the Federal Circuit cases cited above are inapplicable here because they merely "stand for the proposition that a patentee cannot resort to DOE to encompass a feature that is the opposite of the recited limitation." (Doc. No. 354 at 12 (emphasis removed).) The Court rejects Plaintiffs' erroneous attempt to narrow the holdings in Dolly and Enzo. There is no discussion in either Dolly or Enzo regarding whether the accused product included a feature that is the "opposite" of the recited limitation. Indeed, the word "opposite" is not even contained in either of those decisions. See generally Dolly, 16 F.3d at 396-400; Enzo, 702 F. App'x at 972-77. Rather, those two decisions broadly hold that "the concept of equivalency cannot embrace a structure that is

specifically excluded from the scope of the claims." Dolly, 16 F.3d at 400; accord Enzo, 702 F. App'x at 977. As such, the Court rejects Plaintiffs' attempt to distinguish or narrow the holdings in Dolly and Enzo.[8]

Plaintiffs assert that the Federal Circuit has explained that subject matter is not "specifically excluded" from coverage under the doctrine of equivalents unless its inclusion is somehow inconsistent with the language of the claim. (Doc. No. 354 at 14 (citing Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp., 149 F.3d 1309, 1317 (Fed. Cir. 1998)).) See also Augme Techs., Inc. v. Yahoo! Inc., 755 F.3d 1326, 1335 (Fed. Cir. 2014) ("[W]e have found 'specific exclusion' where the patentee seeks to encompass a structural feature that is the opposite of, or inconsistent with, the recited limitation."). The Court reiterates that both the specification of the asserted patents and Plaintiffs' own presentation at the claim construction hearing make clear that using Oct4 to prime a cell for the SCNT process is very different than using Oct4 during the direct reprogramming process. (See Doc. No. 205 at 25-26.) And it would be inconsistent with those statements in the specification and those prior statements made by Plaintiffs to permit the accused directed reprogramming processes to be equivalent to priming a cell to improve the cloning efficiency of the subsequent SCNT process as required by the Court's claim construction. In sum, Plaintiffs' theory of infringement under the doctrine of equivalents fails as a matter of law because the Court has expressly held that direct reprogramming methods are excluded from the scope of the asserted method claims.

/ / /

/ / /

---

[8] Plaintiffs also note that the Federal Circuit's decision in Enzo is non-precedential. (Doc. No. 354 at 12.) The Court acknowledges that Enzo is an unpublished non-precedential decision from the Federal Circuit. But that is of no consequence because the Court may still rely on it as persuasive authority, and the Court finds the decision to be persuasive. In addition, the Court's analysis also relies on the Federal Circuit's decision in Dolly, which is a published opinion that is binding authority on this Court.

ii. Prosecution History Estoppel

Shoreline also argues that Plaintiffs' theory of infringement under the doctrine of equivalents arguments is foreclosed by prosecution history estoppel. (Doc. No. 351 at 15-17.) In response, Plaintiffs argue that prosecution history estoppel does not bar their doctrine of equivalents arguments. (Doc. No. 354 at 15-19.)

"'Prosecution history estoppel applies as part of an infringement analysis to prevent a patentee from using the doctrine of equivalents to recapture subject matter surrendered from the literal scope of a claim during prosecution.'" Pharma Tech Sols., Inc. v. LifeScan, Inc., 942 F.3d 1372, 1380 (Fed. Cir. 2019) (quoting Trading Techs. Int'l, Inc. v. Open E Cry, LLC, 728 F.3d 1309, 1322 (Fed. Cir. 2013)); see Traxcell Techs., LLC v. Nokia Sols. & Networks Oy, 15 F.4th 1136, 1145 (Fed. Cir. 2021) ("If a patentee surrenders some scope during prosecution, that territory isn't available later as a doctrine-of-equivalents battleground."). Prosecution history estoppel can occur in two ways: either (1) by making a narrowing amendment to the claim ("amendment-based estoppel") or (2) by surrendering claim scope through argument to the patent examiner ("argument-based estoppel"). Pharma Tech, 942 F.3d at 1380. "The relevant inquiry is 'whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter.'" Traxcell, 15 F.4th at 1146 (quoting Amgen Inc. v. Coherus BioSciences Inc., 931 F.3d 1154, 1159 (Fed. Cir. 2019)).

"A narrowing amendment is presumed to be a surrender of all equivalents within 'the territory between the original claim and the amended claim.'" Bio-Rad Lab'ys, Inc. v. 10X Genomics Inc., 967 F.3d 1353, 1364 (Fed. Cir. 2020) (quoting Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 728 (2002)). "This presumption can be overcome if the patentee can show that one of the following 'exceptions' to prosecution history estoppel applies: (1) the rationale underlying the amendment bears no more than a tangential relation to the equivalent in question; (2) the equivalent was unforeseeable at the time of the application; or (3) there was some other reason suggesting that the patentee could not reasonably be expected to have described the equivalent." Id.

The Federal Circuit has explained that a court should "'review[] a patent family's entire prosecution history when applying . . . prosecution history estoppel.'" In re McDonald, 43 F.4th 1340, 1347 (Fed. Cir. 2022) (quoting MBO Lab'ys, Inc. v. Becton, Dickinson & Co., 602 F.3d 1306, 1318 (Fed. Cir. 2010)) ("'Because the rule against recapture and prosecution history estoppel both protect the public's interest in relying on a patent's prosecution history, we think equity requires a review of a patent family's prosecution history to protect against recapture in a reissue patent.'"). "Whether prosecution-history estoppel applies is a question of law." Traxcell, 15 F.4th at 1146.

As detailed in the Court's February 28, 2023 claim construction order, during the prosecution of the '536 Patent, the patentees attempted to obtain method claims encompassing "a method of reprogramming a primary somatic cell to a less differentiated state." (Doc. No. 152-4, Snyder Decl. Ex. 27 at 508-09; see also Doc. No. 208 at 27-29.) In an office action dated April 11, 2014, the examiner rejected these claims under 35 U.S.C. § 112 ¶ 1 for failure to comply with the enablement requirement. (Doc. No. 113-5, Ex. B-31 at 1-16; see also Doc. No. 113-3, Ex. B-23; Doc. No. 113-4, Ex. B-28.) In providing the basis for these enablement rejections, the examiner explained:

> The specification provides specific guidance to the production of a transgenic mouse comprising in its genome an inducible exogenous Oct4 gene. The specification provides specific guidance to the isolation of fibroblasts from said transgenic mouse and inducing Oct4 expression in said fibroblasts by treatment with deoxycycline. The specification provides specific guidance to nuclear transfer experiments, wherein said fibroblasts were treated with DOX to induce Oct4 expression and then transferred into enucleated oocytes to produce nuclear transfer units. The specification teaches that the nuclear transfer units were cultured to the blastocyst stage and ES cell were derived from the nuclear transfer units. The specification further teaches that on average blastocyst formation and ES cell derivation is more efficient when Oct4 induced fibroblasts are used as compared to un-induced fibroblasts. The specification thus concludes that inducing Oct4 expression in somatic cells makes these cells more susceptible to reprogramming.
>
> While the specification provides specific guidance to a means of priming somatic cells for reprogramming, the specification fails to provide any guidance to a method that predictably reprograms primary somatic cells

> to a less differentiated state by solely introducing a nucleic acid encoding Oct4 to said somatic cell or by solely introducing an Oct4 protein into said somatic cell. The specification fails to assess the differentiation status of the somatic cells after induction of Oct4 but before reprogramming the somatic cell by nuclear transfer. As such, the specification has provided no evidence that alone the exogenous Oct4 in the cell is reprogramming the somatic cell to a less differentiated state. The specification further fails to provide any teaching to the narrower embodiments of the claims encompassing introduction of Oct4 into an adult stem cell, such as hematopoietic stem cells, neural stem cells, or mesenchymal stem cells. As such, the specification fails to demonstrate that introduction of Oct4 into such adult stem cells or any cells will predictably result in a less differentiated state as the claims require.
>
> Thus, the specification fails to enable the instant claims because the invention disclosed by the specification is not commensurate in scope with the method of the claims. . . .
>
> The specification provides specific guidance to a method of priming a somatic cell for reprogramming by introducing Oct4 activity into said somatic cell. This cannot properly be interpreted as commensurate in scope with a method of reprogramming a somatic cell by solely introducing Oct4 because the specification fails to teach that Oct4 alone reprograms a cell. As such, the specification fails to enable a method of reprogramming a cell to a less differentiated state by introduction of Oct4 because the specification fails to provide specific guidance to such embodiments and actually teaches an invention of a total different scope.

(Doc. No. 113-5, Ex. B-31 at 3-5 (emphasis in original) (citations omitted); see also id. at 7 ("[T]he specification describes a method of priming a somatic cell for reprogramming by solely introducing Oct4.").) Here, in analyzing enablement, the examiner explained the scope of the invention disclosed in the shared specification and explained why that scope did not encompass a method of reprogramming a somatic cell to a less differentiated state by introduction of Oct4 alone.

In response to the examiner's enablement rejections, the patentees amended the claims at issue to claim a method of making a primary somatic cell more susceptible to reprogramming to a less differentiated state. (Doc. No. 113-5, Ex. B-32; see also Doc. No. 151 at 6.) For example, the patentees amended claim 1 of the application as follows:

> 1. (Currently amended) A method of making ~~reprogramming~~ a primary

> somatic cell more susceptible to reprogramming to a less differentiated state, comprising: introducing an exogenous nucleic acid encoding an Oct 4 protein operably linked to at least one regulatory sequence into the somatic cell, wherein expression of the exogenously introduced nucleic acid results in making ~~reprogramming~~ the somatic cell more susceptible to reprogramming to a less differentiated state.

(Doc. No. 113-5, Ex. B-32 at 2 (underlining and strike outs in original).) In providing these amendments, the patentees did not dispute the examiner's characterizations of the scope of the invention disclosed in the specification. Rather, the patentees stated with respect to enablement:

> Applicants submit that the presently claimed subject matter is enabled by the as-filed specification, as acknowledged by the Office in the Actions mailed August 20, 2013, and April 11, 2014. *See* Office Action mailed April 11, 2014, last sentence of second paragraph of page 3, paragraph bridging pages 3-4, paragraph bridging pages 4-5, and first full paragraph of page 7.
>
> Accordingly, this basis for rejection is now moot and properly withdraw.

(Id. at 5.) The examiner allowed the claims as amended. (See Doc. No. 113-5, Ex. B-33.)

In the claim construction order, the Court held that the above amendments and correspondence with the examiner constitute a prosecution disclaimer, and the Court held that, as a result of that disclaimer, "the claims at issue are limited to a method of 'priming' a somatic cell for reprogramming." (Doc. No. 208 at 30 (citing Biogen Idec, Inc. v. GlaxoSmithKline LLC, 713 F.3d 1090 (Fed. Cir. 2013); SandBox Logistics LLC v. Proppant Express Invs. LLC, 813 F. App'x 548 (Fed. Cir. 2020)). These amendments and disclaimer are also relevant to the Court's analysis of prosecution history estoppel.

Because the patentees amended the claims at issue in light of the examiner's enablement rejection, there is a presumption that the patentees surrendered "all equivalents within 'the territory between the original claim and the amended claim.'" Bio-Rad, 967 F.3d at 1364 (quoting Festo, 535 U.S. at 728). The original claim at issue encompassed reprogramming generally, including direct reprogramming. (See Doc. No. 385 at 33 (Plaintiffs explaining: "Professor Jaenisch was attempting to get a claim that covered direct

reprogramming. And, to be clear, it's going to cover any form of reprogramming, direct or SCNT. He was trying to get a claim that was going to cover reprogramming using exogenous Oct4."), 65-66.) But that claim was rejected by the examiner on enablement grounds. Indeed, the examiner specifically stated that "the art at the time [of the invention] was not developed to the point of demonstrating any methods of direct reprogramming with pluripotency factors, let alone, solely the use of Oct4." (Doc. No. 113-5, Ex. B-31 at 5.) The claims as amended were narrowed to only encompass a two-step method of priming a cell to improve the cloning efficiency of the subsequent reprogramming step. (See Doc. No. 208 at 22-26, 31-32; Doc. No. 255 at 18-28.) As such, there is a presumption that by amending the claims in the above manner, the patentees surrendered any equivalent related to direct reprogramming, including any method of purportedly priming a cell to improve the efficiency of direct reprogramming.

Plaintiffs argue that Shoreline's prosecution history estoppel argument fails because the rationale for the amendments at issue only bore a tangential relation to the equivalent in question. (Doc. No. 354 at 16-19.) The presumption that a patentee has surrendered all equivalents within the territory of the original claim and the amended claims can be overcome if the patentee can show that "the rationale underlying the amendment bears no more than a tangential relation to the equivalent in question." Bio-Rad, 967 F.3d at 1364. This criterion asks, in other words, "whether the reason for the narrowing amendment was peripheral, or not directly relevant, to the alleged equivalent." Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 344 F.3d 1359, 1369 (Fed. Cir. 2003). The inquiry "focuses on the patentee's objectively apparent reason for the narrowing amendment." Id. Plaintiffs cannot make the required showing for demonstrating a tangential relation.

Plaintiffs assert that the examiner's rejection focused on the lack of enablement for reprogramming with Oct4 alone. (Doc. No. 354 at 17.) Although the Court agrees with Plaintiffs that this was one of the issues that the examiner focused on in making her enablement rejection, it was not the only issue. The examiner also focused on the fact that "the art at the time [of the invention] was not developed to the point of demonstrating any

methods of direct reprogramming with pluripotency factors, let alone, solely the use of Oct4." (Doc. No. 113-5, Ex. B-31 at 5.) In addition, the narrowing amendments at issue were made in acquiescence to the examiner's repeated characterizations of the specification as disclosing only a method of "priming" a somatic cell to improve the cloning efficiency of the subsequent SCNT reprogramming. (See id. at 4 ("The specification provides specific guidance to a method of priming a somatic cell for reprogramming by introducing Oct4 activity into said somatic cell"), 7 ("The specification describes a method of priming a somatic cell for reprogramming by solely using Oct4"), 8 ("[T]he experiments described in the specification . . . solely demonstrate[] that addition of Oct4 expression enhances nuclear transfer cloning efficiency and nuclear transfer's reprogramming process."), 13 ("[T]he nuclear transfer experimental model is only informative to the impact of Oct4 exogenous expression on the degree of cloning efficiency or the degree reprogramming completeness or effectiveness upon the number of reprogrammed fibroblast nuclei."); see also Doc. No. 255 at 18-28.) Because the equivalent in question is an attempt to expand the claim beyond SCNT and cloning efficiency and to instead encompass a method of using Oct4 during the direct reprogramming process, it is directly related to the narrowing amendments and the prosecution history at issue. As a result, prosecution history estoppel applies and bars Plaintiffs' theory of infringement under the doctrine of equivalents as to the "[makes/making/make] the [somatic] cell more susceptible to reprogramming" claim limitation.

Plaintiffs argue that Shoreline's prosecution history estoppel argument is faulty because Shoreline ignores that the earlier-issued '856 Patent always included the "making a cell more susceptible to reprogramming" limitation. (Doc. No. 354 at 15.) Plaintiffs further state that Shoreline's motion fails to explain how the amendments in the later '536 Patent estop Plaintiff from relying on the doctrine of equivalents for the '856 Patent. (Id.) That the claims of the '856 patent were never amended and issued before the '536 Patent is of no consequence. The Federal Circuit has explained that a court should review "'a

patent family's entire prosecution history'" when applying prosecution history estoppel.[9] McDonald, 43 F.4th at 1347 (quoting MBO, 602 F.3d at 1318); see also, e.g., Microsoft Corp. v. Multi-Tech Sys., Inc., 357 F.3d 1340, 1350 (Fed. Cir. 2004) (applying the prosecution history of one patent to an earlier issued related patent). The '856 Patent and the '536 Patent are part of the same patent family. (See Doc. No. 162, Supp. FAC ¶ 132 ("The Asserted Patents are related, share a common specification, and claim priority to at least November 26, 2003."); Doc. No. 354-24, Ex. 37, Plath Expert Report ¶ 36 ("I understand that each of the Patents-in-Suit claim priority to provisional application No. 60/525,612, filed on November 26, 2003 and provisional application No. 60/530,042, filed on December 13, 2003.").) As such, the '536 Patent's prosecution history is relevant to the '856 Patent, and, thus, prosecution history estoppel applies to the '856 Patent. See McDonald, 43 F.4th at 1347.

In sum, prosecution history estoppel applies and bars Plaintiffs' theory of infringement under the doctrine of equivalents as to the "[primes/priming/prime] the [somatic] cell to improve the cloning efficiency of the subsequent reprogramming" claim limitation. As such, this is an additional reason why Plaintiffs' claim for infringement under the doctrine of equivalents fails as a matter of law.

/ / /

/ / /

---

[9] Plaintiffs note that the Federal Circuit has explained that "[w]hen multiple patents derive from the same initial application, the prosecution history regarding a claim limitation in any patent that has issued applies with equal force to subsequently issued patents that contain the same claim limitation." Elkay, 192 F.3d at 980. (See Doc. No. 354 at 15-16.) Although this is a correct statement of the law, Plaintiffs fail to acknowledge that there is nothing in Elkay stating that the prosecution history regarding a certain limitation only applies to subsequently issued patents. There is nothing in Elkay stating that the prosecution history cannot also apply to earlier issued patents if they contain the same limitation at issue. Both the Federal Circuit's decisions in McDonald and MBO state that "'a patent family's entire prosecution history'" is relevant in applying prosecution history estoppel. McDonald, 43 F.4th at 1347 (quoting MBO, 602 F.3d at 1318).

iii. Insubstantial Differences Test

Shoreline argues that Plaintiffs cannot satisfy the insubstantial differences test to support their theory of infringement under the doctrine of equivalents. (Doc. No. 351 at 17-18.) Specifically, Shoreline argues that Plaintiffs cannot satisfy the insubstantial differences test because it is undisputed that SCNT and iPSC direct reprogramming are substantially different processes. (Id.) In response, Plaintiffs contend that Shoreline's argument is improper because it focuses on the differences between SCNT and direct reprogramming techniques as opposed to specifically on the differences between "direct reprogramming efficiency" and "SCNT cloning efficiency." (Doc. No. 354 at 19.)

Under the insubstantial differences test, an element in an accused method "'is equivalent to a claim limitation if the only differences between the two are insubstantial.'" UCB, 927 F.3d at 1284. Plaintiffs assert that they can satisfy the insubstantial differences test because "the efficiencies of SCNT and direct reprogramming are identical in that both are measures of the yield of pluripotent stem cells from somatic cells." (Doc. No. 354 at 19-20 (citing Doc. No. 313-4, Ex. 8, Plath Decl. ¶ 23; Doc. No. 354-7, Plath Decl. ¶ 55).)

Again, the Court rejects Plaintiffs' attempt to isolate the phrase "cloning efficiency" and divorce that phrase from the rest of the Court's claim construction for the relevant claim limitation. The relevant limitation for the purposes of evaluating the doctrine of equivalents and the insubstantial differences test is "[primes/priming/prime] the [somatic] cell to improve the cloning efficiency of the subsequent reprogramming." (Doc. No. 208 at 33.)

The specification of the asserted patents notes that there are important differences between using Oct4 to prime a cell for subsequent SCNT reprogramming – as claimed in the method claims at issue – and using Oct4 in direct reprogramming processes. See '856 Patent col. 2 ll. 4-13 (explaining that SCNT depends on "controversial sources" that have "greatly compromised and slowed the study of such cells and their application" and that there is "a great demand for alternative methods of generating pluripotent cells," such as direct reprogramming); see also id. col. 3 ll. 61-67 ("It would be useful to reprogram

somatic cells directly into pluripotent cells. Nuclei from somatic cells retain the totopotency potential to direct development of an animal, as demonstrated by nuclear transfer technology. It would be useful to reprogram somatic cells directly into ES cells without the use of oocytes and nuclear transfer technology.").) Indeed, at the claim construction hearing, Plaintiffs themselves described many important differences between using Oct4 to prime a cell for subsequent SCNT reprogramming and using Oct4 in the direct reprogramming process. (See Doc. No. 218 at 3-6.) For example, Plaintiffs described SCNT as "an old technique for reprogramming" that is an "incredibly difficult challenging technical technique that can only be done by a handful of labs in the world." (Doc. No. 218 at 3.) Plaintiffs contrasted that technique with "[d]irect reprogramming" which according to Plaintiffs has "much more commercial appeal and universal applicability."[10] (Doc. No. 218 at 4.) In light of these undisputed statements in the specification and the statements made by Plaintiffs at the claim construction hearing, no reasonable jury could find that the accused processes satisfy the insubstantial differences test.

/ / /

---

[10] At the claim construction hearing, Plaintiffs also described the technique of SCNT as taking "a somatic cell" and either: (1) taking the nucleus out of that somatic cell and "put[ting] it into an egg cell" that has had its "genetic material removed;" or (2) taking "the entire somatic cell" and "fus[ing] it together with an egg cell" that has had its genetic material removed. (Id.) Either method then "creates, in effect, a fertilized egg cell." (Id. at 4.) See also '369 Patent col. 1 ll. 46-55, col. 2 ll. 4-11 (describing the technique of SCNT and referring to it as a method that "depend[s] on controversial sources" such as "embryos (either created naturally or via cloning)").

In contrast, Plaintiffs described the technique of direct reprogramming as including the following steps: taking somatic cells and inserting DNA that encodes certain proteins "collectively called the Yamanaka factors;" then allowing the cells "to express the[] transcription factors in [a] first step;" then transferring the cells into "a priming medium;" and then "transfer[ring] them to the reprogramming step where the mediums change." (Id. at 5.) See also '369 Patent col. 3 ll. 60-67 (describing "directly" reprogramming as reprogramming that does not use "oocytes and nuclear transfer technology" and does not use "controversial sources").

iv. Function-Way-Results Test

Shoreline argues that Plaintiffs cannot satisfy the function-way-results test because the function, way, and result of improving reprogramming efficiency for SCNT versus iPSC reprogramming are substantially different. (Doc. No. 351 at 18-21.)

Under the function-way-result test, a process "that does not literally satisfy a claim limitation may nevertheless infringe 'if it performs substantially the same function in substantially the same way to obtain the same result.'" Ajinomoto, 932 F.3d at 1356 (quoting Duncan Parking, 914 F.3d at 1362).

As for the "function" part of the test, Plaintiffs and their expert assert that Oct4 operates on a somatic cell nucleus in the same way during direct reprogramming as it does in the SCNT experiment in the specification of the asserted patents. (Doc. No. 354 at 21-22.) But based on Plaintiffs' own assertions, priming with Oct4 provides a different function in the direct reprogramming process than it does in the SCNT process.

Plaintiffs and their expert assert that Oct4 is "essential," "critical," and "necessary" to the direct reprogramming process. (See Doc. No. 354 at 18 n.10 (asserting that Oct4 is "critical and necessary" to the overall direct reprogramming process for making iPSCs), 23-24; Doc. No. 351-11, Plath Depo. at 430 (testifying that Oct4 "is an essential step of the entire [direct reprogramming] process"); Doc. No. 354-7, Plath Decl. ¶¶ 35, 112-24 (testing showing that direct reprogramming was unsuccessful without the inclusion of Oct4); Doc. No. 354-24, Plath Expert Report ¶¶ 567-69.) Indeed, at the summary judgment hearing, Plaintiffs responded to the question of whether Oct4 is essential to the direct reprogramming process: "[T]he answer is emphatically yes. Oct4 is required for reprogramming. Priming with Oct4, as this Court has construed it, is required for direct reprogramming." (Doc. No. 385 at 28.)

In contrast, the intrinsic record of the asserted patents, including the specification and the prosecution history, make clear that Oct4 is not essential to the SCNT process and instead is merely an "additive factor" to the SCNT process that improves "nuclear transfer cloning efficiency." During the prosecution history of the asserted method patents, the

examiner explained:

> In regards to Oct4, one must remember that the results of the nuclear transfer experiments [in the specification] demonstrate that regardless of exogenous Oct4 induction (i.e. in both fibroblast nuclei induced to express the exogenous Oct[4] and the fibroblast lacking such induction) the nuclear transfer units comprising fibroblast nucleic produce clones (i.e. reprogram the fibroblast nuclei). This is important to remember because it demonstrates that regardless of exogenous Oct[4] expression reprogramming is occurring in both nuclear transfer units with fibroblasts nuclei exogenously expressing Oct4 and nuclear transfer unit with fibroblast nuclei lacking endogenous expression of Oct4. As such, the measure of cloning efficiency between the two groups is solely able to measure changes in the completeness of reprogramming or changes in the reprogrammed nuclear transfer units because regardless of Oct4 some degree of reprogramming occurs due to present[*sic*] of the fibroblast nuclei in a nuclear transfer unit. Given that reprogramming is going to occur in the nuclear transfer experiments regardless of exogenous Oct4 expression, the nuclear transfer experimental model is only informative to the impact of Oct4 exogenous expression on the degree of cloning efficiency or the degree of reprogramming completeness or effectiveness upon the number of reprogrammed fibroblast nuclei, not the ability of Oct4 alone to reprogram a fibroblast nuclei as Applicant suggests.

(Doc. No. 113-5, Ex. B-31 at 13; see also id. at 8 ("The art and Applicant's own experiments demonstrate that reprogramming is occurring by the process nuclear transfer. As such, the experiments described in the specification provided limited information to the degree that exogenous Oct4 itself is able to reprogram and solely demonstrates that addition of Oct4 expression enhances nuclear transfer's reprogramming process."). Consistent with this, the specification of the asserted method patents explains that SCNT is a method for creating pluripotent ES cells, and the specification discloses that the addition of Oct4 only made the process more "efficient." See '856 Patent col. 1, ll. 46-55, col. 19, ll. 21-33 (Table 1). Indeed, at the summary judgment hearing, Plaintiffs conceded that "reprogramming occurs anyway in somatic cell nuclear transfer." (Doc. No. 385 at 29.) As such, it is undisputed that the use of Oct4 serves a substantially different function in the accused direct reprogramming processes compared to the claimed SCNT process.

As for the "way" part of the test, it is also undisputed that the accused direct

reprogramming processes use Oct4 in a different way than the claimed SCNT process. As explained earlier, Plaintiffs and their expert Dr. Plath concede that Oct4 is part of the direct reprogramming process with Dr. Plath conceding that it is used as "the initial step" of the direct reprogramming process. (Doc. No. 351-11, Plath Depo. at 430; see Doc. No. 354 at 10 ("The reprogramming process still entails two steps: Oct4 first primes the somatic cell genome for subsequent reprogramming independent of the other transcription factors."); see also Doc. No. 354-7, Plath Decl. at pp. 23, 24, 26.) In contrast, the claimed SCNT process encompasses a two-step method where there is an initial priming step involving the use of Oct4 and then a subsequent SCNT reprogramming step. (See Doc. No. 208 at 22-26, 31-32; Doc. No. 255 at 18-28.) As such, it is undisputed that the accused direct reprogramming processes and the claimed SCNT process use Oct4 in substantially different ways.

As for the "results" part of the test, it is undisputed that the two processes at issue produce different results. The specification of the asserted patents explains that the results of the claimed process is increased "blastocyst formation and ES cell derivation." '856 Patent col. 19 l. 28. It is undisputed that the accused direct reprogramming processes do not "result" in increased blastocyst formation and ES cell derivation. At the claim construction hearing, Plaintiffs explained that "blastocyst formation" is "specific" to SCNT. (Doc. No. 218 at 17 (explaining that "blastocyst formation" is "specific to the particular technique . . . SCNT"); see also id. at 18 ("[T]he problem that we have with the Court's tentative constructions is that they read into the claim -- some of them seem to recognize this concept of improved efficiency, but they read into the claims words . . . that are unique to SCNT, things like blastocyst or cloning . . . .").) Further, at the summary judgment hearing, Plaintiffs conceded that direct reprogramming does not result in increased blastocyst formation. (Doc. No. 385 at 36-37.) In addition, it is undisputed that ES cells are not the same as iPSC cells. (See Doc. No. 354 at 20 (conceding that "SCNT generates ES cells, while direct reprogramming generates iPSCs").) In their briefing, Plaintiffs assert that although they are different, ES cells are "functionally identical" to

iPSC cells. (Id. at 22.) But that assertion is directly contradicted by statements in the asserted patents' specification, which explains that there are important differences between ES cells generated from "controversial sources," such as SCNT, and cells that are generated through direct reprogramming. See '856 Patent col. 2 ll. 4-13, col. 3 ll. 61-67. As such, it is undisputed that the use of Oct4 in the claimed SCNT process produces substantially different "results" compared to the use of Oct4 in the accused direct reprogramming processes.[11]

In sum, the undisputed evidence in the record demonstrates that the claimed SCNT process and the accused direct reprogramming processes utilize Oct4 for different functions, in different ways, and with different results. As such, no reasonable jury could find that Plaintiffs have satisfied the function-way-results test for the claim limitation "[makes/making/make] the [somatic] cell more susceptible to reprogramming."

C. Conclusion

For the foregoing reasons, no reasonable jury could conclude that the accused direct reprogramming processes satisfy the Court's claim construction for the term "[makes/making/make] the [somatic] cell more susceptible to reprogramming," whether under a literal infringement analysis or a doctrine of equivalents analysis. Thus, Plaintiffs' claims for patent infringement under § 271(g) fail. As a result, the Court grants Shoreline's motion for summary judgment of Plaintiffs' claims for patent infringement under

---

[11] The Court notes that even if it were to accept Plaintiffs' contention that the relevant claim limitation is the phrase "cloning efficiency" by itself, Plaintiffs would still be unable to satisfy the function-way-results test. Even when focused on just "cloning efficiency," it is undisputed that the two processes at issue produce different results (i.e., increased blastocyst formation and ES cells versus iPSC cells).

In addition, even if "cloning efficiency" is examined by itself, Plaintiffs also cannot satisfy the insubstantial differences test for the same reasons. The specification of the asserted patents itself makes clear that there are substantial differences between ES cells and iPSC cells. See '856 Patent col. 2 ll. 4-13, col. 3 ll. 61-67. And Plaintiffs have conceded that direct reprogramming does not result in increased blastocyst formation. (Doc. No. 385 at 36-37.)

§271(g).[12]

---

[12] In its motion for summary judgment, Shoreline also argues that it is entitled to summary judgment of Plaintiffs' § 271(g) claims because the subsequent iPSC reprogramming by the third parties at issue materially changes of the results of those methods, precluding infringement under § 271(g)(1). (Doc. No. 351 at 21-23.) In addition, Shoreline argues that it does not infringe under § 271(g) as to the FCDI and ASC iPSC lines because Plaintiffs cannot show that the claimed methods were carried out after the issuance of the asserted method patents. (Id. at 8-10.) Because the Court grants summary judgment of Plaintiffs' claims for patent infringement under §271(g) for the reasons above, the Court declines to address these additional grounds for summary judgment of those claims.

Nevertheless, the Court briefly addresses Shoreline's argument that it does not infringe the asserted method patents under § 271(g) as to the Lonza line of iPSCs because Plaintiffs cannot show that the claimed methods were carried out after the issuance of the asserted method patents. (See Doc. No. 351 at 8-10.) In order for there to be infringement under § 271(g), the product at issue must have been manufactured "by a process patented in the United States." 35 U.S.C. § 271(g). If the asserted patent was not in existence at the relevant time of the manufacturing, then the product at issue was not made via a patented process. See Gustafson, Inc. v. Intersystems Indus. Prod., Inc., 897 F.2d 508, 510 (Fed. Cir. 1990) ("It is obvious that a party cannot be held liable for 'infringement' . . . of a nonexistent patent, i.e., no damages are payable on products manufactured and sold before the patent issued.").

The earliest issued asserted method patent in this case – the '856 Patent – was issued on January 13, 2023. '856 Patent at [45]; see also '536 Patent at [45]; '744 Patent at [45]; '917 Patent at [45]. As such, in order for there to be infringement under § 271(g), Plaintiffs must demonstrate that for the iPSCs at issue, Lonza "primed" the cells with Oct4 on January 13, 2023 or later. The Court agrees with Shoreline that Plaintiffs have not made that showing. Rather, the only evidence in the record shows that Oct4 was used by Lonza during the manufacturing of the iPSCs at issue by October 2014 or earlier. (See Doc. No. 351-10, Ex. 9 at p. 182, Baghbaderani Supp. Decl. ¶ 9; id. at pp. 270-271; id. at p. 310.)

Plaintiffs note that there is evidence in the record stating the iPSCs at issue were reprogramed in 2015 and that the manufacturing date of the iPSCs is January 29, 2015. (Doc. No. 354 at 2-3 (citing Doc. No. 68-1, Ex. T; Doc. No. 68, Counterclaims ¶ 112; Doc. No. 354-10, Ex. 2, Cherok Decl. ¶ 5); see also Doc. No. 385 at 24-27.) But this is of no consequence. The asserted method patents do not claim a method of reprogramming a cell or a method of making iPSCs. (See Doc. No. 208 at 18 (citing Doc. No. 149 at 7-8; Doc. No. 151 at 6; Doc. No. 113-5, Ex. B-31 at 2-16; Doc. No. 113-3, Ex. B-23; Doc. No. 113-4, Ex. B-28); see also Doc. No. 385 at 66 (Plaintiffs conceding: "We can't claim that we

III. Plaintiffs' Claims for Induced Infringement Under 35 U.S.C. § 271(b)

In the operative complaint, Plaintiffs allege claims for induced infringement of the asserted patents under 35 U.S.C. § 271(b) against Shoreline. (Doc. No. 162, Supp. FAC ¶¶ 172-75, 207-10, 244-47, 279-82, 317-20, 352-55, 392-95.) Shoreline moves for summary judgment of Plaintiffs' claims for induced infringement. (Doc. No. 351 at 23-27.) Specifically, Shoreline argues that it cannot be liable for induced infringement because Plaintiffs cannot demonstrate any underlying act of direct infringement with respect to the asserted method claims. (Id. at 24.) In addition, Shoreline argues that it cannot be liable for induced infringement because it did not know how the iPSCs were created by the third-party manufacturers at issue. (Id. at 24-25.)

Under 35 U.S.C. § 271(b), "whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). Liability for induced infringement under § 271(b) must be predicated on an underlying act of direct infringement. Eli Lilly & Co. v. Teva Parenteral Medicines, Inc., 845 F.3d 1357, 1363–64 (Fed. Cir. 2017); see Nalco Co. v. Chem-Mod, LLC, 883 F.3d 1337, 1355 (Fed. Cir. 2018) ("'It is axiomatic that [t]here can be no inducement or contributory infringement without an underlying act of direct infringement.'" (quoting In re Bill of Lading Transmission & Processing Sys. Pat. Litig., 681 F.3d 1323, 1333 (Fed. Cir. 2012))).

"The patentee must also show that the alleged infringer possessed the requisite intent to induce infringement, which [the Federal Circuit] ha[s] held requires that the alleged infringer 'knew or should have known his actions would induce actual infringements." Eli Lilly, 845 F.3d at 1364 (quoting DSU Med. Corp. v. JMS Co., 471 F.3d 1293, 1304 (Fed.

---

have a method of direct reprogramming.").) As such, the relevant time period for determining infringement under § 271(g) as to the asserted method patents is not when the iPSCs at issue were manufactured or when reprogramming was completed by. Rather, it is when Oct4 was specifically used during the manufacturing process. The only evidence in the record shows that Oct4 was used prior to 2015. As such, this is an additional reason why Shoreline is entitled to summary judgment of no infringement under § 271(g) as to the Lonza line of iPSCs.

Cir. 2006) (en banc)). Mere knowledge of the possibility of infringement by others is insufficient; "specific intent and action to induce infringement must be shown." HZNP Medicines LLC v. Actavis Lab'ys UT, Inc., 940 F.3d 680, 702 (Fed. Cir. 2019); see Warner–Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1364 (Fed. Cir. 2003). "Inducement can be found where there is '[e]vidence of active steps taken to encourage direct infringement,' which can in turn be found in 'advertising an infringing use or instructing how to engage in an infringing use.'" Takeda Pharms. U.S.A., Inc. v. W.-Ward Pharm. Corp., 785 F.3d 625, 630–31 (Fed. Cir. 2015) (quoting Metro–Goldwyn–Mayer Studios Inc. v. Grokster, Ltd., 545 U.S. 913, 936 (2005)). "But such instructions need to evidence 'intent to *encourage* infringement.'" Id. at 631 (emphasis in original) (quoting Vita–Mix Corp. v. Basic Holding, Inc., 581 F.3d 1317, 1329 (Fed. Cir. 2009)).

A. Inducement to Infringe Under § 271(g)

To support their claims for induced infringement, Plaintiffs assert that Shoreline induced the third-party iPSC suppliers to infringe under § 271(g). (Doc. No. 354 at 28; see also Doc. No. 354-245, Ex. 37, Plath Expert Report ¶¶ 574-91.) The Court has granted summary judgment of Plaintiffs' § 271(g) claims and held that no reasonable jury could find that the accused iPSC direct manufacturing processes at issue satisfy the Court's claim construction for the term "[makes/making/make] the [somatic] cell more susceptible to reprogramming." (See supra Section II.) As such, this theory of induced infringement fails because there is no underlying direct infringement under § 271(g). See Eli Lilly, 845 F.3d at 1363–64 ("liability for induced infringement under § 271(b) 'must be predicated on direct infringement'"); Nalco, 883 F.3d at 1355 ("'It is axiomatic that [t]here can be no inducement or contributory infringement without an underlying act of direct infringement.'" (quoting Bill of Lading, 681 F.3d at 1333)). As such, the Court grants summary judgment of Plaintiffs' induced infringement claims to the extent they are based on underlying acts of direct infringement under § 271(g).

/ / /

/ / /

B. Induced Infringement by Thermo Fisher

In support of their claims for induced infringement, Plaintiffs also assert that Shoreline induced Thermo Fisher Scientific ("Thermo Fisher") to infringe the asserted composition patents. (Doc. No. 354 at 28; see also Doc. No. 354-245, Ex. 37, Plath Expert Report ¶¶ 592-666.) Shoreline argues that it is entitled to summary judgment of these induced infringement claims because Plaintiffs' evidence does not raise a triable issue of fact as to Shoreline's knowledge of Thermo Fisher's manufacturing process. (Doc. No. 351 at 24-25.)

In December 2021, Shoreline obtained four iPSC lines from Thermo Fisher. (Doc. No. 351 at 5; see Doc. No. 354-22, Ex. 35.) Shoreline provided Thermo Fisher with two types of somatic cells, and Thermo Fisher reprogrammed the cells into the four iPSC lines. (See Doc. No. 351 at 5; Doc. No. 354-29, Ex. 42 at Rogge Depo. at 32, 37; Doc. No. 354-24, Plath Expert Report ¶¶ 123-26.) This was a standard service that Thermo Fisher offered to anyone. (Doc. No. 351-16, Ex. 15, Rogge Depo at 103; see Doc. No. 385 at 15, 38.) The four iPSC lines were created using Thermo Fisher's commercially available CytoTune 2.0 kit. (See Doc. No. 351 at 5; Doc. No. 354-24, Plath Expert Report ¶¶ 124, 127-63.) Plaintiffs' expert Dr. Plath opines that Thermo Fisher's manufacturing of the iPSCs at issue via the CytoTune 2.0 kit infringes the asserted composition patents. (See Doc. No. 354-24, Ex. 37, Plath Expert Report ¶¶ 592-666.)

Plaintiffs assert that Shoreline possessed the requisite knowledge for induced infringement because Shoreline knew of and instructed Thermo Fisher's manufacturing of iPSCs using the CytoTune 2.0 kit from the cells that Shoreline provided. (Doc. No. 354 at 29.) The evidence in the record shows that during the purchasing process, on July 7, 2021, Mr. Huafeng Wang of Shoreline emailed Thermo Fisher and provided Thermo Fisher with a paper entitled Hiramatsu et al., "An analysis of monocytes and dendritic cells differentiated from human peripheral blood monocyte-derived induced pluripotent stem cells," *Med. Mol Morphol*. ("Hiramatsu"). (Doc. No. 354-22, Ex. 35 at p. 742.) In the email, Mr. Wang stated: "We came across a paper using CytoTune 2.0 to generate iPSCs

from PB monocytes. It is attached here." (Id.) In one sentence of the ten-page paper, Hiramatsu briefly discloses that "[c]ells were infected with the commercial Sendai virus vector CytoTune®-iPS 2.0 L" on culture day 2. (Id. (citing TFS_FATE_000238).) On July 21, 2021, Thermo Fisher request some information from Shoreline on "protocols on growth condition for the monocytes" and attached the Hiramatsu paper. (Doc. No. 354-24, Ex. 37, Plath Expert Report ¶ 124 (citing TFS_FATE_000136).) In response, Shoreline told Thermo Fisher that the Hiramatsu paper would be "ok to use . . . for our project." (Id. (citing TFS_FATE_000134).)

Viewing this evidence in the light most favorable to Plaintiffs, this evidence at best shows that Shoreline knew that Thermo Fisher would use the CytoTune 2.0 kit to manufacture the iPSCs at issue. But this evidence does not show that Shoreline knew of the precise processes utilized by the CytoTune 2.0 kit, and there is no evidence in the record showing that Shoreline ever instructed or directed Thermo Fisher to specifically use Oct4 during the manufacturing process for the iPSCs at issue.[13] Indeed, the unrebutted evidence in the record demonstrates that the relevant actors at Shoreline did not know what the CytoTune 2.0 kit is or how it works. (See Doc. No. 351-13, Ex. 12, Rodgers Depo. at 200-201, 204 ("I do not know anything about the CytoTune 2.0 kit . . . ."); Doc. No. 351-3, Ex. 2, Cherok Depo. at 236-37, 336.) And, at the summary judgment hearing, Plaintiffs conceded that the Hiramatsu paper does not "specifically say Oct4." (Doc. No. 385 at 52.) Further, the unrebutted evidence demonstrates that Shoreline did not know what reprogramming factors Thermo Fisher was going to use to manufacture the iPSC line at

---

[13] It is important that there is no evidence in the record demonstrating that Shoreline specifically instructed or directed Thermo Fisher to use Oct4. As Plaintiffs conceded at the hearing, the asserted composition patents do not claim a method of direct reprogramming. (Doc. No. 385 at 40.) Rather, they merely claim a somatic cell that has exogenous Oct4. (Id. at 40-41.) As such, in order for Plaintiffs to demonstrate the requisite intent for their claims of induced infringement, they must specifically show that Shoreline took active steps to encourage the use of Oct4 with a somatic cell during the manufacturing process at issue. See Takeda, 785 F.3d at 630–31.

issue, and Shoreline did not give Thermo Fisher any direction of how to perform the reprogramming. (See Doc. No. 351-13, Ex. 12, Rodgers Depo. at 126, 129, 202-04; Doc. No. 351-3, Ex. 2, Cherok Depo. at 239, 336; Doc. No. 351-16, Ex. 15, Rogge Depo at 39-40, 103.) Plaintiffs have not provided the Court with any evidence to the contrary. As such, the undisputed evidence in the record demonstrates that Shoreline did not know what specific process or reprogramming factors Thermo Fisher was going to use to manufacture the iPSC line at issue. Thus, the evidence in the record is insufficient to demonstrate that Shoreline encouraged or had intent to encourage Thermo Fisher's alleged infringement of the asserted composition patents. See Takeda, 785 F.3d at 630–31.

Plaintiffs assert that there is evidence in the record showing that prior to Shoreline soliciting and purchasing the infringing iPSCs from Thermo Fisher, Dr. Kaufman used the CytoTune 2.0 reprogramming kit and, thus, knew the reprogramming process entailed by that kit. (Doc. No. 354 at 29 (citing Doc. No. 354-15, Kaufman Depo. at 81-86; Doc. No. 319-1, Ex. 45). But, even assuming this is true, this fact is of no consequence because Plaintiffs do not identify any evidence in the record showing that Dr. Kaufman had any involvement in the solicitation and purchase of the iPSCs at issue from Thermo Fisher. (See also Doc. No. 385 at 39.) As such, Kaufman's potential knowledge of the CytoTune 2.0 reprogramming process cannot be utilized to demonstrate that Shoreline induced Thermo Fisher to infringe the asserted composition patents.

Plaintiffs also note that their technical expert, Dr. Plath, has explained that all commercially available iPSCs, including those acquired by Shoreline, are made by introducing exogenous Oct4 during the reprogramming process. (Doc. No. 354 at 29 (citing Doc. No. 354-24, Ex. 37, Plath Expert Report ¶¶ 109, 567-70).) But, at most, this evidence demonstrates that Shoreline knew that it possible that Thermo Fisher might use Oct4 during the iPSC manufacturing process. "[M]ere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven." Warner–Lambert, 316 F.3d at 1364; see Takeda, 785 F.3d at 630–31. Again, there is no evidence in the record demonstrating that Shoreline ever instructed,

directed, or encouraged Thermo Fisher to specifically use Oct4 during the manufacturing process for the iPSCs at issue. As such, the evidence in the record is insufficient to demonstrate intent to induce infringement. See Takeda, 785 F.3d at 630–31.

In sum, Plaintiffs have failed to present sufficient evidence to raise a triable issue of fact as to the required intent by Shoreline to support a claim for induced infringement based on Thermo Fisher's manufacturing of the iPSCs at issue. See, e.g., Gammino v. Cellco P'ship, 527 F. Supp. 2d 395, 399 (E.D. Pa. 2007) (granting summary judgment of induced infringement claims and noting "nothing in this record suggests that [defendant] specifically intended for the local providers to infringe [plaintiff]'s patents. Rather, the evidence indicates that [defendant] merely purchased call-blocking features in the normal course of trade and left it to the providers of those features to ensure that their methods complied with the patent laws"). As such, the Court grants summary judgment of Plaintiffs' claims for induced infringement under § 271(b).

IV. Plaintiffs' Claims for Direct Infringement Under 35 U.S.C. § 271(a)

In the operative complaint, Plaintiffs allege that Shoreline directly infringes the asserted patents under 35 U.S.C. § 271(a). (Doc. No. 162, Supp. FAC ¶¶ 159-69, 192-204, 232-41, 264-76, 304-14, 337-49, 377-89.) Shoreline moves for summary judgment that it does not directly infringe the asserted patents under § 271(a). (Doc. No. 351 at 27-28.) Specifically, Shoreline argues that it is entitled to summary judgment of Plaintiffs' § 271(a) claims because it is undisputed that Shorelines does not reprogram somatic cells to iPSCs, does not use iPSCs made by the claimed methods, and does not make or use the claimed compositions. (Id. at 27.)

In response, Plaintiffs assert that based on Shoreline's representations above, "there is no activity to accuse of direct infringement." (Doc. No. 354 at 32-33; see Doc. No. 385 at 22, 41.) Plaintiffs argue, therefore, there is nothing to adjudicate, and the Court should deny Shoreline's motion for summary judgment of the direct infringement claims under § 271(a) as moot. (Id.) As such, the Court denies Shoreline's motion for summary judgment of Plaintiffs' claims for direct infringement under § 271(a) as moot.

V. Plaintiffs' Motion for Partial Summary Judgment

Plaintiffs move for partial summary judgment regarding the underlying direct infringement of the '369 Patent by ThermoFisher in support of their claim for induced infringement under § 271(b). (Doc. No. 352-14 at 1, 7-8.) In addition, Plaintiffs move for summary judgment of certain affirmative defenses and certain counterclaims that the asserted method claims are invalid under 35 U.S.C. §§ 101, 102, and 103. (Id. at 1-2, 8-15.)

The Court has granted Defendants' motion for summary judgment of all of Plaintiffs' claims for patent infringement in this action, including Plaintiffs' claims for induced infringement under § 271(b). (See supra.) As a result, Plaintiffs' motion for partial summary judgment is now moot, and the Court denies the motion as moot.

/ / /

/ / /

/ / /

Conclusion

For the reasons above, the Court grants Shoreline's motion for summary judgment of non-infringement,[14] and the Court denies Plaintiffs' motion for partial summary judgment as moot. The Clerk of Court is directed to enter a judgment in favor of Defendant Shoreline and against Plaintiffs Fate and Whitehead and close the case.[15]

IT IS SO ORDERED.

DATED: August 30, 2023

MARILYN L. HUFF, District Judge
UNITED STATES DISTRICT COURT

---

[14] In its motion, Shoreline also argues that the Court should grant summary judgment of non-infringement for its use of the Lonza iPSC line because Shoreline's use of the Lonza line falls within the safe harbor for activities reasonably related to FDA regulatory submissions. (Doc. No. 351 at 28-30.) Because the Court grants Shoreline's motion for summary judgment of non-infringement for the reasons above, the Court declines to address this additional basis for summary judgment by Shoreline.

[15] Along with their motions for summary judgment, Shoreline filed a Daubert motion to exclude the expert report of Plaintiffs' damages expert Dr. Michael C. Keeley, and Plaintiffs filed: (1) a motion to strike a certain witness, Dr. Behnam Ahmadian Baghbaderani; (2) a Daubert motion to exclude the opinions of Shoreline's invalidity expert Dr. Martin F. Pera; (4) a Daubert motion to exclude the opinions of Shoreline's technical expert Dr. Evan Y. Snyder; and (5) a Daubert motion to exclude portions of the expert report of Shoreline's damages expert Mr. Schoettelkotte. (Doc. Nos. 280, 281, 287, 288, 291.) In light of the Court's entry of a judgment in this action in favor of Shoreline and against Plaintiffs, the Court denies these five motions as moot. In addition, the Court notes that this order does not cite to or rely on any of the testimony or opinions challenged in those Daubert motions and the motion to strike.