IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLORADO

Civil Action No. 17-cv-00944-WJM-NYW

XY, LLC, INGURAN, LLC, and BECKMAN COULTER, INC.

Plaintiffs,

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TRANS OVA GENETICS, LC,

Defendant.

RECOMMENDATION OF UNITED STATES MAGISTRATE JUDGE

Magistrate Judge Nina Y. Wang

This matter comes before the court on two motions:

- (1) Defendant Trans Ova Genetics, LC's ("Defendant" or "Trans Ova")
 Renewed Motion to Dismiss Count VI of Plaintiffs' Operative Complaint
 Pursuant to Fed. R. Civ. Proc. 12(b)(6) ("Renewed Motion to Dismiss Count
 VI"), [Doc. 439, filed May 20, 2021]; and
- (2) Trans Ova's Opposed Motion for Leave to File a Second Amended Answer and Counterclaims to Plaintiffs' Fourth Amended Complaint ("Motion to

¹ Where the court refers to the filings made in Electronic Court Filing ("ECF") system in this action, it uses the convention [Doc. ___]. When the court refers to the ECF docket number for a different action, it uses the convention [ECF No. ___]. In either case, the court identifies the page number as assigned by the ECF system.

Amend Answer" and, together with the Renewed Motion to Dismiss Count VI, the "Motions"), [Doc. 446, filed June 11, 2021].

The Motions were referred to the undersigned Magistrate Judge pursuant to 28 U.S.C. § 636(b), the Order Referring Case dated April 19, 2017, [Doc. 17], and the Memoranda dated May 28, 2021 and June 15, 2021, respectively, [Doc. 443; Doc. 448]. Upon consideration of the briefing associated with these two Motions, the entire docket, and the applicable law, this court respectfully **RECOMMENDS** that Trans Ova's Renewed Motion to Dismiss Count VI be **DENIED without prejudice** and Motion to Amend Answer be **GRANTED**.

BACKGROUND

The background of this action has been discussed in detail in prior orders of the court, see, e.g., [Doc. 275], and therefore, this discussion will focus on the instant Motions. Plaintiff XY, LLC ("XY") initially brought suit against Trans Ova in a separate action first before the United States District Court for the Western District of Texas ("Western District of Texas") and then transferred to this court, XY, LLC v. Trans Ova Genetics, LC, No. 13-cv-0876-WJM-NYW ("XY I" or "the 2012 Lawsuit"). The case proceeded to trial by jury on January 26, 2016, see [ECF. No. 419], and final judgment entered on April 19, 2016.² [ECF No. 507].

² Ultimately, an Amended Final Judgment and Second Amended Judgment entered after an appeal to the United States Court of Appeals for the Federal Circuit ("Federal Circuit"). [ECF No. 648; ECF No. 702]. These amended judgments are not relevant to the issues at hand.

After the trial on XY I, on December 6, 2016, XY initiated this action against Trans Ova in the Western District of Texas, asserting a variety of causes of action, including infringement of four patents, United States Patent Nos. 9,145,590 ("590 Patent"), 7,723,116 ("116 Patent"), 9,365,822 ("822 Patent"), and 7,208,265 ("265 Patent"), trade secret misappropriation, and unfair competition. See [Doc. 5]. On December 19, 2016, prior to Trans Ova filing a responsive motion or pleading, XY filed a First Amended Complaint asserting two additional patents, United States Patent No. 6,372,422 ("422 Patent") and 8,652,769 ("'769 Patent"). See [Doc. 6]. Then, on April 21, 2017, following the transfer of this action to this District, XY filed a Second Amended Complaint adding co-plaintiff Beckman Coulter, Inc., ("Beckman Coulter") and an additional patent, United States Patent No. 9,134,220 ("'220 Patent"). See [Doc. 24]. On May 5, 2017, Trans Ova moved to dismiss, based on its court-imposed license theory and that the asserted claims of the '116, '265, '422, and '769 Patents, as well as the claims for trade secret misappropriation under the Defend Trade Secrets Act, common-law trade secret misappropriation, common-law unfair competition, quantum meruit, and unjust enrichment, were barred by claim preclusion. See [Doc. 31 ("Motion to Dismiss")].

XY subsequently filed Third and Fourth Amended Complaints without objection from Trans Ova. See [Doc. 51, filed July 26, 2017; Doc. 74, filed October 18, 2017]. The Third Amended Complaint added another co-plaintiff, Inguran, LLC d/b/a STGenetics ("Inguran"), an exclusive licensee to the '590, '116, '822, '265, '422, and '769 Patents (referred to collectively with XY and Beckman Coulter as "Plaintiffs"). See [Doc. 50-1]. The currently operative Fourth Amended Complaint, [Doc. 74], replaced the '220 Patent

with a reissued patent, United States Patent No. RE46,559 ("559 Patent"). The Parties also filed a Joint Status Report informing the court that the Motion to Dismiss directed at the Second Amended Complaint could be determined as if directed at the Fourth Amended Complaint. See [Doc. 83]. Around that same time, Trans Ova filed a Motion to Supplement its Preliminary Invalidity Contentions. [Doc. 84].

On January 11, 2018, the presiding judge, the Honorable William J. Martinez, granted in part and denied in part Trans Ova's Motion to Dismiss. See [Doc. 120]. Judge Martinez rejected Defendant's theory regarding the royalty imposed in XY I but dismissed the asserted claims of the '116, '265, '422, and '769 Patents with prejudice, leaving the asserted claims of the '590, '822, and '559 Patents at issue. See [id. at 5–6]. In light of the January 11, 2018 Order, and based on Trans Ova's withdrawal of its request to supplement its invalidity contentions, see [Doc. 133 at 2–3], this court denied as moot Trans Ova's Motion to Supplement its Preliminary Invalidity Contentions. See [Doc. 134].

On February 21, 2018, XY and Inguran filed a Motion for Leave to File a Fifth Amended Complaint seeking to add two new patents, United States Patent Nos. 9,625,367 ("'367 Patent") and 9,835,541 ("'541 Patent"), as well as adding Inguran as a named Plaintiff on the currently pleaded Count XII, which alleges infringement of the '559 Patent. See [Doc. 137]. Trans Ova objected to the addition of the '367 Patent. See [id. at 1]. The following day, Trans Ova filed a Motion for Judgment on the Pleadings with respect to the '559 Patent, arguing that the patent claimed unpatentable subject matter. See [Doc. 138]. On August 9, 2018, Judge Martinez granted Trans Ova's Motion for Judgment on the Pleadings as to the '559 Patent, and denied the Motion for Leave to File

a Fifth Amended Complaint. [Doc. 262].³ Given Judge Martinez's ruling, as of August 2018, the only remaining claims arose from the '590 and the '822 Patent.

In light of Judge Martinez's ruling, this court directed the Parties to meet and confer and file a Joint Status Report regarding the impact of that ruling upon the motions then-referred to the undersigned Magistrate Judge. *See* [Doc. 263]. Among those referred motions were Plaintiffs' Motion to Exclude New Invalidity Arguments, [Doc. 170]. *See* [Doc. 263; Doc. 265]. The Parties agreed that the arguments with respect to the dismissed '559 Patent were moot, but that the arguments with respect to the '590 Patent remained intact. *See* [Doc. 265]. On October 2, 2018, after full briefing, this court recommended that Plaintiffs' Motion to Exclude New Invalidity Arguments be granted in part and denied in part. *See* [Doc. 341]. Trans Ova objected to the court's Recommendation on October 12, 2018. [Doc. 350].

On August 31, 2018, the Parties filed their respective dispositive motions. [Doc. 290; Doc. 293]. Trans Ova also sought to withdraw its prior Stipulation regarding infringement, [Doc. 88], and substitute it with a different stipulation, based on its argument that as of May 7, 2018, the MoFlo SX instruments had been operating in a range that did not infringe the asserted claims of the '590 Patent. See [Doc. 292]. XY and Inguran objected to the withdrawal of the prior Stipulation regarding infringement, and filed a Motion to Strike. [Doc. 315]. On December 5, 2018, this court recommended that the Motion to Strike be denied, allowing Trans Ova to move forward with its argument that as

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³ Judge Martinez subsequently denied summarily a Motion for Reconsideration on August 22, 2018. [Doc. 276]. The Fourth Amended Complaint, [Doc. 74], remains the operative pleading in this matter.

of May 7, 2018, it did not infringe the asserted claims of the '590 Patent. See [Doc. 363]. The court also then permitted limited discovery with respect to the voltage of the MoFlo SX. See [Doc. 369; Doc. 374]. Plaintiffs objected to the Recommendation with respect to the Motion to Strike, [Doc. 371], and Defendant responded, [Doc. 373].

On September 20, 2018, this court entered a Final Pretrial Order, [Doc. 326], and Judge Martinez set the action for a five-day trial to commence on July 29, 2019, see [Doc. 335]. On March 7, 2019, XY and Inguran sought a stay of the proceedings related to one of the two remaining patents, the '822 Patent, based on a ruling of invalidity by the United States District Court for the Western District of Wisconsin. [Doc. 382]. In response, facing the potential of successive trials in this matter, Judge Martinez issued an Order to Show Cause as to why the court should not enter a Rule 54(b) judgment on all counts except Count I (as to the '590 Patent) and Count III (as to the '822 Patent). [Doc. 383]. After Responses to the Order to Show Cause, [Doc. 386; Doc. 387], Final Judgment was entered pursuant to Rule 54(b) in favor of Trans Ova and against Plaintiffs, [Doc. 389], and appeal was taken to the Federal Circuit, [Doc. 391].

On July 31, 2020, the Federal Circuit issued its opinion, reversing the district court's judgment that the asserted claims of the '559 Patent were ineligible under 35 U.S.C. § 101; vacating the district court's judgment with respect to claim preclusion as to the '422, '116, and '769 Patents; and remanding for further proceedings. [Doc. 408]. After the Mandate issued, [Doc. 411], the Parties sought, and this court convened, a number of status and scheduling conferences to determine the scope of the case moving forward. See [Doc. 412; Doc. 427; Doc. 432]. On May 11, 2021, the Parties filed a Stipulation,

identifying the counts, asserted patents and claims, and defenses that were as to six patents before the court and not subject to pending motions: the '590 Patent, the '116 Patent, the '822 Patent, the '422 Patent, the '769 Patent, and the '559 Patent. [Doc. 435 at 2]. The Parties further acknowledged that Trans Ova indicated its intent to move for leave to amend its Answer and Counterclaims, [Doc. 75]. See [Doc. 435 at 2–3].

On May 20, 2021, Trans Ova filed the instant Renewed Motion to Dismiss Count VI based on claim preclusion grounds. [Doc. 439]. Then, on June 11, 2021, Trans Ova filed the instant Motion to Amend Answer, seeking leave to file a proposed Second Amended Answer and Counterclaims to include, *inter alia*, a counterclaim against XY and Inguran for invalidity based on inequitable conduct as to the '769 Patent and a counterclaim against all Plaintiffs of invalidity based on inequitable conduct as to the '559 Patent. [Doc. 446]. On July 2, 2021, the Parties filed a Joint Stipulation regarding the '559 Patent-in-Suit and the Related U.S. Patent No. 10,495,562 ("'562 Patent"), whereby Plaintiffs stipulated that they "shall not sue TOG for infringing any claim of the '562 Patent by making, using, offering to sell, or selling the Accused Sperm Sorting Systems in this Litigation or any future lawsuit," and "TOG hereby withdraws its pending motion for leave to add declaratory judgment counterclaims pertaining to the '562 Patent . . ." [Doc. 457 at ¶ 1 (footnote omitted)]. Trans Ova expressly maintained the instant Motion to Amend pertaining to the '769 Patent and the '559 Patent. [Id. at ¶ 1 n.1].

The Parties proceeded with limited discovery and briefing on claim construction. See, e.g., [Doc. 456; Doc. 466; Doc. 470]. Judge Martinez conducted a claim construction hearing on December 14, 2021, see [Doc. 497], during which he ordered the Parties to

proceed with a mediation lasting at least three days. See [Doc. 498]. The case, and the consideration of the pending motions and claim construction, were stayed during the mediation process. [Id.]. As a result of the mediation, the Parties stipulated to the dismissal of the '422 Patent. See [Doc. 506].

Finally, on June 6, 2022, the Parties filed a Unified Stipulation Regarding Infringement. [Doc. 526]. In that Stipulation, the Parties identified the following claims remain:

Count	Patent	Plaintiffs	Asserted Claims	Stipulated Infringement
I	'590	XY & Inguran	1, 3–10, 23, 26, 27, and 29-36	All asserted claims up to and including May 6, 2018
II	'116	XY & Inguran	1–5, 8–12, 15–18, 20–22, 24, 26, 33– 34, and 38-41	All asserted claims, except cl. 38, up to and including January 6, 2022 ⁴
VI	'769	XY & Inguran	1–4, 7–11, 14–16	All asserted claims up to and including May 22, 2022 ⁵
XII	'559	XY, Inguran, & Beckman Coulter	1, 3–4, 7–8, 12–16, 18–21	All asserted claims up to and including August 1, 2021

However, in the Final Invalidity Contentions filed by Trans Ova on June 3, 2022, it identifies Count III, which asserts claim 11 of the '822 Patent, as still at issue. [Doc. 527-

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⁴ Specifically, Trans Ova asserts that the below-identified sorting facilities ceased infringing any Asserted Claim of the '116 Patent as follows: Maryland sorting facility: November 3, 2021 (all sorters); Texas sorting facility: November 22, 2021 (all sorters); lowa sorting facility: September 19, 2021 (two of the four sorters), and December 5, 2021 (the two remaining sorters); Wisconsin sorting facility: December 20, 2021 (all sorters); and California sorting facility: January 6, 2022 (all sorters). [Doc. 526 at ¶ 4(b)].

⁵ The '769 Patent expired on May 22, 2022. [Doc. 526 at ¶ 4(c)].

1 at 1; 528-2]. In reviewing the voluminous docket, this court finds no dismissal of Count III between the filing of the Joint Status Report on May 11, 2021 and the Final Invalidity Contentions on June 3, 2022. Accordingly, it is unclear whether XY and Inguran continue to assert Count III, but Trans Ova has withdrawn its stipulation of infringement, *compare* [Doc. 526] *with* [Doc. 88; Doc. 292], or that XY and Inguran are no longer asserting the '822 Patent. Nevertheless, because the pending Motions do not involve the '822 Patent, this court need not resolve this ambiguity in this Recommendation.

Against this backdrop, the court turns to the two Motions pending before it.

ANALYSIS

I. Renewed Motion to Dismiss Count VI

Originally, Judge Martinez dismissed Count VI on claim preclusion grounds, reasoning that "[a]s for the 769 Patent, which issued after the 2012 Lawsuit started, the Court agrees under the circumstances that XY had a duty to move to amend (as it had already moved to amend to add an after-acquired claim) given that it would be accusing the same Trans Ova products and processes, and that the 769 Patent was a continuation of a patent already in suit." [Doc. 120 at 14]. On appeal, the Federal Circuit observed that "the parties' only dispute concerns whether the district court properly concluded that XY's 2012 and 2016 lawsuits present the same cause of action", and found that its decision in *SimpleAir, Inc. v. Google LLC*, 884 F.3d 1160, 1165 (Fed. Cir. 2018) should control. XY, LLC v. Trans Ova Genetics, LC, 968 F.3d 1323, 1334 (Fed. Cir. 2020). Because the district court had "erred in its claim-preclusion analysis by failing to compare the scope of the patent claims asserted in the 2012 lawsuit with the scope of the patent

claims asserted in the 2016 lawsuit," the Federal Circuit vacated the dismissal of the '769 Patent, and remanded to the district court to conduct a claim preclusion analysis consistent with *SimpleAir*. *Id.* at 1335.

A. Legal Standard

SimpleAir had initiated a series of patent infringement actions against Google's Cloud Messaging and Cloud to Device Messaging Services; each case involved one or more patents from a family of patents owned by SimpleAir. *SimpleAir*, 884 F.3d at 1163. In the fourth action, SimpleAir asserted claims for infringement of two patents that were linked with a parent patent that had been subject to, but dismissed out of, a prior suit. *Id.* The district court dismissed the action on claim preclusion grounds, reasoning that the patents-in-suit were essentially the same as previously adjudicated patents because they derived from the same parent application – and thus shared a common specification – and were terminally disclaimed to the parent. *Id.* at 1164. The district court did not compare the claims of the two patents to the previously adjudicated patents. *See id.*

SimpleAir argued two theories on appeal. First, it argued that because the particular patents-in-suit had not been previously adjudicated, no claim preclusion could apply. *SimpleAir*, 884 F.3d at 1164. Second, it argued that even if claim preclusion could apply across different patents derived from the same family, it did not apply in its particular circumstance because Google had failed to establish that the causes of action were "essentially the same[.]" *Id.* The Federal Circuit determined that claim preclusion was not foreclosed simply because the patents-in-suit had not been adjudicated in a prior suit. *Id.* However, the common specification and terminal disclaimer were insufficient to

sustain the district court's holding of claim preclusion. *Id.* at 1166. Instead, the Federal Circuit adopted a standard that "where different patents are asserted in a first and second suit, a judgment in the first suit will trigger claim preclusion only if the scope of the asserted patent claims in the two suits is essentially the same. . . . [C]laims which are patentably indistinct are essentially the same." *Id.* at 1167.

B. Application

The Parties correctly acknowledge that the Federal Circuit instructed the district court on remand to compare the scope of the asserted claims to those asserted in the prior litigation in the first instance. See [Doc. 439 at 7; Doc. 445 at 7–8].⁶ Trans Ova, as the party asserting claim preclusion, bears the burden of proof. See Johnson v. Spencer, 950 F.3d 680, 712 (10th Cir. 2020).

First, this court notes that when determining whether causes of action are the same, it defines "a cause of action by the transactional facts from which it arises." *In re PersonalWeb Techs. LLC*, 961 F.3d 1365, 1375 (Fed. Cir. 2020), *cert. denied sub nom. PersonalWeb Techs., LLC v. Patreon, Inc.*, 142 S. Ct. 2707 (2022). Claim preclusion does not apply unless the products or processes are essentially the same. *See id.* Here, there is no dispute that the accused products and processes between the 2012 Lawsuit and this action are, for the purposes of the claim preclusion analysis, essentially the same. Indeed, Trans Ova's non-infringement arguments do not suggest otherwise, as they go

⁶ To the extent that XY and Inguran suggest that the decision and mandate of the Federal Circuit necessarily determined that the Asserted Claims of the '769 Patent are broader than the previously adjudicated patents from XY I, or there would be no need for remand, this court respectfully disagrees.

to whether the Asserted Claims are patentably indistinct and not whether there is a material difference in the accused products, and Trans Ova's non-infringement arguments do not involve the steps in dispute.

Next, this court addresses the correct framework for comparison of the Asserted Claims. In its Renewed Motion to Dismiss, Defendant compares independent claim 1 of the '769 Patent with claims 1, 10, 11, and 15 of the '687 Patent and claims 1, 8, 9, and 19 of the '921 Patent. [Doc. 439 at 7–8]. XY and Inguran contend that in the 2012 Lawsuit, XY asserted claims 1, 2, 6–9, 12, and 13 of the '687 Patent and claims 1, 2, 5, 18, and 20 of the '921 Patent. [Doc. 445 at 9 n.3 (citing Doc. 445-3 at 2)]. On Reply, Defendant does not dispute XY's and Inguran's contention. See [Doc. 449]. Thus, this court will compare independent claim 1 of the '769 Patent to the broadest of the claims of the '687 and '921 Patents previously asserted -- independent claim 1 of the '687 Patent and independent claim 1 of the '921 Patent.⁷

Independent claim 1 of the '769 Patent discloses:

A method of producing a frozen-thawed sorted artificial insemination sample comprising:

thawing frozen sperm cells;

staining said thawed sperm cells with a concentration of a Hoechst 33342 greater than 40 micromolar;

establishing the staining temperature between about 30 C and about 40 C;

determining a sex characteristic of said sperm cells;

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⁷ Claim 20 of the '921 Patent is also an independent claim, but has additional limitations than Claim 1 of the '921 Patent. In addition, "[b]y definition, an independent claim is broader than a claim that depends from it[.]" *Littelfuse, Inc. v. Mersen USA EP Corp.*, 29 F.4th 1376, 1380 (Fed. Cir. 2022).

separating said sperm cells according to the determination of their sex characteristic;

isolating sperm cells separated according to the determination of their sex characteristic in a collection element at a rate of greater than 1000 sperm per second for either X-chromosome bearing sperm or Y-chromosome bearing sperm;

establishing a frozen-thawed sorted artificial insemination sample from said sperm cells isolated in said collection element; and

fertilizing an egg with said frozen-thawed sorted artificial insemination sample at success levels of at least about 70% of the success levels with sperm cells that have not been separated and/or frozen.

[Doc. 439-2 at 40, col. 30 II. 19-40].

Independent claim of the '687 Patent discloses:

A method of using stained sperm cells collected from mammals, comprising the steps of:

collecting semen from a male of a non-human mammal;

freezing said semen;

thawing said semen;

incubating sperm cells contained within said semen in a concentration of a Hoechst 33342 greater than 40 micro-molar;

establishing the temperature at which said sperm cells in said concentration of Hoechst 33342 stain are incubated between about 30 degrees centigrade and about 40 degrees centigrade;

adjusting a duration of time said sperm cells are incubated with said concentration of Hoechst 33342 stain;

staining DNA within said sperm cells with sufficient uniformity to allow X-chromosome bearing sperm cells to be differentiated from Y-chromosome bearing sperm cells based upon the magnitude of fluorescence;

determining the sex characteristic of a plurality of sperm cells contained within said frozen-thawed semen;

separating said sperm cells according to the determination of their sex characteristic;

isolating sperm cells separated according to the determination of their sex in a collected element;

establishing a sample from said sperm cells isolated in said collection element;

successfully fertilizing at least one egg of a female non-human mammal with said sample at success levels of at least about 70% of success with spermatozoa that have not been separated and/or frozen; and

successfully producing offspring non-human mammal of the desired sex.

[Doc. 439-3 at 41, col. 30, II. 9-42].

<u>Independent claim 1 of the '921 Patent discloses:</u>

A process for preparing sperm cell samples, the process comprising:

collecting semen from a male mammal; freezing said semen to form frozen semen:

thawing said frozen semen to form frozen-thawed semen; incubating sperm cells contained within said frozen thawed semen in a concentration of Hoechst 33342 stain of greater than 40 micro-molar,

establishing the temperature at which said sperm cells are incubated between about 30 degrees centigrade and about 40 degrees centigrade; adjusting a duration of time said sperm cells are incubated in said concentration of Hoechst 33342 stain;

staining said sperm cells with Sufficient uniformity to allow X-chromosome bearing sperm cells to be differentiated from Y-chromosome bearing sperm cells based upon the magnitude of fluorescence;

determining the sex characteristic of a plurality of sperm cells contained within said frozen-thawed semen; separating said sperm cells according to the determination of their sex characteristic; isolating sperm cells separated according to the determination of their sex in a collection element;

establishing a sample from said sperm cells isolated in said collection element; wherein fertilizing at least one egg of a female mammal with said sample at success levels of at least about 70% of Success with spermatozoa that have not been separated and/or frozen is achieved.

[Doc. 493-4 at 40, col. 29 II. 33-62].

The Parties concede that patent claims do not need to include identical steps to be "essentially the same." See Puget Bioventures, LLC v. Biomet Orthopedics LLC, No. 3:17-cv-502 JD, 2018 WL 2933733, at *3 (N.D. Ind. June 11, 2018). Instead, the Parties' dispute over whether the scope of these claims are "essentially the same" focuses upon the steps of "collecting" and "freezing" the sperm cells prior to thawing them. See [Doc. 439 at 9; Doc. 445 at 6]. Trans Ova insists that these two steps are "meaningless" because the asserted claims of the '769 Patent expressly recite "thawing frozen sperm cells[,]" and "[p]lainly, before frozen sperm cells can be thawed, they must first be collected and frozen." [Doc. 439 at 9]. Trans Ova points to the prosecution history of the '769 Patent to support its conclusion: (1) the Examiner allowed the claims because the prior art failed to teach fertilizing an egg with frozen-thawed sperm at success levels at least about 70% of sperm that had not been separated and/or frozen; and (2) XY overcame the Patent Examiner's rejection of the '769 Patent for double patenting over the '687 and '921 Patents by the filing of a terminal disclaimer. [/d. at 10–11]. While

⁸ While some courts have declined to determine claim preclusion prior to claim construction, see, e.g., Oyster Optics, LLC v. Cisco Sys., Inc., No. 2:20-cv-00211-JRG, 2021 WL 1530935, at *4 (E.D. Tex. Apr. 16, 2021), the Parties have represented to the court, and this court agrees, that the ruling on the instant Renewed Motion to Dismiss is not dependent upon claim construction.

acknowledging that the terminal disclaimer was not dispositive as to claim preclusion, Trans Ova points to the Federal Circuit's language in *SimpleAir* that observes that terminal disclaimers are a "strong clue" of patentable indistinctness. [*Id.* at 11].

XY and Inguran disagree, in part pointing to Trans Ova's own non-infringement theories in the 2012 Lawsuit. See [Doc. 445 at 10]. Specifically, XY and Inguran contend that Trans Ova's argument that it did not infringe the Asserted Patents in the 2012 Lawsuit because it did not, itself, conduct the "collecting" and "freezing" steps is a tacit admission that these steps are not "meaningless" and the scope of Asserted Claims of the '769 Patent is not essentially the same as the scope of the asserted claims in either the '687 or '921 Patents. [Id.]. XY and Inguran further argue that to find otherwise would allow Trans Ova to avoid infringement under the '769, '687, or '921 Patents by simply avoiding any direct involvement or control over the collecting and freezing of sperm. See [id. at 12]. XY and Inguran urge the court to conclude that the Asserted Claims of the '769 Patent are broader than those of the '687 and '921 Patents, and thus, not subject to claim preclusion. [Id.].

This court begins by considering the shared specification of the '769, '687, and '921 Patents and the prosecution history of the '769 Patent. The Patent Examiner for the '769 Patent acknowledged that they were not identical. See [Doc. 439-6 at 10]. Instead, the Patent Examiner rejected claim 90 of Application No. 12/853,196 (which ultimately matured into claim 1 of the '769 Patent) over claims 1, 8, and 13 of the '687 Patent based on non-statutory obviousness-type double patenting, because the conflicting claims were not patentability distinct, as:

both inventions are drawn to similar method comprising the steps of; collecting/obtaining frozen semen from a male mammal; thawing the semen, staining the semen with Hoechst 33342 at the same concentrations, temperature range and times; determining the sex characteristic of a plurality of sperm cells in the semen (at least about 85% bearing X or Y); separating the sperm cells according to the determination of their sex characteristic; isolating sperm cells according to their sex characteristic in a collection element; establishing a sample from said isolated sperm cells; . . . successfully fertilizing at least one egg at success levels of at least about 70% of success with spermatozoa that have not been separated and/or frozen; and successfully producing offspring of non-human mammal of the desired sex.

[Doc. 439-6 at 9-10]. The Patent Examiner reached a similar conclusion as to claims 89–97 of the '196 Application compared to claims 1, 2, 5, and 15–17 of the '921 Patent. [Id.]. The Examiner further explained when comparing claims 89–97 of the '196 Patent to the identified claims of the '687 and '921 Patents, that while not identical, the differences were superficial and would have been obvious to one of ordinary skill in the art at the time of the invention. [Id.]. In addition, this court notes the Patent Examiner suggested that references, including Seidel et al., "teach a method wherein collected bovine sperm was frozen, thawed, staining nuclear DNA" and "teach a method of obtaining frozen sperm cells[.]" [Id. at 14; Doc. 439-5 at 13]. Finally, this court acknowledges that the existence of the terminal disclaimer in the context of a continuation patent, while not dispositive, is a "strong clue" that claim 1 of the '769 Patent is not patentably distinct from claim 1 of the '687 Patent and claim 1 of the '921 Patent. See Indivior Inc. v. Dr. Reddy's Laboratories, S.A., 752 Fed. Appx. 1024, 1035 (Fed. Cir. 2018) ("While not dispositive, the filing of a terminal disclaimer here is a 'strong clue' that the claims of the '305 patent are patentably indistinct from those of the '514 patent." (citing SimpleAir, 884 F.3d at 1168)).

But obviousness is a mixed question of fact and law, and without expert testimony regarding the steps of "collecting" and "freezing," and whether or not such steps are inherent in "thawing," or otherwise immaterial to patentability distinction, this court is hesitant to conclude, at this juncture, that such steps are "meaningless" as a matter of law. See, e.g., Stragent, LLC v. BMW of N. Am., LLC, No. CV 20-510-LPS, 2021 WL 1147468, at *6 (D. Del. Mar. 25, 2021) (holding that without the benefit of an expert opinion, the court was not in a position to hold that the additional limitations "would not materially impact the question of patentability"). The Patent Examiner does not discuss the "collecting" and "freezing" steps as part of the Office Action, though in his own amendments, he eliminated the step of "obtaining frozen sperm cells" without explanation. See [Doc. 439-5 at 9, 12]. And as SimpleAir and its progeny recognize, there is no prohibition on broadening claims in continuation patents subject to a terminal disclaimer. See SimpleAir, 884 F.3d at 1167–68. Nevertheless, this court is not persuaded the mere existence of additional steps of "collecting" and "freezing" necessarily mean that the Asserted Claims are patentably distinct, particularly when "mere obvious variations of the same invention" are not patentably distinct. Cf. Gilead Scis., Inc. v. Natco Pharma Ltd., 753 F.3d 1208, 1213 (Fed. Cir. 2014).9

Thus, this court cannot conclude that Trans Ova has carried its burden at this juncture (nor can it conclude as a matter of law that the inventions are patentably distinct),

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⁹ This court notes that Trans Ova has withdrawn certain arguments with respect to invalidity of the '769 Patent based on anticipation and obviousness. *See* [Doc. 527; Doc. 528]. This Recommendation should not be interpreted as an invitation to re-introduce those invalidity arguments, even if Trans Ova does not agree that it is estopped from asserting that the Lu Paper is prior art.

based on the record before it and, in turn, respectfully recommends that the instant Motion to Dismiss be **DENIED without prejudice**, to be renewed if appropriate *in limine* or at trial.

II. Motion to Amend Answer

In its Motion to Amend Answer, Trans Ova seeks leave to file a Second Amended Answer and Counterclaims to assert a counterclaim of inequitable conduct against XY and Inguran as to the '769 Patent and a counterclaim against all Plaintiffs of invalidity based on inequitable conduct as to the '559 Patent. [Doc. 446 at 1]. Because the deadline for amendment of pleadings had long passed by the time Trans Ova sought to amend its Answer, this court applies a two-part test to determine whether leave should be granted. First, the court considers whether the moving party demonstrates good cause pursuant to Rule 16(b) of the Federal Rules of Civil Procedure. See Gorsuch, Ltd., B.C. v. Wells Fargo Nat'l Bank Assoc., 771 F.3d 1230, 1242 (10th Cir. 2014); SIL-FLO, Inc. v. SFHC, Inc., 917 F.2d 1507, 1518 (10th Cir. 1990). Next, the court weighs whether the amendment should be allowed pursuant to Rule 15(a). Gorsuch, 771 F.3d at 1242. Trans Ova contends that it satisfies both prongs required to amend its Answer to include affirmative defenses of inequitable conduct with respect to the '769 and the '559 Patent. See [Doc. 446].

Good Cause. Rule 16(b) provides that a scheduling order "may be modified only for good cause and with the judge's consent." Fed. R. Civ. P. 16(b)(4). "In practice, this standard requires the movant to show the 'scheduling deadlines cannot be met despite [the movant's] diligent efforts." *Gorsuch*, 771 F.3d at 1240 (citing *Pumpco, Inc. v.*

Schenker Int'l, Inc., 204 F.R.D. 667, 668 (D. Colo. 2001)). "Rule 16(b) does not focus on the bad faith of the movant, or the prejudice to the opposing party. Rather, it focuses on the diligence of the party seeking leave to modify the scheduling order to permit the proposed amendment." Colo. Visionary Acad. v. Medtronic, Inc., 194 F.R.D. 684, 687 (D. Colo. 2000).

Leave to Amend. Rule 15(a) provides that leave to amend "shall be freely given when justice so requires." Fed. R. Civ. P. 15(a). Courts have described the standard under Rule 15(a) as "more lenient" than that under Rule 16(b). See Pumpco, 204 F.R.D. at 668. Refusing leave to amend is generally only justified upon a showing of undue delay, undue prejudice to the opposing party, bad faith or dilatory motive, failure to cure deficiencies by amendments previously allowed, or futility of amendment. See id.; Frank v. U.S. West, Inc., 3 F.3d 1357, 1365 (10th Cir. 1993). Whether to allow amendment is within the trial court's discretion. Burks v. Oklahoma Publ'g Co., 81 F.3d 975, 978–79 (10th Cir. 1996).

A. '769 Patent

With respect to the '769 Patent, Trans Ova argues that it was diligent in asserting its affirmative defense of inequitable conduct based on evidence gathered during a parallel *inter partes review* ("IPR") proceeding that took place after the dismissal of the '769 Patent. See [Doc. 446 at 3–7]. Specifically, Defendant contends that certain facts came to light during the IPR (which ranged from June 2018 to June 2019) that were not otherwise known to it, and that once the stay was lifted on April 22, 2021, see [Doc. 429], it acted promptly by filing the motion by the June 11 deadline set by the court. [Doc. 446

at 3–7]. Courts have found that the burden to establish diligence is satisfied, for example, when a party learns of new information in a deposition or that the governing law has changed. See Gorsuch, 771 F.3d at 1240. Based on the record before it, this court finds that Trans Ova has demonstrated sufficient diligence under Rule 16(b)(4).

Next, Trans Ova asserts that amendment is appropriate under Rule 15(a) because there has been no undue delay or bad faith by it; Plaintiffs will not be prejudiced by it; and the proposed amendment is not futile. See [Doc. 446 at 13–15]. In response, XY and Inguran assert, and argue in detail, that the proposed amendment is futile and that it will be prejudiced. See [Doc. 458 at 7–12]. Given the detail of and complexity of the arguments, this court respectfully **RECOMMENDS** that, rather than forcing these arguments into the context of this instant Motion to Amend Answer, the court exercise its discretion and decline to engage in the various aspects of the futility analysis at this juncture, and **GRANT** the Motion to Amend Answer as to the '769 Patent, reserving issues of the viability of such affirmative defense.

B. '559 Patent

With respect to the '559 Patent, Defendant contends that it first learned of possible inequitable conduct during the Rule 30(b)(6) depositions of XY's in-house counsel, Ryan Christensen, on April 18–19, 2018. [Doc. 446 at 7–8]. Then, on April 24–25, 2018, and May 15 and 17, 2018, other witnesses corroborated Mr. Christensen's testimony. [*Id.* at 9]. No later than May 22, 2018, Trans Ova informed Plaintiffs' counsel that it was contemplating an inequitable conduct defense but wished to complete some depositions prior to seeking amendment. [*Id.* at 10]. Those depositions were completed no later than

June 21, 2018. See [id.]. Then, on August 3, 2018, Trans Ova filed a motion to amend its Answer to include a counterclaim for inequitable conduct that was subsequently mooted when the court granted judgment on the pleadings as to the '559 Patent. See [Doc. 259; Doc. 262].

XY and Inguran oppose, setting forth a very different account, describing Trans Ova's decision to "backload its discovery efforts and drag its feet on formulating and formalizing its defenses." [Doc. 458 at 6–7]. Namely, they point to the fact that discovery opened in this action in March 2017, and Trans Ova did not request its first deposition until February 2018. See [id.]. XY and Inguran contend that Trans Ova's "inexcusable delay" in seeking discovery has deprived them of the opportunity to defend against the charge of inequitable conduct. [Id. at 4].

While this court respectfully agrees that the delay in initiating discovery may, in some instances, preclude the finding of good cause, this court is not persuaded that Trans Ova did not act in a sufficiently diligent manner based on the circumstances before the court. This court notes that in late 2017–early 2018, the Parties were engaged in multiple telephonic discovery dispute conferences before this Magistrate Judge. See, e.g., [Doc. 58; Doc. 60; Doc. 77; Doc. 79]. Document production was ongoing, and issues with respect to privilege had been raised. See [Doc. 104]. Furthermore, Plaintiffs sought to further amend their operative pleading. See [Doc. 137]. Given the general tenor of discovery at that juncture and that the affirmative defense of inequitable conduct is subject to the heightened pleading standard of Rule 9(b), this court finds good cause under Rule 16(b)(4).

Having found good cause under Rule 16(b)(4), this court also finds that amendment is appropriate under Rule 15. While XY and Inguran argue that they have been deprived the opportunity to defend against the charge of inequitable conduct, this court notes that (and XY and Inguran have recognized), as with all affirmative defenses, the burden to establish inequitable conduct by clear and convincing evidence rests with Trans Ova. See, e.g., [Doc. 458 at 11 n.5]. In addition, if there is any asymmetry of information regarding the conduct associated with the prosecution of the '559 Patent, such asymmetry favors Plaintiffs – not Defendants. Finally, based on the course of litigation in this and the 2012 Lawsuit, this court cannot conclude that Plaintiffs could have been reasonably surprised that inequitable conduct was raised as an invalidity theory with respect to the '559 Patent. See, e.g., [Doc. 80]. Accordingly, this court respectfully RECOMMENDS that Trans Ova's Motion to Amend Answer be GRANTED. In so recommending, this court does not pass on the substantive issues of viability of these additional defenses.

CONCLUSION

Accordingly, for the foregoing reasons, this court respectfully **RECOMMENDS** that:

(1) Defendant Trans Ova Genetics, LC's Renewed Motion to Dismiss Count VI of Plaintiffs' Operative Complaint Pursuant to Fed. R. Civ. Proc. 12(b)(6) [Doc. 439] be **DENIED without prejudice**;

(2) Trans Ova's Motion for Leave to File a Second Amended Answer and Counterclaims to Plaintiffs' Fourth Amended Complaint [Doc. 446] be **GRANTED**. 10

DATED: July 13, 2022 BY THE COURT:

Nina Y. Wang

United States Magistrate Judge

¹⁰ Within fourteen days after service of a copy of the Recommendation, any party may serve and file written objections to the Magistrate Judge's proposed findings and recommendations with the Clerk of the United States District Court for the District of Colorado. 28 U.S.C. § 636(b)(1); Fed. R. Civ. P. 72(b); In re Griego, 64 F.3d 580, 583 (10th Cir. 1995). A general objection that does not put the District Court on notice of the basis for the objection will not preserve the objection for de novo review. "[A] party's objections to the magistrate judge's report and recommendation must be both timely and specific to preserve an issue for de novo review by the district court or for appellate review." United States v. One Parcel of Real Property Known As 2121 East 30th Street, Tulsa, Oklahoma, 73 F.3d 1057, 1060 (10th Cir. 1996). Failure to make timely objections may bar *de novo* review by the District Judge of the Magistrate Judge's proposed findings and recommendations and will result in a waiver of the right to appeal from a judgment of the district court based on the proposed findings and recommendations of the magistrate judge. See Vega v. Suthers, 195 F.3d 573, 579-80 (10th Cir. 1999) (District Court's decision to review a Magistrate Judge's recommendation de novo despite the lack of an objection does not preclude application of the "firm waiver rule"); International Surplus Lines Insurance Co. v. Wyoming Coal Refining Systems, Inc., 52 F.3d 901, 904 (10th Cir. 1995) (by failing to object to certain portions of the Magistrate Judge's order, crossclaimant had waived its right to appeal those portions of the ruling); Ayala v. United States, 980 F.2d 1342, 1352 (10th Cir. 1992) (by their failure to file objections, plaintiffs waived their right to appeal the Magistrate Judge's ruling). But see Morales-Fernandez v. INS, 418 F.3d 1116, 1122 (10th Cir. 2005) (firm waiver rule does not apply when the interests of justice require review).