IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLORADO Judge William J. Martínez

Civil Action No. 17-cv-0944-WJM-NYW

XY, LLC, BECKMAN COULTER, INC., and INGURAN, LLC d/b/a STGENETICS,

Plaintiffs,

٧.

TRANS OVA GENETICS, LC,

Defendant.

ORDER GRANTING MOTION FOR JUDGMENT ON THE PLEADINGS, DENYING MOTION TO AMEND COMPLAINT AS FUTILE, AND DENYING MOTION TO AMEND COUNTERCLAIMS AS MOOT

In this lawsuit, Plaintiffs XY, LLC, Beckman Coulter, Inc., and Inguran, LLC

(together, "XY") bring patent infringement claims, as well as certain non-patent claims,

against Defendant Trans Ova Genetics, LC ("Trans Ova"). Currently before the Court

are three motions:

- Trans Ova's Rule 12(c) Motion for Judgment on the Pleadings as to U.S. Patent No. RE46,559 Under 35 U.S.C. § 101 ("Motion for Judgment on the Pleadings") (ECF No. 138);
- XY's Motion for Leave to File a Fifth Amended Complaint ("Motion to Amend Complaint") (ECF No. 137); and
- Trans Ova's Motion for Leave to File a Second Amended Answer and Counterclaims to Plaintiffs' Fourth Amended Complaint ("Motion to Amend

Counterclaims") (ECF No. 259).

For the reasons stated below, the Court will grant the Motion for Judgment on the Pleadings, deny the Motion to Amend Complaint as futile, and deny the Motion to Amend Counterclaims as moot.

I. BACKGROUND

Broadly speaking, this case centers around technology that attempts to sort, and usually succeeds in sorting, non-human mammalian semen based on whether a sperm cell carries an X chromosome or a Y chromosome. Such "sexed semen" is useful in artificial insemination to ensure the gender of the offspring. One patent related to this technology is U.S. Patent No. RE46,559 ("559 Patent"). Count XII of XY's Fourth Amended Complaint accuses Trans Ova of infringing "at least claim 1" of the 559 Patent. (ECF No. 74 ¶ 105.)

The 559 Patent discloses a method that improves the accuracy of systems designed to detect the differences between "particles" of "at least two populations" during flow cytometry. 559 Patent at Abstract. When the "particles" are sperm cells and the "populations" are X-chromosome cells and Y-chromosome cells, a typical way to distinguish them under the current state of the art is to: (1) apply a special dye that bonds to the chromosomes and will fluoresce when struck with a laser beam; (2) "entrain" each dyed sperm cell in a fluid droplet that moves through a laser beam, causing the dye to fluoresce; (3) use a light-detecting mechanism to judge whether the cell contains an X chromosome or a Y chromosome (X chromosomes contain more DNA and so fluoresce more); (4) apply a charge to the droplet based on whether the light detector has detected an X chromosome or a Y chromosome; and (5) use charged

plates to pull the droplet toward the collecting vial for X-chromosome cells or Y-chromosome cells, as the case may be. *Id.* at 1:53–61, 3:4–63.

Sometimes the difference in fluorescence between X and Y chromosomes "may be so small" that "it may be difficult to categorize the data points into a population." *Id.* at 3:67–4:4. The 559 Patent purports to overcome or ameliorate this problem by using two or more sensors (such as the light detectors in the above-described embodiment) that view the particles from different angles, thus providing multi-dimensional data. *Id.* at 4:10–6:48. The data can then be processed through multi-dimensional mathematical equations (what the patent calls "compensation algorithms") that allow for rotation, translation, scaling, zooming, and tracking. *Id.* at 7:16–10:12. It is the application of these equations (not the idea of using more than one sensor to gather multi-dimensional data) that the patent claims to be novel. *Id.* at 6:52–7:25. The equations, alone or in combination, can show distinctions between detected signals (*e.g.*, the light detected from fluorescing dye) that might otherwise go unnoticed, and so provide "[c]larity of delineation, … allow[ing] each population to be selected more accurately than in any other separation system." *Id.* at 6:54–56.

Claim 1 of the 559 Patent (the only independent claim) reads as follows:

A method of operating a flow cytometry apparatus with at least n detectors to analyze at least two populations of particles in the same sample, the method comprising:

(a) establishing a fluid stream in the flow cytometry apparatus with at least n detectors, the at least n detectors including a first detector and a second detector;

(b) entraining particles from the sample in the fluid stream in the flow cytometry apparatus;

(c) executing instructions read from a computer readable

memory with a processor, the processor being in communication with the first detector in the flow cytometer, to detect a first signal from the first detector based on individual particles in the fluid stream;

 (d) executing instructions read from the computer readable memory with the processor, the processor being in communication with the second detector in the flow cytometer, to detect a second signal from the second detector based on the individual particles in the fluid stream;

(e) executing instructions read from the computer readable memory with the processor to convert at least the first signal and the second signal into n-dimensional parameter data for detected particles in the sample, wherein the n-dimensional parameter data for particles from the at least two populations overlap in at least one of the dimensions;

(f) executing instructions read from the computer readable memory with the processor to rotationally alter the ndimensional parameter data so that spatial separation of the data from the particles from the at least two populations in the at least one dimension that is overlapped is increased;

(g) executing instructions read from the computer readable memory with the processor to real-time classify each of the individual detected particles into one of a first population and a second population of the at least two populations based on at least the rotationally altered n-dimensional parameter data; and

(h) using the real-time classification, sorting the individual particles with the flow cytometer.

Id. at 16:54–17:44.

Claims 2–23 present variations on Claim 1's method. The Court particularly

notes Claims 4, 7, 11, and 12, which call for scaling equations; Claims 7 and 12, which

additionally call for multiple simultaneous mathematical transformations (e.g., rotation

plus scaling); Claim 6, which calls for zooming and tracking; Claim 18, which covers an

implementation specifically intended to sort sperm; and Claim 19, which calls for laser-

generated fluorescence as the means of distinguishing particles. *Id.* at 17:48–20:2.

II. LEGAL STANDARDS

A. Rule 12(c)

A motion for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c) is evaluated under the same standard applicable to a Rule 12(b)(6) motion to dismiss. See Corder v. Lewis Palmer Sch. Dist. No. 38, 566 F.3d 1219, 1223–24 (10th Cir. 2009). Therefore, in ruling on a motion for judgment on the pleadings, courts look to the specific allegations of the complaint to determine whether they plausibly support a legal claim for relief—that is, a complaint must include "enough facts to state a claim for relief that is plausible on its face." TON Servs., Inc. v. Qwest Corp., 493 F.3d 1225, 1236 (10th Cir. 2007); Alvarado v. KOB-TV, LLC, 493 F.3d 1210, 1215 (10th Cir. 2007). The Court accepts as true the well-pleaded factual allegations of the opposing party and draws all reasonable inferences in its favor. See Nelson v. State Farm Mut. Auto. Ins. Co., 419 F.3d 1117, 1119 (10th Cir. 2005). In ruling on a motion for judgment on the pleadings, the Court may consider the complaint, any material that is attached to the complaint, and the answer. See Park Univ. Enters. v. Am. Cas. Co., 442 F.3d 1239, 1244 (10th Cir. 2006). Additionally, the Court may take judicial notice of court documents. Denver Health & Hosp. Auth. v. Beverage Distrib. Co., LLC, 546 F. App'x 742, 747 n.3 (10th Cir. 2013).

B. The "*Alice*" Patentability Test

Trans Ova's Motion for Judgment on the Pleadings raises a "patentability" challenge to the 559 Patent, *i.e.*, whether the 559 Patent claims anything that the Patent Act, 35 U.S.C. §§ 1 *et seq.*, deems patent-protectable. The following principles are

therefore relevant.

The Patent Act provides that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101. The Supreme Court has "long held," however, "that this [broadly worded] provision contains an important implicit exception: Laws of nature, natural phenomena, and abstract ideas are not patentable." *Alice Corp. Pty. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2354 (2014) (internal quotation marks omitted).

"[D]istinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts" first requires a court to "determine whether the claims at issue are directed to one of those patent-ineligible concepts." *Id.* at 2355. If the answer is no, the inquiry ends; but if the answer is yes, a court must then determine whether the claims in question nonetheless offer "an inventive concept—*i.e.*, an element or combination of elements that is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the ineligible concept itself." *Id.* (internal quotation marks omitted; alterations incorporated). This second inquiry requires the court to "consider the elements of each claim both individually and as an ordered combination to determine whether the additional elements transform the nature of the claim into a patent-eligible application." *Id.* (internal quotation marks omitted).

A court may undertake the foregoing inquiries at the pleading phase. *See, e.g., Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352, 1360 (Fed. Cir. 2017), *cert. denied*, 138 S. Ct. 2621 (2018); *Genetic Techs. Ltd. v. Merial LLC*, 818 F.3d

1369, 1373–74 (Fed. Cir. 2016), *cert. denied*, 137 S. Ct. 242 (2016). But the second inquiry, in particular, sometimes requires the court to consider whether claim limitations are "well-understood, routine and conventional to a skilled artisan in the relevant field." *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1368 (Fed. Cir. 2018). If so, the court is faced with a fact question. *Id.* If it is a genuine dispute of material fact, resolution at the pleading phase is not appropriate. *See, e.g., Aatrix Software, Inc. v. Green Shades Software, Inc.*, 882 F.3d 1121, 1129 (Fed. Cir. 2018); *Berkheimer*, 881 F.3d at 1370.

III. ANALYSIS

The proper application of the Supreme Court's *Alice* standard is an evolving area of law. The Federal Circuit has remarked on the difficulty, at times, of distinguishing the first *Alice* inquiry from the second, *see, e.g., Elec. Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1353 (Fed. Cir. 2016) ("*EPG*"); and distinguishing the two *Alice* inquiries (comprising a patentability analysis rooted in 35 U.S.C. § 101) from other common inquiries such as invalidity (a novelty analysis rooted in 35 U.S.C. §§ 102–03), *see, e.g., Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1052 & n.2 (Fed. Cir. 2016). Despite the potential ambiguities, the Court is convinced under the current state of the case law that the 559 Patent, at bottom, claims nothing substantially more than a patent-ineligible abstract concept, and therefore should not have been issued.

A. *Alice*, Step One: Are the Claims "Directed To" Patent-Ineligible Subject Matter?

Because Claim 1 is the 559 Patent's only independent claim, a finding that it is "directed to" patent-ineligible subject matter, *Alice*, 134 S. Ct. at 2355, will dictate the same finding as to the remaining claims. The Court therefore focuses on Claim 1 at this stage, and concludes that Claim 1 is, indeed, directed to patent-ineligible subject matter.

In reaching this conclusion, the Court finds most instructive the Supreme Court's decisions in *Parker v. Flook*, 437 U.S. 584 (1978) ("*Flook*"), *Diamond v. Diehr*, 450 U.S. 175 (1981) ("*Diehr*"), and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012); and the Federal Circuit's decisions in *Cleveland Clinic, supra*, and *EPG, supra*.¹

In *Flook*, the Patent Office rejected a patent claiming an improved method of calculating an "alarm limit," which is a numerical value useful for judging the efficiency and safety of catalytic conversion processes. 437 U.S. at 535. The Supreme Court ultimately upheld the Patent Office's decision because the "only novel feature" was a new mathematical algorithm that the applicant had developed. *Id.* at 538, 594–95. Mathematical algorithms are not patentable: "Whether the algorithm was in fact known or unknown at the time of the claimed invention, as one of the basic tools of scientific and technological work, it is treated as though it were a familiar part of the prior art." *Id.* at 591–92 (internal quotation marks and citation omitted). Further, it was not enough that the proposed patent was limited to applying the algorithm within the field of catalytic conversion:

The notion that post-solution activity, no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process exalts form over substance. A competent draftsman could attach some

¹ *Flook*, *Diehr*, and *Mayo* predate *Alice*; *EPG* and *Cleveland Clinic* postdate *Alice* and explicitly draw upon it. This turns out to be a distinction without a difference. *Mayo* employed a two-part analysis that *Alice* explicitly systematized two years later. *See Alice*, 134 S. Ct. at 2355 ("In *Mayo* . . . we set forth [the relevant] framework"); *cf. Aatrix*, 882 F.3d at 1126 (referring to the *Alice* test as the "*Alice/Mayo* analysis"). And both *Alice* and *Mayo* drew on *Flook* and *Diehr* as proto-examples of the proper two-part inquiry. *See Alice*, 134 S. Ct. at 2355 & n.3, 2358; *Mayo*, 566 U.S. at 71–73, 80–82. Thus, it is appropriate to draw upon all of these cases when analyzing patentability under what is now known as the *Alice* test.

form of post-solution activity to almost any mathematical formula; the Pythagorean theorem would not have been patentable, or partially patentable, because a patent application contained a final step indicating that the formula, when solved, could be usefully applied to existing surveying techniques.

Id. at 590. Thus, "once [the] algorithm [was] assumed to be within the prior art, the

application, considered as a whole, contain[ed] no patentable invention." Id. at 594.

Three years later, the Supreme Court resolved the Diehr case, which presented

a similar patentability dispute about the use of a mathematical equation, although in

Diehr the equation was well-known and the field of the invention was the process of

curing synthetic rubber. 450 U.S. at 177-78. In contrast to Flook, Diehr upheld the

patentability of the invention because, the court explained,

[the inventors] do not seek to pre-empt the use of [the] equation. Rather, they seek only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process. These include installing rubber in a press, closing the mold, constantly determining the temperature of the mold, constantly recalculating the appropriate cure time through the use of the [equation] and a digital computer, and automatically opening the press at the proper time.

Id. at 187. The Supreme Court reasoned that whether these various steps, in

combination, embodied a novel invention was best evaluated under 35 U.S.C. § 102,

not under a § 101 patentability inquiry. Id. at 189-91.

The Supreme Court's next major pronouncement in this area was the Mayo

decision, decided almost two decades after Diehr. In Mayo, the Supreme Court

confronted certain patents where the only novel features were, in fact, "laws of nature."

566 U.S. at 77. Specifically, the inventors had discovered that concentrations of a

certain metabolite in the bloodstream within a certain measurable range correlated with

an effective dosage of a particular drug, whereas concentrations below that range correlated with ineffectiveness and concentrations above that range correlated with potentially dangerous side effects. *Id.* at 73–74. The resulting patents essentially instructed doctors to measure the metabolite in the patient's bloodstream and then adjust the patient's dosage if the metabolites were above or below the specified range. *Id.* at 74–75. The Supreme Court held that the patents were improperly issued because "the claims inform a relevant audience about certain laws of nature; any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately." *Id.* at 79–80.

Mayo also compared and contrasted *Diehr* and *Flook*, "two cases in which the Court reached opposite conclusions about the patent eligibility of processes that embodied the equivalent of natural laws." *Id.* at 80. *Flook*, the court said, involved an invention where, "putting the [new mathematical] formula to the side, there was no inventive concept." *Id.* at 81 (internal quotation marks omitted). *Diehr*, by contrast,

nowhere suggested that [the steps in addition to the use of the rubber-curing equation] were in context obvious, already in use, or purely conventional. . . . These other steps apparently added to the [equation] something that in terms of patent law's objectives had significance—they transformed the process into an inventive application of the formula.

Id. In other words, by the time of its decision in *Mayo*, the Supreme Court saw the outcome in *Diehr* as heavily bound to arguments the parties failed to make in that case.

The Federal Circuit's *EPG* decision is also instructive. The patent in question there described a method of monitoring data gathered from sensors spread across a large-scale electric power grid, displaying the data in helpful visual forms, and using the

data to assess the grid's reliability. 830 F.3d at 1351-52. In its Alice "directed to"

analysis, the Federal Circuit noted that the patent was potentially no more than a

collection of patent-ineligible abstract ideas:

Information as such is an intangible. Accordingly, we have treated collecting information, including when limited to particular content (which does not change its character as information), as within the realm of abstract ideas. In a similar vein, we have treated analyzing information by steps people go through in their minds, or by mathematical algorithms, without more, as essentially mental processes within the abstract-idea category. And we have recognized that merely presenting the results of abstract processes of collecting and analyzing information, without more (such as identifying a particular tool for presentation), is abstract as an ancillary part of such collection and analysis.

Id. at 1353-54 (citations omitted). Turning to the patent itself, the Federal Circuit found

that its claims were

clearly focused on the combination of those abstract-idea processes. The advance they purport to make is a process of gathering and analyzing information of a specified content, then displaying the results, and not any particular assertedly inventive technology for performing those functions. They are therefore directed to an abstract idea [and so patentineligible].

Id. at 1354.

Finally, the Court notes the Federal Circuit's *Cleveland Clinic* decision. There,

the supposedly innovative portion of the patent was the discovery that "[w]hen an artery

is damaged or inflamed, the body releases the enzyme myeloperoxidase, or MPO, in

response. MPO is an early symptom of cardiovascular disease, and it can thus serve

as an indicator of a patient's risk of cardiovascular disease." 859 F.3d at 1355. The

patent thus claimed various methods of assessing cardiovascular risk by testing for

MPO. Id. at 1356–58. However, all of the testing methods were previously known in

the art (including, for example, flow cytometry). *Id.* at 1355. Thus, the patent's only real advance over the prior art was the correlation between MPO and cardiovascular disease. *Id.* at 1360–61. The patent was therefore directed to a patent-ineligible natural law. *Id.*

Taking all of these decisions together, the Court finds that Claim 1 of the 559 Patent is directed to patent-ineligible subject matter, specifically, the mathematical equation that permits rotating multi-dimensional data. Although this equation may help to discriminate between particles of varying populations, thereby increasing a flow cytometer's overall effectiveness, the innovation still reduces to nothing more than applying a mathematical concept. This is materially no different from *Flook*, where the proposed patent's only innovation was an algorithm that supposedly produced more useful data. See 437 U.S. at 585–88. It is also similar to Cleveland Clinic, given that the equation is applied in the context of hardware that is already well-known in the art. See 859 F.3d at 1355. EPG, moreover, emphasizes that gathering, processing, and displaying data is considered an abstract mental process (or ancillary to it). See 830 F.3d at 1353–54. And *Flook*, again, forecloses any argument that Claim 1's abstractness may be overlooked because it teaches a way of using a mathematical equation specifically in flow cytometry, rather than claiming a patent on the equation generally. See 437 U.S. at 590. Accordingly, Claim 1 is directed to a patent-ineligible concept.

B. Alice, Step Two: Are the Claims Nonetheless Sufficiently Inventive?

Given the foregoing, the Court proceeds to *Alice*'s second inquiry: whether "the patent in practice amounts to significantly more than a patent upon the ineligible

concept itself." 134 S. Ct. at 2355. In this regard, Trans Ova argues that everything in Claim 1 of the 559 Patent save for the mathematical equation was disclosed in U.S. Patent No. 9,145,590 ("590 Patent"),² which is specifically listed in the 559 Patent as relevant prior art. (*See* ECF No. 138 at 10–11.) *See also* 559 Patent at 13:64. XY does not respond to this argument. Instead, it asserts that fact questions prevent disposition under the second *Alice* inquiry, particularly whether the added element of mathematical analysis was more than a well-understood, routine, or conventional addition to the pre-existing process. (ECF No. 143 at 15–17.) XY's argument implicitly admits that there is nothing of note in Claim 1 beyond the application of math, which is a patent-ineligible abstract concept. By definition, then, the patent cannot amount to significantly more than a patent upon the ineligible concept itself. And the 559 Patent's dependent claims fare no better—again, they offer nothing beyond the prior art but a direction to apply additional mathematical concepts, like scaling equations.

In sum, the 559 Patent presents nothing that rises to the level of a patentable invention, and so should not have been issued. Trans Ova's Motion for Judgment on the Pleadings is well-taken.

C. XY's Proposed Fifth Amended Complaint & Trans Ova's Proposed Second Amended Answer and Counterclaims

This disposition affects two other pending motions. The first is XY's Motion to Amend Complaint. (ECF No. 137.) This motion seeks leave to file a fifth amended complaint, which would add: (1) a new cause of action for infringement of U.S. Patent No. 9,625,367 ("367 Patent"), (2) a new cause of action for infringement of U.S. Patent

² The 590 Patent is another of the patents-in-suit here. (See ECF No. 74 ¶¶ 23–28.)

No. 9,835,541 ("541 Patent"), and (3) Plaintiff Inguran as a named plaintiff on the current cause of action for infringement of the 559 Patent. (*Id.* at 1.) However, the third item of relief is moot given that the Court will grant Trans Ova's Motion for Judgment on the Pleadings as to the 559 Patent. As for the 367 and 541 Patents, the Court finds that amendment would be futile. *See Foman v. Davis*, 371 U.S. 178, 182 (1962) ("futility of amendment" is a proper ground to deny leave to amend).

Both the 367 and 541 Patents derive from the 559 Patent.³ The Specification is the same for each of the three patents. The only material difference between the 367 Patent and the 559 Patent is that the 367 Patent takes the method described in the 559 Patent and maps it onto an apparatus—or in other words, instead of describing a method for sorting particles, as claimed in the 559 Patent, the 367 Patent describes a flow cytometer configured to carry out the 559 Patent's method. *See* 367 Patent at 17:28–18:39.

As for the 541 Patent, it presents nearly the same method claims as the 559 Patent, with the only material difference being that it does not claim multiple "detectors" (*e.g.*, light detectors for measuring fluorescence). It instead only requires the *ability* to detect "a plurality of signals" from a single particle. 541 Patent at 17:21. The method of the 541 Patent could thus be implemented in a flow cytometer with a single detector capable of discerning more than one signal. But the 541 Patent does not claim that a single multitasking detector is innovative; the claimed innovation continues to be the application of multi-dimensional mathematical equations to the data gathered by the

³ More precisely, they ultimately derive from the application that resulted in U.S. Patent No. 9,134,220, which itself was reissued as the 559 Patent. *See* "Related U.S. Patent Documents" section in all three patents.

detector. Accordingly, the 367 and 541 Patents would fail an *Alice* patentability analysis for the same reasons as the 559 Patent, making XY's proposed amendment futile. *See, e.g., Gohier v. Enright*, 186 F.3d 1216, 1218 (10th Cir. 1999) ("The futility question is functionally equivalent to the question whether a complaint may be dismissed for failure to state a claim.").

Finally, just last week, Trans Ova filed its Motion to Amend Counterclaims. (ECF No. 259.) Trans Ova seeks leave to "add one new counterclaim against all Plaintiffs for unenforceability of [the 559 Patent] due to inequitable conduct." (*Id.* at 1.) This motion will be denied as moot given the Court's conclusion that the 559 Patent should not have issued in the first place.

IV. CONCLUSION

For the reasons set forth above the Court ORDERS as follows:

- Trans Ova's Rule 12(c) Motion for Judgment on the Pleadings as to U.S. Patent No. RE46,559 Under 35 U.S.C. § 101 (ECF No. 138) is GRANTED and XY's Count XII of the Fourth Amended Complaint (ECF No. 74) is accordingly DISMISSED WITH PREJUDICE;
- XY's Motion for Leave to File a Fifth Amended Complaint (ECF No. 137) is DENIED; and
- Trans Ova's Motion for Leave to File a Second Amended Answer and Counterclaims to Plaintiffs' Fourth Amended Complaint (ECF No. 259) is DENIED AS MOOT.

Dated this 9th day of August, 2018.

BY THE COURT:

William J. Martinez United States District Judge