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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

ILLUMINA, INC., et al.,

Plaintiffs,

v.

ARIOSIA DIAGNOSTICS, INC., et al.,

Defendants.

Case No. [18-cv-02847-SI](#)

**ORDER GRANTING DEFENDANTS'
MOTION FOR SUMMARY
JUDGMENT**

Re: Dkt. No. 48

On May 15, 2018, plaintiffs Illumina, Inc. and Sequenom, Inc. (collectively “plaintiffs”) filed this action against Ariosa Diagnostics, Inc. (“Ariosa”), Roche Sequencing Solutions, Inc., and Roche Molecular Systems, Inc., (collectively “Roche”), alleging infringement of U.S. Patent Nos. 9,580,751 (“the ’751 patent”) and 9,738,931 (“the ’931 patent”). Dkt. No. 1. This case was assigned to this Court on June 6, 2018. Dkt. No. 16.

Roche answered the complaint on July 9, 2018 and counterclaimed against plaintiffs, seeking declaratory judgment of noninfringement and invalidity of both asserted patents. Dkt. No. 21. Ariosa responded to the complaint with substantially the same answer and counterclaims on July 9, 2018. Dkt. No. 25. On August 9, 2018, both defendants modified their responses and submitted amended answers and counterclaims against plaintiffs. Dkt. Nos. 40, 41. Plaintiffs answered the amended counterclaims on August 23, 2018. Dkt. Nos. 46, 47.

On August 31, 2018 all defendants moved for summary judgment, seeking a finding that claims 1, 2, 4, 5, and 9-10 of U.S. Patent No. 9,580,751 and claims 1-2 and 10-14 of U.S. Patent No. 9,738,931 are invalid and unenforceable because they are not drawn to patent-eligible subject

1 matter under 35 U.S.C. §101. Dkt No. 48 at 1:10-14. The parties stipulated to an enlargement of
2 time for plaintiffs to respond, which the Court granted. Dkt. Nos. 51-53. Oral argument was held
3 on December 21, 2018.

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5 **I. The '751 Patent**

6 Illumina is the exclusive licensee of the '751 patent pursuant to an amended 2014 Pooled
7 Patents Agreement between Illumina and Sequenom. Dkt. No. 1 ¶ 7. The '751 patent is titled “Non-
8 Invasive Detection of Fetal Genetic Traits,” and was issued to inventors Sinuhe Hahn, Wolfgang
9 Holzgreve, Bernhard Zimmermann, and Ying Lim on February 28, 2017 and assigned to Sequenom,
10 Inc. U.S. Patent No. 9,580,751. The '751 patent relates to prenatal detection methods performed
11 on a maternal serum or plasma sample from a pregnant female, and the claims specifically focus on
12 procedures to separate fetal and maternal DNA in a maternal blood sample. *See id.* at 7:55-9:8. The
13 basis for the patent is the “surprising finding” that “fetal DNA has a relatively small size of
14 approximately 500 base pairs or less” and separating the smaller fragments “provides a possibility
15 to enrich for fetal DNA sequences from the vast bulk of circulatory extracellular maternal DNA.”
16 *Id.* at 1:56-2:6.

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19 According to the patent, “the presence of circulatory extracellular DNA in the peripheral
20 blood is a well established phenomenon” and it has been shown that “fetal DNA is present in the
21 maternal circulation.” *Id.* at 1:22-25. However, it can be difficult to examine the fetal DNA because
22 that “major proportion (generally > 90%) of the extracellular DNA in the maternal circulation is
23 derived from the mother.” *Id.* at 1:35-44. Separation by size discrimination from maternal DNA
24 “leads to a fraction which is largely constituted by fetal extracellular DNA” that can then be analyzed
25 for various fetal genetic traits. *Id.* at 2:7-20.

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27 The only independent claim of the '751 patent is as follows:
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1. A method for preparing a deoxyribonucleic acid (DNA) fraction from a pregnant human female useful for analyzing a genetic locus involved in a fetal chromosomal aberration, comprising:

(a) extracting DNA from a substantially cell-free sample of blood plasma or blood serum of a pregnant human female to obtain extracellular circulatory fetal and maternal DNA fragments;

(b) producing a fraction of the DNA extracted in (a) by:

(i) size discrimination of extracellular circulatory DNA fragments, and

(ii) selectively removing the DNA fragments greater than approximately 500 base pairs,

wherein the DNA fraction after (b) comprises a plurality of genetic loci of the extracellular circulatory fetal and maternal DNA; and

(c) analyzing a genetic locus in the fraction of DNA produced in (b).

Id. at 7:53-8:56.

II. The '931 Patent

Illumina is the exclusive licensee of the '931 patent pursuant to an amended 2014 Pooled Patents Agreement between Illumina and Sequenom. Dkt. No. 1 ¶ 7. Like the '951 patent, the '931 patent is entitled “Non-Invasive Detection of Fetal Genetic Traits,” and was issued to inventors Sinuhe Hahn, Wolfgang Holzgreve, Bernhard Zimmermann, and Ying Lim on February 28, 2017 and assigned to Sequenom, Inc. U.S. Patent No. 9,738,931. The '931 patent relates to prenatal detection methods performed on a maternal serum or plasma sample from a pregnant female and the claims specifically focus on procedures to separate fetal DNA from a maternal sample through size discrimination methods. *See id.* at 7:55-9:8. The basis for the patent is the “surprising finding” that “fetal DNA has a relatively small size of approximately 300 base pairs or less” and separating the smaller fragments “provides a possibility to enrich for fetal DNA sequences from the vast bulk of circulatory extracellular maternal DNA.” *Id.* at 2:14-18.

1 The '931 patent has substantially the same specification as the '751 patent discussed above.¹
2 The only significant difference is that the patent specifies and claims an invention that separates
3 fetal DNA that is 300 base pairs or smaller, rather than 500 base pairs in the '751 patent. *Id.* at 7:58-
4 8:61; '751 patent at 7:54-9:8. The only independent claim of the '931 patent is as follows:

5
6 1. A method, comprising:

7 (a) extracting DNA comprising maternal and fetal DNA fragments
8 from a substantially cell-free sample of blood plasma or blood serum
9 of a pregnant human female;

10 (b) producing a fraction of the DNA extracted in (a) by:

11 (i) size discrimination of extracellular circulatory fetal and maternal
12 DNA fragments, and

13 (ii) selectively removing the DNA fragments greater than
14 approximately 300 base pairs,

15 wherein the DNA fraction after (b) comprises extracellular circulatory
16 fetal and maternal DNA fragments of approximately 300 base pairs
17 and less and a plurality of genetic loci of the extracellular circulatory
18 fetal and maternal DNA fragments; and

19 (c) analyzing DNA fragments in the fraction of DNA produced in (b).

20 LEGAL STANDARD

21 I. Summary Judgment

22 Summary judgment is proper if the pleadings, the discovery and disclosure materials on file,
23 and any affidavits show that there is no genuine dispute as to any material fact and that the movant
24 is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56(a). The moving party bears the
25 initial burden of demonstrating the absence of a genuine issue of material fact. *Celotex Corp. v.*
26 *Catrett*, 477 U.S. 317, 323 (1986). The moving party, however, has no burden to produce evidence
27 showing the absence of a genuine issue of material fact. *Id.* at 325. Rather, the burden on the

28 ¹ There is an additional paragraph in the specification of the '931 patent that is not in the
specification of the '751 patent. This paragraph merely highlights that a Sequence Listing is
included in the specification. *See id.* at 1:25-30. The Sequence Listing is included in both patents.

1 moving party may be discharged by pointing out to the district court that there is an absence of
2 evidence to support the nonmoving party’s case. *Id.*

3 Once the moving party has met its burden, the burden shifts to the non-moving party to
4 “designate ‘specific facts showing that there is a genuine issue for trial.’” *Id.* at 324 (quoting then
5 Fed. R. Civ. P. 56(e)). To carry this burden, the non-moving party must “do more than simply show
6 that there is some metaphysical doubt as to the material facts.” *Matsushita Elec. Indus. Co., Ltd. v.*
7 *Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). “The mere existence of a scintilla of evidence . . .
8 will be insufficient; there must be evidence on which the jury could reasonably find for the [non-
9 moving party].” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986).

10 In deciding a summary judgment motion, the evidence of the non-movant is to be believed,
11 and all justifiable inferences are to be drawn in his favor. *Id.* at 255. “Credibility determinations,
12 the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury
13 functions, not those of a judge . . . ruling on a motion for summary judgment” *Id.* However,
14 conclusory, speculative testimony in affidavits and moving papers is insufficient to raise genuine
15 issues of fact and defeat summary judgment. *Thornhill Publ’g Co., Inc. v. Gen. Tel. & Elec. Corp.*,
16 594 F.2d 730, 738 (9th Cir. 1979). The evidence the parties present must be admissible. Fed. R.
17 Civ. P. 56(c)(4).
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21 **II. Subject Matter Eligibility Under § 101**

22 Under Section 101 of Title 35 of the United States Code, the scope of patentable subject
23 matter encompasses “any new and useful process, machine, manufacture, or composition of matter,
24 or any new and useful improvement thereof.” *Bilski v. Kappos*, 561 U.S. 593, 601 (2010) (quoting
25 35 U.S.C. § 101). Section 101 “contains an important implicit exception: Laws of nature, natural
26 phenomena, and abstract ideas are not patentable.” *Alice Corp. Pty. v. CLS Bank Int’l*, 134 S. Ct.
27 2347, 2354 (2014) (internal quotations omitted). They are not patent-eligible because “they are the
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basic tools of scientific and technological work,” which are “free to all men and reserved exclusively to none.” *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 70 (2012) (internal quotations omitted). The United States Supreme Court has explained that allowing patents for such purported inventions would “tend to impede innovation more than it would tend to promote it,” thereby thwarting the primary objective of patent laws. *Id.* at 71.

In *Alice*, the leading case on patent-eligible subject matter under §101, the Supreme Court refined the “framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts” originally set forth in *Mayo*. *Alice*, 134 S. Ct. at 2355 (citing *Mayo*, 556 U.S. 66). This analysis proceeds in two steps.

The first step looks to determine whether claims are directed to a patent-ineligible concept. If they are, the second step is to consider whether the additional elements recited in the claim transform the nature of the claim into a patent-eligible application by reciting an inventive concept that is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.

Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1380 (Fed. Cir. 2015) (internal quotations and citations omitted). When additional elements involve only “well-understood, routine, conventional activity previously engaged in by researchers in the field,” the additional elements are insufficient to transform a patent-ineligible concept into a patent-eligible application. *Mayo*, 566 U.S. at 73. “Whether something is well-understood, routine, and conventional to a skilled artisan at the time of the patent is a factual determination.” *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1369 (Fed. Cir. 2018). However, summary judgment is appropriate for questions of §101 eligibility where no genuine disputes of fact exist. “When there is no genuine issue of material fact regarding whether the claim element or claimed combination is well-understood, routine, conventional to a skilled artisan in the relevant field, this issue can be decided on summary judgment

1 as a matter of law.” *Id.* at 1368. “To the extent that the Court must resolve underlying questions
2 of fact related to eligibility, they must be proven by clear and convincing evidence.” *Broadband*
3 *iTV, Inc. v. Oceanic Time Warner Cable, LLC*, 135 F. Supp. 3d 1175, 1188 (D. Haw. 2015), *aff’d*
4 *sub nom. Broadband iTV, Inc. v. Hawaiian Telcom, Inc.*, 669 F. App’x 555 (Fed. Cir. 2016).

6 DISCUSSION

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8 Defendants seek summary judgment on the grounds that both the ’931 and ’751 patents claim
9 patent-ineligible subject matter. Defendants assert that both patents are directed toward patent-
10 ineligible subject matter and that there are no additional elements that transform the patents’ claims
11 into patent-eligible concepts. *See* Dkt. No. 48. Plaintiffs contest defendants’ characterization of its
12 patents, arguing the patents cover a laboratory technique for preparing a new and useful composition
13 of cell-free DNA that is enriched for fetal DNA. *See* Dkt. No. 56.

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15 Whether the patents are directed towards ineligible subject matter and whether there is
16 nonetheless an inventive concept that transforms otherwise unpatentable subject matter are
17 discussed in turn below.

19 **I. Directed Towards a Patent-Ineligible Concept**

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21 Defendants argue that the asserted claims are directed to natural phenomena. Dkt. No. 48 at
22 7. Specifically, defendants argue that “[t]he claimed method begins with a sample of cell-free DNA
23 and ends with an analysis of it,” meaning that it is directed to patent-ineligible subject matter. *Id.*
24 at 8:12-18. Defendants compare this case to both *Genetic Techs. Ltd v. Merial LLC*, 818 F.3d 1369
25 (Fed. Cir. 2016) and *Ariosa v. Sequenom, Inc.*, 788 F.3d 1371, 1376 (Fed. Cir. 2015). In both cases,
26 the Federal Circuit held the claims were directed to detecting the presence of naturally occurring
27 things or phenomena.

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Plaintiffs argue the patent claims are directed to a laboratory method for preparing new and

1 useful DNA fractions that do not exist in nature and are thus not a natural phenomenon. Dkt. No.
2 56. Plaintiffs argue the patents are directed to a process that yields a non-natural composition of
3 cell-free DNA fragments that is enriched for fetal DNA.

4 The “‘directed to’ inquiry applies a stage-one filter to claims, considered in light of the
5 specification, based on whether ‘their character as a whole is directed to excluded subject matter.’”
6 *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1335 (Fed. Cir. 2016) (quoting *Internet Patents*
7 *Corp. v. Active Network, Inc.*, 790 F.3d 1343, 1346 (Fed. Cir. 2015)) (citing *Genetic Techs.*, 818
8 F.3d at 1375 (Fed.Cir.2016)). “The courts have recognized that it is not always easy to determine
9 the boundary between abstraction and patent-eligible subject matter.” *Internet Patents*, 790 F.3d at
10 1347 (Fed. Cir. 2015) (citing recent precedent highlighting patents that attempt to preempt use of
11 the laws of nature or abstract ideas when determining the boundary); *See also Parker v. Flook*, 437
12 U.S. 584, 589 (1978) (“The line between a patentable ‘process’ and an unpatentable ‘principle’ is
13 not always clear.”).

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16 Regarding patent-ineligible concepts, the Supreme Court has held that there is a “rule against
17 patents on naturally occurring things . . .” *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*,
18 569 U.S. 576, 589 (2013). The Supreme Court ruled that “[l]aws of nature, natural phenomena, and
19 abstract ideas are not patentable.” *Id.* at 589 (citing *Mayo*, 132 S. Ct. at 1293) (internal quotations
20 omitted).

21 During prosecution (application no 13/757, 637) Mathias Ehrich, the Senior Vice President
22 of Research and Development at Sequenom, Inc. filed a declaration in support of the patent. Dkt.
23 No. 48-3 (“Ex. 2”) ¶ 2. He stated that “[t]he claimed methods are not directed to a natural
24 phenomenon – a difference in size of the maternal and fetal DNA in maternal blood plasma do not
25 result in a natural phenomenon.” He claimed that “the DNA in maternal blood plasma is not the
26 size discriminated fraction produced by the claimed methods” and that “[t]he fetal and maternal
27 DNA found in nature is structurally different and does not exhibit the discussed new utility.” *Id.*
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¶ 20. After size discrimination, “the ratio” of fetal DNA to maternal DNA “changes and has a new value that does not exist in nature.” *Id.*

The fetal and maternal DNA in maternal blood plasma were subject to size discrimination based on a chosen fragment length (e.g., less than approximately 500 base pairs) to produce a fraction of the maternal and fetal DNA useful for a specific purpose (e.g., detection of a fetal genetic locus that is present in the maternal DNA and that is related to fetal chromosomal aneuploidy). The size distribution of the DNA from maternal blood plasma substantially changed after this size discrimination was performed: certain DNA fragments mostly of maternal origin were preferentially removed and were no longer present in the sample. The difference in structure is directly related to and demonstrated by the new utility for the altered DNA of maternal blood plasma in the claimed methods: detection of certain fetal genetic loci.

Id.

In sum, plaintiffs contend that changing the concentration of fetal DNA relative to maternal DNA in the sample creates a “difference in structure” which is not naturally occurring.

The PTO originally rejected plaintiffs’ applications stating:

Nothing is added by identifying the techniques to be used in selecting nucleic acids based on size because such techniques were the well-understood, routine and conventional techniques that a scientist would have thought of when instructed to enrich fetal DNA from a cell-free sample of maternal blood plasma or serum.

Id. ¶ 21.

Plaintiffs responded that “it was thought the similarity of the fetal and maternal genomes and the complex mixture of fetal and maternal fragments, in terms of fragment sizes and diversity of sequences exhibited for a given fragment size, were insurmountable” in isolating fetal DNA. *Id.*

¶ 21. However, plaintiffs’ representations to the patent office conflate the two prongs of the *Alice* test. Changing the ratio of two natural products in a mixture and analyzing one of those products does not impact whether an invention is directed towards a natural phenomenon.

Here, the Court finds that both the ’931 and ’751 patents are directed towards patent-ineligible concepts, namely naturally occurring phenomena. Both patents claim results from a test of naturally occurring fetal DNA and do not transform the naturally occurring product into

1 something new. Instead the patents lay claim to test results obtained from the use of fetal DNA.
2 This use alone is insufficient to overcome the “directed to” inquiry.

3 Plaintiffs cite to *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042 (Fed. Cir. 2016)
4 in support of their argument. There, the Federal Circuit found a technique for cryogenically freezing
5 liver cells called hepatocytes was patentable. The Federal Circuit noted that “the claims are simply
6 not directed to the ability of hepatocytes to survive multiple freeze-thaw cycles. Rather, the claims
7 of [the patent] are directed to a new and useful laboratory technique for preserving hepatocytes.”
8 *Id.* at 1048. The court found that the inventors “employed their natural discovery to create a new
9 and improved way of preserving hepatocyte cells for later use.” *Id.*

10
11 In *CellzDirect*, the inventors created a patent to solve a systemic issue with hepatocytes,
12 namely that “certain factors limit their use: fresh hepatocytes can only be obtained from liver
13 resections or non-transplantable livers or organ donors, and their life space is short.” *Id.* at 1045.
14 While prior cryopreservation techniques existed before the invention, “the process could damage
15 the hepatocytes, leading to poor recovery numbers of viable cells.” *Id.* In addition, “prior methods
16 were unsuitable for preparing a multi-donor hepatocyte pool..[and]...[r]esearchers desired to pool
17 hepatocytes from various source livers to create a hepatocyte preparation approximating average
18 cell livers. Such pools are useful research tools.” *Id.* The inventors discovered that some
19 hepatocytes are capable of surviving multiple freeze-thaw cycles. Armed with this discovery, the
20 inventors then developed an improved process of preserving hepatocytes. This process included
21 subjecting previously frozen and thawed cells to density gradient fractionation, recovering the viable
22 cells, and refreezing the viable cells. *Id.* The claims specified that the resulting preparation could be
23 thawed and used immediately.

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26 In distinguishing *CellzDirect* from prior precedent, the Federal Circuit noted the difference
27 between the claims in *CellzDirect* and the patent ineligible concepts amounting to nothing more
28 than observing or identifying the ineligible concept in *Ariosa* and *In re BRCA1– & BRCA2–Based*

1 *Hereditary Cancer Test Patent Litig.*, 774 F.3d 755, 761–62 (Fed. Cir. 2014). The court noted,
2 “although the claims in each of these cases employed method steps, the end result of the process,
3 the essence of the whole, was a patent-ineligible concept.” *Id.* *CellzDirect*, however, was the result
4 of a new and useful artisan technique. “The inventors certainly discovered the cells’ ability to
5 survive multiple freeze thaw cycles, but that is not where they stopped, nor is that what they
6 patented.” 827 F.3d at 1048.

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8 The Court finds the facts at hand more analogous to *Ariosa* than to *CellzDirect*. In
9 *CellzDirect*, the end result was cryogenically *frozen* useful liver cells that did not occur in nature.
10 In *Ariosa*, as is the case here, the claims are directed to a testable quantity of genetic information
11 found in nature. Unlike *CellzDirect*, the end result is naturally occurring. Accordingly, the Court
12 finds plaintiffs’ arguments unpersuasive and holds that the patents are directed to patent ineligible
13 concepts.

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16 **II. Inventive Concept**

17 Defendants argue the asserted claims do nothing more than list a series of conventional steps
18 to detect and analyze DNA fragments. Defendants argue that nothing in the patent specifications or
19 prosecution history identifies novelty or inventiveness beyond the natural phenomenon itself.
20 Plaintiffs counter that, analyzing the claims as a whole, the inventors present a novel process that
21 exploits the discovery that in a maternal cell free DNA sample from a pregnant woman, the fetal
22 DNA is on average smaller than the maternal DNA. Plaintiffs argue the composition of DNA
23 presents new and useful utility in allowing for improved detection of fetal genetic traits, such as
24 aneuploidy. Plaintiffs also argue the selection of 300 to 500 base pairs is human ingenuity and
25 scientific judgment. In addition, plaintiffs argue that dependent claims include several laboratory
26 steps that do not occur in nature, including PCR and ligase chain reactions for amplification, as well
27 as the use of chromatography and electrophoresis. *See* Dkt. No. 56.
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1 An inventive concept occurs when the claims are “more than a drafting effort designed to
2 monopolize the [abstract idea]” and “claims may be read to ‘improve[] an existing technological
3 process.’” *Bascom Glob. Internet Servs., Inc. v. AT&T Mobility LLC*, 827 F.3d 1341, 1351 (Fed.
4 Cir. 2016) (quoting *Alice*, 134 S. Ct. at 2356-57). Moreover, “well-understood, routine,
5 conventional activity. . . is normally not sufficient to transform an unpatentable law of nature into a
6 patent-eligible application of such a law.” *Mayo*, S. Ct. at 1291 (citing *Parker*, 437 U.S. at 590).

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8 “To put the matter more succinctly, [where] the claims inform a relevant audience about
9 certain laws of nature; any additional steps consist of well-understood, routine, conventional activity
10 already engaged in by the scientific community; and those steps, when viewed as a whole, add
11 nothing significant beyond the sum of their parts taken separately,” then there is no incentive
12 concept. *Mayo*, 566 U.S. at 79-80.

13 Plaintiffs rely on *CellzDirect* in support of their argument. 827 F.3d 1042 (Fed. Cir. 2016).
14 There, the court explained that the end result of the patent at issue was not simply an observation or
15 detection of the ability of the liver cells to survive multiple freeze-thaw cycles, but rather a new and
16 useful method of preparing the hepatocyte cells. In so holding, the court distinguished the case
17 from *Myriad* noting that whereas “the processes used by *Myriad* to isolate DNA were well
18 understood[,]” in *CellzDirect* the “claims [were] directed to a new and useful process of creating [a]
19 pool [of the cells], not to the pool itself.” *Id.* at 1049. The court also distinguished the patent from
20 those at issue in *Genetic Techs* and *Ariosa*, noting “[a]lthough the claims in each of these cases
21 employed method steps, the end result of the process, the essence of the whole, was a patent-
22 ineligible concept.” *CellzDirect*, 827 F.3d at 1048.

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25 This Court finds the facts at hand far closer to those in *Ariosa* and distinguishable from
26 *CellzDirect*. The invention in *CellzDirect* went beyond applying a known laboratory technique to
27 a newly discovered natural phenomenon, and instead created an entirely new laboratory technique
28 that “is not simply an observation or detection” based on the natural phenomenon. *Id.* Here, as in

1 *Ariosa*, the claims extend only to isolation and analysis of a naturally occurring phenomenon and
2 employ routine, well-known laboratory techniques. *See Roche Molecular Sys., Inc. v. CEPHEID*,
3 905 F.3d 1363, 1373 (Fed. Cir. 2018) (distinguishing the patent at issue by noting that the patent in
4 *CellzDirect* “went beyond applying a known laboratory technique to a newly discovered natural
5 phenomenon, and instead created an entirely new laboratory technique that is not simply an
6 observation or detection based on natural phenomenon[,]” while “[i]n contrast the [patent at issue]
7 claims a method of detection based on a natural phenomenon and employs only conventional, well-
8 known laboratory techniques.”).

9
10 The Court finds that the claims of each patent are not inventive. The independent claims
11 require three phases: extraction, size production, and selective removal. Each of the steps is
12 described as well- known and conventional. *See* Dkt. No. 61. Plaintiffs suggest that the novelty of
13 their invention is in the use of routine and conventional steps to isolate and analyze smaller DNA
14 fragments. However, the Court finds that the ‘inventive concept’ is the application of the well-
15 known routine and conventional techniques for extraction and removal. For example, the patents
16 require “extracting DNA,” “producing a fraction of DNA”, and discuss “discrimination” and
17 “removal steps.” These broad terms are “well-understood, routine, conventional activities
18 previously known to the industry,” particularly given that the claims provide them no more explicit
19 definition. *Broadband iTV, Inc.*, 135 F. Supp. 3d at 1188.

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21 Accordingly, the Court finds that plaintiffs’ evidence does not raise genuine issues of
22 material fact sufficient to defeat summary judgment. The “novelty” of an idea is not enough in itself
23 to confer patentability, where the novelty does not exceed the “inventive concept” limitations. *See*,
24 *e.g., Diamond v. Diehr*, 450 U.S. 175, 188–89 (1981) (“The ‘novelty’ of any element or steps in a
25 process, or even of the process itself, is of no relevance in determining whether the subject matter
26 of a claim falls within the § 101 categories of possibly patentable subject matter.”).

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28 In addition, the Court finds that the dependent claim limitations do not add enough to render

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the patents eligible. The claimed combination of elements lacks an inventive concept because the combination was well-understood, routine and conventional at the time of invention. *Exergen Corp. v. Kaz USA, Inc.*, 725 F. App'x 959, 974 (Fed. Cir. 2018). Accordingly, the Court GRANTS defendants' motion for summary judgment.

CONCLUSION

For the foregoing reasons and for good cause shown, the Court hereby GRANTS defendants' motion for summary judgment. The parties are directed to file a joint statement identifying the issues which remain to be decided in this case and proposing a schedule for same. **Such joint statement must be filed no later than January 9, 2019.**

IT IS SO ORDERED.

Dated: December 24, 2018



SUSAN ILLSTON
United States District Judge