No. 20-892

In the Supreme Court of the United States

ARIOSA DIAGNOSTICS, INC., ET AL., PETITIONERS

v.

ILLUMINA, INC., ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION

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QUESTION PRESENTED

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 cover methods of preparing a fraction of cell-free DNA that is enriched in fetal DNA, by using defined size parameters to filter out maternal DNA strands and increase the proportion of fetal DNA in the fraction. The question presented is whether the Federal Circuit correctly held that those claimed enrichment processes are claims for "process[es]," within the meaning of 35 U.S.C. 101.

RELATED PROCEEDINGS

United States District Court (N.D. Cal.):

Illumina, Inc. v. *Ariosa Diagnostics, Inc.*, No. 18-cv-02847-SI (Jan. 8, 2019)

United States Court of Appeals (Fed. Cir.):

Illumina, Inc. v. *Ariosa Diagnostics, Inc.*, No. 2019-1419 (Aug. 3, 2020)

RULE 29.6 STATEMENT

Laboratory Corporation of America Holdings owns 10% or more of the stock of respondent Sequenom Inc.

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BRIEF IN OPPOSITION

STATEMENT

Respondents brought this action against petitioners in the United States District Court for the Northern District of California, alleging infringement of claims 1-2, 4-5, and 9-10 of U.S. Patent No. 9,580,751 (the "'751 patent") and claims 1-2 and 10-14 of U.S. Patent No. 9,738,931 (the "'931 patent"). The patents cover "methods of preparing a fraction of cell-free DNA that is enriched in fetal DNA." Pet. App. 4a. The district court granted summary judgment to petitioners. *Id.* at 85a-88a. The Federal Circuit reversed and remanded for further proceedings. *Id.* at 19a.

1. The patents at issue claim a new and useful process for enriching the amount of fetal DNA in a maternal blood sample. It was previously known that blood plasma contains small fragments of DNA outside of any

cell, known as "cell-free" or "extracellular" DNA, and that a pregnant woman's plasma contains fragments of both her own DNA *and* small amounts of DNA from the fetus. Pet. App. 3a. The presence of fetal DNA in maternal blood created the possibility of non-invasive fetal genetic testing.

Researchers and clinicians faced a practical problem, however: "[T]he major proportion (generally >90%) of the extracellular DNA" in a mother's blood is her own DNA. *Ibid.* That made it "difficult, if not impossible," to "distinguish and separate the tiny amount of fetal DNA from the vast amount of maternal DNA." *Ibid.* In essence, there was a signal-to-noise problem.

The inventors of the '751 and '931 patents devised a process for solving that problem. First, they studied the size distributions of fetal and maternal DNA fragments in five pregnancies and discovered that fetal cell-free DNA tends to be shorter than maternal cell-free DNA. *Id.* at 4a. The study showed that, although many maternal DNA fragments were relatively short and many fetal DNA fragments were relatively long, it was *more common* for fetal DNA fragments to be shorter. See Resps. C.A. Br. App. 32 tbl. 1 (size distributions from study). Specifically, their study found that "the majority of the circulatory extracellular fetal DNA has a relatively small size of approximately 500 base pairs or less, whereas the majority of circulatory extracellular maternal DNA in maternal plasma has a size greater than approximately 500 base pairs." Pet. App. 3a.

"Having made that discovery regarding the relative size distributions," the inventors "used their discovery to develop a solution to the identified problem" by creating methods for using size discrimination—with specified length parameters—to filter out longer fragments

and thereby produce an output enriched in fetal DNA. *Id.* at 4a. The inventors selected size thresholds that "balance the need to remove enough longer maternal DNA fragments to enrich the sample but also leave behind enough shorter fetal DNA fragments to allow for testing." *Ibid.*

Claim 1 of the '751 patent is for:

> 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 5a. Claim 1 of the '931 patent uses a size parameter of approximately 300 base pairs rather than 500 base pairs, thus producing a fraction with less genetic material but a higher proportion of fetal DNA. *Id.* at 5a-6a. Dependent claims include additional laboratory steps, including centrifugation, chromatography, and

use of microarrays. *Id.* at 6a-7a. Respondents own the '751 and '931 patents.

2. On May 15, 2018, respondents brought this infringement action against petitioners. The district court later granted summary judgment to petitioners, holding that the claimed enrichment methods were not eligible for patent protection under 35 U.S.C. 101. Pet. App. 71a-88a.

Section 101 provides that "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof," may be patented, "subject to the conditions and requirements of" the Patent Act of 1952. 35 U.S.C. 101. The Patent Act's further conditions and requirements include, among other things, that a claim must be novel, nonobvious, and particularly described. 35 U.S.C. 102, 103, 112; see *Bilski* v. *Kappos*, 561 U.S. 593, 602 (2010). Section 101 thus defines in "expansive" terms the subject matter that may be patented, *Diamond* v. *Chakrabarty*, 447 U.S. 303, 308 (1980), and expressly makes "process[es]" eligible for patent protection, 35 U.S.C. 101.

This Court has long held that Section 101 "contains an important implicit exception: Laws of nature, natural phenomena, and abstract ideas are not patentable." *Alice Corp. Pty. Ltd.* v. *CLS Bank Int'l*, 573 U.S. 208, 216 (2014) (citation omitted). This Court has set forth a two-step test for "distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts." *Id.* at 217. First, a court asks whether the claims are "directed to" a law of nature or natural phenomenon. *Ibid.* "If so," the court looks to the claim limitations to determine whether they "transform the

nature of the claim into a patent-eligible application." *Ibid.* (citation omitted).

Applying that test, the district court determined that the claims were "more analogous" to claims the Federal Circuit had found not patent eligible in *Ariosa Diagnostics, Inc.* v. *Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015), than those that the Federal Circuit had previously found patent eligible in *Rapid Litigation Management Ltd.* v. *CellzDirect Inc.*, 827 F.3d 1042 (Fed. Cir. 2016). Pet. App. 71a-88a.

3. The Federal Circuit reversed and remanded, holding that "the claims of the '751 and '931 patents are directed to patent-eligible subject matter." *Id.* at 19a. At the outset, the Federal Circuit observed that this is neither a "diagnostic" case nor a "method of treatment" case, but instead a "method of preparation" case. *Id.* at 9a. To determine whether the methods are patentable, the Federal Circuit then stated the two-step *Alice* test. See *id.* at 8a-9a. Applying that well-settled test to the claims in this case, the Federal Circuit determined that the claims are eligible for patent protection because they are not "'directed to' the natural phenomenon." *Id.* at 11a.

First, the Federal Circuit explained that the phenomenon is "that cell-free fetal DNA tends to be shorter than cell-free maternal DNA in a mother's bloodstream." *Ibid.* Second, the Federal Circuit determined that the claims "are *not* directed to that natural phenomenon but rather to a patent-eligible method that utilizes it," namely, a "method[] for preparing a fraction of cell-free DNA that is enriched in fetal DNA." *Ibid.* "The methods include specific process steps—size discriminating and selectively removing DNA fragments that are above a specified size threshold—to increase

the relative amount of fetal DNA as compared to maternal DNA in the sample." *Ibid.* The court observed that the "claimed size thresholds are human-engineered parameters that optimize the amount of maternal DNA that is removed from the mixture and the amount of fetal DNA that remains in the mixture in order to create an improved end product that is more useful for genetic testing than the original natural extracted blood sample." *Ibid.* The process steps then "change the composition of the mixture, resulting in a DNA fraction that is different from the naturally occurring fraction in the mother's blood." *Id.* at 12a.

The Federal Circuit distinguished *Association for Molecular Pathology* v. *Myriad Genetics, Inc.*, 569 U.S. 576 (2013), on the ground that *Myriad* involved a claim for a preexisting gene, not "a process for isolating [it]." Pet. App. 14a-15a; see *Myriad*, 569 U.S. at 595-596 ("[T]here are no method claims before this Court."). "Here, in contrast, the claims are directed to more than just the correlation between a DNA fragment's size and its tendency to be either fetal or maternal," and they "do not cover a method for detecting whether a cell-free DNA fragment in a previously-prepared sample is fetal or maternal based on the natural size distribution of cell-free DNA fragments." Pet. App. 13a-14a. Rather, they "remove some maternal DNA from the mother's blood" to prepare a fraction of cell-free DNA that is enriched in fetal DNA. *Id.* at 14a. The Federal Circuit then found the claims more analogous to those in *CellzDirect* than *Ariosa*. *Id.* at 15a-17a.

Judge Reyna dissented. Pet. App. 20a-37a. Judge Reyna noted that the written description labels "surprising" the finding that cell-free fetal DNA "tends to be shorter than cell-free maternal DNA." *Id.* at 21a. In his

view, that discovery was the only claimed advance and the claims were "directed to" that phenomenon.

Petitioners filed a petition for rehearing. The panel issued a modified opinion. See *id.* at 1a-19a. En banc review was denied without any noted dissent.

REASONS FOR DENYING THE PETITION

Petitioners contend (Pet. 11) that the Federal Circuit's decision conflicts with *Association for Molecular Pathology* v. *Myriad Genetics, Inc.*, 569 U.S. 576 (2013). But no such conflict exists, as the Federal Circuit correctly distinguished *Myriad*. In *Myriad*, this Court emphasized that there were "no method claims before th[e] Court." 569 U.S. at 595. This case, however, exclusively involves method claims, namely, methods for enriching the proportion of fetal DNA in a blood fraction. To determine whether those claims are patent-eligible, the Federal Circuit applied the settled two-part test from *Alice Corp. Pty. Ltd.* v. *CLS Bank Int'l*, 573 U.S. 208 (2014). As the Federal Circuit explained, the claims here are for a new, specific enrichment process that creates a novel substance (a blood fraction enriched in fetal DNA) that is useful for medical treatment and diagnosis. The Federal Circuit's determination that this enrichment process is eligible for patent protection does not conflict with *Myriad* and instead is factbound and correct: The claims are not directed at a natural phenomenon. They apply knowledge of a phenomenon to create a novel human-engineered process for producing a novel substance that overcomes a barrier to non-invasive fetal genetic testing. That enrichment process is a "process" under 35 U.S.C. 101. Further review is unwarranted.

1. The Federal Circuit correctly held that the claimed enrichment methods are patent-eligible processes. See Pet. App. 9a-19a.

a. At the outset, the claimed enrichment methods are plainly new and useful "process[es]" as a matter of ordinary meaning. Section 101 provides that "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof," is eligible for a patent. 35 U.S.C. 101. In ordinary English, a "process" means "a series of actions, motions, or operations definitely conducing to an end." *Webster's New International Dictionary* 1958 (2d ed. 1950); see also *Webster's Third New International Dictionary* 1808 (1986) ("the action of passing through continuing development from a beginning to a contemplated end"); *Oxford English Dictionary* (3d ed. 2007) ("A continuous and regular action or succession of actions occurring or performed in a definite manner, and having a particular result or outcome; a sustained operation or series of operations.").

The claims here are clearly for a series of steps definitely conducing to an end: they are for a new, specific method for enriching a blood fraction. The inventors of the '751 and '931 patents created a series of specific steps—starting with a blood sample, then size discriminating and selectively removing DNA fragments that are above a specified threshold—to increase the relative amount of fetal DNA compared to maternal DNA, and produce a new enriched fraction. That defined series of steps thus changes the composition of the mixture, resulting in a DNA fraction that is different from the naturally occurring fraction in the mother's blood. Just like a process for enriching ore, refining oil, or purifying water, that process for enriching a blood sample is a "process." Cf. *Virginia Uranium, Inc.* v. *Warren*, 139 S. Ct. 1894, 1900 (2019) (describing the "leaching process" for removing uranium from ore); *Merritt* v. *Welsh*, 104 U.S.

694, 704 (1881) (describing "processes" for refining sugar).

The Federal Circuit correctly determined that the claimed enrichment methods are also "process[es]" under this Court's precedents. In *Alice*, this Court set forth a two-part test for "distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts." 573 U.S. at 217. First, a court asks whether the claims are "directed to" a law of nature or natural phenomenon. *Ibid.* "If so," the court looks to the claim limitations to determine whether those additional elements "transform the nature of the claim into a patent-eligible application." *Ibid.* (citation omitted).

To determine whether a patent is "directed to" a natural phenomenon, one must first identify the phenomenon itself. The Federal Circuit correctly identified it as the fact "that cell-free fetal DNA tends to be shorter than cell-free maternal DNA in a mother's bloodstream." Pet. App. 11a; accord *id.* at 22a (Reyna, J., dissenting) (cell-free fetal DNA "tends to be shorter than cell-free maternal DNA").

As the Federal Circuit determined, the claims are not "directed to" that tendency, "but rather to a patent-eligible method that utilizes it," namely, a "method[] for preparing a fraction of cell-free DNA that is enriched in fetal DNA." Pet. App. 11a. They claim specific steps for creating an enriched fraction that is "different from the naturally occurring fraction in the mother's blood" in that it contains more fetal DNA, overcoming a practical problem that had impeded fetal genetic testing using maternal blood. *Id.* at 12a. Contrary to petitioners' suggestions (Pet. 12), the claims do not recite in abstract

terms the idea of using size to separate "larger" fragments from "smaller" fragments. They specifically identify the selective removal of longer DNA from a maternal sample to enrich the fraction in fetal DNA, for use in fetal genetic testing. *Id.* at 4a. And they specify thresholds—approximately 500 base pairs or 300 base pairs—for performing the useful enrichment.

Notably, no natural law dictates that fetal cell-free DNA is always shorter than maternal cell-free DNA—much less dictates a uniform cutoff at approximately 500 (or 300) base pairs. Instead, the "claimed size thresholds are human-engineered parameters that optimize the amount of maternal DNA that is removed from the mixture and the amount of fetal DNA that remains in the mixture in order to create an improved end product that is more useful for genetic testing." *Id.* at 11a. Nor is there a natural law that, in any given pregnant woman's blood, most fetal fragments will be shorter than those thresholds whereas most maternal fragments will be longer. See *id.* at 4a-5a. To the contrary, in any given sample, there is a distribution above and below those thresholds—and there is significant variability in the distributions from woman to woman. See Resps. C.A. Br. App. 32 tbl. 1.

For example, in a sample from one pregnant woman, 22% of the fragments shorter than 300 base pairs were determined to be fetal; from another woman, the figure was 87%. *Ibid.* And in one sample, 12.5% of the fragments between 1000 and 1500 base pairs—considerably longer than the thresholds here—were determined to be fetal. *Ibid.* The 500/300 thresholds thus are not preexisting laws of nature. They are man-made figures the inventors selected to make this enrichment process useful: They reflect a judgment that those thresholds

increase the proportion of fetal DNA enough, while leaving enough of the sample behind that the fraction is "useful for analyzing a genetic locus involved in a fetal chromosomal aberration." Pet. App. 5a; see *id.* at 4a ("[T]he inventors selected [the thresholds] to balance the need to remove enough longer maternal DNA fragments to enrich the sample but also leave behind enough shorter fetal DNA fragments to allow for testing."). The claims thus are not directed at the tendency of fetal DNA to be shorter. Instead, they apply knowledge of that phenomenon to create a useful enrichment process.

Petitioners thus wrongly characterize (Pet. 11) the Federal Circuit's decision as holding "that the mere separation of smaller human DNA fragments from larger ones is sufficient to survive a Section 101 challenge, without regard to the inventiveness of techniques used to achieve that separation." The Federal Circuit held merely that "the claims of the '751 and '931 patents are directed to patent-eligible subject matter." Pet. App. 19a. Those claims are for specific, defined processes with human-selected numerical thresholds for creating a new enriched substance—a fraction with more fetal DNA—that is useful for genetic testing.

Even if the claims were "directed at" fetal cell-free DNA's tendency to be shorter, they would still be patent eligible at *Alice* step two because they include limitations that "'transform the nature of the claim' into a patent-eligible application." *Id.* at 9a (quoting *Alice*, 573 U.S. at 217). Namely, the specified thresholds of approximately 500 (or 300) base pairs make clear that the claims are not seeking to monopolize the mere tendency of fetal DNA to be shorter. The inventors instead applied their knowledge of that phenomenon in a specific

way, to create an enriched fraction that overcomes the prior difficulty in "distinguish[ing] and separat[ing] the tiny amount of fetal DNA from the vast amount of maternal DNA." *Id.* at 3a.

The claims in turn do not preempt the natural phenomenon. As noted above, they define specific processes for enriching maternal blood in fetal DNA, using specified, human-selected size thresholds. The claims do not cover size differentiation methods outside that context or other mechanisms for differentiating fetal from maternal cell-free DNA. Even in this context, they do not preempt use of different thresholds (say, approximately 1500 base pairs), nor size filtering to enrich the portion of *maternal* DNA by excluding smaller fragments. And it does not reach other as-yet-unknown applications of the knowledge that maternal cell-free DNA tends to be longer. Quite simply, these claims are for a new and useful man-made enrichment process, not a preexisting natural phenomenon.

b. Petitioners contend (Pet. 3) that the Federal Circuit's decision conflicts with this Court's decision in *Myriad* as well as the Federal Circuit's decision in *Ariosa*. But in their brief on appeal, petitioners correctly recognized that neither decision was directly on point. See Pet. C.A. Br. 23 (contending merely that the case "closely resemble[s]" *Ariosa*; see *id.* at 30 ("much closer" to *Ariosa* than *CellzDirect*). In any event, the Federal Circuit correctly distinguished *Myriad* and *Ariosa* on the facts.

Petitioners quote this Court's statements in *Myriad* that "a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated," and that "separating [a] gene from its surrounding genetic material is not an act of invention."

Pet. 11 (quoting *Myriad*, 569 U.S. at 580, 591). But petitioners are taking those statements out of context. In *Myriad*, this Court held that a *preexisting gene itself* does not become patentable merely because it was isolated—but "expressly declined to extend its holding to method claims reciting a process used to isolate DNA." Pet. App. 14a; see *Myriad*, 569 U.S. at 595-596 (emphasizing that "there are no method claims before this Court" and that "this case does not involve patents on new *applications* of knowledge" about particular genes (emphasis in original)).

This case involves "the opposite situation." Pet. App. 15a. It *only* presents method claims and they are for "new applications of knowledge": the inventors exploited their knowledge that maternal DNA fragments tend to be longer than fetal DNA fragments to invent a method for enriching a fraction, using man-made size thresholds, so that it can be used in testing fetal DNA. To put it another way, the claim in *Myriad* was analogous to an effort to patent the genetic material in isolated cell-free fetal DNA itself—as in *Ariosa*—not a new method for enriching a sample so that fetal DNA may be usefully analyzed.

As the Federal Circuit explained, this case is instead analogous to *CellzDirect*. *Ibid.* In *CellzDirect*, the inventors discovered that some hepatocytes (liver cells) survive multiple freeze-thaw cycles, then obtained a patent on a process for increasing the proportion of viable hepatocytes by subjecting them to multiple freeze-thaw cycles so that the output would be more than 70% viable. See 827 F.3d at 1046. The process did not claim any advance in the conventional steps of freezing or thawing. The Federal Circuit upheld the claims at *Alice* step one, concluding that they "are directed to a new and

useful laboratory technique for preserving hepatocytes." *Id.* at 1048. The inventors "exploited" their knowledge of a natural phenomenon by creating a "patent-eligible method" for enriching a sample so that it has a greater proportion of a desired property. Pet. App. 16a. "So too here." *Ibid.* Here, the inventors did not patent the phenomenon that cell-free fetal DNA tends to be shorter than maternal cell-free DNA; they used their discovery of that tendency to invent a useful lab technique for enriching a sample in fetal DNA to facilitate fetal genetic testing. *Ibid.*

Petitioners rely (Pet. 18) on the Federal Circuit's decision in *Ariosa*. But the Federal Circuit itself correctly distinguished *Ariosa*. As the Federal Circuit explained in *CellzDirect*, "[t]he existence and location of [cell-free fetal DNA] is a natural phenomenon; identifying its presence was merely claiming the natural phenomena itself." 827 F.3d at 1048. "Here, in contrast, the claims are directed to more than just the correlation between a DNA fragment's size and its tendency to be either fetal or maternal," and they "do not cover a method for detecting whether a cell-free DNA fragment in a previously-prepared sample is fetal or maternal based on the natural size distribution of cell-free DNA fragments." Pet. App. 13a-14a. "[R]ather, the claimed methods exploit that natural size distribution *during* the sample preparation steps to remove some maternal DNA from the mother's blood," and thereby "produce a mixture enriched in fetal DNA." *Id.* at 14a, 16a. In any event, even if there were tension between the Federal Circuit's decisions in this case and *Ariosa*, that would not warrant this Court's review.

Finally, petitioners rely (Pet. 12) on *Funk Bros. Seed Co.* v. *Kalo Inoculant Co.*, 333 U.S. 127 (1948). But petitioners did not even cite *Funk Brothers* in their brief on appeal, and it is readily distinguishable. In *Funk Brothers,* this Court rejected a patent on the mere combination of four naturally occurring strains of bacteria, holding that the claim involved an effort to patent the "discovery of the fact that certain strains of each species of [root-nodule] bacteria can be mixed." *Id.* at 131. But the Court noted that it was not "presented the question whether the methods of selecting and testing the non-inhibitive strains are patentable." *Id.* at 130. Here, the claims do not claim the bare tendency of fetal strands to be smaller than maternal strands. The claims are directed to a method of enriching fetal DNA in a material blood sample, using defined size parameters, thereby creating a new fraction that is useful for non-invasive fetal genetic testing. *Funk Brothers* is accordingly inapposite.

2. For the reasons set forth above, the Federal Circuit's decision is correct. It is also factbound, involving application of the settled legal test (*Alice*) to the specific method claims in these specific patents. That case-specific holding does not warrant this Court's review.

Petitioners contend that the Federal Circuit's holding is important because it "brings the law one step closer to effectively permitting the patenting of DNA." Pet. 22. But the Federal Circuit's decision does not permit the patenting of DNA, nor does it get closer to that result. The Federal Circuit merely held that this generalized enrichment process is a "process," and that process does not target any specific gene sequence. There is accordingly no risk of patenting DNA itself.

Petitioners contend (*ibid.*) that the Federal Circuit's decision "further complicate[s]" this Court's jurisprudence. But that is based on the premise that the Federal Circuit classified patent claims into *per se* categories for purposes of the Section 101 analysis. It did not. The Federal Circuit described this a "method of preparation case," "not a diagnostic case" or "method of treatment" case. Pet. App. 9a. But that is descriptive, not prescriptive. Indeed, if attaching a label were enough, the Court could have stopped there. The Court instead conducted a full *Alice* inquiry, concluding (correctly) that these claims are for patent-eligible enrichment processes that apply (but are not directed at) natural phenomena. The Court thus did not hold that methods of preparation are always eligible or that mere separation is always enough. It applied *Alice* to "conclude that the claims of the '751 and '931 patents are directed to patent-eligible subject matter." *Id.* at 19a. That fact-specific holding will not complicate this Court's jurisprudence, as the Federal Court made clear that the *Alice* test remains the lodestar.

Petitioners' pond water hypothetical (Pet. 15) is similarly misplaced and vividly illustrates why petitioners are wrong on the merits. The claims here do not resemble a mere instruction to "filter larger material from a sample of pond water before analyzing a microorganism contained therein." *Ibid.* They are more like a method to use an approximately 5-micron diameter filter on water from a specific kind of brackish pond, to enrich the proportion of a particular microorganism that had previously been too diffuse to study. Such a claim may be obvious or insufficiently enabled, but it is still a "process" within Section 101—not a patent directed at the microorganism itself or its size.

Indeed, removing bacteria from water is commonly known as water purification. Section 101 plainly encompasses processes for water purification, notwithstanding that the starting point (dirty water) and ending point (clean water) are both natural substances and purification mechanisms involve application of laws of nature and natural phenomena to remove the contaminants. Cf. *Ecolochem, Inc.* v. *S. California Edison Co.*, 227 F.3d 1361 (Fed. Cir. 2000) (reversing judgment of invalidity as to methods of purifying water); *Water Techs. Corp.* v. *Calco, Ltd.*, 850 F.2d 660 (Fed. Cir. 1988) (upholding infringement of method for purifying water); see also *Warner-Jenkinson Co.* v. *Hilton Davis Chemical Co.*, 520 U.S. 17 (1997) (doctrine of equivalents as to a method of purifying dye).

Petitioners' sweeping position that separation of naturally occurring materials is not patent eligible (Pet. 1-2) thus would cast a cloud of uncertainty over a vast array of important patents on processes like purifying water, cleaning air, enriching gas, refining oil, filtering noise, and "thousands of others that recite processes to achieve a desired outcome." *CellzDirect*, 827 F.3d at 1048. The correct approach under Section 101 is not to ask whether a method involves "separation *alone*." Pet. 1-2. It is to apply *Alice* and ask whether the claim is "directed to" a law of nature and, if so, whether the claim includes additional elements that "transform the nature of the claim" into a patent-eligible application of the law of nature (rather than a patent on the ineligible law of nature itself). *Alice*, 573 U.S. at 217-218. That is exactly the approach the Federal Circuit followed here.

3. Finally, this would be a poor vehicle for review. This petition arises on an interlocutory posture, as the Federal Circuit remanded the case to the district court.

On remand, the district court may address the remainder of the case, including any issues related to infringement, obviousness, and damages, and petitioners could seek review following entry of a final judgment. The interlocutory posture of a case "of itself alone furnishe[s] sufficient ground for the denial" of a petition for a writ of certiorari. *Hamilton-Brown Shoe Co.* v. *Wolf Bros. & Co.*, 240 U.S. 251, 258 (1916); see also, *e.g.*, *Abbott* v. *Veasey*, 137 S. Ct. 612, 613 (2017) (Roberts, C.J., statement respecting denial of certiorari); *Virginia Military Inst.* v. *United States*, 508 U.S. 946, 946 (1993) (Scalia, J., statement respecting denial of certiorari). Petitioners provide no basis for this Court to depart from its ordinary practice.

This is further a poor vehicle for addressing petitioners' broad arguments about *Alice* step one because respondents could prevail under *Alice* step two. Specifically, even if the claims were found to be "directed to" cell-free fetal DNA's tendency to be shorter than cell-free maternal DNA, as petitioners contend, the claims contain additional elements that establish that they apply that tendency to create an inventive, new, and useful enrichment process and thus do not amount to a patent on any law of nature itself. See *Alice*, 573 U.S. at 217-218. The claims use human-selected size limitations of 300 or 500 base pairs to produce an enriched fraction with a sufficiently greater proportion of fetal DNA, without filtering out too much material, so that the enriched fraction may be used for non-invasive fetal genetic testing. See Pet. App. 11a. These limitations amount to a "new and useful" and "inventive application" of the fact that cell-free fetal DNA has a tendency to be shorter than cell-free maternal DNA. *Alice*, 573 U.S. at 222, 223 (citations omitted).

Moreover, petitioners' broad arguments about Section 101 would not even address all the claims. For example, dependent claims include the use of microarrays, which had not previously been used with cell-free DNA. See Pet. App. 16a n.1. The Federal Circuit's decision accordingly does not conflict with any decision of this Court and instead is fact-specific and correct, and in any event this case arises on an interlocutory posture and this would be a poor vehicle for addressing petitioners' contentions. Further review is unwarranted.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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