Section 101: Cert. Denied . . . Now What?

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Background on § 101

35 U.S.C. § 101

Whoever 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.

Exceptions to § 101

- Natural phenomena
- Law of nature
- Abstract ideas

Background on § 101

Mayo v. Prometheus, 566 U.S. 66 (2012)

- Patent on drug dosing determined using patient metabolism found invalid – correlation between metabolites and efficacy is "natural law."
- A process reciting a law of nature is not patentable if it involves "well-understood, routine, conventional activity previously engaged in by researchers in the field."

Alice v. CLS Bank, 573 U.S. 208 (2014)

- Patent on financial-trading system found invalid – abstract idea merely implemented on computer patent ineligible without "something more."
- Bars patents on software and computer processes claimed at too high of a level of abstraction from underlying computer process.

Mayo/Alice Test

1. **Are the claims "directed to" patent-ineligible concept?**
   - If no, eligible.
   - If yes, move to step 2.

2. **Do the claims involve an "inventive concept" (i.e., do the elements taken individually and as an ordered combination transform the claim into a patent eligible application)?**

Recent Cert. Denials

Cert. Denied on 1/13/2020

- ***Athena Diagnostics v. Mayo***
- ***Hikma Pharms. v. Vanda Pharms.***
- ***HP v. Berkheimer***

- **Solicitor General's recommendations:**
  - *Vanda*: grant cert. in *Athena*, and hold
  - *Berkheimer*: grant cert. in *Athena*, and hold
  - *Athena*: SG never asked for views

Athena v. Mayo

- Patent-in-suit was directed to methods of diagnosing neurological disorders like *myasthenia gravis* ("MG") by detecting antibodies to a protein called muscle-specific tyrosine kinase ("MuSK")

- Patent specification expressly admitted that the claimed methods employ "immunological assay techniques ***known per se in the art***"

Athena v. Mayo: Sample Claim

- 1. (not on appeal) A method for diagnosing neurotransmission or developmental disorders related to [MuSK] in a mammal comprising the step of detecting in a bodily fluid of said mammal autoantibodies to an epitope of [MuSK].

- Claim 9, the most specific claim at issue, depends from claim 1 and requires:

  (1) contacting MuSK or an epitope thereof having a 125I label, with bodily fluid;

  (2) immunoprecipitating any anti-body/MuSK complex; and

  (3) monitoring for the label on the complex, wherein the presence of the label indicates the presence of a MuSK related disorder.

Athena v. Mayo

Key Federal Circuit Holding: "[W]e conclude that claims 7-9 are directed to a natural law because the claimed advance was only in the discovery of a natural law, and that the additional recited steps only apply conventional techniques to detect that natural law."

915 F.3d 743, 751 (Fed. Cir. 2018).

Athena v. Mayo: Rehearing En Banc Denied

- Federal Circuit denied Athena's rehearing petition by 7-5 vote, in an 85-page precedential order with multiple different opinions, with the majority finding the claims ineligible as a proper application of the *Mayo v. Prometheus* test

- Key point: "In contrast, new method of treatment patents do not fall prey to *Mayo*'s prohibition. … Nor have unconventional arrangements of known laboratory techniques, even if directed to a natural law." (Lourie opinion)

927 F.3d 1333 (Fed. Cir. 2019)

Athena v. Mayo

Question Presented to Supreme Court: "Whether a new and specific method of diagnosing a medical condition is patent-eligible subject matter, where the method detects a molecule never previously linked to the condition using novel man-made molecules and a series of specific chemical steps never previously performed."

Hikma Pharms. v. Vanda Pharms.

- Patent-in-suit related to treatment of schizophrenia patients with iloperidone, marketed as Fanapt®.

- Drug had potential side effect of QT prolongation, a serious cardiac issue.

- Inventors discovered that a certain gene contains an enzyme that was known to metabolize certain drugs, including iloperidone, and determining in advance whether a patient is a poor metabolizer allows selection of appropriate drug dose that reduces risk of QT prolongation

Vanda: Sample Claim

1. A ***method for treating*** a patient with iloperidone, wherein the patient is suffering from schizophrenia, the method comprising the steps of:

determining whether the patient is a CYP2D6 poor metabolizer by:

obtaining or having obtained a biological sample from the patient; and

performing or having performed a genotyping assay on the biological sample to determine if the patient has a CYP2D6 poor metabolizer genotype; and

if the patient has a CYP2D6 poor metabolizer genotype, then internally administering iloperidone to the patient in an amount of 12 mg/day or less, and

if the patient does not have a CYP2D6 poor metabolizer genotype, then internally administering iloperidone to the patient in an amount that is greater than 12 mg/day, up to 24 mg/day,

wherein a risk of QTc prolongation for a patient having a CYP2D6 poor metabolizer genotype is lower following the internal administration of 12 mg/day or less than it would be if the iloperidone were administered in an amount of greater than 12 mg/day, up to 24 mg/ day.

Hikma Pharms. v. Vanda Pharms.

Key Federal Circuit Holding: "The inventors recognized the relationships between iloperidone, CYP2D6 metabolism, and QTc prolongation, but that is not what they claimed. They claimed an ***application of that relationship***. Unlike the claim at issue in *Mayo,* the claims here ***require a treating doctor to administer iloperidone in the amount of either (1) 12 mg/day or less or (2) between 12 mg/day to 24 mg/day***, depending on the result of a genotyping assay."

887 F.3d 1117 (Fed Cir. 2018)

Question Presented to Supreme Court: [W]hether patents that claim a method of medically treating a patient automatically satisfy Section 101 of the Patent Act, even if they apply a natural law using only routine and conventional steps."

Hikma Pharms. v. Vanda Pharms.

Solicitor's Views: Federal Circuit correctly held methods of treatment to be eligible. But the standards in *Mayo v. Prometheus* and *Bilski* are overly restrictive and have led to confusion.

- "An approach that disregards 'routine' or 'conventional' steps in applying Section 101 to a process claim threatens the patent-eligibility of numerous valuable innovations that incorporate existing steps into new and useful processes." (Govt. Amicus Curiae Br.)

Urged denying certiorari in *Vanda* because result was right, but says Court should grant in a different case (like *Athena*) "where the current confusion has a material effect on the outcome of the Section 101 analysis."

HP v. Berkheimer

Key Federal Circuit Holding: "Whether something is well-understood, routine, and conventional to a skilled artisan at the time of the patent is a factual determination. Whether a particular technology is well-understood, routine, and conventional goes beyond what was simply known in the prior art. The mere fact that something is disclosed in a piece of prior art, for example, does not mean it was well-understood, routine, and conventional."

881 F.3d 1360, 1369 (Fed. Cir. 2018); *see also Aatrix Software, Inc. v. Green Shades Software Inc.,* 882 F.3d 1121 (Fed. Cir. 2018) ("[w]hether a claim recites patent eligible subject matter is a question of law which may contain disputes over underlying facts."

HP v. Berkheimer

Question Presented to Supreme Court: "[W]hether patent eligibility is a question of law for the court based on the scope of the claims or a question of fact for the jury based on the state of the art at the time of the patent."

HP v. Berkheimer

Solicitor's Views: Scope of Section 101 Must Be Addressed Before Procedure.

"Resolution of the question presented in the petition logically depends on the substantive standard for assessing patent-eligibility under Section 101. As explained in the government's brief filed today in response to the Court's invitation [*Vanda]*, this Court's recent decisions have fostered uncertainty concerning those substantive Section 101 standards. In light of that uncertainty, review to address the logically subsequent, procedural question presented in the petition here is premature. The Court should grant review in an appropriate case to clarify the substantive Section 101 standards and then address any ancillary issues that remain."

Takeaways

- ***Mayo/Alice* two-step test remains the law.**
- **Claims that call for observing a natural law (even if newly discovered) through the use of well-known and routine steps are likely ineligible.**
  - Recitation of specific as opposed to general steps does not save the claims if those steps are still well-known and routine
- **A method's use of man-made materials does not necessarily confer eligibility.**
- **Methods of treatment that use a natural law to inform a subsequent treatment step likely patentable.**
- ***Berkheimer* will continue to provide cover in motion practice.**

Federal Circuit Framework
Post-Cert. Denials

Rapid Litigation Management v. CellzDirect

Rapid Litigation Mgmt. v. CellzDirect, Inc., 827 F.3d 1042 (Fed. Cir. 2016)

- Patent-in-suit was directed to method of cryopreservation for producing cultures of liver cells known as hepatocytes.

- These cells are often frozen to preserve for later use, and inventors discovered that some hepatocytes had the ability to survive multiple freeze-thaw cycles.

CellzDirect: Sample Claim

1. A method of producing a desired preparation of multi-cryopreserved hepatocytes, said hepatocytes being capable of being frozen and thawed at least two times, and in which greater than 70% of the hepatocytes of said preparation are viable after the final thaw, said method comprising:

(A) subjecting hepatocytes that have been frozen and thawed to density gradient fractionation to separate viable hepatocytes from nonviable hepatocytes,

(B) recovering the separated viable hepatocytes, and

(C) cryopreserving the recovered viable hepatocytes to thereby form said desired preparation of hepatocytes without requiring a density gradient step after thawing the hepatocytes for the second time, wherein the hepatocytes are not plated between the first and second cryopreservations, and wherein greater than 70% of the hepatocytes of said preparation are viable after the final thaw.

Rapid Litigation Management v. CellzDirect

- At step one, Federal Circuit concluded that, although claims relied on a law of nature (the discovery that hepatocytes are capable of surviving multiple freeze-thaw cycles), they were not ***directed to*** that law of nature
- "The inventors certainly discovered the cells' ability to survive multiple freeze-thaw cycles, but that is not where they stopped, nor is it what they patented. Rather, 'as the first party with knowledge of' the cells' ability, they were 'in an excellent position to claim applications of that knowledge.' … That is precisely what they did. They employed their natural discovery to create a ***new and improved way of preserving hepatocyte cells for later use***."

Natural Alternatives v. Creative Compounds

Natural Alternatives Int'l, Inc. v. Creative Compounds, LLC, 918 F.3d 1338 (Fed. Cir. 2019)

- Patents-in-suit generally related to the use of beta-alanine in a dietary supplement to increase the anaerobic working capacity of muscle and other tissues

Natural Alternatives: Sample Claim

1. ***A method of increasing anaerobic working capacity in a human subject***, the method comprising:

a) providing to the human subject an amount of an amino acid to blood or blood plasma ***effective to increase beta-alanylhistidine dipeptide synthesis*** in the tissue, wherein said amino acid is at least one of:

i) beta-alanine that is not part of a dipeptide, polypeptide or oligopeptide;

ii) an ester of beta-alanine that is not part of a dipeptide, polypeptide or oligopeptide; or

iii) an amide of beta-alanine that is not part of a dipeptide, polypeptide or oligopeptide; and

b) exposing the tissue to the blood or blood plasma, whereby the concentration of beta-alanylhistidine is increased in the tissue,

wherein the amino acid is provided through a ***dietary supplement***.

Natural Alternatives: Eligible Subject Matter

- Step 1: Method claims are directed to patent eligible new ways of using an existing product, beta-alanine.
    - The method claims “cover using a natural product in unnatural quantities to alter a patient’s natural state. We hold, therefore, that the Method Claims are not directed to ineligible subject matter.
- Step 2: Fact issues exist as to conventionality because prior art supplements typically used to compensate for reduced levels of nutrients, not dosing in excess of normal levels.

Natural Alternatives: Eligible Subject Matter

- Product Claims to "dietary supplements" pass step 1 under patentee's proposed claim construction because they are directed to "treatment formulations that incorporate natural products, but they have different characteristics and can be used in a manner that beta-alanine as it appears in nature cannot."

- Manufacturing Claims also pass step 1 based on claim constructions that implicate the manufactured dietary supplements will increase athletic performance.

INO Therapeutics v. Praxair

Ino Therapeutics, LLC v. Praxair Distribution, Inc., 782 F. App'x 1001 (Fed. Cir. Aug. 27, 2019) (non-precedential)

- Relevant patent-in-suit was directed to methods for treating patients with inhaled nitric oxide (iNO) that involved identifying patients with a particular congenital heart condition called left ventricular dysfunction (LVD) and treating them differently than patients without that condition.
- Inventors had discovered that neonatal patients with LVD were at significant risk of pulmonary edema if treated with iNO gas.

INO Therapeutics: Sample Claim

- 1. A method of treating patients who are candidates for inhaled nitric oxide treatment, which method reduces the risk that inhalation of nitric oxide gas will induce an increase in pulmonary capillary wedge pressure (PCWP) leading to pulmonary edema in neonatal patients with hypoxic respiratory failure, the method comprising:
- (a) identifying a plurality of term or near-term neonatal patients who have hypoxic respiratory failure and are candidates for 20 ppm inhaled nitric oxide treatment;
- (b) determining that a first patient of the plurality does not have left ventricular dysfunction;
- (c) determining that a second patient of the plurality has left ventricular dysfunction, so is at particular risk of increased PCWP leading to pulmonary edema upon treatment with inhaled nitric oxide;
- (d) administering 20 ppm inhaled nitric oxide treatment to the first patient; and
- (e) ***excluding the second patient from treatment with inhaled nitric oxide, based on the determination that the second patient has left ventricular dysfunction, so is at particular risk of increased PCWP leading to pulmonary edema upon treatment with inhaled nitric oxide***.

INO Therapeutics: Ineligible Subject Matter

- Panel majority rejected argument that phrasing the claims as "methods of treating" automatically makes them eligible.
- "Properly understood, this added step is simply an instruction not to act. In effect, the claim is directed to detecting the presence of LVD in a patient and then doing nothing but leaving the natural processes taking place in the body alone for the group of LVD patients."
- Not a new way of treating LVD patients that uses the discovery of natural phenomenon—"Instead, the broad directive to exclude all neonatal patients with LVD from iNO treatment (while continuing to treat other patients according to the established dose) collapses into a claim focused on the natural phenomenon."

Illumina v. Ariosa

A method involving:

(1) extracting DNA from a cell-free fluid sample;

(2) preparing a fraction of DNA by size discrimination and removal of DNA over a certain size; and

(3) analyzing a genetic loci in the fraction.

356 F. Supp. 3d. 925 (N.D. Cal. Dec. 24, 2018)

Illumina v. Ariosa

’751 patent, claim 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).

Illumina v. Ariosa

’731 patent, claim 1:

A method, comprising:

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

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

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

(ii) selectively removing the DNA fragments greater than approximately 300 base pairs, wherein the DNA fraction after (b) comprises extracellular circulatory fetal and maternal DNA fragments of approximately 300 base pairs and less and a plurality of genetic loci of the extracellular circulatory fetal and maternal DNA fragments; and

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

Illumina v. Ariosa

District Court granted summary judgment of lack of eligibility.

Step 1:

“Both patents claim results from a test of naturally occurring fetal DNA and do not transform the naturally occurring product into something new. Instead the patents lay claim to test results obtained from the use of fetal DNA. This use alone is insufficient to overcome the ‘directed to’ inquiry.”

Illumina v. Ariosa

Step 2:

"The Court finds that the claims of each patent are not inventive. The independent claims require three phases: extraction, size production, and selective removal. Each of the steps is described as well-known and conventional. *See* Dkt. No. 61. Plaintiffs suggest that the novelty of their invention is in the use of routine and conventional steps to isolate and analyze smaller DNA fragments. However, the Court finds that the 'inventive concept' is the application of the well known routine and conventional techniques for extraction and removal. For example, the patents require 'extracting DNA,' 'producing a fraction of DNA', and discuss 'discrimination' and 'removal steps.' These broad terms are 'well-understood, routine, conventional activities previously known to the industry,' particularly given that the claims provide them no more explicit definition.

Illumina v. Ariosa (Fed. Cir.)

Appeal No. 19-1419

- Argued Jan. 9, 2020
- Judges Lourie, Moore, Reyna
- Argument focused on Step 1 “directed to” inquiry.

Take Away Points from Federal Circuit Framework

- "Directed to" inquiry invokes both the claims and the specification's description of the invention/discovery.
- Claims need to recite an "inventive concept" to transform the ineligible law of nature into a patent-eligible application—requires that the claimed method steps do more than using conventional steps with newly discovered natural law.
  - Avoid saying any technique mentioned in the claims is standard or routine in the specification.
- Method-of-treatment claims reciting an ***application*** of a natural law can be patent eligible.
  - Using preamble "method of treating …" preamble can be helpful, particularly where the claim involves dosage steps taken in response to testing.
- Claims setting forth what a natural correlation "indicates," with no required action taken, are likely ineligible.

Notes on Non-Life Sciences Decisions

- Claims that focus on ‘the specific asserted improvement in computer capabilities” as opposed to abstract idea that uses computer as a tool have been found eligible
  - *Ancora Techs., Inc. v. HTC America, Inc*., 908 F.3d 1343 (Fed. Cir. 2018) – improving computer security by moving security verification structure to a location not previously used for that purpose
  - *Koninklijke KPN N.V. v. Gemalto M2M GmbH*, 942 F.3d 1143 (Fed. Cir. 2019) – improving accuracy of data transmission by using certain varying devices

Notes on Non-Life Sciences Decisions

- Federal Circuit has found some claims appearing on their face to be directed to particular system or device to be ineligible
  - *Chamberlain Grp. v. Techtronic Indus. Co*., 935 F.3d 1341 (Fed. Cir. 2019) – claims to a "movable barrier operator" ineligible as directed to abstract idea of communicating information wirelessly
  - *Am. Axle & Mfg. v. Neapco Holdings LLC*, 939 F.3d 1355 (Fed. Cir. 2019) – method for manufacturing a propeller shaft ineligible as directed to natural law related to vibration frequency

District Court Decisions

CareDx v. Natera

Claims generally related to assessing blood samples for rejection of transplants by measuring concentrations of cell-free DNA in the blood.

2020 U.S. Dist. LEXIS 23119 (D. Del. Feb. 10, 2020)

CareDx v. Natera

’652 patent, claim 1:

A method for detecting transplant rejection, graft dysfunction, or organ failure, the method comprising:

(a) providing a sample comprising cell-free nucleic acids from a subject who has received a transplant from a donor;

(b) obtaining a genotype of donor-specific polymorphisms or a genotype of subject-specific polymorphisms, or obtaining both a genotype of donor-specific polymorphisms and subject-specific polymorphisms, to establish a polymorphism profile for detecting donor cell-free nucleic acids, wherein at least one single nucleotide polymorphism (SNP) is homozygous for the subject if the genotype comprises subject-specific polymorphisms comprising SNPs;

(c) multiplex sequencing of the cell-free nucleic acids in the sample followed by analysis of the sequencing results using the polymorphism profile to detect donor cell-free nucleic acids and subject cell-free nucleic acids; and

(d) diagnosing, predicting, or monitoring a transplant status or outcome of the subject who has received the transplant by determining a quantity of the donor cell-free nucleic acids based on the detection of the donor cell-free nucleic acids and subject cell-free nucleic acids by the multiplexed sequencing, wherein an increase in the quantity of the donor cell-free nucleic acids over time is indicative of transplant rejection, graft dysfunction or organ failure, and ***wherein sensitivity of the method is greater than 56% compared to sensitivity of current surveillance methods for cardiac allograft vasculopathy (CAV).***

CareDx v. Natera

’497 patent, claim 1:

A method of detecting donor-specific circulating cell-free nucleic acids in a solid organ transplant recipient, the method comprising:

(a) genotyping a solid organ transplant donor to obtain a single nucleotide polymorphism (SNP) profile of the solid organ transplant donor;

(b) genotyping a solid organ transplant recipient to obtain a SNP profile of the solid organ transplant recipient, wherein the solid organ transplant recipient is selected from the group consisting of: a kidney transplant, a heart transplant, a liver transplant, a pancreas transplant, a lung transplant, a skin transplant, and any combination thereof;

(c) obtaining a biological sample from the solid organ transplant recipient after the solid organ transplant recipient has received the solid organ transplant from the solid organ transplant donor, wherein the biological sample is selected from the group consisting of blood, serum and plasma, and wherein the biological sample comprises circulating cell-free nucleic acids from the solid organ transplant; and

(d) determining an amount of donor-specific circulating cell-free nucleic acids from the solid organ transplant in the biological sample by detecting a homozygous or a heterozygous SNP within the donor-specific circulating cell-free nucleic acids from the solid organ transplant in at least one assay, wherein the at least one assay comprises high-throughput sequencing or digital polymerase chain reaction (dPCR), and

wherein the at least one assay detects the donor-specific circulating cell-free nucleic acids from the solid organ transplant when the donor-specific circulating cell-free nucleic acids make up at least 0.03% of the total circulating cell-free nucleic acids in the biological sample.

CareDx v. Natera

Magistrate Judge recommended denying motion to dismiss for lack of eligibility.

Step 1:

"But here, the claims do make reference to the claimed advance described by the specification: the use of digital PCR/high-throughput sequencing/multiplex sequencing, at certain levels of sensitivity, to identify homozygous or heterozygous SNPs in the blood of a transplant recipient (all in order to determine the amount of donor-specific cfDNA in the recipient)."

"It is these purportedly new, unconventional combination of steps that the claims are directed to, not the natural law itself."

Ni-Q v. Prolacta

A method for determining if a donated mammary fluid sample is from a particular subject:

(a) testing a donated biological sample for a biomarker;

(b) testing the donated mammary fluid for the marker;

(c) comparing the two samples;

(d) processing the matched mammary fluid sample,

(e) wherein the mammary fluid has a particular nutrient profile.

367 F. Supp. 3d 1221 (D. Or. Feb. 13, 2019).

Ni-Q v. Prolacta

’921 patent, claim 1:

A method for determining whether a donated [human] mammary fluid was obtained from a specific subject, the method comprising:

(a) testing a donated biological sample from the specific subject to obtain at least one reference identity marker profile for at least one marker;

(b) testing a sample of the donated mammary fluid to obtain at least one identity marker profile for the at least one marker in step (a);

(c) comparing the identity marker profiles, wherein a match between the identity marker profiles indicates that the mammary fluid was obtained from the specific subject; and

(d) processing the donated mammary fluid whose identity marker has been matched with a reference identity marker profile, wherein the processed donated mammary fluid comprises a human protein constituent of 11-20 mg/mL; a human fat constituent of 35-55 mg/mL; and a human carbohydrate constituent of 70-120 mg/mL.

Ni-Q v. Prolacta

District court granted summary judgment of lack of eligibility.

Step 1:

“Claim 1 merely describes the natural law that two different biological samples from the same individual contain the same identity markers and thus can be tested and compared.”

“Claim 1(d) does not require that nutrient levels of donated mammary fluid be altered. Nor does the text of the claim include anything about optimal nutrient levels. It merely requires that after processing is complete, the mammary fluid consist of wide-ranging levels of nutrients that, as conceded by Prolacta, are naturally found in human breast milk.”

Ni-Q v. Prolacta

Step 2:

“The '921 Patent acknowledges that obtaining identity markers was known in the art and that testing identity markers also was known in the art. Using such tests to match a subject's identity is not new or inventive.”

“The claims cover laws of nature—identity markers that exist in a subject and mammary fluid with nutrient levels that occur in nature. The remaining steps (testing the identity markers for a match, pasteurization) ‘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.’ *Mayo*, 566 U.S. at 79-80. The claims, thus, fail at step two.”

Bio-Rad v. 10X Genomics

A method of reducing contamination associated with sample handling comprising:

(a) introducing an aqueous sample into an apparatus main chamber containing an immiscible liquid;

(b) partitioning the fluids to generate droplets in the main chamber;

(c) flowing droplets to a separation chamber of a certain configuration that is in communication with the main chamber;

(d) separating droplets from immiscible liquid based on densities.

2019 U.S. Dist. LEXIS 60038 (D. Del. Apr. 8, 2019).

Bio-Rad v. 10X Genomics

’722 patent, claim 1:

A method of reducing contamination associated with sample handling, comprising:

providing an aqueous fluid comprising a sample through a sample inlet;

providing an immiscible fluid flowing through a main channel that is in fluidic communication with the sample inlet, wherein the main channel is in a horizontal plane;

partitioning the aqueous fluid with the immiscible fluid to form a plurality of droplets in the main channel, wherein at least one droplet comprises a sample;

flowing the droplets toward a downstream separation chamber that is in fluidic communication with the main channel,

wherein the separation chamber has a wider cross section than the main channel cross-section and the separation chamber is disposed perpendicular to the main channel; and

separating the plurality of droplets from the immiscible fluid in the separation chamber based on the different densities of the droplets and the immiscible fluid.

Bio-Rad v. 10X Genomics

District court denied motion to dismiss for lack of eligibility, relying on *CellzDirect*.

Step 1:

"While the claims certainly utilize the separation of liquids with different densities to effect the desired outcome, this is insufficient to determine that the claims are wholly directed to a patent ineligible concept."

"[H]ere, '[t]he end result of the [] claims is not simply an observation or detection of the ability' of liquids to separate by density. . . . The recited steps and assembly achieve an improved way of handling samples that reduces the sample contamination that would otherwise occur."

Takeaways

- **Moving Parties:**
  - Important strategic considerations at play in deciding under what Rule (and when) to move for invalidity.
  - Don’t overlook Step 1 “directed to” inquiry.
  - At Step 2, be mindful that prior disclosure does not necessarily amount to “conventional” activity.

- **Patentees:**
  - Pleading and claim construction can play important roles.
  - Highlight improvements and draw analogies to *CellzDirect*.

USPTO & Congress

USPTO Guidance: Subject Matter Eligibility

October 2019 Patent Eligibility Guidance Update (issued Oct. 17, 2019)
Appx 1: October 2019 Examples 43-36
Appx 2: Index of Examples
Appx 3: Chart of Subject Matter Eligibility Court Decisions

available at https://www.uspto.gov/patent/laws-and-regulations/examination-policy/subject-matter-eligibility

Five Themes Addressed

- (I) evaluating whether a claim recites a judicial exception;
- (II) the groupings of abstract ideas enumerated in the 2019 PEG;
- (III) evaluating whether a judicial exception is integrated into a practical application;
- (IV) the prima facie case and the role of evidence with respect to eligibility rejections; and
- (V) the application of the 2019 PEG in the patent examining corps.

Courts Not Bound by USPTO's Guidelines

- ***Cleveland Clinic Found. v. True Health Diagnostics LLC***, 760 Fed. App'x 1013 (Fed. Cir. 2019)
  - Medical diagnostic patent covering test for determining patient's risk for cardiovascular disease affirmed as patent ineligible
  - Federal Circuit declined to follow USPTO's guidance
    - "While we greatly respect the PTO's expertise on all matters relating to patentability, including patent eligibility, we are not bound by its guidance. And, especially regarding the issue of patent eligibility and the efforts of the courts to determine the distinction between claims directed to natural laws and those directed to patent-eligible applications of those laws, we are mindful of the need for consistent application of our case law."
- ***Facebook Inc. v. Windy City Innovations LLC***, No. 18-1400 (Fed. Cir.) (pending)
  - USPTO argued in amicus brief that patent office Precedential Opinion Panel decisions should receive *Chevron* deference

Proposed Legislation on §101

- Bipartisan bill introduced in May 2019 to revise §101 by:
  - Clarifying that "useful" in §101 "means any invention or discovery that provides specific and practical utility in any field of technology through human intervention"
  - Adding that eligibility "shall be determined only while considering the claimed invention as a whole, without discounting or disregarding any claim limitation"
- Proposed bill includes statements that §101:
  - "shall be construed in favor of eligibility"
  - no exceptions "shall be used to determine patent eligibility under section 101,"
  - "all cases establishing or interpreting those exceptions to eligibility are hereby abrogated"
- Senate Subcommittee on Intellectual Property held hearings on the proposed bill in June and promised further revisions to address testimony, but progress seems to have stalled

Legislative Update

Congress Isn't Giving Up On Patent Eligibility Fix, Rep. Says

By **Britain Eakin**

Law360 (February 11, 2020, 11:16 PM EST)

- Tillis/Coons efforts, including three hearings, did not lead to a bill.
- Per Rep. Hank Johnson (D-Ga.), House & Senate still working on a proposed bill.

Thank You!

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