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Exploring the Legal Contours of Patent Subject Matter Eligibility

USPTO Roundtable on Patent Subject Matter Eligibility
Stanford, CA

December 5, 2016

Konstantin Linnik, PhD
Nutter McClennen & Fish, LLP
Boston, MA

Sequenom v Ariosa amici support

- The BioIndustry Association (UK)
- EuropaBio (pan-European)
- HollandBIO
- Swiss Biotech Association
- AusBiotech (Australia)
- BIOTECanada (Canada)
- Japan Bioindustry Association

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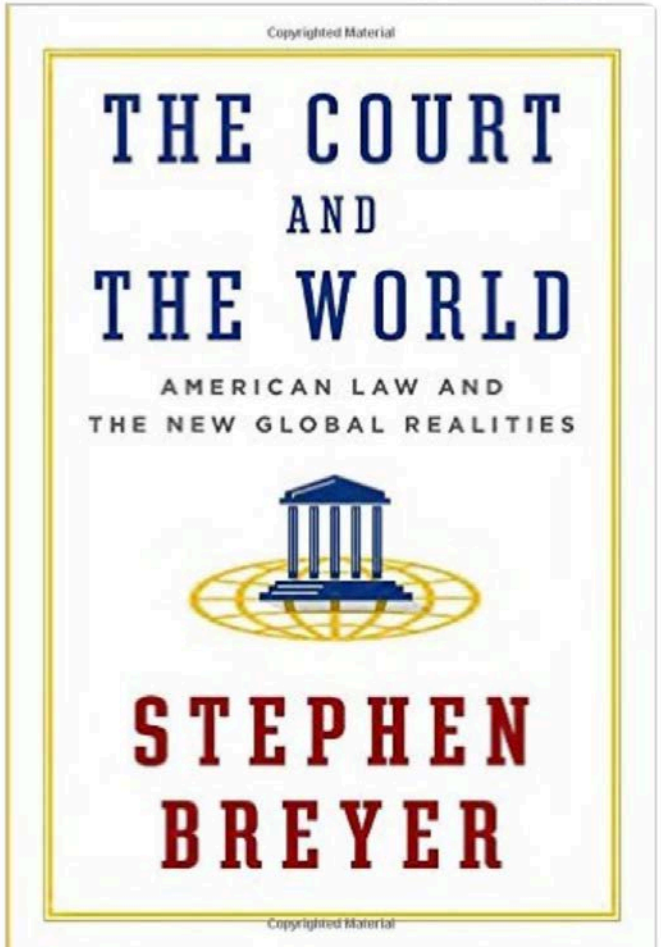
Industry Position

"Harmonized, clear and predictable intellectual property laws are essential for the smooth functioning of today's economy. Biomedical innovation, in particular, depends on the proper balance of incentives as well as certainty upon which billions of dollars are invested in our and future generations' health and well-being."



"To find answers today, the Court must increasingly consider foreign and domestic laws together, as if they constituted part of a broadly interconnected legal web."

"The Court has increasingly sought interpretations of domestic law that would allow it to work in harmony with related foreign laws, so that together they more effectively achieve common objectives."

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35 USC § 101*
*Supreme Court's version

Inventions patentable—

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, provided that any such invention is **significantly more** than an abstract idea or a law of nature or a natural phenomenon.

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Related Exclusions: EPC, UK, Germany

- Article 52(2) EPC

> "[t]he following in particular shall not be regarded as inventions...:
> (a) discoveries, scientific theories and mathematical methods..."

- *See also* UK Patent Act, Section 1(2)(a)
- *See also* German Patent Act, Section (1)(3)

Related Exclusions: Canada, Australia

- "any mere scientific principle or abstract theorem" (Canadian Patent Act, Section 27(8))

- "discoveries with no means of putting them into effect," "mere ideas," and "scientific theories" (Australia)

Ariosa Diagnostics v. Sequenom

EP '963 patent	**US '540 patent**
1. A detection method performed on a maternal serum or plasma sample from a pregnant female, which method comprises detecting the presence of a nucleic acid of foetal origin in the sample, wherein said nucleic acid is a paternally inherited sequence which is not possessed by said pregnant female.	1. A method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female, which method comprises amplifying a paternally inherited nucleic acid from the serum or plasma sample and detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample.
4. A method according to [claim 1], wherein said detecting comprises amplifying said nucleic acid.	

“Does the problem lie with the analytical legal framework rather than the merits of the inventions?”

Patent-eligible	Patent-ineligible
1. A method of detecting JUL-1 in a patient, said method comprising: a. obtaining a plasma sample from a human patient; and b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody.	3. A method of diagnosing julitis in a patient, said method comprising: a. obtaining a plasma sample from a human patient; b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with a porcine anti-JUL-1 antibody and detecting binding between JUL-1 and the porcine antibody; and c. diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample is detected.

Suggested approach: express disclaimer of implicit exceptions

Patent-eligible	**Patent-eligible**
1. A method of detecting JUL-1 in a patient, said method comprising: a. obtaining a plasma sample from a human patient; and b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody.	3. A method of diagnosing julitis in a patient, said method comprising: a. obtaining a plasma sample from a human patient; b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with a porcine anti-JUL-1 antibody and detecting binding between JUL-1 and the porcine antibody; and c. diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample is detected, **provided that the method claimed amounts to significantly more than an abstract idea or a law of nature or a natural phenomenon.**

Express Disclaimer of Implicit Exceptions

- Disclaimer acknowledges the *status quo* of the law until § 101 is amended otherwise
- Avoids the need for *Mayo/Alice* broad tests which produce unpredictable and irreconcilable results, especially in combination with BRI
- Improves examination efficiency

Express Disclaimer of Implicit Exceptions

- Express disclaimer **should automatically** satisfy patent-eligibility inquiry of § 101 (but not any other statutory or non-statutory requirement)
- "The § 101 eligibility disclaimer" should not require § 112 support in the specification as it is implicit in the law
- Serves the policy rationale by confining the "outer limits" of claimed subject matter irrespective of "draftsman's skill"

Suggested Course

- Provide examples of acceptable disclaimer language
- Establish that an express disclaimer is *prima facie* sufficient to satisfy the patent-eligibility inquiry of § 101
- Provide narrowly tailored examples where the disclaimer-based presumption can be rebutted

Conservative example of the disclaimer approach

1. A method comprising introducing into a cancer cell an effective amount of a synthetic miR-215 molecule[..].

2. The method of claim 1, wherein the synthetic miR-215 molecule is non-naturally occurring and markedly different in sequence from naturally occurring miR-215.

3. The method of claim 1, wherein the synthetic miR-215 molecule is non-naturally occurring and markedly different in chemical structure from naturally occurring miR-215.

4. The method of claim 1, wherein the sequence of the synthetic miR-215 molecule is not naturally occurring.

5. The method of claim 1, wherein at least one nucleobase of the synthetic miR-215 molecule is chemically modified.

US Patent No. 9,068,219

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