

Personalized Medicine Coalition Public Policy Committee Meeting

Gene and Method Patents: Review of Court Cases and the Implications for Personalized Medicine

Richard S. Meyer, Partner, Kilpatrick Townsend & Stockton LLP
Sandra Park, Staff Attorney, ACLU Womens Rights Project
David Resnick, Partner, Co-Leader, Patents, Nixon Peabody LLP

The contents of these slides and views expressed by the speakers do not necessarily represent the positions of their respective firms, clients or the PMC.

Agenda



- Overview of Recent Cases Affecting Patentability of Diagnostic Methods and Genes
 - U.S. Supreme Court
 - Court of Appeals for the Federal Circuit
- Arguments Against the Myriad & Prometheus Patents
 - Challenging Patents on Products of Nature, Laws of Nature, and Abstract Ideas
- Views of Other Groups (*Amici* Briefs)
- What do You Think?
 - Policy Discussion/Implications for Personalized Medicine

Overview



David Resnick
Partner, Co-Leader, Patents
Nixon Peabody LLP
dresnick@nixonpeabody.com

Patent Eligible Subject Matter



- U.S. Supreme Court
 - *LabCorp v. Metabolite* (2006)
 - *Bilski v. Kappos* (2010)
 - *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, (2012)
- Court of Appeals for the Federal Circuit
 - *In Re Bilski* (2008)
 - *Classen v. Biogen* (2008); *Classen II* (2011)
 - *Prometheus v. Mayo* (2009); *Prometheus II* (2011)
 - *Association of Molecular Pathology (AMP) / ACLU v. Myriad* (Dist. Ct. 2010; Fed. Cir. 2011)

Patentable v. Patent-ineligible



- Patentable subject matter means the invention as claimed is useful, novel, and not obvious.
- Patent-ineligible means that the subject matter is not eligible for a patent notwithstanding the fact that it may be patentable (i.e., useful, novel, and not obvious).

Patent Eligible Subject Matter



35 U.S.C. SECTION 101 STATES:

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.

- Not changed in the America Invents Act

Examples of Early “Gene” Patents



Issue Date	Patent No.	Representative claim
Dec. 14, 1982	US 4,363,877 (The Regents of the University of California, CA); Re-examination certificate issued May 26, 1998	<p>A recombinant DNA transfer vector comprising codons for <u>human chorionic somatomammotropin</u> [pregnancy-related protein] comprising the nucleotide sequence:...</p> <p>Note: Based on the article on “Gene Patents and Global Competition Issues” (Genetic Engineering & Biotechnology News (2006) Vol.26; No.1), this is the first gene patent, and EPO and JPO started to grant gene patents in 1990s.</p>
Jul. 12, 1983	US 4,393,201 (The Winstar Institute, PA)	<p>The single strand DNA that codes for the glycoprotein of ERA-strain rabies virus beginning with an initiation codon (ATG) and ending with a termination codon (TGA), and having the nucleotide sequence as follows:</p> <p>...</p>
Apr. 19, 1988	US 4,738,931 (Japanese Foundation for Cancer Research, JP)	<p>A DNA consisting essentially of a DNA containing a human interferon β gene and a human interferon-β gene control DNA responsible for controlling the transcription of said human interferon-β gene which has a nucleotide sequence, as follows:...</p>

Examples of Early Diagnostic Patents



United States Patent [19]

Grosser et al.

[11] B **3,999,944**

[45] **Dec. 28, 1976**

[54] **DETECTION OF BREAST CANCER**

3,867,363 2/1975 Hansen 424/12 X

[75] Inventors: **Norman Grosser**, Montreal; **David Marshall Parks Thomson**, Mount Royal, both of Canada

OTHER PUBLICATIONS

Chemical Abstracts, 77:99494p (1972).

[73] Assignee: **Hoffmann-La Roche Inc.**, Nutley, N.J.

Primary Examiner—Joseph Scovronek
Assistant Examiner—Sidney Marantz
Attorney, Agent, or Firm—Samuel L. Welt; Bernard S. Leon; Gerald S. Rosen

[22] Filed: **Feb. 28, 1975**

[21] Appl. No.: **554,039**

[44] Published under the second Trial Voluntary Protest Program on February 24, 1976 as document No. B 554,039.

[57] **ABSTRACT**

The detection of breast cancer in humans by evaluating antigen induced leukocyte adherence inhibition caused by tumor specific cell mediated immunity by incubating a measured amount of a patients blood leukocytes with aqueous basic extracts of human breast tumor, then determining whether the leukocyte adherence inhibition measured by the non-adherence index as compared to a control of a non-specific antigen is high, indicating the presence of breast cancer, or low, indicating the absence of breast cancer.

[52] **U.S. Cl.** **23/230 B; 424/12**

[51] **Int. Cl.²** **G01N 33/16**

[58] **Field of Search** **23/230 B; 424/12**

[56] **References Cited**

UNITED STATES PATENTS

3,594,466	7/1971	Guffroy	424/12
3,663,684	5/1972	Freedman	424/12 X
3,840,655	10/1974	Lerner	424/12
3,852,415	12/1974	Vandervoorde	424/12 X

4 Claims, No Drawings

Examples of Early Diagnostic Patents



1. A method for detecting the presence of breast cancer in humans which comprises incubating a measured amount of a patient's blood leukocytes with aqueous basic extracts of human breast tumor, then determining the leukocytes non-adherence index by comparison to a non-specific antigen control, and concluding that breast cancer is present if the non-adherence index of the patient being tested is higher than the control non-adherence index.

Examples of Early Diagnostic Patents



United States Patent [19]

[11] **4,241,044**

Kim

[45] **Dec. 23, 1980**

[54] **METHOD OF DIAGNOSING CANCER BY
DETECTING ELEVATED ANTI-T ANTIBODY
ACTIVITY**

[75] Inventor: **Yung D. Kim, Lindenhurst, Ill.**

[73] Assignee: **Abbott Laboratories, North Chicago,
Ill.**

[21] Appl. No.: **973,991**

[22] Filed: **Dec. 28, 1978**

[51] Int. Cl.² **G01N 33/16; A61K 43/00**

[52] U.S. Cl. **424/1; 23/230 B;
260/112 B**

[58] Field of Search **424/112; 23/230 B;
260/112 R, 112 B**

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,663,684 5/1972 Freedman et al. **424/1**

3,697,638	10/1972	Hansen	424/1
3,823,126	7/1974	Bjorklund	260/112 R
3,867,363	2/1975	Hansen	260/112 R
3,956,258	5/1976	Hansen	260/112 R
3,960,827	6/1976	Bjorklund	260/112 R
4,132,767	1/1979	Tohmatsu et al.	424/1
4,152,410	5/1979	Ishii	424/1
4,160,817	7/1979	Bucovaz et al.	424/1

Primary Examiner—Benjamin R. Padgett
Assistant Examiner—Christine M. Nucker
Attorney, Agent, or Firm—Neal O. Willmann

[57] **ABSTRACT**

This application discloses a method for diagnosing cancer by employing any of various immunochemical procedures to detect elevated levels of anti-(blood group T antigen) antibodies in a biological sample.

8 Claims, No Drawings

Examples of Early Diagnostic Patents



U.S. PATENT 4,122,000 (1978)

1. A method of diagnosing cancer which comprises immunochemically detecting elevated anti-T antibody activity in a biological sample from an untreated individual.

Challenges to Diagnostic Patents



Diagnostic type claims were typically challenged in litigation for lack of novelty (section 102) or obviousness (section 103) **not** for patent lack of eligible subject matter (section 101).

LabCorp v. Metabolite Labs



Then came *LabCorp v. Metabolite* and Justice Breyer.

13. A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of: assaying a body fluid for an elevated level of total homocysteine; and correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.



- **Three U.S. Supreme Court Justices:** “...[T]his case is not at the boundary [of the law]...There can be little doubt that the correlation between homocysteine and vitamin deficiency...is a ‘natural phenomena’ [and] not patent-eligible.”

In re Bilski



- *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008), an en banc decision of the U.S. Court of Appeals for the Federal Circuit.
- The case dealt with business method patent claims, but the Court rationalized the whole field.
- The Federal Circuit held that an applicant may show that a process claim satisfies Section 101 either by showing that the claim is tied to a particular machine or transforms any article to a different state or thing.
- Machine-or-transformation test (MOT).
- Judge Radar's dissent.

Classen Immunotherapies

- *Classen Immunotherapies v. Biogen Idec et al.* (Fed. Cir. 2008)
- The decision, in its entirety, states as follows: “In light of our decision in *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (en banc), we affirm the district court’s grant of summary judgment that these claims are invalid under 35 U.S.C. § 101. Dr. Classen’s claims are neither “tied to a particular machine or apparatus” nor do they ‘transform[] a particular article into a different state or thing.’ *Bilski*, 545 F.3d at 954. Therefore we affirm.”
- Judge Moore

Prometheus v. Mayo (Fed. Cir. 2009)



- The patented test provides a means to measure the level of 6-thioguanine (“6-TG”) and 6-methylmercaptapurine (“6-MMP”), which indicates that an adjustment in drug dosage may be required at certain metabolite levels. Claim 1 is representative:
- 1. A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:
 - (a) **administering** a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and
 - (b) **determining** a level of 6-thioguanine or 6-methyl-mercaptapurine in said subject having said immune-mediated gastrointestinal disorder,
 - wherein a level of 6-thioguanine less than about 230 pmol per 8×10^8 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and
 - wherein a level of 6-thioguanine greater than about 400 pmol per 8×10^8 red blood cells or a level of 6-methyl-mercaptapurine greater than about 7000 pmol per 8×10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.
- District court found the claim invalid for lacking patentable subject matter.

Prometheus v. Mayo



- Federal Circuit applied the “machine or transformation” test, and held that “method of treatment” claims remain patent eligible because any such claims recite a step of “administering” a drug to a subject, thus “transforming” the subject
- Transformation must be central to the purpose of the claim
- Determining the level of a specific compound involves a transformation
 - Cannot be by mere inspection
 - Must use a machine, e.g., HPLC
- Even claims without an “administration step” were patentable because some form of manipulation is necessary to extract a metabolic from a bodily sample
- Presence of a mental step (“wherein” clauses) does not detract from patentability
- Judge Radar

Bilski U.S. Supreme Court



- Bilski et al. v. Kappos, 561 U.S. _____, 130 S. Ct. 3218 (2010)
- Decided June 28, 2010
- Court noted that its precedents provide three non-statutory exceptions to the broad principles of §101:
 - Laws of nature
 - Physical phenomena
 - Abstract ideas
- Court also pointed out that the §101 patent eligibility inquiry is **only a threshold test**

Bilski U.S. Supreme Court



- The day after the decision, with respect to Classen and Prometheus, the Court granted certiorari, vacated the Federal Circuit's decisions, and remanded the cases back to the Federal Circuit for reconsideration in view of Bilski
- What happened at the Federal Circuit?

Prometheus II



- December 2010
- The Federal Circuit reconsidered *Prometheus* and reached exactly the same result upholding the '623 and '302 patents as valid under Section 101.
- In each of its decisions, the Federal Circuit held that the patents at issue in *Prometheus* are valid because a method of treatment to “ameliorate the effects of an undesired condition” is “always transformative,” thus clearing the bar to patentability under Section 101.
- On June 20, 2011, the United States Supreme Court granted Mayo’s petition for certiorari.
- Being argued tomorrow-December 7, 2011.

Prometheus II/LabCorp Claim

- 13. A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of: assaying a body fluid for an elevated level of total homocysteine; and correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.

Prometheus II Claim



- 1. A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:
 - (a) **administering** a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and
 - (b) **determining** a level of 6-thioguanine or 6-methyl-mercaptopurine in said subject having said immune-mediated gastrointestinal disorder,
 - wherein a level of 6-thioguanine less than about 230 pmol per 8×10^8 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and
 - wherein a level of 6-thioguanine greater than about 400 pmol per 8×10^8 red blood cells or a level of 6-methyl-mercaptopurine greater than about 7000 pmol per 8×10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

Association of Molecular Pathology (AMP) et al. v. Myriad Genetics, U.S. Patent and Trademark Office et al.

- Association of Molecular Pathology et al. v. U.S. Patent and Trademark Office et al. 2010 WL 1233416 (S.D.N.Y.)
- Decided March 29, 2010
- U.S. Patent Nos. 5,747,282; 5,837,492; 5,693,473; 5,709,999; 5,710,001; 5,753,441; and 6,033,857

AMP v. Myriad Genetics



- The challenged patents cover diagnostic tests for mutations in genes, known as BRCA1 and BRCA2, which are responsible for most cases of hereditary breast and ovarian cancers.
- 7 patents
- 15 claims
 - Composition of matter claims
 - Method/process claims
- Terms extend from 2015-2018
- Myriad hold 16 other BRCA1/2 not in suit (expiring 2023)

AMP v. Myriad Genetics

- Plaintiffs
 - Associations
 - Researchers
 - Advocacy Groups
 - Patients



AMP v. Myriad Genetics



- Example of a Composition of Matter claim
- An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2.

AMP v. Myriad Genetics



- Example of a method claim:
- 2. A method for diagnosing a predisposition for breast cancer in a human subject which comprises **comparing** the germline sequence of the BRCA2 gene or the sequence of its mRNA in a tissue sample from said subject with the germline sequence of the wild-type BRCA2 gene or the sequence of its mRNA, wherein an alteration in the germline sequence of the BRCA2 gene or the sequence of its mRNA of the subject indicates a predisposition to said cancer.

AMP v. Myriad Genetics



- Key Arguments/Issues
- Genes are products of nature, not inventions
- The law prohibits patenting of laws of nature, products of nature and abstract ideas
- No second opinions
- High prices limit access
- First Amendment concern

AMP v. Myriad Genetics



- Defendants key arguments
- Patents claim “isolated” DNA
- “These isolated molecules are man-made chemical compositions, structurally and functionally distinct from any substance found in the human body-indeed, in all of nature.”
- The method claims involve unique molecular tools
 - Probes and primers
- The inventions made familial breast/ovarian cancer testing practical
- Cases imperils the biotechnology industry

AMP v. Myriad Genetics



March 29, 2010 Judge Sweet's Ruling

- “DNA represents the physical embodiment of biological information, distinct in its essential characteristics from any other chemical found in nature.”
- DNA's existence in an isolated form alters neither this fundamental quality...nor the information it encodes.”
- Therefore, the patents at issue directed to ‘isolated DNA’ containing sequences found in nature are unsustainable as a matter of law and are deemed unpatentable subject matter under 35 U.S.C. § 101.”

AMP v. Myriad Genetics



March 29, 2010 Judge Sweet's Ruling (*continued*)

- Judge Sweet ruled that human genetic sequences and the scientific enquiry of looking at a gene or comparing two genes constitute natural phenomena, laws of nature and abstract ideas, and are not patentable.
- The court held the method claims invalid, because they were not directed at patentable subject matter under the M-o-T test.

AMP v. Myriad, *Federal Circuit*



- July 29, 2011
- The majority held all “isolated DNA” claims at issue patent-eligible under 35 U.S.C. §101.
- the isolated DNA molecules are patent eligible because “*BRCA1* and *BRCA2* in their isolated state are not the same molecules as DNA as it exists in the body; human intervention in cleaving or synthesizing a portion of a native chromosomal DNA imparts on that isolated DNA a distinctive chemical identity from that possessed by native DNA.”
- The majority also held as patent-ineligible certain diagnostic method claims that in effect recited only “comparing” or “analyzing” DNA sequences.

AMP v. Myriad, *Federal Circuit*



- “We conclude that Myriad’s claims to ‘comparing’ or ‘analyzing’ two gene sequences fall outside the scope § 101 because they claim only abstract mental processes.”
- “This claim thus recites nothing more than the abstract mental steps necessary to compare two different nucleotide sequences.”
- “The claims do not specify any action prior to the step of ‘comparing’ or ‘analyzing’ two sequences.”

AMP v. Myriad

(U.S. Patent 5,710,001)



- Patent ineligible
- Claim 1: A method for screening a tumor sample from a human subject for a somatic alteration in a BRCA1 gene in said tumor which comprising...**comparing** a first sequence selected from the group consisting of a BRCA1 gene...with a second sequence selected from the group consisting of BRCA1 gene...wherein a difference in the sequence...indicates a somatic alteration in the BRCA1 gene in said tumor sample.

AMP v. Myriad, *Federal Circuit*



- AMP et al. and Myriad both requested further review at the Federal Circuit
- Denied (September 2011)
- Off to the Supreme Court for review?
 - Up to the Court to decide.

Genomic Health / Oncotype Dx® Breast Cancer Test U.S. Patent 7,526,387



What is claimed is:

1. A method for determining the likelihood of breast cancer recurrence or response to hormonal therapy in a mammalian subject comprising:
 - (a) Measuring the expression levels of the RNA transcripts of GRB7, HER2, Est R1, PR, Bc12, CEGP1, SURV, Ki.67, MYBL2, CCNB1, STK15, CTSL2, and STMY3, or their expression products in a biological sample containing tumor cells obtained from said subject;

Genomic Health / Oncotype Dx® Breast Cancer Test



- (b) Creating the following gene subsets comprising:
 - (ii) growth factor subset: GRB7 and HER2;
 - (ii) estrogen receptor subset: EstR1, PR, Bc12, and CEGP1;
 - (iii) proliferation subset: SURV, Ki.67, MYBL2, CCNB1, and STK15;
and

- (c) Calculating a recurrence score (RS) for said subject by weighting the measured expression levels of each of the gene subsets by contribution to breast cancer recurrence;

Genomic Health / Oncotype Dx® Breast Cancer Test



- (d) Using said RS to determine the likelihood of breast cancer recurrence or response or response to therapy; and
- (e) Creating a report summarizing the result of said determination.

Challenging Patents on Products of Nature, Laws of Nature, and Abstract Ideas



**Sandra Park, Staff Attorney
ACLU Women's Rights Project
spark@aclu.org, www.aclu.org/brca**

Patents and Progress



The Congress shall have the power... To promote the Progress of Science and the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.

- United States Constitution, Article I, Section 8, Clause 8

Social benefits:

- Incentives for investment
- Disclosure of the invention

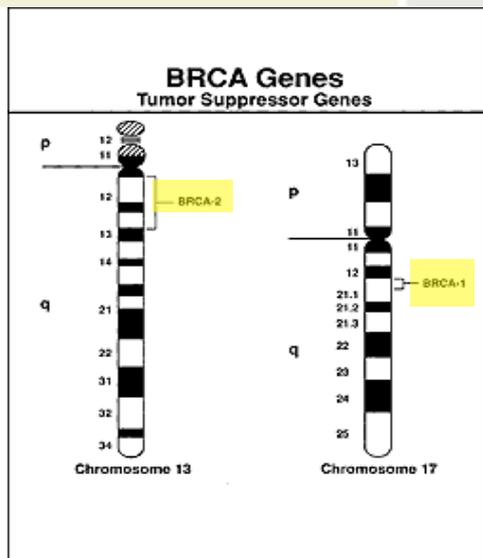
???
>/<

Social costs:

- Restricting the use of knowledge
- Monopoly power



Patents on BRCA1 and BRCA2



1990 Linkage to chromosome 17 found by Dr. Mary-Claire King

1994 Dr. Mark Skolnick with Myriad Genetics sequenced the gene and filed for BRCA1 patents

1998 BRCA2 patents obtained

1998 Myriad sent cease-and-desist letters

Claim 1: “An isolated DNA coding for a BRCA1 polypeptide...”



US005747282A

United States Patent [19]
Skolnick et al.

[11] **Patent Number:** **5,747,282**
[45] **Date of Patent:** **May 5, 1998**

[54] **17Q-LINKED BREAST AND OVARIAN CANCER SUSCEPTIBILITY GENE**

[75] **Inventors: Mark H. Skolnick; David E. Goldgar; Yoshio Miki; Jeff Swenson; Alexander Kamb; Keith D. Harshman; Donna**

[56] **References Cited PUBLICATIONS**
E. Marshall (1995) *Science* 269:1050–1055.
Vila et al (1995) *Targeted Gene Therapy* 9:190–199.
Molecular Biology of the Gene, 4th Edition, vol. 1 Eds. J. D.

Challenged BRCA Patent Claims

- Composition of Matter Claims to “Isolated DNA” - E.g., Claim 1 of patent 5,747,282:

“An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID No. 2.”

- Methods Claims - E.g., Claim 1 of patent 6,033,857:

“A method for identifying a mutant BRCA2 nucleotide sequence in a suspected mutant BRCA2 allele which comprises comparing the nucleotide sequence of the suspected mutant BRCA2 allele with the wild-type BRCA2 nucleotide sequence, wherein a difference between the suspected mutant and the wild-type sequence identifies a mutant BRCA2 nucleotide sequence.”

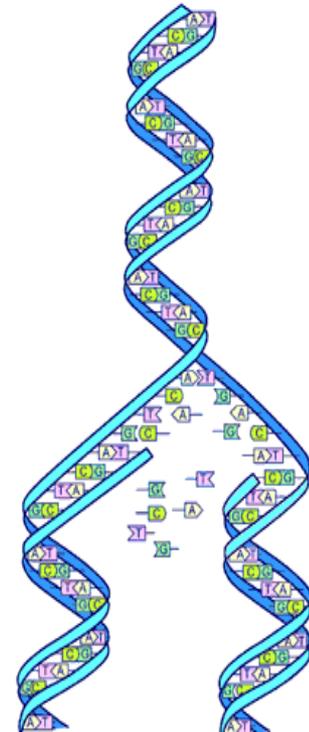
* Not challenged: claims on primers, kits

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Patenting Genes – Promoting the Progress of Science

“The information contained in our shared instruction book is so fundamental, and requires so much further research to understand its utility, that patenting it at the earliest stage is like putting up a whole lot of unnecessary toll booths on the road to discovery.”

-- Dr. Francis Collins, *The Language of Life: DNA and the Revolution in Personalized Medicine* (2010)



Effects of Human Gene Patenting



- Diagnostic Testing
- Patient Care
- Data Sharing
- Research
- New technologies

Lawsuit Challenging BRCA1/2 Patents



PLAINTIFFS

Organizations

Association For Molecular Pathology
American College Of Medical Genetics
American Society For Clinical Pathology
College Of American Pathologists
Breast Cancer Action
Our Bodies Ourselves

Researchers/Clinicians

Haig Kazazian, MD
Arupa Ganguly, PhD
Wendy Chung, MD, PhD
Harry Ostrer, MD
David Ledbetter, PhD
Stephen Warren, PhD

Genetic Counselors

Ellen Matloff, MS
Elsa Reich, MS

DEFENDANTS

United States Patent
and Trademark Office
(PTO)

Myriad Genetics

University of Utah
Research Foundation
(UURF) directors

Patients

Lisbeth Ceriani
Runi Limary
Genae Girard
Vicky Thomason
Kathleen Raker
Patrice Fortune

More information: www.aclu.org/brca

Legal Arguments



Challenged 15 patent claims in 7 patents: DNA claims and method claims

1. Section 101 of the Patent Act
2. U.S. Constitution, Article I, Clause 8 and First Amendment

Supreme Court Precedent on Section 101



“The laws of nature, physical phenomena, and abstract ideas have been held not patentable . . . Such discoveries are ‘manifestations of nature, free to all men and reserved exclusively to none.’ ”

Chakrabarty

- Diamond v. Chakrabarty (1980): “markedly different characteristics from any found in nature”
- Funk Bros. Seed Co. v. Kalo Inoculant Co. (1948): “whether the patentee had discovered ‘only some of the handiwork of nature’ ”
- American Fruit Growers, Inc. v. Brogdex Co. (1931): any change does not render a natural product patentable

Isolated DNA – Product of Nature



- Isolated DNA does not have markedly different characteristics
- Genetic sequence remains the same after isolation
- New uses for isolated DNA cannot alone meet the section 101 standard
- Claims are on a segment of the genetic code, a law of nature

Prometheus: Challenged Claims



A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

- (a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and
- (b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6-thioguanine less than about 230 pmol per 8×10^8 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and wherein the level of 6-thioguanine greater than about 400 pmol per 8×10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

Legal Arguments



1. Patent covers abstract ideas and laws of nature.
 - “Allowing petitioners to patent risk hedging would pre-empt use of this approach in all fields, and would effectively grant a monopoly over an abstract idea.” *Bilski* (2010)
 - “The mathematical formula involved here has no substantial practical application except in connection with a digital computer . . . the patent would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself.” *Gottschalk v. Benson* (1972)
2. Patent restricts thought and scientific inquiry, in violation of the Constitution.

--ACLU amicus brief in *Prometheus*

Views of *Prometheus* Amici



Richard S. Meyer
Partner

Kilpatrick Townsend & Stockton LLP
rmeyer@kilpatricktownsend.com

Comparison of the Question Presented for Supreme Ct. Review



- Mayo Question

Whether 35 U.S.C. § 101 is satisfied by a patent claim that covers observed correlations between blood test results and patient health, so that the claim ***effectively preempts all uses of the naturally occurring correlations***, simply because ***well-known methods*** used to administer prescription drugs and test blood may involve “transformations” of body chemistry.

- Prometheus Question

Whether the Federal Circuit correctly held that ***concrete methods for individually calibrating the appropriate dosages of specific synthetic drugs for treatment*** of patients suffering from particular serious autoimmune diseases are patentable processes under 35 U.S.C. § 101.

Views of *Prometheus Amici*



- Broad Patent Protection Camp
 - **15 Amicus Briefs** in Favor of Respondents (Prometheus)
 - Including: BIO; PhRMA; Health Law, Policy, and Ethics Scholars; Myriad Genetics Inc.; AIPLA; SAP; etc.
- Narrow Patent Protection Camp
 - **7 Amicus Briefs** in Favor of Petitioner (Mayo)
 - Including: AARP; Public Patent Foundation; American Medical Associations; UP Laboratories; Labcorp; American Civil Liberties Union; Verizon; HP; etc.
- Neutral (Sort of)
 - **5 Amicus Briefs** in Favor of Neither
 - Including: United States; Microsoft; EMC Corp.; Intel Corp.; Biopharmaceutical Companies (Roche Molecular Systems, Ventana Medical Systems, Hoffmann-La Roche, and Abbott Laboratories); etc.

Views of *Prometheus Amici* (cont.)



- Not so Neutral
 - **United States** (Patentable Subject Matter, but not novel or non-obvious):
 - Prometheus claims are clearly patentable subject matter. However, Mayo challenges are to novelty and non-obviousness.
 - **Microsoft, EMI, Intel** (Lower the 35 U.S.C. § 101 standard):
 - “To be eligible for patenting, a claimed process invention includes both the means and the result, i.e., one or more disclosed physical things used to produce a practical result or effect in the physical world. But that is all that is required to establish its patent eligibility.”

Views of *Prometheus Amici* (cont.)



- Notable Positions
 - **AMA (Narrow Patent Protection):**
 - “The use of patents, trade secrets, confidentiality agreements, or other means to limit the availability of medical procedures places significant limitation on the dissemination of medical knowledge, and is therefore unethical.”
 - **Health Law and Policy Scholars (Broad Patent Protection):**
 - “The AMA's position overemphasizes the immediate concerns of individual patients to the detriment of long-term public health. Although the medical associations raise legitimate practical concerns about the consequences of patent protection for medical processes, these concerns are for Congress or the Executive rather than this Court to address.”

Views of *Prometheus Amici* (cont.)



- Notable Positions (cont.)
 - **AARP and Public Patent Foundation (Narrow Patent):**
 - “The patenting of medical correlations - which are nothing more than expressions of laws of nature - has led to severe restraint on the provision of medical care and a greatly increased cost and reduced availability of vital medical services, damaging the public health of the nation.”
 - **Genomic Health et al. (Broad Patent):**
 - “Eliminating biomedical process patents, or creating uncertainty about their enforceability would likely cause a fatal crack in the industry's already-weakened foundation, setting back hopes for a new era of targeted and thus less expensive medicine.”

Policy Discussion/Implications for Personalized Medicine (“PM”)



- Does strong patent protection for genes and diagnostic methods enable or disable commercialization of PM?
 - Are patents really needed to foster investment and commercialization in this field?
 - How easy is it to reverse engineer PM inventions?
 - Are regulatory barriers sufficient?
 - Should we have data rights protection as in Europe instead of or in conjunction with patents?
 - Will patients be hurt or helped by allowing patents of the type at issue in *Prometheus* and *Myriad* to be deemed eligible for patent protection?
- Will Supreme Court *Prometheus* decision dramatically change the law or just set forth broad, general principles for lower courts to work out?
- Should the Supreme Court make dramatic changes in what qualifies as patentable subject matter given:
 - Congress did not address in AIA, Patent Reform Act of 2011?
 - In 1996, Congress dealt with this issue by eliminating liability for doctors and other health care providers in 35 U.S.C. § 287(c)(1)?
- Are court cases/amicus briefs the best way to make patent policy
 - Is legislation any better?

Gene and Method Patents: Review of Court Cases and the Implications for Personalized Medicine

Contact Info.

**Richard S. Meyer, Partner, Kilpatrick Townsend & Stockton LLP,
rmeyer@kilpatricktownsend.com**

**Sandra Park, Staff Attorney, ACLU Womens Rights Project,
spark@aclu.org, www.aclu.org/brca**

**David Resnick, Partner, Co-Leader, Patents, Nixon Peabody LLP,
dresnick@nixonpeabody.com**