

The Gene Patent Controversy: Is It Over?



William Golden
Kelley Drye & Warren LLP

Constitutional Dimensions of Patent Protection

Patent Clause:

Authorized Patents to Promote the “Progress of Science and useful Arts.”

U.S. Const. Art. I, § 8, cl. 8

First Amendment:

Protects “freedom of thought.”

Constitutional Avoidance Doctrine:

Statute should be interpreted to avoid serious constitutional problems unless any other reasonable interpretation is plainly contrary to the intent of Congress.

Patentable Subject Matter: § 101 of Patent Act

- Section 101 provides: “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement... may obtain a patent... subject to the conditions and requirements of this title.”
- Section 101 acts as the gatekeeper of the patent system and “defines the subject matter that may be patented.” *Bilski v. Kappos*, 130 S.Ct. 3218, 3225 (2010).

Statutory Change: America Invents Act

- The America Invents Act (AIA) did not amend § 101, but provides in § 33(a):

Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism.
- A recent USPTO directive states this provision “does not change existing law or ... USPTO policy that a claim encompassing a human being is not patentable.”

Caselaw Overview - § 101

- The courts have long held that § 101 excludes laws of nature, physical phenomena, or abstract ideas from patent protection. See, e.g., *Bilski*, 130 S.Ct. at 3225.

USPTO's Policy on Gene Patents

- In 2001, the USPTO's *Utility Examination Guidelines* indicated that an isolated and purified DNA molecule may be patented as it does not occur in that isolated form in nature.
- After *Chakrabarty*, the USPTO began granting patents on genomic DNA molecules, including genes, complementary DNA molecules (*c*DNA), and useful genetic methods.

The Controversy Over the Patentability of Genes

- Change, if it is to come, must originate:
 - With Congress; or
 - With the Courts.
- Congress has traditionally left it to the courts to define the scope of § 101, so any change as to the patentability of genes will come from the courts.

The Supreme Court has never decided whether purified and isolated DNA is patent eligible.

Clashing Views on § 101 Patent Subject Matter Boundaries

- Federal Circuit:
 - Has advocated an expansive interpretation of § 101 as a “coarse eligibility filter” not the final arbiter of patentability, which is the role of other provisions of the Patent Act.
- Supreme Court:
 - While the Supreme Court is uncomfortable with scientific issues, some justices have expressed concern that the gatekeeper role of § 101 in protecting freedom of thought, best medical judgments, and the right of academic inquiry from patent monopolies has been neglected.

Supreme Court Caselaw: *Lab. Corp. Dissent*

Three justices dissenting from the dismissal of *certiorari*, opined that a process for detecting a vitamin deficiency was “an unpatentable ‘natural phenomenon.’”

- Justice Breyer’s dissent called into question the patentability of diagnostic methods involving the detection or measuring of biomarkers.
- The dissent reasoned that laws of nature are not patentable as patent protection “would impede rather than ‘promote the Progress of Science and useful Arts.’”

Lab Corp. of Am. Holdings v. Metabolite Labs, Inc., 548 U.S. 124 (2006)

Recent Change In Government's Position on Gene Patents – *Myriad Genetics* Amicus Brief

- While admitting that the denial of patent protection to “isolated” DNA is contrary to the longstanding practice of the USPTO, NIH, and other federal agencies, the Justice Department asserted that the isolated DNA segment *itself* remains, in structure and function, what it was in the human body.
- Section 101 is broad, but still requires something more than identifying and isolating what has always existed in nature, no matter how difficult or useful the discovery.

Recent Change In Government's Position on Gene Patents – *Myriad Genetics* Amicus Brief

- “Isolated” DNA, without further alteration or manipulation, is not patent eligible. It is not patent eligible merely because of utility or the substantial investment made in its discovery.
- The chemical structure of native human genes is a product of nature, and remains a product of nature when “isolated” from its natural environment.

Federal Circuit Caselaw: *Prometheus I* Decision

The Federal Circuit applied the *Bilski* “machine or transformation” test to a method of calibrating the proper dosage of a drug for treating a gastrointestinal disease, deciding:

- Though certain method claims involved “mental steps” and were *per se* unpatentable, the claims as a whole met the *Bilski* criteria.
- Administering and determining dosages of a drug is necessarily *transformative*, as “drugs do not pass through the body without affecting it.” Thus the drug transforms the patient’s body chemistry for a new and useful end.

Federal Circuit Caselaw: *Prometheus II*

The Supreme Court remanded *Prometheus* for reconsideration by the Federal Circuit after handing down its *Bilski* opinion.

Federal Circuit Caselaw: *Prometheus II*

The Federal Circuit again reversed, stating that the Supreme Court's decision in *Bilski* did not require a "wholly different analysis or a different result on remand." The Court reasoned that the patents are directed to transformative methods of altering a patient's body chemistry with specific drugs, and do not "simply cover natural correlations and data-gathering steps."

Invalidity of DNA Patents

Myriad Genetics

The district court divided Myriad's claims into two categories:

- Composition claims for isolated DNA or DNA sequences.
- Method claims analyzing or comparing DNA sequences associated with a higher breast cancer risk.

Judge Sweet held both types of claim were invalid because:

- Isolated DNA claimed was not “markedly different” from native DNA.
- Isolation and analysis of DNA sequences is a data-gathering step, not the central focus of the claimed diagnostic method.

Ass'n for Molecular Pathology v. US PTO, 2010 WL 1233416 (S.D.N.Y. Apr. 5, 2010)
 (“Myriad Genetics”)

Federal Circuit Reversal

Myriad Genetics

Judge Lourie for the Court:

- “Cleaving” DNA out of its natural chromosomal environment makes it fundamentally different from DNA as it occurs in nature, and thus patent eligible.
 - Removing DNA from its natural environment breaks covalent bonds, altering its “chemical identity.”
 - “Cleaved” DNA is thus chemically unique as compared with native DNA.

Federal Circuit *Myriad Genetics* Decision

Judge Moore's concurrence:

- Both structure and function play a role in patentability.
 - Not certain that full-length isolated genes have enough new utility/identity to be patentable, but based on US PTO's practice of granting gene patents, decided genes are patent eligible.
 - Did not wish to upset 30 years of “settled expectations and extensive property rights”.

Federal Circuit *Myriad Genetics* Decision

Judge Bryson's dissent:

- No difference between isolated/cleaved genes and native genes—the only material changes are those “incidental to the extraction of genes,” which is not enough to make them patentable.
 - No “magic chemical bond” that – when broken – makes something patentable.
 - Genetic coding material is the same “structurally and functionally, in both the native gene and the isolated form of the gene.”

Federal Circuit *Myriad Genetics* Decision Divergent Approaches

Necessary Human Intervention

Judges' Views

Purification Alone

Judge Moore – Mere purification not enough

Judge Lourie – Purification merely makes pure what was previously the same material so not enough

Judge Bryson – Purification not enough

Purification and Isolation

Judge Lourie – Isolated DNA molecules are “chemically cleaved” so patent eligible

Judge Moore – Historical background makes full-length genes patentable, and gene fragments are patentable because they are chemically unique

Judge Bryson – Isolated DNA is not patent eligible. There is no magic to chemical bonds

Will the Supreme Court Act on *Myriad Genetics*?

- The Supreme Court granted *certiorari* in *Prometheus II* and heard oral argument in December.
- The ACLU filed a petition for *certiorari* in *Myriad Genetics* with the Supreme Court in December.
- Although *certiorari* is rarely granted, many commentators believe that the Supreme Court will take and decide the *Myriad Genetics* case.

Predicting the Supreme Court's Action

Recommendations of the Solicitor General:

- Over the past 20 years, the U.S. Government's recommendations in briefs filed with the Supreme Court often correctly predict the eventual outcome.
- *Amicus* briefs otherwise have had little or no impact on the Supreme Court in patent cases.
 - C. Chien, "Patent *Amicus* Briefs: What the Court's Friends Can Teach Us About the Patent System," Santa Clara University Research Paper (unpublished).

Conclusion

If the Supreme Court grants *certiorari* and does decide the *Myriad Genetics* case, the controversy over gene patents may be over, at least for now.