

CLASS 23

THE SUBJECT MATTER OF PATENTS

PATENT LAW & POLICY
PROFESSOR WAGNER



Today's Agenda

Overview of Subject Matter Limits

Patenting Life

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Overview of Subject Matter Limits

The Standards for Patentability

A valid patent must be . . .

- Fully and appropriately described (§ 112)
- In compliance with statutory bars (§ 102)
- Novel (§ 102)
- Nonobvious (§ 103)
- The work of the inventors (§ 116)
- Useful (§ 101)
- Within the appropriate subject matter (§ 101)

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Categories of Subject Matter Limitations

Products of Nature / Living Things

Living Organisms

Naturally-Occurring Products

Mathematical Algorithms

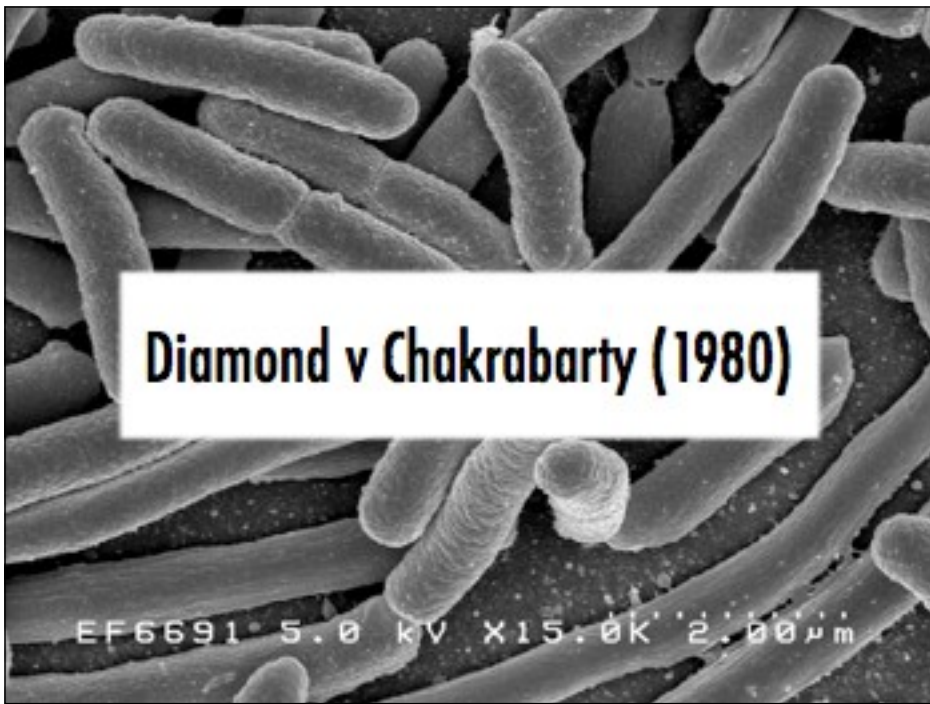
Abstract Ideas

Computer Software?

Business Models?

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Patenting Life



Diamond v Chakrabarty (1980)

Claims at issue:

- 1) Process of producing a bacterial organism
- 2) Method of using a bacterial organism
- 3) The bacterial organism

Why does the examiner allow 1 & 2, but not 3?

Does it have any real effect on the scope of coverage?



Diamond v Chakrabarty (1980)

The Section 101 categories:
“process, machine, manufacture, or
composition of matter”

Why doesn't the claim fall clearly within
these categories?

What is the “real” issue here?



Diamond v Chakrabarty (1980)

What is the “rule” of Chakrabarty?

Can you patent living things?

What living things?



Diamond v Chakrabarty (1980)

The relevant legislative history also supports a broad construction. The Patent Act of 1790, authored by Thomas Jefferson, defined statutory subject matter as "any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement [thereof]." Act of Feb. 21, 1790, § 1, 1 Stat. 328. The Act embodied Jefferson's philosophy that "ingenuity should receive a liberal encouragement." 15 Writings of Thomas Jefferson 75-76 (Washington ed. 1871). See *Graham v. John Deere Co.*, 383 U.S. 1, 7-10, 86 S.Ct. 684, 693-696, 15 L.Ed.2d 545 (1966). Subsequent patent statutes in 1800, 1870, and 1874 employed this same broad language. In 1952, when the patent laws were recodified, Congress replaced the word "art" with "process," but otherwise left Jefferson's lan-

2d Sess., 5 (1952); H.R.Rep.No.1923, 82d Cong., 2d Sess., 6 (1952).⁴



Diamond v Chakrabarty (1980)

[1.2] This is not to suggest that § 101 has no limits or that it embraces every discovery. The laws of nature, physical phenomena, and abstract ideas have been held not patentable. See *Parker v. Flook*, 437 U.S. 584, 98 S.Ct. 2522, 57 L.Ed.2d 451 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 67, 93 S.Ct. 253, 255, 34 L.Ed.2d 273 (1972); *Pink Brothers Seed Co. v. Otto Inconstant Co.*, 330 U.S. 127, 130, 68 S.Ct. 443, 441, 92 L.Ed. 588 (1948); *O'Reilly v. Morse*, 15 How. 62, 112-121, 14 L.Ed. 601 (1854); *Le Roy v. Fathall*, 14 How. 156, 175, 14 L.Ed. 367 (1850). Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$, nor could Newton have patented the law of gravity. Such discoveries are "manifestations of . . . nature, free to all men and reserved exclusively to none." *Pink*, *supra*, 330 U.S. at 130, 68 S.Ct. at 441.



Discovery vs. Invention

Chakrabarty:

Discovery \neq Patentability

Invention = Patentability

Why impose this distinction?

If I spend \$100M to discover a naturally-occurring product that cures cancer, have I benefited society less than if I had spent \$100M to invent a synthetic product with the same properties?

Discovery vs. Invention

Won't a denial of patentability for "products of nature" destroy a promising part of the biotech industry? (Aren't many modern biotechnologies new uses for already-existing natural materials?) What about advances in genetics and "targeted" therapies? How are DNA patents legitimate?

Discovery vs. Invention

Parke-Davis (SDNY 1911)

Claim: An "isolated and purified" version of material in adrenal glands. ("Insulin").

Is this patentable? How?

Isn't it invalid in light of the natural product?

Doesn't it run afoul of the "natural products" restriction?

Discovery vs. Invention

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Can you reconcile Chakrabarty and Parke-Davis?

What do these holdings suggest about biotech patenting?

Challenges to Biotech Patenting

The Discovery/Invention Distinction
[Does this distinction have any real meaning?]

Challenges to Biotech Patenting

Ownership Issues
[If we are going to allow patenting of pseudo-products-of-nature, how should we deal with (international) ownership issues?]

Challenges to Biotech Patenting

The Patenting of More Complex Organisms

[What does the Chakrabarty / Parke-Davis framework suggest about patenting chimeras, clones, etc?]

Chakrabarty is the Supreme Court's latest word on biotech patentability.

In OT 2005, the Court granted cert. in Labcorp v. Metabolite

claim element: "correlate test results"

later, cert. dismissed, with a long dissent by Breyer (with Stevens & Souter)

**Ass'n for Molecular Pathology v. USPTO
(Myriad)**

Claims at Issue

Composition Claims to BRCA1/2 Genes

Method of screening for cancer therapeutics.

Methods "comparing" or "analyzing" DNA sequences.

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What does the dispute between
the majority and the dissent turn on?

Who has the better argument?

[How does the majority respond to the over-breadth argument?]

Myriad and Patent Policy

The Myriad patent claims appear to have very substantial impact in the marketplace for testing / therapeutic screening.

Is this okay?

Is Section 101 the appropriate vehicle for these concerns?

NEXT CLASS

**THE SUBJECT MATTER OF PATENTS II:
BUSINESS MODELS & SOFTWARE**

**PATENT LAW & POLICY
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