

PATENTABLE SUBJECT MATTER & PATENT POLICY

INTRODUCTION TO INTELLECTUAL PROPERTY LAW & POLICY PROFESSOR WAGNER



Lecture Agenda

An Overview of Subject Matter Limits Patenting Life Patenting Algorithms

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 (\S 102)
- Nonobvious (§ 103)
- The work of the inventors (\S 116)
- Useful (§ 101)
- Within the appropriate subject matter (§ 101)

35 U.S.C § 101 - Inventions patentable

The Utility Requirement

35 U.S.C § 101 - Inventions patentable

The Subject Matter Requirement

35 U.S.C § 101 - Inventions patentable

Categories of Subject Matter Limitations

"Laws of Nature"

Gravity

Relativity

Categories of Subject Matter Limitations

"Laws of Nature"

Gravity

Living Organisms

Relativity

"Natural Phenomonena"

Naturally-Occurring Products

Categories of Subject Matter Limitations

"Laws of Nature"

Gravity

Relativity

"Natural Phenomonena"

Living Organisms

"Abstract Ideas"

Mathematical Algorithms

Naturally-Occurring Products

Computer Software(?)

Business Models(?)

35 U.S.C § 101 - Inventions patentable

There isn't clear support in the statute for the limits on subject matter!

Subject Matter Limitations are a key "policy lever" developed by the Courts.

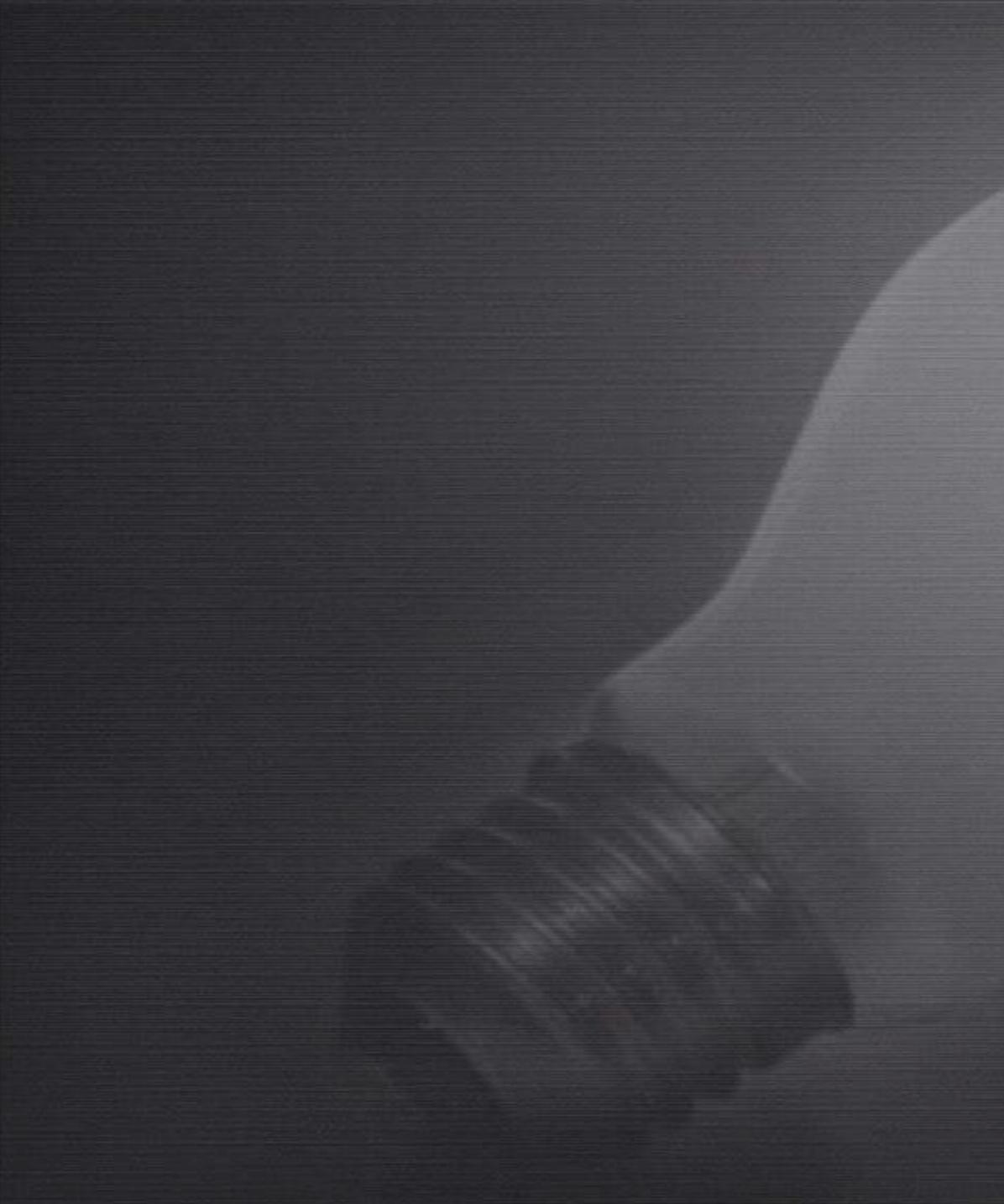
Subject Matter Limitations are a key "policy lever" developed by the Courts.

The other standards for validity operate on an invention-byinvention basis; Subject Matter Limitations operate on entire categories of inventions.

Subject Matter Limitations are a key "policy lever" developed by the Courts.

The other standards for validity operate on an invention-byinvention basis; Subject Matter Limitations operate on entire categories of inventions.

By design, they are flexible and adaptable. This also means unclear and uncertain!



"Natural Phenomonena"

EF6691 5.0 kV X15.0k'2.00Pm



Man-made bacterial organism with applications for cleaning oil spills.



Claims at issue:

- Process of producing the bacterial organism 1.
- Method of using the bacterial organism 2.
- The bacterial organism itself 3.



Claims at issue:

Process of producing the bacterial organism 1. Method of using the bacterial organism 2. The bacterial organism itself 3.

The Patent examiner allowed claims 1 & 2, but not 3.



35 U.S.C § 101 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 A bacterial organism clearly falls within the "composition of matter" category.

And yet the examiner rejected the claim...

On a 5-4 vote, the Court finds the claim to the organism valid.

Reasoning: this bacteria was not naturallyoccurring, and thus not subject to the "natural phenomena" limitation.



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

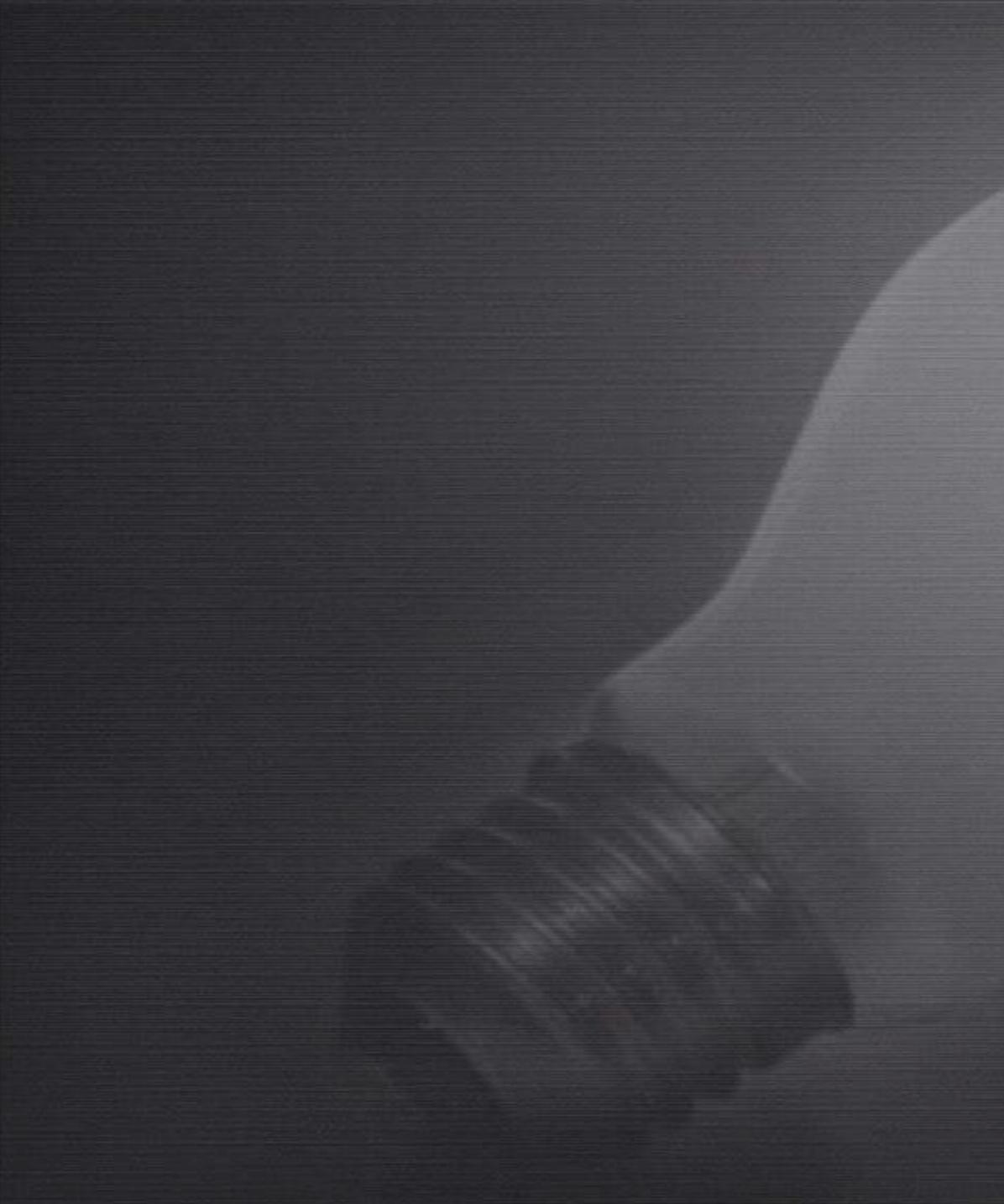
Chakrabarty: Discovery ≠ Patentability ... but ... Invention = Patentability

Why impose this distinction?

We want to encourage new knowledge, not exploitation of existing knowledge. We suspect that many 'discoveries' may not really be 'new' anyway.

Discovery vs. Invention

Chakrabarty: Discovery ≠ Patentability ... but ... Invention = Patentability



Held: patentable. Not a "natural phenomena" because it was isolated and purified.

Parke-Davis (SDNY 1911) Claim: An "isolated and purified" version of material in adrenal glands. ("Insulin").

<u>Chakrabarty</u>

Non-natural organisms are patentable.

Parke-Davis

"Isolated and purified" versions of natural products ands nonnatural

(Almost) anything in the biological area becomes patentable

A boom in the bio industry?

Overpatenting of nature?



By the early 2010s, tens of thousands of patents on segments of human DNA had been granted, with many more in the pipeline.

These were 'isolated and purified' versions of naturally-occuring DNA.

Myriad obtained a patent on BRCA1 and BRCA2 genes. These genes had been found through (extensive) research to be associated with likelihood of cancer, especially breast cancer in women.

Myriad sells testing using the BRCA1/BRCA2 genetic information allowing for screening for these genes (and thus propensity for cancer).

Because of the patent, Myriad is the only provider. The costs of testing are much higher and the availability is lower.







AMP (and many others) sue Myriad, arguing that the patent claims to the BRCA1/BRCA2 genes are unpatentable "natural phenomena" and thus invalid



Assn of Molecular Pathologies v Myriad (2013) "Isolated DNA" versus "cDNA"

1. An isolated DNA coding for a BRCA1 polypeptide ... which has the amino acid sequence ... [DNA sequence typical of BRCA1]

2. An isolated DNA coding for a BRCA1 polypeptide ... which has the amino acid sequence ... [cDNA sequence typical of BRCA1]

"Isolated DNA" versus "cDNA" { According to the Supreme Court }

solated DNA sequences do exist in nature (<u>except</u> that the chemical bonds between the ends of the sequence and the rest of the genome are broken).

cDNA is synthetic: it is (typically) created in the lab, and while it performs functionally the same as natural DNA, it does not include certain non-coding nucleotides, and thus is not the same as DNA that occurs in the body.





1. Myriad's invention is unlike Chakrabarty's: there the bacterium was not natural, and had "markedly different characteristics" from natural products. 2. Here Myriad's invention does not alter the nature or function of the natural DNA.

The Supreme Court's Analysis

The Supreme Court's Analysis

The Court upholds the validity of the cDNA claims: although the function is dictated by nature, they are manmade materials and thus patentable!

... but ...

The Supreme Court's Analysis

The Court upholds the validity of the cDNA claims: although the function is dictated by nature, they are manmade materials and thus patentable!

A footnote: if cDNA claims happen to be naturally-occurring, then they are likely unpatentable.

... but ...

Clearly, isolated (and purified?) natural materials are not, themselves, patentable. 1.

What is Patentable?

Basic rule: man-made materials are patentable, naturally-occurring materials are not.

Basic rule: man-made materials are patentable, naturally-occurring materials are not.

Clearly, isolated (and purified?) natural materials are not, themselves, patentable. AN Man-made mixtures/combinations of natural materials may not be enough; A look to "distinct 2. characteristics"? Or the "process of invention"?

What is Patentable?

1.

- Man-made mixtures/combinations of natural materials may not be enough; A look to "distinct 2. characteristics"? Or the "process of invention"?
- However: The holding on cDNA shows that the differences between natural and man-made need not 3. be large (or even functionally significant).

What is Patentable?

- Basic rule: man-made materials are patentable, naturally-occurring materials are not.
- Clearly, isolated (and purified?) natural materials are not, themselves, patentable.

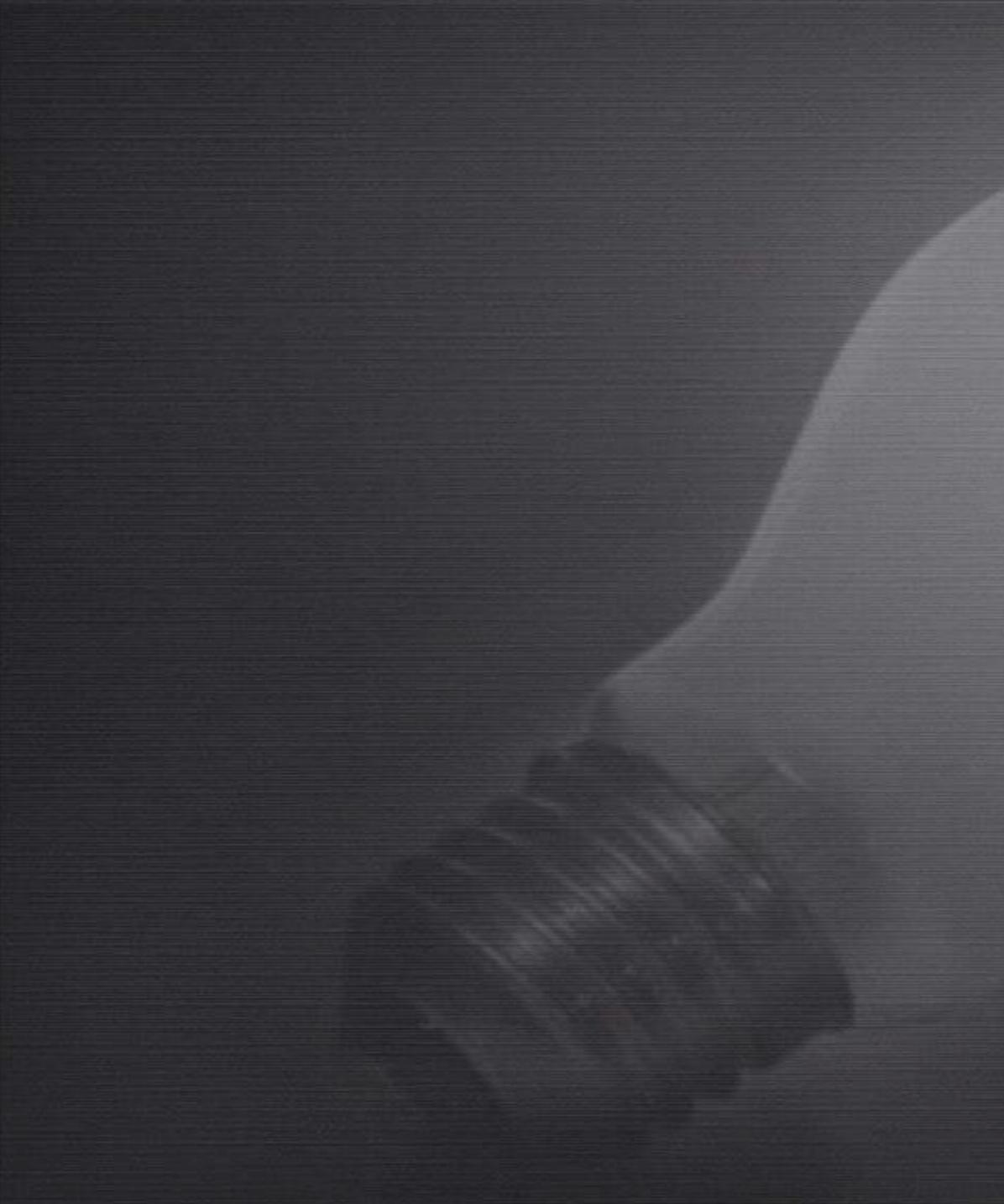


Basic rule: man-made materials are patentable, naturally-occurring materials are not.

Is the rule of <u>Myriad</u> just a form of $\S 102$ (Novelty) analysis?

... and if so, then is the "natural phenomena" limitation the right vehicle to express this concern? Why not analyze each claim for novelty instead?

What is Patentable?



"Abstract Ideas"

Categories of Subject Matter Limitations

"Laws of Nature"

Gravity

Relativity

"Natural Phenomonena"

Living Organisms

"Abstract Ideas"

Mathematical Algorithms

Naturally-Occurring Products

Computer Software(?)

Business Models(?)

The Jurisprudential Evolution of the 'Abstract Ideas' Limitation



Diamond v. Diehr

1980

In re Alappat

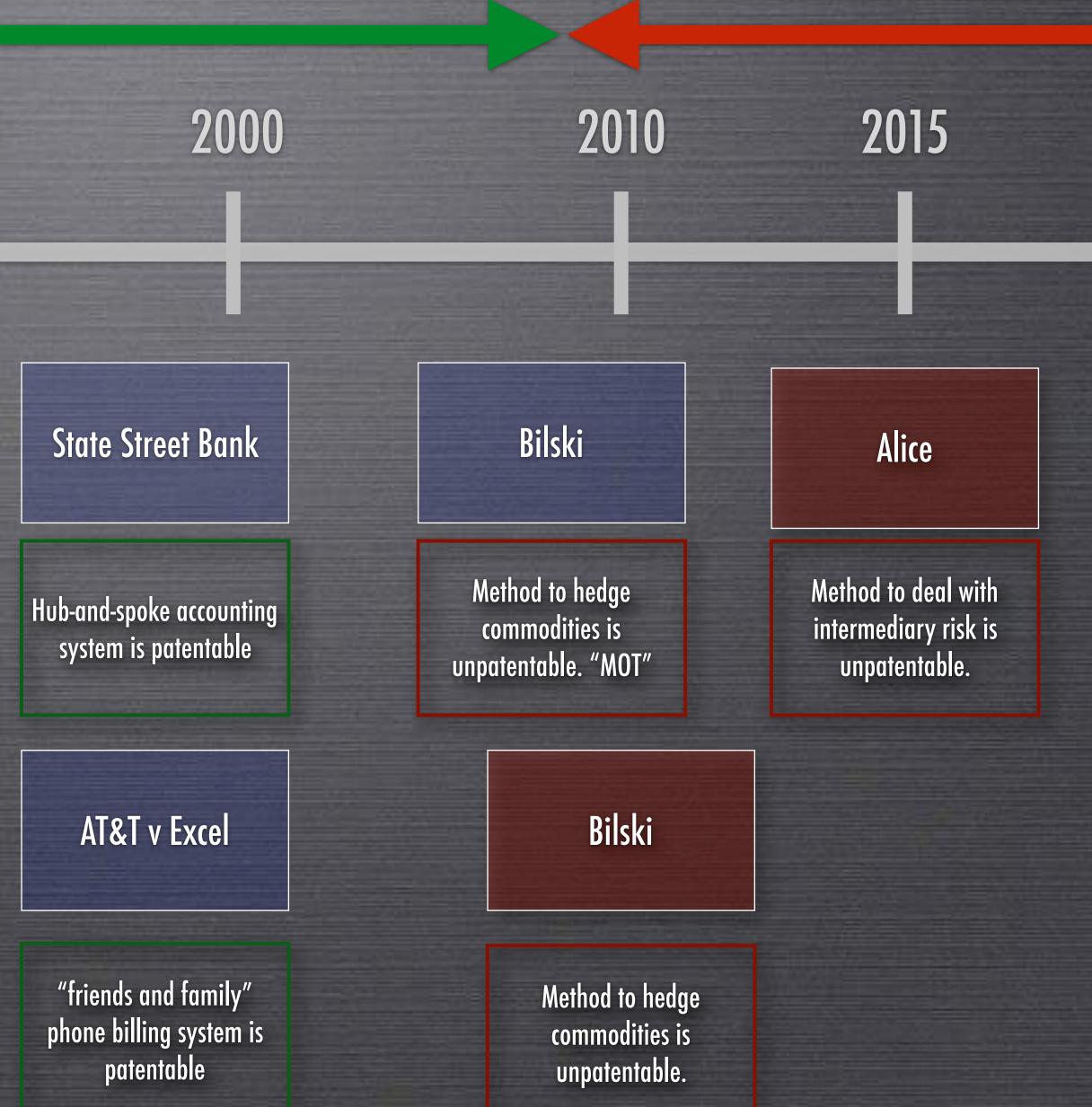
1990

Method to convert decimals <-- binary-coded decimals unpatentable. Method to cure rubber using equation is patentable Machine using antialiasing algorithms is patentable

Supreme Court

1970

Federal Circuit





Bilski v Kappos (USSC 2010)

(Slip Opinion)

OCTOBER TERM, 2009

Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See United States v. Detroit Timber & Lumber Co., 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

BILSKI ET AL. v. KAPPOS, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR, PATENT AND TRADEMARK OFFICE

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

No. 08–964. Argued November 9, 2009—Decided June 28, 2010

Petitioners' patent application seeks protection for a claimed invention that explains how commodities buyers and sellers in the energy market can protect, or hedge, against the risk of price changes. The key claims are claim 1, which describes a series of steps instructing how to hedge risk, and claim 4, which places the claim 1 concept into a simple mathematical formula. The remaining claims explain how claims 1 and 4 can be applied to allow energy suppliers and consumers to minimize the risks resulting from fluctuations in market demand. The patent examiner rejected the application on the grounds that the invention is not implemented on a specific apparatus, merely manipulates an abstract idea, and solves a purely mathematical problem. The Board of Patent Appeals and Interferences agreed and affirmed. The Federal Circuit, in turn, affirmed. The en banc court rejected its prior test for determining whether a claimed invention was a patentable "process" under Patent Act, 35 U.S.C. §101-i.e., whether the invention produced a "useful, concrete, and tangible result," see, e.g., State Street Bank & Trust Co v. Signature Financial Group, Inc., 149 F. 3d 1368, 1373-holding instead that a claimed process is patent eligible if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing. Concluding that this "machine-or-transformation test" is the sole test for determining patent eligibility of a "process" under §101, the court applied the test and held that the application was not patent eligible.

Held: The judgment is affirmed.

Claims directed to a method of hedging risk in a commodity.

Unclear whether the method was novel under $\S102$.

Federal Circuit: unpatentable because "neither a machine nor a transformation."



Bilski's claims are unpatentable abstract ideas

MOT test is not the "exclusive test," but a useful and important clue

MOT test may not be useful for "inventions in the information age," (though no suggestion for the correct test)

Business methods are not categorically excluded from patentability

The Federal Circuit <u>could</u> craft rules that exclude most / many business methods









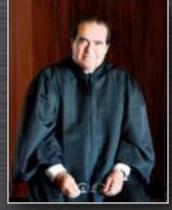




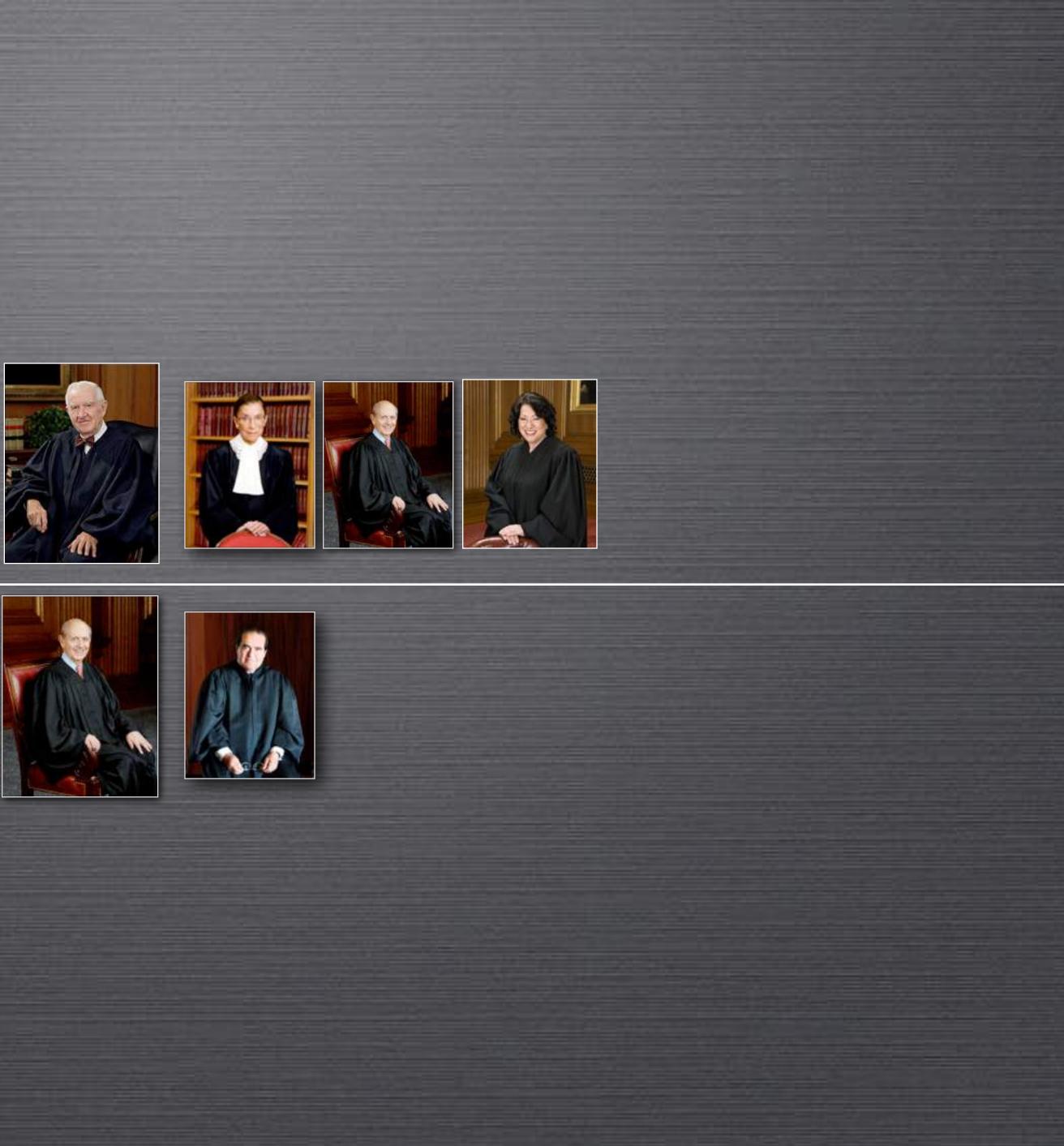






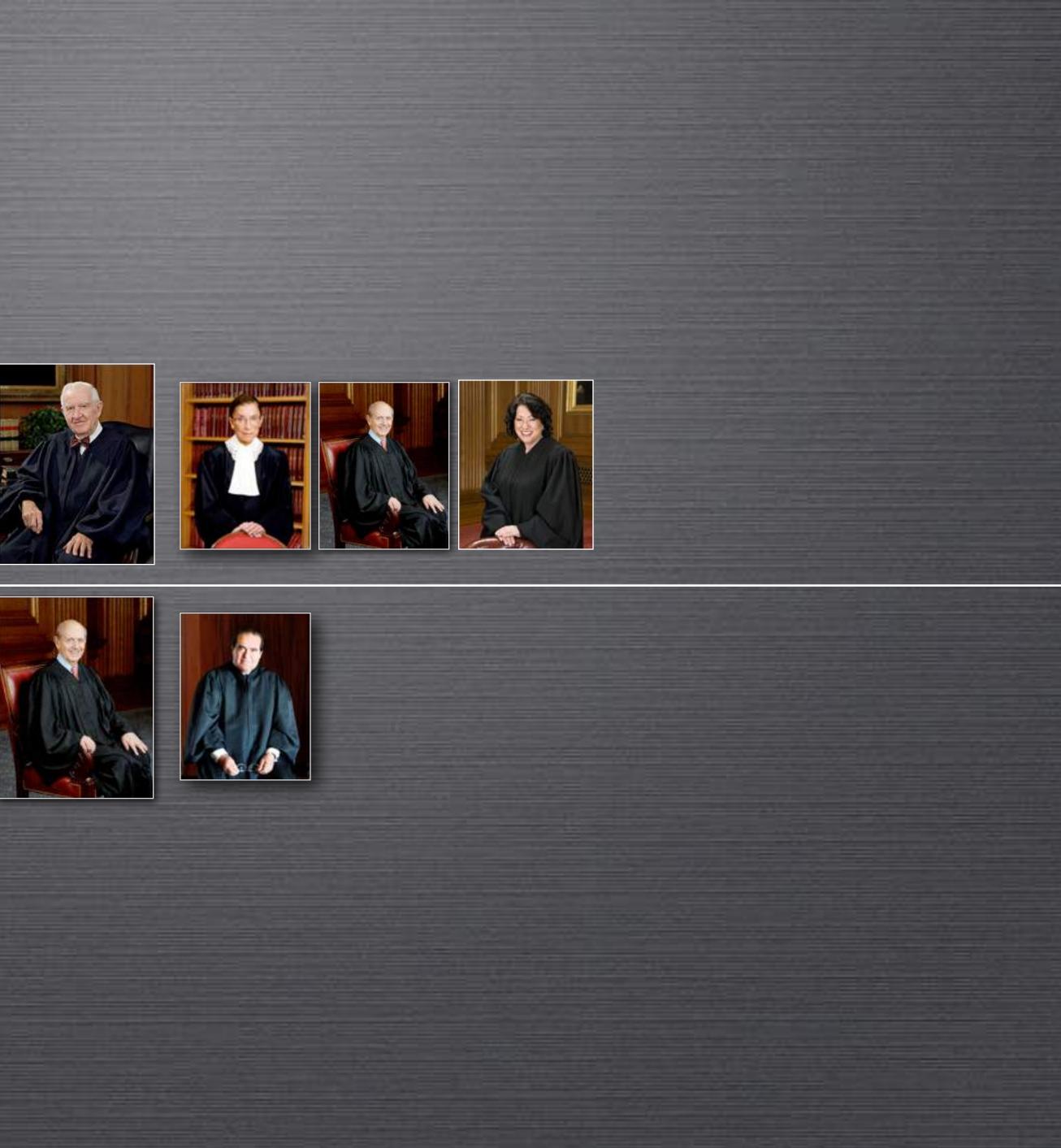






Methods of doing business are <u>not</u> patentable subject matter

MOT test is not the "exclusive test," but not many processes lie beyond its reach



Why are the claims unpatentable?

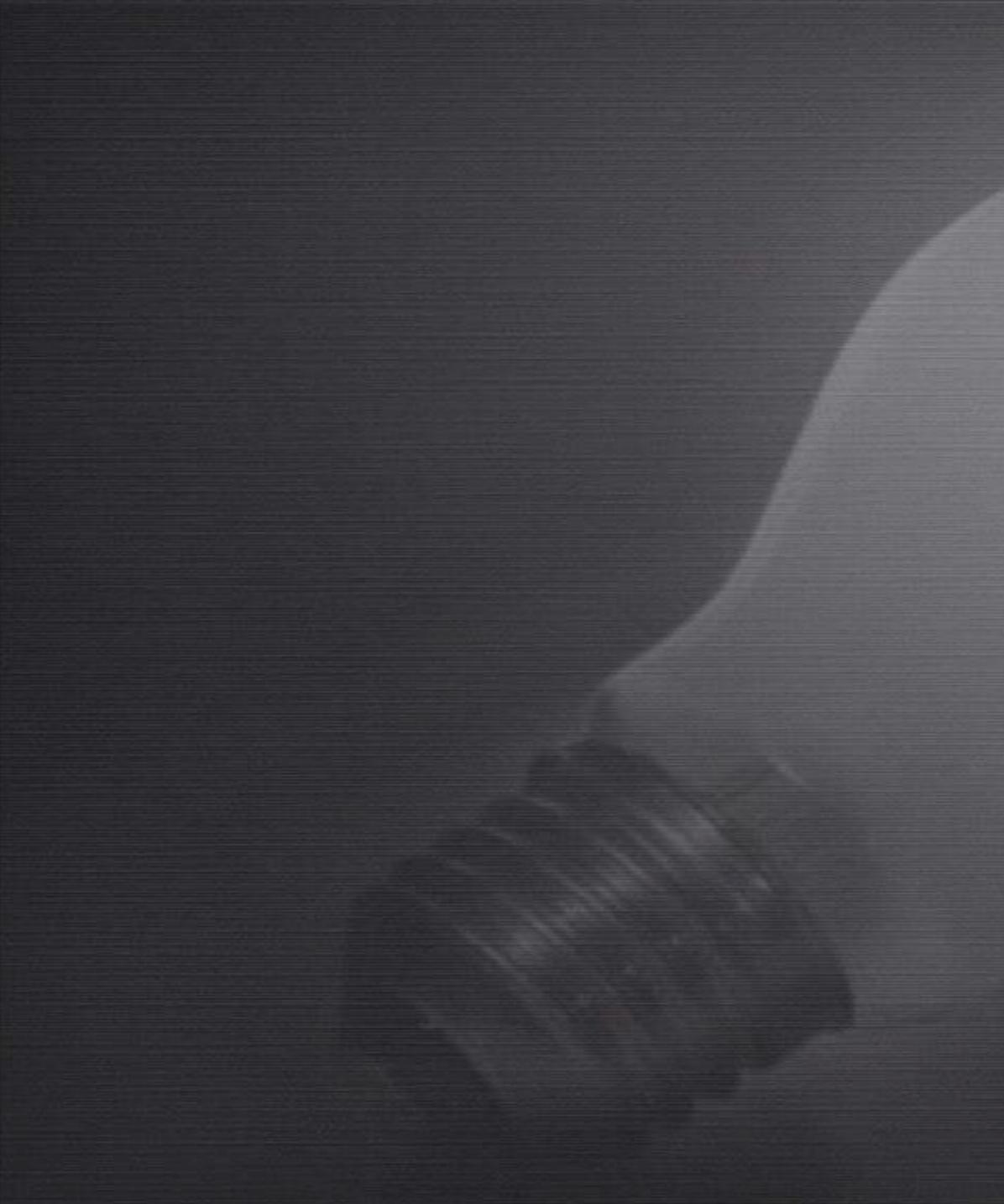
"Hedging is a fundamental economic practice long prevalent in our system of commerce and taught in any introductory finance class."

"Allowing patents on risk hedging would pre-empt use of this approach in all fields, and would effectively grant a monopoly over an abstract idea."

After Bilski: Confusion

Many courts and the USPTO relied heavily on the "machine or transformation" test, even though the <u>Bilski</u> opinion said it was not the exclusive test.

Still many patents on "algorithms" upheld: for example software patents, not involving non-novel concepts (i.e., risk hedging) or limited to computers.



Alice v CLS Bank (USSC 2014)

(Slip Opinion)

OCTOBER TERM, 2013

Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See United States v. Detroit Timber & Lumber Co., 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

ALICE CORPORATION PTY. LTD. v. CLS BANK INTERNATIONAL ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

No. 13–298. Argued March 31, 2014—Decided June 19, 2014

Petitioner Alice Corporation is the assignee of several patents that disclose a scheme for mitigating "settlement risk," *i.e.*, the risk that only one party to an agreed-upon financial exchange will satisfy its obligation. In particular, the patent claims are designed to facilitate the exchange of financial obligations between two parties by using a computer system as a third-party intermediary. The patents in suit claim (1) a method for exchanging financial obligations, (2) a computer system configured to carry out the method for exchanging obligations, and (3) a computer-readable medium containing program code for performing the method of exchanging obligations.

Respondents (together, CLS Bank), who operate a global network that facilitates currency transactions, filed suit against petitioner, arguing that the patent claims at issue are invalid, unenforceable, or not infringed. Petitioner counterclaimed, alleging infringement. After Bilski v. Kappos, 561 U.S. 593, was decided, the District Court held that all of the claims were ineligible for patent protection under 35 U.S.C. §101 because they are directed to an abstract idea. The en banc Federal Circuit affirmed.

Held: Because the claims are drawn to a patent-ineligible abstract idea, they are not patent eligible under §101. Pp. 5–17.

(a) The Court has long held that §101, which defines the subject matter eligible for patent protection, contains an implicit exception for "[l]aws of nature, natural phenomena, and abstract ideas." Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S.

____, ____. In applying the §101 exception, this Court must distinguish patents that claim the "'buildin[g] block[s]'" of human ingenuity, which are ineligible for patent protection, from those that integrate

Claims directed to a method of addressing counterparty risk in financial transactions, using a trusted intermediary.

Unclear whether the method was novel under $\S102$. Federal Circuit: unpatentable, but barely (and split)





The (New) Framework for 'Abstract Ideas'

Step 1: Are the claims directed to an "abstract idea"? Step 2: if so, "what more is in the claims" to avoid the limitation?

Alice Step 1: Is this an abstract idea?

- The Court answers 'yes': the idea of the claims is 'intermediated settlement'.
- How do you know which claims are "abstract" and which are not?
- The Court says: "on their face, the claims before us are drawn to the concept of intermediated settlement, i.e., the use of a third party to mitigate settlement risk.... [T]he concept of intermediated settlement is a fundamental economic practice long prevalent in our system of commerce."



Alice Step 1: Is this an abstract idea?

The Court answers 'yes': the idea of the claims is 'intermediated settlement'.

The Court says: "on their face, the claims before us are drawn to the concept of intermediated settlement, i.e., the use of a third party to mitigate settlement risk.... [T]he concept of intermediated settlement is a fundamental economic practice long prevalent in our system of commerce."

How do you know which claims are "abstract" and which are not?

Novelty? Or analogy (to <u>Bilski</u>)?



Alice Step 2: "What Else is There"?

Here the Court says that "generic computer implementation" does not "transform" the claims into patentable subject matter.

Flook

adding conventional computer-implei steps known in the art is not enou



adding conventional measuring steps known in the art is not enough

unpatentable

unpatentable

What else is required?

Benson



emented	adding computer-implemented steps is not	the addi
ough	enough	measuren

ition of a thermocouple to record ments was an inventive application of the idea

unpatentable

patentable



Alice Step 2: "What Else is There"?

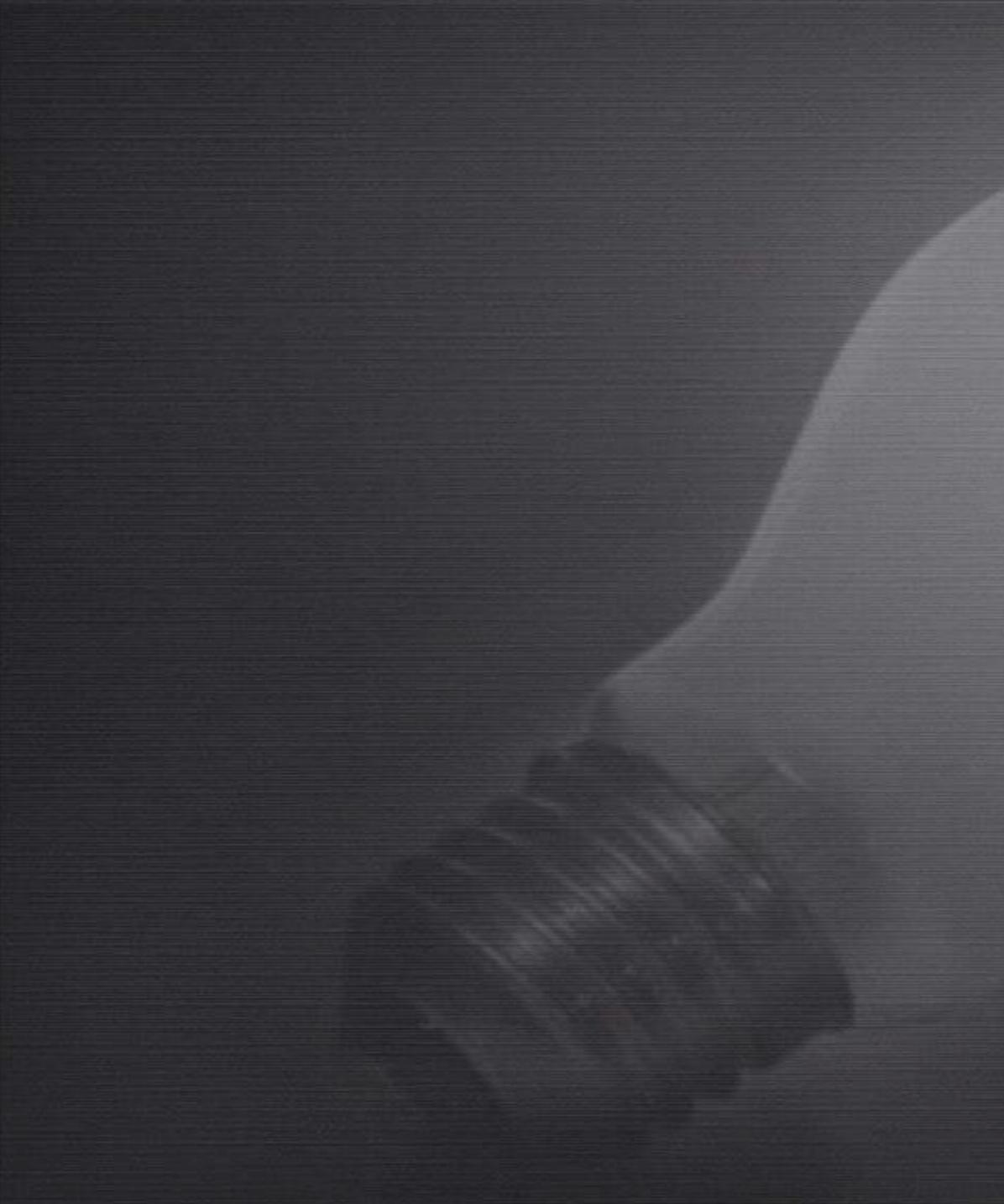
Does this mean that all software-based patent claims are invalid!?

Unclear. Software methods that are either "new" (Step 1) or involve an "inventive application" of the method (Step 2) are seemingly okay.

- Here the Court says that "generic computer implementation" does not "transform" the claims into patentable subject matter.
 - What else is required?







Step 1 is a focus on "have we seen this before" / analogy / (maybe) novelty.

The Abstract Ideas Limitation

Bilski seems to have been bypassed.

Step 2 is focused on something more: "inventiveness"?

The Convergence of Patentable Subject Matter Limits

The Supreme Court seems mostly concerned with

The <u>newness</u> of the category of subject matter.

The breadth of the resulting patents in that category.

The Convergence of Patentable Subject Matter Limits <u>Myriad</u> (2013)

A focus on the man-made versus natural distinction.

<u>Alice</u> (2014)

A focus on the "newness" versus "old" distinction.

An analysis of what more the invention does.

Ongoing Questions about Subject Matter Limitations

If Subject Matter Limitations are simply about policy, what, exactly, is the policy concern? (And ... might these concerns be better addressed invention—by-invention?)

Ongoing Questions about Subject Matter Limitations

If Subject Matter Limitations are simply about policy, what, exactly, is the policy concern? (And ... might these concerns be better addressed invention-by-invention?)

Are the courts (the Supreme Court) the right institution to make these policy decisions?