The Fourth Annual Stoel Rives IP Seminar Series

Bilski Round Two

What Is Patentable in Light of the Supreme Court's Recent Decision?

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Seminar 5 • Thursday, November 18, 2010

Overview

I. Review
- State of law before *In re Bilski*
- *In re Bilski* (Fed. Cir.)

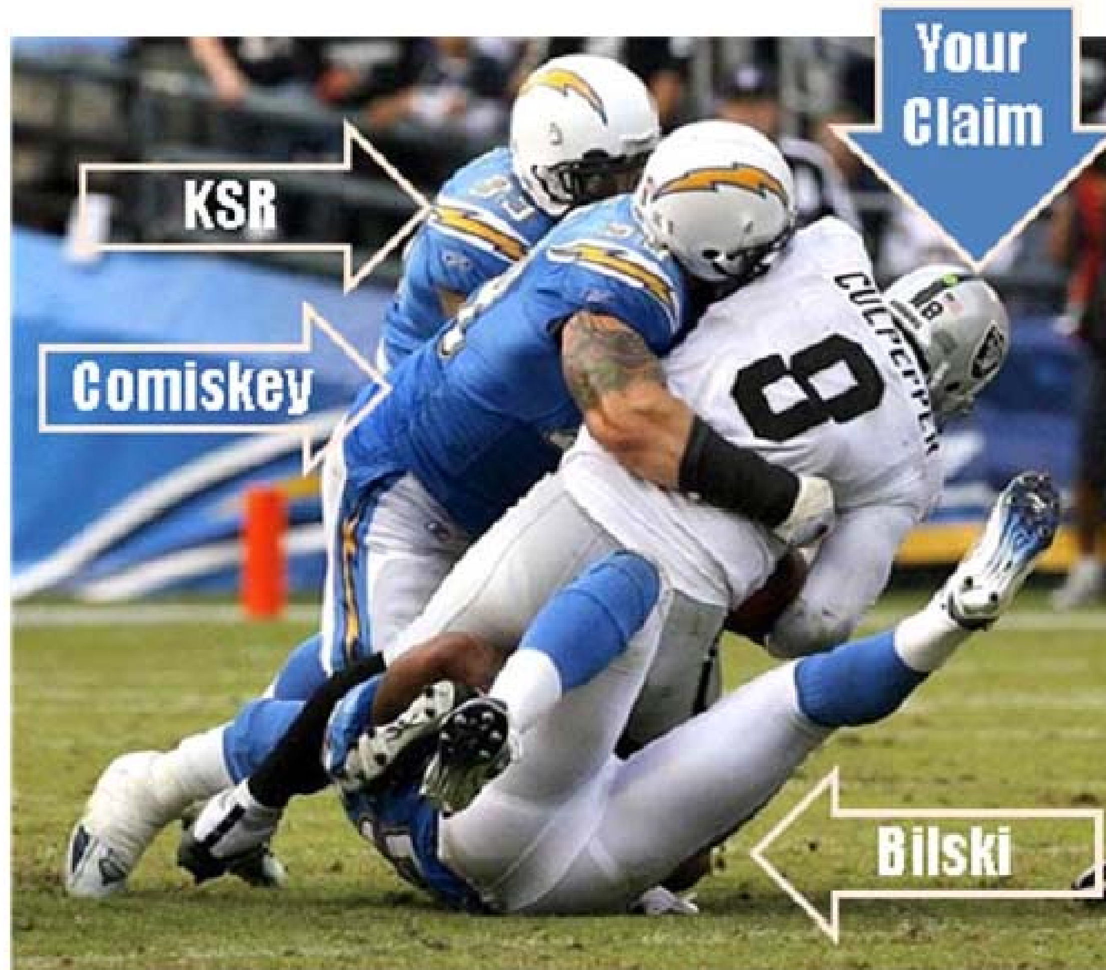
II. Analyze *Bilski v. Kappos* (Supreme Ct.)

III. Impact of *Bilski* - practical application
- Machine-or-transformation test
- Medical treatment and diagnostic methods

Increasing Challenges for Software, Business Methods and Medical Diagnostics Inventions

- *KSR* - routine creativity and innovation not patentable
- *Comiskey* - routine addition of modern electronics to an otherwise unpatentable invention typically is obvious
- *Bilski v. Kappos* - "Abstract" business methods not patentable
- *Prometheus Labs* – Medical diagnostics?

Recent Changes in Patent Law



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How This Presentation Has Evolved

2006: Unabashedly Enthusiastic

Good News for Inventors of Business Methods:

Is Anything Unpatentable After *Ex Parte Lundgren*?

What Every Business Should Know

SAVE THE DATE

September 20, 2006 > 11:30 a.m to 1 p.m. > Stoel Rives LLP

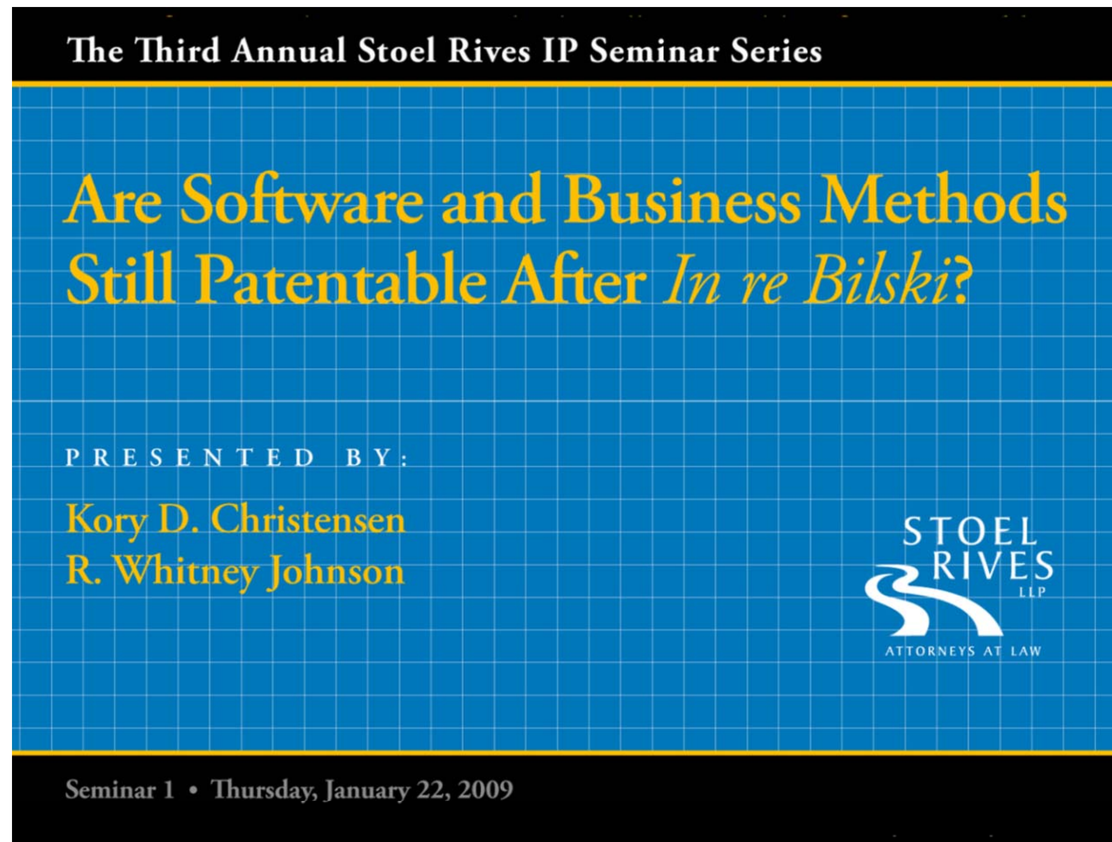
Lunch will be provided at 11:30 a.m. Presentation begins at noon.

Next Intellectual Property Series Seminar:

Trademark Traps > November 16

How This Presentation Has Evolved

2009: Guardedly Pessimistic



How This Presentation Has Evolved

Today: Cautiously Optimistic

Before *In re Bilski* – *State Street*

- Why we were so enthusiastic in 1998
- *State Street Bank & Trust Co. v. Signature Financial Group*
  - decided Jul. 23, 1998
- Invention – ***system*** for computerized mutual funds pooling - "hub and spoke" configuration

State Street Bank (cont.)

"anything under the sun made by man"

Except three categories (unpatentable subject matter)

1. laws of nature
   - $E=MC^2$
2. natural phenomena
   - electromagnetism
3. abstract ideas
   - mathematical algorithms

The *State Street* Test

"Useful, Concrete and Tangible Result" Test

- a business method is patentable if it produces a "useful, concrete and tangible result"
  - encompasses most business methods

The *State Street* Court Holding

"the transformation of data, representing discrete dollar amounts, by a machine . . . into a final share price, [is patentable], because it produces 'a useful, concrete and tangible result' …."

The concrete, tangible result is "a final share price momentarily fixed . . . and relied upon by regulatory authorities and in subsequent trades."

In re Bilski - CAFC

- Decided October 20, 2008
  - 10 years after *State Street*
- Invention - a method of hedging risks in commodities trading
  - not tied to any particular form of technology
- CAFC found claims <u>not</u> patentable

Claim at Issue in *Bilski*

1. A method for managing the consumption risk costs of a commodity sold by a commodity provider at a fixed price comprising the steps of:

(a) **initiating a series of transactions** between said commodity provider and consumers of said commodity wherein said consumers purchase said commodity at a fixed rate based upon historical averages, said fixed rate corresponding to a risk position of said consumer;

(b) **identifying market participants** for said commodity having a counter-risk position to said consumers; and

(c) **initiating a series of transactions** between said commodity provider and said market participants at a second fixed rate such that said series of market participant transactions balances the risk position of said series of consumer transactions.

Test for Patent Eligibility per *Bilski*

- "Machine-or-Transformation" Test
  - sole test of subject matter eligibility for a process

- "A claimed process is surely patent-eligible under §101 if: (1) it is tied to a particular ***machine*** or apparatus, or (2) it ***transforms*** a particular article into a different state or thing."

Old Test Under *State Street Is* Out

- "[W]e also conclude that the 'useful, concrete and tangible result' inquiry is inadequate and reaffirm that the machine-or-transformation test outlined by the Supreme Court is the proper test to apply."

Basic Premise (Underlying Policy)

"Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work."

In re Bilski (citing *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972))

Bilski v. Kappos (Round Two)

- Supreme Court
  - Affirmed the judgment of the CAFC
    - Bilski's claims are not patentable
  - Rejected holding of CAFC that M-or-T test is sole test for patent eligibility of processes
  - Rejected notion that business methods should be categorically excluded from patent eligibility

Bilski v. Kappos - S.C. Analysis

- "Section 101 thus specifies four independent categories of inventions or discoveries that are eligible for protection."
  - processes
  - machines
  - manufactures
  - compositions of matter

Bilski v. Kappos - S.C. Analysis *(cont.)*

- "In choosing such expansive terms … modified by the comprehensive 'any,' Congress plainly contempalted that the patent laws would be given wide scope."

- "The Court's precedents provide three specific exceptions . . . 'laws of nature, physical phenomena, and abstract ideas.'"

Bilski v. Kappos - S.C. Analysis *(cont.)*

Part II.B.I

- "The Court is unaware of any 'ordinary, contemporary, common meaning' of the definitional terms 'process, art or method' that would require these terms to be tied to a machine or to transformation of an article."

Bilski v. Kappos - S.C. Analysis *(cont.)*

- "[T]he machine-or-transformation test is a useful and important clue . . . for determining whether some claimed inventions are [patent eligible] processes [but] ***not the sole test***."

Bilski v. Kappos - S.C. Analysis *(cont.)*

Part II.B.2

- "Section 101's terms suggest that new technologies may call for new inquiries."

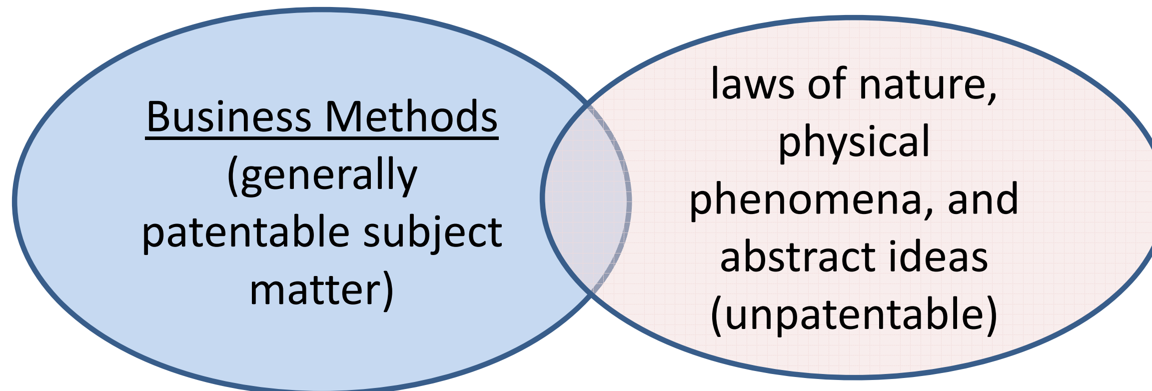
Part II.C.1

- Can't exclude entire business method category

Bilski v. Kappos - S.C. Analysis *(cont.)*

Part II.C.2

- Supreme Court gives an invitation to the CAFC to exclude some business methods.



- Invitation strongly suggests that some business methods are outside 101

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Bilski v. Kappos – Summary of S.C. Analysis

- Business methods cannot be categorically excluded
- M-or-T is one test under 101
- Look to *Benson*, *Flook*, and *Diehr*
- CAFC is invited to develop new tests
- ***Affirms*** CAFC judgment – Bilski's claims recite non-statutory subject matter

Bilski Impact

- The M-or-T test remains the principal test for patent eligibility of processes.
- Decisions illuminating the M-or-T test prior and post *Bilski v. Kappos* are relevant.

"Particular Machine" Branch

A process claim may be patent eligible if

(1) tied to a particular machine or apparatus

- *Bilski* provides little guidance
  - Patentee admitted a machine was not necessary

"Particular Machine" Branch *(cont.)*

- Not sufficient to link claim to a computer if claimed process has no use other than on that computer
- *Gottschalk v. Benson*
  - claims drawn to a process of converting data in binary-coded decimal ("BCD") to pure binary format
  - process was not limited to any particular art or technology, to any apparatus or machinery, or to any particular end use

"Particular Machine" Branch *(cont.)*

"The mathematical formula involved here has no substantial practical application except in connection with a digital computer . . . [meaning that] the patent would ***wholly pre-empt*** the mathematical formula and in practical effect would be a patent on the algorithm itself."
Gottschalk v. Benson

"Transformation" Branch

A process claim may be patent eligible if

(2) transforms a particular article into a different state or thing

– *e.g.*, a method of curing rubber

"Transformation" Branch *(cont.)*

- *Diamond v. Diehr*, 450 U.S. 175 (1981)
  - Process for producing cured synthetic rubber products
  - The claimed process took temperature readings during curing and used a mathematical algorithm, the *Arrhenius equation*, to calculate the time when curing would be complete.

"Transformation" Branch (*cont.*)

"Their process admittedly employs a well-known mathematical equation, but they ***do not seek to pre-empt the use of that equation***. Rather, they seek only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed [rubber curing] process." *Diehr*, 450 U.S. at 187 (emphasis added).

"Transformation" Branch (*cont.*)

Patent Eligible Transformation

- Chemical or physical transformation of tangible objects or substances
  - *e.g.*, tanning, dying, curing rubber, reducing fats
- Transformation of data representing a physical object into particular visual depiction
  - *e.g.*, data from X-ray displayed on screen to show body tissue

Considerations Under Either Branch

- machine or transformation "must impose ***meaningful limits*** on the claim's scope to impart patent-eligibility"
- "involvement of the machine or transformation in the claimed process must not merely be ***insignificant extra-solution activity***"

USPTO "Interim Guidance"

- Provides factors to consider in determining whether a claim is directed to an abstract idea

- Factors that weigh in favor of patent-eligibility:
  - Satisfy the criteria of M-or-T test

    OR

  - Provide evidence of practical application

USPTO "Interim Guidance" *(cont.)*

- Leaves open the possibility that "factors beyond those relevant to [M-or-T] may weigh for or against a finding that a claim is directed to an abstract idea."

Factors Weighing Toward Eligibility

- Recitation of a machine or transformation
  - M-or-T is particular (processor)
  - M-or-T meaningfully limits execution
  - Machine implements the claimed steps
  - Article being transformed is particular
  - Article undergoes a change in state or thing
  - Article transformed is object/substance

Factors Weighing Toward Eligibility *(cont.)*

- Claim is directed toward applying law of nature
  - Law is practically applied
  - Application meaningfully limits the execution of the steps

Factors Weighing Toward Eligibility *(cont.)*

- Claim is more than mere statement of a concept
  - Claim describes a particular solution to a problem to be solved
  - Claim implements a concept in some tangible way
  - Performance of the steps is observable and verifiable

What Seems to Be Out

- Limitations reciting:
  - Data gathering
  - Field of use limitations
  - Insignificant post-solution or extra-solution activity
    - does displaying count?
  - Purported transformations or manipulations of public or private legal obligations or relationships, business risks, or other such abstractions
  - Nominal / non-limiting machine involvement

What Remains Unanswered by *Bilski*?

- What is a sufficient transformation of data?
- When is data sufficiently representative of "things"?
- When is post-solution activity trivial?
- What is a particular machine?

Prometheus Laboratories, Inc. v. Mayo Collaborative Services (Fed. Cir. 2009)

- Medical diagnostic claims considered under the Federal Circuit's original *Bilski* decision.
- Rigid application of machine-or-transformation test.
- Decision applies old test, but provides insight regarding how medical diagnostic and treatment claims may be treated in the future.

Prometheus' Claims

Claim 1 of U.S. Patent No. 6,335,623

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 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 8x108 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 8x108 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

District Circuit Decision

- Granted summary judgment in favor of defendants that the claims were invalid under 35 U.S.C. § 101 for failure to recite patent-eligible subject matter.
- Asserted that the claims were directed to "the correlations between certain thiopurine drug metabolite levels and therapeutic efficacy and toxicity."
- Claimed these correlations were "natural phenomena," and thus unpatentable "because the correlations resulted from a natural body process."

Federal Circuit Decision

- CAFC reversed – **claim found patentable**
  - administering and determining steps are transformative and satisfy M-or-T test.
- "[T]he transformation is of the human body following administration of a drug and the various chemical and physical changes of the drug's metabolites that enable their concentrations to be determined."

Federal Circuit Decision *(cont.)*

- Administering and determining steps were essentially "method of treatment" steps, "which are ***always transformative*** when a defined group of drugs is administered to a body to alleviate the effects of an undesired condition."
- A human body to which drugs such as thiopurines are administered "necessarily undergoes a transformation," since "the drugs do not pass through the body untouched without affecting it," characterized by the court as "the entire purpose of administering the drugs."

Federal Circuit Decision *(cont.)*

- The transformation caused by the administering step is not a "natural process."
- It is "virtually self-evident that a process for a chemical or physical transformation of ***physical objects or substances*** is patent-eligible subject matter." (Emphasis in original.)

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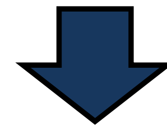
Prometheus Today

- Petition for certiorari of the Federal Circuit's decision granted by the U.S. Supreme Court, case vacated and remanded to the Federal Circuit for reconsideration in view of *Bilski*.
- As *Bilski* upheld the M-or-T test as one possible rationale for rejecting claims as non-statutory, the Federal Circuit will likely again decide Prometheus' claim is patentable subject matter.



Takeaway

- Draft medical diagnostic and treatment claims to involve the administration of compounds to a subject that causes an internal chemical effect or transformation in the subject.
- Processes involving chemical or physical transformation of substances, including those occurring in human body, are generally patent-eligible subject matter.

Association for Molecular Pathology et al. v. United States Patent and Trademark Office, et al. (S.D.N.Y. 2010)

- Patents held by Myriad Genetics

- "Are isolated human genes and the comparison of their sequences patentable?"

Myriad Patents

- Claims directed to:
  1. Isolated DNA containing all or portions of the BRCA1 and BRCA2 gene sequence
  2. Methods for "comparing" or "analyzing" BRCA1 and BRCA2 gene sequences to identify the presence of mutations correlating with a predisposition to breast or ovarian cancer

District Court Holding

- Composition claims are invalid under 101
  - Isolated DNA is not markedly different from DNA as it exists in nature.

- Method claims are invalid under 101
  - "Analyzing" and "comparing" are merely abstract mental processes.

Questions for Your Patent Counsel

1) **What is the plan for currently pending applications**?
   - audit all pending applications
   - amend claims
   - CIP (if cannot amend)

Questions for Your Patent Counsel *(cont.)*

2) **What is your approach for issued patents**?

- How do we fix issued business method patents and software patents that may have been invalidated by *Bilski*?
- Is reissue appropriate?
  - ***pros and cons***

Summary

- Software, business methods, and medical diagnostics are still patentable with skillful drafting
- mental processes and abstract intellectual concepts are not patentable
- "field-of-use" limitations are not sufficient
- consider pending applications and recently issued patents
- *Bilski* impacts other areas

Questions?

Thank You