

Impact of Bilski on Biotechnology

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1980-2005: An Era of Expanding Patent Eligibility

- Product claims
 - Diamond v. Chakrabarty (1980)
 - J.E.M. Ag Supply Inc. v. Pioneer Hi-Bred (2005)
 - PTO Guidelines on patentability of animals (1987) and isolated genes (2001)
 - Parke-Davis & Co. v. H.K. Mulford & Co. (1911)
 - Funk Brothers Seed Co. v. Kalo Inoculant Co. (1948)

1980-2005: An Era of Expanding Patent Eligibility

- Process claims
 - Diamond v. Diehr (1981)
 - State Street Bank and Trust v. Signature Financial Group (1998)

Traditional Test for Patent Eligibility

- Product or process
- “made by man”
 - “isolation” is generally sufficient
- Not a “fundamental principle”
 - principle of nature
 - Natural phenomenon
 - Abstract idea
 - Mental process

LabCorp v. Metabolite 548 U.S. 124 (2006)

- Claim 13: A method of molecular diagnosis/personalized medicine
 - 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.

Supreme Court's Question in *Metabolite v. LabCorp*

- Is the patent invalid because one cannot patent “laws of nature, natural phenomena, and abstract ideas”? *Diamond v. Diehr*, 450 U.S. 175, 185 (1981).

US Government's Amicus Position

- [No] one patent a process that comprises every "substantial practical application" of a law of nature, because such a patent "in practical effect would be a patent on the [law of nature] itself."
- The record is not sufficiently developed to permit comprehensive consideration of the question whether claim 13 satisfies the subject matter requirements of Section 101.
 - What does "assay" mean?

LabCorp v. Metabolite 548 U.S. 124 (2006)

- June 22, 2006
 - Writ of certiorari dismissed as improvidently granted.
 - Dissent by Justice BREYER, with whom Justice STEVENS and Justice SOUTER join.

Breyer's Dissent

- The justification for the principle does not lie in any claim that “laws of nature” are obvious, or that their discovery is easy, or that they are not useful. . . . Rather, the reason for the exclusion is that sometimes *too much* patent protection can impede rather than “promote the Progress of Science and useful Arts,” the constitutional objective of patent and copyright protection

Breyer's Dissent

- The problem arises from the fact that patents do not only encourage research by providing monetary incentives for invention.
- Sometimes their presence can discourage research by impeding the free exchange of information, for example by forcing researchers to avoid the use of potentially patented ideas, by leading them to conduct costly and time-consuming searches of existing or pending patents, by requiring complex licensing arrangements, and by raising the costs of using the patented information, sometimes prohibitively so.

Breyer's Dissent

- One way in which patent law seeks to [avoid the dangers of overprotection] is through rules that bring certain types of invention and discovery within the scope of patentability while excluding others.

Breyer's Dissent

- There can be little doubt that the correlation between homocysteine and vitamin deficiency set forth in claim 13 is a “natural phenomenon.” . . . At most, respondents have simply described the natural law at issue in the abstract patent language of a “process.” But they cannot avoid the fact that the process is no more than an instruction to read some numbers in light of medical knowledge.

Breyer's Dissent

- One might, of course, reduce the “process” to a series of steps, e.g., Step 1: gather data; Step 2: read a number; Step 3: compare the number with the norm; Step 4: act accordingly. But one can reduce *any* process to a series of steps. The question is what those steps **embody**.

Breyer's Dissent

- [H]ere, aside from the unpatented test, they **embody** only the correlation between homocysteine and vitamin deficiency that the researchers uncovered. In my view, that correlation is an unpatentable “natural phenomenon,” and I can find nothing in claim 13 that adds anything more of significance.

Classen v. Biogen, No. 04-2607 (N.D. Md.)

■ Claim

- A method of determining whether an immunization schedule affects the incidence or severity of a chronic immune-mediated disorder in a treatment group of mammals, relative to a control group of mammals, **which comprises immunizing mammals** in the treatment group of mammals with one or more doses of one or more immunogens, according to said immunization schedule, and comparing the incidence, prevalence, frequency or severity of said chronic immune-mediated disorder or the level of a marker of such a disorder, in the treatment group, with that in the control group.

Classen v. Biogen, No. 04-2607 (N.D. Md.)

■ August 16, 2006

- The district court held that the relationship between vaccination schedule and autoimmune disorders is without question a **natural phenomenon**, and that the claims at issue impermissibly **embodied** that natural phenomenon.
- The court did not address the issue of whether a biological phenomenon that exists only as a result of human intervention (the introduction of vaccine in the human body) is accurately characterized as a natural phenomenon.

Ariad v. Lilly, 529 F.Supp.2d 106 (D. Mass. 2007)

■ Claim

- A method for inhibiting expression, in a eukaryotic cell, of a gene whose transcription is regulated by NF- κ B, the method comprising reducing NF- κ B activity in the cell such that expression of said gene is inhibited.

Ariad v. Lilly, 529 F.Supp.2d 106 (D. Mass 2007)

■ July 6, 2007

- The district court found the claims patent eligible based on the following findings:
 - The relevant natural phenomenon is the so-called NF- κ B “Autoregulatory Loop”
 - The Autoregulatory Loop is “an incomplete model ... subject to a significant amount of ambiguity and inconsistency” and
 - “Lilly has failed to prove by clear and convincing evidence that the Autoregulatory Loop exists in living cells in a way that is encompassed by Ariad's claims.”

Prometheus v. Mayo, 2008 WL 878910 (S.D. Cal. 2008)

■ Claim

- 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 levels 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 levels 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.

Unpatentable Mental Step?

■ March 28, 2008

- the claims include only two active steps: “administering” the drug and “determining” metabolite levels, which are ***merely data-gathering steps***; plus the additional ***mental step*** that the doctor be warned (by the metabolite levels) that an adjustment in dosage may be required. Therefore, the claims recite the correlations themselves.

Unpatentable Natural Phenomena?

- [T]he inventors of the patents-in-suit did not “invent” the claimed correlation.
- Rather, 6-TG and 6-MMP are products of the natural metabolizing of thiopurine drugs, and the inventors merely observed the relationship between these naturally produced metabolites and therapeutic efficacy and toxicity.
- [T]here can be little doubt that the claimed correlations are “*natural phenomena*.”

Persuaded by *LabCorp* Dissent

- The facts of the present case are clearly analogous to those of *LabCorp*
- Although this Court notes that the dissent in *LabCorp* does not have precedential value, the Court finds Justice Breyer's reasoning persuasive

District Court Rejected Machine-Transformation Test

- [C]ontrary to Plaintiff's contention, Defendants need not meet the additional burden of showing that the claims do not **“transform”** an article or physical object to a different state or thing
- In *Flook*, for example, the Supreme Court did not even mention the alternative transformation/result standard, and instead focused on whether the claims “wholly pre-empt” all uses of the natural phenomenon.
- Thus, this Court finds that the claims at issue are not subject to □ the transformation test

“Wholly Pre-empts”

- The case law is clear, if a claim that recites unpatentable subject matter **“wholly pre-empts”** all practical use of the unpatentable subject matter, the claim is invalid under Section 101

District Court Applies “Wholly pre-empts” Test

- [T]he “administering” and “determining” steps are ***merely necessary data-gathering steps*** for any use of the correlations, and the “warning” step is only a mental step whereby the metabolite levels warn the doctor that an adjustment in dosage may be required.
- Thus, the claims cover the correlations themselves.
- Because the claims cover the correlations themselves, it follows that the claims “wholly pre-empt” the correlations.

District Court Applies “Wholly pre-empts” Test

- Plaintiff outlines six possible uses not foreclosed by the claimed methods: (1) use in research; (2) for diseases other than autoimmune or gastrointestinal diseases; (3) use when results are given in units other than red blood cells; (4) building upon the correlations; (5) publishing articles in scientific journals concerning the correlations; and (6) testing and determining metabolite levels so long as no warning is given.

District Court Applies “Wholly pre-empts” Test

- Despite these supposed alternate uses, the claims “wholly pre-empt” use of the correlation such that the “practical effect is a patent on the [correlation] itself.”
- The law does not require that every conceivable use be preempted to invalidate the claim. Rather, it is enough that the unpatentable subject matter recited in the claims has “no substantial practical application” outside the context of the claims.

In re Bilski, 545 F.3d 943 (Fed. Cir. 2008) (en banc) (Bilski I)

- Claim
 - 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.

The Fundamental Test

- The fundamental test is:
 - whether Applicants' claim recites a ***fundamental principle*** and, if so,
 - whether it would ***pre-empt substantially all uses*** of that fundamental principle

The Fundamental Test

- Unfortunately, this inquiry is hardly straightforward. How does one determine whether a given claim would pre-empt all uses of a fundamental principle?
- The Supreme Court, however, has enunciated a definitive test to determine whether a process claim is tailored narrowly enough to encompass only a particular application of a fundamental principle rather than to pre-empt the principle itself

The Machine-Transformation Test

- The Supreme Court test addresses what is **sufficient** for patentability
 - 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
- The Federal Circuit subverts it into a test for what is **necessary** for patentability
 - The machine-or-transformation test is a two-branched inquiry; an applicant may show that a process claim satisfies § 101 either by showing that his claim is tied to a particular machine, or by showing that his claim transforms an article

The Machine-Transformation Test

- [F]uture developments in technology and the sciences may present difficult challenges to the machine-or-transformation test, just as the widespread use of computers and the advent of the Internet has begun to challenge it in the past decade.
- Thus, we recognize that the Supreme Court may ultimately decide to alter or perhaps even **set aside this test to accommodate emerging technologies**.

Insignificant Extra-Solution Activity

- The use of a specific machine or transformation of an article must impose meaningful limits on the claim's scope to impart patent-eligibility
- The involvement of the machine or transformation in the claimed process must not merely be *insignificant extra-solution activity*.

What Constitutes an Article?

- The transformation [of an article into a different state or thing] must be central to the purpose of the claimed process.
- [W]hat sorts of things constitute “articles” such that their transformation is sufficient to impart patent-eligibility under § 101[?]
- It is virtually self-evident that a process for a **chemical or physical transformation of physical objects or substances** is patent-eligible subject matter.

What Constitutes Transformation?

- The transformation must be central to the purpose of the claimed process
- The transformation of [raw data representing physical and tangible objects, such as the structure of bones, organs, and other body tissues] into a particular visual depiction of a physical object on a display [is] sufficient to render [the] process patent-eligible

Data-Gathering Steps

- [A]t least in most cases, ***gathering data would not constitute a transformation of any article***, and adding a data-gathering step to an algorithm is insufficient to convert that algorithm into a patent-eligible process
- A requirement simply that data inputs be gathered-***without specifying how***-is a meaningless limit on a claim to an algorithm because every algorithm inherently requires the gathering of data inputs
- [T]he inherent step of gathering data can also fairly be characterized as insignificant

Questions Raised by *Bilski I*

- What is the applicability to claims in the life sciences, or involving natural phenomena?
- Will the test be augmented or refined, particularly in the context of biotechnology?
- What exactly is a particular machine or apparatus?
 - Most diagnostic methods involve the use of a machine or apparatus

Questions Raised by *Bilski I*

- What constitutes a transformation?
 - Is therapeutic treatment transformative?
- Under what circumstances can a claim limitation be dismissed as mere “insignificant extra-solution activity”?
 - Many personalized medicine claims will include a data-gathering step

Bilski I Dissents

- Newman - Test excludes from patentability many of today's most important innovations, particularly in the growth industries of the U.S. economy, such as the computer and information service fields
- Mayer - Test easily circumvented by clever drafting of patent claims, will prove exceedingly difficult to apply in practice, and will only lead to further uncertainty regarding the scope of patentable subject matter.

Bilski I Dissents

- Rader
 - Metabolite claim (*Labcorp*) provides an elegant and simple way of testing for a vitamin deficiency
 - Denying patent protection for this sort of innovation will undermine and discourage future research for diagnostic tools
 - The machine-transformation test "inadvertently advises investors that they should divert their unprotectable investments away from discovery of scientific relationships within the body to diagnose breast cancer or Lou Gehrig's disease or Parkinson's or whatever."

Classen v. Biogen, 2008 WL
5273107 (Fed. Cir., unpublished)

- “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.”

Prometheus v. Mayo, 581 F.3d 1336,
(Fed. Cir. 2009)

- Claim
 - 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 levels 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 levels 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.

Administering step is transformative

- The 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
- The asserted claims are in effect claims to **methods of treatment, which are always transformative** when a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition.
- The invention's **purpose** to treat the human body is **made clear in the specification and the preambles** of the asserted claims.

Determining step is transformative

- Determining the levels of 6-TG or 6-MMP in a subject necessarily involves a transformation, for those levels cannot be determined by **mere inspection**.
- Some form of manipulation, such as the high pressure liquid chromatography method specified in several of the asserted dependent claims or other modification of the substances to be measured, is necessary to extract the metabolites from a bodily sample and determine their concentration.

Determining step is transformative

- [T]his transformation is central to the purpose of the claims, since the determining step is, like the administering step, a significant part of the claimed method of treatment.
- The determining step, by working a chemical and physical transformation on physical substances, likewise sufficiently confines the patent monopoly, as required by [Bilski I].

Mental steps are not patent-eligible

- We agree with the district court that the final “wherein” clauses are ***mental steps and thus not patent-eligible per se.***
- A subsequent mental step does not, by itself, negate the transformative nature of prior steps.
- Thus, when viewed in the proper context, the final step of providing a warning based on the results of the prior steps does not detract from the patentability of Prometheus's claimed methods as a whole.

A Look at Personalized Medicine

[Presented at the
Biotechnology/Chemical/Pharmaceutic
al Customer Partnership Meeting
December 3, 2008; available at

http://www.eabc.com/bcp/120308/KBradon_PM.ppt]

Example 1: Pharmacogenetics Claim

- 1. A method of treating a human subject having a thrombosis with a dosage of warfarin, said method comprising:
 - a) obtaining a nucleic acid sample from said human subject;
 - b) subjecting the sample to PCR and identifying i and/or ii:
 - i) in the subject's *VKORC1* gene, the nucleotide base at position X of SEQ ID NO:1 in the sample from the subject and/or
 - ii) in the subject's *CYP2C9* gene, the nucleotide base at position Y of SEQ ID NO:2 in the sample from the subject; and
 - c) treating the human subject with a dosage of warfarin indicated by their genotype as identified in b.

Example 2: SNP Claim

2. An isolated nucleic acid sequence comprising SEQ ID NO:1.

- The specification teaches that SEQ ID NO:1 is a variant of the *ERBB2* gene having an A (adenine) to C (cytosine) mutation at position 101 (A101>C).

- *this mutation (A101>C) is typically found in breast cancer patients.

- *this mutation (A101>C) correlates with a significantly better response to “breast cancer drug X” versus placebo.

- *without mutation (A101>C), “breast cancer drug X” is an ineffective treatment.

Example 3: Methods Correlating SNPs and Diseases

3. A method for determining whether a human subject having breast cancer will be effectively treated with “breast cancer drug X”, said method comprising:

- a) considering data in a database comprising genetic patient information about the *ERBB2* gene at position 101 of SEQ ID NO:1; and

- b) correlating the presence of a cytosine at position 101 of SEQ ID NO:1 with effective treatment of the human subject with “breast cancer drug X”.

Neither tied to a machine/apparatus nor performing a transformation, therefore, does **not** meet the requirements for 35 USC 101

Example 4: Methods of Treating Diseases that Correlate with SNPs

- 4. A method for treating a human subject having breast cancer, said method comprising:
 - a) obtaining a nucleic acid sample from said human subject;
 - b) subjecting the sample to PCR and identifying the nucleotide present at position 101 of SEQ ID NO:1; and
 - c) treating the human subject with “breast cancer drug X” when a cytosine is detected at position 101 of SEQ ID NO:1.

Examples of Product Claims Found Patent Ineligible in *AMP v. USPTO*

- US patent number 5,747,282
 - 1. An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2.
 - Compare with claim found valid and infringed in *Amgen v. Chugai*
 - 2. The isolated DNA of claim 1, wherein said DNA has the nucleotide sequence set forth in SEQ ID NO:1. [cDNA]
 - 5. An isolated DNA having at least 15 nucleotides of the DNA of claim 1.

Gene Patents and Biologic Drugs

- *Amgen v. Chugai* (1987)
 - “A purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin.”
- Patent on human erythropoietin (the actual drug) was not available for Amgen

The Court's Rationale for Invalidating Product Claims

- Caselaw pre-dating *Chakrabarty* and Federal Circuit
- Claimed molecules lack “markedly different characteristics” from naturally occurring genetic sequences
 - Nobel Prize for PCR?
- Genetic Exceptionalism: DNA is qualitatively different from other biomolecules capable of conveying information

Why Is the Patent Eligibility of Isolated Genes Still Unresolved?

- Biotech litigants have not surprisingly refrained from challenging patent eligibility of gene patents
- Judge Dyk recently took pains to point out that Federal Circuit silence on the issue of patent eligibility does not imply assent. *Intervet v. Merial Ltd.*, (Fed. Cir 2010).

Examples of Invalidated Process Claims

- US patent number 5,710,001
 - 1. A method for screening a tumor sample from a human subject for a somatic alteration in a BRCA1 gene in said tumor which comprises gene **comparing** a first sequence selected from the group consisting of a BRCA1 gene from said tumor sample, BRCA1 RNA from said tumor sample and BRCA1 cDNA made from mRNA from said tumor sample with a second sequence selected from the group consisting of BRCA1 gene from a nontumor sample of said subject, BRCA1 RNA from said nontumor sample and BRCA1 cDNA made from mRNA from said nontumor sample, wherein a difference in the sequence of the BRCA1 gene, BRCA1 RNA or BRCA1 cDNA from said tumor sample from the sequence of the BRCA1 gene, BRCA1 RNA or BRCA1 cDNA from said nontumor sample indicates a somatic alteration in the BRCA1 gene in said tumor sample.

Examples of Invalidated Process Claims

- US patent number 5,753,441
 - 1. A method for screening germline of a human subject for an alteration of a BRCA1 gene which comprises comparing germline sequence of a BRCA1 gene or BRCA1 RNA from a tissue sample from said subject or a sequence of BRCA1 cDNA made from mRNA from said sample with germline sequences of wild-type BRCA1 gene, wild-type BRCA1 RNA or wild-type BRCA1 cDNA, wherein a difference in the sequence of the BRCA1 gene, BRCA1 RNA or BRCA1 cDNA of the subject from wild-type indicates an alteration in the BRCA1 gene in said subject.
- Court applied *In re Bilski* machine-or-transformation test

Court Dicta Contrary to Prometheus

- "Even if the challenged method claims were read to include the transformations associated with isolating and sequencing human DNA, these transformations would constitute no more than data-gathering steps that are not central to the purpose of the claimed process."
- This appears contrary to *Prometheus*, which explicitly found analytical processes used to determine drug metabolite levels sufficiently transformative

Importance of Method Claims

- Myriad's Amicus Brief filed in Prometheus
 - "Fundamental composition of matter claims, e.g., isolated nucleic acids and proteins, are unavailable because the Human Genome Project has made the entirety of the genome, along with all of its encoded proteins, prior art. Claims like those at issue in this case, therefore, are virtually all that remains to incentivize the research and development of new personalized medicine products."

Myriad's Cell Based Assay Claim Also Ruled Patent Ineligible

- US patent number 5,747,282
 - 20. A method for screening potential cancer therapeutics which comprises: growing a transformed eukaryotic host cell containing an altered BRCA1 gene causing cancer in the presence of a compound suspected of being a cancer therapeutic, growing said transformed eukaryotic host cell in the absence of said compound, determining the rate of growth of said host cell in the presence of said compound and the rate of growth of said host cell in the absence of said compound and comparing the growth rate of said host cells, wherein a slower rate of growth of said host cell in the presence of said compound is indicative of a cancer therapeutic.
- Poorly reasoned
 - No reference to *Bilski*
- Such a sweeping interpretation of patent eligibility could prove devastating for biotechnology patenting

Bilski v. Kappos, 130 S.Ct. 3218
(2010) (*Bilski II*)

- The Supreme Court clarified that involvement of machine or transformation is highly relevant, but not exclusive test for patent eligibility
- Returns focus to whether patent “claims” a fundamental principle, such as abstract idea, natural phenomenon or mental process

Bilski v. Kappos, 130 S.Ct. 3218
(2010) (*Bilski II*)

- Only applies to method claims, but these claims will be critical for biopharma, particularly with respect to personalized medicine
- Prometheus and Classen vacated and remanded to Federal Circuit

Critical Issues to Be Addressed Post-Bilski II

- What exactly is a “fundamental principle”?
 - Particularly in the context of personalized medicine, what is a biological “natural phenomenon”?
- What does it mean to impermissibly patent a biological “natural phenomenon”?
- What does it mean to impermissibly patent “mental processes”?

Defining biological “natural phenomena”

- Federal Circuit should address this question in *Prometheus* and *Classen*
- Potential policy lever to distinguish between *Prometheus* and *LabCorp/Myriad*

What constitutes claiming a fundamental principle?

- “Wholly preempts”
 - *Benson* (1972) suggests this is the test, but *Diehr* (1981) and *Bilski II* arguably refute
 - This was US government position in *LabCorp*
 - [No] one can patent a process that comprises every “substantial practical application” of a law of nature, because such a patent “in practical effect would be a patent on the [law of nature] itself.”
 - District court applied “preemption of every substantial practical application” test in *Prometheus*

What constitutes claiming a fundamental principle?

- Treated as part of the prior art
 - *Parker v. Flook* (1978)
 - *In re Comiskey* (prior to revision)

What constitutes claiming a fundamental principle?

- “Embodies”
 - Justice Breyer in *LabCorp*
 - Used by district court in *Classen*
 - Implied in *Bilski II*
 - Finding that dependent claims are patent ineligible implies wholly preempted is not the test
 - Patent ineligibility “cannot be circumvented by limiting claim to a particular technological environment or adding insignificant post-solution activity”

What constitutes claiming a fundamental principle?

- Supreme Court has given lower courts a wild card to invalidate unworthy claims

Problems with Using Patent Eligibility Doctrine

- Collateral damage to biotechnology
 - Biologics
 - Personalized medicine
 - More complex genetic diagnostic testing

Problems with Using Patent Eligibility Doctrine

- Investment backed expectations
 - This implicates thousands of patents, many of which are the foundations upon which biotechnology companies have been built
 - PTO Guidelines
 - *In re Fisher*
 - European Patents Upheld

Problems with Using Patent Eligibility Doctrine

- Many of the expressed concerns could have been addressed using sections 102, 103 and 112 and claim construction
- Proposals to limit liability for research and genetic diagnostic testing

Personalized Medicine and Diagnostics

- No clear demarcation between personalized medicine and diagnostics
 - Genentech patents claim methods of detecting over-expression of HER2 gene
 - Metabolite patent claims method of detecting vitamin B deficiency
 - Myriad patents claim methods of detecting BRCA mutations
- Can patent eligibility doctrine distinguish between diagnostic patents and personalized medicine?

Divided Infringement Claims

- Recent decisions demonstrate challenges in enforcing method claims wherein the method steps are not all performed by the same entity
 - *Muniauction v. Thompson*, 532 F.3d 1318 (Fed. Cir. 2008)

Divided Infringement Claims

- Could result in Catch-22 for personalized medicine inventors
 - Inclusion of treatment step, or data acquisition step, could result in divided infringement
 - Omission of such steps could render claim patent ineligible for preempting a natural phenomenon
 - But see, *Eli Lilly and Co. v. Actavis Elizabeth LLC*, 676 F.Supp.2d 352 (D.N.J. 2009) ("The actions of the doctors and patients will be treated together, and will be considered a directly infringing act.")

Do we want personalized medicine to be patentable?

- Drug companies might prefer freedom to operate
 - Extract value from sale of drug
- Patent on diagnostic component might play important role in extracting value from personalized medicine invention, particularly if drug is off patent
 - FDA might require generic drug to include diagnostic testing on label, resulting in induced infringement

Patent eligibility as a policy lever

- Can “natural phenomenon” be defined in a manner that distinguishes between BRCA patents and *Prometheus*?
 - BRCA and HER2?
- Does Metabolite claim (*Labcorp*) preempt all uses of the natural phenomenon in the body?
 - Embody the natural phenomenon?

Patent eligibility as a policy lever

- Could be used to require explicit recitation of data acquisition or treatment step
 - This raises divided infringement problem
 - Implication of individual whole genome sequencing
- Treating natural phenomenon as part of prior art could distinguish BRCA from Herceptin
 - Definition of natural phenomenon would be critical

Is patent eligibility the appropriate policy lever?

- Concerns that have been expressed implicate Sections 103 and 112
- Exemption from infringement liability for doctors, patients and researchers could defuse much of the concerns
- Ariad NF-kB claims
 - Amgen defeated using claim construction
 - Eli Lilly defeated using written description
- After arising technology could confer patent eligibility

DOJ Amicus Brief

- Attempts to draw a line between patent ineligible genomic DNA that has been merely “excised” from the chromosome and “engineered” cDNA
- There is real concern in some quarters that gene patents will block personalwhole genome sequencing