Murky Waters: The Fight Over What Subject Matter is Eligible for Patent Protection

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Topics

- Recent Case Law Affecting Subject Matter Eligibility
- USPTO Response
- Strategies for Obtaining Diagnostic and Nature-Based Product Type Patents
Basis for Patent Eligible Subject Matter

- 35 U.S.C. § 101
  - 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

- Threshold Test for Eligibility
  - Claims must also be novel, non-obvious, and accompanied by a complete and enabling written description
Basis for Patent Eligible Subject Matter

- Judicial Exceptions to § 101
  - Abstract ideas / mental processes
  - Laws of nature / natural principles
  - Natural phenomena and products of nature

- Purpose of Exceptions
  - Exceptions are basic tools of scientific and technological work, without these exceptions there would be considerable danger that the grant of patents would ‘tie up’ the use of such tools and inhibit future innovation premised upon them.
Supreme Court’s Hand in Defining Judicial Exceptions to Subject Matter Eligibility

- Parker v. Flook (S. Ct. 1978)
- Diamond v. Chakrabarty (S. Ct. 1980)
- Alice v. CLS Bank (S. Ct. 2014)
- Bilski v. Kappos (S. Ct. 2010)
Recent Case Law “Refining” the Judicial Exceptions

- **Bilski v. Kappos, 130 S.Ct. 3218 (2010)**
  - Business method patent
  - Challenged claims directed to a method for protecting or hedging against the risk of price changes of commodities in the energy market
  - Claims *unpatentable* – directed to an abstract idea
  - Supreme Court rejected the “machine-or-transformation” test as the sole criterion for determining subject matter eligibility
Recent Case Law “Refining” the Judicial Exceptions

  - Personalized medicine technology
  - Challenged claims directed to a method of optimizing therapeutic dose of drug for the treatment of a gastrointestinal disorder, involving:
    - administering the drug, and determining the drug metabolite level, where the metabolite level was informative of needing to increase or decrease the dosage of the drug
  - Claims held unpatentable - the relationship between the metabolite concentration and optimized dosages was a law of nature
  - The instructions add nothing specific to the laws of nature other than well-understood, routine, conventional activity, previously engaged in by those in the field
Recent Case Law “Refining” the Judicial Exceptions

- The test for patent eligible subject matter after *Mayo*
  - Is the claim directed to a patent-ineligible concept?
  - If yes, what else is in the claim to ensure it amounts to significantly more than a patent upon the ineligible concept itself?
    - Examine the elements of the claim to determine whether it contains an “inventive concept” sufficient to “transform” the claimed ineligible concept into a patent-eligible application
    - The claim cannot pre-empt the use of the natural law or natural principle by others
    - The claim must recite more than mere directions to apply a fundamental principle
Recent Case Law “Refining” the Judicial Exceptions

- Assoc. for Molecular Pathology v. Myriad Genetics, Inc. 133 S. Ct. 2107 (2013)
  - Claims directed to Isolated DNA
    1. An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2.
    2. The isolated DNA of claim 1, wherein said DNA has the nucleotide sequence set forth in SEQ ID NO: 1 (cDNA sequence).
    3. An isolated DNA having at least 15 nucleotides of the DNA of claim 2.
Recent Case Law “Refining” the Judicial Exceptions

- Assoc. for Molecular Pathology v. Myriad Genetics, Inc. (Cont.)
  - Claim 1 unpatentable - a naturally occurring DNA segment is a product of nature, *mere isolation does not render it patent eligible*
  - Claim 2 patentable - cDNA is not a product of nature
    - cDNA is an “exon only” molecule created in the laboratory
  - Claim 3 unpatentable - covers short segments of DNA where no intervening introns were removed for its creation, *i.e.*, it is indistinguishable from the natural DNA
Recent Case Law “Refining” the Judicial Exceptions

- **In Re BRCA1 and BRCA1 Based Hereditary Cancer Test Patent Litigation, 774 F.3d 755 (2014)**
  - Claims directed to a pair of single-stranded DNA primers for determination of a nucleotide sequence of a BRCA1 gene by PCR
  - Claims unpatentable
    - Cover short segments of DNA that are structurally indistinguishable from the natural DNA
    - Although single-stranded DNA not found in body, separating DNA from its surrounding genetic material is not an act of invention
    - Function is the same as natural DNA, i.e., use to initiate PCR is a result of its naturally occurring sequence, a primary function of DNA structure in nature is to bind to its complementary sequence
    - Even if synthetically created, if structurally identical, it is not patentable
Recent Case Law “Refining” the Judicial Exceptions

- Alice Corp. v. CLS Bank International, 2014
  - Software based invention
  - Claims directed to a method of determining the risk that only one party to an agreed-upon financial exchange will satisfy its obligation
  - Application of Mayo Test - claims unpatentable
    - Drawn to an abstract idea
    - The required implementation of the method on a general purpose computer is not “enough” to transform an ineligible abstract idea into a patent eligible method
December 2014 USPTO Interim Guidelines for Determining Subject Matter Eligibility in view of *Mayo, Myriad, and Alice*
Evolving Guidance on Subject Matter Eligibility from the USPTO

July 2010
- Guidance in view of *Bilski* decision
- Applicable to claims directed to abstract ideas

July 2012
- Guidance in view of *Mayo* decision
- Applicable to claims directed to law of nature or natural product

March 2014
- Guidance in view of *Myriad* decision (superseded July 2012 Guidance)
- Applicable to claims directed to law of nature or natural product

June 2014
- Guidance in view of *Alice Corp* decision
- Applicable to claims directed to abstract ideas

December 2014
- Revised Guidance applicable to abstract ideas, laws of nature, and natural products
- Supersedes March 2014 Guidance/Supplements June 2014 Guidance
December 2014 USPTO Subject Matter Eligibility Test

(Step 1) IS THE CLAIM TO A PROCESS, MACHINE, MANUFACTURE OR COMPOSITION OF MATTER?

- NO

- YES

(Step 2A) [PART 1 Mayo test] IS THE CLAIM DIRECTED TO A LAW OF NATURE, A NATURAL PHENOMENON, OR AN ABSTRACT IDEA (JUDICIALEY RECOGNIZED EXCEPTIONS)?

- NO

- YES

(Step 2B) [PART 2 Mayo test] DOES THE CLAIM RECITE ADDITIONAL ELEMENTS THAT AMOUNT TO SIGNIFICANTLY MORE THAN THE JUDICIAL EXCEPTION?

- YES

CLAIM QUALIFIES AS ELIGIBLE SUBJECT MATTER UNDER 35 USC 101

- NO

CLAIM IS NOT ELIGIBLE SUBJECT MATTER UNDER 35 USC 101
USPTO Subject Matter Eligibility Test

- **Determine What the Claim is “Directed to” (Step 2A)**
  - Directed to a judicial exception when a law of nature, a natural phenomenon, or an abstract idea is recited
    - Nature-Based Product: Are the structure, function, and/or other properties of claimed product “markedly different” from naturally-occurring counterpart?

- **Does the claim as whole amount to **significantly more** than the judicial exception (Step 2B)?**
  - Improvements to another technology or technical field
  - Applying the exception with, or by use of, a particular machine
  - Effecting a transformation or reduction of a particular article to a different state or thing
  - Addition of unconventional steps that confine the claim to a particular useful application
  - Limitations that go beyond linking the use of the judicial exception to a particular technology environment
Is There a Future for Diagnostic and Nature Based Product Patents?

YES!
There has been NO categorical exclusion of diagnostic or nature based product patents.
Claim Strategies for Diagnostic-Type Claims

- Types of “Diagnostic” Claims
  - Diagnosis Claims
    - Methods of diagnosing disease X
  - Prognosis Claims
    - Methods of determining the course of disease X
  - Risk Prediction Claims
    - Methods of determining a subject’s risk of disease X
  - Personalized Medicine Claims
    - Methods of optimizing a subject’s treatment for disease X
Claim Strategies –
Exemplary Prognostic Claim

A method for determining the prognosis of a subject with disease X comprising:

comparing protein Y expression level in disease X cells in a biological sample from the subject to a baseline level Y expression, wherein an elevated level of Y expression in relation to the baseline level of Y expression may indicate poor prognosis or aggressive course of disease in the subject.
Claim Strategies –
Re-Drafting Prognostic Claim

A method for determining the prognosis of a subject with disease X comprising:

obtaining a disease X cell sample from the subject;

measuring the level of Protein Y in the sample using an amplification based assay; and

comparing the level of Y expression in the disease cells in the sample to a baseline level of Y expression in a control sample…; and

administering to the subject, based on said comparing, a therapeutic treatment suitable to treat the aggressive form of the disease.
Claim Strategies –
Re-Drafting Prognostic Claim

A method for determining the prognosis of a subject with disease X comprising:

obtaining a disease X cell sample from the subject;

subjecting the sample to an amplification reaction to generate amplified Y cDNA;

measuring the level of amplified Y cDNA in the sample as a result of said subjecting;

comparing the level of amplified Y cDNA in the sample to a baseline level of amplified Y cDNA in a control sample....
Diagnostic Method Claim Strategies – Summary

- Tie steps recited in claim together to avoid overly broad claim scope and ensure law of nature is tied to a physical step

- Better define “measuring” and “detecting” steps:
  - Incorporate language that defines a physical transformation (i.e., chemical reaction) of the sample in a somewhat limited fashion
  - Measure non-naturally occurring reaction products
  - Specify a reagent used to measure or detect

- Include an active step that is an application of the diagnostic/prognostic method

- Include claims of varying scope
Claim Strategies for Nature Based Product Claims

• Nucleic acid molecules
  – cDNA Sequence
  – Variants – nucleotide additions, substitutions, deletions
  – Labeled or tagged

• Proteins and peptides
  – Fragments that are structurally or functionally distinct from naturally occurring counterpart
  – Chimeric or fusion peptides

• Naturally-occurring small molecules
  – Derivatives
  – Purified forms
  – Non-naturally occurring combinations with other elements
Claim Strategies for Nature Based Product Claims

• Antibodies
  – Humanized, chimeric, having variant portions
  – Monoclonal, neutralizing, or other attributes not found in naturally occurring counterparts

• Isolated cell populations
  – Claim in combination with a biological scaffold or delivery vehicle
  – Expression of proteins not expressed in nature
Claim Strategies for Nature-Based Products – Summary

- Recite limitations that structurally or functionally distinguish claimed product from natural product (e.g., purified, variant, humanized, etc.)
  - Expect to prove structural/functional differences
- Claim combinations (e.g., pharmaceutical additives, such as carriers, excipients, etc.)
- Claim molecules including non-native portions (e.g., fusion or chimeric proteins, rather than isolated fragments)
- Claim compositions including the nature-based product having concentrations not found in nature
- Include product-by-process claims
- Include claims of varying scope
Thank You

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