

## Patentability Requirements Relating to Personalized Medicine:

### *Considerations and Pitfalls for the Unwary*

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## Personalized medicine industry benefits from patent protection

- Patents are often key assets for technology companies
- Protects practical applications of ideas

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## What is a Patent?

- A limited grant from the U.S. government giving an inventor the right to exclude others from:
  - Making
  - Using
  - Selling
  - Offering for sale
  - Importingthe patented invention in the U.S
- “Negative Right” — Not a right to do anything except exclude others for a limited time.

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## Why Get Patents?

1. To protect your investments in R&D, and prevent others from copying
2. To prevent others from patenting your technology
3. To license your invention to others, and thereby generate licensing revenues
4. To have bargaining chips for cross licensing
5. To create assets that can be bought and sold
6. To increase your company's value overall

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## Requirements to obtain (and keep) U.S. patents

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### Patentability Requirements: 35 U.S.C.

- § 101 (Subject matter/Utility)
  - *Bilski* (CAFC 2008)
- § 102 (Novelty)
- § 103 (Non-Obviousness)
  - *KSR* (S. Ct. 2007)
- § 112 (Disclosure)
  - Specification must describe and enable how to make and use invention

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## Example Claims

- Devices/apparatus
- Diagnostics (methods/kits)
- Methods of screening
- Therapeutics/method of treatment or use
- Antibodies
- Gene therapy
- Nucleic acids and proteins
- DNA chips
- Based on biological deposits (e.g., cell lines)
- Living organisms

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## Claim Drafting

- Careful claim drafting requires careful drafting of the specification
- Define relevant claim terms in the specification
  - e.g., terms corresponding to new/non-obvious elements
  - e.g., terms allowing broader breadth
- *Ex parte Miyazaki* (BPAI Nov. 2008) – USPTO may raise indefiniteness rejection if a “claim is amenable to two or more plausible claim constructions”

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## Hot issue affecting claim drafting

- Patentable subject matter under §101 as relating to diagnostic methods
- U.S. case law
  - *Lab Corp. v. Metabolite* (Sup. Ct. 2006) (dissent regarding dismissal of case)
  - *In re Bilski* (Fed. Cir. 2008)
  - *Prometheus Labs. v. May Collaborative Svcs.* (S.D. Cal. March 2008) (pending at Fed. Cir.)

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## 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 improvements thereof, may obtain a patent therefor, subject to the conditions and requirements of this title”

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## Uncertainty Remains on Subject Matter Scope

- Supreme Court has interpreted §101 broadly
- **Chakrabarty**. “Anything under the sun that is made by man” is patentable, including:
  - genes and gene products in isolated form, e.g., on DNA chips
  - laboratory techniques and assays, such as molecular diagnostic tests
- **BUT ...**

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## Limits on Patentable Subject Matter

- Not patentable: laws of nature, natural phenomena or abstract ideas
  - mathematical formulas or algorithms
  - products and processes of nature
  - gene, protein, cell or organism as occurring in nature
  - mental processes
- Human-made or synthetic products or processes may be patentable

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## Biotechnology claim drafting

- Recite terms such as:
  - “non-natural”
  - “synthetic”
  - “chimeric”
  - “recombinant”
  - “isolated”
  - “purified”
- In method claims, recite steps involving human or machine action
- Pursue claims directed to devices, apparatus and kits

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## *Lab. Corp. v. Metabolite* (2006) (J. Breyer dissenting)

- Three justices addressed issue of patentable subject matter as it related to diagnostic methodology and kits
- Issue: When does a process claim inappropriately cover a phenomenon of nature?

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## Claim at issue in *Lab. Corp.*

- 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 homocysteine; and

correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.

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## *Lab. Corp. v Metabolite*

- The “assaying” step related to methods known in the field for assaying homocysteine levels
- The “correlating” step provided the novel component

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## ***Lab. Corp. v. Metabolite***

What does “correlating” mean?

- “relating total homocysteine levels to cobalamin or folate deficiency, a deficiency in both, or a deficiency in neither
- Any doctor who reads and thinks about assay test results engages in “correlating”

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## ***Lab. Corp. v. Metabolite***

- Claim is “not a process for transforming blood or any other matter,” but rather “instructs the user to (1) obtain test results and (2) think about them.”
- “[T]he process is not more than an instruction to read some numbers in light of medical knowledge.”
- The recited “correlation is an unpatentable ‘natural phenomenon’” and nothing in the claims “adds anything more of significance.”

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## *In re Bilski* (Fed Cir) (2008)

- Bilski claims related to business methods, but holding may apply to biotechnological, medical diagnostics, therapeutic methods, and personalized medicine

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## *In re Bilski*

- “Machine or transformation” test for patent eligibility under 35 U.S.C. §101.
- Invention meets requirements if:
  - (1) it is tied to a particular machine or apparatus, or
  - (2) it transforms a particular article into a different state or thing.

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## *In re Bilski*

- The claimed “use of a specific machine or transformation of an article must impose meaningful limits on the claim’s scope”
- The machine or transformation must not consist merely of “insignificant extra-solution activity”
- The “transformation must be central to the purpose of the claimed process”
- In most cases, merely “gathering data would not constitute a transformation of any article”

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## **On appeal to Fed. Cir. now ...**

- *Prometheus Labs. v. Mayo Collaborative Srvs.* (S.D.Cal., March 28, 2008)
  - Important case to watch regarding diagnostics and personalized medicine
  - Claims are directed to measuring metabolite levels in patients after administration of a drug to avoid toxic side effects

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## Example claim at issue in *Prometheus Labs.*

- 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 ...; and
  - (b) determining a level of 6-thioguanine or 6-methyl-mercaptopurine ... , [wherein certain levels indicate the need to increase or decrease the amount of the drug in subsequent administrations]

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## *Prometheus Labs.*

- Dist. Ct followed *Lab. Corp.* reasoning, holding that the “correlation” of metabolite levels and toxicity was a natural phenomenon
- BIO and AIPLA (and others) have filed amicus briefs asking court to uphold patentability, arguing:
  - (1) *Bilski* “transformation” occurs via transformation of drug to metabolite, and (2) no weight should be given to *Lab. Corp.* dissent
  - Distinction exists between naturally occurring metabolites vs. non-naturally occurring drug breakdown products

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## Claim drafting considerations

- Pursue claims to new and non-obvious compositions and products
  - E.g., DNA chip containing a new gene
- Pursue claims to devices, kits or apparatuses, if component(s) or combination are new and non-obvious

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## Claim drafting considerations

- Pursue claims to methods of testing, if action step(s) or combination of steps are new and non-obvious
  - in *Lab. Corp.*, “assaying” step was not new

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## Avoid Potential Pitfalls

- Careful about drafting claims that encompass a natural phenomenon or law of nature
- Careful about “thinking” language in method claims, such as “correlating,” “determining,” “identifying,” “detecting,” “calculating,” “deriving,” or “comparing”
- OK to recite “thinking” steps, but a problem may arise if such steps provide the only new or non-obvious aspect of the claimed method

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## Avoid Potential Pitfalls

- Careful with “thinking” steps in method claims – consider *Bilski*
  - If possible, tie process to a particular apparatus
  - If possible, include changing some material to a “different state or thing”

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## Avoid Potential Pitfalls

- Include at least one “non-thinking” step that provides a new/non-obvious element
- Consider physical action language: “providing,” “obtaining,” “adding,” “combining,” “blending,” “subjecting,” “contacting,” “mixing,” “inoculating,” “converting” or “treating”

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## Patents are a Way of Life

- Innovative companies must deal with patents
- Patenting inventions as early as possible protects R & D investment
- Careful drafting of specification and claims makes a big difference!

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**Thank you!**



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