Life after Myriad: The U.S. Supreme Court Restricts Patentable Subject Matter

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new or useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

“conditions” of title 35 include novelty, nonobviousness, written description and enablement.
Historically three judicial exceptions to patentable subject matter:

- Laws of nature
- Natural phenomena, and
- Abstract ideas

Diamond v. Diehr, 450 U. S. 175, 185 (1981)
Section 101 Law Awakens at the Supreme Court with a non-decision

LabCorp v. Metabolite, Inc. (2006)

- Method of determining vitamin deficiency by measuring blood protein levels (homocysteine)

- LabCorp was licensee of Metabolite’s test

- Decided to use a different test from Abbott Labs that was “far superior.”

- Metabolite sued, relying on a broader claim that was not limited to their test methodology.
Section 101 Law Awakens at the Supreme Court with a non-decision

*LabCorp v. Metabolite, Inc.* (cont’d)

- Metabolite was awarded $4.7 million in damages, upheld on appeal

- Supreme Court granted cert. on section 101 challenge, then dismissed as improvidently granted (DIG)

- Justice Breyer authored a 14-page dissent (joined by Justices Stevens and Souter), noting unpatentability of scientific principles
J. Breyer’s Statements in LabCorp

- Should have struck down claims under judicial exception for patent eligibility of a natural law

- Not to say that any law of nature is obvious, or that its discovery is easy, or that it is not useful

- Research may be costly and time-consuming; monetary incentives may matter; and the fruits of great benefit to the human race

- But “too much” patent protection can impede rather than “promote the Progress”
Myriad District Court Decision

• March 2010, Judge Sweet in S.D.N.Y.

• Struck down composition claims to isolated DNA on summary judgment to BRCA1 and BRCA2, mutations of which show substantial likelihood of developing breast and ovarian cancer

• Ineligible subject matter under section 101 for being directed to a law of nature

• DNA considered vehicle of natural genetic information, even when isolated

• Went against a decade of Patent Office policy, and the patent community expected the Federal Circuit to reverse
Section 101 Exceptions Officially Back with *Bilski*


- Method of hedging risk
- Held: Unpatentable abstract idea
- Machine or transformation (MOT) not sole test for statutory subject matter of a process

- Unanimous U.S. Supreme Court decision authored by Justice Kennedy
- Little guidance going forward on where to draw line
Life After *Bilski* – Lemley et al. 2010

- For a decade after *State Street Bank* in 1998, until the Fed. Cir. en banc *Bilski* decision, patentable subject matter was “effectively a dead letter” in the courts.

- Decision could have gone further: Four of the U.S. Supreme Court justices would have held business methods not patentable altogether.

- But despite the decision, PTO and courts have continued to apply MOT.
Life After *Bilski* (cont’d)

- The real issue is overclaiming, overbreadth

- Tailored claims should survive even if they aren’t transforming anything physical, but broad claims that encompass any sort of data should not

- Patent claims can and often do employ abstract ideas or scientific principles to a useful and practical end

- But patents should not provide broad ownership over fields of exploration rather than specific applications within those fields
Myriad Appeal to Federal Circuit

- Federal Circuit panel reversed on composition claims
- Isolated DNA was “markedly different” from the natural DNA existing in humans
- Judge Lourie distinguished from “purification” cases because change in chemical structure from breaking bonds
- Judge Moore noted a significant broadening of utility of the isolated DNA
- Judge Bryson dissent: isolating DNA is like “snapping a leaf from a tree”
Back in Time: “Purification” Case Law

- **American Wood-Paper Co. v. Fibre Disintegrating Co. (1874)**
  - Patent on purified wood pulp **struck down**
  - Cannot patent product **merely separated** from its surrounding materials and unchanged
  - At time of filing, well understood that wood contained the cellulose to make paper, but no known processes by which the cellulose could be purified by chemical treatment alone

- **Ex Parte Latimer (1889)**
  - Patent on fiber discovered in the needle of a particular species of pine
  - Held **not patentable** because extracted from natural source, merely purified, so product was naturally occurring, irrespective of how beneficial its properties may have been
Back in Time: “Purification” Case Law

- **Union Carbide Co. v. American Carbide Co.** (1910)
  - Patent upheld for new form of crystalline calcium carbide
  - Crystalline product had different physical properties from amorphous product known in the prior art
  - Better suited for commercial use

- **Kuehmsted v. Frabenfabriken of Elberfeld Co.** (1910)
  - Patent upheld for purified form of synthetic chemical compound (aspirin) made by new process
  - Product of the different process had different chemical properties
  - The fact that two products have the same substance chemically does not mean they have the same substance physically, and their therapeutic value may be widely different
Back in Time: “Purification” Case Law

- **Parke-Davis & Co. v. H. K. Mulford & Co.** (1911)
  - Judge Learned Hand upheld product patent for purified adrenaline
  - Chemically converted adrenaline from salt form into a base during purification
  - Difference not in degree, but in kind
  - Became for every practical purpose a new thing commercially and therapeutically
Back in Time: “Purification” Case Law

- **General Electric Co. v. De Forest Radio Co.** (1928)
  - New method to convert natural tungsten into element of great ductility and high tensile strength, giving it many new uses
  - Patent struck down – merely isolated pure tungsten from its oxide found in the earth
  - No patent on an element of nature with characteristics that nature alone has given it

- **In re John Wesley Marden and Malcolm N. Rich** (1931)
  - Patent on ductile vanadium struck down
  - It was “nothing more or less than vanadium freed from all impurities”
  - The ductility of pure vanadium is inherent
Back in Time: “Purification” Case Law

- **Merck & Co. v. Olin Mathieson Chemical Corp.** (1958)
  - Patent upheld on substance in the liver of cattle useful to treat anemia (later found to be vitamin B12).
  - Patentee succeeded in isolating it.
  - Composition claimed with a defined range of purity and derived from reactions of specific fermentates.
  - Product was of such purity that it differed not only in degree but in kind, with a new utility in which inventions may rest.
“Biological exception”? 

- Multiple commentators have felt that the case law seemed more favorable based on the product protected.

- Biological science inventions upheld as different in kind, while physical elements struck down as having different properties given by nature (though not realized until purification).

- Promote economic incentives to develop new therapeutics?
  - "A substance prepared from fresh pancreatic or related glands containing in concentrated form the extractive from the ductless portion of the glands sufficiently free from injurious substances for repeated administration and having the physiological characteristics of causing a reduction of blood sugar useful for the treatment of diabetes mellitus." (Banting, Best, and Collip, US Patent No. 1,469,994 (Oct. 9, 1923)).
Historical § 101 Law on Compositions

**Funk Brothers Seed Co. v. Kalo Inoculant Co. (1948)**

- Claims to mixed cultures of certain strains of nitrogen-fixing bacteria, which had been found to not mutually inhibit each other
- Held **not** patent-eligible
- Qualities of non-inhibition were the **work of nature**, and **no species acquired a different property or use**
- “The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of the laws of nature, free to all men and reserved exclusively to none.”
Historical § 101 Law on Compositions

Diamond v. Chakrabarty (1980)

- Bacteria genetically engineered with four naturally occurring DNA plasmids, each of which enabled the breakdown of a different component of crude oil.

- Held patent eligible as product of human ingenuity.

- While cannot patent things that exist in nature, can patent things that are derived from nature.

- Bacteria had markedly different characteristics from those found in nature based on the efforts of the patentee.

- U.S. Supreme Court struck down method claims as directed to a “law of nature” (unanimous)

- Appending *conventional steps, specified at a high level of generality*, to laws of nature, natural phenomena, and abstract ideas cannot render them patent-eligible

- Trumps any finding of a MOT (had been held eligible as transformation by Fed. Cir.)

- [declining the Government’s suggestion that the claim should be handled under sections 102, 103, 112]: This approach would make the “law of nature” exception to §101 patentability a *dead letter*
Claim 1 is representative:
A method of optimizing therapeutic efficacy for treatment...
comprising:

(a) administering a drug providing 6-thioguanine to a subject...
; and

(b) determining the level of 6-thioguanine in said subject...

wherein the level of 6-thioguanine less than about 230 pmol per
8x 10^8 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
8x 10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.
Court’s Analysis of *Prometheus* Claims

- Because the law of nature recited by the patent claims - the relationships between concentrations of certain metabolites in the blood and the likelihood that a thiopurine drug dosage will prove ineffective or cause harm - are not themselves patent-eligible, the claimed processes are likewise not patent-eligible unless they have additional features that provide practical assurance that the processes are genuine applications of those laws instead of drafting efforts.

- Here, the remainder of the claim adds nothing but well-understood, routine, conventional activity already engaged in by the scientific community. Those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately.
At the time of invention, scientists understood that the levels in a patient’s blood of certain metabolites, including, in particular, 6-thioguanine, were correlated with the likelihood that a particular dosage of a thiopurine drug could cause harm or prove ineffective. But did not know the precise correlations between metabolite levels and likely harm or ineffectiveness. The patent claims at issue set forth processes embodying findings that identified these correlations with some precision.
Factual History of the Case

- Prometheus Laboratories sells diagnostic tests that embody the processes in the asserted claims.

- For some time Mayo bought and used those tests. But in 2004 Mayo announced that it intended to begin using and selling its own test—a test using somewhat higher metabolite levels to determine toxicity (450 pmol per $8 \times 10^8$ for 6–TG and 5700 pmol per $8 \times 10^8$ for 6–MMP).

- Prometheus then sued for patent infringement.

- Very similar to Metabolite!
So what methods ARE patentable?

- Application must be “significant,” not “too broadly preempt” use of the law

- Include other elements that constitute an “inventive concept” that is significant and separate from the natural law itself

- “Additional features” to provide “practical assurance that the process is more than a drafting effort”

- Even a narrow law, such as in *Prometheus*, can run afoul of the judicial exception to patent eligibility

- Long on prose, short on where to draw the line
Myriad remand to Federal Circuit

- U.S. Supreme Court granted cert in Myriad after Federal Circuit panel decision, vacated the decision and remanded to reconsider in view of Mayo v. Prometheus

- Remand went to same panel of judges, and the decision, dealing with a composition of matter rather than a process invention, was the same

- Another petition to grant cert. to U.S. Supreme Court
Three Questions Presented to the U.S. Supreme Court

By petitioners ACLU and PubPat:

1. Are human genes patentable?
2. Did the court of appeals err in upholding a method claim by Myriad that is irreconcilable with this Court's ruling in Mayo v. Prometheus?
3. Did the court of appeals err in adopting a new and inflexible rule, contrary to normal standing rules and this Court's decision in Medimmune that petitioners who have been indisputably deterred by Myriad’s “active enforcement” of its patent rights nonetheless lack standing to challenge those patents absent evidence that they have been personally and directly threatened with an infringement action?
Certiorari GRANTED on question 1:

Single Question: Are human genes patentable?
A naturally occurring gene segment is not patent eligible merely because it is “isolated”.

No markedly different characteristics from those found in nature.

But, claims limited to cDNA sequences or otherwise manipulated from genetic form are eligible because they are not naturally occurring.
“Isolated” DNA not eligible

- Matters not that chemical bonds severed during isolation
- Claims simply not written in terms of chemical structure
- No endorsement of PTO practice where the Government argues against it
- Another unanimous decision, authored by Justice Thomas
Shift to a different “I” word

- “Isolated” no longer able to confer patent-eligibility, but “intron” removal now can

Arti Rai and Robert Cook-Deegan, Moving Beyond “Isolated” Gene Patents (July 2013)

- Because intron removal is relatively routine, the Court’s decision could be seen as stepping back to some degree from Prometheus
- Court “did not connect the dots” on why cDNA is okay when gDNA is not
Policy considerations for line in the sand

Rai and Cook-Deegan, *supra*

- “Dissipating the shadow of patent infringement liability” for whole-genome sequencing was an “important factor” that motivated the NIH and Office of Science and Technology Policy to persuade the solicitor general to reject the PTO’s position allowing claims on isolated DNA.

- Claims on cDNA can generally be worked around for genomic research purposes.
Unanswered Questions

- What about compositions of matter of other biological molecules?
  - Primers
  - Isolated proteins
  - Antibodies
  - RNAi
  - Antigens/Vaccines

- Court challenges are underway
  - Myriad has already brought suit against companies offering discounted BRCA genetic testing
Myriad Goes on the Offensive

- Asserted multiple claims in 10 of its portfolio of patents relating to the BRCA genetic testing against Ambry, Gene by Gene
- Includes cDNA, primer claims, methods of screening
- Myriad has 24 patents containing 520 claims concerning the BRCA1 and BRCA2 genetic testing
- The *Myriad* Supreme Court decision had only struck down 5 of those claims, and they still have 515 patent claims relating to this testing
- Stay tuned for more!
Life After *Myriad*: How Should Innovators React?

- Apart from the gDNA/cDNA line drawn by the *Myriad* Supreme Court decision, accept that uncertainty will exist in the near term.
- Be mindful of statutory subject matter concerns and adjust strategies accordingly.
- Continue to pursue innovation in personalized medicine and related technologies.
The Era of Personalized Medicine

- Tailoring medical treatment to the individual or particularly defined subgroup of people
- Predictions of disease onset, course, responsiveness to treatment, minimize danger of side effects
- Save money by avoiding ineffective treatments, significantly improve outcomes
- Individuals are embracing and also becoming more proactive in their own healthcare
The FDA is Interested

- Very interested in personalized medicine: right drug; right patient; right dose.


- In fact, companies now face pressure from regulators and insurers to develop tests to pinpoint which patients are most likely to benefit.

Andrew Pollack, A Push to Tie New Drugs to Testing (2011)

- FDA denied approval for a drug developed by ChemGenex for leukemia treatment because they had not specified a companion test that could reliably detect the mutation so that the drug could be targeted to the patients it is intended to help.
Patent Protection in Personalized Medicine

- Supports investment in research and development to refine patient populations and validate efficacy of targeted treatments, and significant investment required to conduct prospective Phase III clinical trials, itself carrying the risk that safety and efficacy will not be shown, and subsequent launch of product to market
  - Only one in 4 or 5 anti-cancer compounds entering Phase I testing achieves regulatory approval (Bates et al., Clin. Cancer Res. 2012; 18: 32)

- However, companies are accustomed to the traditional model of patent protection for a new medicinal entity (NME) and may be unclear on how to integrate a personalized medicine component into their IP portfolio
Incorporate Personalize Medicine

• Companion diagnostics are becoming more common for both new medicinal entities and new uses of known entities as the field embraces a new era of personalized medicine.

• Effective patent coverage of these products is more complex than the traditional compound per se and composition patents.

• Think strategically and present claims covering potential companion diagnostic early in the portfolio building process.
Special Challenges Faced by Personalized Medicine IP in the US

- Patent eligible subject matter
  - Active steps required, cannot merely perform by thinking (Classen)
  - Must be more than just a natural law (Mayo v. Prometheus)
  - Composition of matter protection (Myriad v. ACLU)

- Divided infringement
  - Steps may be performed by different actors: competitor drug company, doctor, lab, patient, etc.
  - May not need one actor to perform all steps to show induced infringement
    - *Akamai en banc* 6-5 Federal Circuit decision, but Supreme Court review on the horizon
Special Challenges Faced by Personalized Medicine IP Outside the U.S.

- Diagnostic methods and methods of medical treatment, and of themselves, are generally not patent eligible subject matter

- Alternative claiming strategies and formats directed to therapeutic product must be employed

- Need to collaborate with foreign counsel for protecting inventions on the cutting edge of personalized medicine
Life After *Myriad* – Closing Thoughts

- Navigating the law for patent protection for inventions in the field of life sciences is more challenging, especially in the near term as the case law and Patent Office procedures continue to develop after big decisions from the U.S. Supreme Court such as *Myriad* and *Prometheus*.

- However, given the trajectory of many life science innovations towards more biological-based inventions, patent protection for life science inventions will continue to be a valuable asset.
Life After *Myriad* – Recommendations

- Spend more time and effort drafting and developing details around inventions
- The AIA ensures that a poorly-developed disclosure can rarely be fixed later
- Draft for both U.S. and ex-U.S. filings
- Keep informed as the case law continues to develop and adjust strategy accordingly
Life After *Myriad* – Recommendations

- Draft multiple types of claims at multiple levels of scope
- No “one size fits all” claim strategy in the post-Myriad life
  - See also Kenneth D. Sibley: *The Uncertain Status of Patentable Subject Matter at the CAFC and Supreme Court: Impact of Patent Prosecution* (2013)
- Include active steps in method claims that cannot be done by thinking
- Include additional features in composition claims apart from a natural correlation, preferably features that are, themselves, novel
“Life” After *Myriad* Will Go On

Cited References


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