Outline

- PSM exceptions
  - “Product of nature” (product patents/biopharma)
  - “Law of nature” (process patents/biopharma)
  - Abstract idea (process patents/software)
Recent cases

- **Supreme Court**
  - AMP v. Myriad (decision by end of term) (product of nature)
  - Prometheus v. Mayo (2012) (law of nature)

- **CAFC**
  - CLS Bank v. Alice (last Friday!)
History of “product of nature” doctrine

- 19th century history quite murky (also no codified non-obviousness doctrine until 1952)
- Parke-Davis (1911)
  - ‘176 patent isolated i.e. not in salt form and purified
  - ‘177 patent purified (as contrasted with von Furth’s salt – note that Hand does not address isolation piece)
  - General gloss: “for every practical purpose a new thing commercially and therapeutically” (shades of utility)
- Funk Brothers Seed Co. v. Kalo Inoculant Co. (1948) (no patent on nitrogen-fixing bacteria for leguminous plants e.g. soy, alfalfa ...)
- Diamond v. Chakrabarty (1980) (“bacterium for the genus Pseudomonas containing therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway”)
“Gene” Patents

- Post *Chakrabarty*, assumption that isolated *and/or* purified DNA sequences were patentable (essentially so long as claimed DNA was not on chromosome, it was patentable)
- Many early claims to plasmids, other vectors containing DNA sequences
  - Generally claimed DNA sequences coding for *therapeutic proteins*
- When drafting claims, prosecutors didn’t always draw distinctions drawn between cDNA and gDNA
  - What is difference?
Schematic drawing for the formation of the spliceosome
The Diversity of “Gene Patents”

- *Methods* as well as composition of matter (e.g. in *Myriad* case, methods of comparing BRCA1 sequence from tumor sample to BRCA1 sequence in non-tumor sample)

- Among composition of matter patents:
  - Patents on DNA coding for proteins used as “research tools” (e.g. receptors)
  - Patents on DNA useful for diagnostic purposes (e.g. BRCA1, BRCA2)
  - Patent on DNA useful for therapeutic purposes (e.g. erythropoeitin)
The pre-Myriad Law

- USPTO 2001 guidelines – a DNA sequence that has been “isolated” is not a product of nature “because that DNA molecule does not occur in that isolated form in nature.”
- Prior to Myriad, *no* court had previously addressed whether an isolated DNA molecule is patentable subject matter.
- USG brief in Myriad: “Nor has the United States previously expressed its view on that question in litigation”
  - USG draws distinction between gDNA and other DNA-related claims (e.g. cDNA, plasmids containing DNA etc.)
  - At oral argument, “magic microscope” test
‘282 patent

- An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2 (genus claim encompassing lots of gDNA)
- The isolated DNA of claim 1, wherein said DNA has the nucleotide sequence set forth in SEQ ID NO:1 (cDNA)
  - At time, Myriad probably thought there might be some therapeutic value
- An isolated DNA having at least 15 nucleotides of the DNA of claim 1 (very broad genus claim, encompassing gDNA and cDNA)
  - 15mers used as primers in Dx screening process (as Judge Moore points out)
Positions of Judges

- **Lourie**
  - all gDNA and cDNA patentable because “covalent bonds” are broken (hence “isolation”)
  - Leaves open whether purification is enough (cf. Parke-Davis, p. 24)

- **Moore**
  - cDNA patentable;
  - 15 mers patentable
  - full-length gDNA?

- **Bryson**
  - Full-length cDNA patentable
  - Full-length gDNA and 15mer cDNA, gDNA *not* PSM
  - Concerned about impact of 15mer claims on whole genome sequencing
Supreme Court oral argument

- Justices Breyer, Sotomayor seem quite receptive to government position (differentiating cDNA from gDNA)
- Industry probably most concerned about impact on “purified” therapeutics
  - E.g. BIO brief (citing examples of rapamycin, tacrolimus, exenatide, phytase, glucoamylase, and muromonab)
Laws of Nature -- *Prometheus*

- Another “ping-pong” case (like *Myriad*)
- Method of optimizing therapeutic efficacy for treatment of GI disorder comprising:
  - Administering drug containing metabolite
  - Determining level of metabolite
  - Adjusting dosage if <230 picomoles or >400 picomoles
- On second round, CAFC (per Judge Lourie, again!) relied on “machine or transformation” idea, rendered the same opinion (focused on “transformation” in “administering” step)
Prometheus at Court

- Supreme Court: covers “relationships between concentrations of certain metabolites in the blood and likelihood that dosage with prove ineffective” (too low or too high)
- “If a law of nature is not patentable, then neither is a process reciting a law of nature, unless that process has additional features that provide practical assurance that this is not a drafting effort “to monopolize the law of nature itself”
  - In this case, “any additional steps constitute well-understood, routine, conventional activity”
- Distinguishes Diehr by suggesting that additional steps were *not obvious*
- Point of novelty approach (but then derides using point of novelty approach under 102 or 103)
Prometheus, cont’d

- Emphasis (as in Bilski) on “preemption”
- But if preemption is the concern, does it matter that the “law of nature” i.e. people metabolize differently, such level of thiopurine metabolite < 230 and > 450 can be used to adjust administration for thioguanine drug is *very narrow*

**Pre-solution activity**

1. A method of diagnosing the risk of disease A in a patient, comprising:
   - (a) **analyzing** gene mutation X in a nucleic acid sample
   - (b) **determining** the genotype of the nucleic acid sample
   - (c) **assessing**, based on the genotype, that the patient is at risk for disease A

2. **Possibly patent eligible**

**Post-solution activity**

3. A method of treating a patient having disease A, comprising:
   - (a) **determining** the presence of gene mutation X in a nucleic acid sample
   - (b) **treating** the patient, based on presence of mutation X, with therapy to delay the onset of disease A

4. **Likely patent eligible**

**Non-specific**

78.64% Likely patent ineligible

**Specific**

20.11%

A method of evaluating the risk of disease A in a patient, comprising:

- (a) **analyzing** gene mutation X in a nucleic acid sample using technique Y and a primer of sequence Z
- (b) **determining** the genotype of the nucleic acid sample
- (c) **assessing**, based on the genotype, that the patient is at risk for disease A

**Possibly patent eligible** 0.83%

A method of selecting therapy for a patient having disease A, comprising:

- (a) **determining** the presence of gene mutation X in a nucleic acid sample, and
- (b) **selecting**, based on the presence of gene mutation X, a therapy that included the administration of drug Y

0.72%
Software/Business Methods (abstract ideas?)

  - Software patentable as part of process that effects physical transformation of matter (rubber)
  - Uses language about machine-or-transformation
- 1980s through *Alappat*: where claim (product or process) recites an algorithm, look for machine or physical transformation (*Freeman-Walter-Abele* test)
Software/Business Methods, cont’d

- *In re Alappat* (Fed. Cir. 1994)
  - For purposes of satisfying FWA, the computer on which the software runs is the relevant “machine”
  - FWA not so important in any event; utility is what counts
- *State Street* (Fed. Cir. 1998) (means plus function)
  - Business methods are patentable
  - Utility is *only* test for PSM (*see also AT&T v. Excel*, which reaches same conclusion re: process patents)

In *Bilski*, PTO fights back against naked business methods (advance M or T test for process claims)
Bilski v. Kappos majority (*not* II-B-2 and II-C-2)

- M-or-T a “clue”: using it as sole test violates textualism principles
- Textualism means business methods are not categorically out; also 273(b) prior user right for business methods
- Abstract ideas that “preempt” not patentable, even if limited to one “field of use”
  - Why? As concurrence points out, why are restrictions to particular types of data and analysis of that data mere “token post-solution components”
  - Breyer seems to ignore this issue in *Prometheus*
Immediate aftermath of *Bilski: RCT v. Microsoft* (CAFC 2010)

- Broadest claim:
  - “A method for the halftoning of gray scale images by utilizing a pixel-by-pixel comparison of the image against a blue noise mask in which the blue noise mask is comprised of a random non-deterministic, non-white noise single valued function which is designed to produce visually pleasing dot profiles when thresholded at any level of gray scale images.”
Opinion by Judge Rader (joined by Newman, Plager)

- “[T]his court also will not presume to define “abstract: “beyond the recognition that this disqualifying characteristic should exhibit itself so manifestly as to override the broad statutory categories of eligible subject matter”
- “The inventions presents functional and palpable applications in the field of computer technology”
- “The fact that some claims . . . require a “high contrast film,” “a film printer,” “a memory,” and “printer and display devices” also confirm . . that the invention is not abstract”
Cybersource Corp. v. Retail Decisions

- A method for verifying the validity of a credit card transaction over the Internet comprising the steps of:
  - obtaining information about other transactions that have utilized an Internet address that is identified with credit card transaction
  - constructing a map of credit card numbers based upon the other transactions and;
  - Utilizing the map of credit card numbers to determine if the credit card transaction is valid
(No specific fraud detection algorithm)
Opinion by Judge Dyk (joined by Bryson, Prost)

- Court below (pre-\textit{Bilski}): No M-or-T

- Dyk:
  - No M-or-T (Internet is just a source of data)
    - data-gathering steps don’t make an otherwise nonstatutory claim statutory
  - Also “unpatentable mental process”
    - Could be done by pencil and paper (like Gottschalk, Parker v. Flook)
    - Fact of practical application doesn’t make mental process patentable
“Beauregard” claim

- “Computer-readable medium containing program instructions for detecting fraud in a credit card transaction between a consumer and a merchant over the Internet . . .”
  - CyberSource says this is a “manufacture,” not a process

- Dyk:
  - We care about underlying invention, not statutory category
  - Not patent-eligible because not drawn to a “specific” computer readable medium
  - Distinguishes *Alappat* by saying “we have never suggested that simply reciting the use of a computer to execute an algorithm that can be performed entirely in the human mind falls within *Alappat*”
Dealertrack v. Huber

A computer aided method of managing a credit application, the method comprising the steps of:

- [A] receiving credit application data from a remote application entry and display device;
- [B] selectively forwarding the credit application data to remote funding source terminal devices;
- [C] forwarding funding decision data from at least one of the remote funding source terminal devices to the remote application entry and display device;
- [D] wherein the selectively forwarding the credit application data step further comprises:
  - [D1] sending at least a portion of a credit application to more than one of said remote funding sources substantially at the same time;
  - [D2] sending at least a portion of a credit application to more than one of said remote funding sources sequentially until a finding [sic, funding] source returns a positive funding decision;
  - [D3] sending at least a portion of a credit application to a first one of said remote funding sources, and then, after a predetermined time, sending to at least one other remote funding source, until one of the finding [sic, funding] sources returns a positive funding decision or until all funding sources have been exhausted; or,
  - [D4] sending the credit application from a first remote funding source to a second remote finding [sic, funding] source if the first funding source declines to approve the credit application.
DealerTrack v. Huber (Linn, Plager, Dyk)

- “We are compelled to conclude that the claims are invalid as being directed to an abstract idea”
- Simply adding a “computer-aided limitation to a claim covering an abstract concept, without more, is insufficient . . .”
CLS Bank Int’l v. Alice

- Contested method, computer-readable medium, and system claims
- All involve handling of settlement risk
En banc questions

- What test should the court adopt to determine whether a computer-implemented invention is a patent ineligible "abstract idea"; and when, if ever, does the presence of a computer in a claim lend patent eligibility to an otherwise patent-ineligible idea?

- In assessing patent eligibility under 35 U.S.C. § 101 of a computer-implemented invention, should it matter whether the invention is claimed as a method, system, or storage medium; and should such claims at times be considered equivalent for § 101 purposes?
“Result” (??)

- Per curiam majority opinion
- “A majority of the court affirms the district court’s holding that the asserted method and computer-readable media claims are not directed to eligible subject matter. An equally divided court affirms the district court’s holding that the asserted system claims are not directed to eligible subject matter . . .”
- 5 opinions, “additional reflections” by Judge Rader