Protecting Valuable IP in the Face of New Challenges to Patent Eligibility

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Panelists

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Moderators

- **Matthew McFarlane:** Principal, Robins Kaplan LLP
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The Current State of Patent Eligibility – the Courts

- In the U.S., abstract ideas, laws of nature, and natural phenomenon not eligible for patent protection.
  - Reluctance to remove natural laws and natural compositions from public domain.
  - Ex-U.S., broader eligibility for patent protection.
- U.S.P.T.O granting patents on human genes since 1980s.
- Myriad had patents on isolated gene sequences for BRCA.
  - Threatens commercial diagnostic labs as well as university researchers.
  - Some threatened parties sue Myriad.
- Myriad case declares isolated DNA sequence not eligible for patentability.
  - Isolated DNA sequence identical to portions of natural DNA
  - Sequence not created or altered therefore not a *new* composition of matter
  - Drug discovery claims survived.
The Current State of Patent Eligibility – the Courts

- Modified gene sequences are patent eligible if not naturally occurring.
  - Diagnostic probes (e.g., DNA *modified* with a label)
  - Multi-exon cDNA sequence is patent eligible since it *omits* introns (not natural).
    - But watch very short DNA segment since it naturally may not have introns
  - Myriad implies that unusual/rare phenomenon that randomly creates a natural molecule similar to a synthetic molecule does not necessarily eliminate patent eligibility for the synthetic molecule.
- In healthcare space, some modified gene sequence patents may be easy to avoid.
  - Synthesize naturally-occurring DNA instead.
- In industrial space, some modified gene sequence patents may be difficult to avoid.
  - Is any natural sequence even close?
The Current State of Patent Eligibility – the Courts

- Prometheus case struck down diagnostic that helped identify ideal dosage
  - Method *merely* correlated metabolite level with dosage level
  - Method to use genes may be patent eligible if active step after effect of gene
    - Ex.: Administer adjusted medicinal dose after determining metabolite levels.
- Alice case struck down computerized escrow software patent.
  - Using 3rd Party Intermediary to mitigate transaction risk is well-known abstract idea.
  - Added steps were routine/well-known.
  - Abstract ideas, laws of nature, and natural phenomenon are the “*basic tools*” of scientific & technological work; the “*building blocks*” of human ingenuity.
  - Granting patents that cover building blocks may preempt entire field(s).
The Current State of Patent Eligibility – the USPTO

- Three Supreme Court decisions → four examination guideline documents in the USPTO
- Since *Mayo*, 101 rejections more than tripled in AU 1630, 40, 50 (mol. Biology; immunology; fermentation/enzyme/microbiol.)
- In AU 1650, probability of 101 rejection now around 30%.
- Effect on prosecution:
  - Applicants do NOT seem to abandon many applications
  - But: many more office actions (30% increase)
  - Possibly, applicants focus on allowable claims; deferring 101 issues
- Applicants are still “getting patents.” Are these patents “good enough?”

The Current State of Patent Eligibility – the USPTO

- Examples of typical technologies affected:
  - Enzymes and enzyme preparations, fermentation products, oils, vitamins, extracts and distillates, food and feedstock additives, bacterial and fungal cultures, bactericidal food and feedstock preservatives;

- Applicants have tried to overcome rejections by claiming e.g.
  - Enzyme compositions instead of enzymes
  - Methods of using compositions instead of compositions

- Making claim more like “industrial application;” adding limitations; not preempting others from using “natural phenomenon.”
The Current State of Patent Eligibility – the USPTO

- USPTO examination guidance:
  - March 2014 “Myriad/Mayo” guidance
  - December 2014 revised “Interim” guidance
- USPTO guidance examples:
- December 2014 guidance contains significant revisions. Described as more permissive; contains helpful examples.
- So far, frequency of rejections under 101 has not decreased
Adapting to a New Climate for Patent Protection

- Picket fence approach remains
- Don’t ignore the application space
- Patents plus trade secrets
Adapting to a New Climate for Patent Protection

- Trade Secret Protection
  - Forever, no time limit
  - No Maintenance fees
  - Advisable with high degree of know-how
    - Manufacturing processes
    - R&D knowledge
    - Process improvement
  - Requires business policies and contracts with employees
Adapting to a New Climate for Patent Protection

- Trade Secret Pitfalls
  - Maximum protection is difficult to achieve
  - No exclusive rights
  - Once lost remains lost
  - May reduce licensing potential
Adapting to a New Climate for Patent Protection

- Trade Secret Enforcement
  - Detecting infringement can be difficult
    - Chemical reactions mask identity
    - Can’t see inside a plant
  - Costs can be high
    - Improper misappropriation hard to determine