Impact of Constitutional Rights and Freedoms on IP Decisions of the US Supreme Court

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Innovation Policy

Art. I, Sec. 8, Clause 8

(Copyright & Patent Clause)

- The Congress shall have Power to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.
- Similar to provisions identifying the goals of copyright and patent systems in European and Asian countries.

Justification for US IP System

Utilitarian/Economic

- Patents and copyrights are analogous to a monopoly by blocking access to inventions and information which may inhibit innovation and dissemination of information
- Patents and copyrights may conflict with human rights, particularly rights for health and the freedom of expression
  - Benefits from innovation promotion should exceed the social costs resulting from monopoly

Forward Looking Approach

Prof. Helfer: Human Rights Through IP

- IP is Pro-Human Rights if combined with licenses
  - Learn from open source software licensing
  - Need IP for keeping access to creation
- Principle to Practice in Action: Patent Pools to Tackle Neglected Tropical Diseases (NTDs)
  - Gates Foundation
  - Path
  - Intellectual Venture
  - University Technology Transfer

Comparative Law

Common Law

- Flexibility in Judicial Power
- Equitable Doctrines
  - Courts' Inherent power
- Less Exclusions
- Less Limitations
- No Compulsory Licenses

Civil Law

- Inflexibility in Judicial Power
- General Principles
  - Last resort
- More Exclusions
- More Limitations
- More Compulsory Licenses

Comparative Law

India

- Eligibility Exclusions
  - Derivative Drugs
- Limitations
- Compulsory License
  - Natco v. Bayer
- eBay Doctrine
  - *Cipla v. Roche*

Thailand

- Eligibility Exclusions
- Limitations
- Compulsory License
  - *GPO v. Merck*

US IP Statutes

Statutory Limitations

- Copyright: Freedom of Expression
  - Idea exclusion from eligible subject matter
  - Fair Use *Harper & Row v. Nation Enterprises* (1985); *Campbell v. Acuff-Rose Music* (1994)
  - Limitations and compulsory licenses
- Trademark: Freedom of Expression
  - Exclusions from eligible subject matter
  - Fair Use Lanham Act §43(c) (3) (A).
  - Limitations
- Patent: Rights to Life -Access to Medicines, Food, Information
  - Exclusions from eligible subject matter
  - (Non-commercial & experimental use exceptions)
  - Limitations

Access to Health

- Rights for Life, Liberty and the pursuit of happiness
  - Included in US Declaration of Independence
  - No provision in the U.S. Constitution: No explicit support for access to health
  - Even if there was a provision, no positive right guaranteed under U.S. Constitutional law: No constitutional obligation on the government to provide a citizen medical care - *Maher v. Roe* (1977); *Harris v. McRae* (1980)
  - Legislation is necessary-Basis for legislation: Art. I, Sec. 8, Cl. 8: Taxing and Spending Power

    Congress shall have Power to lay and collect Taxes, ... to ... provide for the ... general Welfare of the United States
  - Many European and Asian Countries adopted the rights
    - European Convention on Human Rights
    - International Covenant on Civil and Political Rights
    - France; Germany; Canada; Japan etc.

US Patent Act

Upstream Restrictions

- Exclusions from Patent Eligibility
  - Abstract Ideas, laws of nature & natural phenomena
  - AIA §33 : Exclusion of human organisms
  - No exclusion for medical methods or plant varieties.
- Beneficial Utility
  - Subject matter conflicting with public order or being immoral – CAFC marginalized the function of beneficial utility

Downstream Restrictions

- Non-Commercial & Experimental Use Exceptions
  - Case law is unclear regarding the scope of exceptions
- Limitations on Remedies for Medical Practitioners' Performances
  - Biotech-related medical processes are excluded from the limitations
  - No exception for the preparation of medicine according to a medical prescription

eBay v. MercExhange (2006)

US Courts have more power in selecting IP infringement remedies than civil law courts

- No automatic injunction
- Patentee must establish:
  1. Irreparable injury
  2. Inadequacy of a remedy at law to compensate for the injury
  3. Balance of hardships between the plaintiff and defendant
  4. Public Interest factors (health and safety) do not preclude injunction

eBay v. MercExhange (2006)

Compulsory Licenses

- No authorization by Patentee
- Grant by Government
- Remuneration
  - Royalty
- Scope
  - Limited by TRIPS Art. 31

Denial of Injunction

- No authorization by Patentee
- Grant by Court
- Remuneration
  - Past: Damages
  - Future: Royalty
- Scope
  - No limitation

U.S. Sup. Ct. Decisions

Patent Eligibility

- *Funk Brothers v. Kalo* (1948)
  - No patent on a discovery of a natural principle
  - Patent Eligible Inventions: An application of a law of nature to a new and useful end
- *Diamond v. Chakrabarty (1980)*
  - No patent on laws of nature, physical phenomena and abstract ideas
  - Anything under the sun that is made by man is patentable
- *J.E.M. AG Supply Inc. v. Pioneer High-Bred* (2001)
  - Patent eligible inventions: Sexually-reproduced plants which fall within the subject matter of the Plant Variety Protection Act
  - Utility patents overriding farmers' rights to saving seeds and research exceptions

Mayo v. Prometheus (2012)

- Prometheus' claims are directed to a method for determining the proper dosage of thiopurine drugs, which are metabolized differently by different patients with autoimmune diseases, to avoid harmful side effects or ineffectiveness
  - A medical treatment method for administrating a proper dosage of drugs to treat autoimmune diseases
  - Information: Correlation between thiopurine metabolite levels and the toxicity and efficiency of thiopurine drugs
  - Not tied to any machine

Mayo v. Prometheus (2012)

- Prometheus is the exclusive licensee of the patents at issue and brought an action against Mayo alleging that Mayo infringed their patents. Mayo asserted that the subject matter of the patents were invalid for lack of patent eligibility.
- CAFC agreed with Prometheus and found the Prometheus patents to be valid and infringement.
- U.S. Sup. Ct. reversed CAFC decision by finding that the method is equivalent to a law of nature.

Mayo v. Prometheus (2012)

Sup. Ct. found that Prometheus claims are not patent eligible by holding that they are directed to a law of nature

- Patenting Prometheus' claims too broadly preempt the use of a natural law and thus inhibits the development of more refined treatment methods.
- Conventional or obvious pre-solution activity is normally not sufficient to transform an unpatentable law of nature into a patent eligible application of such a law.
- Failing to meet the transformation prong of the machine-or-transformation test.

Mayo v. Prometheus (2012)

- **Amicus Brief: American Medical Associations etc.**
  - Prometheus patents convert a routine, sound medical practice into prohibited infringement
  - If such claims to exclusive rights over the body's natural responses to illness and medical treatment are permitted to stand, the result will be a vast thicket of exclusive rights over the use of critical scientific data that must remain widely available if physicians are to provide sound medical care.
  - Laboratories will risk indirect infringement merely by educating doctors about advances in scientific understanding. It is hard to imagine how the clinical diagnostic community will continue to provide quality patient care and how physicians will continue to practice medicine in an ethical and effective manner under such a regime.

Ass's for Molecular Pathology v. Myriad (Pending)

Should an isolated human DNA be patent eligible?

- A claim directed to an isolated DNA coding for a BRCA polypeptide having the amino acid sequence defined by an attached table.
  - BRCA genes correlates with an increased risk of breast and ovarian cancers.
  - Structurally different but functionally the same as the BRCA1 DNA sequence in human body
  - Isolated from the human body through a conventional method.

Ass's for Molecular Pathology v. Myriad (Pending)

- **Amicus Brief: American Medical Associations etc.**
  - Patents are not needed to create an incentive for the discovery of human genes, and patent law does not exist to reward such scientific and medical discoveries. Rather, they must remain "free to all men and reserved exclusively to none," both to meet shared ethical commitments and to foster further scientific discovery and more rapid sequential innovation.
  - there is no need to provide patent incentives to health care professionals, clinicians, and scientists to discover and study gene sequences and the correlations at issue in this case. Indeed, a recent report by the Secretary of Health and Human Service's Advisory Committee on Genetics found that patents "do not serve as powerful incentives for either genetics research in the diagnostic arena or the development of genetic tests."

Bowman v. Monsanto (pending)

- Asserted claims directed to gene, plant cell, and DNA sequences for genetically modified herbicide resistant soybeans (Roundup Ready® seeds)
- Bowman, a farmer, purchased licensed seeds, agreeing that he will not use any harvested seeds for planting in subsequent seasons.
- Bowman planted licensed seeds for his first crops but planted unauthorized "commodity seed" for his second crops which included Roundup Ready® seeds.
- Monsanto sued Bowman. Dist. Ct. found infringement and awarded $84,457.20 in damages.
- Federal Circuit affirmed the Dist. Ct. judgment.

Bowman v. Monsanto (pending)

- What is the scope of patent exhaustion for self-reproducing biological materials?
  - The Court has already addressed the issue relating to conflicting scope of exclusive rights between utility patents and PVPA in *J.E.M. AG Supply Inc. v. Pioneer High-Bred.*
  - EU member states addressed this issue in EU Biotech Directive, although some uncertainty remains regarding the Monsanto v. Cefetra CJEU decision
- To what extent do use restrictions imposed on licensees prevent patent rights from being exhausted?
  - The most recent Sup. Ct. decision, Quanta v. LGE, did not squarely address this issue.

Bowman v. Monsanto(pending)

- **Amicus Briefs: American Antitrust Institute & National Famers Union etc.**
  - **Anti-Competitive Effect**: Whether a commodity seed purchaser's added costs flow from infringement liability itself, the expense associated with seed sorting (whether incurred directly by farmers or passed on to farmers by grain elevators), or self-imposed seed-saving restrictions on commodity seed, the net effect is to increase the price of the product to the farmer or to devalue the product sold by the grain elevator. This loss of competitive discipline from commodity seed is magnified by the fact that Monsanto has a substantial market share in the certified seed market.
- The majority of amicus briefs are filed in favor for Monsanto: Emphasizing the need for patent protection to promote plant innovations.
- At the oral arguments held last February, Supreme Court justices appeared to favor Monsanto.

Watch Out for the Outcomes of Supreme Court Decisions

Thank You!

If you have any questions, please email

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