Outline

- Why focus on patents on medical technologies?
- Two cases:
  1. Gene patenting: Myriad and BRCA
     - Question at stake: what counts as 'nature'/a 'law of nature' not eligible for market protection? What counts as a sufficient transformation of that nature that is eligible for market protection?
  2. Incentivizing vaccine development
     - Question at stake: even for inventions that are eligible for patents, does patenting provide the correct set of incentives or should we adopt other models?
U.S. intellectual property (IP) landscape: medical technology in perspective

<table>
<thead>
<tr>
<th>NAICS code</th>
<th>Industry Title</th>
<th>Patents (number)</th>
<th>Employment (1000 jobs)</th>
<th>Patent Intensity (patents/1000 jobs)</th>
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<tbody>
<tr>
<td>3341</td>
<td>Computer and peripheral equipment</td>
<td>105476</td>
<td>160.2</td>
<td>658.40</td>
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<td>Navigational, measuring, electromedical, and control Instruments</td>
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Two features of patents over medical technology that can make debates socially salient

1. Social idea of health as an important human right
2. Due to #1, large array of relevant social groups (RSG’s) with stakes in medical technology-related patents
Preview of RSG’s…

- Scientists:

- Taxpayers/govt funders:

- Pharmaceutical funders/ producers:

- Individual patients:

- Insurers financing tx for pools of patients:
Case one: Myriad Genetics and BRCA mutations
From transforming natural acorns to genetically modifying natural organisms to characterizing natural genetic sequences

John Locke (1689)
From transforming natural acorns to genetically modifying natural organisms to characterizing natural genetic sequences

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Someone who eats the acorns he picked up under an oak...Well, then, when did they begin to be his?
From transforming natural acorns to genetically modifying natural organisms to characterizing natural genetic sequences

John Locke (1689)

Someone who eats the acorns he picked up under an oak...Well, then, when did they begin to be his?...It is obvious that if his first gathering didn’t make them his, nothing else could do so. That labour marked those things off from the rest of the world’s contents; it added something to them beyond what they had been given by nature, the common mother of all; and so they became his private right.
From *transforming* natural acorns to genetically modifying *natural* organisms to *characterizing* natural genetic sequences

- IP law in U.S. and Europe: formalize intuition that man can own (via a patent) naturally-occurring material if he transforms it with his ideas/labor
- Review from Monday of three criteria for that ownership:
  1. Novel
  2. Inventive/non-obvious
  3. Useful/utility
From transforming natural acorns to genetically modifying natural organisms to characterizing natural genetic sequences

Diamond v. Chakrabarty (1980)
From transforming natural acorns to genetically modifying natural organisms to characterizing natural genetic sequences

Diamond v. Chakrabarty (1980)

The patentee [Chakrabarty] has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature’s handiwork, but his own; accordingly it is patentable subject matter.
From transforming natural acorns to genetically modifying natural organisms to **characterizing natural genetic sequences**

- *Diamond v. Chakrabarty* (1980) established that researchers could take naturally-occurring entities and as long as they *transformed* the naturally-occurring entity sufficiently (and that transformation met the three criteria for a patent), they could receive a patent.

- The case that this week’s readings focus on—Myriad Genetics’ patents over the sequencing of/mutations on two naturally-occurring genes (BRCA1 and BRCA2)—raised questions about *what constituted a sufficient transformation of nature* to allow the inventor to seek a patent.
Returning to Locke and acorns, does it count as a sufficient transformation if the individual does the following:

1. Finds and separates an acorn from a tree (isolates it from its naturally-occurring environment)?
2. #1 + describes it in a way that allows others to detect which acorns are predisposed to grow larger than other acorns?
3. #2 + creates a slightly different synthetic acorn that contains the parts of an acorn that shapes how large it grows/other properties and removes the parts of an acorn that don’t serve any function?
Myriad case: not naturally-occurring acorns but naturally-occurring genes/mutations
Myriad and BRCA: evolution from idea to larger system involved expanded array of relevant social groups

1. **Invention (1970’s-1980’s):**

2. **Development of invention into innovation to survive (1991): #1 +**


4. **Growth, competition, consolidation: #3 +**

5. **Momentum: monopoly over testing (not to expire until ~ 2014) creates momentum over #4 that can continue even past formal expiration**
What happened between the Poste/Williams-Jones readings (Myriad owns patents) and the Liptak reading (some aspects of patents overturned by Supreme Court)?

▶ **Shifting legal landscape (not our focus):** *Mayo v. Prometheus* (2012)
Our focus instead: RSG’s, diverging interests, and social contention

- Two slides ago, we outlined a large list of RSG’s that ranged from patients to Myriad’s investors/shareholders by the time the genetic testing technology was disseminated.

- **To discuss with your partner:** what conflicts might emerge between different RSG’s about the merits versus drawbacks of Myriad retaining its patents on BRCA, related mutations, and testing for those mutations? What avenues can they pursue to try to resolve those conflicts?
One answer: ACLU-organized coalition against Myriad as an illustration of RSG’s, diverging interests, and social contention

- **Plaintiffs:** American Civil Liberties Union (ACLU) became interested in challenging patents on human genes as a matter of public interest law (Cook-Deegan and Niehaus, 2014) and assembled a diverse set of RSG’s with a stake in either more widespread access to BRCA-related genetic testing or fewer barriers to genetics research:
  - Individual females with or with family history of breast cancer
  - Researchers at universities like Columbia/NYU not involved in BRCA patents

- **Defendants:** Myriad Genetics and Trustees of University of Utah
Supreme Court’s decision: distinction between nature v. nature transformed by human labor/ingenuity

1. 'Non-patentable subject matter' (nature or natural law): nucleotide sequence characterizing BRCA1 and BRCA2 even if it’s isolated from surrounding genetic material

   The location and order of the nucleotides existed in nature before Myriad found them. Nor did Myriad create or alter the genetic structure of DNA.... A naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated.

2. Patentable innovation: complementary DNA (cDNA)- can think of as edited version of sequence in #1 but with regions that don’t code for proteins removed:

   The lab technician unquestionably creates something new when cDNA is made... cDNA is not a “product of nature” and is patent eligible
Broader lessons from Myriad case

- Williams-Jones (2002): in the U.S. (in precepts, can discuss cross-national variation between gene patenting’s reception in the U.S. versus Canada/Europe) Myriad had momentum due to its monopoly over BRCA testing
  - Widespread insurance coverage, adoption by large healthcare organizations, acceptance by patients for clinical use
- Momentum *might* have ended with patent expiration in 2014
- But...it also might not have (e.g., recent EpiPen controversy)
- RSG’s opposed to the consequences of that momentum pursued legal intervention that brought it to fairly abrupt halt and in doing so, shape the future of IP on genetics research
Case two: Vaccine development
What’s different from gene patenting case

- Gene patenting case: is the invention distinct enough from a naturally-occurring entity to be patented at all?
- Vaccine case: accept that new vaccines are patent eligible, but characteristics of the technology and its potential users can mean patent system ill-suited to incentivize innovation
Vaccines: technology, users, and patenting

Source: Worldmapper
Vaccines: technology, users, and patenting

**Technology**
- Collective benefit and potential for free riding (in this case, benefit > # units sold)
- Can be one-time vaccination

**Potential users**
- Global burden of disease: infectious disease in lower-income nations

**Implicit script in many patents**
- Benefits of technology accrue to individuals who each pay to help company recoup costs
- In med. tech, often pay repeatedly through life of patent
- Assume consumer (or insurance) can pay cost to recoup
New systems for incentivizing innovation for vaccines and other therapies for diseases affecting low-income nations

- New relevant social groups: Public-private partnerships: e.g., Global Vaccine Alliance (GAVI) partnership between Gates Foundation, WHO, World Bank, and others
- These RSG’s promote systems other than patenting- returning to historical pluralism from Monday’s lecture of patents existing among other ways of incentivizing innovation
  - Priority review vouchers
  - Compulsory licensing
  - Prizes
  - Advanced market commitments
Example: advanced market commitments

Source: Batson et al., 2006
Concluding: lessons from each case applicable beyond medical technology and beyond patenting

▶ **Myriad and BRCA**
  - As technologies go through process described in Hughes, often increase in RSG’s
  - With increase in RSG’s, greater potential for diverging interests in technology’s meaning/uses
  - Conflict can erupt and halt momentum of technology
  - Bidirectional shaping of users and technology

▶ **Vaccine development**
  - Just as technologies contain scripts, legal frameworks for regulating those technologies also contain scripts
  - Misalignment between social goals for the technology’s use and those scripts can lead actors/organizations to seek alternative legal frameworks