How intellectual property rights can shape health care: The US and UK in comparative perspective

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Main points

- Different policies and scientific and commercial cultures play an important role in the development of BRCA testing
  - Access
  - Costs
  - Technological design
  - "Management" of at-risk individuals
- Patents and patent policies play an important role in this story
  - Opposition mechanism may be an important tool
- *Building Genetic Medicine: Breast Cancer, Technology, and the Comparative Politics of Health Care* (MIT Press, 2007)

Discovering and patenting BRCA genes

- Sept. 1994: BRCA1 found by Myriad Genetics (Utah)
- Dec. 1995: BRCA2 found by UK Cancer Research Campaign-funded group—priority disputed by Myriad
- Myriad and UK group apply for multiple patents at USPTO and European Patent Office (EPO)
  - US company Oncormed also applies for patents on BRCA1 consensus sequence
  - UK CRC licenses patent to Oncormed, conditions include: free NHS access, mandatory sublicensing and counseling

US: Early on, a competitive environment

- Genetics and IVF Institute (reproductive service)
- University of Pennsylvania (laboratory research)
- OncorMed (clinical research)
- Myriad Genetics (commercial laboratory analysis)

- Myriad Genetics uses legal/economic position to become sole provider of BRCA testing in US
  - GIVF folds early, Oncormed sues and then folds
  - Penn argues that it is only conducting research, but eventually folds (In so doing, Myriad influences definitions of "research" and "health care)

Myriad's testing system and its implications

- Straightforward commercialization of patented technology
  - State-of-the-art laboratory service:
  - Focus on DNA analysis; Specialized genetic counseling not required
  - Can be ordered through any physician
  - Marketed widely
  - Management options defined by mutation status
    - Quick acceptance of tamoxifen as magic bullet
- Service is costly, ranging from 250-$4000
  - Full sequence analysis of both BRCA genes, $3000
  - Sometimes reimbursed, many pay out of pocket
- Client (consumer) has almost unlimited access; Health care professional facilitates process

Britain: Regulatory/biomedical context

- Genetics care emerges in regional NHS clinics
  - Combined clinical and laboratory services
  - De facto NHS control of clinic and laboratory
  - No private genetics clinics
- Equal access is important goal
  - Both national and regional administration
- Patent policy similar to US, but contemporaneous debates about biotech patenting (EU Biotech Directive)

NHS BRCA testing system

- Patent holders not involved
- BRCA testing first controlled by regional NHS clinics
- Then, a national risk assessment and triage system
  - Stratification at primary or secondary care level
  - Risks defined *before* laboratory analysis
  - Based on family history (low, moderate, or high risk)
  - *Moderate* risk: genetic counseling, but NOT testing
  - *High* risk: genetic counseling and laboratory analysis
    - Affected individual tested first
  - Focus on standardizing clinical care
- All paid by NHS

Britain: Implications for users

- Focus on public health goals and clinical care
  - Identifying and treating ALL "at risk" (according to family history)
  - Testing integrated into other elements of risk assessment and health care
  - DNA analysis methods vary, but counseling is standardized
- DNA analysis is additional tool, not focus
  - Testing used to refine *high risk* category
  - Moderate risk: mammographic screening study
  - Increased surveillance and prophylactic surgery also available to "not tested" high risk
  - Tamoxifen not approved; deemed to increase risk and provide equivocal benefit
- Client—here a citizen and patient—cannot demand access to specific services, while health care professional has authoritative role

Clash of scientific and commercial cultures

- In anticipation of BRCA1 patents being issued by EPO, Myriad tries to shut down British services
  - Vigorous opposition erupts
    - Patient advocates, scientists, and health care professionals question Myriad's patent rights (some opposition had already mobilized in response to EU directive)
    - Clash of scientific, health care, and commercial cultures
- Resolution? Myriad opens UK satellite laboratory (eventually closed), provides NHS free access, requires counseling
- Pan-European coalition files opposition against Myriad's BRCA1 and BRCA2 patents (4 in total) at European Patent Office
  - 28 opponents: scientific organizations, health care professionals, governments, patient groups, political parties, Greenpeace

Opposition proceedings against Myriad

- How/why do you oppose a patent?
  - Any patent can be challenged by ANYONE
  - Must be challenged within 9 months of its issue
  - Moderate fees (€613=$600 to file, total estimated costs $5000-$15000)
  - Grounds
    - Claimed invention not patentable
    - Contrary to ordre publique (public morality)
    - Insufficient disclosure
    - Added subject matter
  - Citizen has explicit role in influencing patentability
- Myriad's opponents questioned novelty, inventive step, implications for health care
- DECISION: Patents revoked and narrowed (Company now holds patents on two mutations); Decision under appeal

Concluding remarks

- Different approaches to and policies for gene patenting and licensing have significant implications for health care
  - Cost
  - Access
  - Technological design
  - Management options
  - International technology transfer
- Significant public opposition in Europe to patenting biotechnological inventions, and specifically genes
  - This seems to be growing in the US as well
- Opposition mechanism (proposed in US patent reform act) can not only reduce costs of patent disputes, but also address public interest issues