Regulating Science: A Focus on Intellectual Property

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What's in a Patent?

- Publicizes invention for the public good
- Government grants right to control innovation for limited period (20 years)
- Can be used to direct or forbid R&D
- Increasingly central in scientific practice
  - Important symbols of scientific merit
  - Pivotal to commercialization processes

Patents as regulatory sites

- Controversy over public good
- Political site, opportunity for S&T governance
  - Opportunistic involvement (US and beyond)
  - Structural mechanism (European system)
- Advantages
  - Common passage point
  - Corporate as well as academic and government science
  - Not just forbidding science

Ad hoc control through IP agreements (1)

- Oncormed-CRCT agreement (BRCA2 gene)
  - CRCT researchers find BRCA2 gene, patent it
  - Licensed patent to Oncormed (1997)
  - Charity stipulated how counseling should be provided, free NHS access, and widespread research and availability of technology
- PXE International patent (PXE gene)
  - PXE international, a genetic support group, gathers funding for gene discovery research and works directly with researchers
  - Researchers find PXE gene (2004)
  - Group members listed as inventors on patent, giving them control over future licensing deals

Ad hoc control through IP agreements (2)

- Yale-BMS agreement (anti-HIV drug)
  - Yale scientists prove d4T is potent against HIV in cell cultures (1984)
  - Yale gets patent, gives Bristol Myers Squibb exclusive license (1988)
  - BMS commercializes d4T (sales of ~$500M/year)
  - Médicins Sans Frontières asks Yale to allow importation of generic drug to South Africa, Yale says it is up to BMS (2001)
  - MSF responds that one of Yale's objectives is the "benefit of society in general"
  - Public controversy erupts
  - Yale/BMS eventually persuaded to lower d4T's price and not interfere with importation of generic drugs
- Who controls access to technology?

Patent approval process as potential regulatory site (1)

- 1973 European Patent Convention
  –Exceptions to patentability (Article 53)

  “(a) inventions the publication or exploitation of which would be contrary to "ordre public" or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;”
- EU Biotech Patent Directive (1998)

Patent approval process as potential regulatory site (2)

- EPO public challenge mechanism
  - Any patent can be challenged
  - 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

Embryonic Stem Cell Patent

- EP 0695351, UEdinburgh, Stem Cell Sciences
  - Method of genetically modifying animal stem cells to give survival advantage over differentiated cells.
  - Term “animal” not limited, could include humans
- 14 parties, including Greenpeace, German, Dutch, Italian governments file oppositions
- Inventors limit patent to exclude humans
- EPO decides to limit patent to exclude animal AND human embryonic stem cells (contrary to public morality)
- Decision has been appealed
- Morality in the process of scientific investigation

BRCA gene patents

- Four patents (BRCA1 and BRCA2) owned by Myriad Genetics
- 28 opponents: scientific organizations, health care professionals, governments, patient groups, political parties, Greenpeace
- Questioned novelty, inventive step, implications for health care
- Decision: all patents narrowed
- Decision under appeal
- What is ownable? Shape of future R&D?

Feasibility

- Ad hoc mechanisms
  - Already being used
  - Depends on individual initiative, not foolproof
- Opposition mechanism
  - Structural mechanism for democratic governance of science and technology (influence direction)
  - Addresses current controversies over patent scope
  - International implications?
  - In the corporate interest?
    - Reduce the usually protracted (and costly) legal battles over many patents
  - Does not cover non-patented S&T, doesn't address unforseeable harms or unintended consequences