Possible Policy Responses: 
Tools to Achieve Balance 
Between Ethics and Commerce

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Health Goals

- Prevention of illness
- Early diagnosis of illness
- Containing costs
- Comprehensiveness/universality
- Access
- Choice

Technological Innovation and 
Cost Containment

- Innovation often adds costs to health care
  - Rarely would a new technology replace an old one
  - Health care providers usually have greater duty to patient than to system itself (Caulfield, forthcoming)
- In Canada, health care costs are 30-40+% of provincial budgets
- In the US, cost control becoming more important with HMOs (Flood, 2000)
Positive Impact of Patents

- Encourage development of new health diagnostic and treatment options
  - Economic data ambiguous (Smith, forthcoming; Maskus, 2001; Hall & Ziedonis, 2001)
- Encourage access to information through disclosure

Positive Impact of Patents

- Encourages development of distribution channels
- Investment in biotechnology leads to high-paying, high-skilled jobs

Negative Impact of Patents

- Impedes access to research tools (Reichman, 2000; Heller & Eisenberg, 1998)
- Impedes sharing of information
- Impedes patient access to technology (Earnscliffe Research & Communications, 2000)
- Increases costs of health care (Caulfield, forthcoming)
**Other Possible Negative Effects of Patents**
- Indirectly reduces public health research
- Indirectly encourages premature commercialization

**Why Patents?**
- Justification of patent law is the attainment of public good rather than private good
  - Desert theory more prominent with respect to other forms of IP
- Must measure patent system against the attainment of this public good
- Tinker with patent law until maximize the public good

**Tools to address concerns**
- Mechanisms exist both within patent law and using patents to address the ethical and social concerns over gene patented without unreasonably lessening incentives to invent
**Tools to address concerns**

- Exclusions*
- Standards
- Scope
- Ordre public
- Experimental use
- Competition law
- Compulsory licensing
- Opposition*
- Specialized courts
- Liability rules*

**Exclusions**

- Permissible exclusions under TRIPs:
  - Discoveries (scientific principles, abstract theorems, products of nature)
  - Plants and animals (subject to *sui generis* system for plants) (Art. 27(3)(b))

**Exclusions**

- Diagnostic, therapeutic and surgical methods for treatment of humans or animals (Art. 27(3)(a))
  - Often unworkable distinction between *in vitro* and *in vivo*
  - US approach may be preferable (35 U.S.C. s. 287(c))

- This is a relatively blunt instrument
**Patent Standards**

- Criteria of novelty, inventive step, and industrial application (TRIPs Art. 27(1))
- Application needs to be fully adapted to biotechnology inventions
  - E.g., knowledge of function of gene (experimental vs. modeling)
- Patent office guidelines developing (e.g., USPTO, 2001)

**Implementing Clearer Patent Standards**

- Expensive to challenge; slow to change
  - Leads to uncertainty
- Alternative is to pass legislation; but risk to flexibility

**Patent Scope**

- Patent law designed to protect application of knowledge, not knowledge itself
  - Gene patents threaten this principle
- Potential to distinguish between structural and informational nature of gene patents
- Police identification using PCR; diagnostic tests not covered by patent
**Patent Scope**

- As now, could provide patent holder with ability to prevent commercial reproduction of genetic sequence
- Could provide that patent holder cannot prevent to access to individual genetic information contained in a genetic sequence
  - Police identification using PCR
  - Individual determining genetic sequence
- But could provide that certain methods of getting that information are protected (e.g., specific test procedures as long as room for alternatives).

**Ordre Public or Morality**

- Ability to withhold patents on a case-by-case basis
  - Commercial exploitation of invention must violate ordre public or morality (TRIPs Art. 27(2))
- Much of the world has such a clause
  - Canada and the US do not

**Ordre Public or Morality**

- European Community explicit that some inventions violate morality (Directive 98/44)
  - Processes to clone human beings
  - Processes to modify the human germ lines
  - Processes to use human embryos for commercial purposes
  - Altering genetic identity of animals so as to cause suffering without a substantial medical benefit to humans
Ordre Public or Morality

- In addition or substitution to European Community’s list (Directive 98/44), could add reasons to withhold patents:
  - Failure to provide access to health information
  - Failure to share benefits (Gold & Caulfield, forthcoming)
- Would need to establish separate administrative body (CBAC, 2001)

Administrative Body re Ordre Public

- Independent of patent office and of examination process
- Need flexible powers
  - Suspend rather than withhold patent
- Need experts making decisions

Experimental Use

- Ability of researcher to use a patented invention
- In US and Canada, specific exemption for generic drugs and general exemption for purely non-commercial research (Eisenberg, 2000)
- In Europe, can conduct commercial research on subject matter of patent
  - Leaves uncertainty regarding research using subject matter, such as development of antisense technology (Gold & Gallochat, 2001)
Implementation of Experimental Use

- In Canada, CBAC (2001) recommended exemption for:
  - private or non-commercial study, or
  - research on the subject-matter of the patented invention to investigate its properties, improve upon it, or to create a new product or process

Competition Law

- Interaction between Competition and Patent law becoming of greater interest (Barton, 1997; FTC, 1995)
- Generally, mere exercise of patent rights does not trigger competition problems
  - May wish to leave this open if the effect of the limited distribution of a product has negative effect on health care

Compulsory Licences

- At WTO Ministers meeting in Doha, Member States agreed that countries should be able to take measures “to protect public health and, in particular, to promote access to medicines for all.”
- Also stated that countries have the right to determine the grounds upon which they will grant compulsory licences
Compulsory Licences

- If “access to medicines” not to be hollow right, must also have access to diagnostic procedures to determine which medicine to access
- Consider mechanism, as has been proposed in France, to provide that gene patent holder cannot prevent use of gene but retains right to financial benefit (Caulfield et al, forthcoming)
- Likely consistent with TRIPs

Opposition Process

- Provides an administrative means to challenge patents early in their life
  - Helps to provide certainty
- Need to ensure process is faster and less expensive than going through the courts
  - Otherwise, an unfair burden on patentee

Specialized Courts

- US has specialized court, Federal Court of Appeals for the Federal Circuit, with specific expertise in patent law and technology
- Consider creation of specialized patent courts (Straus, 2000)
  - May need specialized patent bar as well
Liability rules

- Liability rules (Caulfield, Gold & Cho, 2000)
  - Hold patent holders directly liable for failure to take due care (e.g., premature commercialization, failure to inform)

Conclusion

- Gene patents present special ethical and social problems
- There are tools available to address concerns
- Need willingness of governments, industry, and civil society to engage in a debate over how to appropriately balance interests of industry against the interests of the general public to have access to health care
References


References


References

- E.R. Gold & T. Caulfield, "The ‘Moral Tollbooth’: Using the Patent System to address Ethical Concerns" (forthcoming)
References