



## *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)

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## *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

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## *Positive Impact of Patents*

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

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## *Negative Impact of Patents*

- ❖ Impedes access to research tools (Reichman, 2000; Heller & Eisenberg, 1998)
- ❖ Impedes sharing of information
- ❖ Impedes patient access to technology (Earncliffe Research & Communications, 2000)
- ❖ Increases costs of health care (Caulfield, forthcoming)

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## *Other Possible Negative Effects of Patents*

- ❖ Indirectly reduces public health research
- ❖ Indirectly encourages premature commercialization

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## *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

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## *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

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## *Tools to address concerns*

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

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## *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))

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## *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

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## *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)

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## *Implementing Clearer Patent Standards*

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

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## *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 identify 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





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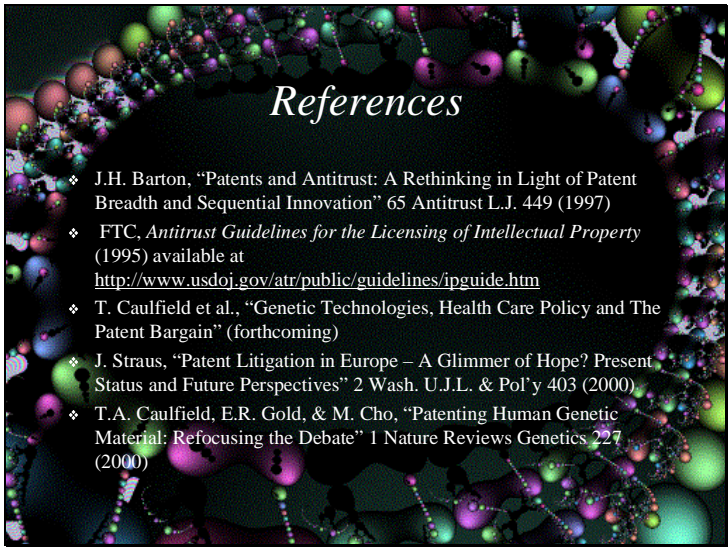
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