General Overview of the International Gene Patents and Licensing Practices Landscape

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Overview

- Gene Patents Internationally
- Concerns raised
- Responses
- Licensing
- What can be learned

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Gene Patents Internationally

- Following on US patenting of biotechnological inventions in 1980, other developed nation patent offices followed suit
- OECD studies in 1982 and 1985 concluded that only the US and Japan had laws that sufficiently addressed biotechnological inventions
- 1983 WIPO Group of Experts called for harmonization of laws re biotechnology

Europe

- The European Commission issued a white paper in 1985 stating its intention act
- Introduced directive on the legal protection of biotechnological inventions in 1988
- Commission of the view that this was a technical directive that merely clarified existing law
- It was therefore surprised by the reaction of the ethics and religious communities to the directive

Europe

- Initial directive defeated by Parliament in 1995
- New version introduced in late 1995
- Directive 98/44 finally passed, with amendments in July 1998
- Directive is ambiguous regarding gene patents
- While article 3(2) calls for the patentability of all artificial or isolated biotechnological material, article 5 muddies the waters

Article 5 of Directive 98/44

- The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.
- An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.
- The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

Europe

- This language was brought into the European Patent Convention through a regulation
- Opposition Division rejected ICOS patent over V28 gene (EP 0 630 405) based on lack of industrial application
  - Need a specific, concrete, credible (not mere hypothesis) industrial application
- (Note that Europe has a restrictive approach to patenting stem cells)

Canada

- No specific legislation on gene patents
- However, the Supreme Court of Canada in *Monsanto* v. *Schmeiser* (2004) upheld a gene patent relating to genetically modified canola
- A patented gene gives rights over entire organism

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Developing Countries

- Brazil: law is ambiguous as to whether patents can be granted over genes
- China: permits gene patents
- India: under 2005 reform to the patent act, India permits patents over genes
- Actual gene patenting rates in developing countries is low

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Conflicting policy statements

The Committee is seriously concerned about the patentability of human material. We are deeply disturbed that the *Patent Act* does not specifically disallow patenting with respect to human genes, DNA sequences, and cell lines. Treating human biological components as patentable property is repugnant to many of us. It entails their commodification and paves the way for their commercialization.

House of Commons Standing Committee on Health 2002

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Conflicting policy statements

Continuing high rates of innovation suggest that the patent system is working well and does not require fundamental changes. We generally agree with that conclusion, but it is clear that both economic and legal changes are putting new strains on the system. … In light of these strains, now is an opportune time to examine the system's performance and consider how it can continue to reinvent itself.

National Research Council , 2004

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Conflicting policy statements

The European Parliament

1. Expresses its dismay at the possible consequences of the granting by the European Patent Office of a patent on a human gene;
2. Reiterates its call on the European Patent Office "to ensure that all ... patent applications in Europe do not violate the principle of non-patentability of humans, their genes or cells in their natural environment...";…
4. Reiterates its call … to adopt the measures required to ensure that the human genetic code is freely available for research throughout the world and that medical applications of certain human genes are not impeded by means of monopolies based on patents.

European Parliament, 2001

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Conflicting policy responses

You ignore or remove intellectual property protection on biotechnology products, and then the next generation of predictive tests and medicines will never materialize. For many biotechnology companies, patents are the only assets from which they attract the investment necessary to develop life-saving products. In the long run, the development of these life saving products will not only save many lives but also save billions of dollars in the Canadian health care system.

BIO, 2001

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Concerns Raised

- Same ethical concerns as raised in the US regarding ‘owning’ life, effect on research, patent criteria
- In addition, concern over effect of gene patents on the management and cost of the provision of health services

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Responses

- Studies
  - Australian Law Reform Commission
  - Canadian Biotechnology Advisory Committee
  - WHO on access related to gene patents in developing countries
  - Nuffield Council
  - Etc.

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Responses

- Little appetite for patent reform
- Fight particular gene patents
  - Myriad's patents in Europe
- Ignore patents
  - Myriad's patents in Canada
- Focus on practice rather than patent law
  - OECD guidelines on the licensing of genetic inventions
- (Exceptions covering methods of medical treatment and diagnosis do not apply since all *ex vivo*)

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Licensing Concerns

- Licensing concerns internationally are the same as in the US except with respect to the licensing of genetic technologies to health care systems
- In this area, concern revolves around the ability of public authorities to manage
  - Whether to introduce technologies
  - How to introduce technologies, and
  - To whom to introduce technologies
  - The suite of services around new technologies

Licensing

- The most significant concern is around the business models used to provide genetic services
  - Traditional models of technology dissemination do not work for genetics within public health care systems
  - Patent law not seen as having sufficient levers to discipline the market to provide better adapted models

What can be learned

- Internationally, same polarization as exists in the US between
  - Those who believe that gene patents are a technical issue having to do solely with private sector incentives to innovation/distribute
  - Thos who believe that gene patents raise fundamental ethical and religious questions
- Similar concerns re the effect of gene patents on research
- Relatively little concern over gene patents in developing countries

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What can be learned

- The more important international debate, however, concerns the effect of gene patents on health care delivery and administration
- Licensing practices are part of this, but not the entire solution
- Europe and Canada has made advances chiefly by refusing to respect patents that are exercised in a manner they find unsuitable

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Conclusion

- US debate more limited than internationally due to increased importance of public health care systems in other countries
- No stable solution found
- Lack of willingness to fundamentally take on the issue through reforms aimed at providing more policy levers
- Instead, *ad hoc* refusal to accept patents

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