BRCA Testing in Canada

E. Richard Gold
Director, Centre for Intellectual Property Policy

Secretary's Advisory Committee on Genetics, Health, and Society
July 10, 2007

Overview

- Timeline
- The business model
- Problems preventing a solution
  - Lack of communication
  - Lack of trust
  - Institutional Failure
- Implications/Conclusion

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BRCA Timeline

- 1989: Breast Cancer Linkage Consortium founded
- 1990: Marie Claire King localizes gene on Chromosome 17
- 1991: Incorporation and spin off of Myriad Genetics
- 1993/1994: Eli Lilly finances Myriad/IPO
- 1994: Myriad applies for 1st patent on BRCA1
- 1995: Cancer Research Campaign files patent over BRCA2
- 1996: Myriad files for patent over BRCA2
- 1996: Myriad provides genetic testing services
- 2002: Myriad launches large rearrangements panel

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Canadian Timeline

- 2000: Myriad and MDS Laboratories enter into distribution agreement
- 2000: Discussions with government procurement department
- May/June 2001: Cease-and-desist letter
- August 2001: Ontario response stating no infringement of valid patent

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Canadian Timeline

- November 2001: Myriad/MDS meeting with Ontario Minister of Health
- December 2001: Minister holds policy forum
- January 2002: Ontario issues report on genetic tests
- Early 2002: BIO threatens to pull BIO 2002 General Meeting from Toronto

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Canadian Timeline

- 2002: Discussions between Ontario (representing the provinces) and Patent Policy Directorate (Industry Canada)
- Spring 2003: SARS hits Toronto
- October 2003: Government of Ontario changes
- Fall 2004: Joint reference by Health Canada and Industry Canada to CBAC
- 2006: CBAC issues report

US Business Model

- Myriad kept proband testing (approx $3000) and licensed out follow-on mutation testing (approx $300) on assumption of 1:10 ratio
- Myriad needed to recoup costs of its lab in Salt Lake City plus offer return on investment

US Business Model

- No license required to conduct research
  - No problem if data provided to patients
  - BUT would not license outsourced sequencing
- Myriad contributed all of its mutation information to the Breast Cancer Information Core Database

International Business Model

- Identify local licensees who would provide mutation testing, sending band testing to Myriad
- Flexibility if this model did not work
  - Japan – where need for clinical trials
  - France – where illegal to export blood samples
  - Australia – where obtained cross-license with GTG
  - Canada - ?

Problems with the Model

- Research community believed that Myriad would commence infringement actions if contributed to public database
- Losing research teams felt unable to continue work in the field
- Public health authorities worried about implications of gene patents on their ability to manage health care system

Myriad's point of view

- Myriad acted as if it were selling a product in the same way as anyone else
  - Approached governments and private laboratories in Europe, Canada, etc.
  - Received no response
  - As a result, escalated threats

Health administrator's view

- Health care administrators saw danger in Myriad's business model
  - Reduced ability to determine which tests should be provided to whom
  - Reduced ability to ensure that genetic counseling required
  - Reduced ability to determine how broad a population should be tested
  - Reduced ability to manage costs across entire health care system
- Wanted time to assess implications of gene patents and formulate responses

Communication Failure

- Myriad interpreted government's non-reaction as a refusal to accept Myriad's patents
- Governments viewed Myriad's quick escalation – before had time to react – as unwillingness to negotiate
- Myriad missed the signal sent in Europe by commencement of Opposition

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Lack of Trust

- Myriad was jaded by its lack of success in Europe and Canada as well as poor reputation in scientific community
- Ontario heard only about intransigence of Myriad from scientific community and international policy community
- Difficult relationship between federal departments

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Institutional Difficulties

- Unwillingness to consider legislative changes to *Patent Act* (research exception, compulsory license)
- Department with jurisdiction over patent law did not see its role as brokering a solution
- Misplaced burden and quantity of proof for decision-making

Institutional Difficulties

- Different speed of decision-making in public and private sectors
- Industry groups took on the issue as a political one rather than as something to be solved
- Other events, notably SARS, that completely altered focus of policy units

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Implications/Conclusions

- Need to foster better communications and trust
- ➢ Need an honest broker
- Industry needs new models
- ➢ Reliance on old models no longer works (Chief Medical Officer, Pfizer)
- Need to conduct technology assessment to understand how to integrate new technologies in health system

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