UNIVERSITY OF CAMBRIDGE

# The Changing IP Landscape for Precision Medicine

**Precision Medicine: Legal and Ethical Challenges**

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# Outline

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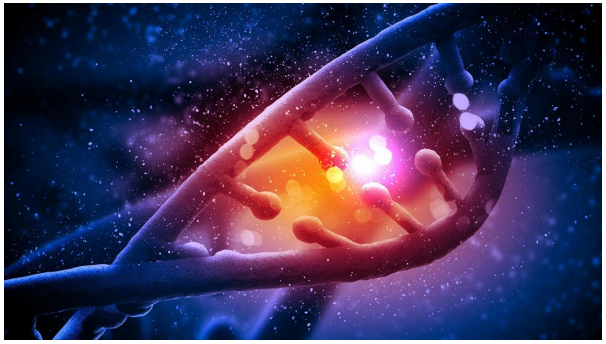
Precision Medicine & Core IP Issues

B. The Changing Legal Landscape #1:

DNA Patents & Related Patent Issues

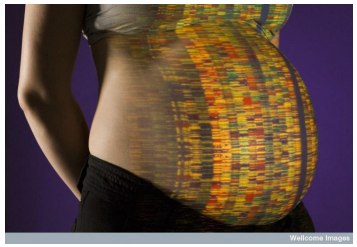
C. The Changing Legal Landscape #2:

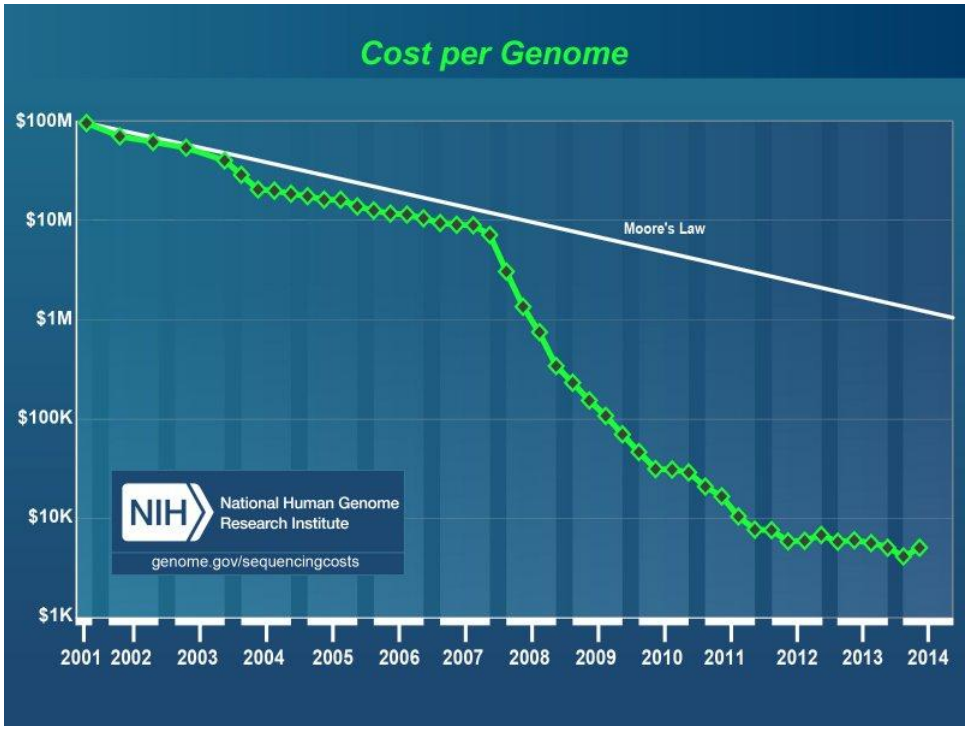
Biobank IP & Access Policies



# Background: Genomic Medicine in the Future

- Sequencing costs dropping dramatically
- Today: reactive, generalised treatment
- Tomorrow: predictive, stratified care



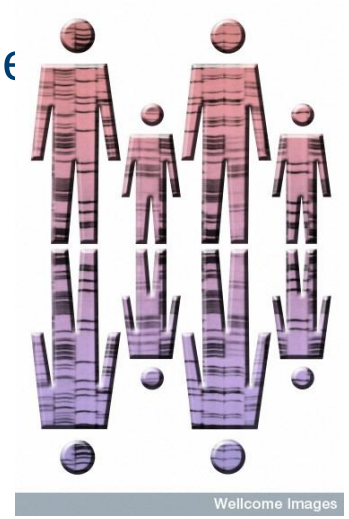


# Background: Challenges

- Translating basic genetic data into reliable, validated economically-viable genetic tests for routine use
  - Lots of biomarkers discovered

  BUT

  - most have low sensitivity and specificity
  - so combine markers and search for sub-populations (age, ethnicity, lifestyle risk factors, disease sub-type)
  - very few have been approved for clinical use



# Background: Challenges… continued

- This means lots of studies with large numbers of specimens
  - Longitudinal retrospective studies
  - Prospective screening studies, and
  - Case control studies
- Computing power
- Analytical tools (e.g. algorithms)

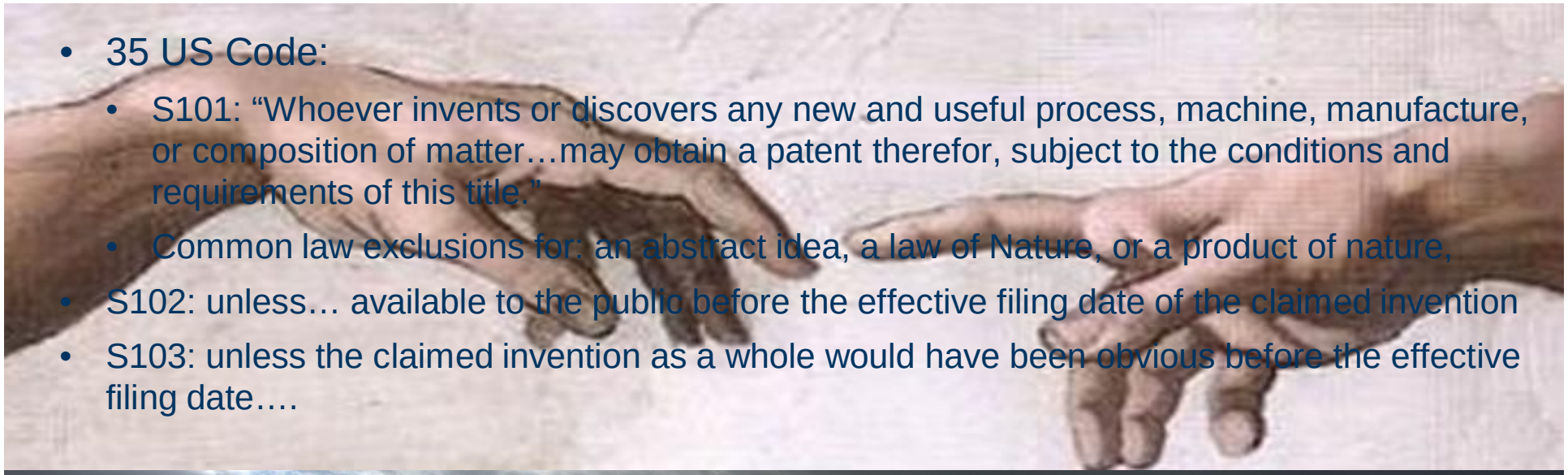
- TRANSLATION AFTER INITIAL BIOMARKER DISCOVERY =

$$$ + RISK

# Background: Core IP Issues

- IP strategies and/or policy developments to improve the clinical translation of genomic data?
- To what extent (and in what ways) are companies relying on IP?
- How significant is IP for the challenges of translation?
- What are the current challenges and difficulties for IP law and practice?

# DNA Patents: An Earlier Landscape



- 35 US Code:
  - S101: “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter…may obtain a patent therefor, subject to the conditions and requirements of this title.”
  - Common law exclusions for: an abstract idea, a law of Nature, or a product of nature,
- S102: unless… available to the public before the effective filing date of the claimed invention
- S103: unless the claimed invention as a whole would have been obvious before the effective filing date….

- USPTO Manual of Patent Examining Procedure, Aug 2012 (old), 2100-19:
  - ‘A natural principle is the handiwork of nature and occurs without the hand of man.’

# DNA Patents: An Earlier Landscape…continued

- UK, other European countries & EPC-Member states
  - Biotech Directive 98/44/EC
  - EPC supplementary rules of Interpretation

*Art 5(2).*

*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…*

# Seismic changes for Genomic Medicine

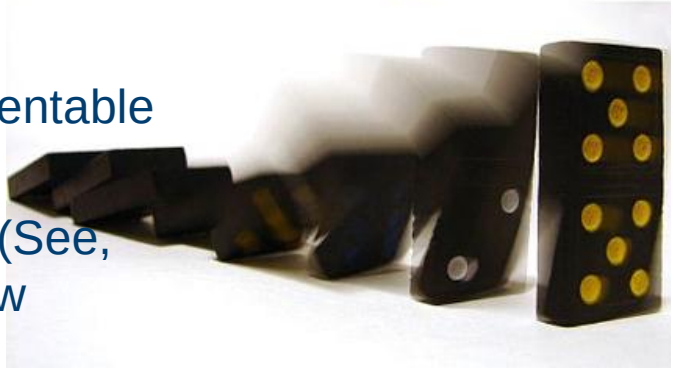
- US Supreme Court decisions
  - *Bilski v Kappos*, 561 U.S. 593 (2010)
  - *Association for Molecular Pathology v Myriad Genetics Inc*, 133 S.Ct. 2107 (2013)
  - *Mayo Collaborative Services. v. Prometheus Laboratories*, 132 S.Ct. 1289 (2012)
  - *Alice Corp. v. CLS Bank International*, 134 S. Ct. 2347 (2014)
  - *Ariosa Diagnostics Inc v Sequenom Inc*, 788 F.3d 1371 (Fed. Cir. 2015), (Sequenom is seeking Sup Crt review)

# DNA Patent Strategies & Policy: Research Questions

- **Practical Issues:**
  - How are business practices evolving?
    - Are companies relying on cDNA claims or other IP rights? (e.g. trade secrets)
    - Has there been a shift to 'open source' strategies?
    - Are patentees 'drafting around' the exclusion?
  - How are companies financing translation?
    - Have companies abandoned the translation of some biomarkers due to a lack of patent protection?

# DNA Patent Strategies & Policy: Research Questions

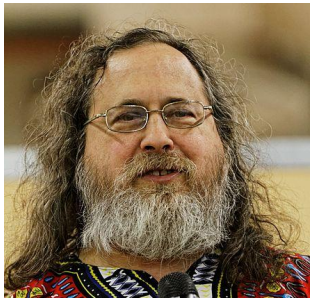
- **Globalisation Issues:**
  - Are European/Asian markets that permit isolated gDNA sequences now more valuable?
  - Will *Myriad* have a domino effect elsewhere? Australia has followed suit and a similar is set to be asked in Canada, but Europe is different.



- **Legal Issues:**
  - What types of DNA related innovations remain patentable in the US?
    - Bioinformatics tools? Labelled DNA probes? (See, Guerrini et al, 2016) Isolated gDNA put to new functions? (See, Rai and Sherkow, 2016)

# IP & Access Policies: A New Topic for Debate?

- Increased attention to ‘open’ IP and Access Policies for publicly-funded biobanks (subject to privacy safeguards)
- BUT what does ‘open’ mean?
  - ‘Open Innovation’ (Chesbrough) cf ‘Open Source’ (Software Industry)



- HOW should biobanks organise access to their resources?
  - accessible
  - appealing tools for transformative research
  - achieve real-world impact

# IP & Access Policies: Some Key Areas of Contention

- ‘Genome England…*owns any new intellectual property generated from the data* but …will license this to third parties the opportunity to commercialise opportunities on *favourable terms*.’
- ‘UK Biobank…will have *no claim* over any inventions that are developed by researchers using the Resource (*unless* they are used to restrict health-related research or access to health-care unreasonably).’


# IP & Access Policies: Research Questions

- What variation in IP and Access policies exists around the world?
- How do various policies compare with economic and legal literature on cumulative and translational innovation? And with literature on public attitudes to biobanks?
  - What approach should governments take?
- What are the various policies' implications for other sorts of IPRs (e.g. database rights, copyright and trade secrets)?
- Are the 'tough' terms enforceable?
  - Eg 'reach through' and 'march in' rights

# Conclusion

IP Law

Genomics

A better medical future with improved, effective and affordable healthcare

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