What can we make of the anticommons theory?

Reviewing the evidence

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The promise of biomedicine

- Understanding the causes and consequences of disease
- Developing better drugs, diagnostic tests and therapies
- Developing personalised medicines: designer drugs tailored to genetic profile

The business of biomedicine

- Bringing good, safe products to market
- Consider time, cost, risks
- Need venture capital, other investment upstream
- Need big pharma involvement downstream
- Return on investment: the patent imperative

Is there an obligation to patent genes and other basic research tools?

The anticommons in biomedical research (1998)

- Concerns about patents over genes and other research tools
- Tollbooths on the road to product development?
- Slow the pace of innovation?

Can Patents Deter Innovation? The Anticommons in Biomedical Research

Michael A. Heller and Rebecca S. Eisenberg

The "tragedy of the commons" metaphor helps explain why people overuse shared resources. However, the recent proliferation of intellectual property rights in biomedical research suggests a different tragedy, an "anticommons" in which people underuse scarce resources because too many owners can block each other. Privatization of biomedical research must be more carefully deployed to sustain both upstream research and downstream product development. Otherwise, more intellectual property rights may lead paradoxically to fewer useful products for improving human health.

could set up shop without first collecting rights from each of the other owners.

Privatization of upstream biomedical research in the United States may create anticommons property that is less visible than empty storefronts but even more economically and socially costly. In this setting, privatization takes the form of intel-

Context: what is a gene, what is DNA

- A gene is a unit of inheritance in a living organism
- Genes provide the information to make all of the proteins that living organisms need through transcription and translation
- Genes are part of long molecules of DNA (chromosomes)
- DNA is made of a code of simple units (A,C,G,T) that line up in a precise order
- All human DNA is 99% the same
- The code for a naturally occurring gene (gDNA) is different from the code for a human made gene (cDNA)

The law and gene patenting

- First gene patents issued in US in 1982
  - Manufactured gene sequences (cDNA)
- Around 1987 onwards expansion
  - Patents granted for full isolated unmodified sequences (gDNA)
- Flood of law reform inquiries
  - Little actual reform
- 1998 EU Biotech Directive/ 2001 US Utility Guidelines
  - Appear to support patentability of isolated and purified gDNA of known function (particularly in Europe)
- AMP v USPTO (2010 ->)
  - Challenging gene patent and methods of diagnosis claims relating to breast cancer susceptibility genes (BRCA 1 and 2)

AMP v USPTO trial on the patentability of cDNA and gDNA

The *Chakrabarty* precedent (1980)

- The patentee has produced a new bacterium with *markedly different* characteristics from any found in nature and one having the potential for significant utility.

Sweet J: both gDNA and cDNA sequence claims are not markedly different

- The unique quality of DNA is the physical embodiment of information
- Preserved between its native and isolated forms

AMP v USPTO appeal on cDNA and gDNA

- 3 judges, all agree cDNA is patentable
- Mixed views on gDNA
- Lourie J:
  - Because isolation requires changes to the chemical structure of DNA, gDNA, just as much as cDNA is patentable
- Moore J:
  - Less certain about gDNA but leave it to Congress
- Branson J:
  - gDNA is not patentable: akin to ‘snapping a leaf from a tree’

Should we be concerned?

- Not just anticommons effects on innovation
- Blocking effect of foundational patents
- Changing norms of science, restricting freedom of inquiry
- Restrictions on consumer access – diagnostics, drugs, therapies
- Jensen and Murray (US, 2005):
  - Nearly 20 per cent of all human genes have been claimed in patents granted in the US, with some genes featuring in up to 20 separate patents

Have these concerns eventuated?

- US FTC
  - Concern that biotechnology patent protection was too strong and would actually obstruct commercialization of new products, thereby hindering follow-on innovation ***has yet to materialize.***
- Holman and Cook-Deegan brief in AMP
  - Although plaintiffs have identified numerous potential concerns with gene patents in the context of some types of genetic diagnostic testing, to date there is insufficient evidence that harms attributable to patents on genes justify broad, subject matter-based invalidation of all patents made of or based on DNA.

Judges in *AMP v USPTO* appeal on the evidence

- Moore J
  - The biotechnology industry is among our most innovative, and isolated gene patents, including the patents in suit, have existed for decades with no evidence of ill effects on innovation.
- Bryson J
  - This may well be one of those instances where too much patent protection can impede rather than 'promote the Progress of Science and useful Arts'

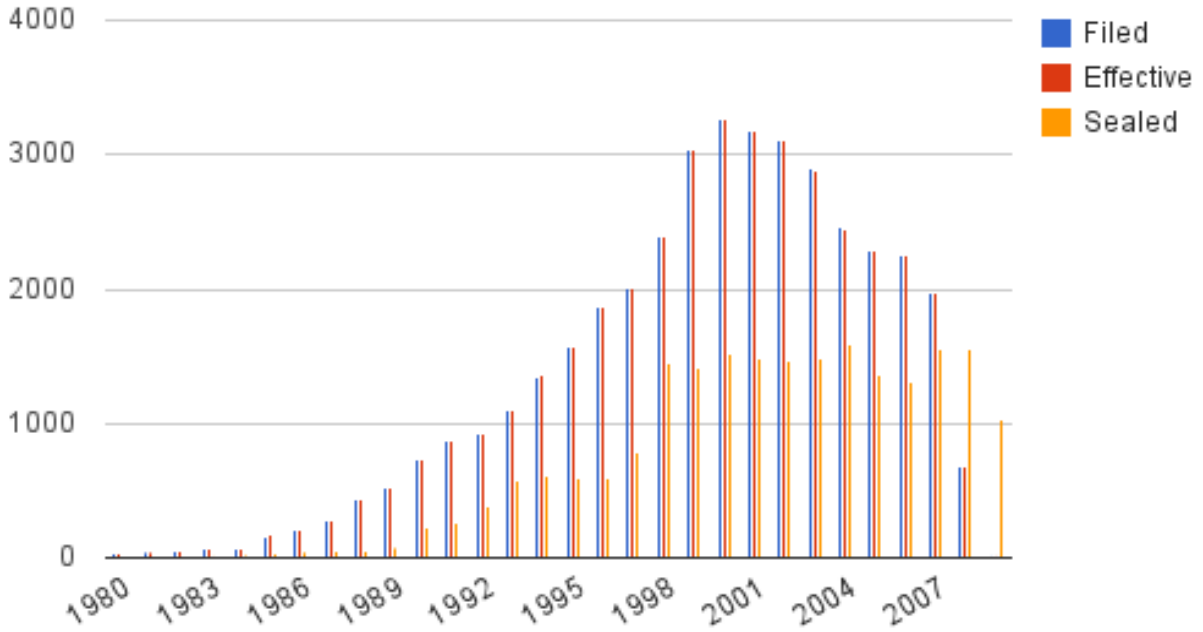
What can we make of the evidence?

Do patterns of litigation indicate problems with patentability?

- US BRCA litigation – 30 years on from *Chakrabarty*
- Holman litigation study (US, 2007)
  - Gene patent litigation is predominantly between competitors developing biologic drugs
  - No instances where basic research activities or noncommercial genetic diagnostic testing led to a patent infringement lawsuit

Is continuing expansion of the biotech patent landscape a problem?

- Adelman and De Angelis (US, 2007)
  - peak of granted patents in 1998, declined by 29% by 2004
- Australia?



Is the landscape actually becoming less complex?

- Hopkins et al (US and Europe, 2006)
  - By 2005 around a third of gene patent applications withdrawn and just under a third of the patents granted in the 1990s had been abandoned

Do gene patents really block innovation?

- Huys et al (US and Europe, 2009)
  - Claims analysis
  - Some blocking effects
  - Method and process claims more often blocking than sequence claims

Does the industry encounter blocking and anticommons?

- Interviews by Walsh et al (US, 2003); Nicol and Nielsen (Aus, 2003) and various others
- Working solutions
  - Prolific licensing activity
  - Inventing around
  - Ignoring patents
  - Challenging patents
- But note Eisenberg (2008)
  - These interviews offer qualified support for the anticommons hypothesis.

Is there an adverse impact on research?

- Walsh Cho and Cohen (US, 2005)
  - Minimal impact on research practice despite Madey
- Nicol and Nielsen (Aus, 2003)
  - 'Practice based' research exemption
- But note Murray and Stern (US, 2007)
  - Patent-publication pairs. Moderate decrease in publication post-patent
  - Anticommons effect?

Is there an adverse impact on consumer access?

- Merz et al (US, 2001)
  - Widespread enforcement against US diagnostic labs
- Nicol and Nielsen (Aus, 2003)
  - Scant evidence of enforcement against Australian diagnostic labs
- Hawkins (UK 2011)
  - Scant evidence of enforcement against UK diagnostic labs
- Gaisser et al (Europe 2009)
  - Scant evidence of enforcement against European diagnostic labs

Do licensing practices exacerbate potential blocking effect?

- Policy developments
  - OECD guidelines (2006)
  - NIH guidelines (US, 1999, 2005)
  - AUTM Nine Points (US, 2007)
- Pressman et al (US 2006)
  - Public sector licensing nuanced mix of exclusive and non exclusive in different fields
- Diagnostic testing
  - Mostly non exclusive, Myriad exclusivity not the norm
  - SACGHS (US 2010): some other problems (but not systemic)

Can gene patenting be short-circuited?

- Human Genome Project Bermuda Declaration
  - Genomic sequence information should be released immediately and freely in the public domain
- SNP Consortium:
  - The SNP Consortium intends to place the SNP map in the public domain and ensure that it is freely accessible to the medical community
- HapMap Project:
  - All data generated by the Project will be released into the public domain
  - Copyleft licensing
- Plus others

Aren't these developments to be expected in any new area of technology?

- Expect broad initial patent grants which narrow later
- Novelty, inventive step will all become more difficult to satisfy

But still, are there sufficient patent benefits to justify the status quo?

- US FTC: patents fuel the R&D engine bringing biologic drugs to patients.
- Other functions
  - Signalling
  - Shielding further innovation
  - Funding, takeovers
- But inevitable transaction costs

Are there ways to reduce transaction costs?

- Ongoing exploration of cooperative licensing strategies to reduce transaction costs
  - Open source
  - Clearinghouses
  - Patent pools

Conclusion

- Do we need to be concerned?
  - Market solutions to anticommons and blocking
  - Minimal impact on research and consumer access (outside US)
- Despite market solutions, are there still costs of bad patenting and licensing practices?
- What needs to be done?
  - Legislative amendments
  - More public interest litigation
  - More support for industry initiatives
- How does this compare with other sectors – eg ICT?