



Walter+Eliza Hall
Institute of Medical Research

Do patents and IP protection hinder research?

A practical perspective

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A perspective from a medical research institute

- In spite of perceived tensions, research activities and IP protection beneficially coexist
- We all have vested interests
- Core drivers
 - Respect rights
 - Recognise contributions
 - Advance science for benefit of all
- A personal view based on direct experience



Question: does the patent system inhibit research?

The claims:

- *“The research exemption is untested”* True
- *“Researchers are unclear with respect to patent infringement”* True
- *“Patents are major inhibitors of research”* Untrue
- *“Patenting inhibits publication”* Untrue



Experimental use and the research exemption

A long history culminating in the current clarity,
ambiguity and confusion, depending on
perspective

“It has been held, and no doubt is now well settled, that an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement, is not an infringement of the rights of the patentee”



Do patents hinder research?

- In the face of little or no significant empirical evidence a myth is promulgated
- The “shadow creation” industry has emerged
- A whole industry has developed around patent commentary - creating shadows so that we can jump
- Commentators and their fellow travelers have delivered very little evidence of significant negative impact



Do patents hinder research?

- Recently promoted major changes to Australia's patent law (genes and biomolecules) are based in part on the unsubstantiated claim that patents hinder research
- The patent system serves us well in spite of ambiguities – empirical evidence is essential



Balance is essential

- In our experience the supposed “*tragedy of the anti-commons*”⁽¹⁾ holds little substance with respect to biomedical research – it appears to be an “*artifactual shadow*”
- Let’s get empirical evidence
- “*..of 381 academic scientists, none were stopped by the existence of third-party patents, and even modifications or delays were rare, each affecting around 1% of our sample.*”⁽²⁾

(1) Heller M, Eisenberg R (1998) Science 280:May 1

(2) Walsh J et al (2005) Science 309:Sept 23



Recent example of serious lack of rigour

Scientific American April 16, 2010 | [6 comments](#)

Case Studies Reveal that Patents Can Hinder Genetic Research and Patient Care

A team of Duke University researchers side with a recent court ruling
against gene patents

By [Larry Greenemeier](#)

- Case studies⁽¹⁾
 - Tay-Sachs and Canavan disease
 - Cystic fibrosis
 - Hearing loss
 - Hemochromatosis
 - Long QT syndrome
 - Spinocerebellar ataxia
 - Alzheimer's disease
 - Breast, ovarian and colon cancer
 - Myriad Genetics



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By [Larry Greenemeier](#)

*“Although theories abound... we actually
have little empirical data..”*

*“Given the state of evidence, no strong
conclusions can be drawn for or against
the patent system in general”*



Where are the predicted threatening letters and court cases?

- The land mark *Madey vs Duke (2002)* ruling was meant to be a “watershed” by concluding that university research is not exempt from liability for patent infringement
- The case was much more complex than simply an academic institution allegedly infringing
- The ruling was predicted to spell the end of the “research exemption” in the US
- Very few cases initiated based on this ruling in spite of the scope of the “patent” and “research” industries



Seriously question the logic

- Recent debate has claimed that gene patents hinder research ⁽¹⁾
- Why only gene patents?
- Why not other patents?
- Clearly if there is to be any validity in the argument, the proposition must be that all patents hinder all research?



Consider the scale

- More than 75,000 researchers in Australia
- Every year in Australia:
 - The Federal government invests \$6 bn in research
 - More than 25,000 scientific articles are published
 - More than 7,200 provisional patents are filed
 - More than 26,000 standard PCT patents are filed
- Approx. 6 million patents are in force globally
- How could a research organisation be expected to confirm freedom-to-operate?

Now let's look for evidence that patents are hindering!



Australian patent infringement cases in the last five years

Venue	Total patent infringement cases (206)	Non-generic biotech cases	Biotech vs generics cases	% generics cases
High Court	13	1	0	0%
Full Federal Court	65	4	4	50%
Federal Court	128	7	19	73%

Of 206 cases:

- 17% biotech (two thirds are generics cases)
- 6% biotech innovation



In the last five years only three cases involved academia

- Wake Forest University (US) vs Smith and Nephew (wound dressing license payments)
- University of Sydney vs ResMed (nasal mask license payments)
- University of Western Australia vs Gray (IP ownership)
- No case linked to the fear of patents hindering research, not a gene was mentioned



What about gene patents that are claimed to be hindering research?

- Several submissions to the Senate enquiry claimed that gene patents hinder research
- Why only gene patents and not all patents – why object now - 10 years after the “gene bubble”
- Myriad’s BRCA patents are given as examples of IP protection that stifles research – more than 10 years after they were granted!
- Where is the evidence for these extravagant claims?

Filed 1995, published 1996
AU 686004 granted June 1998
AU 691331 granted Nov 1998
AU 691958 granted Nov 1998
Expiry 2015



The reality of BRCA1 published research papers?

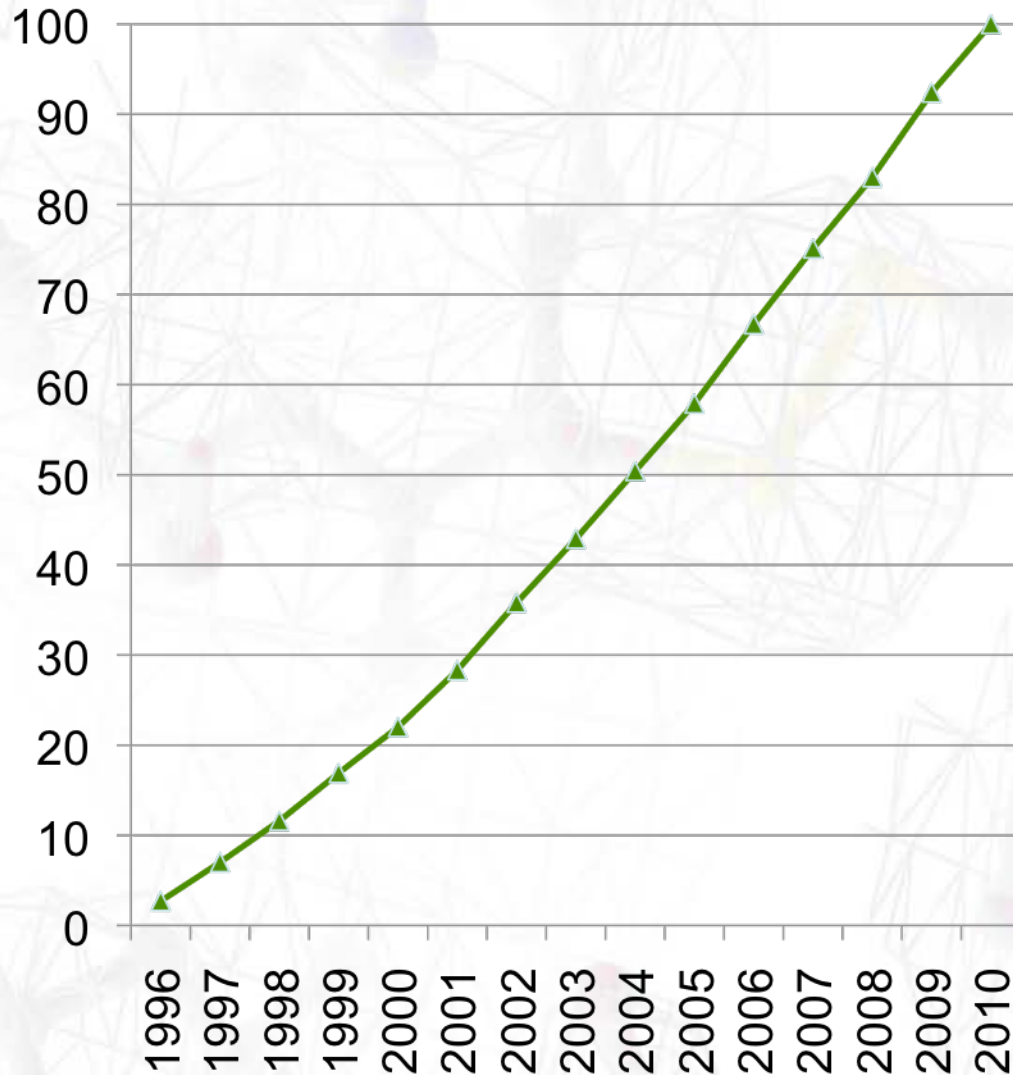
In the period 1998 – 2010 YTD:

It has been asserted that Myriad's 1998 BRCA1 patents have hindered research in Australia

- 5,674 BRCA1 primary sequence publications globally
- 1,933 primary sequence publications from the US (34.1% of total)
- 184 primary sequence publications from Australia (3.2% of total)



BRCA1 publications

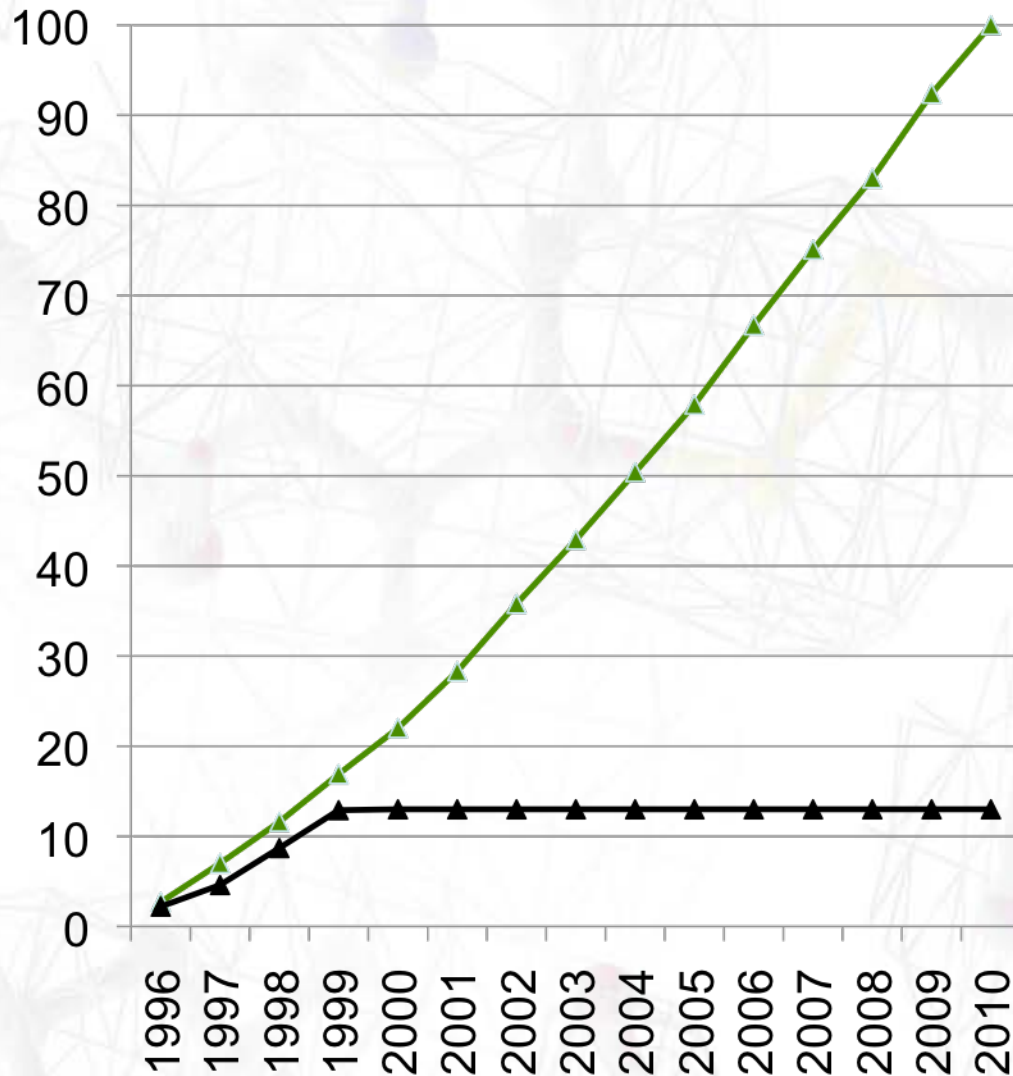


Non-patent territories
2,450 primary publications

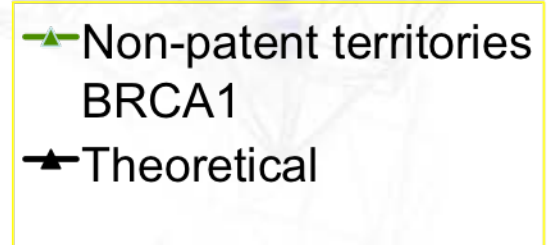
▲ Non-patent territories
BRCA1



BRCA1 publications

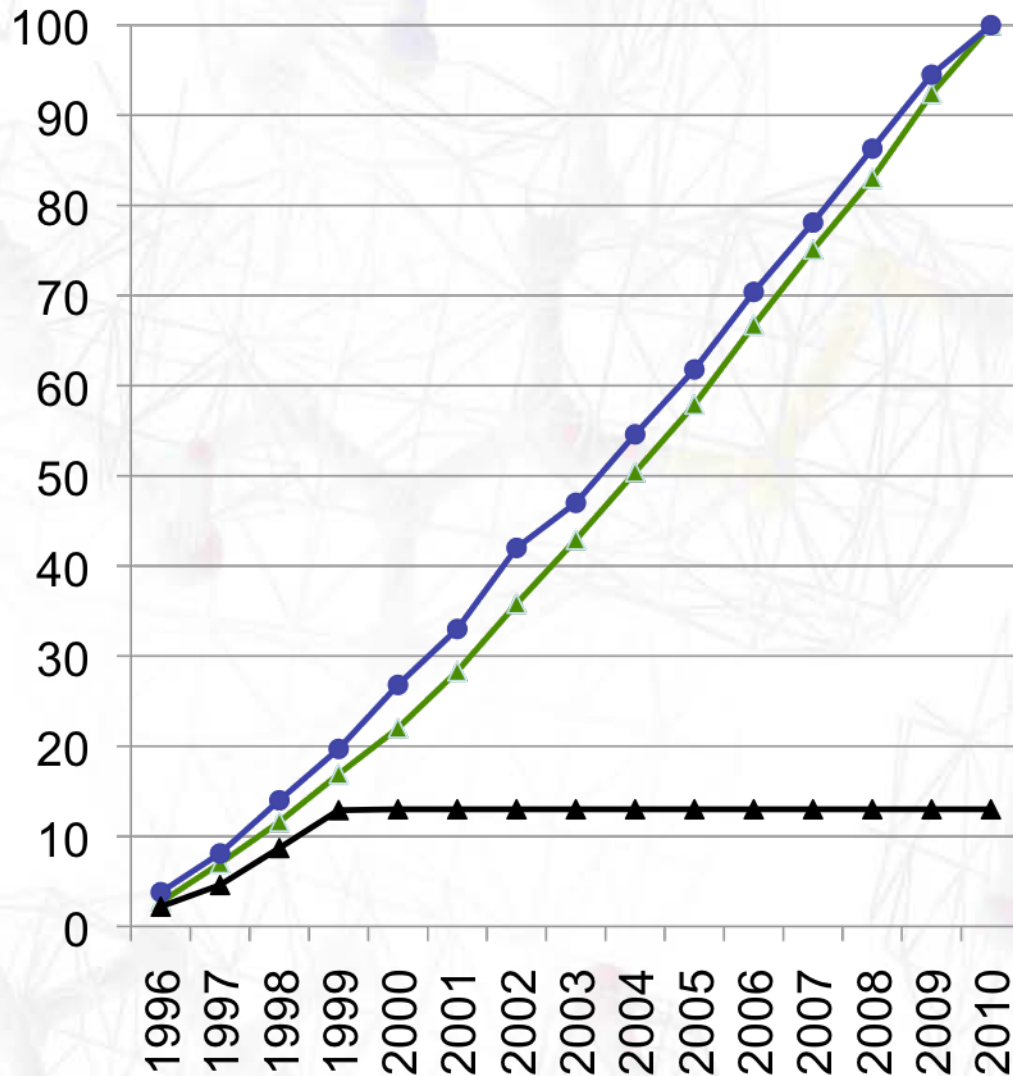


Non-patent territories
2,450 primary publications





BRCA1 publications

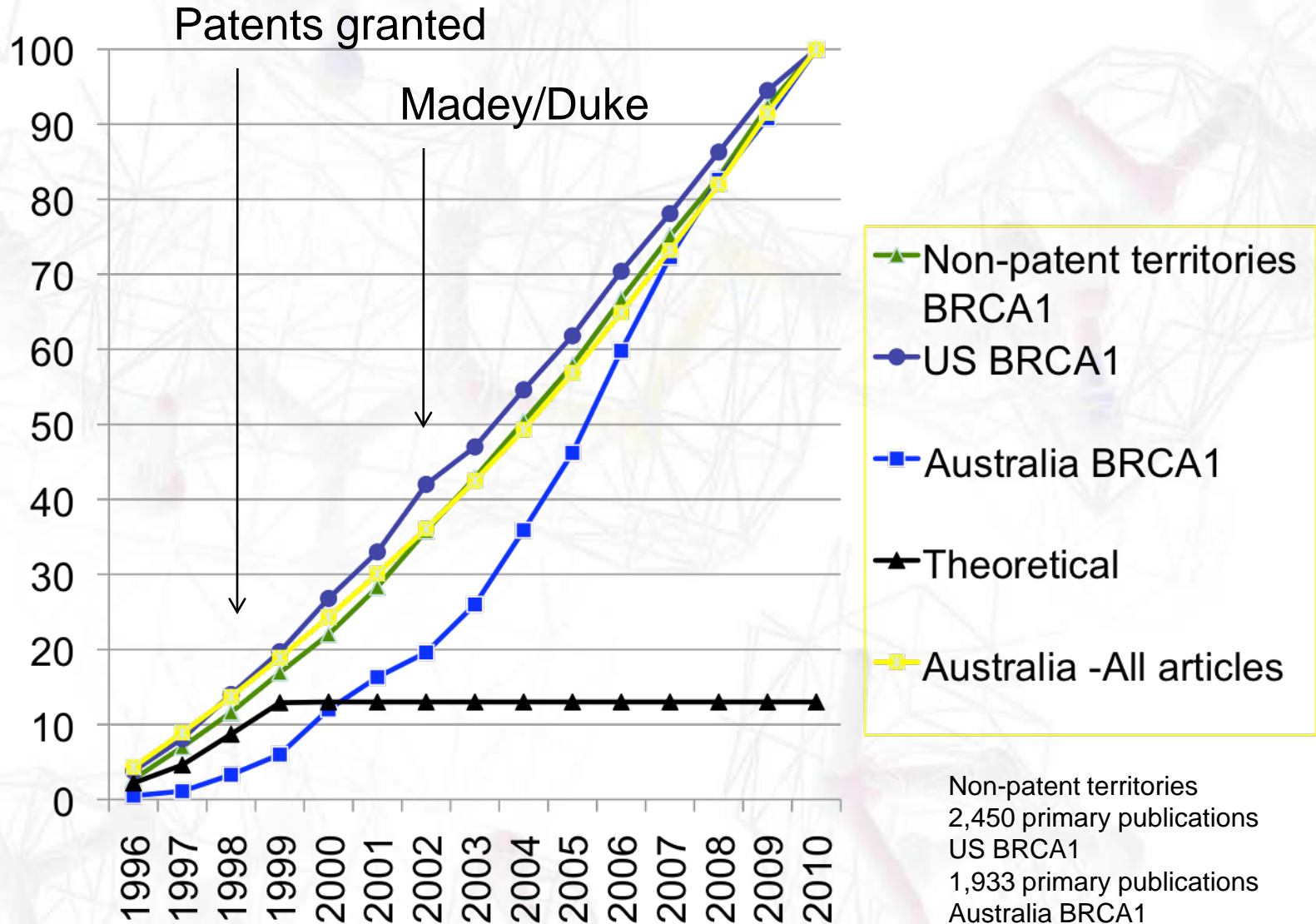


Non-patent territories
2,450 primary publications

US BRCA1
1,933 primary publications

- Non-patent territories BRCA1
- US BRCA1
- Theoretical

BRCA1 publications



Non-patent territories
2,450 primary publications
US BRCA1
1,933 primary publications
Australia BRCA1
184 primary publications
Australia All
169,169 publications



These are the Australian organisations with BRCA1 sequence research publications

University of Melbourne	71
Peter MacCallum Cancer Centre	67
Queensland Institute of Medical Research	60
University of Sydney	38
Royal Melbourne Hospital	16
Westmead	16
Cancer Council Victoria	15
University of Newcastle	12
Prince of Wales Hospital	10
Walter and Eliza Hall Institute	10
Hunter Medical Research Institute	9
Flinders University	9
Royal Brisbane Hospital	8
Australian National University	7
Monash University	7
kconFab	7
Queensland University of Technology	6
Royal Children's Hospital	6
Women's and Children Hospital	6
Princess Anne Hospital	5
University of New South Wales	5
St Vincent's Hospital	5
Queensland Clinical Genetics Services	4
Princess Alexandra Hospital	3
University of Western Australia	3
CSIRO	3
Cancer Council NSW	3
Royal Women's Hospital	3
Genetic Health Services Victoria	2
La Trobe University	2
Queen Elizabeth Hospital	2
Royal North Shore Hospital	2
South Australian Clinical Genetics Service	2
University of Tasmania	1
University of South Australia	1
Sydney West Health	1
Barwon Health	1
Breast Screen NSW	1
Canberra Hospital	1
Griffith University	1
Hanson Institute	1
Hunter Pathology	1
Mater Health	1
Mercy Hospital for Women	1
Murdoch Children's Research Institute	1
Prince Henry's Hospital	1
Royal Adelaide Hospital	1
Royal Perth Hospital	1
Sydney Children's Hospital	1

Approx. 12 years after patent grant in Australia:

- At least 49 organisations have published research results related to the BRCA1 gene and sequences
- The top 20% account for 72% of publications



Perspective to the allegations

- Myriad maintains it has never enforced its patents against researchers ⁽¹⁾
- *“Myriad..fully supported the use of its inventions, without license or payment, by researchers actually carrying out their own research projects”* ⁽²⁾
- *“According to researchers, patents have not impeded research in the field.”* ⁽³⁾
- Myriad has submitted more than 80% of entries to the Breast Cancer Information Core, including approx. 3,000 unique mutations

(1) Cook-Deegan R (2010) Genetics in Medicine 12(4)S15

(2) Gold ER, Carbone J (2010) Genetics in Medicine 12(4)S39

(3) Skeehan K et al (2010) Genetics in Medicine 12(4)S71



Medical research institute patenting activity

Institution	AusPat Total	% Total
Walter and Eliza Hall Institute	300	23.4
Queensland Institute of Medical Research	190	14.8
Garvan Institute	150	11.7
Lions Eye Institute	97	7.6
Florey Neuroscience Institute	68	5.3
Murdoch Children's Research Institute	65	5.1
St Vincent's Institute of Medical Research	63	4.9
Peter MacCallum Cancer Centre	54	4.2
Baker IDI Institute	49	3.8
Telethon Institute for Child Health Research	33	2.6
Prince Henry's Institute of Medical Research	33	2.6
Burnet Institute	31	2.4
Victor Chang Cardiac Research Institute	26	2.0
Bionic Ear Institute	21	1.6
Centenary Institute	19	1.5
Heart Research Institute	15	1.2
Menzies Research Institute	12	0.9
Bernard O'Brien Institute	9	0.7
National Ageing Research Institute	8	0.6
Centre for Eye Research	7	0.5
Menzies School of Health Research	7	0.5
Mater Medical Research Institute	6	0.5
Mental Health Research Institute	6	0.5
Neuroscience Research Institute	6	0.5
Children's Cancer Institute	5	0.4
George Institute	1	0.1
Hanson Institute	1	0.1
Total	1282	100.0

- Most institutes have strong patenting activities and gene sequence claims
- What examples are there of these institutes preventing others from doing research within granted claim areas?



- Survey of 3,350 individual Australian academic researchers ⁽¹⁾ – the foundations to establishing strong empirical evidence
- Overview of some of the findings:
 - Roughly equivalent to Walsh et al (2005/7)
 - High degree of uncertainty about exemption
 - Relatively small number of instances where access to patented research tools and/or materials was denied
- *“Beliefs about the existence of a law are important to the extent that they shape behaviour”*

(1) Jensen PH, Webster B (2010) Details released in October 2010

See www.ipria.org for details



A belief is a belief ... not a proven fact

- There is no empirical evidence that patents actually inhibit biomedical research
- Critical to discriminate between the significant and insignificant - the case is even weaker than that for homeopathy
- Beliefs are modified by risk perception
 - Some parents drive their children to school
 - Some people avoid vaccination
 - Some people believe that companies exist only to be litigious



The Walter and Eliza Hall Institute of Medical Research

- Australia's oldest independent medical research institute (1915)
- \$78 million investment in research per year
- Main focus on cancer, chronic inflammatory and autoimmune disease and infectious disease
- Focus on collaborations



We thrive on collaborations

470 collaborations, 250 projects, 120 cities, 43 countries

Aachen Adelaide Ankara Ann Arbor Argentina Arta Athens Atlanta Auckland Australia Austria Baltimore
 Bangkok Barcelona Beijing Belgium Berkeley Berlin Berne Bilthoven Birmingham (AL) Birmingham (UK)
 Boston Brazil Brisbane Brussels Budapest Buenos Aires Buffalo Bulgaria
 Cambridge Canada Charleston Chicago China Christchurch
 Cincinnati Copenhagen Cork Croatia Cypress Czech Republic
 Darwin Davis Debrecen Denmark Dortmund Dublin
 Dundee Dunedin Durham Ehome Erlangen Estonia
 Finland France Freiburg Garoka Geelong Geneva
 Germany Greece Hamilton Hanoi Heidelberg Helsinki
 Hobart Houston Hungary Innsbruck Iowa City Ireland
 Irvine Italy Ithica Japan Karlstad Kenilworth Kenya La
 Jolla Latvia Lausanne Leiden Ljubljana London Los
 Angeles Lund Lyons Madison Madrid Manchester
 Maputo Marseille Melbourne Memphis Menlo Park Mexico
 Milano Mozambique Munich Nairobi Naples Netherlands New
 York New Zealand Nicosia Nutley Osaka Oxford Papua New
 Guinea Paris Perth Philadelphia Pittsburg Poland Port Moresby Prague
 Research Triangle Park Rome Roskilde Rotterdam Salt Lake City San Diego San
 Francisco Sao Paulo Seattle Shanghai Singapore Slovenia Sofia Spain St Louis Stockholm Strasbourg Sweden
 Switzerland Sydney Taiwan Tallin Tampere Thailand Tokyo Townsville Turkey United Kingdom Uppsala USA
 Utrecht Vancouver Vienna Vietnam Warsaw Washington Wellington Whithouse Station Wollongong Xi'an
 Yokohama Zagreb Zurich



Abbott, BACE Therapeutics, Bionomics, Cancer Therapeutics CRC, Cancer
 Research Technologies, CSL, Genentech, Genera Biosystems, Merck,
 MuriGen Therapeutics, Nexpep



Highly cited world class science

- WEHI science has the highest overall citation impact of all Australian research organisations - 200 publications in the last 10 years have been cited more than 100 times
- No negative impact of patenting activities

Organisation	State	Citations per paper	Relative citations
Walter and Eliza Hall Institute	Vic	19.52	100
Garvan Institute	NSW	13.73	70
Peter MacCallum Cancer Centre	Vic	12.37	63
Baker Medical Research Institute	Vic	11.71	60
Queensland Institute of Medical Research	Qld	9.21	47
Howard Florey Institute	Vic	8.95	46
Murdoch Children's Research Institute	Vic	6.96	36
Institute of Advanced Studies	ACT	6.61	34
Australian National University	ACT	5.71	29
University of New South Wales	NSW	5.45	28

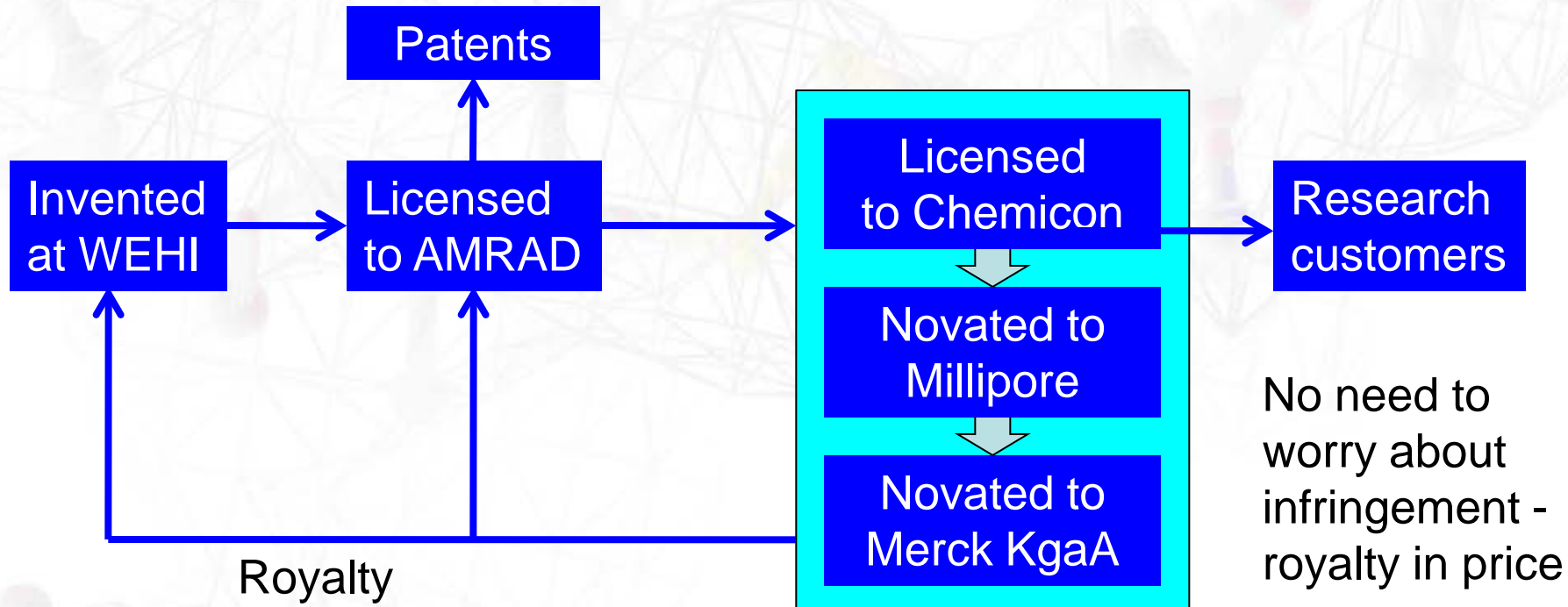


Metric	Last 10 years	Last 3 year average	2009/10
Research expenses	\$601 million	\$74.1 million	\$78.1 million
Lab operating expenses	\$128 million	\$15.7 million	\$16.3 million
Research FTE	5,620	625	661
Publications	2,270	240	249
MTAs	2,100	242	245
Invention disclosures	185	23	24
Patent applications	125	16	10
Commercial agreements	400	69	82

- No negative impact of invention disclosures, patenting or MTAs on competitive position or delivering world class science and commercial collaborations

Research tool example: Leukemia Inhibitory Factor (LIF)

- Main use for culture of mouse stem cells
- Licenses for research market



Similar arrangement for pGEX vectors
(novel glutathione-S- transferase fusion proteins)



The IP system is integral to leading research and participation

Use the IP system to:

- Inform research programs - patent applications are an untapped source of information
- Develop collaborations
- Secure investment – *“no IP, no investment”*
- Define rights and ownership over materials and inventions
- Assist in dissemination and translation of inventions
- Support career recognition



IP protection potential issues

- Patent or publish
 - Mutually compatible – issue of process
 - “Old school” objection
 - Occasional issues with disclosure
- MTA
 - Need for respect and fundamental for science exchange
 - Occasional misuse – academic competition
 - Hidden costs must be considered
- Laboratory notebooks
 - The key IP asset



Laboratory notebooks as the foundation IP asset





Rationale for audit at WEHI

- To secure inventorship determination
- Establishing priority date
- Compliance with collaboration agreement obligations
- Meeting standards under the WEHI Commercialisation Policy

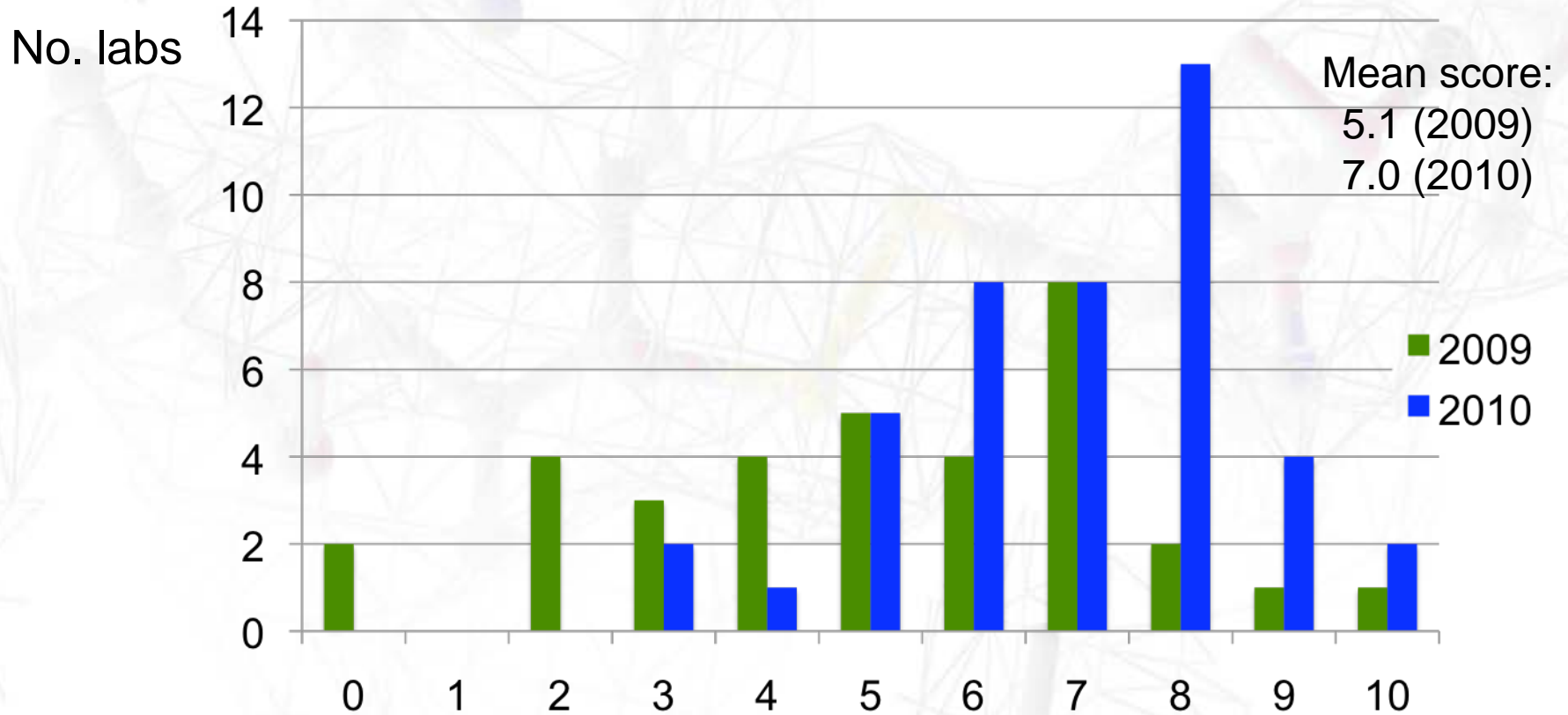


Notebook audits continue

- Approximately 250 researchers per cycle
- Focus on:
 - Signing
 - Dating
 - Witnessing
 - Inserts
 - Spaces
 - Explanations
 - Comments
- Feedback for continual improvement



Notebook audit scores



Compliance: “none” “weak” “acceptable” “excellent”

Legal value: “liability” “asset”

2009 - 34 labs, 2010 - 43 labs

- All electronic “excellent” score



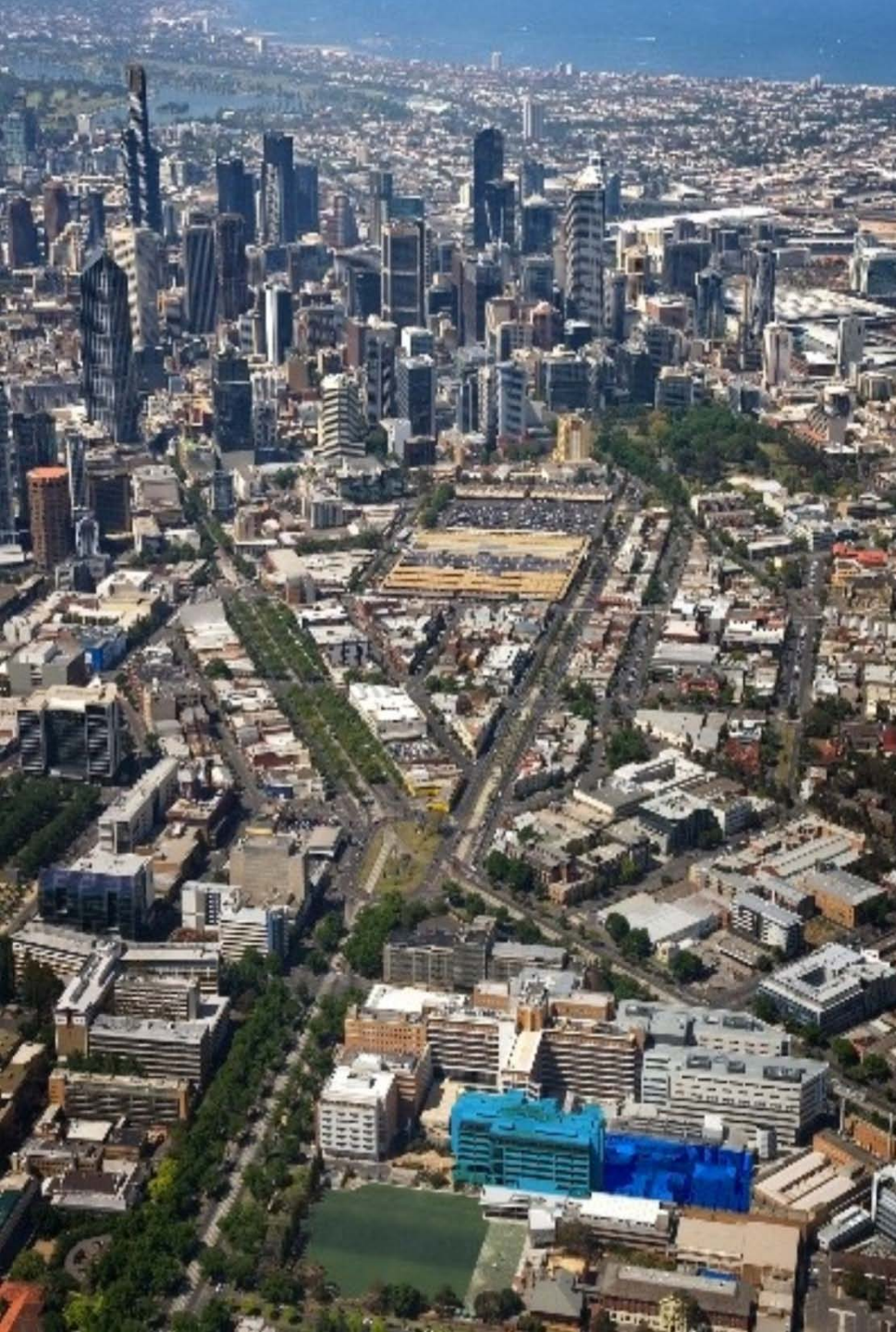
The importance of lab notebooks: recent examples

- Due diligence for industry standard
 - securing major collaboration with Genentech and Abbott
- Establishing priority date in a license and IP pooling negotiation – who was first to invent?
- Determining source of key IP in a two party inventorship determination
- Determining priority date for a potential interference case



Summary...constructive coexistence is the norm

- No evidence of negative impact of IP protection on research or research publication – where is the “tragedy of the anti-commons”?
- Patenting activities inform the research agenda through a wider range of information inputs and collaborations
- Active engagement with researchers is essential



Thank you ...

For more information
about collaborating with
the Walter and Eliza Hall
Institute
please contact

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Walter+Eliza Hall
Institute of Medical Research



Essential to discriminate between the issues

- Research tools vs “downstream” opportunities
- Basic research moves faster than patent grants
 - MTAs are largely driven by “upstream” academic sharing and competition
 - Patents are largely driven by downstream commercial opportunity
- Most researchers are driven by a peer review system based on impact and citation