Patents, Innovation and Policy: Pointing to the Problem

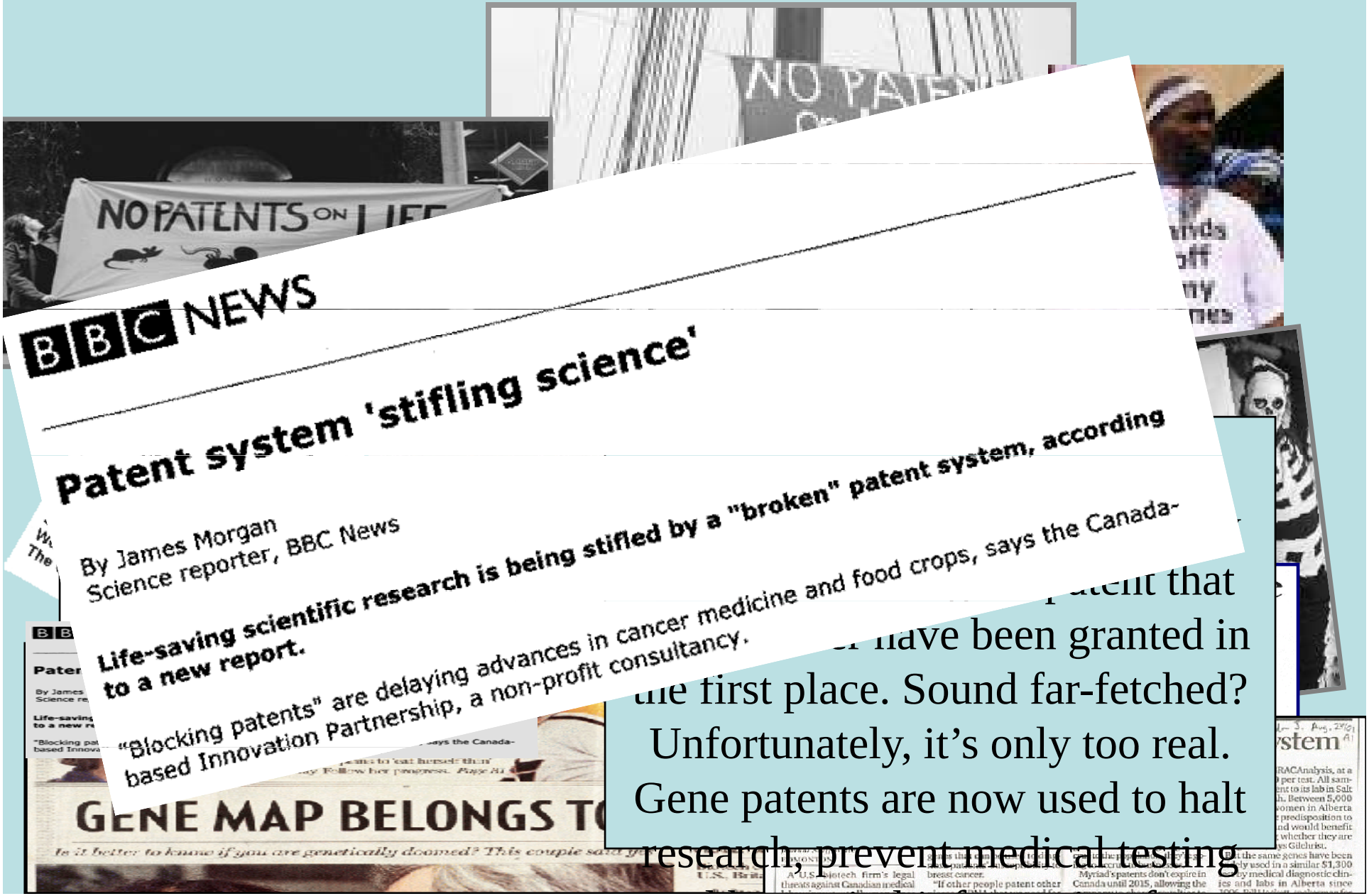
- Patents as *the* problem
- What's the evidence say?
- Why the focus on patents?
- The bigger, tougher issues…

- Focus on biotech patents

Timothy Caulfield

Health Law Institute, University of Alberta

Patents the focus of discussion



…patent that …have been granted in the first place. Sound far-fetched? Unfortunately, it's only too real. Gene patents are now used to halt research, prevent medical testing

Patent Concerns

Moral/Intuitive

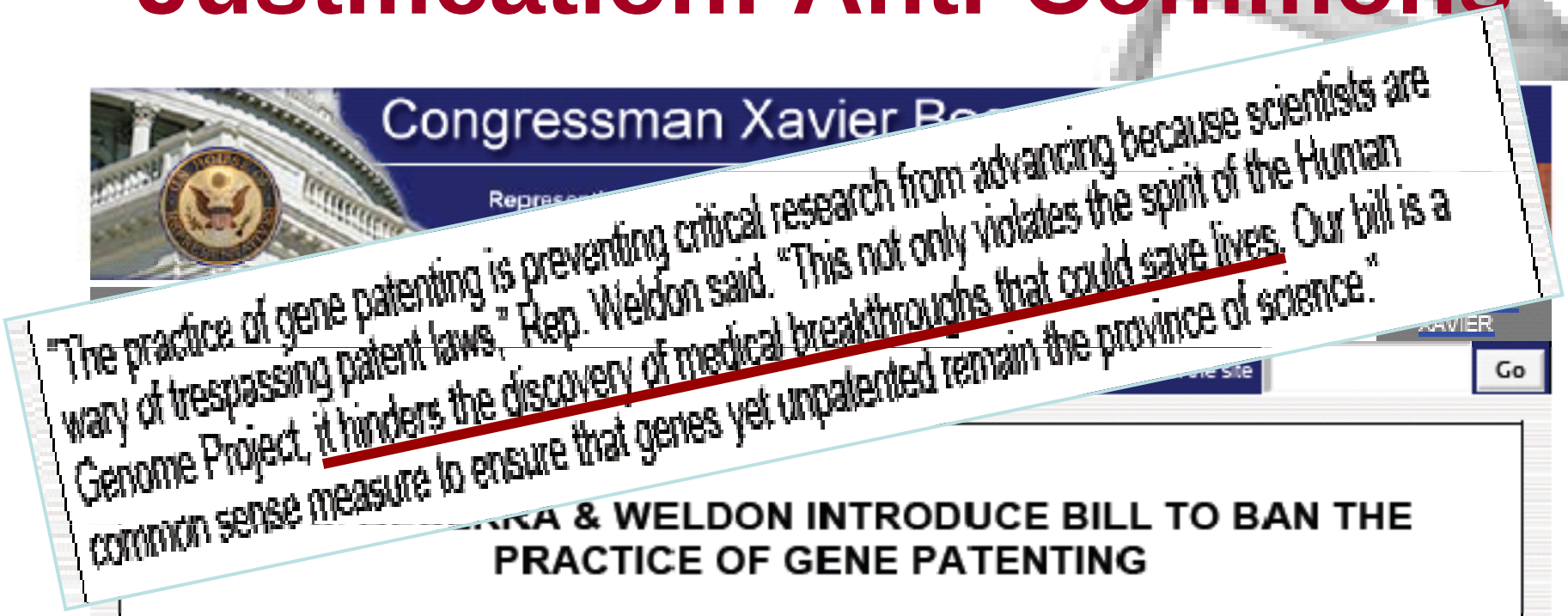
- Wrong to patent "life"
- Yuck factor
- Dignity/Commodification

Practical/Utilitarian

- Adverse impact on research/innovation
- "Anti-commons" or "patent thicket" (Heller/Eisenberg, 1998)
- Hurt access to useful technologies/health care system

Most policy traction: Patent law is meant to encourage innovation..

Justification: Anti-Commons



-20% of human genes are associated with at least one patent
(Jensen and Murray, 2005)

-Over 40,000 human gene patents have been granted
(National Academy of Science, 2005).

-Most patents are worthless and useless
(Kirsten, 2005)

-Most gene patents held by universities and small biotech companies (not big business)
(Scherer, 2002; Adelman, 2007)

© 2006 Nature Publishing Group http://www.nature.com/naturebiotechnology

Evidence and anecdotes: an analysis of human gene patenting controversies

Timothy Caulfield, Robert M Cook-Deegan, F Scott Kieff & John P Walsh

When it comes to gene patenting, policy makers may be responding more to high-profile media controversies than to systematic data about the issues.

Gene patenting has attracted intense scrutiny for decades, raising a host of ethical, legal and economic concerns. Much of the policy debate has focused on seemingly quantifiable and practical concerns about the effect of patents on access to useful technologies in the contexts of both research and the clinic. Here, we summarize the dominant policy concerns and the events that have motivated these debates. We then reflect on what the evidence now says about the major concerns articulated in policy reports. We conclude by discussing what might explain some of the disparity between the empirical evidence and the policy focus.

Although policymakers and advisory groups have long recognized the moral and ethical concerns associated with human gene patents[1–3], such concerns have only rarely led to concrete proposals for reform[4]. A systematic review of the

The timing of the policy activity reflects this tendency. The recommendations for diagnostic-use licensing, for example, followed the inter-

The evidence regarding the anticommons and restricted access concerns is clearer. The empirical research suggests that the fears of widespread anticommons effects that block the use of upstream discoveries have largely not materialized. The reasons for this are

patents in the United States[5]. Internationally, however, the Myriad controversy coincides with the most policy activity. Indeed, as Figure 2 (and Supplementary Data online) shows, the Myriad Genetics–*BRCA1/2* story is, by far, the most referenced patent controversy in the policy documents we reviewed.

A closely related concern was that the strong commercial incentive built into recent policy changes, and the associated pro-commercial

policy activity (Fig. 1). In Canada, an Ontario government report recommended a variety of reforms, including strengthening the research exemption and revising the compulsory licensing provisions in the Patent Act to create an exemption for genetic diagnostic and screening tests[14]. The UK's Nuffield Council on Bioethics

Commercialization, Patenting and Genomics: Researcher Perspectives

Murdoch/Caulfield (Genome Med. In press)

•Only one researcher had refused to license patented technology to someone who approached them with a request for a license (5%), citing as a reason for refusal that "the technology would not be well used by the recipient"

•Only *one* had been refused.

•55% said patents/commercialization cause data withholding behaviour.

Note: N = 20 – but leaders in genomic research community and involved in commercialization activity.

Our Study

In-depth survey of 108 PIs and Trainees
27 PI – 68% response rate and 44% of all SCN PIs

Stem Cell Network Réseau de cellules souches

Timothy Caulfield, Ubaka Ogbogu, Charles Murdoch, Edna Einsiedel, "Patent, Commercialization and the Canadian Stem Cell Community" (2008) 3 Regenerative Medicine 483-496..

Figure A1. Impact of patents on the research environment.

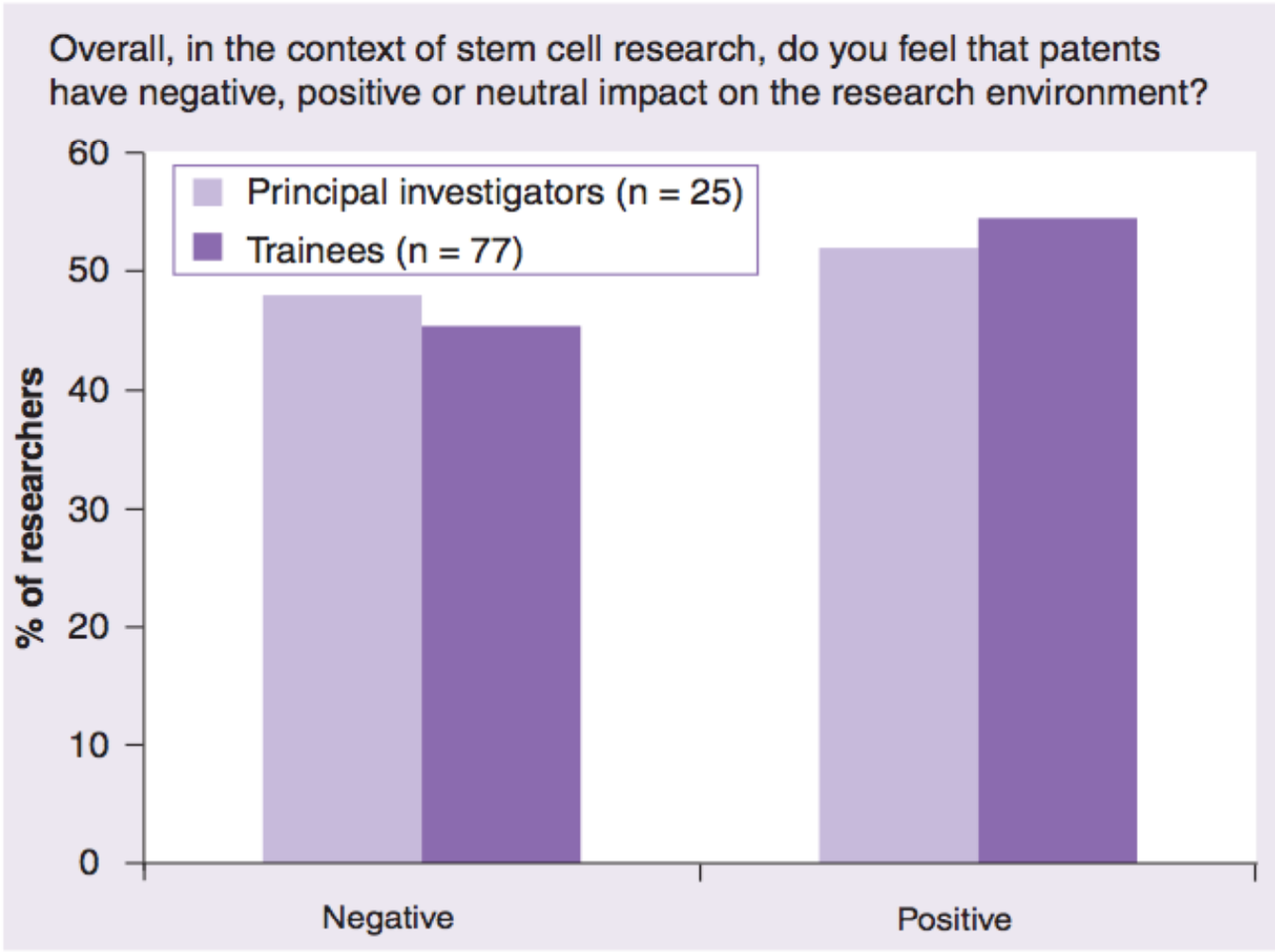
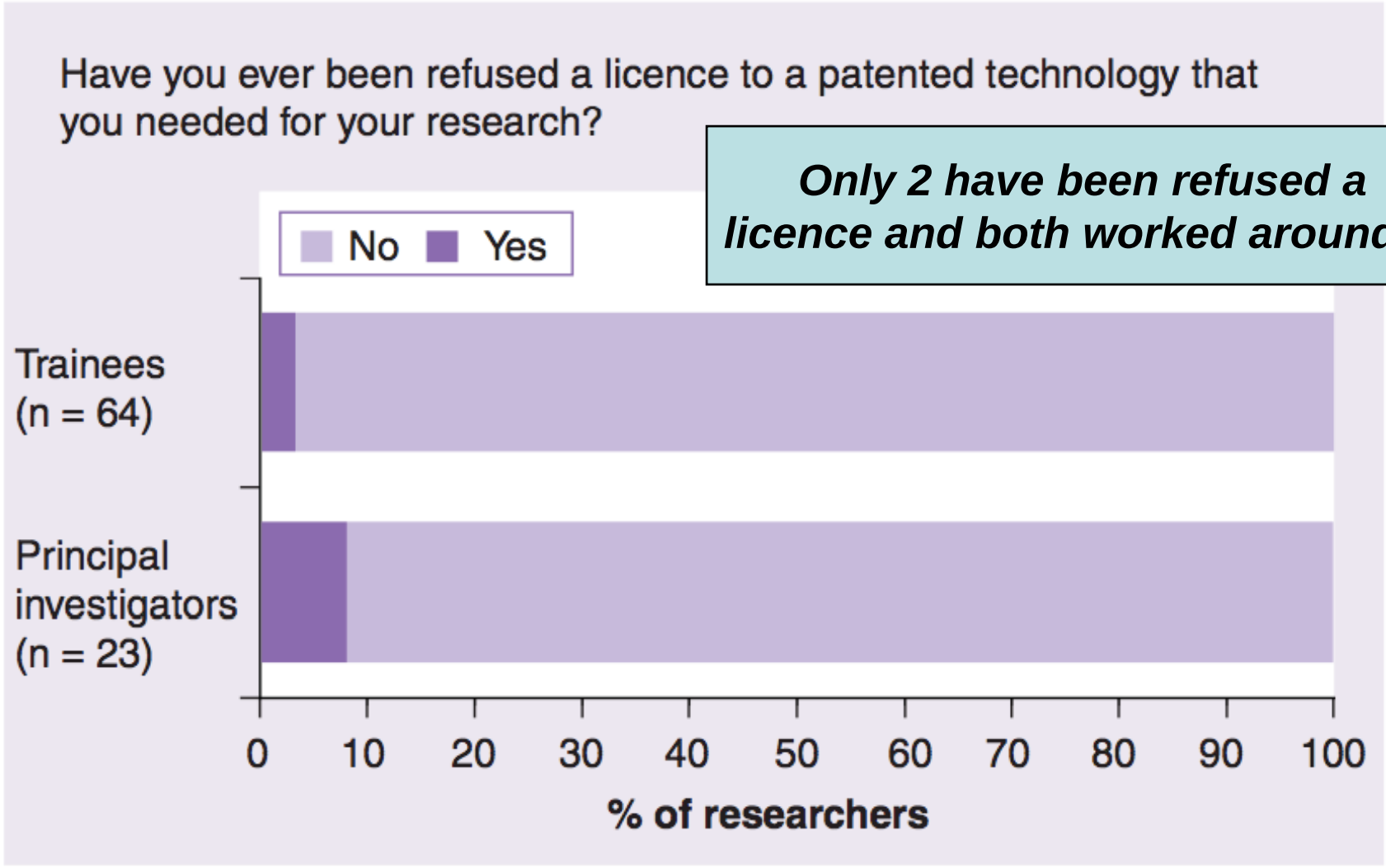


Figure A4. Patent licensing practices: denial of requests for a licence.



Only 2 have been refused a licence and both worked around…

Other

"… results were held to offer ve
of an anticommons problem…
States, United Kingdom, Germ
survey results suggest that
technologies remain accessib
scientific community, and not a
IP protections as many hav
(Hansen /AAAS, 2

Considering the large number of human gene patents (*9*), the substantial amount of patent litigation that has taken place involving biotechnology patents other than human gene patents (*15*), and the high level of concern that has been expressed with respect to the negative impact of human gene patents, 31 seems a relatively small number. For example, since 2000 at least 1294 lawsuits have been filed asserting drug patents, and 278 involving molecular biology or microbiology patents (*16*). Furthermore, rather than increasing, the number of human gene patent litigations pending at any given point in time has fallen off in recent years (see chart, page 199). This decline corresponds to reports of a similar marked decline in the filing (*17*) and issuance (*18*) of DNA patents in the United States since 2001.

POLICYFORUM

31 since 1987

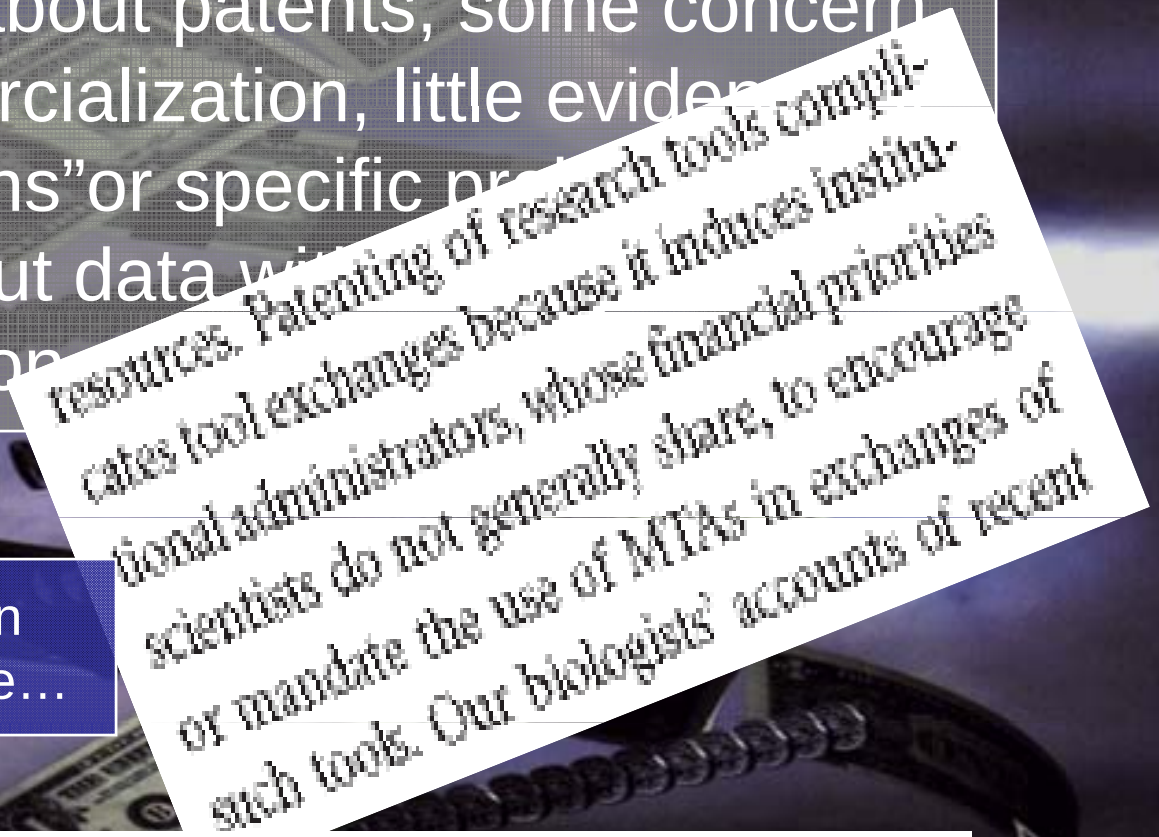
GENETICS

Trends in Human Gene Patent Litigation

Christopher M. Holman

patent litigation.

Some angst about patents, some concern about commercialization, little evide
"anti-commons"or specific pr
patents… but data wi
erosio


resources. Patenting of research tools compli-
cates tool exchanges because it induces institu-
tional administrators, whose financial priorities
scientists do not generally share, to encourage
or mandate the use of MTAs in exchanges of
such tools. Our biologists' accounts of recent

The commercialization environment is the issue…

Patents versus patenting: implications of intellectual property protection for biological research

Zhen Lei, Rakhi Juneja & Brian D Wright

A new survey shows scientists consider the proliferation of intellectual property protection to have a strongly negative effect on research.

Why the focus on patents (and the "anti-commons" problem)?

- A tangible, measur
- Fit

interest and big stories.

December 2007 · Vol. 9 · No. 12

[redacted] article

Myriad and the mass media: the covering of a gene patent controversy

Timothy Caulfield, LLB, LLM[1,2], Tania Bubela, PhD, LLB[3], and C. J. Murdoch, BA (Hons)[1]

Edm J. Aug. 29/01 A1

Gene patent fight imperils health-care system

U.S. biotech firm's legal threats could put breast cancer exams out of reach

SCOTT FOSTER
Journal Staff Writer
EDMONTON

A U.S. biotech firm's legal threats against Canadian medical

In an unprecedented move, Utah-based Myriad Genetics Inc. recently sent cease-and-desist letters to provincial health ministries, demanding public labs and clinics halt genetic tests involving two human genes.

Myriad holds 20-year patents on the sequence of BRCA I and II, genes that can be used to diagnose patients' susceptibility to breast cancer.

"If other people patent other

rector of the University of Alberta's cancer genetics clinic.

She is worried broad patent claims such as Myriad's could make the new age of gene-based tests and treatments inaccessible to those who might benefit from them. "The advantages of finding genetic tests aren't going to accrue to the population, they're going to accrue to businesses."

Myriad's patents don't expire in Canada until 2015, allowing the

ister its test, BRACAnalysis, at a cost of $3,850 per test. All samples must be sent to its lab in Salt Lake City, Utah. Between 5,000 and 10,000 women in Alberta have a genetic predisposition to the disease, and would benefit from knowing whether they are at high risk, says Gilchrist.

But the same genes have been widely used in a similar $1,300 test by medical diagnostic clinics and labs in Alberta since

ublishing Group http://www.nature.com/naturebiotechnology

Gene patents—more evidence needed, but policymakers must act

To the editor:

We congratulate Timothy Caulfield *et al.* for their analysis of major policy documents on gene patents in the September issue (*Nat. Biotechnol.* 24, 1091–1095, 2006) for prompting a timely and interdisciplinary dialog on the policy debate about the appropriate role of gene patents and associated license agreements in the healthcare environment, and the significance to be assigned to the limited empirical evidence available. The authors make several noteworthy points, especially on the importance

unidentified) regime. Of course, finding such data has proved notoriously difficult.

The authors only touch upon broader policy concerns around gene patents and access to diagnostics and treatment particular to countries with public health care systems where most of the controversy erupted, suggesting that the concerns over gene patents are limited to their effects on research. In fact, in Canada, Europe and Australia, one of the primary policy considerations has been the ability of public healthcare systems to introduce new technologies in a

Industry Industrie

In meeting its objectives, the CIHR:*". . . encourages innovation, facilitates the commercialization of health research in Canada and promotes economic development through health research in Canada."*

ercialization

Home

Spe

The Honoura

Minister of S

The government's most im
families and businesses ne
are so com

Minister
do a bett
into com

Ottaw

November 2

CIHR IRSC

Canadian Institutes of Health Research

Instituts de recherche en santé du Canada

Commercialization concerns
Idea
Evidence?
Direction
Collab
Cost
Teaching
Publication
Public reps
Access
Tradeoffs?
Application
Patents?

The Bigger Challenge…

Conclusions

- Evidence based science policy
- We should avoid policy distractions
  - In the area of biotech, much of the commercialization policy discussion tied to patents (the “wrong horse”)
- Research on benefits, harms and “tradeoff” (better methods)
- Conceptual work on nature of rights, and the role of evidence