

Is Bayh-Dole Good for Developing Countries? Lessons from the U.S. Experience

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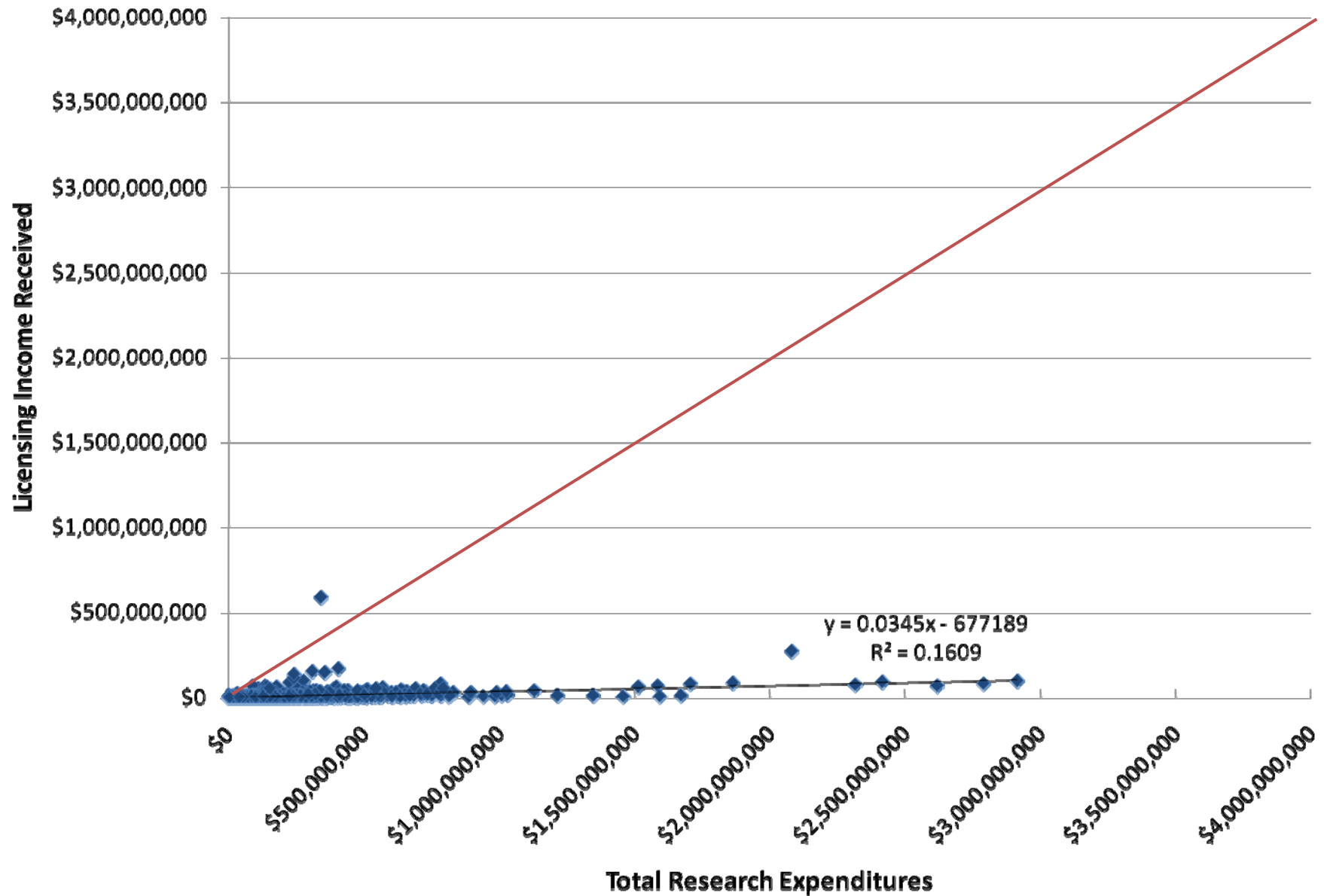
U.S. Bayh-Dole Act and University Tech Transfer

- Enacted in 1980
- Non-profit organizations can retain patent from federally funded research
 - Royalties are to be shared with the inventor
 - Preference to US industry and small business
 - Federal government must be granted a non-exclusive, non-transferable, irrevocable license to the patent
 - March-in right
- Impact and implications
- Emulation of the U.S. Bayh-Dole Act abroad

U.S. University Invention and Innovation (AUTM)

METRICS	1996	2005
Research Expenditures	US\$18.7 Billion	US\$36.7 Billion
Patent Applications Filed	2734	9079
Licenses and Options Executed	2209	4053
Startups	184	404
Licensing Income	US\$365 Million	US\$1.6 Billion

Total Research Expenditures v. Licensing Income Received, 1996-2005 (U.S. universities only)



Concerns

- Scientific exchange norms
- Management of intellectual property
- Commercialization of science

Reasons Why Geneticists Refuse to Provide Data

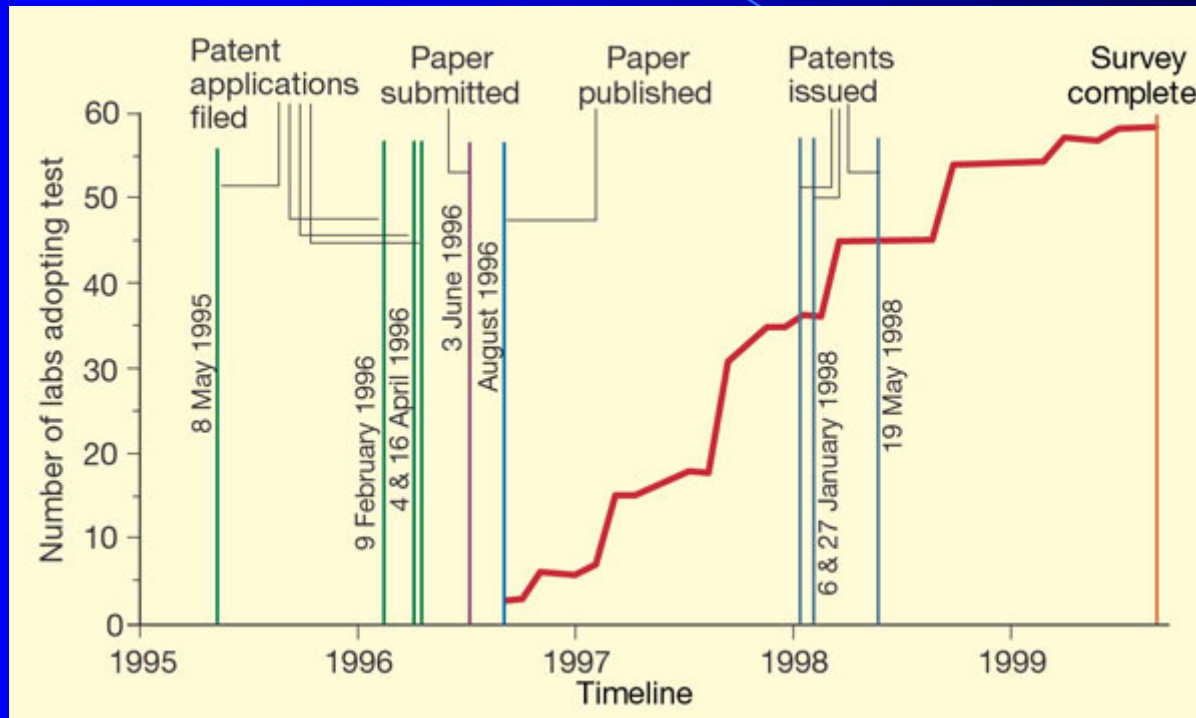
Effort Required to Produce Requested Information or Materials	80%
Need to Protect Graduate Student's, Post-Doctoral Fellow's, or Junior Faculty's Ability to Publish	64%
Need to Protect Own Ability to Publish	53%
Financial Cost of Actually Providing Materials or Information Transfer	45%
Likelihood that Other Person Will Never Reciprocate	28%
Need to Honor Requirements of the Industrial Sponsor	27%
Need to Preserve Patient Confidentiality	23%
Need to Protect the Commercial Value of Results	21%

Source: E. Campbell, B. Clarridge, M. Gokhale, L. Birenbaum, S. Hilgartner, N. Holtzman, D. Blumenthal, "Data Withholding in Academic Genetics: Evidence from a National Survey," *Journal of the American Medical Association* 287:473 (2002).

Management of intellectual property

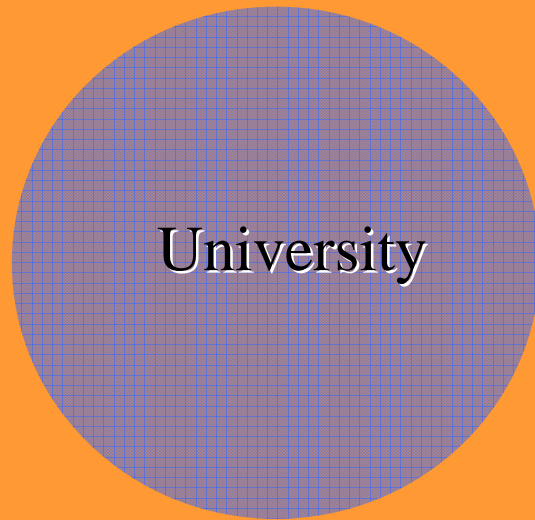
- **Research exemption**
- **Exclusive patenting**
- **Non-exclusive patenting**

Hemochromatosis Testing



Source: Merz, et al., *Nature* 415, 577-579 (07 Feb 2002)

Non-Commercial



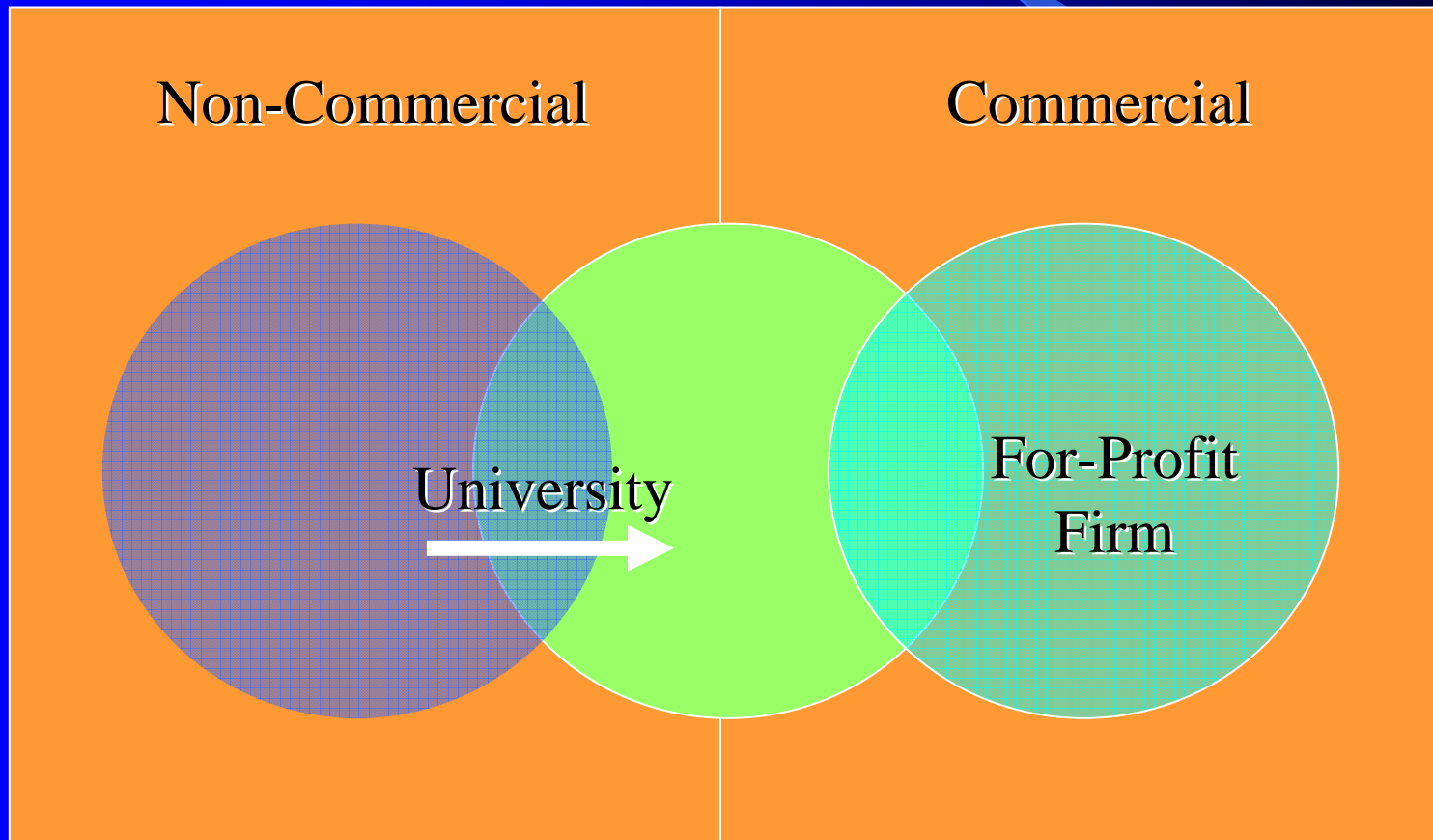
University

Commercial



For-Profit
Firm

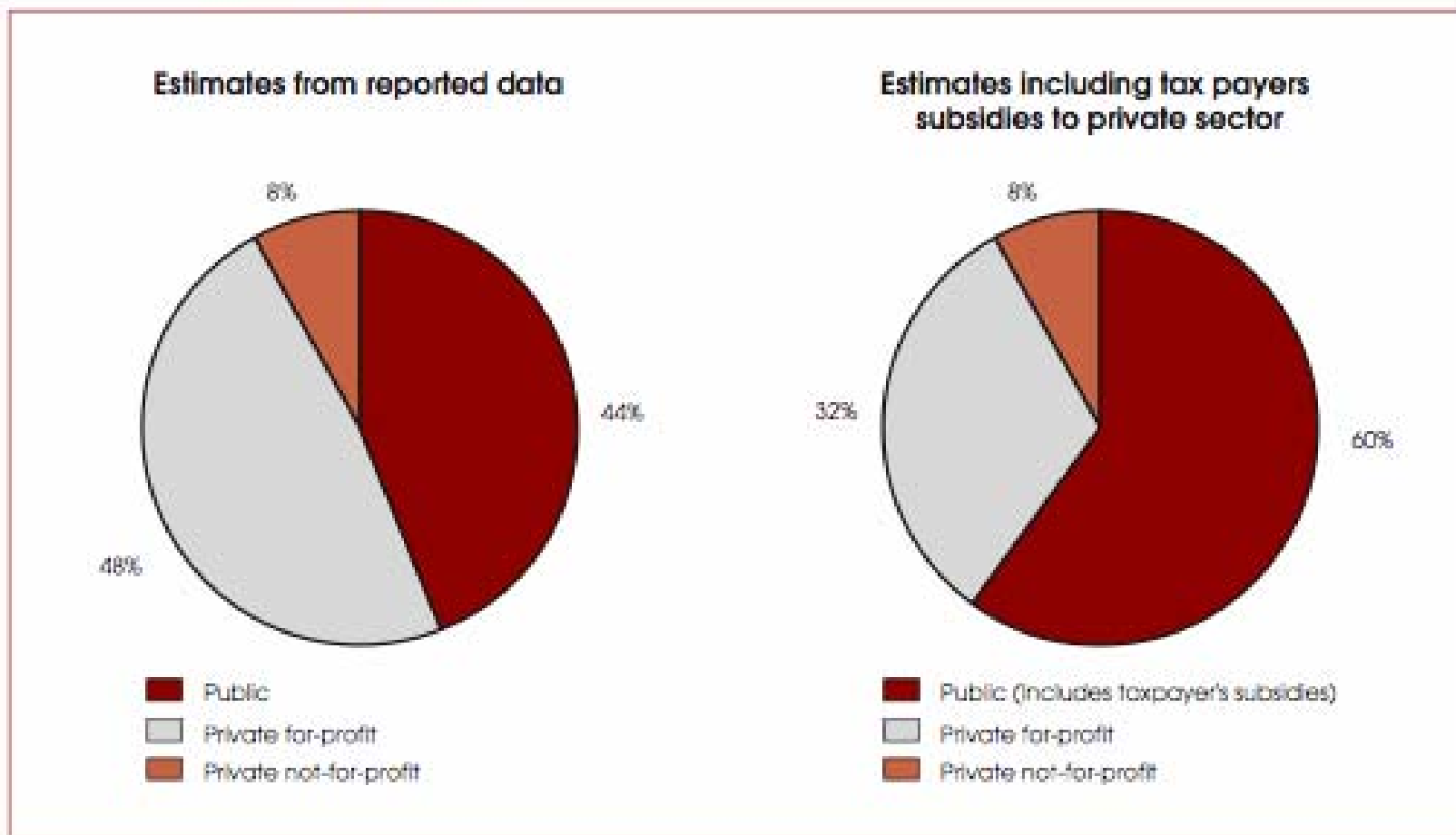
Commercialization of Science



Fair Returns on Public Investment

Figure 2.6

Estimates of R&D for health funding by sector, with and without taxpayers' subsidies to industry, 2003



Source: GFHR estimates based on OECD and RICYT databases, national surveys, pharmaceutical associations and calculations from D. Light³

Sharing Knowledge: Asymmetry from Benchtop to Bedside



Context of Developing Countries

- Level of publicly funded research
- Focus of such research: basic vs. applied
- Capabilities of industry partners
- Nature of university-industry linkages

Bayh-Dole Act and University Tech Transfer

- No exclusive licensing unless necessary for commercialization
- Transparency in patenting and licensing of publicly funded research
- Government authority to issue additional licenses
- Government use rights to inventions arising from its funding
- Access to end products

OPEN ACCESS Freely available online

PLOS BIOLOGY

Perspective

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From Principles to Practice

- Socially Responsible Licensing Program (e.g., University of California, Berkeley)
- University Principles and Metrics (e.g., University of British Columbia)
- Stanford Nine Points

From Practice to Metrics

- **Global health vs. Global access**
- **Lead by principles vs. monitor by metrics**
- **Construct of measures:**
 - **Process measures vs. Outcome measures**
 - **Transparency**
 - **Lag time: “Half of the licensed technologies realized their potential [economic] impact after approximately five years.”**
 - **Outlier problem: Most licensing revenue comes from a small number of licenses.**

Strategic Public Sector Use of IP: Global Vaccines, Inc.

