

What are the roles of the public and private sectors in drug development?

Bhaven Sampat (Columbia University, NBER, NYU)

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Why does knowing the public and private sector roles matter?

Evaluating the returns on NIH investment: Are we getting our money's worth?

High private sector drug costs used to justify high drug prices, patent exclusivity, etc.

Harnessing the public sector role to control prices, promote access, recoup profits

Different types of public sector roles

Direct: Public sector research institutes (NIH or NIH grantees) discovered compound (typically public sector holds patent)

Indirect (“enabling?”): Key insight from public sector (e.g. interfering with angiogenesis kills tumors), research tools and instruments from public sector (e.g. Cohen-Boyer, Axel, computer technology), others

- ▶ *Other roles not in the paper: Public sector tax credits, public sector role in trials, public sector as buyer . . .*

Different implications for different policy debates

Evaluating the returns on NIH investment: Are we getting our money's worth?

(Direct and indirect effect relevant)

High private sector drug costs used to justify high drug prices, patent exclusivity, etc.

(Direct and indirect effect relevant, though the larger the direct effect the less need for private sector incentives)

Harnessing the public sector role to control prices, promote access, recoup profits

(Only the direct effect relevant)

Sampat-Lichtenberg: Direct Effect

National Eye Institute grant R01EY0333,
"Ocular Fluid Composition and Tissue
Physiology"
(First Awarded in 1967)



Patent 4,599,353, "Use of eicosanoids and their
derivatives for treatment of ocular hypertension
and glaucoma"
(Filed in 1982, Granted in 1986)



FDA Approved Drug Xalatan, New Drug
Application Number 20597
(Approved in 1996)

Government interest section of the patent
references the '333 grant:

The invention described herein was made in the
course of work under U.S. Public Health Service
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the National Eye Institute, Department of Health and
Human Services.

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FDA *Orange Book* entry lists the '353 patent:

20597,1,"LATANOPROST; XALATAN", "4599353

Sampat-Lichtenberg: Indirect Effect

National Institute of Child Health and Human Development grant R01HD14661, "Hormonal Control of Fetal Growth" (First Awarded in 1981)



PNAS Publication "Evidence suggesting that the direct growth-promoting effect of growth hormone on cartilage *in vivo* is mediated by local production of somatomedin" (Published in 1986)

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Patent 5,681,814 "Formulated IGF-I Composition" (Granted 1997)

[56]

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OTHER PUBLICATIONS

Schlechter et al., "Evidence suggesting that the direct growth-promoting effect of growth hormone on cartilage *in vivo* is mediated by local production of somatomedin" *Proc. Natl. Acad. Sci. USA*, 83: 7932-7934 (1986).



FDA Approved Drug Increlex, New Drug Application Number 21839 (Approved in 2005)

FDA Orange Book entry lists the '814 patent:

Data

- ▶ All NMEs approved 1988 to 2005 (Drugs@FDA, n=478)
- ▶ Drug patent information (Current and Archival Orange Book)
- ▶ Direct effect: Assignee information and government interest statements in those patents (USPTO)
- ▶ Indirect effect: Citations to publicly funded patents and publications (USPTO; PubMed; NIH RePORTER)
- ▶ Sales in 2006 (MEPS)

New Drugs Approved By The Food And Drug Administration, 1988 to 2005, With Direct Or Indirect Public-Sector Support

	Standard	Priority	All
<i>Number of drugs</i>	224	155	379
Had public sector patent	3%	17%	9%
Cited public sector patent or publications	36%	65%	48%

Limitation 1: Measuring the “indirect” effect

- ▶ What do citations in drug patents to publicly funded literature actually represent?
- ▶ Is the counterfactual that the private sector patent would not exist without each cited academic article? That is would occurred anyhow, but with delay? At higher cost?
- ▶ Many citations for strategic and legal reasons
- ▶ Current work examines the meaning of citations to public sector literature.

Limitation 2: Measuring the “direct” effect

- ▶ Rai and Sampat (2013): Many patents reported to iEdison don't have government interest statements; many patents with government interest statements aren't reported to iEdison
- ▶ Underreporting of government interest by universities? Subject inventions: “conceived of our actually reduced to practice in the performance of work under a funding agreement”
- ▶ Government interest statements do not always extend to continuations

Ongoing work: Filling in the gaps

- ▶ Take union of RePORTER and government interest to track direct government role that is acknowledged
- ▶ Bring in the continuation data to track unacknowledged patents
- ▶ Multiple assignee information
- ▶ Use machine classification techniques to track non-acknowledged patents: look at patents with similar inventor/title as authors on articles resulting from NIH grants

Ongoing work: Extending the scope

- ▶ Biotechnology drugs and patents
- ▶ Other government roles: clinical trials funding; training; Orphan tax credits
- ▶ Government as drug buyer: changing procurement role
- ▶ Examine changes over time
- ▶ Goal: A comprehensive, historical account of the different roles the public sector plays, and how changing over time
- ▶ Other ideas?

Thanks!

bns3@columbia.edu

References

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Sampat, Bhaven N. “The impact of publicly funded biomedical and health research: a review” Appendix D from Merrill, Stephen, and Steve Olson, eds. *Measuring the Impacts of Federal Investments in Research: A Workshop Summary*. National Academies Press, 2011.

Rai, Arti K., and Bhaven N. Sampat. “Accountability in patenting of federally funded research.” *Nature biotechnology* 30.10 (2012): 953-956.