

Private and Public Investments in Biomedical Research

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Private and public biomedical research investments

- Dual public-private development paths are very common
 - ▶ More basic research: Novartis's Gleevec
 - ▶ More applied research: Moderna's SARS-CoV-2 vaccine
- Public debate has focused on policies to reduce prices for drugs that have received public funding
 - ▶ Example: Reasonable pricing agreements for novel AIDS drugs
- Implementation relies on public disclosure of government support for research
 - ▶ 1980 Bayh-Dole Act requires government interest statements in patents
 - ▶ Past work has suggested that these statements may be under-reported [GAO 1999, Rai-Sampat 2012]

This paper

Two conceptual problems with previous attempts to measure these public disclosures of government support for research:

① Certificates of correction

- ▶ Issued by the USPTO to address mistakes in patent grants
- ▶ James Love and the non-profit KEI have documented three examples of corrections adding public funding disclosures
 - ★ Example: 18-year lag in disclosure on a Novartis drug
- ▶ Not systematically investigated

② Parent-induced coverage of continuations

- ▶ Legal and regulatory sources suggest that government interest statements “flow down” the patent record
- ▶ Simple counts of government interest statements may underestimate public funding

This paper

We construct new data to investigate two questions about government funding linked to US FDA-approved drugs:

- 1 How common are public funding disclosures via certificates of correction or parent-induced coverage of continuations?
- 2 Do these two channels appear to be quantitatively important in assessing the completeness of public funding disclosures?

We close by highlighting some key policy issues emerging from our analysis

Data

For the 638 new drugs (“new molecular entities”) approved by the FDA between 1981 and 2014, we collect:

- US FDA records on approval path [drugs@FDA]
- For *Orange Book* patents associated with each drug: [FDA *Orange Book*]
 - ▶ Government interest statements in patent text [as in Sampat-Lichtenberg 2011 and de Rassenfosse et al. 2019]
 - ▶ Any “parent” patents with government interest statements [USPTO Public PAIR data]
 - ▶ Any certificates of correction pertaining to government interest statements [USPTO Full-Text and Image Database]
 - ▶ Flag for whether the patent is assigned to a government agency [as in Sampat-Lichtenberg 2011]
 - ▶ Any patent linkages to NIH grants [NIH RePORTER data (1985 to present), following Rai-Sampat 2012]

**ANTIBODIES AS T CELL RECEPTOR
MIMICS, METHODS OF PRODUCTION AND
USES THEREOF**

**CROSS REFERENCE TO RELATED
APPLICATIONS/INCORPORATION BY
REFERENCE STATEMENT**

[0001] This application is a continuation of Ser. No. 12/380,605, filed Feb. 27, 2009; which claims benefit under 35 U.S.C. 119(e) of U.S. Ser. No. 61/067,328, filed Feb. 27, 2008, and U.S. Ser. No. 61/191,871, filed Sep. 12, 2008. The '605 application is also a continuation-in-part of U.S. Ser. No. 11/809,895, filed Jun. 1, 2007, now abandoned; which claims benefit under 35 U.S.C. 119(e) of U.S. Ser. No. 60/810,079, filed Jun. 1, 2006. The '895 application is also a continuation-in-part of U.S. Ser. No. 11/517,516, filed Sep. 7, 2006, now abandoned; which claims benefit under 35 U.S.C. 119(e) of provisional applications U.S. Ser. No. 60/714,621, filed Sep. 7, 2005; U.S. Ser. No. 60/751,542, filed Dec. 19, 2005; U.S. Ser. No. 60/752,737, filed Dec. 20, 2005; and U.S. Ser. No. 60/838,276, filed Aug. 17, 2006. The '516 application is also a continuation-in-part of U.S. Ser. No. 11/140,644, filed May 27, 2005, now abandoned; which claims benefit under 35 U.S.C. 119(e) of provisional applications U.S. Ser. No. 60/574,857, filed May 27, 2004; U.S. Ser. No. 60/640,020, filed Dec. 28, 2004; U.S. Ser. No. 60/646,338, filed Jan. 24, 2005; and U.S. Ser. No. 60/673,296, filed Apr. 20, 2005. The entire contents of each of the above-referenced applications are expressly incorporated herein by reference in their entirety.

**STATEMENT REGARDING FEDERALLY
SPONSORED RESEARCH OR DEVELOPMENT**

[0002] This inventive concept(s) was made with government support under Grant Number 70NANB4H3048 awarded by the Advanced Technology Program of the National Institute of Standards and Technology. The government has certain rights in the inventive concept(s).

BACKGROUND

Certificate of correction

UNITED STATES PATENT AND TRADEMARK OFFICE **CERTIFICATE OF CORRECTION**

PATENT NO. : 6,365,127 B1
APPLICATION NO. : 09/516352
DATED : April 2, 2002
INVENTOR(S) : Ione A. Kourides and Graham K. Whitfield

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It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the specification at column 1, line 3: Insert

The invention described herein was made in the course of work under Grant No. RO1-CA-23185 from the National Institute of Health. The United States Government has certain rights in this invention.

Measures of public research support

We examine four measures of public research support:

- 1 Patent disclosure: Drug has ≥ 1 *Orange Book* patent disclosing a government-interest statement
- 2 Corrected patent disclosure: Drug has ≥ 1 *Orange Book* patent disclosing a government-interest statement, including in parent patents and corrections published by the USPTO
- 3 NIH disclosure: Drug has ≥ 1 *Orange Book* patent in NIH RePORTER
- 4 Agency disclosure: Drug has ≥ 1 *Orange Book* patent assigned to a federal agency

Measures of public research support: Patents

- Of 5,187 *Orange Book* patents: 90 (1.73%) contain a (parsed) government interest statement
 - ▶ 19 *Orange Book* patents have a certificate of correction that adds a government interest statement
 - ▶ 22 *Orange Book* patents have parent patents that contain a government interest statement
- Corrections and continuations affect a small share of our patent sample - 0.37% and 0.42%, respectively
 - ▶ Compare to the (low) measured rate of government interest disclosure

Measures of public research support: Patents

Corrections and continuations resolve all discrepancies between government interest statement sample and NIH RePORTER data

- 16 patents reported to NIH RePORTER do not directly include government interest statements
- 12 had certificates of correction adding disclosure of NIH funding
- 6 are continuations of parent patents with government interest statements
- 2 fall in both categories

Suggests that under-reporting of public research support may be less of an issue than previously thought

Measures of public research support: Drugs

	All drugs	Standard review	Priority review
# of new molecular entities	683 (100%)	403 (59.0%)	280 (41.0%)
≥1 patent disclosure	44 (6.44%)	17 (2.49%)	27 (3.95%)
≥1 corrected patent disclosure	52 (7.61%)	21 (3.07%)	31 (4.53%)
≥1 NIH patent disclosure	32 (4.69%)	14 (2.05%)	18 (2.64%)
≥1 patent assigned to a federal agency	10 (1.46%)	10 (1.46%)	0 (0.00%)

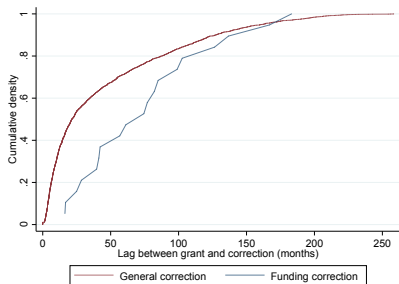
Policy issues

We close by highlighting some key policy issues:

- 1 Is late disclosure of public funding – via certificates of correction – strategic?
- 2 Our corrections are “invisible” to many intended users of patent data
- 3 Implications for drug pricing debates

Strategic disclosure?

- Testing is beyond the scope of this paper
- With caveats about this comparison: compare timing of corrections to *Orange Book* patents that add funding disclosures (n=19) with those that make other changes (n=2,604)



Average gov't interest correction was approved ~ 6.4 years after patent grant, compared to ~ 3.8 years for other types of corrections

Lack of transparency

- Key policy goal of the patent system is public disclosure
- As stressed by James Love/KEI, the fact that certificates of correction are not integrated into standard patent data sets makes these corrections “invisible” to many of the intended users of patent data
- Similarly, more clearly disseminating information on parent-induced disclosures for continuation applications may be warranted

Policy relevance

- Even corrected measures suggest that the share of drugs acknowledging public support is quite small – around 8 percent
 - ▶ Policies leveraging these direct patent rights to control drug prices will necessarily be limited in scope
- Conceptually, the question of which drugs (and which diseases) to target with public research subsidies is – and should be – distinct from the question of how to encourage access to existing drugs
 - ▶ Policy debates should not conflate these two goals as ones that need to be solved jointly [Hemel-Ouellette 2019]