

Pharmaceutical Patent Citations and Real Value

David S. Abrams and Bhaven N. Sampat¹

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Abstract: The number of times a patent is cited by subsequent patents is commonly used in economic research as a proxy for both the private and social value of inventions. Patent citation measures are also increasingly used by policymakers assessing the impact of innovation policies. However, there is surprisingly little direct evidence that more highly cited patents are more valuable ones, and existing validation studies have not considered differences between private and social value. In this project we will examine the relationship between the number of citations to a drug patent and the private and social value of that drug. We also provide new data on the share of social welfare gains appropriated by firms, an important issue in patent law and innovation policy on which there is also little evidence.

¹Abrams: University of Pennsylvania (dabrams@law.upenn.edu) Sampat: Columbia University and NBER. The authors would like to thank Emma Boswell Dean for outstanding research assistance.

I. Introduction

The number of times a patent is cited by subsequent patents is commonly used in economic research as a proxy for both the private and social value of inventions (Gittleman 2012, Sampat and Ziedonis 2004). Patent citation measures are also increasingly used by policymakers assessing the impact of innovation policies. However, there is surprisingly little direct evidence that more highly cited patents are more valuable ones, and existing validation studies have not considered differences between private and social value. In this paper we make use of newly available data on drug efficacy, usage, and revenue to add to our understanding of patent value in the pharmaceutical industry.

The pharmaceutical industry provides a good context to examine relationships between patent citations and value. It is economically important: In the US alone, pharmaceutical sales were nearly \$400 billion last year, and drug costs are among the fastest growing components of U.S. healthcare expenditures.

There are also practical advantages to studying pharmaceuticals. Unlike most other industries, data on product-specific revenues are available, and marginal costs of production quite low, making it possible to measure the private value of new drugs using drug sales. Additionally, one may use quality adjusted life years (QALYs) generated by specific drugs, in order to compute the marginal social value. Unlike previous analyses which rely on econometric machinery to estimate social value of individual technologies (e.g. discrete choice models), in drugs we have a more direct measure – health improvements. Unlike many complex manufactured products that may involve hundreds or thousands of patents, drugs tend to depend on one or two key patents. Using information in the FDA Orange Book and elsewhere, we are able to directly link the underlying patents with the revenues and health benefits they generate.

The pharmaceutical industry is uniquely reliant on patents. There is a sixty-year empirical legacy in economics that patents are more effective at preventing imitation and appropriating returns from R&D in pharmaceuticals than in any other field (Levin et al 1987, Cohen et al 2000) and almost all new drugs are patented. The importance of patent protection in pharmaceuticals may also mean there is less strategic citation: firms have incentives to search for and cite relevant prior art, since the risks of patent invalidation are higher in this field than others.

Exploring the relationship between different measures of value is also particularly

important given policy debates in pharmaceuticals regarding different dimensions of drug value. Some analyses suggest that new drugs deliver significant clinical and economic value on average (Lichtenberg 2001). However there is also considerable heterogeneity in the private and social value of new drugs (Garthwaite and Duggan 2012). In addition to examining the relationships between citations and private value, and between citations and social value, we also provide new data on the relationships between private and social value, and the share of social value captured by originating firms.

We proceed as follows. Section II provides background and literature review. Section III describes our data. Section IV presents basic descriptive statistics and section V shows main results, in the form of simple bivariate scatterplots. Section VI concludes.

II. Background

The difficulty of measuring the value of innovation is a well-known problem in innovation policy (Griliches 1984, Griliches 1990). Though many analyses use patent data to do so, they provide an imperfect solution for several reasons. Most importantly, in many industries most innovations are not patented. The ways in which patents are used also varies by industry, with some sectors using patents mainly for defensive and other strategic purposes beyond appropriating returns from R&D (Cohen et al 2000). In addition, patents vary tremendously in their importance, making simple patent counts (e.g. at a firm, sector, or country level) very noisy measures of innovation (Griliches 1990).

One improvement on this approach is to use the number of times a patent is cited (as prior art) in subsequent patents as a measure of its importance or value. In the first use by economists, Trajtenberg (1990) uses discrete choice demand models to estimate social value of CT scanner technology, and correlates temporal changes in social value with patent counts and citation weighted patent counts for CT scanners. He finds that citation-weighted patent counts perform better at predicting social value than simple patent counts, with correlation coefficients between .4 and .8 depending on assumptions about lag structure and the functional form of the relationship.

He concludes by emphasizing limitations of this approach and difficulties in validating: *"All of my conclusions have been expressed in a qualified manner since they are based upon the findings from a single case study. It is important to emphasize, however, that the sort of validation of the citation-based patent index attempted here could hardly have been done in a wider context simple because the measure of the value of innovations that would be required for that purpose are nowhere to be found"* (185).

Since then there has been widespread use of “forward” citation counts as proxy for not only the social value of inventions, but also private value (Gittleman 2012, Sampat and Ziedonis 2004). Previous validation studies have found mixed evidence for the assumption that citations correlate with private value (Sampat and Ziedonis 2004, Hall 2000, Abrams 2013, Moser et al 2015, Harhoff et al 1997). And, perhaps for reasons Trajtenberg anticipated in the quotation above, there are surprisingly few studies of citations and social value, or the related idea that citations reflect “spillovers” between citing and cited inventors (Jaffe et al 2000).

For reasons we alluded to in the introduction, the drug industry has several features that make examining citations and value of pharmaceuticals empirically tractable. Various databases resulting from FDA regulatory requirements (the Orange Book and PTO list of extended patents) allow for linking of patents to products. It is possible to track sales for individual drugs, and, since marginal costs of production are typically low, these are reasonable proxies for profits.

Profits are a measure of private value. Pharmaceuticals is one industry where it is more plausible to construct social value measures. Indeed, the feasibility of this idea motivates a number of recent policy proposals to replace or supplement patent based incentive systems with prize based systems, with the size of the prize based on the social value of drugs (Hollis and Pogge 2008).² This is typically viewed as being easier to do in drugs than other fields because of the availability of standard pharmacoeconomic measures of drug value and standard (if not uncontroversial) measures of the economic value of additional life years. Specifically, we can use incremental quality adjusted life years (QALYs) associated with each drug. QALYs are a summary measure of the health gains (or losses) from an intervention as compared to an alternative, including the effects of interventions on mortality (life years) and morbidity (quality). An intervention that generates 1 QALY increases life expectancy by one year in perfect health.

QALYs were developed for use in decision analysis and the economic evaluation of new medical technologies. In some countries, public payors use QALYs gains from an intervention as a basis for determining whether it provides good value for money, i.e. whether it is “worth it.” In some health systems, most prominently the United Kingdom, comparison of the QALYs gained from a drug (relative to some alternative, typically the status quo treatment) to incremental costs--the so called incremental cost- effectiveness

² There are also proposals to uses QALYs as basis for value based pricing (Jayadev and Stiglitz 2009), on the idea that this could shift the direction of innovation away from those with only incremental benefits.

ratio--to a societally agreed upon willingness-to-pay per QALY is used to guide reimbursement decisions (Drummond 1992). In Australia, the Pharmaceutical Benefits Advisory Committee (PBAC) also use cost-effectiveness in making their reimbursement decisions, but also other factors (Drummond et al 2007).

In cost effectiveness analyses the threshold value is typically \$50,000/QALY, though this was locked in more by historical accident than any logic (Chambers et al 2014). Analysts have suggested it is too low and should instead be as high as \$150,000 to \$200,000 QALY (Chambers et al 2014). As a practical matter, determining QALY per drug is typically done through in depth analysis of individual treatments, often as component of clinical trials. Our analyses below will use data from the Tufts Cost-Effectiveness Database which reports standardized QALY information for a large number of drugs, based on reviews of the literature.

Using data on QALYs per drug, together with assumptions about willingness to pay per QALY, allow us to calculate social value of drugs in dollar terms which we then compare to private value. It is typically assumed that firms do not always capture full gain from inventive activity (Nelson 1958, Nordhaus 2004) since consumers also benefit from new goods (and improved quality or lower prices for existing goods). While "market failures" are the main focus of most economic analyses of innovation, scholars of pharmaceuticals also emphasize that innovations that generate significant private profits may have low social value, if, for example, consumers are shifted to those goods by advertising, or innovation is characterized by significant business stealing by "me-too" drugs (Jayadev and Stiglitz 2009).

There is limited direct evidence on the share of social returns appropriated. Analyses in Nordhaus (2004) suggest it is very small, though the author also conjectures that given high rates of profits in pharmaceuticals it may be higher there. Philipson and Jena (2006) calculate global life expectancy gains in HIV-AIDS since the 1990s due to new drugs, and suggest that innovators capture only 5 percent of benefits, concluding that there is considerable underinvestment in R&D.³ Sun et al (2009) use a similar approach, finding 5-19 percent of social returns from cancer drugs appropriated by firms. Goldman et al (2010) look at 5 specialty cancer drugs and claims from 71 health plans, and use data on income elasticity and assumptions about demand curve to calculate consumer surplus from the drugs, finding social benefits outweigh costs to consumers by a factor of four. Each of these analyses looks at a small number of select drugs in specific disease areas, and rely on assumptions about demand and modelling to calculate value. To our knowledge no

³ The authors go further, saying that if HIV/AIDS drugs are representative "patients and health plans are getting too good a deal in the short run, which hurts them in the long run by insufficient R&D."

previous analyses use data on QALYs to examine the gap between private and social value of a large set of drugs.

III. Data

Drugs from the Tufts Cost-Effectiveness Database

We started by collecting data on the new molecular entities (NMEs) approved between 1999 and 2011 included in the Tufts Cost-Effectiveness Registry. As described in Chambers et al (2014.) the Tufts CEA Registry is a comprehensive database of 5,655 cost-utility analyses, which compiles and standardizes information from published cost-effectiveness analyses. There were 102 NMEs with CEAs in that database, of the 279 NMEs approved over the same period.

Patent data

Using new drug application (NDA) numbers for these drugs, we found all patents for the drugs on current and archival versions of the FDA Orange Book (Hemphill and Sampat 2011). Of the 102 drugs in the Tufts database, 75 had at least one patent listed in the FDA Orange Book. Of the 27 that did not, 17 are biologic drugs. These drugs were approved through biologic license applications (BLAs) not new drug applications (NDAs). BLAs are not subject to Orange Book patent listing requirements. The remaining 10 NDAs presumably relied on other forms of exclusivity (e.g. Orphan Drug Exclusivity, NCE exclusivity) or non-Orange Book patents for protection (Kapczynszki et al 2012). For the 75 NDAs with Orange Book patents, there were 292 unique patents, an average of just under 4 patents per drug.

In order to find patent data on the 17 biologic drugs, we consulted another source for patent data. The Hatch-Waxman Act requires the FDA and USPTO to produce lists of patents extended under the Act's patent term extension provisions. Unfortunately the online list at the USPTO was incomplete, so we supplemented this with searches for each of the 102 drugs in the Federal Register archives. (Petitions for patent term extension must be announced in the Federal Register.) The patent extensions database includes both NDAs and BLAs. There are two potential issues, however. First, for drugs with extended patents there is typically only one patent extended per drug (unlike the Orange Book, which has all

patents that firms decide to list). The extended patent is typically the main patent: for NDAs it is the “active ingredient” patent (Hemphill and Sampat 2012). Second, not all drugs are entitled to patent extensions; this is determined based on the length of regulatory review and extent of patent term absent extensions.

Of the 102 drugs in the sample, 10 have no associated patents listed in either the Orange Book or the term extension list (6 NDAs, 4 BLAs). For the remaining 92 drugs, there were 313 patents (312 unique), 237 of which were on the Orange Book only, 56 of which were both on the Orange Book and extended patents list, and 20 of which (most associated with biologic drugs) which were on the extended patents list only.

In the analyses we separately examine for each of the drugs (1) citations to the 293 patents on the Orange Book and (2) citations to the 76 “extended” patents (whether or not on the Orange Book). The former set has the advantage of providing more complete list of patents per drug, but excludes biologics. (It includes patents for 75 drugs.) The latter includes biologics but excludes patents that were not extended, and drugs with no patent extensions. (It includes patents for 76 drugs.)⁴

Citation data

Our first value measures are based on patent citations. For each of the 312 patents we collected USPTO data on all “forward” citations in subsequently issued patents. In addition to overall citations, we collected citation data excluding “self” citations (those where citing and cited firm are the same). Of the 312 unique patents 279 were cited at least once. There are 10,550 total citations to the patents (6967 of which are unique).⁵ For the analyses we aggregate patents to the drug level, examining unique citations across all of a drug’s patents.

Private and social value

To construct the measures of private value (drug sales) and social value (based on health improvement) we use data from the Optum ClinFormatics database, which includes administrative health claims (including pharmacy claims) for 2000-2014 for a large managed care company, covering 47 million users over this period. The pharmacy claims

⁴ Only 56 of the drugs are in both sets.

⁵ For patents issued after 2001 (about 60 percent of all the patents) we also distinguished between examiner and other citations (Sampat 2010) since previous analyses suggest these two sources provide different signals of value (Hegde and Sampat 2009). Though we do not use the data here we intend to explore in future analyses.

table data are submitted by pharmacies for drugs dispensed on an outpatient basis. Unlike other databases, Optum also includes data on inpatient drugs. Using the Optum data we constructed data on total expenditures associated with drug (regardless of who paid) , and the total number of new users. We do so by finding all National Drug Codes (NDC) associated with the drugs in the Tufts dataset, and merging with NDC data in Optum pharmacy and inpatient claims tables.

For each of the drugs with patents we determine total annual expenditures from 2000-2014. In the analyses presented below we construct a measure of total sales over this period. This is our measure of private value.

To compute social value we multiply the QALY per drug measure from the Tufts data by the total number of people who took the drug for a course of treatment. One complication is that “course of treatment” can be very different for different drugs. Some medicines (e.g. for acute treatments) are taken only once; others (e.g. for chronic illnesses) may be taken for years. Accordingly for each year from 2000-2014 we determined the total number of new users for each drug--individuals who had not previously taken the drug over this period--on the assumption that a new use represents a new course of treatment. For some of the analyses we convert total QALYs to dollars using both the lower bound in the literature (\$50,000 per QALY) and an upper bound (\$150,000 per QALY). As with private value analyses, in this paper we focus on total social welfare from each drug over the 2000-2014 period, but in future analyses we hope to examine changes over time (over the life course of each drug) as well.

IV. Descriptive statistics

Table 1 Summary Statistics

Variable	Obs	Mean	Std. Dev.	Min	Max
Biologic	102	0.17	0.37	0.0	1.0
Total Cites to Orange Book Patents	75	90.07	112.91	2	613
Total Cites to Orange Book Patents (Excluding	75	81.40	110.00	2	589

Self)

Total Cites to Extended Patent	76	52.11	57.33	0	276
Total Cites to Extended Patent (Excluding Self)	76	45.47	50.63	0	259
Total Unique Users	102	756,945	1,768,220	0	10,200,000
Total Expenditures (\$)	102	185,000,000	434,000,000	0	3,720,000,000
QALYs (Per User) Generated By the Drug	102	0.17	0.88	-5.8	4.2

About 17 percent of the drugs are biologics. For the 75 drugs with a patent listing on the Orange Book, the average number of citations is 90 to all associated patents, and 81 excluding self citations. For the extended patents (whether or not on the Orange Book) there are fewer citations, but note that only one patent per drug is typically extended. (By comparison, drugs on the Orange Book have 3-4 patents on average, and each can generate citations.)

Turning back to the full set of 102 drugs, the total number of unique users recorded in the Optum data over the 2000-2014 period ranges from 0 to 10.2 million, and total sales from zero dollars to nearly \$4 billion.

As Chambers et al (2014) report, the total number of QALYs associated with each drug averages .17 years, worth somewhere between \$8,500 and \$25,500. About a quarter of the drugs have negative QALYs, or provide fewer life year advantages than the previous standard of care.

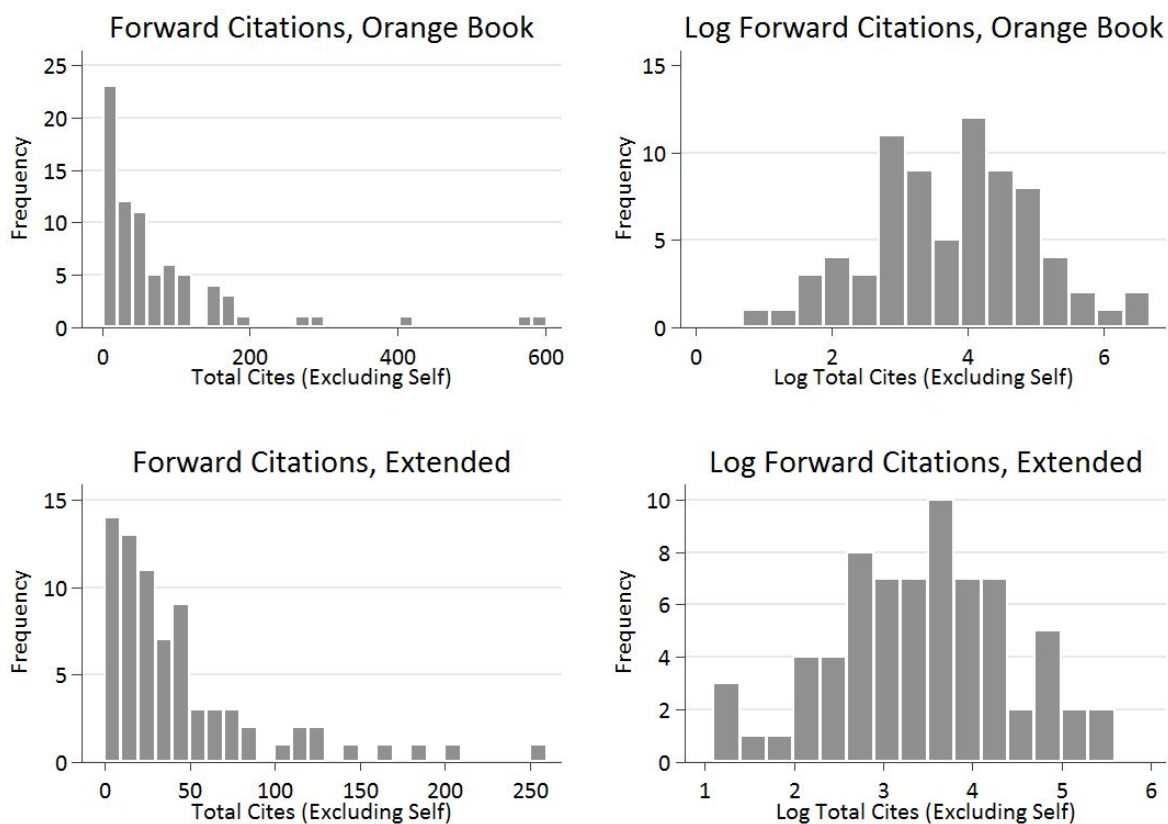


Figure 1

Figure 1 shows the distribution of forward citations to all patents in the data set. The upper two histograms compute citations to all Orange Book patents associated with a drug; the lower two use the citations to the Extended Patent (usually only one). It is clear from the histograms of the left that the distribution is non-normal. The figures on the right, using log citations, appear normal, thus we use log cites for much of the following analysis.

To construct total social welfare we take the product of QALY gains for each drug and multiply it by the number of unique users. In order to validate the integrity of the utilization variables we examined how they evolve over time, and if they respond to known events (e.g. drug approval dates, withdrawals, introduction of competitor drugs, and patent expiration). In Figure 2a and b we present time trends in total drug fills for 8 drugs⁶ where approval and generic entry dates are known:

⁶ Dates derived from Hemphill and Sampat (2012)

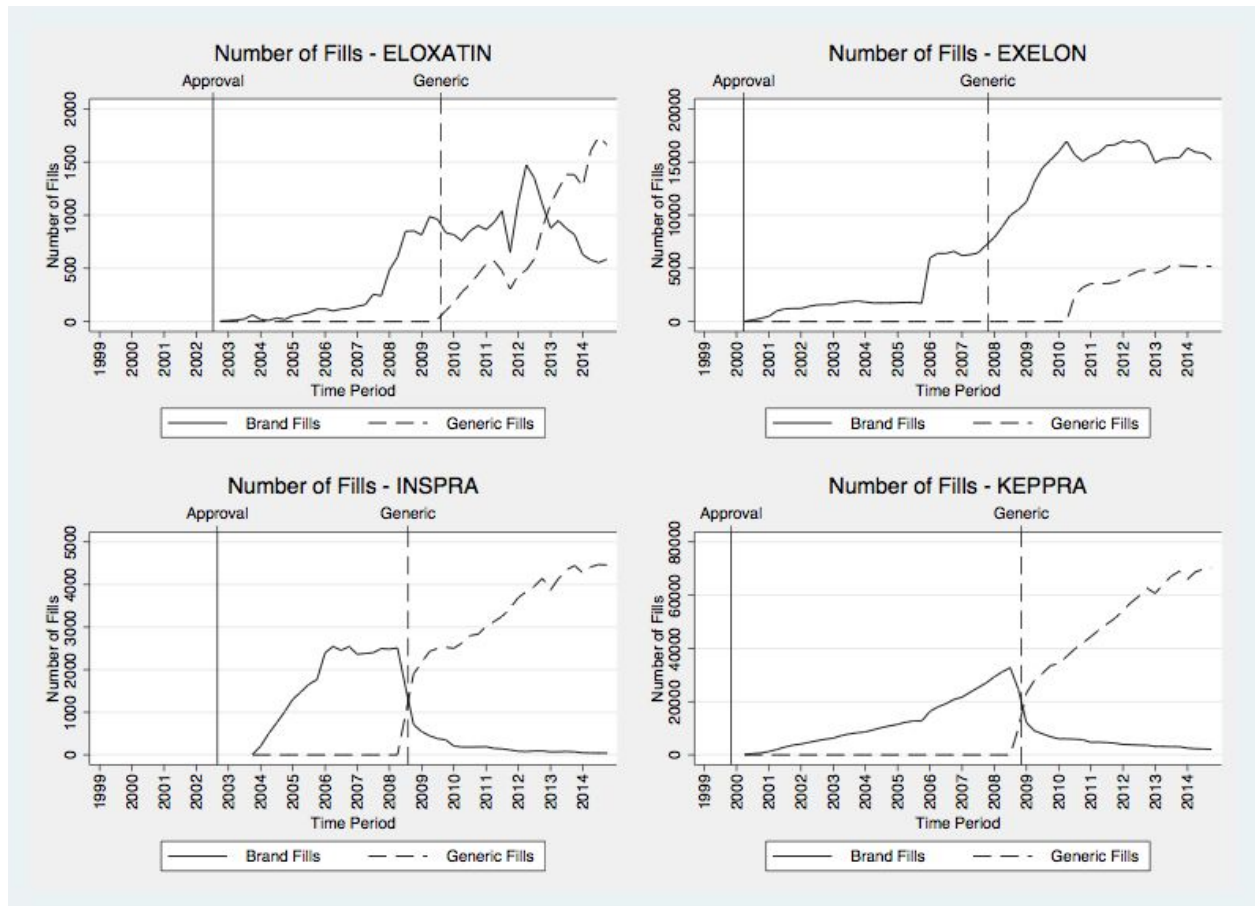


Figure 2a

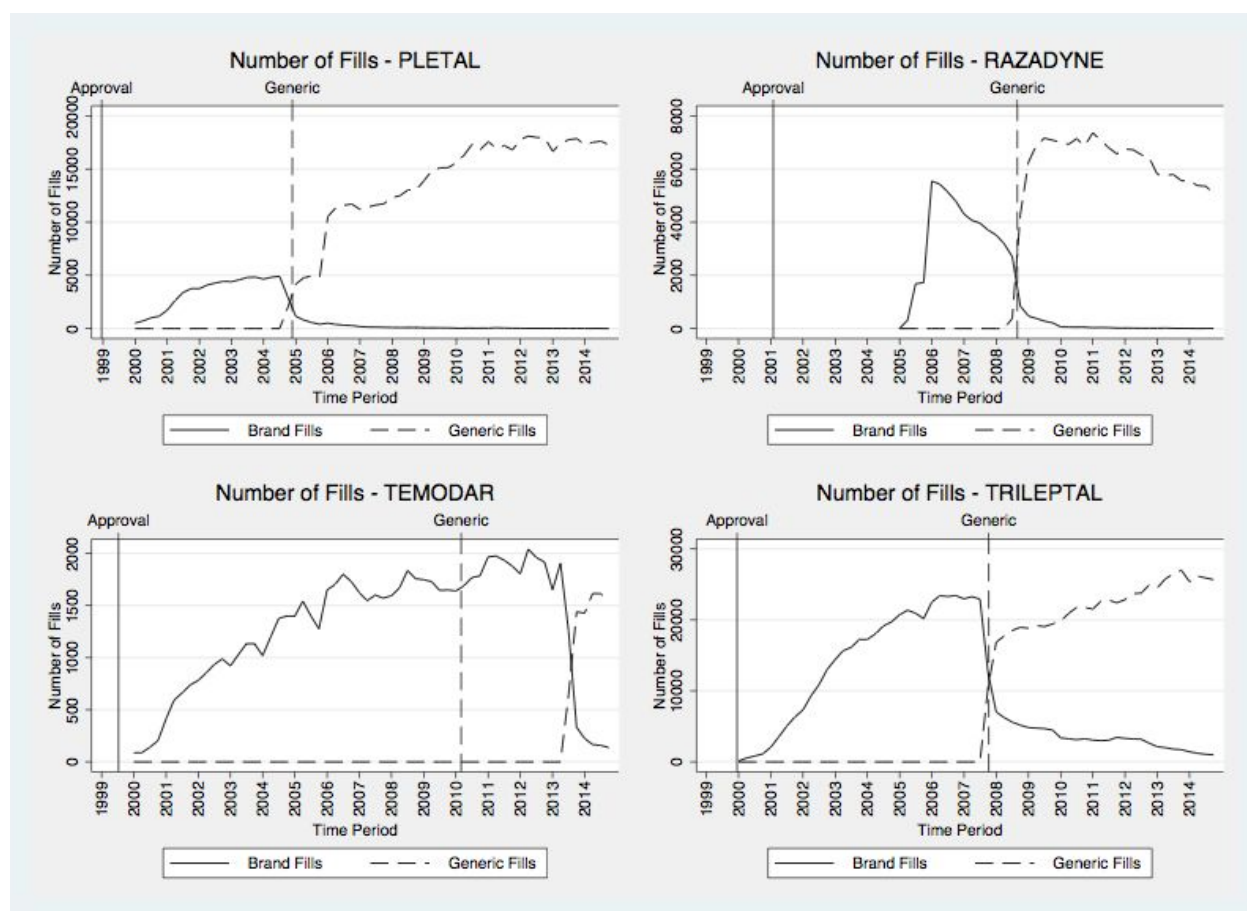


Figure 2b

For all of the drugs, utilization does not begin until after drug approval, reassuringly. And for most we see sharp changes in utilization near or after generic approval data, with many more generic fills.⁷ Though not the focus of this analysis it is interesting that for nearly all of these drugs utilization increases with genericization, contrary to the message of previous work (Lakdawalla and Philipson 2012) on this topic.

V. Empirical analysis

Citations vs. private value

Our first analysis compares total citations to a drug's associated patent or patents (through 2014) to the drug's sales over the same period. For this analysis we include all associated

⁷ For low sales drugs, and for drugs with various types of pay-for-delay settlements, generic launch may lag generic approval (Hemphill and Sampat 2012).

patents listed in the Orange book and compute the total number of non-duplicative citations. For sales, we use aggregate revenues generated by the drugs from 2000 - 2014.⁸ Since both citations and sales are skew, and to facilitate interpretation, we examine these bivariate relationships in (natural) logarithms. Figure 3 reports the relationship between log forward citations and log total revenue. The scatterplot shows little relationship between citations and sales, and not surprisingly, the fitted regression line is essentially flat.

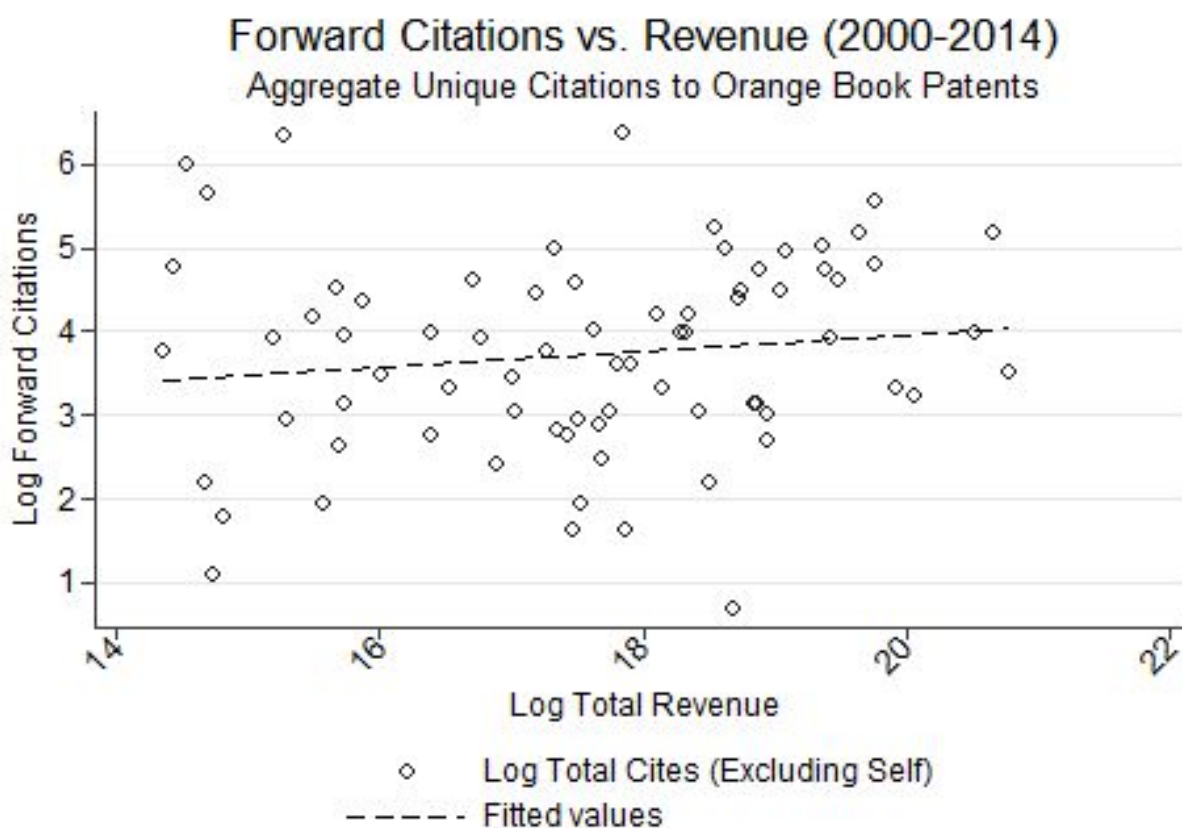
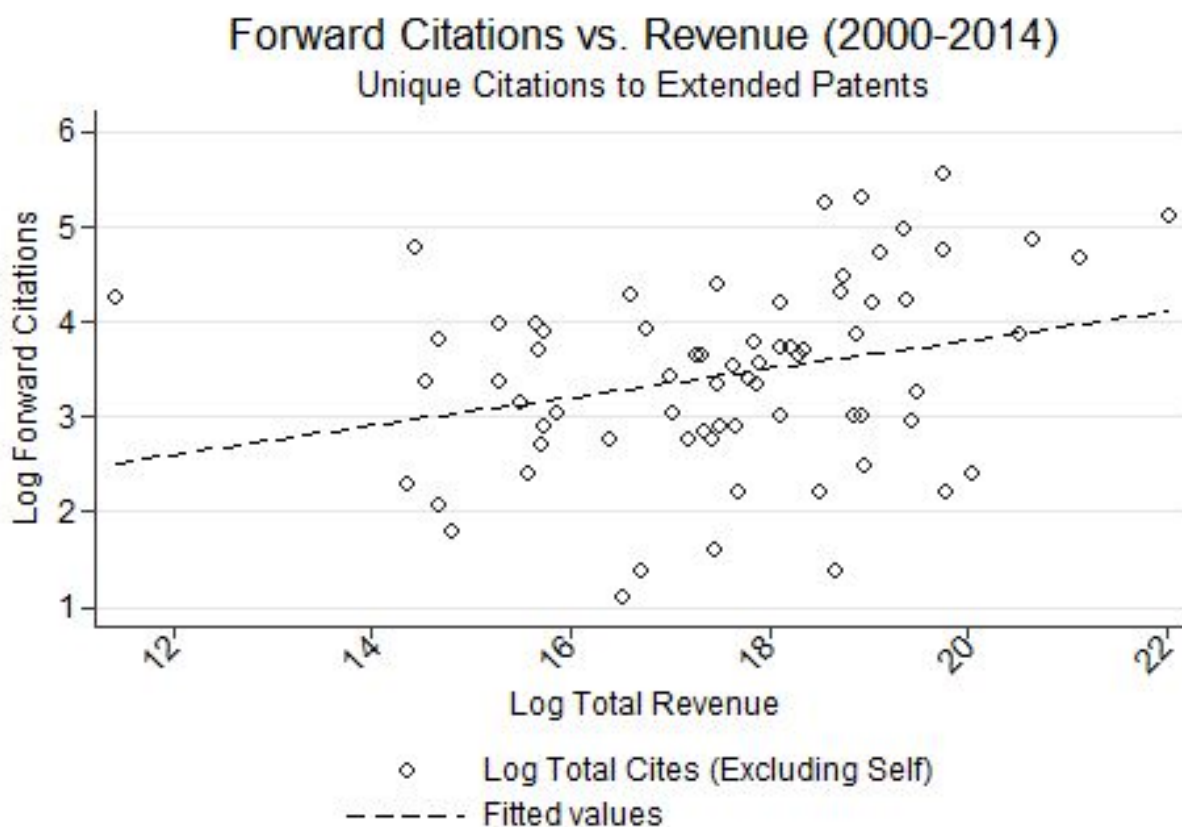


Figure 3

Recall the Orange Book includes multiple patents for each drug. Our other source for patent data, the extended patent list, includes just one, typically the primary one (Hemphill and Sampat 2011). Moreover, the extended patent list includes biologic drugs. Figure 4 shows the same relationship as for Figure 3, but only including citations to the drug's extended patent.

⁸ Note that this is a cross-sectional analysis, where each observation is a drug. Although the drugs are different ages, both citations and revenues should increase over time.

**Figure 4**

Here there is indeed a stronger positive relationship. Complementary regression models show that in each case the relationship is significant at conventional levels. The log-log regression suggests elasticities of around .18. This may be partly driven by the addition of a data point toward the right of the figure, reflecting the inclusion of a biologic drug (Lucentis) that has high sales and did not have any Orange Book patents, but does have an extended patent. The difference between Figure 3 and 4 may also indicate that the extended patent measure is the cleaner one. We discuss this further in Section VI.

Citations vs. social value

In the next analysis we examine the relationship between the citation measures and social value. We compare log citations to the number of QALY's added per drug directly, without accounting for utilization or the value of QALYs. Since QALYs can be negative and have a

less skewed distribution than revenues, we do not log transform them, and instead present a semi-log specification in Figure 5.

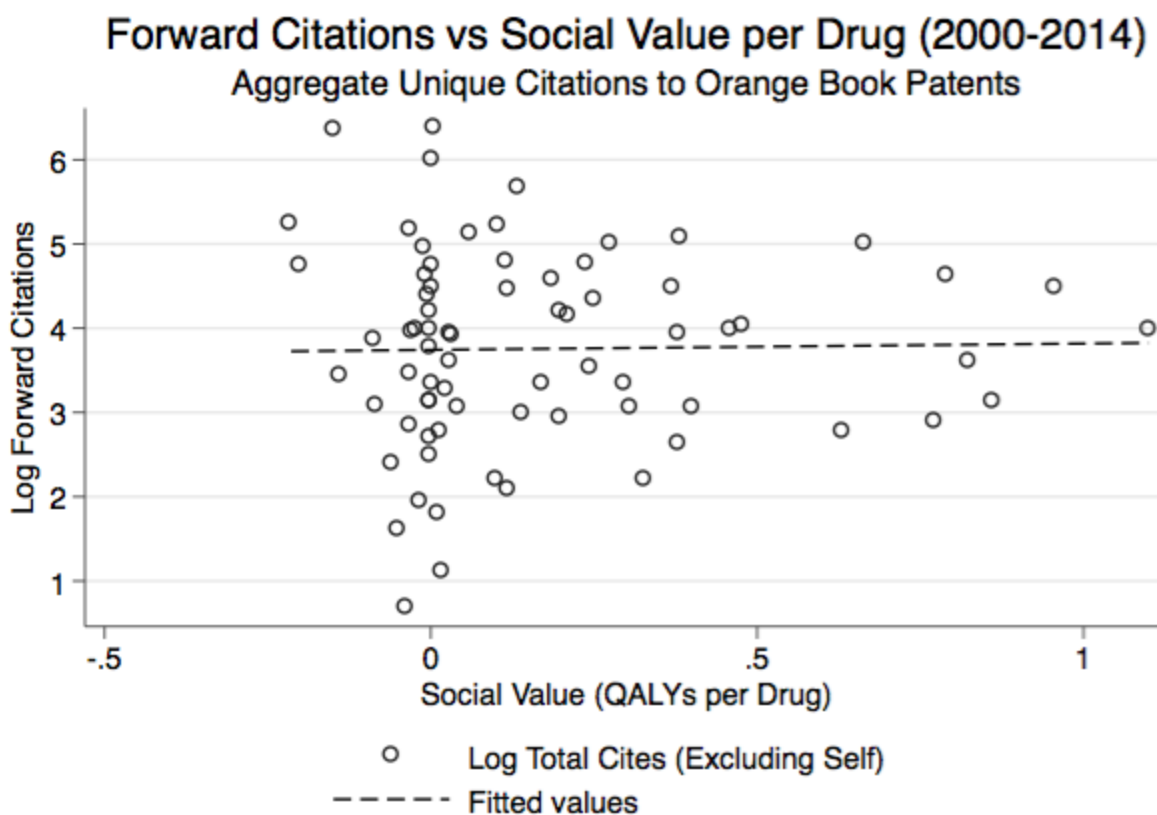
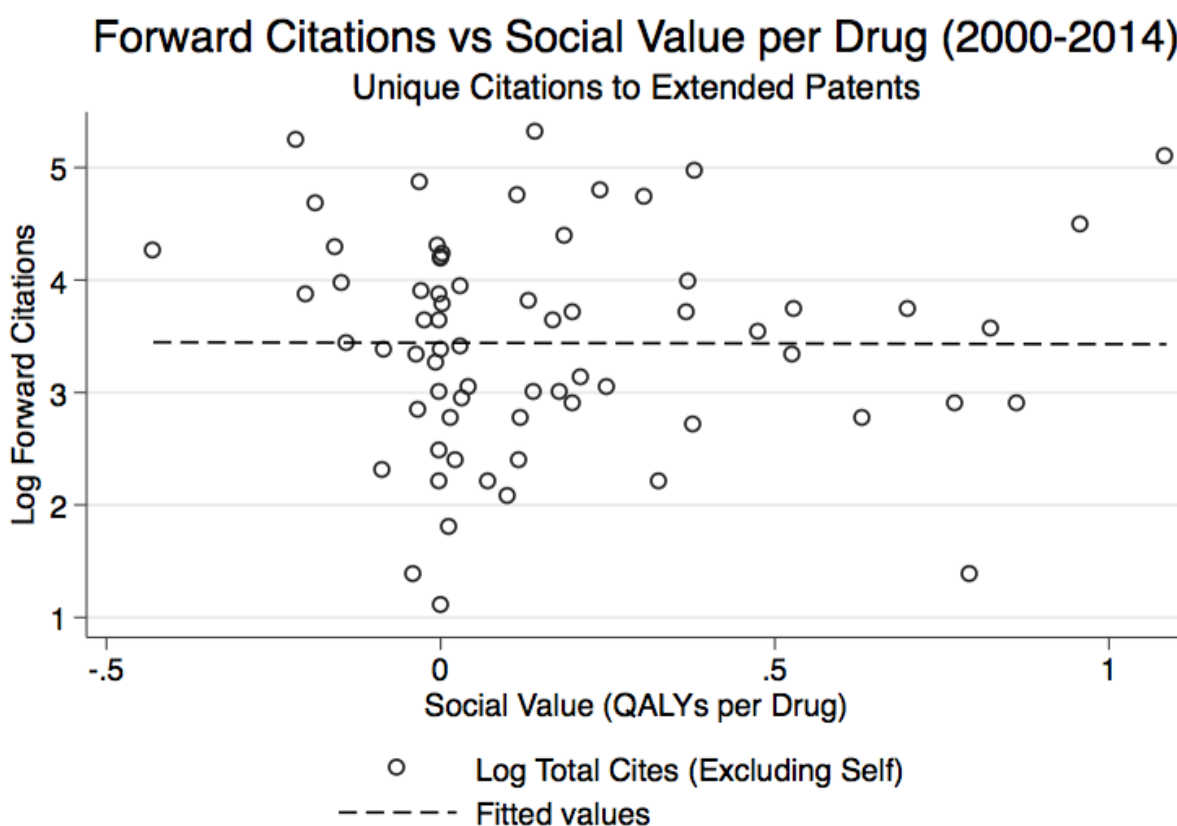


Figure 5

The figure clearly shows no relationship between forward citations and social value. Not surprisingly, regression results also show the coefficient on QALYs is not significantly different from zero. This is similar to what we found for Orange Book citations vs. private value (sales) in Figure 3 above. We also examine the citation-social value relationships based on citations to the extended patents, plotted in Figure 6. This figure looks very similar to Figure 5 and also shows no association between forward citations and social value.

**Figure 6**

It may be that forward citations are a better proxy for total social value, not just social value per user. After all, a high QALY drug for a small number of users may not attract as much entry (and thus generate later citing patents) as a medium QALY drug for a large population. Thus in the next two figures we report the relationship between forward citations and total social value. Total social value is computed by multiplying QALYs per drug by the total number of unique users over the 2000-2014 period.⁹ Figures 7 and 8 display the results based on citations to Orange Book patents and extended patents, respectively. Neither figure indicates a strong relationship between citations and total social value.

⁹ In order to produce a figure in logs we transform any observations with zero or negative total QALYs to 1, although the results are robust to dropping these or assigning them to other values as well. Since this does result in the transformation of a good share of the observations, in future work we plan to include regressions using a linear specification.

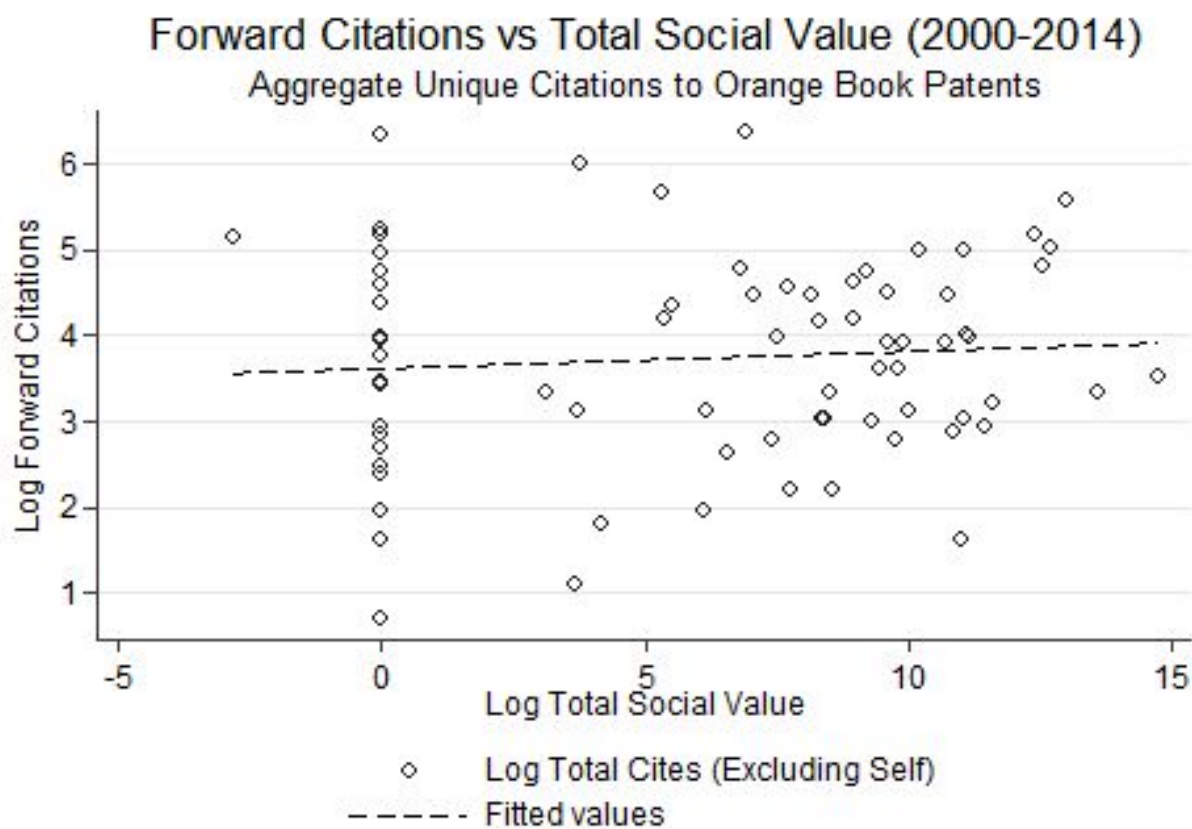
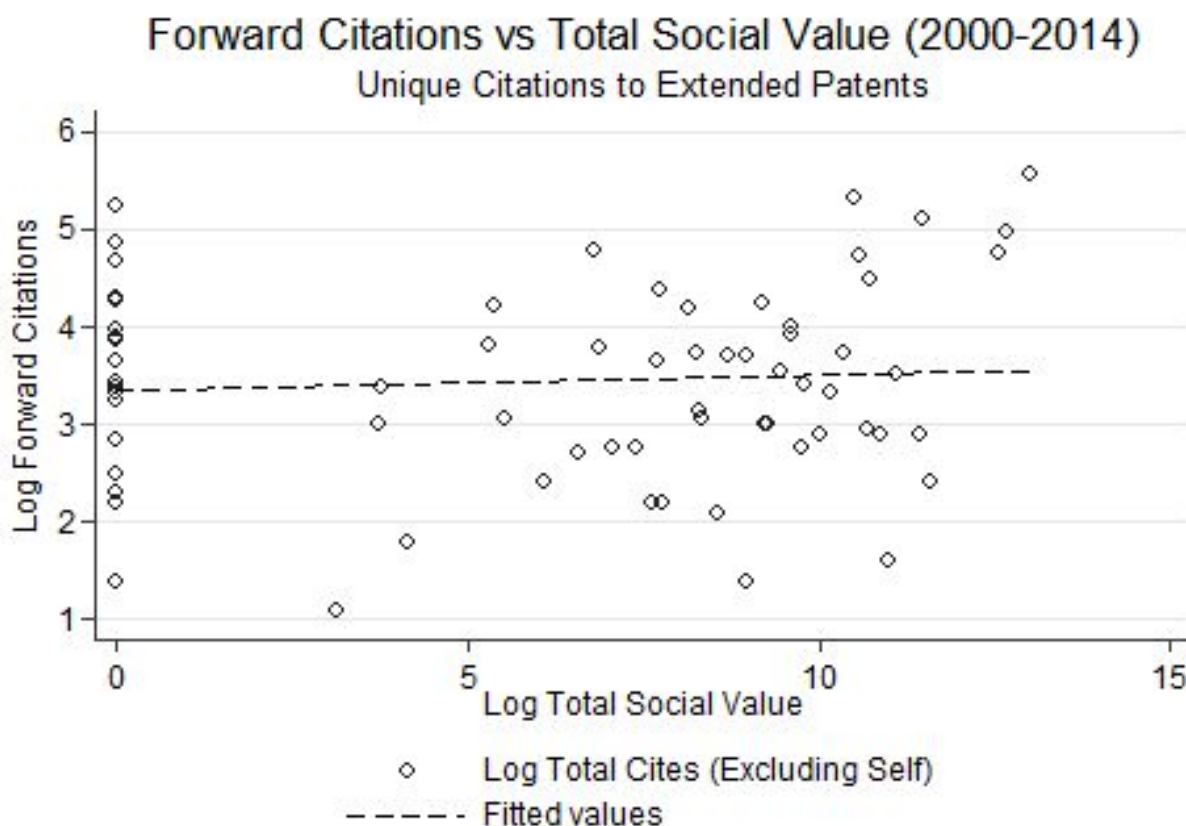


Figure 7

**Figure 8****Private vs. social value**

So far we have attempted to determine whether there is a strong argument for using forward citations as a proxy for either private or social value of pharmaceuticals. The evidence has mostly shown that forward citations do not appear to be strongly correlated with either measure of patent value. Now we examine a different question - the relationship between private and social value. This relationship is crucial in several current policy debates including those surrounding incentives for pharmaceutical companies, drug pricing, and who benefits from new drug development.

As in the analyses immediately above, we construct private value based on total expenditures for the drug between 2000 and 2014 (from Optum) and total social value based on the average QALY (from Tufts) and number of unique users of the drug from 2000 to 2014 (from Optum). To facilitate comparison, we present the social value in dollars.

Since there is no universally agreed upon yardstick, we constructed estimates based on a lower bound of \$50,000 per QALY (and report results based on an upper bound of \$150,000 per QALY in the appendix).

First it is useful to get a sense of the distribution of social and private value per user.. These results may be seen in Figures 9 and 10.

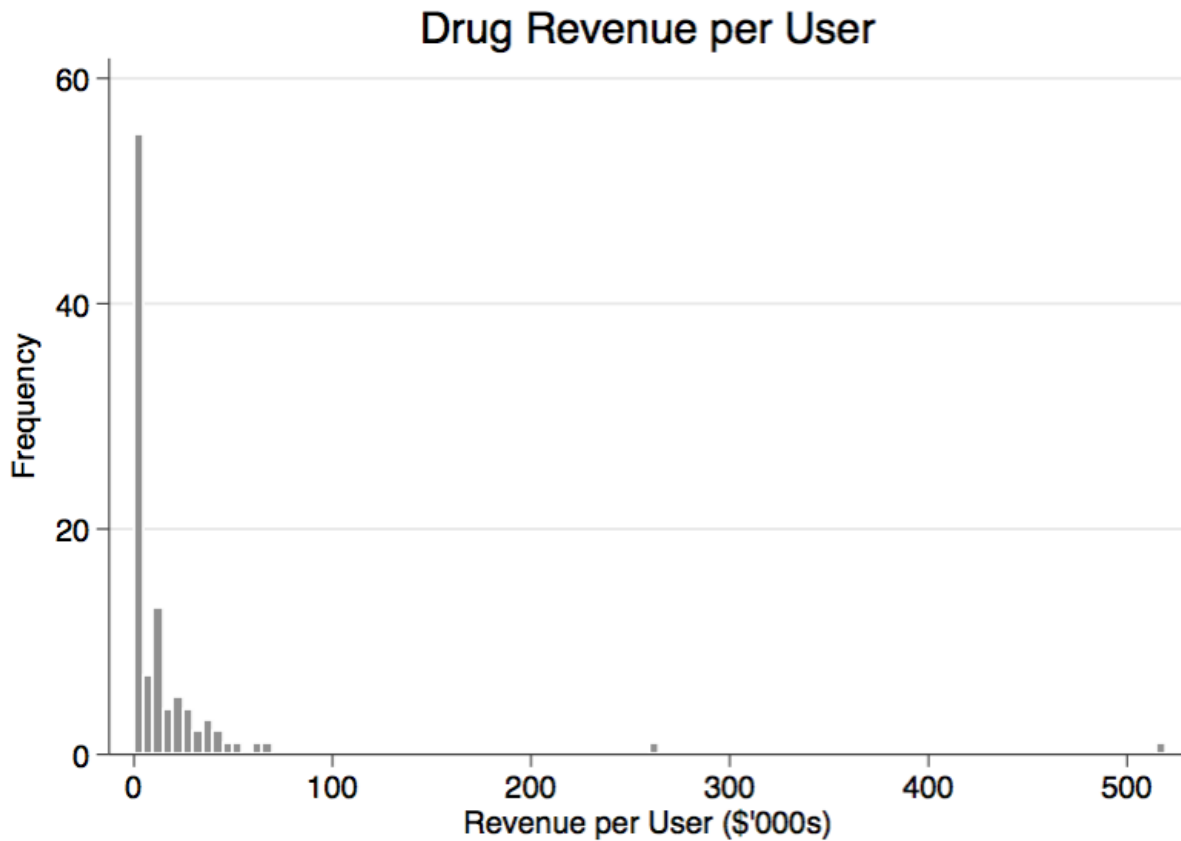
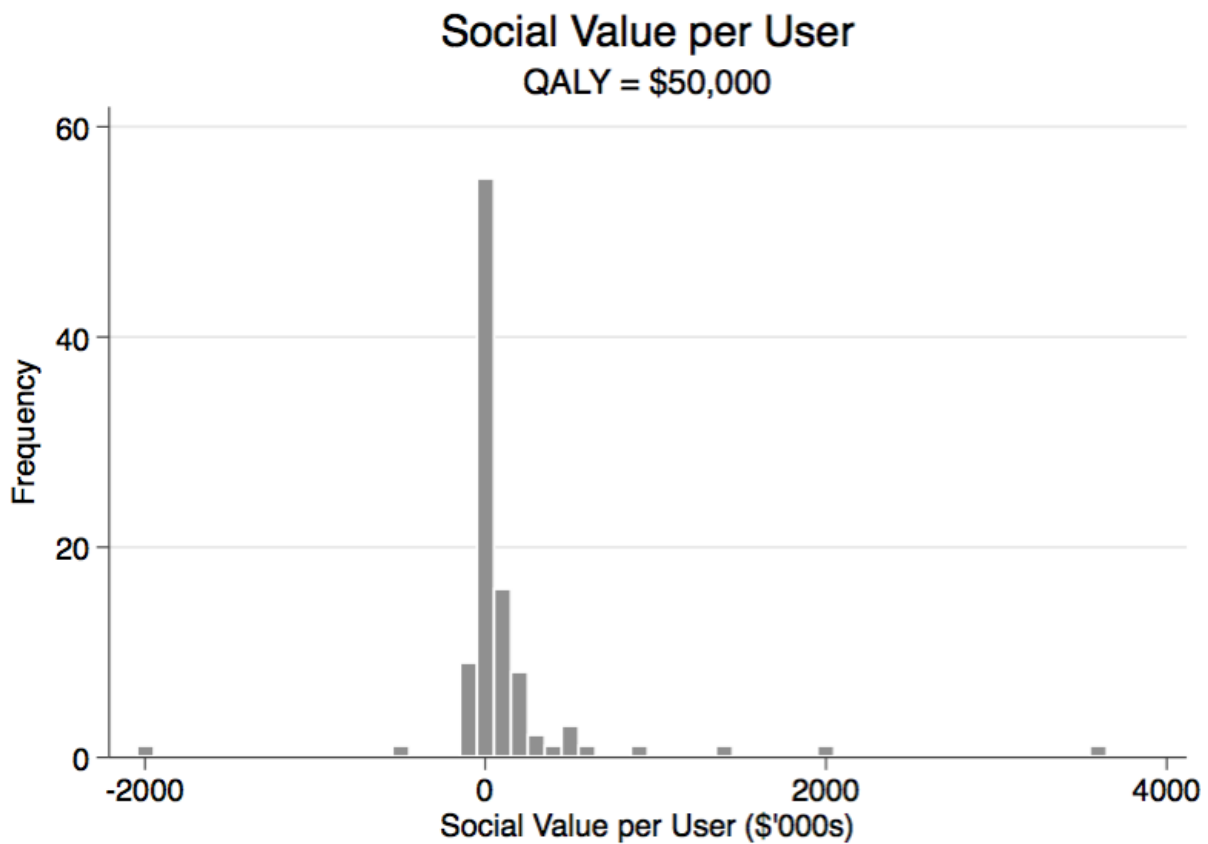


Figure 9

**Figure 10**

Several interesting things may be observed. When examining the per-user figures, it is clear that there is far more variation in the social value per user gained from a drug. The social value per user ranges from around -\$2 million to + \$3.6 million.¹⁰ Recall that social value may be negative since a new drug may be worse than the current treatment. In fact, 32 of the 101 drugs in this analysis are worse than the current treatment. By comparison, private value (revenue per drug) ranges from 0 to about \$500,000 per user.

¹⁰ This analysis uses \$50,000 for 1 QALY, the lower bound of what is typically used.

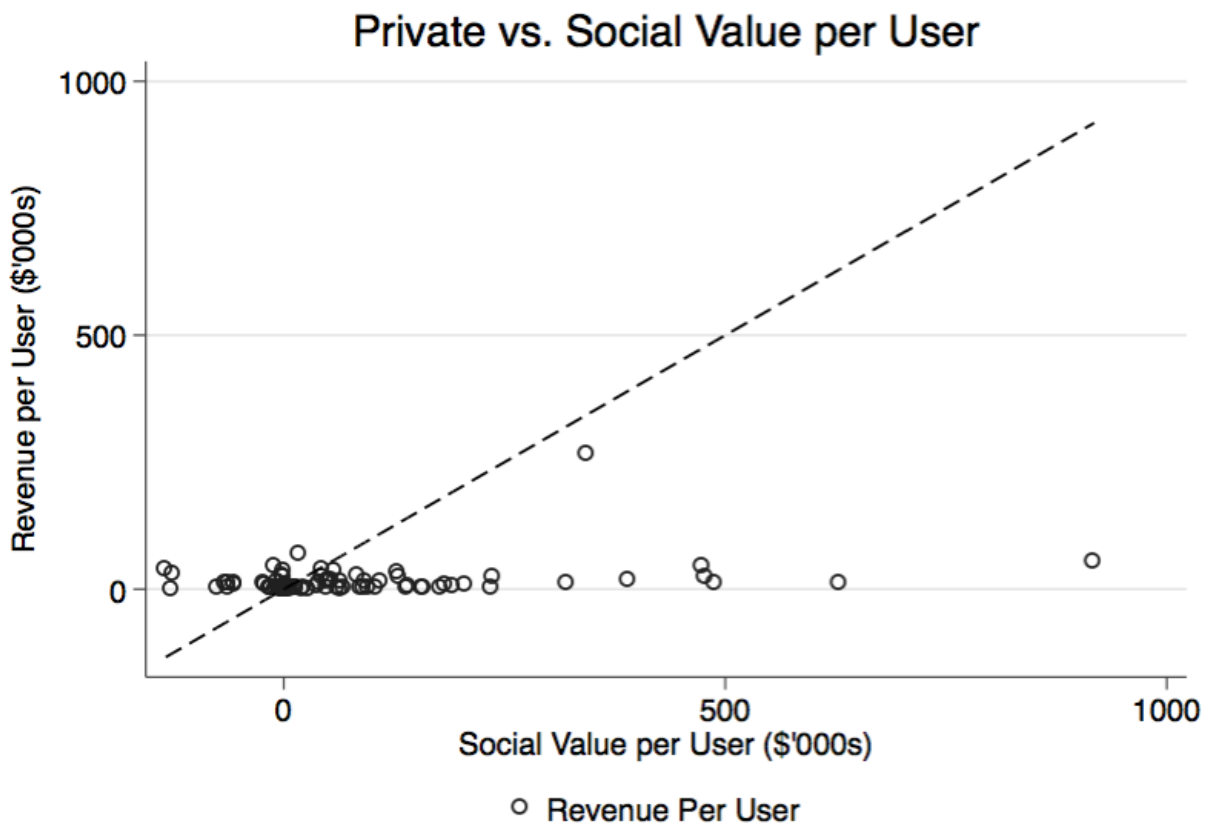


Figure 11

Figure 11 shows private vs. social value per user using the 50,000/QALY value (removing a handful of outliers for readability). The dashed line is a 45 degree line to indicate the point at which private and social value are equal. Points below and to the left of the line represent drugs with greater social than private value; those above and to the right have greater private value than social value. While it is hard to see it on this figure, of the 101 drugs, 43 have lower social than private value. This of course includes the 32 that have negative social value, along with 11 other drugs where the expenditures per user exceed the health gains. The distribution of the ratio of social to private value across drugs is reported in Figure 12. (The ratio is negative for all drugs with negative QALYs.)

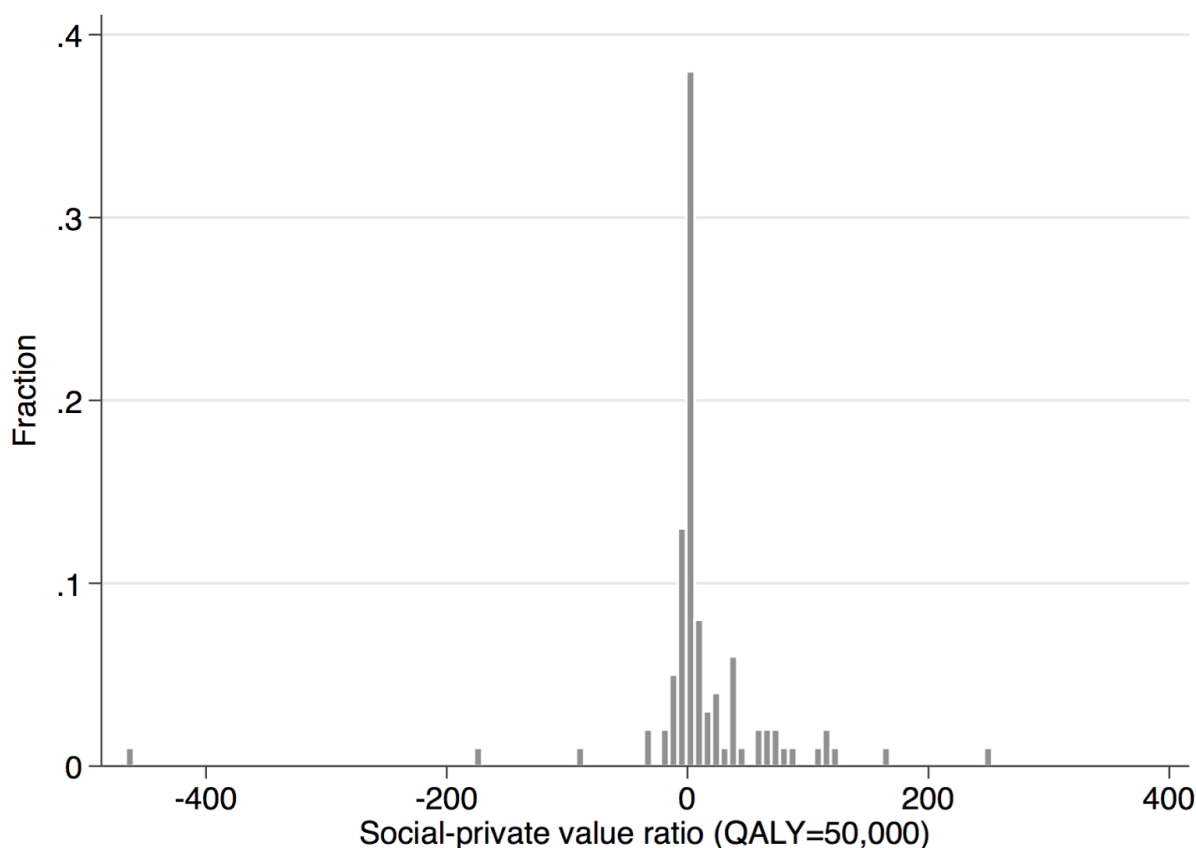


Figure 12

The mean ratio is 10 and the median 2, consistent with the idea that most of the time the benefits of new drugs outweigh their costs. (The aggregate value of the QALYs across all drugs and users in our dataset is \$255 billion, compared to \$19 billion in sales.) But Figures 11 and 12 also shows for about a third of the drugs (accounting for \$6 billion in aggregate sales) incremental QALYs are zero or negative, and for many other drugs quite low.

On one hand, the overall high average ratio of social-private value in our data is consistent with previous work suggesting firms under-appropriate returns from R&D (Philipson and Jena 2006). But by looking at a large cross-section of drugs we also see significant heterogeneity that the averages conceal. The results so far are similar to that from broader work on the economics of medical technology emphasizing that while new innovations generate a lot of value on average, and thus technological change in health care is “worth it” (in the sense of covering its costs), there is also a lot of wasted expenditure (Cutler 2004).

VI. Conclusions

Measuring the value of innovation is important for evaluating a range of science and technology policies. Patent-citation based proxies for private and social value are commonly used, but with limited direct validation. In this paper we leveraged unique administrative data from pharmaceuticals (many of which are available as an unintended result of regulations: FDA patent listing rules, Hatch-Waxman patent extension procedures, the need for CEA for reimbursement in some countries) to link patents to products and products to measures of private and social value. While our analyses are still preliminary, they provide very little support for the hypothesis that citations correlate with private or social value. Though evidence from earlier research on citations and private value is mixed (Jaffe and Rassenfosse 2016), our results are in stark contrast to previous work suggesting citations are good proxies for social value (Trajtenberg 1990). Importantly, our social value measures are based not on discrete choice demand models but QALYs from different cost-effectiveness analyses; each approach has its strengths and weaknesses.

Though our analyses were all cross-sectional, in future work we hope to more explicitly incorporate a time dimension (modeling the timing of citations and evaluation of private and social value, and robustness of results to various approaches to discounting the value measures), to look at differential informational value of different types of citations (examiner vs. applicant), examine the extent to which citations respond to shocks in value (FDA approval and other clinical milestones, generic entry, withdrawal), and conduct complementary qualitative studies of specific drugs to better understand the citations-value relationship (or lack thereof).

Our paper also provides new data on the private and social value of pharmaceuticals. The assumption that private and social value may not be aligned motivates a number of policy proposals (e.g. innovation prizes). Our analysis provides support for this assumption: there are many drugs where private value exceeds social value, and vice versa. In future work it would be interesting to examine what factors (patent strength, extent of competition, advertising) affect the share of social returns appropriated. While our results so far are consistent with previous work suggesting that social returns for drugs are on average high, they also suggest there is considerable heterogeneity, with a large number of drugs where social value is less than private. While the assumption that social returns are on average high motivates classic and contemporary discourse on science and technology policy, including patent policy, the significant heterogeneity across drugs in the private-social welfare gap has been neglected by policymakers and academics alike.

The paper also illustrates the difficulties involved in moving from cost-effectiveness measures to social welfare measures, and assumptions necessary to make along the way, which any reward system based on social welfare (including prize based mechanisms) would have to confront. We had the benefit of a database of published cost-effectiveness analyses on a select set of drugs. But any institutionalized reward system based on QALYs or similar measures would also need to be accompanied by a significant technology assessment infrastructure to work well, which could be the most costly aspect of such a system (Hollis and Pogge 2008).

This points to the main limitation of our analysis, the selected nature of our sample. We examined drugs on which cost-effectiveness analyses of sufficient quality to merit inclusion in the Tufts database were performed. While there is not much we can do about the lack of high quality CEAs, in future work we also plan to assess the extent of selection and its implications for our findings.

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Appendix

Social vs. private value using \$150,000/QALY threshold:

