

Pharmaceutical Patenting in the U.S.A.: Evaluating the Impact of Global Competition

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Abstract

The global pharmaceutical industry is a trillion dollar industry dominated by manufacturers in high income economies. However, in recent years a growing volume of pharmaceutical products have been produced in low and middle income economies. We analyse the impact that this change in production has had on the patenting output of pharmaceutical firms in the U.S.A. Traditional quality ladder models conclude that North firms would increase their innovation as competition increases from firms in both the South and in other North countries. We find that patenting by U.S. pharmaceutical firms does indeed increase as competition from low and middle income countries intensifies, but that it decreases as competition from other high income economies intensifies.

Keywords: Pharmaceuticals, Innovation, Patents

1. Introduction

Theoretical research on the connection between innovation and international trade, such as Krugman (1979), model a product cycle where North countries export new products which, after a time lag, are imitated by competitors in the South. These Southern firms then export the “old” products to the North, forcing manufacturers in the North to continually innovate.

The pharmaceutical industry appears to fit this life cycle description. The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) estimates that the production value of the global pharmaceutical industry grew from approximately \$650 billion in 2006 to \$1 trillion in 2014, with direct employment in that time period growing from 3.6 million workers to over 5 million workers (IFPMA, 2016). The health research company IQVIA estimates that global spending on medicine will reach nearly \$1.5 trillion by 2021 (QuintilesIMS, 2016).

Production in this market is dominated by companies in high income countries. Out of the largest 50 pharmaceutical companies in the world, 47 are from high income economies, with the remaining three from India – Sun Pharmaceutical Industries and Lupin – and South Africa – Aspen Pharmacare (PharmExec, 2017). This imbalance in production is slowly changing, however.

The largest market for pharmaceuticals is the U.S.A., which accounts for approximately 40% of global spending and 17% of the industry's global employment (IFPMA, 2017). Pharmaceutical Research and Manufacturers of America estimates that R&D spending by U.S. pharmaceutical firms was over \$50 billion annually in 2014, compared with only \$2 billion in 1980. (PhRMA, 2015).

As spending on pharmaceutical products in the U.S.A. has grown, the source of those goods has also changed, albeit slowly. Data from the U.S. International Trade Commission indicates that 3.5% of imported pharmaceutical goods in the U.S.A. in 1997 came from low and middle income economies. By 2016, that figure had grown to 10%. In nominal dollar terms, this represented an increase in value of 2211%. In comparison, the dollar value of imports from high income countries increased by 648% over the same period.

In this paper we look at the impact that competition in the pharmaceutical industry has on innovation. Specifically, how do U.S. pharmaceutical companies respond to changes in production from competitors in other high income countries, and to changes in production from competitors in low and middle income economies? North-South models of innovation and product cycles distinguish between competition from innovators in the North and imitators in the South. We use the U.S. pharmaceutical industry to test the conclusions of those models.

2. Previous Research

With seminal works by Vernon (1966) and Krugman (1979), the North-South theory of product life cycles describes how firms in high income countries, with a wealth of human capital, financial capital, and entrepreneurship, compete to develop new capital or technology intensive products. Initially, these products are only produced and consumed in high income economies. Afterwards, the product is produced in the high income North and exported to the low income South. After an additional period of time, firms in low income countries begin to imitate these products, taking advantage of their relatively low labor costs, and eventually they begin to export them to the high income North economies.

Later, Romer (1990), Grossman and Helpman (1991a, 1991b, 1991c), Aghion and Howitt (1992), and others, sought to endogenize innovation and imitation rates, viewing innovation as taking place along a quality ladder. In these approaches, innovators move up a rung on the ladder spurred by the incentive of the short term monopoly power attained by them through legal means (such as patent protection) or due to the time lag that it takes competitors to copy their innovations.

In Grossman and Helpman (1991b) the product cycle begins with firms in the North innovating and earning profits from these innovations. However, after some time, firms in the South imitate the innovation, reducing the Northern firms' profits, and forcing them to invest in and come out with further innovations. The Northern firms also face competition from other innovators in the North, serving as an additional incentive to innovate; these rival Northern firms are innovators themselves, not imitators. In this model, therefore, Southern firms face only the risk that Northern firms will innovate, thereby reducing the Southern firms' profitability. Northern firms, however, face two risks – one of innovation by rival Northern firms and one of imitation by Southern firms.

More recently, researchers have investigated how relaxing some of the simplifying assumptions in the product cycle models affects the conclusions, while others have tested the results empirically. Foellmi, Hanslin Grossmann, and Kohler (2018), for example, modify Grossman and Helpman's (1991c) approach by introducing non-homothetic consumer preferences rather than constant-elasticity-of-substitution preferences, to model income distribution differences; while Chen, Lu, and Zhu (2017) use data on China to look at how product sourcing by multinational enterprises varies along the product cycle.

The approach presented here builds on the existing literature by using patent data to measure innovation in the North, and trade data to measure the magnitude of competition from rivals in the South as well as from those in other Northern economies.

3. Methodology

3.1. Model

While R&D spending measures how much firms put into innovation, patents are frequently used as a way to measure the outcome of innovative efforts. This is based on the work of Jaffe, Trajtenberg, and Henderson (1993), Pavitt and Soete (1997), Jaffe, Fogarty, and Banks (1998), and others.

We model that the number of patents a company acquires depends on its size, how much it spends on research and development (R&D), and the competition it faces. The competition for U.S. firms come from three sources – other U.S. firms, firms in high income economies, and firms in low and middle income economies. Thus, our production function for patents is:

$$\text{PATENTS}_{kt} = f[\ln(\text{REVENUE}_{kt}), \ln(\text{R\&D}_{kt}), \ln(\text{REVENUE}_{\text{US}t} - \text{REVENUE}_{kt}), \ln(\text{IMPORTS}_{\text{G1}t}), \ln(\text{IMPORTS}_{\text{G2}t})]$$

Where

- PATENTS_{kt} is the number of granted pharmaceutical patents that were applied for in the U.S. in year t , where firm k is the assignee.
- REVENUE_{kt} is firm k 's revenue in year t .
- R\&D_{kt} is firm k 's spending on research and development in year t .
- $\text{REVENUE}_{\text{US}t}$ is overall pharmaceutical production in the U.S.A. in year t .
- $\text{IMPORTS}_{\text{G1}t}$ is pharmaceutical imports into the U.S.A. from Group 1 in year t .
- $\text{IMPORTS}_{\text{G2}t}$ is pharmaceutical imports into the U.S.A. from Group 2 in year t .
- Group 1 – high income economies
- Group 2 – low/middle income economies
- Subscript k designates individual U.S. pharmaceutical firms, and t is years. All monetary amounts are in millions of real 2009 U.S. dollars.
- \ln is the natural logarithm

Our prior hypotheses are as follows:

- Positive sign on REVENUE – larger companies tend to patent more aggressively.
- Positive sign on R\&D_k – companies who spend more on R&D will likely end up with more patentable products.
- Positive sign on $\text{REVENUE}_{\text{US}} - \text{REVENUE}_k$ – more domestic competition pushes U.S. companies to innovate more.
- Positive sign on IMPORTSG1 – more competition from firms in other “North” countries pushes companies to innovate more.
- Positive coefficient on IMPORTSG2 – more competition from firms in “South” countries pushes companies to innovate more.

3.2. Data

The time period for our study is 1997-2015. We restrict our choice of U.S. pharmaceutical firms using the following criteria: The firm must (1) be among the world's top 50 largest pharmaceutical producers and (2) have a minimum of 10 consecutive years of sales and R&D spending within the time period of our study.

We apply criterion (1) by using the 2015 ranking of firms by the industrial research company Pharmaceutical Executive (PharmExec, 2015). We use companies' financial reports and the U.S. Securities and Exchange Commission's EDGAR database to retrieve data on their research and development (R&D) spending and overall revenues. After dropping firms that do not satisfy criterion (2), we use data for the following 13 U.S. firms (listed in order of revenue size): Pfizer, Merck & Co.,

Johnson & Johnson, Gilead Sciences, Amgen, Eli Lilly, Bristol-Myers Squibb, Baxter International, Biogen Idec, Mylan, Celgene, Abbott Laboratories, and Alexion Pharmaceuticals.

We obtain data on pharmaceutical imports from the U.S. International Trade Commission's DataWeb database (dataweb.usitc.gov), measuring imports by country of origin for NAICS code 3254 (Pharmaceutical and Medicine Manufacturing). This data only goes back to 1997, which explains the starting year for our study.

We aggregate the import data into two groups. Group 1 comprises countries of origin which are categorized as being high income in the World Bank's 2018 classification (available at <https://datahelpdesk.worldbank.org/knowledgebase/articles/906519>). Group 1 is our proxy for "North" countries. Group 2 comprises countries of origin which are categorized by the World Bank as low, lower-middle, or upper-middle-income economies. Group 2 is our proxy for "South" countries.

We obtain data on domestic U.S. production of NAICS code 3254 from the U.S. Bureau of Economic Analysis' (BEA) online database (available at www.bea.gov), and convert all monetary amounts in our data set into real 2009 dollars using the BEA's U.S. GDP Deflator (available at www.bea.gov).

We use the U.S. Patent and Trademark Office's online patent database (<http://www.uspto.gov>) to count the number of patents granted to U.S. pharmaceutical companies by their year of application. Because the patent application process can take several years, we use 2015 as the ending year for our study.

To account for differences across firms and over time, we use a firm fixed effects model with year dummies. Because PATENTS is a non-negative integer, we use a Poisson regression.

4. Results

Tables 1 and 2 give the regression results and summary statistics. Note that all of the variables listed in Table 1 are measured in natural logarithms. In Table 1, Column (1) presents the results from a standard Poisson regression with both firm-level fixed effects and year fixed effects. Column (2) performs the same regression, but uses lagged values of our control variables as instruments, in order to address potential endogeneity concerns with the estimates in Column (1). As such, Column 2 is our preferred specification.

Table 1: Summary statistics

Variable	Mean	Std.Dev.	Min.	Max.	N.
PATENTS	76.421	84.426	0	377	247
Output	17371.939	17464.688	1.015	68298.846	247
R&D	2537.908	2512.96	11.639	10976.971	247
REVENUE _{US}	190497.569	29509.603	124865.405	234782.569	247
IMPORTS _{G1}	59714.226	21822.885	17453.077	90906.803	247
IMPORTS _{G2}	3580.519	2739.127	633.657	8977.816	247

All monetary amounts are in 2009 \$millions

Table 2: Regression Results

Variable	(1)	(2)
ln(REVENUE)	0.115 (0.0787)	0.168* (0.087)
ln(R&D)	0.574*** (0.153)	0.465** (0.189)
ln(REVENUE _{US} – REVENUE _k)	0.670 (0.709)	1.349 (0.948)
ln(IMPORTS _{G1})	-6.868*** (2.592)	-11.710*** (3.903)

Variable	(1)	(2)
$\ln(\text{IMPORTS}_{G2})$	3.464** (1.507)	6.132*** (2.156)
Firm Fixed Effects	Yes	Yes
Time Fixed Effects	Yes	Yes
Observations	247	234

Cluster Robust standard errors in parentheses (clustered at firm level)

*** $p < 0.01$, ** $p < 0.05$, * $p < 0.1$

The coefficient on REVENUE is positive and weakly significant – suggesting larger firms tend to patent more, when controlling for R&D spending. The coefficient on R&D is positive and significant at the 5% level – increased spending on R&D results in a greater number of patents. The coefficient on $\text{REVENUE}_{US} - \text{REVENUE}_k$ is positive but not significant – greater production from U.S. rivals does not result in a firm patenting more. The coefficient on IMPORTS_{G1} is negative and significant at the 1% level – increased competition in the U.S. market from manufacturers in other high income countries decreases a firm's patenting. The coefficient on IMPORTS_{G2} is positive and significant at the 5% level – increased competition in the U.S. market from manufacturers in low/middle income countries increases a firm's patenting.

6. Summary and Concluding Remarks

The above results provide some support for the traditional North-South innovation models, but are surprising also. The results support North-South models, in that they are consistent with the argument that North firms (in our case, in the U.S.A.) view imports from low and middle income economies as a threat to their profitability and so increase their innovation to stay ahead on the quality ladder.

However, the coefficients representing competition from other North firms – both in the U.S.A. and other high income economies – is perplexing. The quality ladder argument leads us to expect a significant, positive coefficient on both of these variables. The negative and significant sign on the coefficient for imports from other high income economies is particularly confusing.

What could explain this perverse result? One possibility is that competition from other high income economies pushes firms to focus on quality rather than quantity in their patenting. Another possibility, which might coincide with the first, is that firms are not choosing to seek patents on all of their innovations. While our results do not allow us to conclusively identify the cause of these unexpected results, they do suggest possible directions for future analysis.

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