Chapter 2

Patenting in the Pharmaceutical Industry

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Additional information is available at the end of the chapter

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Abstract

The chapter investigates the returns to R&D expenditures on patenting in the pharmaceutical industry, using a panel data of 32 countries. Due to the unique situation in the industry that come from the patent being the new drug and additional clinical trials which must be conducted for safety and efficacy, the pharmaceutical industry is analyzed alone. The results indicated that for pharmaceutical patent applications with the United States Patent and Trademark Office (USPTO), the European Patent Office (EPO) and the triadic family consisting of USPTO, EPO and the Japan Patent Office (JPO), pharmaceutical R&D expenditures had no impact coming from European countries. However, for the six non-European countries in the dataset (Australia, South Korea, Mexico, Romania, Singapore and Taiwan), the R&D always had statistically significant effects on all three patent applications in the industry. The results were more pronounced when the United States and Japan were also included. While China, Brazil and India were excluded due to missing pharmaceutical R&D data, it is hypothesized that the effect of these countries would have made the results stronger.

Keywords: pharmaceutical patents, pharmaceutical R&D, innovation

1. Introduction

Innovation has played a crucial role in channeling the economic growth of countries. Economists have long established a positive link between research and development (R&D) expenditures and innovation, as measured by patenting activity [1]. This has been done at the micro level, across firms [2] and at the macro level, across developed and developing countries with different levels of patent protection and legal systems [3–6] and domestic and foreign flows due to foreign direct investment and the presence of foreign affiliates [7–10]. One of the shortcomings of macro studies is that all industries were lumped together despite the heterogeneous nature of patenting and R&D expenditures across industries. With industry-specific

data available across countries over time, it is possible to study just one industry—namely the pharmaceutical industry which has been considered to be the most successful in attracting private R&D for innovation [11, 12].

A patent gives "exclusive right for a product or process that provides a new way of doing something, or that offers a new technical solution to a problem" [13]. However, patenting in the pharmaceutical industry is quite unlike other industries because the patent is the product itself (a new drug) which is the result of costly R&D and extensive clinical testing [14].[1] For such expensive endeavors, it is not surprising that this is a market that continues to serve primarily Organization for Economic Co-Operation and Development (OECD) countries, in particular, the United States. In 2015, 48.7% of the world pharmaceutical sales occurred in the US market, whereas 22.2% and 8.1% occurred in European and Japanese markets, respectively [16].

Tables 1 and **2** shows time-averaged pharmaceutical patent applications from OECD and non-OECD countries, using OECD's Patent Database. The columns represent the filing office (United States Patent and Trademark Office (USPTO), European Patent Office (EPO) and the triadic families, which include one or more shared applications with Japan Patent Office (JPO), USPTO and EPO. The numbers highlight the vast differences across OECD and non-OECD countries. For almost every country, USPTO filings outnumber the other two filing types. The United States is the unambiguous leader in pharmaceutical patenting, followed by Japan and Germany.

Despite the smaller numbers for non-OECD countries, **Figure 1a–c** show the relative importance of pharmaceutical patents over time. Each data point represents the average ratio of pharmaceutical patents to total patents in each year across OECD countries and non-OECD countries. They range from 5 to 25%, for USPTO, EPO and triadic families. While the ratio is always higher for OECD countries for triadic family patent applications, the ratios for both EPO and USPTO applications are higher for non-OECD countries from the mid-2000s, indicating the growing relative importance of pharmaceutical patents of non-OECD countries.

For ensuring efficacy of the drugs and safety of consumers, government regulations make expensive clinical trials necessary in this industry as the drugs cannot be marketed without approval. In the United States, the Food and Drug Administration (FDA) enforces these regulations. Clinical trials effectively shorten the lives of the patents by several years. To demonstrate efficacy, the clinical trial durations must match the expected survival duration of patients [22]. Patents, on average, delay competition from the entry of generic drugs for approximately 10–14 years in the United States [11]. However, the drug can easily be replicated after patent expiration when generic drugs can be manufactured cheaply without additional investments in R&D or costs associated with clinical trials [11, 14]. This floods the market with competitors. For this reason, proponents of pharmaceutical patents argue that exclusivity through patent protection is crucial to recovering the enormous costs and making profits from the invention of new drugs.

[1]In fact, it was estimated that the out-of-pocket cost per drug was $1395 million, and the capitalized R&D cost per drug was $2558 million in 2013 dollars [15].

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Country	Triadic patents (1999–2012)	EPO patents (1999–2012)	USPTO patents (1999–2011)
Australia	76.91	126.80	192.17
Austria	43.60	78.03	83.03
Belgium	70.83	125.16	152.43
Canada	136.72	252.83	491.59
Chile	2.01	4.74	6.91
Czech Republic	5.47	13.18	12.28
Denmark	91.36	149.50	197.55
Estonia	0.93	1.75	2.42
Finland	21.63	33.19	43.94
France	339.76	500.52	568.82
Germany	605.73	970.46	1,029.34
Greece	2.46	9.79	9.70
Hungary	16.83	26.62	30.21
Iceland	1.92	3.72	5.82
Ireland	12.79	24.48	35.99
Israel	78.51	159.62	289.96
Italy	152.38	277.99	299.40
Japan	621.13	834.87	1,122.74
South Korea	114.59	126.58	242.93
Latvia	2.52	4.80	3.90
Luxembourg	0.72	1.56	2.23
Mexico	3.91	11.28	14.86
Netherlands	79.93	170.33	180.64
New Zealand	13.77	24.09	38.17
Norway	22.06	34.77	44.12
Poland	4.62	12.94	11.21
Portugal	5.71	9.98	10.06
Slovak Republic	1.21	2.34	2.66
Slovenia	4.80	26.63	13.09
Spain	73.59	149.65	134.34
Sweden	104.21	146.58	201.76
Switzerland	171.32	257.35	284.90
Turkey	1.55	22.84	6.55
United Kingdom	409.74	577.86	749.34
United States	2,581.06	3,925.56	9,435.44
OECD total	5,876.29	9098.39	15,950.48
World total	6,119.63	9,570.56	16,740.65

Table 1. Average pharmaceutical patent applications in OECD countries by filing office.

Country	Triadic patents (1999–2012)	EPO patents (1999–2012)	USPTO patents (1999–2011)[2]
Algeria	0.04	0.20	0.14
Andorra	0.01	0.08	0.01
Argentina	2.89	8.55	15.57
Armenia	0.02	0.21	0.33
Belarus	0.11	0.38	0.40
Bermuda	0.12	0.11	0.34
Bosnia & Herzegovina	0.02	0.18	0.13
Brazil	7.75	18.73	26.81
Bulgaria	0.22	1.54	1.10
Cayman Islands	0.04	0.11	0.23
China	84.53	122.24	180.99
Colombia	0.68	1.06	2.67
Costa Rica	0.02	0.35	0.21
Croatia	5.31	8.56	9.79
Cuba	5.72	8.41	9.73
Cyprus	0.37	1.01	0.90
Djibouti	0.00	0.00	0.04
Ecuador	0.02	0.53	0.48
Egypt	0.35	1.17	2.47
El Salvador	0.00	0.00	0.08
Georgia	0.44	0.72	0.86
Guatemala	0.05	0.00	0.03
Hong Kong (China)	2.84	11.33	19.03
India	70.55	160.64	241.89
Indonesia	0.43	0.82	0.90
Iran	0.27	0.57	2.12
Jamaica	0.02	0.02	0.69
Jordan	0.51	3.11	1.85
Kazakhstan	0.18	0.37	0.21
Kenya	0.12	0.45	1.14
Democratic People's Republic of Korea	0.02	0.10	0.07
Kuwait	0.02	0.08	1.33
Lebanon	0.16	0.34	0.72
Liechtenstein	2.83	4.27	3.13
Lithuania	0.14	0.75	0.67

Country	Triadic patents (1999–2012)	EPO patents (1999–2012)	USPTO patents (1999–2011)[2]
Former Yugoslav Republic of Macedonia	0.00	0.09	0.00
Malaysia	2.22	4.41	7.81
Malta	0.05	0.05	0.19
Moldova	0.00	0.11	0.26
Monaco	0.40	0.52	0.74
Mongolia	0.00	0.01	0.03
Morocco	0.41	0.96	0.65
Nigeria	0.00	0.00	0.32
Pakistan	0.01	0.09	1.12
Panama	0.08	0.14	0.20
Peru	0.09	0.29	0.64
Philippines	0.24	0.56	1.17
Puerto Rico	0.00	0.60	0.00
Romania	0.40	1.31	1.44
Russia	13.16	34.29	38.34
Saudi Arabia	0.21	2.66	2.56
Seychelles	0.04	0.18	0.23
Singapore	12.09	20.15	35.05
South Africa	4.06	8.68	13.42
Sri Lanka	0.04	0.16	0.50
Taiwan	20.52	33.25	147.05
Thailand	0.82	1.89	3.79
Trinidad & Tobago	0.07	0.07	0.15
Tunisia	0.40	0.85	1.14
Ukraine	0.59	1.85	2.43
United Arab Emirates	0.26	0.61	1.07
Uruguay	0.27	0.86	1.15
Uzbekistan	0.00	0.02	0.05
Venezuela	0.13	0.41	1.55
Zimbabwe	0.00	0.01	0.08
Non-OECD total	**243.35**	**472.08**	**790.16**
World total	**6,119.63**	**9,570.56**	**16,740.65**

Table 2. Average pharmaceutical patent applications in non-OECD countries by filing office.

[2]There was one less year of available data for patent applications to USPTO.

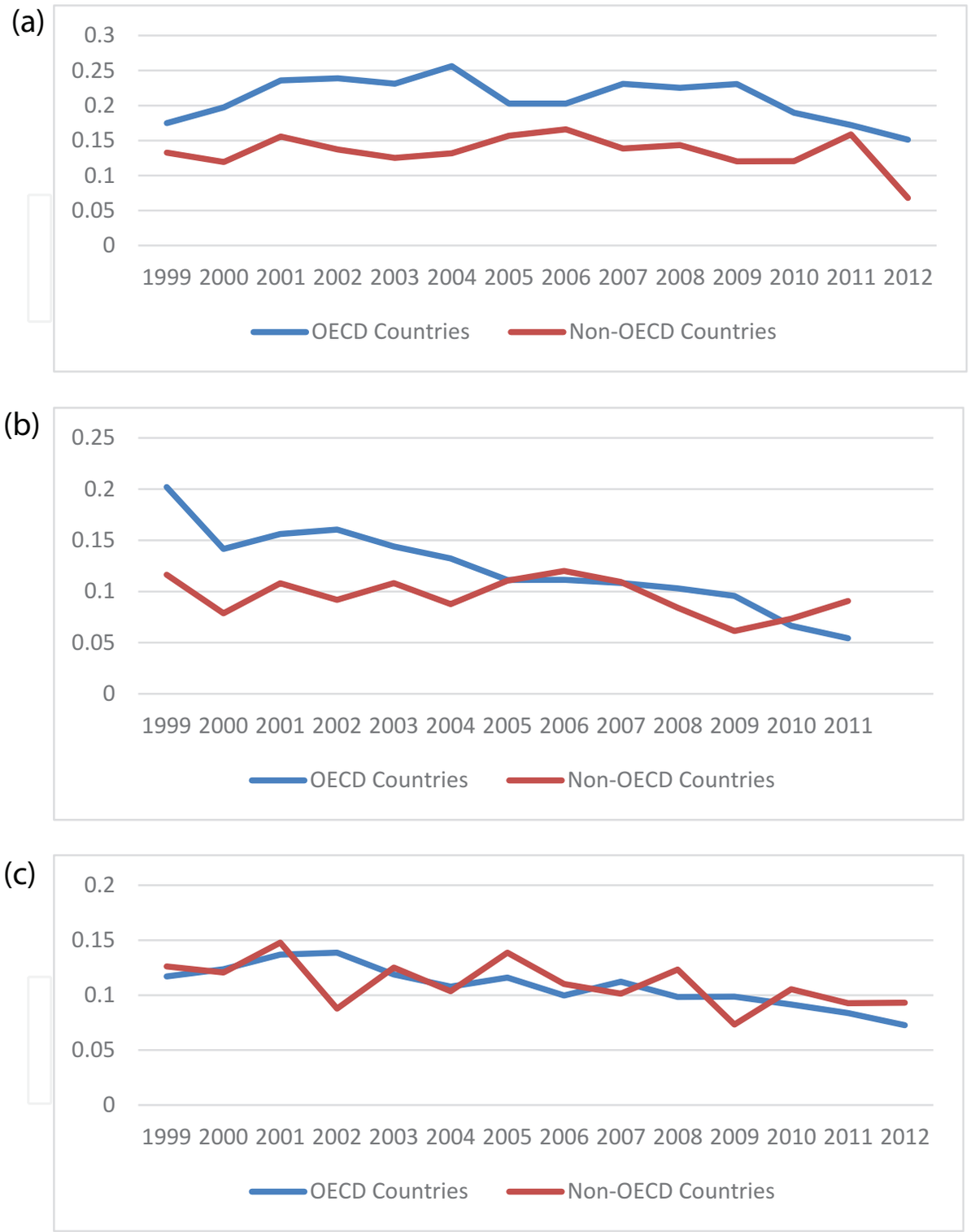

Figure 1. (a) Pharmaceutical patents/total patents to triadic families (USPTO, EPO and JPO). (b) Pharmaceutical patents/total patents to USPTO. (c) Pharmaceutical patents/total patents to EPO.

In this book chapter, I investigate the relationship between R&D expenditures and patents in the pharmaceutical industry alone using panel data estimations. The differences between patent applications to the EPO, USPTO and triadic families (EPO, USPTO and JPO) are compared for groups of countries. This research makes a contribution to the literature that explores R&D

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expenditures with patenting at the macrolevel but separating out the pharmaceutical industry which is quite different from other industries. The chapter continues as follows. After a cross-disciplinary literature review in various areas, I provide the economic model to be estimated. The chapter concludes after a discussion of the empirical results and conclusions.

2. Literature review

Below, a review of the literature is provided in three key areas: (1) the international patenting system; (2) how pharmaceutical patenting and R&D differ from those of other industries; and (3) results from previous studies on innovation relating R&D to patents.

2.1. International patenting system

The Paris Convention of 1883 established the International Union for the Protection of Industrial Property in 1884. This was an important development in international patenting that ensured equal treatment of inventors, regardless of Convention country of origin [10, 12]. Furthermore, the Convention "priority date" entitles the patent applicant the right to claim the filing date of the first application as an effective filing date for corresponding applicants in other Convention countries within a given time frame, which for patents is a year.

The establishment of the European Patent Convention (EPC)[3] in 1977 allowed a single patent application to be filed for European countries, at the newly created European Patent Office (EPO). The approved applications were validated by other member countries which meant that this was essentially a system of filing a "bundle" of national patents. The Patent Cooperation Treaty (PCT) was soon established in 1985. This treaty allowed nationals or residents of 145 contracting signatory countries to file a single international application at their local patent office [10]. A standardized application (one language and one fee) and a single search by an International Search Authority (ISA) reduced costs for filing. In fact, 87% of PCT applications go to one of the patent offices in the United States (USPTO), Europe (EPO) or Japan (JPO) [12].

2.2. Pharmaceutical R&D expenditures and patents

As mentioned earlier, the pharmaceutical industry has been and still is an industry that largely serves developed countries. The disproportionate location of R&D activity has been noted in the literature. In 2002, an overwhelming 82% of the world's R&D expenditures by global pharmaceutical companies occurred in the United States alone due the lack of price controls that enabled them to exploit market power [14] which was more difficult to do elsewhere, including Europe. By 2010, this figure was down to 57% [18] due to growing cross-country

[3]As of June 2012, there are 38 contracting states to the EPC, also known as the members of the EPO. They are Albania, Austria, Belgium, Bulgaria, Croatia, Cyprus Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Macedonia, Monaco, Netherlands, Norway, Poland, Portugal, Romania, San Marino, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom).Bosnia and Herzegovina, and Montenegro are extension states to the EPC.

subsidiary-headquarter relationships of these global companies that impacted the innovation and manufacturing locations. The U.S. dominance in R&D investments lasted for about a decade from 1995 until 2005 [16]. In recent years, in light of fiscal austerity, European countries have faced increasing competition from emerging economies, such as Brazil, China and India [14, 16], who have proven to be important and a growing non-OECD research base for the pharmaceutical industry.

R&D expenditures, in general, only represent tiny fractions of the Gross Domestic Product for most countries. While the average R&D expenditures-to-Gross Domestic Product ratio of OECD countries reported in the World Bank's World Development Indicators (WDI) in 2013 is seemingly low at 2.4%, its "R&D intensity" as measured by R&D expenditures over total sales is the highest across 41 industries at 14.4% [16].

Pharmaceutical patents differ from other technology-based industrial patents as the formula is disclosed publicly in exchange for patent protection (Lehman, 2003). In other words, a new drug cannot be kept a secret until right before marketing of the product. Furthermore, because the patent equals the new product, which is relatively cheap to manufacture, patent protection becomes the only way to receive exclusivity on the market to reap the returns from R&D. In the United States, to obtain approval by the FDA for a new drug, the pharmaceutical company has to file a New Drug Application (NDA) to demonstrate safety and efficacy data from clinical trials [17]. On the other hand, to obtain approval for a generic drug, an Abbreviated New Drug Application (ANDA) is filed, which does not require clinical testing. Instead, the data from the NDA can be used. This additional layer of regulation makes it almost unlikely that a new drug can be developed without patents. No other industry operates in quite the same manner.

Furthermore, it has been argued that not all drugs being developed reach the patent phase as pharmaceutical companies periodically discard ones that are considered to be unpatentable [11]. Legally speaking, the "novelty and non-obvious" requirements of patenting challenge especially inventions in the pharmaceutical industry because patents are not granted if the ideas for the inventions are not new.

2.3. Previous research on the relationship between patents and R&D

Economists have studied whether or not patents are successful in encouraging innovation in both theoretical and empirical research [12]. Among the empirical studies, both micro and macro approaches were taken. At the micro level, the relationship between R&D expenditures and patents was investigated for a cross section of firms. It t was found that the two were almost proportional across firm above a threshold size [2].

At the macro level, strong intellectual property rights positively impacted economic growth through R&D and physical capital accumulation [5] and R&D intensity [6] for a cross section of countries over time. While legal differences were found to be insignificant determinants of patenting to and from the UK [3], strong patent protection positively impacted patenting for a sample of OECD countries [4]. In a later analysis, stronger patent protection was found to attract foreign technology which led to further domestic innovation [7].

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The role of international flows of R&D was recognized in more recent studies. Between 2002 and 2005, North America was the source of fifty percent of R&D Foreign Direct Investment (FDI), with destination R&D affiliates in developing countries such as China and India [9]. Among Japanese multinational firms, there was a high degree of substitutability of domestic and foreign R&D [19]. The sources of R&D expenditures (foreign or domestic) had differential impacts for domestic and foreign patenting [10].

3. Empirical estimation and data

The relationship between patents and R&D with persistence, shown in Eq. (1), was introduced in the literature [20]:

$$P_{ijt} = k\left[R_{ijt} + (1-\delta)\, R^{\beta}_{ijt-1} + \ldots \mu_{ij}\right] + \varepsilon_{ijt} \tag{1}$$

where P_{ijt} denotes patents and R_{ijt} denotes R&D expenditures, both, of j residents in location i at time t. μ_{ij} denotes the time-invariant heterogeneity (fixed-effect or random-effect). It is the country-specific propensity of resident j to patent in location i which takes into account differences in institutions, patent laws, geography and other characteristics which do not change over time. ε_{ijt} is the idiosyncratic error term. R&D depreciates exponentially at the rate of β.

The empirical equation can be derived as a dynamic panel model shown in Eq. (2) as demonstrated elsewhere [10].

$$P_{ijt} = \theta_t \tau_t + \beta \ln R_{ijt} + \gamma P_{ijt-1} + \mu_{ij} + \upsilon_{ijt} \tag{2}$$

The term τ_t denotes the time effects and ν_{ijt} denotes the new idiosyncratic error term. The lagged dependent variable, P_{ijt-1}, on the right side of the equation violates one of the assumptions of the traditional panel model. Equation (2) is best estimated using the Arellano-Bond general method of moments (GMM) model [21]. First differencing of variables will sweep out the heterogeneity, μ_{ij}, and the model uses first-differenced time effects and lagged patents as instruments. The choice of one lag is to simply reduce the number of potential instruments.

Pharmaceutical patent application data to EPO, USPTO and triadic families were collected for 100 countries of inventors' residence for every year (the priority date) from 1997 to 2012 using OECD's Patent Database. The data consisted of most developed countries and about half of non-OECD countries. These seemed to correspond to countries that had positive patents in at least 1 year, as shown in the time-averaged **Tables 1** and **2**. This did not pose potential issues as the pharmaceutical industry primarily deals with OECD countries. Furthermore, the non-OECD countries of growing importance, China, Brazil and India, were included.

However, there were significant problems finding corresponding R&D data especially for the pharmaceutical industry for the same time period. this issue was documented for a previous study on all industries aggregated at the national level [10]. OECD's Patent Database

reported business enterprise R&D expenditure data[4] by industry (ISIC rev.3.1 classification). It was more common to find aggregated R&D (all industries combined or for broader industry groups) than to find data on just the pharmaceutical industry. While these particular pharmaceutical R&D data were potentially available for a longer period spanning 1987–2014, almost every country had missing data in numerous years which were often consecutive. The average years of data for each country were too short to estimate a dynamic panel model with reliable instruments. Hence, I estimated a non-dynamic panel equation without the lagged patent variable, as shown in Eq. (3).

$$P_{ijt} = \theta_t \tau_t + \beta \ln R_{ijt} + \mu_{ij} + \upsilon_{ijt} \quad (3)$$

The assumption of $\gamma = 0$ from Eq. (2) implies that a past patent application does not impact a current patent application. This does not seem to be an unreasonable assumption in the pharmaceutical industry because generic drugs do not require patents. However, the larger problem of R&D data had to do with the fact that non-OECD countries were reduced to 3 countries even though OECD countries were reduced to 29 countries. In addition, these three countries were Singapore, Taiwan and Romania, not China, Brazil and India, which were all dropped due to missing pharmaceutical R&D data. While these would potentially impact the non-OECD country estimates, I proceeded anyway because they would represent the lower bound of the estimates for non-OECD because the three omitted countries would have had larger effects than the three included.

Both patent and R&D data are divided by the population size (in millions) to control for country size and to state them in per capita terms [10]. Total population data from the World Development Indicators (WDI) were collected for all countries in all years, with the exception of Taiwan. Taiwan's population data for all years were compiled from Penn World Tables. I estimated Eq. (3) for EPO patent applications, USPTO patent applications as well as the triad family applications (EPO, USPTO and JPO). Results are presented in the next section.

4. Results

The results of EPO patent applications are presented for various groupings of the countries in **Table 3**. It should be noted that columns (3), (5) and (7) may be potentially larger if the three non-OECD countries of growing importance, China, Brazil and India, were to be included. Fixed-effect models are reported with the Hausman specification tests for rejecting the random-effect models. The results do not show the expected "home advantage" of EPC countries,[5] that the impact of R&D is the highest on EPO patent applications for this group of countries. Rather, the result is a surprising advantage of the non-EPC countries that filed patent applications to EPO. Because a panel regression cannot be run on just

[4]The total reported was supplemented with other government and national funds as well as funds from abroad. The funds from abroad were included to reflect the fact that R&D of foreign affiliates have become important in the multinational firms represented in the pharmaceutical industry.

[5]As mentioned earlier, all EPC and EPO memberships are the same

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	(1) All countries[6]	(2) OECD countries	(3) Non-OECD countries	(4) EPC countries, US and Japan	(5) Non-EPC countries, US and Japan	(6) EPC countries	(7) Non-EPC countries
ln(R&D)	1.34** (0.68)	1.69* (0.93)	0.20 (0.62)	1.44 (9.97)	1.61* (0.85)	1.46 (0.99)	1.93*** (0.75)
Constant	−16.82 (12.01)	−22.48 (16.10)	−0.53 (10.27)	−18.23 (16.74)	−20.13 (13.26)	−17.03 (17.25)	25.15 (12.16)
Number observations	215	184	31	155	60	143	72
Number of countries	32	29	3	26	6	24	8
Average number of years	6.7	6.3	10.3	6.0	10.0	6.0	9.0
Year controls	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Overall R^2	0.45	0.46	0.22	0.45	0.42	0.44	0.38
Hausman specification test (χ^2)	19.47*	13.28	8.58***	54.49***	6.66	103.77***	4.49

Notes: (1) Standard errors in parentheses below coefficients.
(2) Statistical significance at 1% (***), 5% (**) and 10% (*).

Table 3. Regression results for EPO patent applications.

the United States, the differences between columns (4) and (6) and between columns (5) and (7) are used to demonstrate the effect of including/excluding United States and Japan. Since there are only three non-OECD countries in column (3), it is difficult to discern if the non-significance of the slope is simply due to a small cross section of countries represented or not.

The results of USPTO patent applications for the same grouping of countries are presented in **Table 4**. The results in columns (5) and (7) show a "home country advantage," this time, for the United States. Compared to the same columns in the previous table, the returns to R&D for USPTO patent applications are more than double those for EPO applications. Interestingly, the even columns, which present more robust results from having most OECD countries, are the columns that show no effect of R&D on patenting with USPTO.

The results of triadic family patent applications are presented for the same grouping of countries in **Table 5**. As suggested by the smaller number of this type of application for every country in **Tables 1** and **2**, the effects are statistically insignificant, except for columns (5) and (7). The results

[6]Australia, Austria, Belgium, Canada, Czech Republic, Denmark, Estonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Republic of Korea, Mexico, Netherlands, Norway, Poland, Portugal, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom, United States, Romania, Singapore, Taiwan.

	(1) All countries	(2) OECD countries	(3) Non-OECD countries	(4) EPC countries, US and Japan	(5) Non-EPC countries, US and Japan	(6) EPC countries	(7) Non-EPC countries
ln(R&D)	1.92** (0.97)	1.93 (1.26)	0.67 (0.62)	1.08 (1.22)	3.86** (1.97)	1.11 (1.26)	4.11** (1.79)
Constant	−25.49 (16.72)	−26.80 (21.64)	−7.57 (9.21)	−12.05 (21.04)	−57.08 (33.09)	−11.56 (21.62)	−62.89 (30.32)
Number of observations	210	180	30	152	58	141	69
Number of countries	32	29	3	26	6	24	8
Average number of years	6.6	6.2	10.0	5.8	9.7	5.9	8.6
Year controls	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Overall R^2	0.35	0.35	0.53	0.28	0.46	0.28	0.34
Hausman specification test (χ^2)	10.35	7.18	2.04	13.13	2.89	20.52**	7.80

Notes: (1) Standard errors in parentheses below coefficients.
(2) Statistical significance at 1% (***), 5% (**) and 10% (*).

Table 4. Regression results for USPTO patent applications.

	All countries	OECD countries	Non-OECD countries	EPC countries, US and Japan	Non-EPC countries, US and Japan	EPC countries	Non-EPC countries
ln(R&D)	0.44 (0.33)	0.25 (0.44)	0.45 (0.50)	0.01 (0.44)	1.41*** (0.53)	0.07 (0.45)	1.65*** (0.49)
Constant	−4.02 (5.72)	−0.65 (7.85)	−6.36 (8.33)	3.02 (7.68)	−18.73 (8.18)	3.52 (7.84)	−22.67 (7.76)
Number observations	215	184	31	155	60	143	72
Number of countries	32	29	3	26	6	24	8
Average number of years	6.7	6.3	10.3	6.0	10.0	6.0	9.0
Year controls	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Overall R^2	0.31	0.20	0.45	0.03	0.49	0.02	0.46
Hausman specification test (χ^2)	5.72	7.89	6.11**	0.11	0.20	4.10	3.31*

Notes: (1) Standard errors in parentheses below coefficients.
(2) Statistical significance at 1% (***), 5% (**) and 10% (*).

Table 5. Regression results for triadic family patent applications.

are comparable to those in **Table 4** pointing to the importance of countries other than the United States, Japan and European countries.

While not reported, to demonstrate robustness of the results in the pharmaceutical industry, I ran comparable regressions for the aggregate of all industries. The effects of total R&D on total patents followed the same pattern as the results in **Tables 3** to **5** except the effects were almost always larger. This suggests that the returns to pharmaceutical R&D on pharmaceutical patents are not as lucrative as the returns to R&D in all other industries. This may stem from having additional hurdles in the form of clinical trials or from having companies drop potentially unpatentable drugs during the development phase.

5. Conclusions

This chapter investigated the returns to R&D for patenting applications to EPO, USPTO and the triadic family (EPO, USPTO and JPO) in the pharmaceutical industry. The lack of industry-specific R&D data hampered the results of this study in the form of having inadequate number of non-OECD countries. However, it is noteworthy that pharmaceutical R&D has no impact on USPTO, EPO and triadic family applications, coming from European (EPC) countries. The 6 non-European countries (Australia, South Korea, Mexico, Romania, Singapore and Taiwan) always showed positive and statistically significant results. This was unexpected because the three countries of growing importance (China, Brazil and India) were dropped from the analyses due to missing pharmaceutical R&D data. It is hypothesized that the inclusion of these three countries would have made the impact even stronger. The addition of the United States and Japan always made these coefficients larger. With better data availability in the future, this will be important for studying how much non-OECD countries are impacting the pharmaceutical industry. Other implications are that perhaps, the returns to R&D on patenting in pharmaceuticals will have much stronger effects on specific drugs for chronic diseases such as cancer and heart disease which will likely generate larger revenues. Future research may rely on micro firm-level data.

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References

[1] Griliches Z. Patent Statistics as Economic Indicators: A Survey. Journal of Economic Literature. 1990;**28**:1661-1707.

[2] Pakes A. and Griliches Z. Patent and R&D at the Firm Level: A First Look. Economic Letters. 1980;**5**:377-381.

[3] Bosworth D.J. Foreign Patent Flows to and from the United Kingdom. Research Policy. 1984;**13**:115-124.

[4] Eaton J. and Kortum S. Trade in Ideas: Productivity and Patenting in OECD. Journal of International Economics. 1996;**40**:251-278.

[5] Park W. and Ginarte T. Intellectual Property and Economic Growth. Contemporary Economic Policy. 1997;**15**:51-61.

[6] Kanwar S. and Everson R. Does Intellectual Property Protection Spur Technological. Oxford Economic Papers. 2003;**55**:235-264.

[7] Park W. Measuring Global Patent Protection in Fraser Forum. In: Vancouver, B.C.: Fraser Institute;1999.

[8] Chan M., Marinova D. and Lazerow A. Trends in Foreign Patents Registered in the USA. Applied Economics. 2004;**36**:585-592.

[9] Huggins R., Demirbag M. and IankovaRatcheva V. Global Knowledge and R&D Foreign Direct Investment Flows: Recent Patterns in Asia Pacific, Europe, and North Africa. International Review of Applied Economics. 2007;**21**:437-451.

[10] Kumazawa R. and Gomis-Porqueras P. Patents Flows and R&D Flows around the World. Applied Economics. 2012;**44**:4755-4763.

[11] Roin B. Unpatentable Drugs and The Standards of Patentability. Texas Law Review. 2009;**87**:503-570.

[12] Hall B.H. and Harhoff D. Recent Research on the Economics of Patents. Annual Review of Economics. 2012;**4**:541-565.

[13] World Intellectual Property Organization. What is Intellectual Property? In: WIPO Pub. No. 450; 2003.

[14] Lehman B. The Pharmaceutical Industry and the Patent System. In: International Intellectual Property Institute;2003. https://users.wfu.edu/mcfallta/DIR0/pharma_patents.pdf.

[15] DiMasi J.A., Grabowski H.G. and Hansen R.W. Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs. Journal of Health Economics. 2016;**47**:20-33.

[16] The European Federation of Pharmaceutical Industries and Association (EFPIA). The Pharmaceutical Industry in Figures—Key Data 2016 [Internet]. 2016. Available from: http://www.efpia.eu/uploads/Modules/Documents/the-pharmaceutical-industry-in-figures-2016.pdf.

[17] Clancy M., Geradin D. and Lazerow A. Reverse-Payment Patent Settlements in the Pharmaceutical Industry: An Analysis of Antitrust Law and EU Competition Law. The Antitrust Bulletin. 2014;**59**:153-172.

[18] Lyman S. Which Countries Excel in Creating New Drugs? It's Complicated [Internet]. September 2, 2014. Available from: www.xconomy.com.

[19] Belderbos R. and Sala-i-Martin. Foreign and Domestic R&D Investments. Economics of Innovation and New Technology. 2009;**18**:369-380.

[20] Blundell R.,Griffith R. and Windmeijer F. Individual Effects and Dynamic Count Data Models. In: Working Paper Series No. W99/3; The Institute for Fiscal Studies. London: The Fiscal Institute for Fiscal Studies; 1999.

[21] Arellano M. and Bond S. Some Tests of Specification for Panel Data; Monte Carlo Evidence and an Application to Employment Equations. The Review of Economics Studies. 1991;**58**:277-297.

[22] The Economist. Patents that Kill [Internet]. August 8, 2014. Available from: http://www.economist.com/blogs/freeexchange/2014/08/innovation.

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