The Effects of Pharmaceutical Price Regulation on Probability of Patenting in OECD Countries

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Abstract

The introduction of parallel trade mechanisms allowing for the free trade of pharmaceutical goods in the European Economic Area represents a significant departure from the standard monopolistic competition pricing structure in the pharmaceutical market, in which firms have a great deal of control over pricing. Another mechanism, external reference pricing, also contributes to undermining traditional price structures by imposing a price ceiling on drugs. As these methods of regulating pricing in the healthcare market are receiving growing interest in countries such as the United States, which is considering allowing pharmaceutical imports from Canada, it is prudent to consider their effects. It is apparent that parallel trade and external reference pricing decrease average drug costs, but little has been said about their effects on drug availability. Using global patent data from the European Patent Office PATSTAT database as a proxy for drug availability, I investigate how parallel trade and external reference pricing affect the decision of firms to file a pharmaceutical patent in a given country. I accomplish this through a logistic regression model with a difference-in-differences approach to estimate the probability of patenting a pharmaceutical in an OECD country, given that a patent has previously been approved in the United States. I find that the presence of parallel trade in a country significantly decreases the probability of patenting and increases patent lag time while external reference pricing unexpectedly increases the probability of patenting and decreases patent lag time. These findings demonstrate the complexity in attempting to create policy to regulate rising pharmaceutical prices, as doing so may increase affordability of existing drugs in a country while decreasing availability of new ones.

Introduction

The process of gaining approval for the sale of a pharmaceutical in a new country generally involves three main factors: the manufacturer's desire to sell in a given country, safety and efficacy approval, and price negotiations with the country's government. After launching in an initial developed country, the safety and efficacy of the drug is generally not an obstacle to launch in additional countries, leaving the other two factors to affect when and where a drug is launched. Beginning in the 1990s the European Union (EU) has also allowed for additional price regulation mechanisms beyond direct government negotiation, further complicating the launch decision faced by pharmaceutical manufacturers. The two most significant of these mechanisms are parallel trade and external reference pricing.

Parallel trade, also referred to as "gray market" trade, refers to the legal exchange of goods across countries without the permission of the manufacturer. This undermines the monopolistic competition structure typical in pharmaceutical pricing by presenting an opportunity for arbitrage (Dranove, 2020). This leads to a degree of convergence of prices between countries engaging in parallel trade; however, this does not result in complete parity in pricing, primarily due to the need for parallel traders to spend time gaining regulatory approval (Kyle, 2011). Additionally, there exists some distrust amongst both pharmacy stockists and consumers of parallel traded goods, creating a slight price premium for more "trustworthy" drugs that come directly from the manufacturer.

External reference pricing undermines drug pricing structures during initial negotiations with a country's pharmaceutical regulatory agency. Countries that use this strategy set a maximum price that may be charged by a manufacturer for a pharmaceutical by looking at the selling prices negotiated for

that drug in similar countries where it has already launched. If a manufacturer chooses to launch in a country with a lower average wealth level (which likely would have negotiated a lower unit price) before finalizing negotiations with a richer country, the low price charged in the poorer country may factor into the rich country's calculations of the drug's maximum allowed price. When countries employ external reference pricing, agreeing to sell at a lower price in one country is essentially lowering the price ceiling imposed on the manufacturer in all other countries that externally reference using that country, further limiting the firm's ability to profit off of a new drug launch.

Though external reference pricing is popular in many countries in Europe and globally, this strategy has been implemented at different times with little to no coordination across countries. In contrast, parallel trade in the EU is regulated by European law. Parallel trade was first introduced in the EU with the principle of exhaustion clause of the Trademark Directive in the First Council Directive of 1988. The principle of exhaustion states that once a firm sells a good in an EU country, the firm's right to choose whether to allow the good to be sold in other EU countries is exhausted; essentially, once a firm makes a "first sale" in any EU country, it loses the right to regulate the movement of that good throughout the EU. The principle of exhaustion went into effect in December 1991, officially allowing for parallel trade throughout the EU. Countries that join the EU at a later date face a negotiated derogation period in which international pharmaceutical trade is prohibited; they are then required to allow pharmaceutical free trade at the end of this period. Most countries outside of the EU, notably the US and Canada, currently prohibit all parallel trade of pharmaceuticals.

Because parallel trade in the EU allows for free movement of pharmaceuticals across national borders once a drug is first sold in any EU country, the EU has implemented strategies to centralize safety and efficacy approval, ensuring that all medications present in a country can legally be sold there. Two such strategies, the Mutual Recognition Procedure (MRP) and the usage of the European

Medicines Agency (EMA), were both implemented in 1995. The MRP states that once a drug is authorized by one EU country, it is automatically approved in all other EU countries unless a country specifically objects to the automatic approval of that drug. The creation of the EMA furthered consolidation efforts even more, as the organization exists as a centralized regulatory agency to which a pharmaceutical company can submit a single application and gain approval to sell their drug throughout the EU. Both of these processes consolidate and speed up the process of regulatory approval, helping to ensure that the medications are legally able to be sold throughout the EU. However, individual governments continue to negotiate prices independently.

Because parallel trade and external reference pricing interfere with these pricing talks and further undermine the ability of the pharmaceutical firm to control its prices, these mechanisms likely affect firms' decisions about when and where to launch a new drug. Previous studies (Danzon et al., 2004) have examined these relationships by looking at pharmaceutical sales volume data. However, these studies largely focus on the extent to which these mechanisms are present in a country, which in the case of parallel trade is highly reliant on the choices of individuals within the country. This paper attempts to expand upon this research by examining the effects of the legalization of parallel trade and external referencing, as manufacturers and policymakers alike cannot know the extent of uptake of a new policy until after it goes into effect. Thus, in this paper I consider whether the difference in pharmaceutical trade and pricing policies influences the decisions of pharmaceutical manufactures on where and when to launch, and whether this difference is reflected by a change in patenting decisions across countries, using patenting as a proxy for the decision to launch a pharmaceutical.

The rest of the paper proceeds as follows: Section II reviews the relevant literature, Section III introduces a theoretical framework, Section IV provides the empirical specification, Section V describes the data, Section VI presents results, and Section VII concludes.

Literature Review

Several papers study parallel trade either in the pharmaceutical market or in markets with similar pricing structures. Fisher (2007) demonstrates that in international film distribution, movie studios, which have a monopolistic pricing power similar to that of pharmaceutical firms, often stagger releases across countries in order to utilize second degree price discrimination, in which firms charge different per-unit prices based on the quantity consumed, without interference from piracy. Though pharmaceutical manufacturers often face the additional pricing consideration of government price caps with or without parallel referencing, the monopolistic competition market structure of film studios draws a parallel with that of drug companies, suggesting that drug manufacturers would also respond to the potential for arbitrage by limiting official distribution.

Kyle (2011) supports this similarity between pharmaceutical and film distribution markets, finding that the presence of parallel trade causes drug manufacturers to shift from using third degree price discrimination, in which firms charge different prices to different groups based on known characteristics, such as providing a college student or senior discount, to utilizing second degree price discrimination. They do this primarily by "culling," or removing drugs that are likely targets for parallel export in a country from that country's market. Though the paper does not focus on external referencing, this and other price regulation mechanisms are likely common in parallel export countries, as these price controls create the opportunity for arbitrage. Kyle also notes that manufacturers may also sell differently packaged versions of the same medication across countries, reducing profit opportunities for parallel exporters, as they must change the packaging to match that of the destination country in order to successfully export the product.

Several papers study the combined effects of parallel trade and price regulation in the pharmaceutical market. Focusing specifically on price controls, Panos et al. (2020) find that external referencing leads to lower prices, but also decreases medicine availability in that country and can lead to launch delays or withdrawals of a drug from the market approval process. Danzon et al. (2005) reach similar conclusions when looking at pharmaceutical sales and pricing data in twenty-five countries in the 1990s. They conclude that the presence of parallel trade and external referencing in a market are associated with longer pharmaceutical launch delays into some countries and a failure to launch at all in additional countries. Narrowing in on the EU, they also determine that since there exist EU wide regulatory approval mechanisms (MRP and EMA), the difference in drug availability within the EU must be due to firms choosing not to launch due to interference in their ability to price, as there can be no regulatory barrier to entry into some EU countries but not others. Lanjouw (2005) supports these conclusions, further determining that price controls are correlated with launch delay in low income countries and launch prevention in higher income countries, most likely because choosing to launch in a country that otherwise would support a high price for a drug but instead requires a low price due to government regulations undermines the ability of the firm to charge high prices in wealthy countries with fewer price regulations. She also notes that launch delay in low income countries may not significantly affect the countries' populations if a later launch corresponds to lower prices; even if the drug were to launch in a low income country at the same time as its initial launch, it would likely be too expensive for the vast majority of the population to afford, meaning that access to the medication would essentially be nonexistent anyways.

In this paper I continue the line of thought presented by Lanjouw that parallel trade and external referencing have negative consequences on pharmaceutical availability due to their undermining of the manufacturer's ability to freely price. I seek to determine the extent to which this differential access to

medications exists by comparing probability of patenting and patent launch delay across OECD countries before and after the introduction of parallel trade reforms.

Theoretical Framework

When pharmaceutical companies are faced with price controls such as external reference pricing and parallel trade, these factors decrease the maximum price that a firm can charge for a pharmaceutical product when entering into an additional market. With external reference pricing and parallel imports, launching in one country affects a firm's ability to price the drug in similar countries. A firm has to decide not only if launching a pharmaceutical in a given country will be profitable, but also whether launching into a given country will be profitable when considering the effects of the launch on all other markets into which the firm wants to launch the drug.

Lanjouw (2005) formalizes this idea using a log-logistic hazard model of launches of a new drug in a given country. The model is:

$$S(t) = \left[1 + \left(\frac{t}{\exp\{x\beta\}}\right)^{\frac{1}{\gamma}}\right]^{-1} \quad (1)$$

in which *t* is defined as the number of months after first global launch (defined as launch of the drug in any country) and *S(t*) is the probability of failure to have launched in a country. A negative coefficient in the model corresponds to a lower probability of having failed to launch by month *t*, meaning that negative coefficients represent faster launch of a drug. Using this model along with a country fixed effect, Lanjouw finds that more extensive price controls have a significant positive effect on launch hazard, meaning that the presence of extensive price controls in a country are correlated with longer

launch delays or failure to launch entirely for a new drug. This supports the idea that parallel trade and external reference pricing have negative effects on pharmaceutical availability.

Empirical Specification

Due to a lack of access to per-country, per-drug sales information, I define my dependent variable as the probability that a drug was patented in a country, given that the drug was approved for sale in the United States. Patents require time and resources to file, so a pharmaceutical company likely would not file a patent for a drug in a given country if it never intended to launch the drug in that country. In addition, a patent must be filed in each country in which a company plans to sell a pharmaceutical product, as a patent filed in one country does not preclude manufacturers in other countries from producing and selling the product. This country-level specificity makes patents a better proxy for intention to launch than looking directly at regulatory approval in OECD countries, since pharmaceuticals sold in the EU are often approved in many countries at once through mutual recognition procedures and the EMA. As a consequence of these centralized approval mechanisms, a manufacturer may automatically gain approval for a pharmaceutical in an EU country in which it never intends to sell, meaning that looking at patent approval status for a drug in the EU is not a reliable proxy to determine if the drug is likely available for sale in a given country.

By only considering patents for drugs for which a US patent was first approved, as is in keeping with Danzon et al. (2005), I provide additional certainty that the choice not to file a patent in a given country was motivated by a lack of desire to launch in that country and not by doubts about gaining regulatory approval. Due to the costs, both in terms of money and time, to file a patent, it is likely that a manufacturer who files a patent intends to eventually sell the drug in that country, implying that the

company hopes to gain regulatory approval. In order to gain approval in the US, a pharmaceutical product must pass rigorous safety and efficacy testing, meaning that a drug approved by the US Food and Drug Administration (FDA) would likely gain regulatory approval in any country to which it was submitted. Thus, if a pharmaceutical company felt confident about a drug's ability to pass testing in the US, it should also have felt confident about the drug's ability to gain approval in any country. Thus, a failure to file a patent that was also filed and approved in the US in an additional country is likely due to the manufacturer not wanting to sell the drug in that country.

I estimate drug patent probability using a logistic regression with a difference in differences approach, in which patenting probability (*Prob(PatentExists |PatentUSA*)) is a function of the following variables: the presence of the country as part of the European Economic Area (*EEA*); the presence of parallel trade in a given country and year (*Parallel*); the number of years after the first approved US application for a patent to be approved in additional country (*YearsPostUSPatent)*; the usage of external reference pricing (*Referencing*); total pharmaceutical sales in a given country and year, measured in millions of 2015 US dollars (*Sales*); real GDP measured in millions of 2015 US dollars, which shows total wealth in a country and thus relates to total market size for pharmaceuticals (*GDP*); per-capita GDP measured in 2015 US dollars, which serves as a proxy for individual wealth in a country and thus for the ability of individuals in that country to afford pharmaceuticals (*GDPCapita*); the existence of a patent application for the drug filed through the European Patent Office (*EPO*), which offers a streamlined approach for patent approval in EU member states, decreasing the regulatory work of filing a patent; the existence of a patent application for the drug filed through the World Intellectual Property Organization (*WIPO*), which acts similarly to the EPO in streamlining patent approval processes; a time control *(Year)*; a vector of region controls (*Region*); and a vector of OECD country controls (*Country).* The following models provide a specification of the probability of a patent *j* existing in country *i* in year *t*,

given that approval of the parent by the US Patent and Trade Office (PTO) exists in any period prior to *t*. The model in Equation 2 represents the basic model, which does not include GDP or sales data:

$$Prob(PatentExists_{ijt} \mid PatentUSA) = \beta_1 EEA_{it} + \beta_2 Parallel_{it} + \beta_3 YearsPostUsPatent_{ijt} + \beta_4 ExternalReferencing_{ijt} + \beta_5 EPO_{ijt} + \beta_6 WIPO_{ijt} + \beta_7 Year_t + \beta_8 Region_i + \beta_9 Country_i \quad (2)$$

The model in Equation 3 represents the full model, which controls for per-country and per-person demand for pharmaceuticals using GDP, GDP per capita, and sales data:

$$Prob(PatentExists_{ijt} \mid PatentUSA) = \beta_1 EEA_{it} + \beta_2 Parallel_{it} + \beta_3 YearsPostUsPatent_{ijt} + \beta_4 ExternalReferencing_{ijt} + \beta_5 EPO_{ijt} + \beta_6 WIPO_{ijt} + \beta_7 Year_t + \beta_8 GDP_{it} + \beta_9 GDPCapita_{it} + \beta_{10} Sales_{it} + \beta_{11} Region_i + \beta_{12} Country_i \quad (3)$$

Based on the theoretical framework discussed earlier in the paper, negative and statistically significant values for β_2 and β_4 would be consistent with the idea that trade restrictions decrease drug availability, as a decrease in drug patenting implies a decrease in willingness to launch. Positive coefficients are expected for β_5 and β_6, as this would be consistent with the idea that companies are more likely to file patents when it is easier to do so, regardless of their desire to launch the drug in a country post-patenting. Lastly, a positive coefficient on β_8 would suggest that pharmaceutical companies are more likely to pursue patenting and eventual drug entry in higher income countries, which have populations that have more money available to spend on medications.

Using the same approach, I also consider the probability of patenting a pharmaceutical in a given country in a given year, given that a pharmaceutical was first patented and approved in the US (*Prob(PatentYear |PatentUSA*)), both without (Equation 4) and with (Equation 5) GDP, GDP per capita, and pharmaceutical sales data. An additional interaction term between *Parallel* and *YearsPostUSPatent* is included in the full model to evaluate whether parallel trade is associated with greater launch delays.

$$Prob(PatentYear_{ijt} \mid PatentUSA) = \beta_1 EEA_{it} + \beta_2 Parallel_{it} + \beta_3 YearsPostUsPatent_{ijt} + \beta_4 ExternalReferencing_{ijt} + \beta_5 EPO_{ijt} + \beta_6 WIPO_{ijt} + \beta_7 Year_t + \beta_8 Region_i + \beta_9 Country_i \quad (4)$$

$$Prob(PatentYear_{ijt} \mid PatentUSA) = \beta_1 EEA_{it} + \beta_2 Parallel_{it} + \beta_3 YearsPostUsPatent_{ijt} + \beta_4 ExternalReferencing_{ijt} + \beta_5 YearsPostUSPatent_{ijt} * Parallel_t + \beta_6 EPO_{ijt} + \beta_7 WIPO_{ijt} + \beta_8 Year_t + \beta_9 GDP_{it} + \beta_{10} GDPCapita_{it} + \beta_{11} Sales_{it} + \beta_{12} Region_i + \beta_{12} Country_i \quad (5)$$

Again, I expect β_2 and β_4 to be statistically significant and negative, as this reflects the decrease in pharmaceutical availability predicted by the implementation of parallel trade and external referencing. A significant positive coefficient on β_5 in Equation 5 would be consistent with the idea in Danzon et al. that parallel trade and external referencing lead to longer delays before launching a drug in a new country.

Finally, I move to the direct evaluation of the effects of these mechanisms on launch delay, both without (Equation 6) and with (Equation 7) sales data:

$$YearsPostUSPatent_{ijt} = \beta_1 EEA_{it} + \beta_2 Parallel_{it} + \beta_3 ExternalReferencing_{ijt} + \beta_4 EPO_{ijt} + \beta_5 WIPO_{ijt} + \beta_6 Year_t + \beta_7 Region_i + \beta_8 Country_i \quad (6)$$

$$YearsPostUSPatent_{ijt} = \beta_1 EEA_{it} + \beta_2 Parallel_{it} + \beta_3 ExternalReferencing_{ijt} + \beta_4 EPO_{ijt} + \beta_5 WIPO_{ijt} + \beta_6 Year_t + \beta_7 GDP_{it} + \beta_8 Sales_{it} + \beta_9 Region_i + \beta_{10} Country_i \quad (7)$$

Unlike before, I expect the coefficients on the parallel trade and external reference pricing variables (β_2 and β_3) to be significantly positive, as this w7uld reflect a longer launch delay for patents into countries which use these mechanisms. Negative values for β_4 and β_5 would be consistent with the idea that the EPO and WIPO streamline the patenting process, making it more likely for patents to quickly enter into additional countries.

Data

Patent information comes from the European Patent Office (EPO) PATSTAT database, which contains bibliographic and legal event data for patents filed in over 80 countries. Using the International Patent Classification (IPC) code, I filter for patents which contain the "A61K" code, which contains patents involved in "Preparations For Medical, Dental, Or Toilet Purposes". Within the A61K classification, there are several sub-classifications defining pharmaceuticals by the type of molecule they contain, but as the molecular composition has little correlation with the type of disease a pharmaceutical product treats, I found it unnecessary to filter further by subclass. I consider observations for patents filed after 1960, as this is about 30 years before the implementation of parallel trade in the EEC in December 1991. Since the newest patents filed in the dataset are from 2020, this provides approximately the same number of years of data both before and after parallel trade legalization. The resulting dataset contains 795,396 patents spanning 96 countries. The OECD member country in which each of the approved medications is patented is identified using the DOCDB simple family classification (DOCDB family), which tracks patent numbers for the same invention across countries, enabling me to create my conditional patenting variable[1].

The dataset contains 75,191 patents that were filed in the United States, 45,285 of which were approved. These approved US patents are part of 24,960 unique DOCDB families. I consider only patents that are both from OECD countries and part of a DOCDB family that contains an approved US patent, regardless of when the non-US patent was filed relative to the US patent. 103,429 patents remain. Finally, removing the 45,285 patents that are the US patents themselves leaves me with 58,144 patents that were both filed and approved spanning 38 OECD countries other than the US and that are in the same DOCDB family as an approved US patent.

[1] Despite its name, DOCDB simple family classification tracks identical patents, which are filed separately in each country under a separate patent number. Each DOCDB family contains one unique patent and allows me to track the same patent across countries despite its changing patent numbers.

I then generate the *YearsPostUSPatent* variable by measuring the amount of lag time after US patenting before a patent was approved in each additional country. The variable calculates year 1 beginning immediately after the corresponding US patent is approved, meaning that a patent filed in France a month after it is filed in the US would receive a value of 1 for *YearsPostUSPatent*. This generated 711,270 patent-year combinations. However, the *YearsPostUSPatent* variable is intended to capture lag time before patent entry; thus, it should only include patent-year combinations in OECD countries other than the US after a patent is filed in the US up to and including the year in which the patent is filed in a given country, resulting in 38,739 patent-year combinations. Though patents continued to be accepted in additional countries up to 22 years after the initial US approval, the vast majority of entry occurred in the first five years after US approval, shown in Table 1.

Table 1. Timing of Patent Entry

Year of Entry into Additional Country	**Years After US Application (1 = First Year)**				
	1	2	3	4	5
Does Not Enter	6515	3519	2954	2611	2044
	(16.82)	(54.01)	(83.94)	(88.39)	(78.28)
Enters	32224	2996	565	343	567
	(83.18)	(45.99)	(16.06)	(11.61)	(21.72)
Total	38739	6515	3519	2954	2611
	(100.00)	(100.00)	(100.00)	100.00)	100.00

Though the approach of limiting my data set to patents for drugs approved by the US PTO helps to ensure that the major consideration for choosing to file a patent is a profit motive rather than concerns about gaining approval, this approach potentially skews the types of pharmaceutical patents considered. If a manufacturer develops a drug that works well but is not suited to the health needs of the US, such as a malaria drug, the manufacturer may choose not to attempt to sell in the US, as the drug likely would not garner a profit. However, as most of the countries in the OECD are in Europe, North America, and Oceania, they likely do not often face significantly different health issues that would cause different

classes of drugs to be profitable, minimizing the issue that the America-centric approach of using US PTO approval may cause. One downside of this approach is that the US itself cannot be considered in the analysis, as every US PTO-approved drug must have submitted a patent in the US, meaning that the probability of patenting given US PTO approval in the US is one for every year in the study.

The PATSTAT database also includes data on whether a patent was accepted by the EPO or WIPO, both of which make it easier for an applicant to file in any countries belonging to these organizations. Thus, a patent being accepted by the EPO or WIPO should make it more likely for the patent to be filed in member countries due to manufacturers facing a lower cost of filing. A patent being accepted by the EPO is also a sign of the patent's quality, as it reflects the relatively high standards of the European Union in choosing which patents to accept. However, since every country in the dataset is a member of the WIPO and most patents are filed there as a matter of standard procedure, the same quality indication is not necessarily true for patents filed in the WIPO. These assumptions are verified in Table 2.

Table 2. Likelihood of Patent Approval by EPO and WIPO Filing Status

Granted	Patent Filed in EPO		Patent Filed in WIPO		
	No	Yes	No	Yes	Total
No	430101	65919	52143	443877	496020
	(44.36)	(19.39)	(29.18)	(39.25)	(37.88)
Yes	539490	274029	126567	686952	813519
	(55.64	(80.61)	(70.82)	(60.75)	(62.12)
Total	969591	339948	178710	1130829	1309539
	(100.00)	(100.00)	(100.00)	(100.00)	(100.00)

The table shows that patents filed in the EPO are much more likely to be granted in any country than patents that were not. The table also shows that the opposite is actually true for patents filed in the WIPO, as these patents are less likely to be granted in any country than patents that bypassed the WIPO. This may be due to a fundamental difference in patents filed in the WIPO versus other patents. Since the advantage of the WIPO is that it makes it easier for manufacturers to apply for a patent in individual countries, perhaps these patents are more likely to be filed in many countries while other patents that

were created to be used in only one or two countries may bypass the WIPO entirely. This assumption is verified in Table 3, which shows that only 57.56% of patents in the dataset that were filed in fewer than 10 countries were filed in WIPO, while overall 86.35% of patents were filed in WIPO.

Table 3. WIPO Filing Status by Patent Family Size

	Patent Family Size						
Patent Filed in WIPO	0-9	10-19	20-29	30-39	40-49	50+	Total
No	25305	76461	51702	16149	5901	3192	178710
	(42.44)	(19.72)	(13.27)	(7.05)	(5.13)	(2.49)	(13.65)
Yes	34314	311346	338016	212856	109179	125118	1130829
	(57.56)	(80.28)	(86.73)	(92.95)	(94.87)	(97.51)	(86.35)
Total	59619	387807	389718	229005	115080	128310	1309539
	(100.00)	(100.00)	(100.00)	(100.00)	(100.00)	(100.00)	(100.00)

Pharmaceutical sales data comes from the OECD.Stat database, which contains data for OECD countries from 1980 through 2019. I use the full range of available data, which further limits the dataset to 23,156 patents spanning 28 OECD countries, as fewer countries and fewer years are covered in this data set. This more limited dataset is used for the full regression outlined in Equation 3. Total per-country pharmaceutical sales measured in US dollar exchange rates are provided yearly. This sales data is then adjusted for inflation using US Consumer Price Index (CPI) data provided by the Federal Reserve Bank of St. Louis (FRED). 2015 is the index year of the CPI. Data is missing for some countries for some years, with the data tending to be more consistently available in later years. The country with the fewest number of years available is Canada, which has data available only from 2012 onwards.

I also use the OECD.Stat database to obtain yearly real GDP per capita for all OECD member countries. Again, 2015 is the index year for the variable.

External reference pricing data is taken from the Pharmaceutical Pricing and Reimbursement Information Network (PPRI), which details country-specific pharmaceutical pricing mechanisms

including the usage of external referencing. 19 OECD countries use external reference pricing, 15 of which have pharmaceutical sales data available. Since all countries' external reference pricing status is known, no further observations are excluded from the data set.

Results and Analysis

Selected results for the regressions in Equations 2-7 are shown in the tables below. Full regressions showing the set of country controls can be found in Appendix A.

Table 4 shows the results of the patent exists regression described in Equations 2 and 3. Coefficients are written as odds-ratios, meaning that if a variable has coefficient greater than one then the variable either existing (in the case of an indicator variable) or an increase in the variable (in the case of a numeric variable) corresponds to a greater likelihood of the dependent event occurring. Column 1 provides the basic model without sales or GDP data while column 2 adds real GDP and real GDP per capita. The full models for all three dependent variables (patent exists, patent entry, lag time) with sales data can be found in Table 7, as the limited availability of sales data significantly decreases the number of observations in each regression compared to the regressions without sales data presented in Tables 4-6.

The *Parallel Trade* term represents the difference in the outcome variable for OECD countries that utilize parallel trade before and after the legalization of parallel trade in the EEA minus the difference in the outcome variable for OECD countries that do not utilize parallel trade before and after its legalization. The coefficient being less than one in all both versions of the regression validates my assumption that the implementation of parallel trade in a country generates a decrease in the number of patents filed in that country, controlling for factors in the model such as time and filing in the EPO and WIPO. The difference-in-differences approach also allows the model to control for unknown factors that

may have changed over time as long as those factors affected the countries in the EEA that use parallel trade and the rest of the countries in the data set similarly, which is a logical assumption to make since all countries in the data set are OECD countries.

Table 4. Patent Exists Logit with Odds Ratios (Country Controls not Displayed)

	(1)	(2)
	Patent Exists	**With GDP and GDP per Capita**
EEA Status	29.0887***	18.47912***
	(6.47654)	(4.54053)
Parallel Trade	.37442***	.5893***
	(.03886)	(.06503)
Years After US Patent	1.51001***	1.51576***
	(.00425)	(.00432)
Filed in EPO	.64998***	.75294**
	(.07021)	(.0856)
Filed in WIPO	3.61995***	3.17648***
	(.14953)	(.13408)
External Referencing	14.56489***	68.33667***
	(3.80963)	(18.11674)
Real GDP Per Capita		1.00003***
		(0)
Real GDP		1.00001***
		(0)
Year	.8498***	.79781***
	(.00155)	(.00257)
Region Controls		
NAFTA	149.68378***	718.03552***
	(51.18483)	(260.37911)
Soviet	2.02573	14.42746***
	(.94493)	(6.94884)
Asian	1.72055*	.03713***
	(.5427)	(.01305)
Constant	1.53e+141***	1.13e+194***
	(5.58e+141)	(7.11e+194)
Observations	810285	794010
Pseudo R^2	.49134	.49423

Standard errors are in parentheses
**** p<.01, ** p<.05, * p<.1*

The coefficient on the external referencing variable is greater than one, suggesting that the implementation of external reference pricing actually significantly increases the likelihood of a patent

entering an additional OECD country after entering the US. The coefficient on the indicator variable for a patent being filed in the EPO is also unexpected, as it suggests that filing a patent in the EPO is associated with a decreased likelihood of filing the patent in additional countries. Since the EPO increases ease of filing in European countries, which make up the majority of the dataset, and is correlated with an increased likelihood of patent approval (Table 2), I expected that patents filed first in the EPO would be far more likely to enter into additional countries. Filing a patent in the WIPO, however, has the expected effect of increasing the likelihood of filing in additional countries, likely because the EPO decreases the time and effort required to file.

As the vast majority of countries that utilize external reference pricing in the dataset are also members of the EU, which is also the market that employs the EPO as a way to process patents, it is possible that the unexpected coefficients on external referencing and EPO variables are due to a lack of variation in the data set, impeding the variables from accurately capturing the effects they were designed to capture.

The coefficients on real GDP and real GDP per capita are very small, which was to be expected as 1 million dollars as a proportion of total real GDP and 1 dollar as a proportion of real GDP per capita are very low amounts. Still, the results are likely practically significant as well as statistically significant, as total and per capita GDP can vary greatly across countries and years, greatly amplifying the effects of the coefficients. The coefficients being greater than 1 suggests that an increase in country wealth or in individual wealth is associated with an increase in the likelihood of patenting in that country, which is consistent with the idea that pharmaceutical manufacturers want to sell their goods in countries with a large population that has enough disposable income to be able to afford medications.

Alternatively, the unexpected positive effect of external referencing on patent entry may be due to the extent of this practice throughout all of Europe. Since the European market is so sizable,

manufactures may have concluded that it isn't worth the lack of sales to choose not to enter into Europe or to delay entry entirely. Instead, they may have chosen to circumvent concerns about external referencing by entering into countries where they felt they could set the highest prices first, thus undermining the ability of additional countries to insist on lower prices based on previously agreed upon pricing

Finally, another surprising result was the significant negative impact of the year variable on both the likelihood of a patent existing in an additional country and the likelihood of a patent being filed in a given year. However, much of this result was likely driven by the constraints of the dataset, as earlier years contain fewer patents overall and may be biased toward including approved patents. Alternatively, the expansion in technology and increase in utilization of organizations such as the WIPO to file patents may have increased the ease of filing, causing manufacturers to choose to file more often in countries where they face lower odds of approval.

Turning toward my second set of regressions, those for the patent entry logit described in Equations 4 and 5, I discovered some surprising results when incorporating real GDP and and real GDP per capita into the regression (column 3 of Table 5). The addition of only GDP per capita shown in column 2 of Table 5 did not have a large impact on the parallel trade variable, but adding both GDP variables caused the parallel trade variable coefficient to increase to be greater than one and to lose its statistical significance. This went against my expectations, as it suggested that parallel trade either has no effect on whether a patent enters the market in an additional country in a given year, or that it increases the odds of this happening, meaning that a manufacturer would be more willing to sell in a country that has legalized parallel trade. The accuracy of this conclusion seemed unlikely, as it conflicted with the results in Table 4 and the first two columns of Table 5 and with the results of prior papers. Thus, I created the interaction variable between number of years of lag time before a patent

enters an additional country (Years After US Patent) and the parallel trade variable. This interaction was intended to capture the change in lag time prior to patent entry for countries that use parallel trade relative to countries that completely restrict international pharmaceutical trade. Results after the addition of this interaction variable are shown in column 4 of Table 5.

Table 5. Patent Entry in Given Year Logit with Odds Ratios (Country Controls not Displayed)

	(1)	(2)	(3)	(4)
	Entry Odds	**With GDP per Capita**	**With GDP and GDP per Capita**	**With GDP, GDP per Capita, and Interaction Term**
EEA Status	6.13734***	6.52734***	3.9176***	3.88223***
	(1.59848)	(1.86916)	(1.12738)	(1.11363)
Parallel Trade	.69878***	.60954***	1.01952	.69119***
	(.08464)	(.07492)	(.13195)	(.09103)
Years After US Patent	.89217***	.89321***	.89828***	.85136***
	(.00434)	(.00435)	(.00439)	(.00509)
Years After US Patent*Parallel Trade				1.18831***
				(.01176)
Filed in EPO	1.12393	.96826	1.3094*	1.31799*
	(.15295)	(.13528)	(.18677)	(.18609)
Filed in WIPO	2.06435***	2.00114***	1.74379***	1.79135***
	(.11467)	(.11226)	(.09843)	(.10126)
External Referencing	6.71023***	8.80357***	13.57766***	17.08979***
	(1.81735)	(2.42909)	(3.75268)	(4.72898)
Real GDP Per Capita		1.00003***	1.00003***	1.00002***
		(0)	(0)	(0)
Real GDP			1***	1***
			(0)	(0)
Year	.91399***	.90265***	.87158***	.86814***
	(.00198)	(.00287)	(.00355)	(.00354)
Region and Country Controls				
NAFTA	45.17226***	75.21407***	108.81425***	95.56942***
	(16.67446)	(30.02583)	(43.46311)	(38.08017)
Soviet	2.88389**	2.4004*	8.90435***	7.90211***
	(1.39655)	(1.19856)	(4.51444)	(4.00348)
Asian	1.0141	.97644	.0666***	.04665***
	(.34947)	(.35426)	(.02706)	(.01891)
Constant	1.449e+78***	4.437e+88***	1.72e+118***	4.60e+121***
	(6.242e+78)	(2.773e+89)	(1.37e+119)	(3.67e+122)
Observations	61571	60718	60718	60718
Pseudo R^2	.36362	.36249	.36496	.36858

Standard errors are in parentheses
**** p<.01, ** p<.05, * p<.1*

The final regression including the interaction term shows a statistically significant coefficient that is less than one on the parallel trade variable, as expected. This reflects the longer lag time before patent entry in countries in which parallel trade is in place, relative to countries without parallel trade, which is consistent with the idea that manufacturers choose to enter into countries with parallel trade mechanisms later than into other countries. This could perhaps be explained by manufacturers choosing to focus first on countries in which they can make the most profit.

As in the logistic regressions, the coefficient on the external referencing variable is statistically significant and reflects the opposite of the expected results, suggesting that the existence of external referencing increases likelihood of entry in a given year. Again, this may be explained by the fact that most countries in the dataset that use external referencing are in the EU, which is a particularly large market.

Diverging from the first regression results, filing a patent in the EPO now shows a significant increase in likelihood of patent entry. This result is consistent with my expectations, as it reflects the increased ease of filing a patent in the EU if it is first filed in the EPO. Filing a patent in the WIPO shows a similar result, reflecting the increased ease of filing a patent in any country in the dataset.

Finally, the coefficient on the year variable being less than one is likely explained by the same factors as in the first regression.

Table 6 displays the results from my third set of regressions, those described in Equations 6 and 7. The addition of real GDP and real GDP per capita again cause confounding results (column 2), as they cause the coefficient on the parallel trade variable to become significantly negative, suggesting that the implementation of parallel trade decreases lag time before entry for patents that eventually enter a

country. This goes against the results of Danzon et al., who found that parallel trade significantly increases lag time prior to patent entry.

Table 6. Patent Lag Time OLS (Country Controls not Displayed)

	(1)	(2)
	Patent Lag Time	**With GDP and GDP per Capita**
EEA Status	-.91514***	-.50491***
	(.10858)	(.11995)
Parallel Trade	.14061**	-.28925***
	(.06074)	(.06366)
Filed in EPO	.12711**	.05846
	(.06382)	(.0645)
Filed in WIPO	-.78223***	-.7953***
	(.03961)	(.04088)
External Referencing	4.50999***	2.66189***
	(.34669)	(.36973)
Real GDP Per Capita		.00007***
		(0)
Real GDP		0***
		(0)
Year	.06107***	.04477***
	(.00146)	(.00267)
Region Controls		
NAFTA	-1.3843***	-3.16024***
	(.33979)	(.20866)
Soviet	-5.23634***	-2.11209***
	(.18121)	(.27115)
Asian	.18718	
	(.33905)	
Constant	-119.41016***	-89.46608***
	(2.92568)	(5.25261)
Observations	38739	37980
R-squared	.2684	.28374

Standard errors are in parentheses
**** p<.01, ** p<.05, * p<.1*

The regression displays the expected results for external referencing, however, as it shows that external referencing significantly increases lag time. This is consistent with prior literature and likely occurs because manufacturers facing external reference pricing mechanisms choose to enter countries strategically, entering into countries in which they can negotiate the highest prices first so as not to undermine their ability to freely set prices later when entering into additional countries.

The model also shows that filing in the WIPO decreases lag time, which is consistent with the idea that manufacturers can file more quickly due to the increased ease in filing conferred by first filing in the WIPO. The results in the EPO variable, which are not significant in the regression run with the GDP variables, suggest that filing in the EPO is associated with increased lag time. This may be due to a difference in the kinds of patents filed in the EPO compared to patents that aren't, as manufacturers may choose to file in the EPO only if they know it will be difficult and time consuming to file otherwise. Thus, this result may reflect the inherent variability in difficulty of filing and not the direct impact of filing a patent in the EPO.

The model shows that filing a patent in the EEA or a NAFTA country decreases lag time while filing in a former USSR or Asian country increases lag time. This may be due to differences in filing procedures or cost of filing across regions, but it also may reflect differences in the populations of these places. Since all patents in the dataset were first filed in the US, the data may be biased toward the type of pharmaceuticals that US consumers utilize. Manufacturers may first focus on filing a patent in the markets that are most likely to be profitable, then only choose to file in a country that may not be as profitable after they've done market research or are otherwise more certain that a drug will be successful. Since people in NAFTA countries or in the EEA are likely more similar to Americans than people in former USSR countries or in Asia, it would make sense that lag time is smaller in these places if manufacturers are considering profitability when choosing when to file.

Table 7. Full Regressions with Sales Data (Table 7) Displayed with Country Controls

	(1)	(2)	(3)

	Patent Exists Logit	Patent Entry Logit	Patent Lag Time OLS
EEA Status	2.62545***	1.94124***	-2.69852***
	(.39812)	(.55744)	(.56546)
Parallel Trade	-.75658***	-1.26738***	.34153**
	(.18598)	(.22613)	(.16304)
Years After US Patent	.40685***	-.15334***	
	(.00309)	(.0064)	
Years After US Patent * Parallel Trade		.27676***	
		(.01107)	
Filed in EPO	-.27736*	-.1042	.65743***
	(.16658)	(.21872)	(.17033)
Filed in WIPO	1.39065***	.96392***	-.89572***
	(.05019)	(.07155)	(.06974)
External Referencing	4.73467***	4.26272***	4.9192***
	(.39)	(.41582)	(.82785)
Real GDP Per Capita	.00003***	.00002	.00006***
	(.00001)	(.00001)	(.00001)
Real GDP	0***	0***	0***
	(0)	(0)	(0)
Per-Country Sales	.00001***	0***	-.00003***
	(0)	(0)	(0)
Year	-.25013***	-.17453***	.10297***
	(.00446)	(.00584)	(.0043)
Region and Country Controls			
NAFTA	5.80203***	4.45286***	-.64755
	(.52415)	(.65178)	(.8769)
Soviet	.35935	-.16319	-5.62275***
	(.58085)	(.68263)	(.86931)
Asian	-4.06966***	-3.38243***	2.82975***
	(.54292)	(.6817)	(.96377)
Constant	496.9798***	346.87318***	-204.16223***
	(8.66622)	(11.37563)	(8.48526)
Observations	482244	41946	23444
R-squared	.z	.z	.36084

Standard errors are in parentheses
*** p<.01, ** p<.05, * p<.1*

Lastly, I turn to the full regressions with sales data (Table 7). These models show that parallel trade decreases the likelihood of a patent existing, decreases the likelihood of patent entry in a given year, and increases lag time before patent entry in an additional country after being patented in the US. These results are generally consistent with the results from the regressions with the full dataset and with

prior literature. However, the effect on lag time disagrees with the result found when the sales data was not included (Table 6 column 2), suggesting that the more limited sample of countries with available sales data may have underlying differences from the overall dataset. The results for external referencing, filing in the EPO, and filing in the WIPO are also largely consistent with the results from the previous regressions.

The models show that an increased level of per-country pharmaceutical sales increases likelihood of patent entry and decreases lag time. This is consistent with my predicted results, as manufacturers would be more likely to want to quickly enter the market in a county where they expect to sell more and therefore earn more profits.

Overall, the results of these models show that parallel trade and external referencing increase lag time prior to patent entry. While parallel trade decreases likelihood of entry, external referencing may actually increase likelihood, conflicting with the results of earlier papers.

Conclusion

Faced with rising pharmaceutical prices, policymakers in the US and elsewhere are turning toward price control mechanisms such as external reference pricing and relaxation of trade restrictions in order to enable citizens to afford necessary treatment. Though these solutions may seem obviously beneficial to all but the pharmaceutical manufacturers themselves, this paper demonstrates the caveats to approaches that attempt to lower drug prices by undermining the ability of the manufacturers to freely set prices. My results show that legalizing parallel trade, as several US states are currently moving forward with plans to allow following congressional approval, results in a decrease in patenting and an increase in lag time for drugs that are eventually patented. Further research may explore whether these effects are consistent as US pharmaceutical imports begin to occur.

Logically, a reduction in pharmaceutical patenting must lead to a reduction in the number of drugs available in a country. Depending on whether these drugs are better than existing pharmaceuticals, this may lead to adverse health outcomes. Thus, making medications cheaper through implementation of parallel trade would likely improve health outcomes by increasing access to needed treatments, while decreasing access to the number of treatment options would worsen outcomes. The health impacts of parallel trade implementation are likely of great interest to policymakers, so future work should attempt to address this question.

Furthermore, as parallel trade becomes increasingly widespread, it may decrease pharmaceutical manufacturers' profits. Pharmaceutical companies generally subsidize the costs of failed and less profitable medication research with drugs that they know will generate long-term profit, such as blood pressure medication or insulin. Additional research may look into whether this loss of profit is likely, and if so, whether this may contribute to manufacturers choosing not to spend as much money on risky

drug development, potentially causing further adverse effects on health outcomes. For instance, this may lead to a decrease in research into new antibiotics, as the existence of antibiotic resistance necessitates that a given antibiotic be used sparingly, lest it ceases to work at all. Thus, researchers may specifically look at changes in spending on antibiotic development as parallel trade becomes more popular.

The results of this research and the potential future projects mentioned above can provide guidance to policymakers about the risks and benefits of employing parallel trade as a way of bringing down rising pharmaceutical costs. Given the potential negative effects on health outcomes and on research output, alternatives such as government subsidization of drug prices may be considered. If parallel trade is implemented, policymakers may also consider providing additional funding to pharmaceutical manufacturers to make up for lost profits and encourage research into risky drugs.

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Appendix A

Appendix Table 1: Patent Exists Logit (Table 4) Displayed with Country Controls

	(1)	(2)
	Patent Exists	**With GDP and GDP per Capita**
EEA Status	29.0887***	18.47912***
	(6.47654)	(4.54053)
Parallel Trade	.37442***	.5893***
	(.03886)	(.06503)
Years After US Patent	1.51001***	1.51576***
	(.00425)	(.00432)
Filed in EPO	.64998***	.75294**
	(.07021)	(.0856)
Filed in WIPO	3.61995***	3.17648***
	(.14953)	(.13408)
External Referencing	14.56489***	68.33667***
	(3.80963)	(18.11674)
Real GDP Per Capita		1.00003***
		(0)
Real GDP		1***
		(0)
Year	.8498***	.79781***
	(.00155)	(.00257)
Region and Country Controls		
NAFTA	149.68378***	718.03552***
	(51.18483)	(260.37911)
Soviet	2.02573	14.42746***
	(.94493)	(6.94884)
Asian	1.72055*	.03713***
	(.5427)	(.01305)
Austria	.2772***	.88248
	(.04312)	(.15157)
Australia	.43871***	.94218
	(.09871)	(.23867)
Belgium	.00083***	.00275***
	(.00012)	(.00046)
Canada	.06871***	.01513***
	(.02235)	(.00523)
Czech Republic	.14644***	.1427***
	(.06637)	(.06476)
Denmark	8.67249***	222.81028***
	(2.25183)	(62.81983)
Estonia	.20212***	.35073*
	(.11342)	(.19702)
Finland	.00172***	.00751***
	(.00022)	(.00109)
France	.03154***	.00691***

	(.00987)	(.00218)
Germany	5.73726***	.82852
	(1.97299)	(.2891)
Greece	.022***	.45442***
	(.00547)	(.11961)
Iceland	.06841***	2.41584***
	(.01849)	(.72684)
Ireland	.13682**	.67346
	(.138)	(.68072)
Israel	1.81906*	89.38719***
	(.5743)	(31.69481)
Italy	.03179***	.00752***
	(.01377)	(.00328)
Korea	7.09426***	39.07704***
	(2.24541)	(13.04868)
Latvia	.00798***	.0128***
	(.00347)	(.00565)
Lithuania	.03031***	.07068***
	(.01378)	(.03294)
Luxembourg	.00045***	.00074***
	(.00005)	(.00019)
Netherlands	.0007***	.00138***
	(.00008)	(.00019)
Norway	.00455***	.01628***
	(.00067)	(.00331)
Poland	4.13564***	2.98311*
	(2.27584)	(1.6907)
Portugal	3.76218***	33.57672***
	(1.04026)	(9.61395)
Slovakia	.25649***	
	(.12753)	
Slovenia	.2588	
	(.21319)	
Sweden	.47635	8.61004***
	(.24148)	(4.48402)
Switzerland	.26246***	1.45973
	(.08665)	(.53564)
Constant	-119.41016***	-89.46608***
	(2.92568)	(5.25261)
Observations	38739	37980
R-squared	.2684	.28374

Standard errors are in parentheses
*** p<.01, ** p<.05, * p<.1

Appendix Table 2. Patent Entry in Given Year Logit (Table 5) Displayed with Country Controls

	(1)	(2)	(3)	(4)
	Entry Odds	**With GDP per Capita**	**With GDP and GDP per Capita**	**With GDP, GDP per Capita, and Interaction Term**
EEA Status	6.13734***	6.52734***	3.9176***	3.88223***
	(1.59848)	(1.86916)	(1.12738)	(1.11363)
Parallel Trade	.69878***	.60954***	1.01952	.69119***
	(.08464)	(.07492)	(.13195)	(.09103)
Years After US Patent	.89217***	.89321***	.89828***	.85136***
	(.00434)	(.00435)	(.00439)	(.00509)
Years After US Patent * Parallel Trade				1.18831***
				(.01176)
Filed in EPO	1.12393	.96826	1.3094*	1.31799*
	(.15295)	(.13528)	(.18677)	(.18609)
Filed in WIPO	2.06435***	2.00114***	1.74379***	1.79135***
	(.11467)	(.11226)	(.09843)	(.10126)
External Referencing	6.71023***	8.80357***	13.57766***	17.08979***
	(1.81735)	(2.42909)	(3.75268)	(4.72898)
Real GDP Per Capita		1.00003***	1.00003***	1.00002***
		(0)	(0)	(0)
Real GDP			1***	1***
			(0)	(0)
Year	.91399***	.90265***	.87158***	.86814***
	(.00198)	(.00287)	(.00355)	(.00354)
Region and Country Controls				
NAFTA	45.17226***	75.21407***	108.81425***	95.56942***
	(16.67446)	(30.02583)	(43.46311)	(38.08017)
Soviet	2.88389**	2.4004*	8.90435***	7.90211***
	(1.39655)	(1.19856)	(4.51444)	(4.00348)
Asian	1.0141	.97644	.0666***	.04665***
	(.34947)	(.35426)	(.02706)	(.01891)
Austria	.42602***	.29906***	.79607	.98611
	(.06733)	(.05057)	(.14524)	(.18067)
Australia	.37869***	.23778***	.58282*	.58634*
	(.09671)	(.0679)	(.17013)	(.17091)
Belgium	.0194***	.0135***	.03775***	.02942***
	(.00315)	(.00239)	(.00734)	(.00563)
Canada	.16312***	.06401***	.0662***	.06517***
	(.05445)	(.02369)	(.0246)	(.02417)
Czech Republic	.15202***	.17585***	.17316***	.18429***
	(.0703)	(.08168)	(.08047)	(.08575)
Denmark	4.06774***	3.80781***	21.5123***	35.33229***
	(1.09548)	(1.02823)	(6.29813)	(10.43403)
Estonia	.20127***	.28276**	.34337*	.34977*
	(.11587)	(.1632)	(.19832)	(.20209)
Finland	.01308***	.01066***	.03146***	.02718***
	(.002)	(.00168)	(.00549)	(.0047)
France	.13568***	.09342***	.0635***	.04817***
	(.04282)	(.03025)	(.02062)	(.01566)

Germany	4.61463***	4.66208***	1.02059	.97258
	(1.62061)	(1.64072)	(.37173)	(.35454)
Greece	.05162***	.07045***	.26092***	.29759***
	(.01351)	(.01888)	(.07288)	(.08319)
Iceland	.13913***	.11815***	1.0075	1.44202
	(.03999)	(.03425)	(.32442)	(.46717)
Ireland	.86782	.72995	2.33129	2.14468
	(.87812)	(.73911)	(2.3688)	(2.1797)
Israel	.89415	.99394	8.20254***	11.01389***
	(.30851)	(.36269)	(3.20608)	(4.30748)
Italy	.19379***	.1255***	.08622***	.06496***
	(.08493)	(.05589)	(.03843)	(.02898)
Korea	2.40158**	2.8257***	6.1689***	6.40605***
	(.82928)	(1.03401)	(2.27152)	(2.35481)
Latvia	.01392***	.01941***	.02307***	.02427***
	(.00648)	(.00933)	(.01113)	(.01173)
Lithuania	.03152***	.04835***	.06874***	.07035***
	(.01488)	(.02359)	(.03356)	(.03433)
Luxembourg	.00916***	.00179***	.0076***	.00779***
	(.00113)	(.00053)	(.00239)	(.00246)
Netherlands	.00958***	.00648***	.01292***	.00943***
	(.00134)	(.00101)	(.00211)	(.00154)
Norway	.02263***	.01036***	.04496***	.04897***
	(.00386)	(.00224)	(.01086)	(.01182)
Poland	2.84662*	5.06189***	3.07349*	3.42959**
	(1.58546)	(2.93972)	(1.77588)	(1.99503)
Portugal	3.77053***	4.29109***	15.34251***	18.30195***
	(1.04727)	(1.19566)	(4.48897)	(5.35987)
Slovakia	.23828***			
	(.12071)			
Slovenia	.24746*			
	(.20964)			
Sweden	.46343	.43416	1.99275	2.75935*
	(.24681)	(.23181)	(1.0807)	(1.50892)
Switzerland	.40714**	.14545***	.37759**	.4964*
	(.14723)	(.05866)	(.15308)	(.20165)
Constant	1.449e+78***	4.437e+88***	1.72e+118***	4.60e+121***
	(6.242e+78)	(2.773e+89)	(1.37e+119)	(3.67e+122)
Observations	61571	60718	60718	60718
Pseudo R^2	.36362	.36249	.36496	.36858

Standard errors are in parentheses
**** p<.01, ** p<.05, * p<.1*

Appendix Table 3. Patent Lag Time OLS (Table 6) Displayed with Country Controls

	(1)	(2)
	Patent Lag Time	**With GDP and GDP per Capita**
EEA Status	-.91514***	-.50491***
	(.10858)	(.11995)
Parallel Trade	.14061**	-.28925***
	(.06074)	(.06366)
Filed in EPO	.12711**	.05846
	(.06382)	(.0645)
Filed in WIPO	-.78223***	-.7953***
	(.03961)	(.04088)
External Referencing	4.50999***	2.66189***
	(.34669)	(.36973)
Real GDP Per Capita		.00007***
		(0)
Real GDP		0***
		(0)
Year	.06107***	.04477***
	(.00146)	(.00267)
Region and Country Controls		
NAFTA	-1.3843***	-3.16024***
	(.33979)	(.20866)
Soviet	-5.23634***	-2.11209***
	(.18121)	(.27115)
Asian	.18718	
	(.33905)	
Austria	-4.74317***	-3.07221***
	(.13156)	(.16579)
Australia	-5.38361***	-3.23228***
	(.16054)	(.2004)
Belgium	-3.20009***	-1.12192***
	(.15373)	(.19289)
Canada	-4.33076***	
	(.34944)	
Chile	-1.19898	.52366
	(1.65112)	(1.65111)
Czech Republic	-.02734	-.15692
	(.1556)	(.17246)
Denmark	-.58769*	-.95911***
	(.32591)	(.3321)
Estonia	-.04532	.22151
	(.22728)	(.23887)
Finland	-3.16165***	-.97388***
	(.17219)	(.21553)
France	-3.93043***	-1.00582***
	(.15134)	(.20886)
Germany	-.15783	1.78949***
	(.3287)	(.36123)
Greece	2.08313***	2.96475***
	(.3366)	(.34412)
Iceland	1.13327***	.7711**
	(.35776)	(.36377)
Ireland	-4.13829***	-1.66533***
	(.1748)	(.22492)

Israel	.1458	.78486**
	(.33993)	(.35034)
Italy	-4.10169***	-1.22134***
	(.16686)	(.22174)
Japan		3.59017***
		(.40555)
Korea	-.96981***	.67965*
	(.33947)	(.35274)
Latvia	1.73688***	2.52536***
	(.27442)	(.31857)
Lithuania	.50358***	.38256**
	(.14644)	(.172)
Luxembourg	1.33144***	
	(.15755)	
Mexico		4.63692***
		(.35015)
Netherlands		1.86971***
		(.20438)
Norway	-3.15711***	-2.45658***
	(.14276)	(.14978)
Poland	-.12458	.48716***
	(.12453)	(.1529)
Portugal	-5.15232***	-2.37855***
	(.13146)	(.21039)
Slovakia	-.12707	
	(.17155)	
Slovenia	-.09103	-.47934
	(.34864)	(.41998)
Spain	-5.06958***	-1.84955***
	(.12872)	(.20658)
Switzerland	.0697	-.77727**
	(.35011)	(.38846)
Turkey	-1.57207***	.80947**
	(.36274)	(.38017)
United Kingdom	.48421	1.71761***
	(.33281)	(.34529)
Constant	-119.41016***	-89.46608***
	(2.92568)	(5.25261)
Observations	38739	37980
R-squared	.2684	.28374

Standard errors are in parentheses
**** p<.01, ** p<.05, * p<.1*

Appendix Table 4. Full Regressions with Sales Data (Table 7) Displayed with Country Controls

	(1)	(2)	(3)
	Patent Exists Logit	**Patent Entry Logit**	**Patent Lag Time OLS**
EEA Status	2.62545***	1.94124***	-2.69852***
	(.39812)	(.55744)	(.56546)
Parallel Trade	-.75658***	-1.26738***	.34153**
	(.18598)	(.22613)	(.16304)
Years After US Patent	.40685***	-.15334***	
	(.00309)	(.0064)	
Years After US Patent * Parallel Trade		.27676***	
		(.01107)	
Filed in EPO	-.27736*	-.1042	.65743***
	(.16658)	(.21872)	(.17033)
Filed in WIPO	1.39065***	.96392***	-.89572***
	(.05019)	(.07155)	(.06974)
External Referencing	4.73467***	4.26272***	4.9192***
	(.39)	(.41582)	(.82785)
Real GDP Per Capita	.00003***	.00002	.00006***
	(.00001)	(.00001)	(.00001)
Real GDP	0***	0***	0***
	(0)	(0)	(0)
Per-Country Sales	.00001***	0***	-.00003***
	(0)	(0)	(0)
Year	-.25013***	-.17453***	.10297***
	(.00446)	(.00584)	(.0043)
Region and Country Controls			
NAFTA	5.80203***	4.45286***	-.64755
	(.52415)	(.65178)	(.8769)
Soviet	.35935	-.16319	-5.62275***
	(.58085)	(.68263)	(.86931)
Asian	-4.06966***	-3.38243***	2.82975***
	(.54292)	(.6817)	(.96377)
Australia	-1.79181***	-2.15292***	-6.90222***
	(.41552)	(.54702)	(.74171)
Canada			-6.63476***
			(.71682)
Chile			-1.07806
			(1.99158)
Czech Republic	-1.83291***	-1.52553***	-.03647
	(.45596)	(.47063)	(.20636)
Denmark	5.09769***	4.51849***	-1.30609**
	(.42769)	(.4706)	(.63974)
Estonia			-.16332
			(.33436)
Finland	-6.66437***	-5.6086***	-2.26171***
	(.23964)	(.2742)	(.61277)
France	-4.91704***	-3.94304***	-2.81311***
	(.74766)	(.76976)	(.73507)
Germany	-.58003	.08323	1.84035**

	(.43286)	(.46197)	(.722)
Greece	-1.97977***	-1.63961***	3.6851***
	(.38559)	(.42263)	(.66068)
Iceland	-.20338	-.00891	1.30609*
	(.452)	(.50799)	(.67565)
Israel	3.05363***	2.26816***	-.1072
	(.53268)	(.66301)	(.83809)
Korea	4.51002***	3.3776***	-1.58295*
	(.49618)	(.61942)	(.84525)
Latvia	-4.28871***	-3.45174***	3.05201***
	(.46634)	(.54796)	(.49395)
Luxembourg	-8.59872***	-6.46738***	
	(.58014)	(.71852)	
Netherlands	-7.87619***	-6.55385***	.80122
	(.24289)	(.27789)	(.54708)
Norway	-5.53505***	-4.75353***	-4.02362***
	(.36937)	(.45166)	(.42722)
Portugal	2.5568***	2.21535***	-5.25841***
	(.40268)	(.41279)	(.64051)
Spain			-4.83999***
			(.67239)
Sweden	1.07571*	.46407	
	(.61639)	(.70898)	
Switzerland			-2.51767***
			(.91187)
Turkey			-1.48718*
			(.87714)
United Kingdom			1.73596**
			(.70064)
Constant	496.9798***	346.87318***	-204.16223***
	(8.66622)	(11.37563)	(8.48526)
Observations	482244	41946	23444
R-squared	.z	.z	.36084

Standard errors are in parentheses
**** p<.01, ** p<.05, * p<.1*