Regulatory Policy and the Location of Bio-Pharmaceutical FDI in Europe*

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Abstract

This paper examines the relationship bewteen cross-country differences in drug price regulation and the location of biopharmaceutical Foreign Direct Investment (FDI) in Europe. We use a theoretically-grounded location-choice model and data on 294 investments initiated in 27 European countries between 2002 and 2006 to test the hypothesis that biopharmaceutical companies are less likely to locate new investments in countries with more stringent price regulation.

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1 Introduction

As part of the debate over the extent of and reasons for international outward investment, pharmaceutical firms' decisions to invest abroad are at the center of public attention in Europe. The general argument questions the ability of rich countries to remain an attractive location for manufacturing firms when confronted with fierce competition from low-wage countries. A frequent response by economists about such off-shoring is that rich countries have a comparative advantage in high-tech skill-intensive industries and that outflows of traditional manufacturing will be compensated by inflows or creation of innovation-based manufacturing plants. The pharmaceutical industry is one example of this type of industry.

Moreover, the location of pharmaceutical foreign direct investment is of central interest because this industry is among the most regulated ones in most countries of the world. Regulation takes the form of strong safety norms with certification processes for drugs, and price control mechanisms. The justification for price regulation is principally enforcing equity in access to drugs and reducing the costs of health care systems. However, these policies may also have consequences for the countries in which companies choose to invest in new production or research facilities. In countries with stringent price regulations, drug launches are delayed (Kyle (2007a)). This raises questions about the impact of public intervention on the locations of manufacturing plants. It has been suggested that firms respond to controversial policy choices by "voting with their feet" in choosing manufacturing locations. Most recently, Merck was said to be "re-evaluating" its investment in Brazil after that country imposed compulsory licensing on efavirenz, Merck's anti-retroviral AIDS drug. (*The Economist*, May 10 2007, "Brazil's AIDS Program: A conflict of goals").

In this project, we investigate the determinants of the locations of foreign investments in the bio-pharmaceutical sector in 27 European countries. We investigate whether variation in policy regimes across countries helps explain variation in the locations of foreign investments in the pharmaceutical sector.

Studies on location choices constitute an important part of the academic literature quantifying the FDI phenomenon. Carlton (1983) was the first paper to use a discrete choice model to study choice of production sites by firms. The subsequent literature analyzed location choices of FDI with the traditional elements of the expected profit in each location, some studies however including a more complete form of demand with the income of

contiguous locations (Friedman, Gerlowski and Silberman, 1992; Head, Ries and Swenson, 1999). The new trade theory and the new economic geography literatures provide a foundation for the empirical analysis of location choices directly issued from theoretical predictions. Head and Mayer (2004) construct a demand variable taking into account the surrounding export destinations as well as the location of competitors, based on the modelling of Krugman (1992). They clearly show the link between the theory and the estimated equation.

A set of contributions have investigated the influence of public policies on the decision to locate in different countries. Head, Ries and Swenson (1999) study the influence of US states' incentives on the decisions of Japanese affiliates to locate within the United States. Crozet, Mayer and Mucchielli (2004) analyze whether regional policies have an effect on location patterns within France, while Devereux, Griffith and Simpson(2007) apply similar methods to the English case. Those papers end up with mixed evidence of the impact of public policies. In this paper, we present first evidence of the impact of regulatory constraints on the location choice of affiliates by multinational pharmaceutical firms. In the following, we use the theoretically grounded location-choice model from Head and Mayer (2004) to quantify the role of domestic policies as an additional determinant of the location choice of pharmaceutical firms.

We evaluate the role of traditional trade and geography location determinants in the geographical investment choice of pharmaceutical firms, and investigate the role of a new determinant specific to this industry, i. e. national regulatory policies. The paper is structured as follows. Section 2 describes the regulatory policy schemes in the pharmaceutical industry in Europe. Section 3 presents the theoretical model and its empirical implementation. In section 4 we derive the results, and section 5 concludes.

2 Regulatory policy and investment in the pharmaceutical industry

The pharmaceutical industry is perhaps the industry most affected by regulatory choices. Policies concerning the pricing and distribution of drugs and the duration and strength of exclusivity awarded by patents are particularly important. The latter policies are essentially consistent across European

countries (although the pharmaceutical industry has expressed concern over the enforcement of these rights in some countries), as are policies relating to advertising, wholesale distribution, packaging and labeling. These homogenenized policies are by definition not expected to influence the profitability of the different countries. This is not however not the case in the medical sector. As discussed at length by Permanand and Mossialos (2005), "Despite the harmonizing imperative of the SEM, there is still no single European market in medicines." European countries retain control over the pricing of drugs and reimbursement of expenditures. Countries vary in the use of reference pricing, fixed pharmacy profit margins, profit controls for manufacturers, as well as along other dimensions (see Table 2 of Kyle (2007a)). Countries also vary in their attitudes to parallel-trade, or the re-importation of drugs from countries in which prices are lower.

All EU countries exert some degree of influence over expenditures on drugs marketed within their boundaries, but individual governments employ different policies. Governments may use formularies (lists of drugs for which patients will be reimbursed), controls on doctors' prescribing behavior, pharmacists, reimbursements of prescription costs, and/or price controls. A common mechanism for controlling prices is to set a price not higher than that of a currently available generic substitute, or to set the price with reference to prices of the same drug in neighboring countries. Some countries (like Spain and the UK) place controls on the profits of pharmaceutical companies. Others, like Denmark, do not control the price charged by the manufacturer, but prohibit price increases after a drug is introduced. Many EU countries also regulate the profit margins of pharmacists. Some countries (like Belgium, France, Spain and the UK) also regulate expenditures on drug marketing.

Our empirical investigation concentrates on the following price regulation policies, which we now define: price control, reference pricing, therapeutic reference pricing, in each of which price freezes and price cuts can be introduced. Detailed information on the use of these polices in different countries is available in Tables 2 and 3.

Price controls refer to policies that directly control either the manufacturer price or the price reimbursed by the national health service. Reference pricing is a practice in which governments sets a maximum reimbursement amount for drug purchases with reference to prices of substitute drugs. Under reference pricing regimes, the price charged by manufacturers is not directly controlled. Danzon (2001) notes that it is often used in countries without price controls, and is seen as a less stringent alternative to explicit price con-

trols. However, Danzon notes, "In practice, certain forms of reference pricing can be de facto at least as stringent... particularly for new products." The stringency of reference pricing largely depends on which drugs are used for reference. In some cases, only generic equivalents with the same active ingredient fall into the reference group. In other cases, the reference group consists of any therapeutic substitute on the market, and the drug's prices in other countries are taken into consideration. Most, but not all, countries exempt patented drugs from reference pricing schemes. As Danzon notes, "The decision whether to include on-patent products and to cluster on-patent products with off-patent products raises a critical trade-off between cost control and incentives for R&D, in addition to the issues of therapeutic substitutability." These two forms of price setting for reimbursement will be respectively denoted RP (reference pricing) and TRP (therapeutic reference pricing) in the empirical part.

Germany exempted patented drugs from its reference pricing scheme in 1996. However, in 2004 this exemption was removed, causing the sales of a number of on-patent drugs to fall dramatically. This policy shift was preceded in 2003 by a 16% reduction in reimbursed prices on patented medicines. Denmark expanded the scope of its reference pricing program in 2005, moving from one in which reference pricing was only used when generic equivalents were available to one that incorporates therapeutic equivalents. A similar shift took place in Hungary in 2003 for statins (a class of drugs used to lower cholesterol).

Germany's inclusion of patented drugs in its reference pricing scheme was quite controversial. Some pharmaceutical industry participants suggested that firms would react to Germany's policy move by choosing to invest elsewhere. Do firms' investment decisions really respond to regulatory policy relating to drug prices? The goal of this paper is to determine whether the location of pharmaceutical investment in Europe is affected by regulatory policy. Plausible arguments can be made both for and against the null hypothesis that drug price policy has no effect on the location of FDI.

One possible mechanism through which regulation might affect the location of production arises if we assume that firms will launch drugs earlier in the countries in which they chose to locate their plants. In the case of international reference pricing, the price negotiated in the first countries in which drugs are launched will be factored into other countries' reference pricing calculations. Hence lower prices the first countries lead to lower prices elsewhere. Kyle (2007a) argues that this is a strong motivation for firms to

launch drugs in lower-price countries later. If firms launch drugs earlier in the country in which they are produced (possibly because they receive faster approval if the drug is produced locally), we would thus expect the effect of price regulations on the choice of country for manufacturing investments to be negative.[1]

However, given the low costs of transporting drugs from the location of production to target markets, incentives to locate production near demand may be low. If we assume that the location of drug launches are independent from the location of the production, regulatory policies cannot be expected to have any impact on the location choice of investments via this mechanism.

The second mechanism through which regulation could influence location choices is one in which firms attempt to influence policy through their location choices. Pharmaceutical companies have been quoted in the press as threatening to reduce investment in reaction to policy changes. In response to reform proposals in 2002, the Pharma Marketletter reported that the pharmaceutical company Merck KGaA "warned that the reforms could ... influence where it locates a new 300-million euro biopharmaceticals product plant, its largest-ever investment." *Die Welt* reported on August 25, 2003 that "the American pharmaceutical firm Pfizer plans to reduce certain activities in Germany following upcoming reforms to the health system. Pfizer has decided to transfer an R&D group from Freiburg, Germany to the United Kingdom. 150 jobs will be affected by this decision."

As one of the largest markets in Europe, actions taken by Germany may affect other markets in two ways. Prices for drugs charged in Germany may be factored into other countries' reference pricing calculations, and lower prices in Germany lead to lower prices elsewhere. Secondly, Germany's policy changes may have been viewed by the pharmaceutical industry and other regulators as a test case - if the industry did not react strongly to the change, such changes may have appeared more attractive in other countries. Pharma Marketletter quoted a Merrill Lynch analyst who pointed out the potential snowball effects of Germany's change in policy, asking, "what's to stop France and Italy following guidance from Germany?" [2].

However, a plausible argument can also be made that firms choose invest-

[1] Kyle (2007a) finds that firms tend to launch drugs first in the country in which they are headquartered, and that domestic drugs are approved earlier than drugs produced by firms headquartered outside the approving country.

[2] "Govt drug price controls continue to threaten Europe's pharma industry", Pharma Marketletter, December 23, 2002

ment locations to based on factors such as wage and tax costs, proximity to demand, access to a skilled labor force or university scientists, etc., and that avoiding otherwise attractive locations to send a message to governments would rarely be worthwhile. This argument hinges on the assumption that the expected foregone profits associated with attempting to influence policy through investement are larger than the expected profits gained by acting to influence government policy. If this argument is correct, we should find no effect of regulatory policy on investment location choices after controlling for the usual determinants of location choices.

Changes like those that took place in Germany are a key element of this study. Most countries do not change their regulatory policies during the time frame of our sample. For example, all of the countries with explicit price controls in our sample maintain these controls throughout the time frame. As a result, it will be difficult to separate the effects of these invariant policy choices from unobserved, invariant characteristics of the country. However, countries that change their policies during the sample period provide an opportunity to examine investment patterns before and after the change. The change in Germany's reference pricing scheme is one such opportunity. Other changes to reference pricing schemes during our period took place in Denmark and Hungary. Additional variation in the drug price policy environment can be obtained from price freezes that were instituted in several countries during our period. Table 3 lists all the policy changes relevant to this paper.

An increasingly important and controversial factor in the pricing of drugs in the EU is parallel trade, or the re-export of drugs from low-price countries (like Spain, Portugal and Greece). While parallel trade has the potential to lead to price compression within the EU (and has been found to do so in non-drug markets), Kyle (2007b) shows that in fact parallel trade has had little impact on drug prices, due in part to strategic responses by pharmaceutical companies.

Evidence on how regulation policies might influence the decision-making of pharmaceutical firms is given by a number of papers. Kyle (2007a), in a detailed analysis of international drug launch strategies, shows that drug launches are delayed in countries with price controls. With a focus on developing countries, Lanjouw (2005) shows that drugs are launched earlier in countries with stronger enforcement of Intellectual Property Rights (IPRs). Ahlering (2004), in a study of the cross-sectional relationship between regulatory and policy variables in a particular country and the share of a phar-

maceutical company's employment in that country, finds little relationship between employment in a country and such factors as intellectual property protection (using the Ginarte-Park index to measure the strength of IP), drug approval times, corporate tax rates, and R&D incentives. Ahlering does, however, find evidence of a positive relationship between the number of price control mechanisms in a country and the share of a company's employment in that country. This finding is surprising in light of the large amount of interview-based evidence in the paper suggesting that requirements for foreign investment is a key bargaining chip used in pricing negotiations between countries and pharmaceutical companies. However, it may reflect incomplete controls for other factors motivating firms' investment decisions, e.g. the anticipated returns on R&D investment in the country, or the strength of potential academic collaborators in a firm's research areas. Furthermore, the number of price control mechanisms may not be the relevant explanatory variable. In a study of FDI in the global chemical industry, Fosfuri (2004) shows that increases in country risk are associated in reductions in the flow of international activity into a country, and that the effect is largest for wholly-owned investments that require the greatest level of commitment to the country. Fosfuri finds no impact of intellectual property rights on either the amount or the form of the investment.

3 The model and the empirical strategy

We follow Head and Mayer (2004) and sketch the monopolistic competition trade model à la Dixit and Stiglitz (1977). Consider firms from the pharmaceutical industry, located in country i. Each firm produces one variety, which is in our case associated to a particular pharmaceutical product. Demand for a pharmaceutical product produced in country i from a consumer in country j is expressed as

$$q_{ij} = \frac{p_{ij}^{-\sigma}}{\sum_{r=1}^{R} n_r p_{rj}^{1-\sigma}} Y_j, \tag{1}$$

where Y_j is the pharmaceutical consumption in country j, p_{ij} is the delivered price of the pharmaceutical product produced in i and consumed in j, and $\sigma > 1$. The delivered price is the factory price p_i in the home country multiplied by the unit trade cost τ_{ij}. We assume that trade costs comprise all distance and time-related costs of transporting goods.

We want to write the profit that a firm choosing to locate in country r would earn. Firms maximize profits and fix a resulting factory price that is a very simple expression over marginal cost: $p_r = \frac{\sigma}{\sigma-1}c_r$, with c_r being the marginal cost in country r.

Incorporating the equilibrium price in the demand equation, we obtain the quantity that a firm producing in i would ship to each destination j:

$$q_{ij} = \frac{\sigma - 1}{\sigma} \frac{(c_i \tau_{ij})^{-\sigma}}{\sum_{r=1}^{R} n_r (c_r \tau_{rj})^{1-\sigma}} Y_j, \tag{2}$$

where $G_j = \sum_{r=1}^{R} n_r (c_r \tau_{rj})^{1-\sigma}$ is the price index in country j. We now replace the equilibrium price and quantity in the gross profit earned in country j, $\pi_{ij} = p_i \tau_{ij} q_{ij} - c_i \tau_{ij} q_{ij} = (p_i - c_i)\tau_{ij} q_{ij}$, to get

$$\pi_{ij} = \frac{(c_i \tau_{ij})^{1-\sigma}}{\sigma G_j} Y_j. \tag{3}$$

The profit earned by selling in country j is naturally an increasing function of the size of demand in j, represented by the consumption Y_j. The firm will get a share of that aggregate demand, which depends on the final price paid by consumers in j (the numerator) and on a measure of its competitors' prices (the denominator). The lower the costs of production (c_i) or transaction costs (τ_{ij}) of the producing firm in i, and the higher the costs of its competitors (high G_j), the higher its operating profit.

The profit earned in a location r where the firm could locate is equal to the sum of operating profits in all markets to which the firm could export from r, minus the fixed cost F necessary to establish a plant in country r, which we assume is invariant across countries.

$$\Pi_r = \frac{(c_r)^{1-\sigma}}{\sigma} \sum_j \frac{(\tau_{rj})^{1-\sigma}}{G_j} Y_j - F \tag{4}$$

Following Head and Mayer (2004), we express the net profit in r as a function of the Krugman market potential in r, M_r. The net profit appears clearly as an increasing function of the market potential in r and as a decreasing function of production costs in r:

$$\Pi_r = \frac{(c_r)^{1-\sigma}}{\sigma} M_r - F \tag{5}$$

where $M_r = \sum_j \frac{(\tau_{rj})^{1-\sigma}}{G_j} Y_j$.

We assume that firms choose the location with the highest profit. Taking logs, the expression for the profit in r becomes

$$\ln \Pi_r = b + (1-\sigma) \ln c_r + \ln M_r \tag{6}$$

with $b = -(\ln \sigma + \ln F)$.

We specify the cost as a function of local wages w_r (specified here as the unit labor cost of production), and public intervention specific to the pharmaceutical sector. We include PR, a matrix of dummy variables capturing various price regulations, as the major forms of public interventions that govern the pharmaceutical industry relate to the pricing of the products. These dummy variables indicate whether the country 1) controls prices explicitly, 2) employs reference pricing schemes to control the amounts reimbursed, 3) uses therapeutic reference pricing, or 4) has frozen or cut the prices of drugs at a given point in time.

We observe wages in the 27 potential destination countries. To complete labor costs, we add the local statutory tax rate tax_r, which is also likely to affect location decisions as a determinant of the labor market situation.

Finally, we consider the clustering of research-intensive firms in the same location. We include an agglomeration effect variable, to account for the fact that firms may be drawn to locations where a large number of firms of the same industry are agglomerated (Head, Ries and Swenson, 1995). We compute this variable as the number of pharmaceutical producers in country r in year t. The effect may arise from technological spillovers decreasing the input cost v_r, or decreasing the transaction cost τ_{rj}. We expect the spillovers variable to have a positive and significant effect, even after having controlled for market potential. The Krugman market potential is a demand measure that aggregates the expenditures of all regions and takes into the location of competitors. Head and Mayer (2004) show that agglomeration variables survive to the introduction of the theoretically derived market potential. Furman et al. (2007) (among others) have documented the tendency of biopharmaceutical firms to locate in places with greater R&D capabilities, and as a result we also include the country's annual R&D spending in the pharmaceutical sector. We denote these spillover-related variables $Spill_r$. Our estimated equation becomes

$$\ln \Pi_r = \beta_0 + \beta_1 \ln w_r + \beta_2 \ln tax_r + \beta_3 \ln M_r + \beta_4' PR + \beta_5' Spill_r + \varepsilon_r, \tag{7}$$

where β_0 is a constant, and $\beta_1 - \beta_5$ are parameters or vectors of parameters. We assume that firms choose the location yielding the highest profit, and estimate a discrete-choice model as described below.

4 Data

We estimate a model of location choice on 294 investments in the biopharmaceutical sector in 27 European countries during 2002-2006.

4.1 Data sources

The data on inward FDI comes from the Agence française des investissements internationaux (AFII). The database is the result of a comprehensive search by web-crawlers of public announcements of new investments from a variety of sources, including press releases, newspapers and the trade press, and Lexis-Nexis. Because these announcements are voluntary public disclosures, there is a possibility that the dataset contains a disproportionate share of large, publicly-traded firms. Since the R&D-performing pharmaceutical firms tend to be large and publicly traded, we are likely capturing a large majority of investments by these types of firms. However concerns about sample selection are likely to be more significant for smaller, privately-traded biotech firms. It is important to keep in mind the sample composition when interpreting our results. If large, public firms are more likely to alter investment decisions in response to regulatory changes, our estimates will overstate the effect of regulation on investment by small, private firms.

The data come from published sources in several languages. However, there is a possibility that English-language and French-language publications may be over-represented in our database. We deal with this possibility by including in our specifications a dummy variable equal to 1 if the announcement was published in English or French. In response to a concern that investments in France or by French companies were over-represented in our data due to the origin of the dataset, we tried estimating the models without French investments or companies, and found similar results, which are available upon request.

We also deal with issues of potential unevenness of data reliability across countries by including country fixed effects in some of the regressions. Regrettably, not all specifications permit the use of country fixed effects as some

of the key price control variables do not vary over time. For this reason, we view our difference-in-difference specifications as the most stringent test of our hypotheses.

We restrict attention to investments made by R&D-performing firms in the pharmaceutical and biotech sectors. We exclude generic producers, medical device manufacturers, contract research organizations, and suppliers of intermediate inputs. These firms were identified by reading the text of the investment announcement, which typically contained a description of the firm's main activity, and by looking up companies on the web. Origin countries of investing firms are in all parts of the world. Destination countries are the 25 current EU members, minus Malta and Cyprus, and plus Norway, Switzerland, and the Baltic countries (Latvia, Lithuania, and Estonia).

While the AFII database contains information on both new investments and expansion of existing investments, we restrict our attention to investments which represent the creation of a new facility. Out of a total of 294 investments, there are 78 announcements of new investments in sales offices or distribution facilities, 79 manufacturing plants, 84 new R&D facilities, 40 headquarters and administartive offices, and 8 other types of announcements (distribution centers, call centers, etc.)

Explanatory variables mainly come from the Eurostat website, which provides industrial statistics as well as data on education levels by country.

The market potential variable is constructed using the Redding and Venables (2004) method. This definition of the market potential includes consumption in the pharmaceutical sector in country r, weighted by transaction costs between country r and all destination countries j and by an index measuring the degree of competition in each market. Hence, the demand addressed to a firm planning to locate in r is increasing with consumption in all importing markets including r. This consumption is, however, reduced by two items: 1) the number of other pharmaceutical firms in each market (the price index), and 2) the level of transaction costs between r and each market.

These data and their sources are described in more detail in the appendix.

4.2 Specification of the location choice model

As described above, we model an investor's choice among the 27 countries in our dataset as a function of characteristics of the location including market potential, wage costs, taxes, and variables related to pharmaceutical regula-

tion. Following several papers in the location choice literature, we estimate a Conditional Logit model of location choices. This model is particularly well suited to applications in which choices are made based on the observable characteristics of the alternatives. In this case, we model profits as a function of the choice attributes described above and a common set of parameters. Chung and Alcacer (2002) use the Random Parameters Logit model, which allows the effect of location characteristics to vary across investors. While we do not pursue this estimation strategy, we do examine whether different investors respond differently to regulation in some specifications.

5 Empirical results

We begin by presenting results, in the first column of Table 4, which include only the set of explanatory variables related to price regulation. These unconditional estimates show that overall, countries with price controls are less likely to be chosen as a destination for investment than countries without price controls. Countries with reference pricing are also less likely to receive investement, but the effect is not as strong as for price controls. Countries with therapeutic reference pricing see less investment overall than countries with generic-based regimes. And countries that combine all three systems (price controls, reference pricing, and therapeutic reference pricing) see the least investment.

In column 2, we add the market potential variable, which is positively and significantly related to the location of FDI. Controlling for market potential reduces the magnitude of the coefficient on the price control dummy, reflecting the negative correlation between these two variables, and renders the reference pricing dummy insignificant. In column 3 we add variables relating to trade costs. These are a dummy for a common language between investors and potential recipient countries, the distance between countries, and a dummy variable for Eastern European destinations. The first and third of these are highly significant, and their inclusion renders the reference pricing and therapeutic reference pricing dummies statistically insignificant, though the price control dummy retains its negative and significant assocation with the probability of investment. We continue to add the elements of the profit function in columns 4-5. As expected, the nominal corporate tax rate is negatively associated with investment, while the unit cost of production has a positive coefficient (presumably reflecting variation in productivity or la-

bor quality across locations). The latter finding is consistent with Head and Mayer (2004). When the "spillovers" variable (number of pharmaceutical establishments active in the country) is included, the market potential variable becomes insignificant, reflecting the high positive correlation between these variables. The price control dummy also becomes insignificant.[3] We separate manufacturing and non-manufacturing investments in columns 6 and 7, and find that the association between regulation and investment appears to be driven by non-manufacturing investments.

The inclusion of the "spillovers" variable is somewhat problematic. While the theory suggests an important role for inter-firm spillovers, the variable with which we measure spillovers (the number of pharmaceutical establishments in the country) makes it difficult to separately identify spillovers from other motives for investment. If the regulatory regime affects the location choices of firms, this will be influence the number of establishments that previously located in the country. Thus, by controlling for the *existing* number of establishments, we are picking up the effect of the regulatory regime on the *change* in the number of establishments in the country. Since neither the price control variable nor the reference pricing variable vary within countries during our sample (they are fixed over time), it is not surprising that we find no effect of regulation on investment after controlling for the existing number of establishments. As a result, our preferred specifications for interpreting the effects of the time-invariant regulatory variables on investment will be those that exclude the "spillovers" variables. We will then turn to an analysis of time-varying regulatory variables, exploiting policy changes during our sample period to identify the effects of an increase in regulatory stringency on changes in investment choices. In these specifications, we will include the spillovers variables, along with country fixed effects.

Given that investment patterns may differ substantially between Western European countries and locations in Eastern Europe and the Baltic states, we present models estimated separately for these two regions in Table 5. Regulation does not appear to play a role in location decisions in Eastern Europe, while price controls are significantly associated with a 40% reduc-

[3] We do not have data on the spillovers variables for Switzerland, Greece, and Lithuania, which explains why the number of observations are lower in the column that includes spillovers variables. The results associated with the other specifications are practically identical when these countries are omitted, reflecting the relatively small number of investments that take place there during this period (11 in Switzerland, 3 in Greece, and 1 in Lithuania).

tion in the odds of investment in Western European countries (as in the full sample). This distinction may reflect the types of investment taking place in these locations. Indeed, we find that when restricting to Western European countries, the regulatory variables are not significantly related to investment for manufacturing or R&D announcements, but that price controls are associated with a reduction in the odds of other types of investment. The latter types of investment include headquarters, administrative offices, sales offices, logistical and distribution centers, and services to the firm.

There are some additional interesting differences between the different types of investment. The corporate tax rate is strongly negatively associated with manufacturing investments but not the other types, while market potential is positively but insignificantly associated with manufacturing investment. This is perhaps not surprising given that production costs are likely to be the most important determinant of manufacturing locations in this industry, where transport costs are low. What is more suprising is the positive and significant coefficient on market potential for R&D investment. Common language matters for R&D and other investments, reflecting the greater importance of communication barriers in these types of investment relative to manufacturing. The distance between the country of origin and potential destination countries is not significantly related to location choices for manufacturing and R&D investments, but it increases the likelihood of other investments (at the 10% level). This may reflect the establishment of distribution centers and administrative offices associated with distant headquarters. Companies may be able to service neighboring countries from their base, but new facilities are required when expanding in more remote locations.

The specifications presented in Tables 4 and 5 are informative about the general association between price regulation and FDI in European countries. In these specifications, we have controlled for most of the key drivers of location choice. However, it is possible that there are country-specific determinants of location choice that we have omitted and that are correlated with regulatory regimes. In order to guard against this possibility, country fixed effects should be included. However, given that the price control and reference pricing dummies are constant throughout the sample period, it is impossible to measure their coefficients in a specification that includes country fixed effects. However, we are able to exploit other policy changes that took place during the sample period (listed in Table 3). Several countries instituted therapeutic reference pricing regimes or froze prices between

2002 and 2006. The results presented in Table 6 focus on these time-varying regulatory variables, and include country fixed effects. They resemble a "difference in differences" analysis, since we control for country-specific variation in the average level of investment through the country fixed effects, and identify the additional variation in investment that takes place in countries that change their policies relative to countries that do not change their policies.

In these specifications, we do include the spillover variables because we are interested in the change in investment relative to existing levels. We find that countries that instituted therapeutic reference pricing regimes for the first time during the period in question have a 54% lower odds of investment following the policy change than countries that did not change their policies (column 1 of Table 6). Price freezes do not appear to have any relationship with investment. When the data is broken down by type of investment, R&D investments are the only type with a significant coefficient on the therapeutic reference pricing dummy. Most of the country characteristics are insignificant after controlling for country fixed effects, with the exception of the common language dummy, which varies by investor and country and which has a strong positive association with the likelihood of investment. R&D investments are more likely to take place in countries in which more spending on R&D takes place (significant at the 10%) level, but the same is not true for manufacturing investments (in fact, R&D is negatively but insignificantly associated with investment after country effects are included).

To summarize the results discussed above, we find that foreign investors are less likely to locate new investments in countries with explicit price controls than countries with reference pricing regimes or no price regulation. However, this finding is only observed in Western European countries, and appears to be driven by investments in new sales and administrative offices. The latter result may reflect stronger incentives for investments in marketing in countries in which prices are not directly controlled, rather than a strategic action by pharmaceutical firms seeking to send a message to countries with stringent regulatory regimes. When country fixed effects are included, so that we examine the change in investment patterns associated with changes in regulatory policy, we find that new investments significantly reduced in countries that imposed therapeutic reference pricing regimes for the first time after 2002, and that this finding appears to be driven by a reduction in R&D investments.

Why do we observe a significant impact on new R&D investments when country fixed effects are included, but not when they are omitted (Table 5

reports a coefficient on TRP that is negative but significant only at the 10% level)? One possibility is that cross-country variation in investment dominates within-country variation, and that the countries that imposed therapeutic reference pricing regimes for the first time are otherwise attractive destinations for investment. When we include fixed effects, we isolate the impact of policy changes within a country, so that our estimates are no longer confounded by cross-country variation in investment. A related possibility is that country effects control for an omitted time-invariant, country-specific variable that biased our estimates of the regulatory variables towards zero.

The finding that R&D investments are particularly affected by regulatory regimes may at first seem surprising. One might ask why, if firms seek to influence government policy by re-directing investment to countries with more favorable regulatory regimes, they do not do so with manufacturing investments. Manufacturing facilities are less closely tied to the specific science or skill base of a location, and one would expect that firms would incur lower costs in choosing a second-best location for manufacturing. However, the potential impact of locating a new R&D facility may be much greater – much more politically controversial. If governments believe that new R&D facilities contribute more to the tax base and generate greater spillovers for the region than do manufacturing facilities, they may be more sensitive to variations in the location of R&D investment. Thus the potential benefit in terms of political influence associated with the choice of an R&D location may be greater, and this may explain why the effect is mainly observed among R&D investments.

A significant limitation of these findings is that only three countries instituted therapeutic reference pricing during the sample period (Denmark, Germany, and Hungary). Spain began including patented medicince in its reference pricing system in 2007. Once investment data becomes available for 2007, we intend to incorporate it. It would be useful to extend the analysis back in time to examine earlier changes to regulatory regimes, but we do not have data that permits us to do so.

6 Conclusions

This paper examines the relationship bewteen cross-country differences in drug price regulation and the location of biopharmaceutical FDI in Europe. We use a theoretically-grounded location-choice model and data on 294 in-

vestments initiated in 27 European countries between 2002 and 2006 to test the hypothesis that biopharmaceutical companies are less likely to locate new investments in countries with more stringent price regulation. We find that countries with price controls receive fewer new investments, after controlling for other determinants of investment. However, this effect appears to be driven by investments in administrative and sales offices, rather than in manufacturing or R&D facilities. The small number of countries that increased the stringency of price regulation by adding patented medicines to a reference pricing regime during the sample period were approximately 50% less likely to receive an investment after the policy went into effect.

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Data Appendix

AFII data

Data on investments in 27 European countries comes from the Agence francaise des investissements internationaux (France's agency for international investments). It is compiled from press reports on announcements of foreign investments in all sectors in Europe between 2002 and 2006. The dataset contains information on 13,903 investments. It contains information on the date of the announcement, the location of the investment, the activity undertaken (R&D, manufacturing, distribution, administrative, etc.), the identity and country of origin of the investor, and the projected number of jobs created (in some but not all cases).

Country Data

We use data on labor costs, R&D spending, and the number of firms in the pharmaceutical sector from Structural Business Statistics database from Eurostat's Industry, Trade and Services Division. The data are available through 2004. As a result we extrapolate each variable forward to 2006 using data from 2001-2004.

Data on common languages and distances between countries come from CEPII.

Data on corporate taxes come from three sources. The first is the Devereux, M.P., R. Griffith and A. Klemm (2002) database, available from the IFS. This dataset omits information for the new EU members and stops in 2005. We fill in information on statutory tax rates in new EU members in 2003 and 2004 from Finkenzeller and Spengel (2004) (Table 2, page 16). We supplement this data with information from KPMG's Corporate Tax Rate Survey 2006. The latter source provides information for all countries for 2005 and 2006.

Drug price regulation data

Information on regulatory policies by country come from a variety of sources. The starting point was Table 2 of Kyle (2007a). This was supplemented with information on a larger set of European countries and a later time period using the following sources:

Kalo, K, N. Muszbek, J. Bodrogi and J. Bidlo, (2007), "Does therapeutic reference pricing always result in cost-containment? The Hungarian evidence", Health Policy, Volume 80, Issue 3, March 2007, Pages 402-412

Patricia Danzon and Jonathan Ketcham, (2003) "Reference pricing of pharmaceuticals for Medicare: Evidence from Germany, The Netherlands and New Zealand", National Bureau of Economic Research, working paper 10007

Mossiolos, P. et al (eds.) (2004) Regulating pharmaceuticals in Europe: striving for efficiency, equity and quality, Open University Press.

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Karaskevica, J. and E. Tragakes (2001) Health Systems in Transition: Latvia. Copenhagen, WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies.

Jesse M, Habicht J, Aaviksoo A, Koppel A, Irs A, Thomson S. (2004) Health care systems in transition: Estonia. Copenhagen, WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies.

Vladescu, C., S. Radulescu, and V. Olsavsky (2000) Health care systems in transition: Romania. Copenhagen, WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies.

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Office of the U.S. Trade Representative (2005), 2005 National Trade Estimate Report on Foreign Trade Barriers

Figure 1: Manufacturing FDI announcements by country and year, non-pharma and pharma

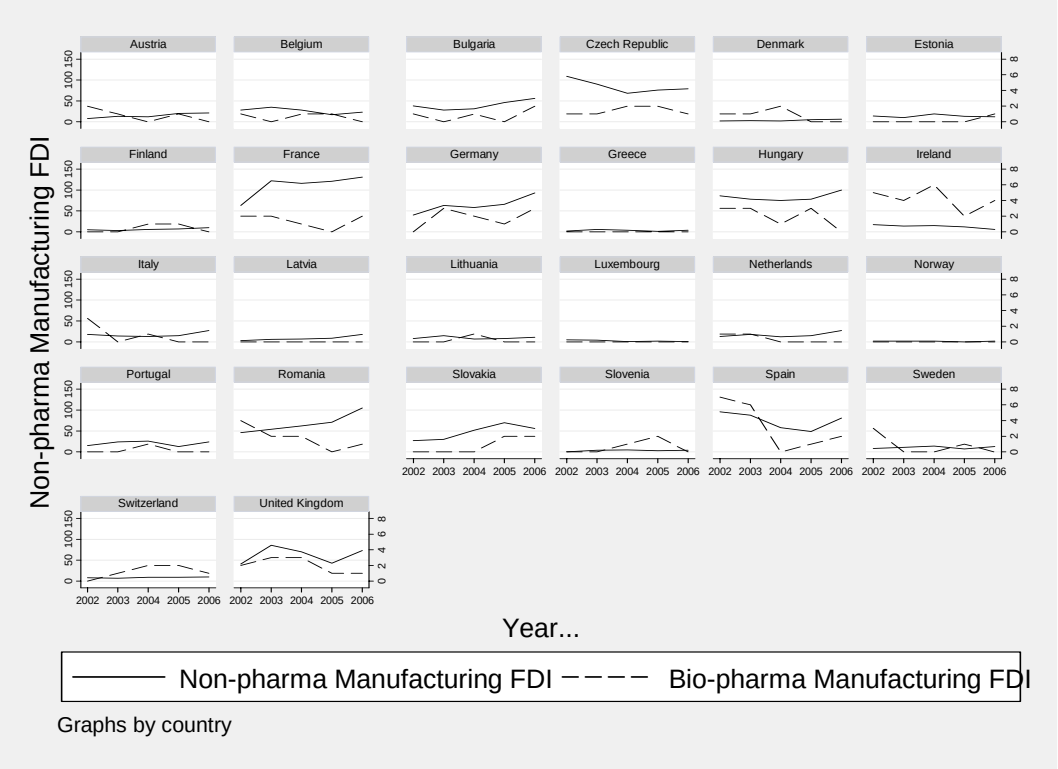

Figure 2: R&D FDI announcements by country and year, non-pharma and pharma

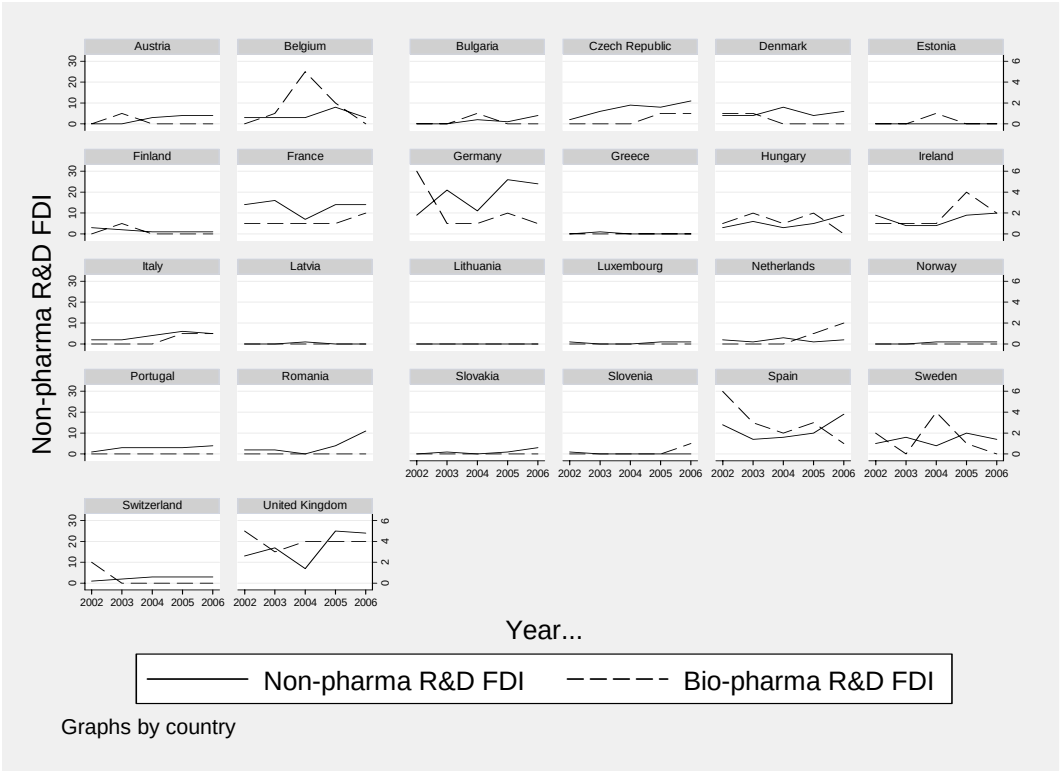

Table 1: Bio-pharmaceutical FDI by country and Year

	Year					
Country	2002	2003	2004	2005	2006	Total
Austria	1	2	0	4	0	7
Belgium	1	2	6	4	1	14
Bulgaria	0	0	1	0	4	5
Switzerland	0	1	3	5	2	11
Czech Republic	1	0	1	1	1	4
Germany	7	6	4	6	11	34
Denmark	3	6	3	2	3	17
Estonia	0	0	2	0	1	3
Spain	12	8	2	3	1	26
Finland	0	1	1	1	0	3
France	5	1	3	7	2	18
UK	7	8	11	14	12	52
Greece	0	1	0	2	0	3
Hungary	3	2	1	3	1	10
Ireland	6	5	8	7	5	31
Italy	1	0	2	2	3	8
Lithuania	0	0	0	0	1	1
Luxembourg	0	0	0	1	0	1
Latvia	0	0	0	0	1	1
Netherlands	0	1	1	2	3	7
Poland	1	2	4	3	1	11
Portugal	1	0	0	3	1	5
Romania	1	0	0	0	0	1
Sweden	4	3	5	5	0	17
Slovenia	0	0	2	0	1	3
Slovakia	0	0	0	0	1	1
Total	54	49	60	75	56	294

Source: AFII database

Table 2: Main regulatory variables used in this study

	Price control	Reference pricing	Therapeutic RP
Austria	Yes	No	No
Belgium	Yes	No	No
Bulgaria	Yes	No	No
Czech	Yes	Yes	Yes
Denmark	No	Yes	Starting in 2005
Estonia	Yes	Yes	No
Finland	Yes	No	No
France	Yes	No	No
Germany	No	Yes	Starting in 2004
Greece	Yes	No	No
Hungary	Yes	Yes	Starting in 2003 for statins
Ireland	Yes	No	No
Italy	Yes	Yes	No
Latvia	Yes	No	No
Lithuania	Yes	Yes	No
Luxembourg	Yes	No	No
Netherlands	No	Yes	Yes
Norway	Yes	Yes	No
Poland	Yes	Yes	No
Portugal	Yes	Yes as of 2003	No
Romania	Yes	Yes	No
Slovakia	Yes	Yes	No
Slovenia	Yes	Yes	No
Spain	Yes	Yes (except 2005-06)	Starting in 2007
Sweden	Yes	Yes	No
Switzerland	Yes	No	No
UK	No	No	No

Source: See Data Appendix

Table 3: Drug Price Policy Changes in Europe, 2002-2007

Price Cuts & Freezes, 2002-2006		
Country	Date	Description
Germany	Oct-03	16 percent reduction in reimbursed prices for patented medicines
Hungary	Apr-04	government froze retail drug prices at 85pc of their previous levels for 180 days
Hungary	Jun-04	Parliament passed an amendment to the Price Act allowing the government to freeze drug prices for up to nine months
UK	Nov-04	7 per cent cut in prescription drug prices after negotiations with the Association of the British Pharmaceutical Industry (ABPI).
Spain	March 2005, March 2006	the Ministry of Health imposed a compulsory 4.2% price cut from March 2005 and a 2% price cut from March 2006 for all products not subject to reference prices and with a price higher than EUR2.
Italy	Approved june 1, effective October 1 2006	The Italian Drug Agency (AIFA) imposed a temporary 5% cut on the price of drugs used by the country's National Health Service (SSN)
Poland	Jul-06	13% price cut for imported products

Changes to Reference Pricing Programs, 2002-2006

Country	Date	Description
Portugal	2003	Adopted reference pricing scheme in which amount reimbursed depends on the price of the least expensive equivalent generic drug available
Hungary	2003	Therapeutic reference pricing for statins
Spain	2004	Reference pricing suspended; price cuts used to compensate
Germany	2004	Included patented medicines in reference pricing scheme
Denmark	2005	Reference pricing scheme shifts from comparisons with cheapest generic drug to comparisons with other European countries.
Spain	2007	Therapeutic reference pricing scheme goes into effect.

Table 4: Baseline results including all countries, types of investment, and investors

Dependent variable: location choice dummy

Estimation method: conditional logit

	(1)	(2)	(3)	(4)	(5)	(6)	(7)
			Full Sample			Manufacturing	Non-manufacturing
price controls	-1.521	-0.880	-0.570	-0.452	-0.286	-0.018	-0.598
	(0.136)***	(0.179)***	(0.187)***	(0.191)**	(0.214)	(0.410)	(0.220)***
reference pricing	-0.388	-0.153	0.249	0.321	0.313	-0.083	0.529
	(0.133)***	(0.144)	(0.155)	(0.178)*	(0.180)*	(0.320)	(0.218)**
Therapeutic RP	-0.503	-0.568	-0.348	-0.329	-0.378	0.450	-0.666
	(0.199)**	(0.201)***	(0.214)	(0.212)	(0.218)*	(0.419)	(0.249)***
ln market potential		0.396	0.272	0.393	0.130	0.213	0.450
		(0.077)***	(0.074)***	(0.104)***	(0.123)	(0.199)	(0.125)***
ln distance			0.136	0.233	0.092	0.260	0.158
			(0.168)	(0.182)	(0.190)	(0.341)	(0.216)
D(common language)			1.159	0.903	0.892	0.654	0.995
			(0.178)***	(0.183)***	(0.191)***	(0.349)*	(0.216)***
Eastern Europe			-0.929	-0.561	-0.224	-0.515	-0.600
			(0.214)***	(0.310)*	(0.350)	(0.557)	(0.386)
Ln unit costs				0.511	0.124	0.562	0.450
				(0.167)***	(0.265)	(0.296)*	(0.206)**
Ln corporate tax rate				-1.103	-1.481	-1.656	-0.638
				(0.298)***	(0.319)***	(0.461)***	(0.398)
ln # firms					0.391		
					(0.102)***		
ln rd expenditure					0.215		
					(0.087)**		
Combined effects of price regulation variables, expressed as odds ratios							
RP + TRP	0.410***	0.486***	0.906	0.993	0.937	1.443	0.872
Observations	7938	7938	7938	7250	6448	1975	5275
Log Likelihood	-909.669	-896.272	-863.446	-824.447	-745.392	-229.344	-581.002
PseudoR2	0.061	0.075	0.109	0.117	0.147	0.098	0.145

Standard errors in parentheses

* significant at 10%; ** significant at 5%; *** significant at 1%

Table 5: Comparing Across Types of Investment

Conditional logit location choice model

	(1) Eastern Europe	(2) Western Europe	(3) W. Europe, Manufacturing	(4) W. Europe, R&D	(5) W. Europe, Other
price controls		-0.496	-0.084	-0.336	-0.879
		(0.204)**	(0.449)	(0.363)	(0.307)***
reference pricing	-0.485	0.426	-0.025	0.591	0.651
	(0.610)	(0.201)**	(0.374)	(0.403)	(0.303)**
Therapeutic RP	1.022	-0.528	0.169	-0.925	-0.838
	(0.653)	(0.238)**	(0.522)	(0.483)*	(0.337)**
corporate tax rate	-0.417	-1.184	-1.864	-1.017	-0.280
	(0.953)	(0.339)***	(0.539)***	(0.709)	(0.604)
ln market potential	-0.343	0.424	0.276	0.612	0.369
	(0.697)	(0.115)***	(0.221)	(0.225)***	(0.175)**
ln distance	-0.695	0.387	0.174	0.285	0.557
	(0.478)	(0.205)*	(0.375)	(0.374)	(0.321)*
Ln unit costs	0.199	0.545	0.479	0.897	0.294
	(0.322)	(0.227)**	(0.427)	(0.491)*	(0.340)
D(common language)		0.938	0.583	1.187	0.977
		(0.190)***	(0.365)	(0.347)***	(0.294)***
Observations	261	4176	1072	1168	1936
Log Likelihood	-59.493	-665.028	-169.625	-175.721	-303.509
PseudoR2	0.066	0.081	0.087	0.132	0.095

Standard errors in parentheses

* significant at 10%; ** significant at 5%; *** significant at 1%

Table 6: Impacts of Policy Changes

"Difference in Difference" analysis of Therapeutic Reference Pricing and Price Freezes

Dependent variable: location choice dummy

Estimation method: conditional logit

Country fixed effects included

	(1)	(2)	(3)	(4)	(5)	(6)
		Full Sample		Manufacturing	R&D	Other
Therapeutic RP	-0.772		-0.696	0.121	-1.979	-0.823
	(0.372)**		(0.376)*	(0.748)	(0.880)**	(0.540)
Price Freeze		-0.327	-0.229	-0.639	0.034	-0.101
		(0.257)	(0.262)	(0.616)	(0.523)	(0.390)
corporate tax rate	-0.001	0.341	0.077	2.229	-3.416	-2.114
	(1.150)	(1.144)	(1.156)	(1.860)	(2.771)	(2.425)
Common language	0.908	0.912	0.912	0.646	1.012	1.128
	(0.200)***	(0.199)***	(0.200)***	(0.372)*	(0.360)***	(0.328)***
ln market potential	0.319	0.099	0.234	-0.167	0.518	0.490
	(0.308)	(0.316)	(0.323)	(0.628)	(0.623)	(0.526)
ln R&D expenditure	-0.007	-0.127	-0.042	-0.165	1.186	-0.128
	(0.250)	(0.241)	(0.250)	(0.411)	(0.684)*	(0.484)
ln distance	0.011	0.023	0.010	0.068	-0.033	-0.032
	(0.191)	(0.191)	(0.191)	(0.368)	(0.354)	(0.292)
Ln unit cost	-0.786	-0.884	-0.730	-0.243	2.552	-1.301
	(0.944)	(0.903)	(0.928)	(1.482)	(2.929)	(1.799)
ln # firms	1.390	1.207	1.478	1.722	1.055	1.758
	(0.610)**	(0.611)**	(0.616)**	(1.219)	(1.185)	(1.055)*
TRP + Freeze (odds ratio)			0.397**	0.595	0.142**	0.397
Observations	6448	6448	6448	1746	1904	2798
Log Likelihood	-721.209	-722.574	-720.825	-190.488	-190.443	-293.316
PseudoR2	0.175	0.173	0.175	0.193	0.261	0.228

Standard errors in parentheses

* significant at 10%; ** significant at 5%; *** significant at 1%

Appendix: Robustness Checks Excluding French Investments

Dependent variable: location choice dummy

Estimation method: conditional logit

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Excluding French-language publications				Excluding France as destination or origin			
		Country FEs	non-mfg	Mfg		Country FEs	non=mfg	mfg
price regulation	-0.420		-0.418	-0.484	-0.286		-0.406	0.172
	(0.230)*		(0.256)	(0.521)	(0.228)		(0.259)	(0.489)
reference price	0.280		0.466	-0.023	0.306		0.530	-0.088
	(0.185)		(0.226)**	(0.339)	(0.216)		(0.267)**	(0.397)
Therapeutic RP	-0.401	-0.768	-0.643	0.095	-0.487	-0.795	-0.652	-0.328
	(0.227)*	(0.395)*	(0.266)**	(0.453)	(0.237)**	(0.411)*	(0.274)**	(0.516)
freeze		-0.209				-0.450		
		(0.272)				(0.288)		
ln market potential	-0.016	0.280	0.134	-0.462	0.172	0.384	0.316	-0.167
	(0.132)	(0.331)	(0.149)	(0.294)	(0.135)	(0.364)	(0.159)**	(0.269)
common language	0.983	1.013	1.033	0.939	0.898	0.911	0.941	0.847
	(0.200)***	(0.212)***	(0.237)***	(0.383)**	(0.208)***	(0.217)***	(0.250)***	(0.396)**
ln distance	0.034	-0.039	-0.050	0.134	0.053	-0.041	0.051	-0.057
	(0.195)	(0.196)	(0.230)	(0.371)	(0.201)	(0.197)	(0.238)	(0.380)
corporate tax rate	-1.320	0.272	-0.921	-1.706	-1.392	0.594	-1.140	-1.533
	(0.330)***	(1.207)	(0.433)**	(0.526)***	(0.347)***	(1.231)	(0.457)**	(0.558)***
lunit	-0.043	-0.891	-0.041	-0.216	0.058	-1.499	0.104	-0.280
	(0.281)	(1.006)	(0.335)	(0.519)	(0.276)	(1.110)	(0.326)	(0.537)
E. Europe	-0.395		-0.405	-0.421	-0.468		-0.504	-0.299
	(0.374)		(0.460)	(0.690)	(0.379)		(0.461)	(0.724)
ln # firms	0.404	1.738	0.340	0.503	0.324	1.966	0.292	0.284
	(0.109)***	(0.643)***	(0.124)***	(0.231)**	(0.115)***	(0.673)***	(0.133)**	(0.231)
ln rd expenditure	0.253	-0.003	0.242	0.320	0.201	-0.115	0.163	0.405
	(0.094)***	(0.259)	(0.107)**	(0.194)*	(0.087)**	(0.273)	(0.095)*	(0.204)**
Observations	6029	6029	4399	1630	5260	5260	3878	1382
Log Likelihood	-692.433	-668.813	-495.207	-185.589	-617.405	-591.735	-443.819	-161.358
PseudoR2	0.153	0.182	0.170	0.158	0.160	0.195	0.181	0.162

Standard errors in parentheses

* significant at 10%; ** significant at 5%; *** significant at 1%