THE IMPACT OF REGULATORY STRINGENCY ON THE FOREIGN DIRECT INVESTMENT OF GLOBAL PHARMACEUTICAL FIRMS

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Abstract
Cross-national regulatory differences in safety, price and intellectual property protection are an inherent feature of the operating environment of the global pharmaceutical firm. Institutional, transaction cost and more recent 'race to the bottom' theories assume that regulation represents a cost to the firm; therefore firms 'vote with their feet' and avoid investment in stringently regulated markets. However, a cross-national empirical study of the FDI levels of 20 firms across 19 markets reveals that regulatory stringency is not related to FDI, and price control stringency is positively related to FDI, when controlling for other market factors. National governments are not powerless in games of regulatory arbitrage, and have in fact developed adaptive strategies to maintain high regulatory standards and FDI simultaneously. Furthermore, global firms weigh various factors in their investment decisions, and suffer from classic optimisation problems, including information asymmetries and bounded rationality, which prevent total 'regulatory optimisation'. The implications for existing theories of international business, globalisation and regulation are discussed.

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1. Introduction: Responses to Regulation

The significance of business responses to regulatory diversity among countries is a topical concern, as well as an empirical quandary. A focus on regulation as a "non-tariff barrier"[1] has begun to enter the theoretical and empirical literature on international business (World Bank, 2000; PhRMA, 2000; Guasch and Hahn, 1999; Hackett, 1998; OECD, 1997). Much of the literature on the topic assumes that firms interpret regulation as a cost; thus they compare regulation cross-nationally in order to invest in the least regulated environments, eventually leading to a 'race to the bottom' in regulatory standards (Drezner, 2001; Drezner, 2000; Gray, 1998; Nivola, 1997; Cerny, 1995; Stopford and Strange, 1991). Yet, is there empirical evidence that international firms respond to regulatory differentials in strategic ways?

This study explored this proposition using pharmaceutical industry data to conduct a cross-national regression and post-hoc qualitative interviews in relation to three types of regulation: safety, price control and intellectual property. It finds that in a stringently-regulated strategic industry, regulation is not related to FDI levels, and price control stringency is positively related to FDI, when controlling for other market factors. Further qualitative interviews reveal that national governments are not powerless in games of regulatory arbitrage, and have in fact developed adaptive strategies to maintain high regulatory standards and FDI simultaneously. Furthermore, global pharmaceutical firms weigh various factors in their investment decisions, and suffer from classic optimisation problems, including information asymmetries and bounded rationality, which prevent total 'regulatory optimisation'.

2. Literature Review: The effects of regulation on trade and FDI

While much of the economic theory of trade and investment developed independently of empirical hypothesis testing, some recent efforts at empiricism have produced relevant results (Leamer and Levinsohn, 1995). Increasingly, empirical insights have challenged and enhanced economic assumptions (Gusinger, 2001; Thompson, 2001; Maskus et al., 2000; Caves, 1996; Rugman, 1980). Empirical testing of these economic theories, as they relate to regulation and institutional factors, roughly fall into two categories, based on the type of international economic activity: empirical explorations of the determinants of trade (namely imports into regulated zones) and empirical explorations of country-level influences on FDI levels and foreign firm location choices.

Regulation and Trade

First, the most developed of these empirical traditions has been econometric and bilateral gravity model studies of the impact of regulation and policy on trade flows. Quantitative econometric studies have included regression analyses of regulation and trade. Swann et al (1996) reported that, when levels of standards were regressed with levels of imports from 1985-1991 in the UK, a positive relationship was noted between standards and imports. Thus, the authors concluded that standards signal quality and increase import demands (Swann et al, 1996).

Additionally, micro-level qualitative studies have produced compelling results. The OECD conducted a study in which it asked 55 firms in telecommunications, dairy products and automotive components industries to assess the extent to which technical regulations and conformity requirements were an impediment to trade (1999). The study reported diverse results for the sectors, with some reporting no influence on trade of technical standards, and others reporting large impediments across a small range of products (Maskus et al, 2000). Most estimated the standards-imposed cost increase in the range of zero to ten percent. Smaller firms reported more difficulties with meeting standards and were more deterred from entering high-stringency markets or those in which the standards were unfamiliar, suggesting that firm-level factors such as size and resources also mediate the impact of regulatory standards on trade (OECD, 1999). When asked about regulatory agencies, most firms advocated harmonisation and some reported that competition among regulatory agencies had lowered regulatory costs to some extent (Maskus et al, 1999).

The United States International Trade Commission undertook a set of interviews with executives, trade associations and regulators in the information technology sector to ascertain the effect of divergent technical safety standards on industry trade. Respondents reported the costs imposed by divergent standards (requiring a logistical challenge in sourcing components), regulatory delays and various labelling requirements as trade barriers affecting the sector (USITC, 1998). Moreover, many firms had in place their own internal quality assurance systems and viewed the proliferation of further standards to be redundant.

Henson et al (2000) also undertook a qualitative study of the costs of developed world food standards to developing country producers. He found that regulatory standards on food imports were ranked as the most significant constraint on trade, above tariffs, quotas and transport costs. Moenius (1999) regressed bilateral trade volumes on countries' numbers of shared standards across 12

countries, and found that a one percent rise in shared standards leads to a 0.32 percent increase in trade. This suggests that more similar standards among countries have a positive effect on trade.

Regulation and foreign direct investment

Trade and foreign direct investment of course differ, both representing alternative methods of entering foreign markets. In times of high tariffs on imports, these activities were commonly substitutes for each other, but more recently the motivation for foreign direct investment has been to create integrated subsidiaries, rather than to partake in import-substituting investment (Cantwell in Pitelis and Sugden, 1991). Subsequently, trade and FDI have been explored as two separate types of international economic activity. Similar to the work done in the trade field, the consideration of the role of regulation in foreign direct investment choice has led to a rich hypothesis base and nascent empirical tradition. Caves, in his seminal survey of theoretical and empirical work in the area, details a comprehensive survey of empirical studies which consider the relationship between regulation or institutional environment and FDI (1996). Several of these studies, documented in Caves' work, deserve specific mention.

Wheeler and Mody (1992) found that foreign direct investment was not necessarily attracted to lower-wage countries. However, when adding other human capital indicators, such as literacy and education levels, some researchers found a positive relationship (Koechlin, 1992). Several researchers have explored bilateral aggregate foreign investment flows through 'gravity models'; in other words, they attempt to explain aggregate investment flows between countries through similarities or differences in the countries' factor endowments. Brainard found, through exploring U.S. investment relationships with other countries, that differences in skilled labour endowments are a deterrent to foreign direct investment, while mutually high national income and population levels have a positive influence (1993). Cantwell and Sanna-Randaccio considered factor endowment levels and aggregate investment among European countries, and found that reciprocal patent holdings were an inducement to bilateral investment (1992).

The potential effects of direct government policy and regulation, rather than traditional factor endowments, on foreign investment have been considered explicitly in several studies. A country's openness to foreign investment and a supportive economic infrastructure have been found to increase FDI (Lecraw, 1984; Wheeler and Mody, 1992; Li and Guisinger, 1992). This includes factors

such as the absence of restrictions on foreign ownership and a favourable macroeconomic climate, as well as special incentives to attract investment.

Political risk, including governmental instability and conflict, has been found to have an ambiguous relationship to FDI (Lecraw, 1984; Wheeler and Mody, 1992). Additionally, recent studies have considered the role of supportive regulation, such as intellectual property protection, as an attractor for investment, and found a positive relationship (Smarzynska, 2002; Park, 2001; Fink, 1999). And others find compelling regulation-specific localisation reasons for firms to partake in FDI, suggesting a positive relationship between regulatory stringency and FDI. Fina and Rugman (1995), in a longitudinal company case study of the Upjohn Company, found that the company invested abroad to avoid barriers to trade, but also to "reduce information costs in dealing with host country regulatory forces" (p.15).

Tannenwald (1997) conducted a comprehensive survey of studies dealing with the relationship between environmental regulatory stringency and economic activity, and reported that most studies find a statistically significant, negative relationship between regulatory stringency and economic activity on the part of firms and industries, including location decisions and employment; yet these estimated effects tend to be small (Duffy-Deno, 1992; Crandall, 1993; McConnell and Schwab, 1990; Bartik, 1989). He suggests that the relationship is due to the increase in production costs induced by regulatory stringency. Additionally, the Tannenwald survey makes several important methodological points, underlining the fact that while measuring regulatory stringency is a difficult practice, there is valuable insight to be gained from progress in this important field. These studies are summarised in Table 1.

A review of the history of empirical studies reveals several traits of the literature. Authors have focused on different country, industry or firm aspects, as well as several different types of regulatory field, including product standards, supportive subsidies and policies, as well as environmental regulation. Notably, import and trade studies tend to allow more time series exploration, due to the availability of this data across multiple years. However, FDI studies contain more strategic importance for governments attempting to attract investment to meet industrial competitiveness goals. There are several areas which would benefit from closer study: a focus on particular strategic industries, and in particular, industry-specific regulations; a focus at firm level, which allows firm-level heterogeneity to be explored; and a focus on well-controlled multiple regressions, which would allow exploration of market and regulatory factors. Thus, due to its strategic importance and the significant

variation in its regulation cross-nationally, the pharmaceutical industry has been chosen as a focus for study.

Table 1. *Empirical Studies of the Relationship Between Regulatory Stringency and Trade or Investment*

Study	Scope	Independent Variable	Dependent Variable	Outcome
Henson et al (2000)	Developing country food firms	Regulatory standards on imports into developed world	Perceptions of relative importance of standards as a trade barrier	Firms rated regulatory standards as more significant barrier than tariffs or transport costs.
Moenius (1999)	12 countries, 1980-1995	Numbers of product standards	Bilateral trade volumes	Common standards among countries increase trade flows.
OECD (1999)	55 firms	Divergent regulatory product standards	Perceptions of cost of standard implementation	Divergent standards affect smaller firms more than larger ones.
USITC (1998)	US firms in telecoms	Divergent regulatory standards	Perceptions of trade barriers	Respondents perceived regulatory differences and delays as trade barriers.
Swann et al (1996)	UK, 1985-1991	Numbers of product standards	Imports	Numbers of standards had a positive, significant effect on imports
Smarzynska (2002)	Transition economies	Intellectual property protection	FDI	IP protection increases FDI.
Tannenwald (1997)	Various	Environmental regulation	FDI	Environmental regulatory stringency deters FDI.
Brainard (1993)	US bilateral FDI relationships	Differences in population, national income and skilled labour	FDI	Similarities in population and national income increase FDI; differences in skilled labour decrease FDI.
Wheeler and Mody (1992)	US firms in 42 countries	Wage levels; good economic infrastructure	FDI	FDI is not attracted to low wage countries; good economic infrastructure increases FDI.
Koechlin (1992)	US firms in OECD countries	Wage levels, education, literacy	FDI	FDI is attracted to low wage countries when controlling for other factors.
Cantwell and Sanna-Randaccio (1992)	EU countries	Reciprocal patent holdings	FDI	Reciprocal patent holdings increase FDI.

3. The Regulation of Pharmaceutical Products

The global pharmaceutical industry exists in a regulatory environment characterised by significant cross-national variation. The regulation of pharmaceutical products has a documented history dating from the 5th century BC, when regulation of Egyptian pharmacopoeias began. However, the guidelines and specifications for clinical trials, proof of safety, intellectual property protection and the regulation of price have their roots in more modern times. Modern regulation began in the late 19th century, when laws and regulations to monitor and license pharmacist standards came into effect in most developed countries (Braithwaite and Drahos, 2000). While certain commonalities have emerged in governments' regulation of the industry, there are still some distinct patterns of regulation among industrialised countries, creating different institutional environments. Table 2 summarises the characteristics of the pharmaceutical regulatory environment across 19 countries, which will be described further in this section.

Table 2. *Summary of Country Pharmaceutical Regulatory Environments*

Country	Price Mechanism	Drug Approval Process Length (Months)	Intellectual Property Protection (Ginarte-Park Index)
Australia	6.0	28.8	3.9
Austria	4.0	33.0	4.2
Belgium	6.0	34.0	3.9
Canada	6.0	25.2	3.2
Denmark	4.0	10.0	3.7
Finland	5.0	36.0	4.2
France	5.0	24.0	4.0
Germany	3.0	30.0	3.9
Greece	6.0	33.0	2.3
Ireland	4.0	13.5	3.0
Italy	7.0	23.0	4.2
Japan	3.0	38.4	3.9
Netherlands	5.0	21.0	4.2
Portugal	5.0	54.0	3.0
Spain	7.0	25.0	4.0
Sweden	5.0	13.0	4.2
Switzerland	3.0	30.0	3.8
UK	5.0	15.0	3.6
USA	1.0	11.7	4.9
Total	4.7	26.2	3.8

Source: EFPIA, 2000; PhRMA, 2000; National regulatory agencies; Kanavos and Mossialos, 1999; Ginarte and Park, 1997.

Note: All values are for the year 1999 except the Intellectual Property Protection Index, which represents the latest-collected data from 1995.

The pharmaceutical industry is naturally a government concern. The industry is considered important from a government policy perspective due to its inherent position in public health programmes and its importance for national growth and competitiveness in a global knowledge-based economy (Govindaraj et al., 2000). Health systems globally are facing a unique set of challenges as drug and other costs rise, populations develop greater expectations for new medicines, and emergent public health and security threats enter the public consciousness. Governments, equally, face changing discourses in industrial policy, with less focus on import substitution and more focus on developing and attracting successful industries for local needs as well as export promotion (Dunning, 1997; Porter, 1990). The pharmaceutical industry finances in the range of 3 to 36 percent of overall pharmaceutical R&D within most countries, and is a significant contributor to overall R&D-based activities within advanced countries (Kanavos, 1999). Additionally, the industry itself can be a valuable source of employment. Thus, in both the health care and industrial policy realms, the pharmaceutical industry and their related products, jobs, and research are significant foci of government policy. The tensions between regulating and promoting the industry are clear, and are one of the main focal points in the study of the relationship between regulation and foreign direct investment.

Most importantly, pharmaceutical firms are rarely simply subject to domestic regulation. Globally minded M&As, joint ventures, research partnerships, licensing agreements and subsidiaries mean that pharmaceutical firm managers increasingly face a plethora of different regulatory requirements and regimes (Dorris and Rosener, 2003). Differences in national regulation as well as attempts to harmonise regulation internationally, both affect and are affected by the globalisation of pharmaceutical firms. Firms are subject to a 'regulatory portfolio', which includes both distinct and harmonised elements across national boundaries. Most significantly, regulation has the ability to constrain or facilitate pharmaceutical business decisions and strategy, and according to the Ernst and Young Life Sciences survey, is one of the primary concerns of pharmaceutical executives as the industry enters the 21st century (2002).

Drug Safety

In most industrialised countries, the systematic regulation of safety procedures and requirements for pharmaceutical product testing and market entry has a recent history (Comanor, 1986). Drug safety and approval regulation, similar to other types of safety regulation, was given impetus partly through high-profile disasters and partly through increasing pressure to regulate new technological advances (Braithewaite and Drahos, 2000). Most drug approval administrations

are set up as federal institutional arms of departments of health, and given statutory powers to regulate and enforce. To illustrate the regulatory stringency of the drug approval process, it is estimated that in the United States, for every 10,000 chemically synthesised chemicals discovered, only one becomes a drug product which obtains market approval (Reuters, 2000). It now takes a company, on average, $500 million or more to bring a drug to market, involving a development and approval time of 7-10 years (Centre for Medicines Research, 1999).

Over the past four decades, drug development times have increased. Safety regulation, in the form of the drug approval process, has now become an institutionalised part of the process of drug discovery and development in industrialised countries. Such processes exist in all major pharmaceutical markets. While the process used to differ considerably among countries, there has been significant harmonisation of technical requirements and procedures in recent years.

Price Control Regulation

Price controls across national borders represent a much more varied picture of regulation, both in the divergence of regulatory norms and in the techniques used to regulate the price of pharmaceutical products (Danzon, 1997). An examination of price control regulation in the pharmaceutical industry globally provides insight into the way in which different regulatory instruments and norms can evolve over time and in different institutional environments, reflecting divergent and changing national health priorities. Interestingly, it is one of the few regulatory fields surrounding pharmaceuticals, which shows significant procedural variation, due to cross-national harmonisation in other realms. Additionally, since pharmaceutical tariffs were lowered or abolished in most developed nations by the WTO in 1994, price control remains as an area of strong government control in a market that has undergone significant trade liberalisation (Dorriss and Rosener, 2003).

Average price levels on pharmaceutical products are available cross-nationally, but would be relatively meaningless as a measure of regulatory stringency in price. The difficulty with comparing prices of pharmaceutical products cross-nationally has been discussed thoroughly in the literature (Danzon, 1999). This is largely due to the fact that different countries have different product class demand profiles and other market factors, which determine price in addition to the regulatory process of price control. National price indexes for pharmaceutical products are often constructed in different, non-comparable ways. Furthermore, the difficulty in using pharmaceutical price comparisons as

an indicator of government price control is also problematic due to the fact that pharmaceutical prices reflect market, economic and political pressures, the separation of which is difficult. Therefore, there was a close examination of the pharmaceutical pricing process as it existed in each of the 19 major markets identified for study. A basis for comparison became evident.

An examination was conducted by reviewing the secondary literature on price regulation mechanisms for pharmaceutical products (CMR, 2002; Kanavos, 2001; Bailey, 2001; Kanavos and Mossialos 1999; Kanavos and Mossialos, 1999b; Danzon, 1999; Gross and Ratner, 1994). Past research had identified many mechanisms used by governments to control pharmaceutical prices, and typologies had been developed (Bailey, 2001; Kanavos, 1999). Kanavos identifies these mechanisms as supply-side measures, proxy-demand side measures and demand-side measures, each of which can influence the system of selling and buying pharmaceuticals and seek to limit price and/or volume of pharmaceuticals sold (1999). Using and cross-checking information from various sources, including trade and industry sources, national regulatory agencies and market research organisations, it was possible to adopt and adapt a previous typology of price control mechanisms to fit the markets under consideration. Variability in the number of mechanisms used by governments became apparent in this typology.

Non-weighted indexes, based on the presence or absence of regulatory mechanisms in a regulatory field, have been used by previous researchers (Botero et al, 2003; LaPorta et. al, 1996; Ginarte and Parke, 1997). Governments, in the case of pharmaceutical price control regulation, use a range of mechanisms to limit prices. The reasons for this vary by country but, in most countries, government is also a purchaser of pharmaceutical products through national health systems or subsidised health provision plans, and therefore has an interest in controlling the cost of pharmaceutical products to the national purse. Notably, in countries with more publicly funded health care systems, governments also have more monopsony power as a purchaser of drug products. A count was constructed by country of the number of price control mechanisms used by governments.

Intellectual Property Protection

Intellectual property protection is the protection of patents. Patents are legal documents describing the rights of a person or entity to use a scientific invention for technological or commercial reasons. The patent operates as a document of ownership over a piece of intellectual property, and cannot be infringed by other agents without a license or purchase (Park, 2001). Usually

ownership of this property is temporary, lasting up to 20 years in most countries, during the course of which time the owner has exclusive rights to commercialise the technology or invention on which the patent is based.

Intellectual property protection is one of the most often-cited areas of regulatory importance to pharmaceutical companies (Europe Economics, 2001). As a supportive regulatory mechanism that protects the property rights of patent owners, the presence or absence of intellectual property protection has often been theoretically positioned as a crucial feature of the regulatory framework. This is based in the economic theories of Schumpeter and North, in which economic growth is assumed to be driven by innovation, which in turn is driven by the existence of property rights (Schumpeter, 1943; North, 1995). In the Northian world, there is no incentive for innovators unless intellectual property rights exist to ensure that they will receive returns to innovation (Europe Economics, 2001). Yet governments vary in the extent to which they protect and enforce patent rights. Studies have found that this variability is largely related to factors such as levels of economic development and measures of economic freedom (Park, 2001).

Due to the pioneering work of Ginarte and Park (1997), an increasingly widely used index of cross-national intellectual property protection is available. Their index is constructed in the following way. The national index scores lie on a scale of 0 to 5, with higher numbers corresponding to higher levels of protection (Park, 2001). Ginarte and Park created the index by reviewing information about patent law and institutional mechanisms related to patent protection for 26 nations. They selected institutional features in which there was considerable variability, due to the fact that many of the nations for which information was available and patent systems existed, contained some of the same institutional features, which add nothing to the index. Similarly, the index is based on 'macro' legal features and is selective using the subset of legal features with the most variability among nations (Park, 2001). It has been used by several other researchers to explore similar questions in relation to other industries (Smarzynska, 2002).

4. Empirical Study

Hypotheses

This study tests the theory that regulatory stringency is negatively related to FDI using a multiple regression model. The main explanatory variables selected for inclusion are the length of the drug approval process, price control regulation and intellectual property protection. Thus, the hypotheses to be explored are:

H_1: Countries with longer drug approval processes will have significantly lower levels of foreign direct investment, all else being equal. In other words, the longer the drug approval process, the lower the level of FDI.

H_2: Countries with higher numbers of price control mechanisms will have significantly lower levels of foreign direct investment, all else being equal. In other words, the more price control mechanisms used, the lower the level of FDI.

H_3: Countries with higher levels of intellectual property protection will have higher levels of foreign direct investment, all else being equal. In other words, the higher the level of intellectual property protection, the higher the level of FDI.

Dependent variable: Foreign direct investment

Foreign direct investment is defined as investment in affiliates outside the country of a firm's headquarters for the purpose of production or market access (UNCTAD, 1999). Currently, over 500,000 foreign affiliates established by over 60,000 parent companies exist in the world. FDI is a growing phenomenon, with employment in foreign affiliates increasing from 30 to 35 billion between 1996 and 1998, and global FDI inflows increasing at an average of 25 percent per year for the past decade (UNCTAD, 1999).

Multinational corporations (here defined as corporations with operations in more than one country), continue to pursue foreign direct investment as a strategy to enter and produce in foreign markets. FDI is equally important to governments as a source of private sector investment and to help achieve industrial and development policy goals. Foreign direct investment usually consists of financing the "establishment, acquisition or expansion of a foreign affiliate" (UNCTAD, 1999, p.14). FDI is reflected in measurements of foreign

affiliate assets, FDI stocks and flows, numbers of employees by a firm in a country, and sometimes equity investments in existing local companies.

Reliable data on disaggregated sectoral foreign direct investment is notoriously sparse. Challenges in government measurement capacity and comparability are rife, including the absence of universal definitions of FDI and limited government data collection. These challenges have been detailed at length by previous researchers (Falzoni, 2000; UNCTAD, 1998). OECD, the European Commission, the IMF and the UN collect data on foreign direct investment, however, none of it is disaggregated to the sectoral level of the pharmaceutical industry. Yet several market intelligence providers such as IMS regularly collect information on how large, in terms of employee numbers, multinational firms' affiliates are within host countries.

Towards the beginning of this study, rich data became available from IMS on multinational firm level presence in many countries. IMS is a market research agency providing intelligence to the pharmaceutical industry. Through an agreement with IMS, data on firm employee levels by country was obtained. No other data source viewed was comparable to the IMS database in terms of level of detail, reliability and comparability. Gathered through a comprehensive annual survey of global pharmaceutical companies, IMS is a market leader in their field and so maintains a high response rate to their surveys, with data available for each of the top twenty companies in my sample.

This study uses the proportion of a firm's global workforce within a country as the dependent variable of interest[2]. The reasons for choosing this proxy were twofold. First, the number of employees by country had been used successfully by other studies as a proxy for FDI (Greenstone, 1998; Keller and Levinson, 1999; Kuemmerle, 1999). This proxy has in fact been noted by several studies to be a more realistic indicator of company commitment to FDI, in particular locations, due to the longer term nature of investment in significant in-country employment. Second, the expanded sample size of a cross-section of the data set (of 20 firms in 19 countries) would perhaps allow for more variation and a strengthened consideration of the hypothesis.

Firm sample selection posed difficulties in that pharmaceutical firms in the global population cluster around very large in size or very small (a trend reinforced by recent consolidations). Therefore, the sample used in this study included as many of the large R&D-based pharmaceutical firms for which reliable data was available. This study attempts to investigate the activities of the largest R&D-based pharmaceutical companies, as their activities represent the majority of the economic activity of the industry itself (see *Sample*). In fact,

the 20 largest firms together account for $308 billion in revenues, or approximately 85 percent of the global revenues for pharmaceutical products. Figure 1 details the average firm FDI for countries in this study. In other words, firms' foreign investment levels in each country were averaged, and firms' investments in their country of headquarters were excluded.

Figure 1. Average Firm FDI by Country

Average Pharmaceutical Firm FDI by Country
(based on top 20 firms globally)
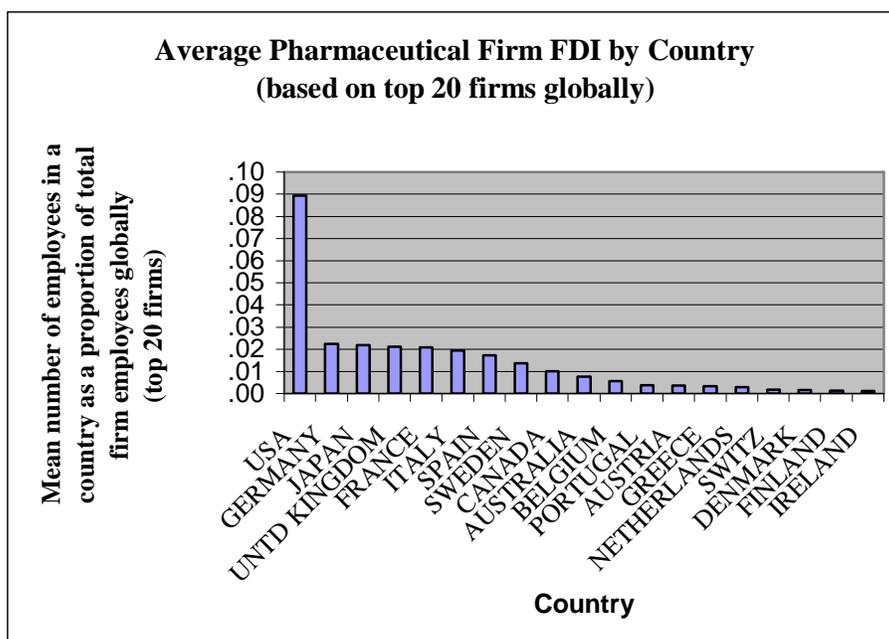
Source: IMS, 2000.

Notes: Employment levels are for the year 1999.
Means represent the average foreign direct investment levels of the top twenty firms in each country. Foreign direct investment by firm is measured by the number of firm employees in a country normalised by the firm's total number of employees. For example, firms place, on average, about 2 percent of their investment in Italy, as proxied by employee numbers. Employment in the firms' country headquarters are excluded from the means (i.e. the US mean includes only non-US firms' employment levels in the US).

The United States attracts more FDI than other countries, on average, with foreign firms installing about 9 percent of their employees in their US subsidiaries. Germany attracts the second largest proportion of company investment, on average, followed by Japan. It should be noted that this indicator can give very little information about the purpose or function of foreign direct investment. In all of these markets, however, according to the IMS database, preliminary testing revealed that nearly all (i.e. 99%) of the foreign direct investments represented fully owned subsidiaries, with virtually no joint ventures. Additionally, though cross-border research partnerships between big pharmaceutical companies and smaller biotechs have become more common in recent years, those types of joint ventures were not represented by this database.

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In other words, most of the investment accounted for in these data represent employment in a wholly-owned subsidiary focused on research, manufacturing, sales or a combination of all three (IMS, 2000).

Independent Variables: Regulatory, Country-Level and Firm-Level Factors

In considering regulatory and other impacts on foreign direct investment, many independent variables could play a role. A review of the theoretical and empirical literature on determinants of FDI was conducted to ascertain independent variables to include in the regression model. The independent variables selected as indicators of regulatory stringency for the purpose of this study are drug approval times, price control regulation and intellectual property protection levels, as described in detail in the previous chapter.

Previous studies and theories identify other independent variables for inclusion in the model. Market size was naturally found to be important in several other studies of new market entry and foreign direct investment (Smarzynska, 2002; Kyle, 2001; UNCTAD, 1999). Actual pharmaceutical market sizes were not freely available for every market in this study, so several proxies were explored, including population, GNI per capita and overall health expenditure per capita by market[3]. GNI per capita had also been confirmed in previous studies of foreign investment decisions to be a reliable indicator of development and market size (UNCTAD, 1999). Other country-level factors suggested or hypothesised in previous literature to be of importance were included, including corporate tax rates, availability of science-skilled labour, and labour costs[4]. Especially due to the fact that proportion of company employees in-country was used as a proxy for FDI, a labour costs index was used in the model to control for other factors affecting employment levels.

Additionally, because the FDI data was at firm-level, a firm dummy variable was included to control for firm-specific effects on differences from mean FDI levels. Table 3 details all variables used in the model, their measures and data sources.

Table 3. *Dependent and Independent Variables*

Variable	Measure	Source
D E P E N D E N T V A R I A B L E		
Foreign direct investment (Firm-level)	proportion of company employees located in a particular country= employees$_{ij}$ / employees$_i$	IMS Health, 1999 (published 2000)
I N D E P E N D E N T V A R I A B L E S		
Country-Level Regulatory Stringency Variables		
Drug approval times	average time from product dossier submission to marketing; national and EMEA	PhRMA, CMR, national drug authorities, 1998/1999
Price control	number of price control mechanisms used by government	Urch, Kanavos, Reuters Business Insight, 1999
Intellectual property protection levels	score on IP index	Ginarte-Park index, 1995
Country-Level Market Variables		
Market Size	population	UNDP, 1999
Level of Development	GNI per capita	UNDP, 1999
Health Spending	government health spending per capita	WHO, 1999
Science Base	number of scientists and engineers in R&D per capita	World Competitiveness Report, 1999
Corporate tax rate	tax rate on corporate profits	national government information, Ernst and Young, 1999
Labour costs	index of hourly labour costs	US Department of Labor, 1999
R&D tax credit	rate of tax subsidies for one US dollar of R&D, large firms (e.g. 1$ of R&D = x of a dollar in tax relief)	OECD, 1999
Market Competition and Health	total number of pharmaceutical and generic firms active in market	IMS Health, 1999
Firm-Level Variables		
Firm dummy variable	0,1	

Notes: i= firm, j= country.
All data are from 1999, except the intellectual property protection index, which was last measured in 1995 and drug safety approval times, some of which were measured in 1998.

Table 4 gives the values of the additional independent variables under consideration in this study.

Table 4. *Values of Country-Level Independent Variables*

Country	Population (millions)	Gross National Income Per Capita	Total Expenditure on Health Per Capita	Scientists Per Capita	Average Corporate Tax Rate on Profit	Index of Hourly Labour Costs	R&D Tax Credit (Proportion of a Dollar per One US Dollar spent)	No. of Firms Active in Market
Australia	19.0	20120.0	2080.0	3357.0	36.0	82.0	.1	105.0
Austria	8.1	25230.0	1919.0	1627.0	34.0	117.2	.1	115.0
Belgium	10.2	25070.0	2122.0	2272.0	40.2	129.5	.0	136.0
Canada	31.0	21720.0	2363.0	2719.0	44.6	86.3	.2	108.0
Denmark	5.3	31770.0	2138.0	3190.0	32.0	125.8	.0	76.0
Finland	5.2	25090.0	1570.0	2799.0	28.0	117.6	.0	72.0
France	59.1	23990.0	2074.0	2659.0	40.0	95.2	.1	197.0
Germany	82.6	25130.0	2382.0	2831.0	53.0	144.3	.0	317.0
Greece	10.6	11730.0	1220.0	773.0	40.0	52.0	.0	100.0
Ireland	3.8	22870.0	1583.0	2319.0	32.0	71.7	.1	95.0
Italy	57.6	20130.0	1712.0	1318.0	37.0	87.2	.0	185.0
Japan	126.3	35420.0	1763.0	4909.0	34.5	97.5	.0	181.0
Netherlands	15.8	25260.0	2056.0	2219.0	35.0	114.2	.1	126.0
Portugal	10.0	11190.0	1217.0	1182.0	37.4	33.3	.2	93.0
Spain	40.0	14760.0	1215.0	1305.0	35.0	63.2	.3	177.0
Sweden	8.9	27420.0	1731.0	3826.0	28.0	115.4	.0	89.0
Switzerland	7.2	39650.0	2861.0	3006.0	31.0	130.4	.0	153.0
UK	59.4	25200.0	1512.0	2448.0	31.0	92.0	.0	198.0
USA	273.1	34370.0	4055.0	3676.0	40.0	99.5	.1	396.0
Total Mean	43.8	24532.6	1977.5	2549.2	36.2	97.6	.1	153.6

Source: OECD, IMS, World Competitiveness Yearbook, WHO.

Sample

Selection of countries

Initially, 220 countries were included in the database on which this study is based. However, this had to be narrowed to a sample of 19, depending on the availability of comprehensive regulatory data on countries. Thus, the dataset comes from a cross-section of 20 firms' employment levels across 19 countries, for a total of 265 data points (representing firm-level instances of FDI by country) after accounting for missing data.

While missing data has the potential to introduce bias into the model, this is only likely if there is a systematic misreporting of data (Chatterjee and Price, 1991)[5]. There were two missing data challenges to be addressed with the dataset; one concerning the country independent variable data and one concerning the firm-level FDI data (which will be discussed in the next section). First, some countries had to be excluded due to the absence of data (or reliable comparable data) on the regulatory independent variables. Inevitably, these were developing country markets in which pharmaceutical products were absent or in which regulatory data was not available or collected.

This could introduce a selection bias into the model if it were generalised to explain all FDI in the pharmaceutical industry. Therefore, this study cannot make generalisations about countries outside the sample, but focuses instead on developed pharmaceutical markets with institutionalised systems of pharmaceutical regulation; in other words, the industrialised, developed nations within North America, Europe, Australia and Japan which constitute a large majority of the existing active pharmaceutical markets. The countries included constitute the geographic locations of approximately 85% of global pharmaceutical sales (as a proportion of total global revenues, which were $370 billion in 1999). Based on calculations derived from IMS, IMF and OECD, the foreign direct investment represented by the firms and countries in the sample represents about 25 percent of pharmaceutical FDI globally (as measured by employee levels).

Selection of Firms

This paper uses the definition of multinational corporation espoused by Rugman and Hodgetts (1995): a firm with production or distribution facilities in more than one country[6]. For companies, the 20 largest global pharmaceutical firms were included in the sample, encompassing 85 percent of the global pharmaceutical market in terms of revenues. This number represented a good

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deal of innovative and sales activity in the industry as a whole, due to the consolidation and concentration inherent in the pharmaceutical sector. As explained by Bottazzi et al (2000), the industry operates from an "oligopolistic core", with the top 20 firms in the world initiating 80 percent of the introductions of new pharmaceutical products onto American and European markets in the 1990s.

Therefore, the sample did not aim to be entirely representative of the total industry, but to capture an important economic activity (FDI) of the most powerful actors. Additionally, because the focus of the study was *foreign* direct investment, firm investment levels in the country in which it is headquartered were excluded (i.e. employment levels by a firm in its own 'home' country were excluded from the database). Missing or ambiguous values were also present in the firm employee data. However, even within this sample, there were some un-reported employee levels by some firms in some countries, which introduces the problem of whether to code these as 'zero investment' or 'missing values'. Scanning the dataset and conferring with the database owners confirmed that the missing values were not systematically misreported or unreported, and it was decided to conservatively code them as 'missing' rather than 'zero', due to the larger potential bias the latter might add to the model.

While random sampling is desirable, it is rarely achievable in social research (King, Keohane and Verba, 1994). In summary, the resulting sample is inherently a representation of the largest markets and the largest global firms. The sampling procedure described above was used due to genuine econometric data limitations, yet every effort has been made to recognise any potential bias this may have introduced. While the policy and regulatory questions at hand are of most concern to countries with large pharmaceutical markets and to large global firms, caution must be applied to generalising the results of this study. The decision not to include developing countries or undeveloped pharmaceutical markets was made for practical reasons, and also to recognise that regulatory competitiveness has largely been a concern of industrialised developed nations. Missing data were dealt with in ways that sought to minimise any potential bias (Chatterjee and Price, 1991). While it was not possible to explore the situation in developing countries or to correct for missing data in this particular study, future studies may have the benefit of improved data sources and availability.

Table 5 details the characteristics of firms included in the sample.

Table 5. *Firm Characteristics*

Company	Firm Revenues (US$ billions)	Firm Size (# employees)	Firm Degree of Globalisation (# countries)	Firm Founding Year	Country of Headquarters
AHP	14	52289	86	1931	USA
Abbott	16	71426	60	1937	USA
Amgen	4	7700	18	1980	USA
AstraZen	16	54600	56	1953	UK
Aventis	20	91729	66	1858	France
BMS	19	46000	48	1887	USA
Bayer	26	116900	29	1863	Germany
Boehringer	6	27980	44	1885	Germany
GSK	30	100000	39	1830	UK
J&J	33	101369	54	1886	USA
Lilly	12	41100	42	1876	USA
Merck	48	78100	32	1930	USA
Novartis	19	68000	64	1860	Switzerland
Pfizer	32	90000	64	1849	USA
Pharmacia	14	59600	60	1886	Sweden
Roche	16	63717	66	1896	Germany
Sanofi Synthelabo	6	30514	100	1973	France
Schering	4	25000	130	1851	Germany
Schering-Plough	10	29850	50	1928	USA
Takeda	8	13248	13	1781	Japan
MEAN	18	58456	56	1892	---

Source: IMS, Hoover's, firm websites.

Notes: All data are from 1999.

Finalising the Model

To test the hypotheses, the following model was estimated:

$$\text{Ln}(emp_{ij}/emp_i) = \beta_0 + \beta_1 \text{DrugApproval}_i + \beta_2 \text{PriceControl}_i + \beta_3 \text{IP Protection}_i + \beta_4 \text{Ln(Pop)}_i + \beta_5 \text{GDPPC}_i + \beta_6 \text{HealthPC}_i + \beta_7 \text{TaxRate} + \beta_8 \text{Science} + \beta_9 \text{LabCosts} + \beta_{10} \text{R\&DTaxCred} + \beta_{10} \text{Compet} + \gamma \text{Firm} + \eta_i$$

Notes

emp= firm employment (number of people); i= firm, j= country; ß= regression coefficient. DrugApproval= National drug approval times; DrugApprovalEMEA= Approval times using EMEA for all European countries; PriceControl= Number of price control mechanisms; IPProtection= Intellectual property protection; Ln (Population)= Log of population; GDPPC= GDP per capita; HealthPC= Health spending per capita; TaxRate= Corporate tax rate on profits; Science= Scientists per capita; LabCosts= Labour Costs; R&DTaxCred= R&D Tax Credit; Compet= Number of pharmaceutical firms in market; Firm= firm dummy variable; η_i= error term.

Results

As detailed in Table 6, the model was estimated, generating an adjusted R^2 of .794. In order to test for the suitability of the model, a Durbin-Watson statistic was computed at 2.104, indicating that the independent variables represented stable and useful predictors of the dependent variable and that the error terms do not display problematic autocorrelation. Multicollinearity was minimal and within acceptable limits. As can be seen in Table 6, the factors that significantly and positively affected foreign direct investment in this model were population, price control and competition (or number of firms in the market). The effect of population was strongest, while price control and competition both showed a slight but consistent positive slope. On the other hand, length of national drug approval processes, intellectual property protection, GDP per capita, health spending per capita and scientists per capita did not have any significant effect on levels of FDI.

Table 6. *Regression Results*

Dependent Variable: Firm-level FDI = Ln (employees $_{ij}$/ total firm employees $_i$)			Coefficient (Standard Error)
HOST COUNTRY FACTORS	Regulatory Factors	Intellectual Property Protection	-.179 (.149)
		Drug Approval Times	.007 (.004)
		Price Control	.185 ** (.061)
	Market Factors	Ln (Population)	1.717 ** (.241)
		GNI Per Capita	.000 (.000)
		Health Spending Per Capita	.000 (.000)
		Corporate Tax Rate	-.013 (.016)
		Scientists Per Capita	.000 (.000)
		Labour Costs Index	.000 (.003)
		R&D Tax Credits Index	.829 (.587)
		Competition (Number of Firms Registered in Market)	.005 ** (.002)
MODEL FIT		Firm Dummy	√
		Adj R^2 Sig N	.794 (.000) 265
		Durbin-Watson	2.104

Notes: Numbers in windows are regression coefficients.
Numbers in parentheses are standard errors.
i= firm, j= country.
* represents $p<.05$ (none); ** represents $p<.01$.

5. Discussion with Insights from Interview Data

Drug approval times

No significant dampening of foreign direct investment seems to be related to longer approval times under the national systems. Post-hoc interviews with industry experts and executives helped to discern some of the potential reasons for this result. They will be discussed in this section in relation to theory and the results of the regression model.

Insignificance of Drug Approval Times

The negative finding in relation to national drug approval times could be due to the fact that, compared to other factors in the context of foreign direct investment decisions, national drug approval times are comparatively unimportant. The possibility of this was borne out in the post-hoc interviews, with several respondents saying that national drug approval times were a small factor compared to others such as market size, and that more firms were relying on regional regulatory comparisons rather than national ones, especially within Europe where there was a significant amount of harmonisation occurring in approval processes. In other words, the reason for the lack of significance of national approval times as a predictor of investment is that these distinctions are becoming obsolete as the regulatory procedure harmonises and centralises. However, different firms' representatives had different views on the importance of drug safety regulation, a finding to be explored further in Section 7. One executive in a UK company explained that regulatory approval times are "extremely important" in foreign direct investment decisions (Senior VP, Global Government Affairs and Public Policy, European pharmaceutical company, 2003).

Another finding was that larger markets have more leverage in their regulatory stringency due to the fact that market size trumps regulation as a factor in investment. As explained by one respondent, "In the US, for example, one would not have expected that time to approval would affect investment. Even if there are delays, it is the biggest market in the world, so companies have about 50 or 60 percent of their overall profits there. So even in the case where drug approval is delayed, which is not the case but this could be the case, one would not have expected significant problems for the countries regarding companies" (Academic Health Economist, UK University, 2003). The superior importance of market size as a factor in investment was borne out by the regression model. In this case, from the regression results, it is clear that multiple factors enter the decision to invest, with drug approval times an insignificant consideration overall.

Additionally, some interview respondents have emphasised that drug approval is the one portion of the regulatory process that is non-negotiable, and is taken as a 'given' in order to achieve market entry. Therefore, in all the main markets, drug safety approval times are not "discriminating factors" on which to base FDI decisions (Director of Global Public Policy, UK pharmaceutical company, 2003). Instead, drug approval times constitute inherent institutionalised features of the market, which are already assumed.

Rather than being a deterrent to investment, some respondents emphasised that the drug safety approval system in a country can serve as an attractor if it is a "high quality" regulatory approval system, giving the company and its products a significant legitimacy benefit. Other researchers have noted that regulation can play this role (Gladwin, 1993). Some firm respondents suggested that more stringent drug approval times can, in certain instances, signal a strong country-level science base, which is an investment-attracting feature.

Past research has suggested that firms make decisions from a starting point of 'bounded rationality', often acting in less than optimal ways (Simon, 1982). While it was considered that perhaps firms do not have enough information about drug approval times for this to be a factor in their investment decisions, interviews disconfirmed this possible explanation. Executives and firm representatives displayed robust knowledge about the drug approval process and length in different countries, with one executive explaining that she keeps a card in her wallet with the length of the approval process for each country in which her firm is considering investments or product launches.

Several industry experts commented that the establishment of the EMEA as a centralised procedure for drug approvals (though still used in conjunction with nationalised procedures) could possibly have been a reason why national approval times no longer have a dampening effect. It is difficult to explore this suggestion without time series data, and there are inherent statistical difficulties in using harmonised data in a cross-national study (allowing little variability). However, according to various sources, the national approval process with mutual recognition is still most widely used among pharmaceutical firms, though the EMEA centralised procedure is expected to become the most widely used in the future (CMR, 2002).

Yet, another possible support to the suggestion that national approval times are not important comes from the empirical decision-making literature, which recognises that it is easier for economic actors to make optimising decisions among few options rather than among many options (Simon, 1982; Cyert and March, 1963). With the establishment of the EMEA and the single currency, perhaps national differences in drug approval times are decreasing in importance within Europe. In other words, regional harmonisation may be levelling potentially competitive regulatory differences nationally. Additionally, cross-regional regulatory comparisons may be easier to make than cross-national comparisons, according to Simon's theory, possibly leading to more optimising behaviour cross-regionally rather than cross-nationally. Although it is impossible to explore within the scope of this study, this possible explanation deserves further research.

Price Control Regulation

The finding of a positive and significant relationship between price control regulatory stringency and foreign direct investment was unexpected, given that it is contrary to the race to the bottom hypothesis, and to the economic logic of the firm as a short term profit-maximising entity. The model was examined thoroughly to ensure that the finding was in fact robust. All post-hoc tests indicated a good fit and substantiation for the relationship. Interviews with industry executives garnered a near unanimous explanation for the positive and significant relationship. According to one expert,

> "the pharmaceutical industry agrees to invest in exchange for political capital in price negotiations" (Health Economist, UK University, 2003).

Interviews revealed that the drug price regulation relationship between industry and regulators is a complex one. In particular, governments and regulators developed bargaining relationships with firms, which included giving firms more leverage on price if the firms would agree to invest in the country. While governments were able to attain their economic development and investment goals in terms of R&D, manufacturing jobs and industrial policy promotion, firms were able to achieve some degree of pricing flexibility in highly price-regulated markets. Specific country examples of these types of relationships will be explored in the next section.

Most respondents in the study viewed these inducements with a certain amount of disdain. One executive explained, "For years, governments have blackmailed us. They won't let a drug on the market or give a good price unless we invest in a manufacturing plant" (Senior VP, Global Government Affairs and Public Policy, European pharmaceutical company, 2003). Additionally, the bargaining relationship involving price and investment was used as a sanction if investment levels decreased. One executive reported having the price of their firm's drugs cut by 5 percent when the firm decided to close a plant in the country in question (Senior VP, Global Government Affairs and Public Policy, European pharmaceutical company, 2003). This type of bargaining was extremely pronounced among European governments.

Furthermore, this process of regulatory bargaining was usually opaque and negotiations were implicit rather than explicit, according to one industry expert:

> "You get perverse incentives. And it is all done with great subtlety. Even verbally, and it would certainly never be written down. The government regulator would say 'You have a very big business, and while we don't assume you would put your investments here, we notice that you don't currently put your investments here. We think it would be a good idea if you would consider some more investment'. They say that as you explain to them what a wonderful new product you have and that you want to commercialise it. Then there is just a disconnect in the discussion and you are expected to understand their meaning. And then you get FDI in places like [Country X] and FDI by coercion if you… could gain leverage in things like technical approval and pricing. Some trading does occur. Only major companies have invested in R&D in [Country Y]. Again, in [Country Y] nobody will respect you and treat you as a serious company if you don't have a manufacturing unit there. The government simply reads off a list of all the other multinational companies who have manufacturing units there. And the companies say 'fair deal'... you have this enormous market, we want to get into it" (Former Director of Global Manufacturing Operations, European pharmaceutical company, 2003).

However, several countries, notably the UK, France and Italy, use very specific formulae to set drug prices, which include levels of in-country investment by firms as an explicit factor (Former Director of Global Manufacturing Operations, European pharmaceutical company, 2003). In France, one executive explained, if a firm built a manufacturing plant, they would receive another 2 percent of profits, and for an R&D facility, another 5 percent (Senior VP, Global Government Affairs and Public Policy, European pharmaceutical company, 2003).

This finding is important for several reasons. First, it negates the view of national governments as powerless to set high levels of price control for fear of losing investment. In fact, governments, in the view of industry players, display high levels of adaptability and shrewdness in balancing industrial policy and regulatory goals, contrary to the race to the bottom hypothesis. Perhaps because governments, especially in European markets, are primary purchasers of drugs, pricing is a crucial domain in which governments have taken significant pre-emptive measures to ensure that they are able to maintain stringent regulatory and industrial policy goals simultaneously. This type of balancing allows them to weigh industrial and pricing policies in the balance in order to

maximise welfare. In the case of the pharmaceutical industry, this fact is borne out by the evidence of the current study.

Second, this finding is important because it revises the economic view of the firm as a pure profit-maximiser, as well as the economic logic by which firms make foreign direct investment decisions. Firms also balance competing goals: pricing flexibility versus purely economically-driven foreign direct investment per se. It appears that firms invest more in highly price-regulated markets in order to 'buy' favourable regulatory outcomes, especially if these markets are also large in size. While it was clear from the regression results that market size is a huge factor in determining investment, it is also clear that foreign direct investment is more than an economic decision made by firms according to pure market size factors; it can also be a bargaining tool in highly price-regulated markets.

Finally, this finding is important because it revises the view of regulation as a purely linear process of regulation-compliance, and supports the process-based view that regulation is a complex negotiating process between regulator and firm. Governments and firms in fact possess bargaining powers and maintain negotiating relationships that are ongoing and in which regulatory outcomes are not necessarily pre-determined by the regulation itself.

Intellectual Property Protection

It was expected that intellectual property protection, as is so often hypothesised, would be a strong positive inducement to invest. However, this relationship was not substantiated in the current study, and quite significant variability was in evidence in terms of how firms' investments were related to IP protection.

Interview respondents gave several reasons for this outcome:

1) high intellectual property protection is assumed as a 'given' in advanced industrialised markets, and therefore is not a discriminating factor;

2) increasing cross-national harmonisation in intellectual property protection (most notably, through TRIPS[7]) means that the advantage in locating in areas of high protection is disappearing;

3) industry looks for a stable, rather than necessarily high, IP environment in which to operate.

Regarding the first two points, it was noticeable that intellectual property protection displayed a lower degree of variability relative to that of the other two regulatory variables. In the main pharmaceutical markets, IP protection is usually assumed. Also, due to the TRIPS agreement, harmonisation of IP protection at high levels is expected to increase, which may be dampening the differential advantage of investing in more highly-protected markets. An alternative interpretation is that regulation may only act as a barrier or inducement to investment when large regulatory disparities exist between countries.

This outcome was, however, also interesting due to the fact that intellectual property protection is a regulatory domain about which the industry exudes a high level of rhetoric. When asked about the potential importance of supportive IP regulation, several executives gave detailed examples of how strengthening intellectual property protection had led to some countries being able to attract more investment, and insisted that it was an important factor in their own investment decisions, although it appeared insignificantly important based on the data used in the current study (Director, European pharmaceutical regulatory advisory body, 2003; Regulatory and Government Affairs Consultant, 2003). However, the possibility that this particular index may not capture the factors of importance to pharmaceutical companies cannot be ignored.

6. Conclusions

This paper explored, through a regression model and qualitative data, hypotheses surrounding the relative importance of several regulatory variables in the foreign direct investment levels of pharmaceutical firms. The results suggest that regulatory stringency does not necessarily act to deter investment, and may in fact act as an inducement as part of a larger bargaining relationship between regulator and firm. The type of regulation, relationships between regulators and firms, and certain types of global and regional regulatory harmonisation dynamics, may act to determine the role that national regulation plays in foreign direct investment.

The implications of this study are threefold. First, at country-level, governments display adaptive strategies aimed at balancing industrial policy and regulatory goals (outlined in Table 7). The results of this study suggest that governments bargain (or can bargain) with companies to achieve their goals in the game of globalisation. Countries are not powerless pawns in a competitive deregulatory game, and do in fact exhibit individual and cooperative strategies that have helped avoid competitive deregulatory dynamics.

Table 7. *Classification of Country Strategies*
   (Country-level strategies in high regulatory stringency/high FDI environments)

	Country Strategy	Strategy Characteristics	Example
1	Leveraging Market Size	Leveraging large population, GDP, or pharmaceutical demand	Japan USA Germany
2	Leveraging Strong Science Base	Offering government R&D support or fostering strong science education and skilled population as an attractor	USA UK Germany Spain
3	Leveraging Low Labour Costs	Using comparative advantage in labour costs	Spain
4	Investment/Regulation Trade-off Approach	Inducing investment (either explicitly or implicitly) as a bargaining tool in regulatory negotiations	France Italy UK
5	International Regulatory Referencing	Setting levels of regulation in partnership with other countries or through imitation to avoid differences that could lead to competitive deregulation, or harmonisation of regulation at high levels of stringency.	US, EU, Japan — ICH process in drug safety regulation EU countries — EMEA, price referencing Germany, Italy, UK — parallel imports as a more stringent price control

Second, there are several implications for theories of regulation and the economic assumptions related to regulation as a *cost*. Certain types of regulatory stringency in a firm's 'regulatory space' are more important than others in foreign direct investment decisions. In the pharmaceutical industry, price control was the most salient regulation, but it was related to *higher* FDI. However, stringent regulation is not always a deterrent and may even induce foreign direct investment. Firms do not always view comparatively stringent regulation as a cost to the firm. In some cases, such as drug safety regulation, stringent regulation can signal a well-developed science base and accepted technical standards, and can afford the firm a significant legitimacy value.

Finally, at firm-level, this study provided evidence that multinational firms view differences in national regulation with a view to 'satisficing', rather than 'optimising' in their foreign direct investment decisions. Multinational firms exhibit classic limitations to optimisation surrounding regulatory stringency, including bounded rationality, information asymmetries, multiple strategies and priorities which keep them from gravitating solely or most heavily to lesser regulated areas.

Notes

[1] Beginning with the GATT (General Agreement on Tariffs and Trade), significant and binding agreements were made among countries to lower tariff barriers; i.e. to lower charges issued on imports of foreign products into countries by foreign firms. Thus, many of the most onerous financial burdens on international trade have been removed, shifting the focus of scholarship to potentially enduring "non-tariff barriers", in other words social and technical regulations and policies that may impede foreign products.

[2] Thus, the numerical representation of this proportion is a number between 0 and 1.

[3] In order to test the reliability of these variables as proxies of market size, they were correlated against the market sizes of those countries for which this data was available. Each was positively and significantly correlated with market size (Population, .952; GDP per capita, .706; GNI per capita, .729; Health Expenditure per capita, .771; all significant at the .01 level).

[4] Several theories suggest factors affecting firm globalisation. Robock and Simmons (1989) suggest the following firm motivations: market seeking, resource seeking, production-efficiency seeking, technology seeking, risk avoiding and counter-competitive threat. European Economics (2000), based on interview and industry experience, suggest that market, resource, and production-efficiency seeking are particularly relevant to the pharmaceutical industry. Thus, independent variables that represent these factors have been included.

[5] If missing data is random, we would expect the addition of the missing data to simply strengthen whatever relationships are found to exist in the model without the missing data included.

[6] "Transnational corporation" and "International corporation" have also been put forward as descriptors for firms with market focus that is not entirely domestic. This thesis treats these terms as equal, however with the understanding that conceptual distinctions have been highlighted by other authors.

[7]   TRIPS, the agreement on Trade-Related Aspects of Intellectual Property Protection, is the agreement signed in 1995 by members of the World Trade Organization (GATT Uruguay Round) to increase protection of intellectual property rights cross-nationally through multilateral trading rules protecting these rights.

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