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# Cross-Border Alliances for Local Market Entry in Pharmaceuticals\*

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## Abstract

Pharmaceuticals are promoted worldwide, and thus international marketing and branding strategies are important. When launching drugs onto the market, there are two choices; launching the drugs directly, or forming marketing alliances to utilize a partner firm's promotional activities. This paper examines the choice of international entry mode by Japanese pharmaceutical firms. Estimation results indicate that firms with smaller product portfolios prefer alliances when intellectual property right protection (IPP) is moderately strong. Because licensed-out and imitation products may cannibalize sales of a firm's own products, when these risks are low, alliances are chosen. We also find that firms with larger portfolios and higher productivity prefer direct launches of high-quality products, implying that marketing activities tend to be internalized when the originator firm's contribution to raising profits becomes more important than that of the partner firm, as the residual rights theory suggests.

**Keywords:** Strategic alliance, Internalization, Entry patterns, Pharmaceuticals

**JEL code:** F23, L24, L65

## 1 Introduction

Pharmaceutical companies supply both domestic and foreign markets, so pharmaceutical products are promoted worldwide. It is often observed that firms supplying foreign markets enter into alliances. An originator firm and a (potential) rival firm sign a contract for marketing and promotion. The rival firm supplies the originator firm's drug under its name, or the firms jointly engage in local clinical trial activities and sell the product together. For example, an HMG-CoA reductase inhibitor developed by Novartis is sold under the name "Lescol" in Canada and the US. In Japan, Novartis and Mitsubishi-Tanabe Pharma jointly undertook clinical trials and sold it under the name of "Lochol." This type of alliance practice has been observed in other industries, such as the automotive and electronics industries.<sup>1</sup> In recent years, there has been concern about

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<sup>1</sup> For example, the Japanese automotive company Subaru sells cars for the Swedish company Volvo in Japan, and the Taiwanese personal computer manufacturer Acer produces its own brand of PC and also supplies Japanese PC makers.

the remarkable surge in the number of international strategic alliances in the global economy and the consequences of such cross-border activities (OECD, 2001).

Alliances can be classified into two types: technology-oriented and market-oriented (Roth01, 2001). While technology-oriented alliances include R&D joint ventures and technology transfer licensing, the activities we focus on here are market-oriented alliances, including regulatory management, marketing, and sales. Pharmaceutical products are advertised and promoted extensively, so marketing and branding strategies are important to raise revenue (Rizzo, 1999). If foreign firms face difficulties establishing their brand names or desire to take advantage of local brand names and distribution channels, while local firms wish to obtain new goods to enrich their product portfolios, the firms form market-oriented alliances to utilize their complementary assets. Then, drug supply patterns can be affected significantly by alliance behavior. Because improving medicinal access is a fundamental priority for people, if entry mode choice matters for supply pattern, it is important to detect impediments and facilitators for international entry modes.

This paper addresses the question of what kinds of factors are significant for the choice between market-oriented alliances (using other firms' brand names and marketing activities) and direct launches (supplying products by their own or through an independent wholesaler) using Japanese pharmaceutical company data. Pharmaceutical entry patterns are an important issue in the literature on the pharmaceutical industry (Scott Morton, 1999; Danzon, Wang and Wang, 2005; Lanjouw, 2005; Kyle, 2006, 2007). We investigate not only entry patterns, but also entry mode choice in detail to provide additional insights into pharmaceutical firm entry strategies. Exploiting detailed drug-level data allows us to discover how decisions on internalization of marketing and branding activities are made not only among firms, but also across drugs and markets. Because entry mode choice is made on product and market base, our approach matches the real unit and the theory of internalization (for example, Ethier and Markusen, 1996). In this study, we empirically examine the modes of drug supply to 40 countries of 91 drugs developed by 28 Japanese firms in 2007.

Previous literature on international strategic alliances is relevant to this paper. Because of recent increases in the numbers of international alliances, several studies such as Chen (2003), Chen, Ishikawa, and Yu (2004), Qiu (2006), and Ishikawa, Morita, and Mukunoki (2008) have examined cases in which manufacturers horizontally competing with each other enter foreign markets using rivals' distribution channels. This horizontal structure, which is different from the vertical structure where manufacturers and retailers are vertically separated, raises important issues in the relationship between entry mode and distribution strategies in the product market. However, the literature on international horizontal alliances, or what we call marketing alliances, is, to our knowledge, limited to theoretical works. Many empirical studies on international alliances deal with technology-oriented alliances and analyze the determinants of the alliances (for example, Fosfuri, 2004). Because the focus of this paper is on the choice between marketing alliances and nonalliance supply strategies, which has not been extensively studied in the literature, our study contributes to the international strategic alliance literature.

Because we address the choice of distribution channel into foreign markets, our study is related to those on foreign market entry mode choice. In the international trade literature, the determinants of the choice between export, licensing, and direct investment have been analyzed (Ethier and Markusen, 1996). In particular, because we regard marketing licensing, comarketing, or copromoting agreements as alliances, our study is closely related to the international licensing literature. HorstMar87 examine the foreign market entry mode choice between licensing and direct investment. This paper applies the framework of Horstmann and Markusen (1987) to consider a similar distribution channel choice: alliance versus direct launch. In the pharmaceutical market,

even if there are affiliates in local markets, drugs can be supplied through alliances. Therefore, the choice between an alliance and direct launch is appropriate. In previous empirical studies on international licensing, the international licensing pattern has been investigated using country-level aggregated data on royalty payments (Smith, 2001; Yang and Maskus, 2001). This paper studies the problem of firms' alliance choices for each product in each market. Thus, as in McCalman (2004), our approach approximates a model illustrating firm behavior. Therefore, our contribution to the licensing literature is to show the relationship between the firms' choice on an alliance and firm-, drug-, and market-specific characteristics, such as product portfolio, drug profitability, and intellectual property protection (IPP).

Various (firm, drug, and market) characteristics are incorporated because these heterogeneities play a central role in determining foreign entry strategy. The trade literature focuses on the role of firm heterogeneity in the decision to serve foreign markets: exporting and investing abroad were studied by Melitz (2003) and Helpman, Melitz and Yeaple (2004), respectively. However, unlike these and technological alliances, marketing alliances have not been extensively empirically examined. In addition to firm heterogeneity, because there are studies examining the relationship between trade and product quality (Schott, 2004; Hummels and Klenow, 2005), characteristics other than firm heterogeneity, such as product and market heterogeneity, have become important focuses. Our empirical specification considers firms' entry choices to be no entry, direct launch, and alliances, and we investigate three types of determinants: firm-specific, drug-specific, and market-specific factors.

From our estimations, we identify the determinants of international strategic alliances. We show the effects of firm characteristics on entry channel: large product portfolios discourage alliances but encourage direct launches. As Kyle (2006, 2007) stated, while licensed-out products may cannibalize sales of their own products, such effects are not severe for firms with small product portfolios. Thus, when such risks are low, alliances are likely to occur. This reveals the importance of considering multiproduct firms' strategies to examine entry modes, while many trade models use a single-product firm framework. Our firm portfolio variable, which is the number of drugs, may also be a proxy for scope economies, because firms with scope economies can maintain a large number of research projects. This implies that scope economies affect direct launches positively. We also find positive effects of scale economies on direct launches. As Henderson and Cockburn (1996) show, scope economies and research productivity are positively related and scale economies are considered to be related to manufacturing productivity, which implies that if firms are productive in research and manufacturing, those firms are capable of running their own distribution. The trade literature focuses on the relationship between foreign entry mode and productivity. For example, Helpman, Melitz and Yeaple (2004) show that most productive firms invest abroad. Our results provide additional findings about the relationship between firm characteristics and foreign entry strategy. Productive firms tend to launch directly.

Because we consider entry mode pattern in each market and product, variations in our data can help to identify the kinds of determinants, in addition to firm heterogeneity, that are significant for market entry strategy. The positive determinant of alliances is the strength of IPP, which is consistent with studies showing that trade and IPP are positively related (Smith, 2001; Yang and Maskus, 2001). Furthermore, our results indicate that moderate IPP encourages alliances most strongly, which McCalman (2004) found by using Hollywood film studio data. The likelihood of alliance behavior is nonmonotonic with respect to IPP in intellectual property intensive industries: IPP that is too weak or too strong may discourage alliances. As long as IPP is moderate, the risk of imitation is sufficiently low and thus alliances are chosen. On the other hand, in a stronger IPP country, alliances are unlikely to occur. For product characteristics, the positive determinant of

direct launch is the size of the world market for the drug that can be a proxy for drug quality in terms of profitability. Previous literature shows that high-income countries export high-quality goods (Schott, 2004; Hummels and Klenow, 2005). Our result implies that high- rather than low-quality goods are supplied through direct launches. We can consider that when the productivity of originator firms, protection of intellectual property rights, and quality of drugs are high, the contribution of the originator firm to raising profits is high. Thus, local marketing activities tend to be internalized when the originator firm's position is important, which is consistent with the residual rights theory (Grossman and Hart, 1986; Hart and Moore, 1990).

Our results also provide findings consistent with the theories of the licensing literature: innovations capturing large markets are more likely to be supplied by the originators (Katz and Shapiro, 1985), and products with less uncertain sales volumes are likely to be licensed (Rockett, 1990). Although our conceptual and empirical frameworks are not directly based on these licensing models, our study provides additional empirical insights into the determinants of licensing transactions.

As we mentioned, this study considers marketing licensing as an alliance. With respect to marketing or sales strategies, the role of local distribution sectors has been investigated in the trade literature (for example, by Richardson, 2004). However, this paper does not deal with structures where manufacturers and retailers are vertically separated. Rather, it focuses on cases where manufacturers use a rival's distribution channel or brand name to enter the market. In this sense, our study differs from the retail contract literature (see, for example, Lafontaine and Slade, 1997). Therefore, our empirical findings are complementary to those of the empirical studies of franchise.

This paper is organized as follows. In Section 2, we introduce the data set, and in Section 3, we demonstrate firm behavior in the choice between direct launches and marketing alliances and specify our empirical framework. Then we report our estimation results and discuss the implications in Section 4. The final section concludes.

## 2 Data

The data source we use in this study is *Pharmaprojects* by Informa. This data source includes about 40,000 drug data developed worldwide. The data are recorded by the following categories: drugs, companies, and therapies. The data file contains detailed information on drugs. Hence, we can ascertain, for example, the originator, whether the drug is licensed and country where the drug has been launched. *Pharmaprojects* uses the therapy classification code of the European Pharmaceutical Market Research Association, which has 17 broad and 218 narrow classifications. For example, one broad classification is "A: Alimentary/Metabolic products" and "A1A: stomatological" is a narrow class. In addition, the data include the current status of drugs in 40 countries in 2007. Examples are "pre-clinical", "phase I", "launched", and "suspended." The status we focus on in this paper is "launched", because our focus is on market entry strategies, not on technological development strategies. In the previous literature, Kyle (2006, 2007) use *Pharmaprojects* data to analyze the determinants of drug launches and examine the effect of price regulations and firm-specific characteristics.

This paper uses data from Japanese pharmaceutical companies. We selected the firms that launched new drugs on a market between 1997 and 2007. We then identify the market in which a drug has been launched and the therapy for which it is intended. Hence, we constructed a drug-country pair and considered each pair as a unit of the sample. Our source of financial data is

the *Japan Company Handbook 2007*, published by Toyo Keizai. This data publication also contains R&D expenditures, which are considered less noisy than accounting for R&D input data (for example, Branstetter (2006) uses this data source). After omitting firms without R&D data from the sample, 28 sample firms with 91 launched drugs remained. Thus, the number of units in the sample is  $91 \text{ drugs} \times 40 \text{ countries} = 3640$ . The sample drugs fall into 48 therapeutic classes according to narrow classification.

To ascertain whether a particular drug is supplied through a marketing alliance in a particular country, we checked the data file on each drug. As mentioned previously, the file contains information on the status of drugs. If the data file reports that the drug is supplied by companies other than the originator firm in a country where the drug's status is "launched", we consider it launched by a marketing alliance. In addition, if a comarketing or copromotion agreement is recorded, we also regard this as a marketing alliance. If the drug is licensed for worldwide marketing, we consider it launched by an alliance. An exception is in markets where there is a special note such as "excluding ASEAN countries." Because we use the updated data file from 2007, we may consider a case a marketing alliance when licensing occurred at a clinical stage before 2007, the firms passed clinical trials, and then sold the drug jointly in 2007. Therefore, our sample data may include a broader class of alliance. We also treat an entry mode as an alliance when firms not only launch a drug on their own, but also form alliances to supply the same drug in the market, a practice which is called second sourcing (for example, see Choi and Davidson, 2004).

On the other hand, we consider a direct launch as one where the drug is launched but there is no mention of an alliance in the data file. Thus, direct launch means that the originator firm neither collaborates with other firms' marketing efforts, nor uses other firms' brand names. In other words, marketing and branding activities are internalized by the originator firm. This construction of the direct launch variable may make the likelihood of direct launches in our analysis a conservative assessment. We cannot distinguish the case in which the originator uses its own distribution network and that in which it supplies its drugs through an independent wholesaler or retailer. Hence, we consider both cases as direct launches, because the brand name is the originator firm's name and partner firms' marketing activities are not involved. There might be bias in the sample when the publisher does not report an alliance agreement, even though one exists.

We use variables associated with markets and drugs to control for these characteristics. Table 1 reports summary statistics. The market variables are population, GDP (from the World Development Indicators Database), an IPP measure (from Park and Wagh, 2002), the number of drugs in the same class in a country ("Same Class in a Country"), and the number of local pharmaceutical firms ("Local Firms"). IPP measure is an index of each country's strength of IPP, which ranges from 0 (lowest protection) to 5 (highest protection). The average score of sample countries is 3.69. As in the previous literature on the relationship between IPP and cross-border transactions, this variable is a key factor in investigating whether strong IPP affects firm entry mode. The number of drugs in the same therapy class in a country indicates the characteristics of local patterns of health and disease and the local regulatory regime. The presence of many drugs may reflect local demand patterns for particular diseases. The Local Firms variable is the number of pharmaceutical companies in a country, which may reflect imitation opportunities and local competition. On average, there are 12.7 pharmaceutical firms in each country.

With respect to drug characteristics, "World Competitors" is the number of companies producing drugs in the same therapy class anywhere in the world. Thus, these data do not show variation across firms, but rather across drugs. It shows potential competitive pressure globally. With respect to firm characteristics, "Drugs Each Firm" is the number of drugs with which a firm

**Table 1: Summary Statistics**

	Mean	Standard Deviation	Max	Min
Population (thousands)	106,355.9	260,888.3	1,311,798	462
GDP (mil. USD)	1,085,523	2,152,976	13,201,819	41,382
IPP	3.69	0.71	5	2.18
Same Class in a Country	6.432	5.295	33	0
Local Firms	12.7	31.537	192	0
World Competitors	257.987	196.287	1129	29
Drugs Each Firm	248.319	181.978	546	9
Drugs Active	35.758	26.475	75	0

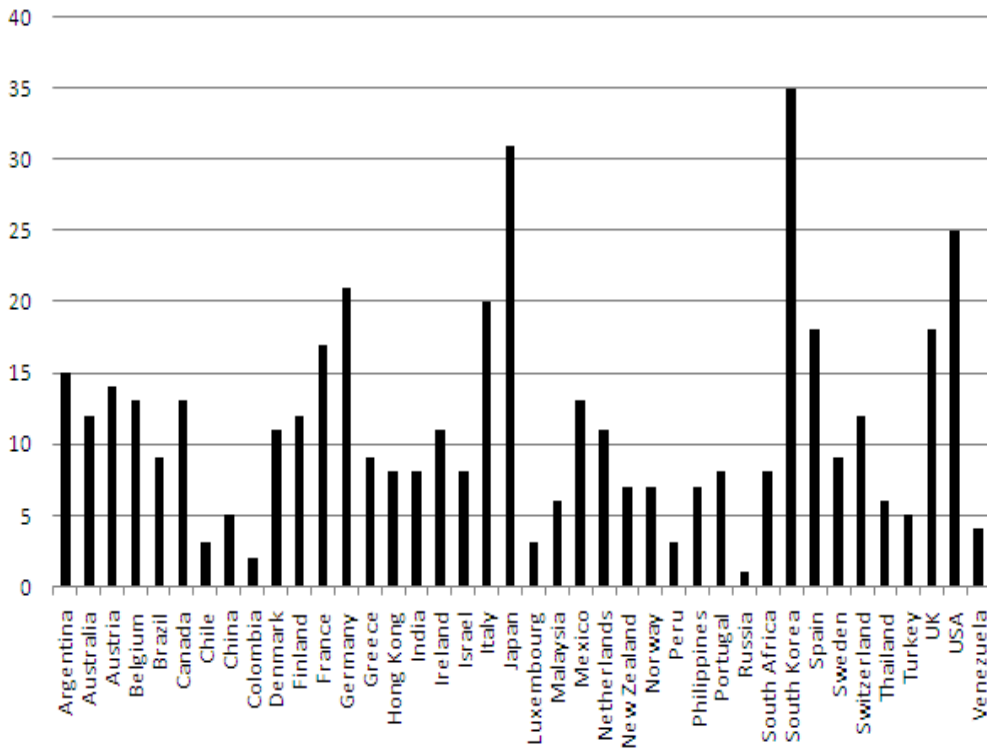
Number of Countries = 40  
Number of Drugs = 91  
Number of Firms = 28  
Sample Size (Country–Drug pairs) = 3640

is associated (including developing, licensing, launching, and even suspended), indicating the product portfolio or scope economies of firms. The number of drugs can be a proxy for firm portfolio size, as Kyle (2006, 2007) suggests. Firms with large portfolios tend not to license out their products, because licensed-out products compete with other products of their own. This variable may also be a proxy for scope economies, because firms with scope economies can run multiple research projects to develop a large number of drugs. On the other hand, “Drugs Active” is the number of active drugs of each firm, where active drugs mean drugs under development or expected to be launched on a market. Thus, drugs that are currently supplied in markets but not scheduled to be launched in new markets are not considered active. Because there are two firms that did not have active drugs in 2007, the minimum value is 0. Although we use Drugs Each Firm for the analysis, the correlation between Drugs Each Firm and Drugs Active is high at 0.883.

Our empirical analysis examines the firm entry pattern in each market. Figure 1 shows the number of alliances by our sample firms in each market. Because many drugs are supplied through alliances in several countries, the number of alliances is larger than that of drugs in our sample. While we can see that the number of alliances is large in Germany, Japan, Korea, and the US, alliances occur all over the world. In addition to the characteristics considered above, it is interesting to take partner firms’ characteristics into account. However, it is difficult to collect data on local partner firm characteristics. Moreover, because such data vary only over alliances, it is not possible to use these data to examine the choice between alliances and direct launches. Therefore, we explore market-, product-, and originator-specific data variations in this study.

### 3 Model

In this section, we introduce a simple conceptual framework for alliances and establish the empirical specifications.



**Figure 1: The number of drugs supplied by alliances among sample firms in each country**

### 3.1 Marketing Alliance

This study treats each drug–country pair as a sample unit and examines the firm strategies of each local market entry. There are basically three choices for originator firms: no launch, direct launch, and an alliance. The choice problem is formulated as the choice among these three alternatives. Because we do not consider technology licensing, but consider alliances including distribution activities such as promotion and marketing, we apply a simplified version of the Horstmann and Markusen (1987) framework, in which the choice between direct investment and licensing to enter a foreign market is examined.

Consider the case in which an originator firm (licensor) has a new drug and seeks to launch it in a market. The available channels for a firm to enter the market are either launching it independently (direct launch) or finding a partner firm (licensee) to form an alliance to sell the drug. Assume that when firms negotiate an alliance, the originator firm that owns the intellectual property has all the bargaining power and makes a take-it-or-leave-it offer. Therefore, we consider the decision to form an alliance to be made by the originator.

The payoffs of each entry mode are as follows. When the originator decides to launch directly, the per-period profit is expressed by  $\pi$ . On the other hand, when an alliance occurs, if the licensing fee is  $S$ , the profit for the partner firm is  $\pi^A - S$ , where  $\pi^A$  is gross profit. We consider that this licensing fee is paid per period, so if the contract continues, the partner firm pays  $S$  in each period. We assume that if the partner firm's assets (e.g., local marketing and brand names) are more important than the originator firm's in raising profits, then  $\pi < \pi^A$  holds. On the other hand, if the originator firm's assets (e.g., drug quality) are more important,  $\pi > \pi^A$  holds.



Because alliances and licensing agreements do not perfectly cover intellectual property rights, we assume that a partner firm can produce an imitation product at low cost. If the partner firm does so, the partner firm's profit is  $\pi^C - S$ , where  $\pi^A < \pi^C$ . However, in this case we assume that the alliance is terminated in the next period and the partner firm will obtain zero profit thereafter because of the inaccessibility of the intellectual property. If the partner firm does not produce an imitation good, the alliance contract continues forever. Therefore, the incentive compatible condition for the partner to remain in the alliance is:

$$\frac{\pi^C - S}{1+r} \leq \frac{\pi^A - S}{r}, \quad (1)$$

where  $r$  is the discount rate.

In equilibrium, if the direct launch profit  $\pi$  is sufficiently low, an alliance occurs. The equilibrium licensing fee is  $S^* = (1+r)\pi^A - r\pi^C$  from Inequality (1). In this case, the originator firm obtains  $S^*$ . Therefore, the choice among no launch, direct launch, and an alliance depends on the following relationship: if  $\pi > S^*$  and  $0$ , direct launch is chosen, if  $S^* > \pi$  and  $0$ , an alliance is chosen, and if  $0 > \pi$  and  $S^*$ , no launch is chosen. Note that if the originator firm's assets are more important than the partner firm's, i.e.,  $\pi > \pi^A$ , then  $S^* < \pi$  holds.

The payoff from each choice is a function of the revenues and costs from the local market. Therefore, the factors affecting profits have an impact on the choice of mode. In the empirical specification section, we consider several factors of each company-, product-, and market-specific characteristic affecting entry mode choice. Here we present typical empirical hypotheses associated with company, drug, and country characteristics. The first hypothesis is related to company characteristics.

**Hypothesis 1.** *If a firm has a large product portfolio, the likelihood of an alliance is low and that of a direct launch is high.*

If firms with large portfolios license out their products, the risk that these products cannibalize own products is high. That is, the net profits from alliance is  $S^* - (\text{forgone profits because of cannibalization})$ . The magnitude of cannibalized profits is large for large portfolio firms, thus  $S^* - (\text{forgone profits because of cannibalization})$  is low. Hence, the profits from launching the drug by itself ( $\pi$ ) are likely to exceed those from an alliance. This hypothesis deals with the perspectives inherent in multiproduct firms. The validity of this hypothesis sheds light on the importance of involving a multiproduct firm to examine entry strategies. This firm characteristic is also related to productivity and is a central issue in examining the link between productivity and entry modes. The second hypothesis is related to drug characteristics.

**Hypothesis 2.** *If a drug can capture a large market, a direct launch tends to be chosen.*

If a drug can capture a large market, it means that drug quality in terms of profitability is high. Therefore, the originator firm's asset is important. Then the profits from a direct launch ( $\pi$ ) are greater than those of the partner firm ( $\pi^A$ ). In this case, a direct launch is chosen. This is consistent with the residual rights theory view that residual rights should be allocated to the party whose assets are most important (Grossman and Hart, 1986; Hart and Moore, 1990). For multiproduct firms, entry patterns may differ across products. However, this type of hypothesis has not been examined empirically because of data limitations; firm-level data do not usually contains

product-level data. In this study, data on both firm-specific and product-specific factors are available, so the product-specific effect can be identified separately. Finally, the third hypothesis is related to country characteristics.

**Hypothesis 3.** *If IPP is severe, an alliance is likely to be chosen. In addition, moderate IPP most strongly encourages alliances.*

The positive IPP effect on the probability of an alliance exists because the imitation cost of the partner firm is high; therefore, the partner has lower profits (low  $\pi^C$ ) and thus has less incentive to imitate. This makes  $S^*$  large, so an alliance tends to be chosen. Moreover, the relationship between IPP and alliances can be nonlinear, as McCalman (2004) considered. This means that as long as IPP is moderately strong, the risk of imitation is sufficiently low and alliances are chosen. However, it is possible that alliances are less likely to be chosen when IPP is stronger. As discussed by McCalman (2004), in strong IPP countries, the originator firm's contribution to raising revenues is high, because the innovations are highly protected. Because residual rights should be allocated to a party that contributes most to the value of a relationship, it is less crucial to provide residual rights to local firms that conduct marketing alliance-specific investment. This corresponds to the case that direct launch profits ( $\pi$ ) are greater than the partner firm's profits under an alliance ( $\pi^A$ ). In such a case, alliances are unlikely to be chosen in stronger IPP countries, because alliances allocate more residual rights to the partner firm than direct launches do. The empirical model takes this aspect into account with the quadratic term of the IPP measure. Below, we introduce other factors affecting these alliance and direct launch choices.

### 3.2 Empirical Specification

To estimate the probability of the firm choosing an alliance, we specify the payoffs in the linear form as follows:

$$\begin{aligned} S^* &= \beta^a X + e_a \\ \pi &= \beta^d X + e_d, \end{aligned}$$

where  $X$  represents the factors affecting the payoffs,  $\beta^a$  and  $\beta^d$  are the coefficients specific to each choice,  $e_a$  and  $e_d$  are error terms, and  $a$  corresponds to an alliance and  $d$  to a direct launch. By assuming that the distribution of error terms is an extreme distribution, we can express the choice probability in multinomial logit form:

$$Pr(m) = \exp(\beta^m X) / \sum_{m'} \exp(\beta^{m'} X), m, m' = n, a, d,$$

where  $m$  shows choice and  $n$  corresponds to no launch. The coefficients depict the relative effect from the base choice: no launch.

The estimation specification of  $\beta^m X$  for firm  $k$ , drug  $i$ , and country  $c$  is:

$$\begin{aligned} \beta^m X_{kic} &= \beta_0^m + \beta_1^m \text{Distance}_c + \beta_2^m \text{Subsidiary}_k + \beta_3^m \text{Portfolio}_k + \beta_4^m \text{Scale Econ}_k + \beta_5^m \text{R\&DINT}_k \\ &+ \beta_6^m \text{Size}_k + \beta_7^m \text{Drug Age}_i + \beta_8^m \text{World Market Size}_i + \beta_9^m \text{World Comp}_i + \beta_{10}^m \text{Pop}_c + \beta_{11}^m \text{GDP}_c \\ &+ \beta_{12}^m \text{Other Class Drugs}_{ic} + \beta_{13}^m \text{IPP}_c + \beta_{14}^m \text{IPP}_c^2 + \beta_{15}^m \text{Local Firms}_c + \gamma^m W_{ic} + e_m. \end{aligned}$$

We use the variables associated with company, drug, and country characteristics. The covariates considered in the international trade literature are also included. Table 2 shows the list of covariates and the predicted signs.

**Table 2: Variables and Predictions**

Variables	Direct Launch	Alliance
Distance: distance from Japan	–	–
Subsidiary: presence of a subsidiary in a country	+	+
Portfolio: number of drugs associated with each firm	+	–
Scale Econ: total sales	+	–
R&DINT: R&D intensity (R&D divided by total assets)	+	?
Size: number of employees	?	?
Drug Age: years since first launch	+	+
World Market Size: worldwide drug sales calculated by Informa	+	–
World Comp: number of competitors (firms) in the same broad, but different narrow therapy class	–	?
Pop: population in 2006	+	+
GDP: per capita GDP in 2006	+	+
Other Class Drug: the number of drugs in the other therapy classes in the country	?	?
IPP: IPP measure by Park and Wagh (2002)	?	+
IPP2: IPP squared (McCalman (2004))	+	–
Local Firms: the number of local firms with at least one launched drug in the same country	–	?

We use distance to control for trade and management costs, a decision inspired by gravity models (see for example, Disdier and Head, 2008). This will have a negative effect on both direct launches and alliances. The distance is the Great Circle distance between capital cities. The index of the presence of a foreign subsidiary is used to control for the effect of local base on not only direct launches but also alliances. This is because the presence of a local subsidiary may affect the bargaining process of alliances; therefore, it may raise direct launch profit,  $\pi$ , and licensing fee,  $S^*$ . It is expected to affect both direct launches and alliances positively. This index takes the value of 1 if there are foreign affiliates in a country and 0 otherwise.

Portfolio is the number of drugs the firm has been associated with. As described in Hypothesis 1, we are able to identify whether product portfolio affects entry mode choice. We also incorporate Scale Econ to capture scale economies by using total sales. These economies make their own costs low and profits ( $\pi$ ) high, implying a positive effect on direct launch. In the pharmaceutical industry, R&D is considered a major source of competitive edge. The variable R&DINT is R&D intensity of a firm, which enables us to examine the effect of innovation on entry mode. R&D intensity may increase profits ( $\pi$ ), thus implying a positive effect on direct

launches. However, the effect on alliances is ambiguous. We used the number of employees to control for firm size. Firm size may have a positive or negative impact on entry mode choice. As Fosfuri (2004) has shown, large firms are unlikely to sign licensing contracts, because they tend to have a distribution sector. On the other hand, as Gallini (1984) and Kim (2004) have shown, large firms may use alliances to keep a dominant position in a market, or large firms can form alliances. This is because they are not threatened by alliances, due to their dominant position. Note that several chemical and food companies have large numbers of employees, so we include a chemical and food firm dummy to take those firm characteristics into account.

For drug characteristics, Drug Age is the year since a drug was first launched, which controls for the market perception of drugs. The greater Drug Age is, the less uncertainty there is in drug sales. Therefore, because the profits rise, Drug Age will have positive impact on both direct launch and alliance. World Market Size, as mentioned in Hypothesis 2, is the index of total world sales estimated by Informa taking a value from 1 (minimum) to 5 (maximum), which controls for the market potential of each drug. This is a proxy for drug quality in terms of profitability. World Comp represents the number of pharmaceutical firms in the world that produce drugs in the same broad therapy class. To control for endogeneity of the number of competitors, we exclude the number of companies that produce drugs in the same narrow therapy class from the number of firms producing the same broad class. That is, we use the number of firms producing different narrow but same broad therapy class drugs, except for cases where such data are not available. This is considered competitive pressure in the world market, therefore decreasing profits has a negative effect on entry predictions. Because alliances can be used to mitigate competitive pressure, the sign for alliance is ambiguous.

Pop is the population and GDP is per-capita gross domestic product. These variables capture a country's general characteristics on the demand side. Firms are likely to enter large markets. Other Class Drug is the number of drugs in other therapy classes in each country. This can be a proxy for local patterns of health and disease and local regulations. A particular health and disease pattern may create demand for drugs, and regulatory regimes affect the availability of drugs in each country. As Kyle (2007) shows, a country's adoption of a price control policy affects entry decision significantly. Because in those data there is a correlation between the price control index and other country-specific variables, and data on price control are not available for all 40 countries, including price control creates a multicollinearity problem and a reduction in sample size. A similar problem occurs with country dummies. Therefore, we include region dummies instead to consider market-specific effects common within each region. It emerges that, because it is difficult to create a proper measure of regulations, we consider Other Class Drug a control for these country-specific health and regulatory effects. Using the number of drugs in the same therapy class may create an endogeneity problem; therefore, we use the number of other therapy class drugs in the estimations. Because this is merely a control variable, we do not assign a particular interpretation to the results.

We also examine IPP, as described in Hypothesis 3, and local market imitation opportunities. IPP is the IPP measure developed by Park and Wagh (2002). IPP is expected to have a positive effect on alliances. To consider the nonlinear relationship between IPP and cross-border transactions, the quadratic term for IPP is used and is expected to have negative coefficient for alliances. Local Firms is the number of local pharmaceutical firms. This may show imitation opportunities in a local market. Imitation opportunities discourage alliances. This variable may also capture local competitive pressure and entry barriers in local markets. As we mentioned above, because we do not use regulation measures directly in the estimations, the significance of this variable and Other Class Drug is important. Finally, the variables in  $W$  are dummies. We use a

Japan dummy to control for Japanese market-specific effects and region dummies (North America, South America, Europe) to control for market-specific effects common within each region; we use broad class therapy dummies to control for therapy-specific effects. Because of the multicollinearity problem, we do not use all therapy dummies.

## 4 Estimation Results

In this section, we report our estimation results and discuss the implications for company strategies and market supply patterns. Table 3 reports the results of multinomial logit estimation of entry mode choice. The odd numbered columns—1, 3, 4, and 7—show the choice of direct launch, and the even numbered columns—2, 4, 6, and 8—show the choice of alliance. While the sample size is 3640, it is 3185 when we use the IPP measures (columns 5, 6, 7, and 8) because of data availability.

We first discuss the coefficients of distance and subsidiaries. In all estimations, distance has a negative effect on both direct launches and alliances. On the other hand, the presence of a foreign subsidiary has a positive effect on these. The results for distance indicate that it can be a proxy of trade and management costs, and therefore discourages cross-border activities. This implication is related to those of gravity models. One thing to note is that among 40 sample countries, the countries far from Japan where few drugs are launched are in South America. Because our estimation includes region dummies, we obtain a negative effect for distance after controlling for South American country effects. The result that presence of a subsidiary positively affects the probability of direct launches implies that a local base is important for distributing products locally. The impact of a local subsidiary on alliances is also significantly positive. This result supports the theoretical result by Qiu06 that alliances and direct investment are complementary.

The first two columns report the results of direct launches and alliances when we use only company characteristics in the estimation. Portfolio size positively affects direct launches, while it has a negative effect on alliances. Therefore, firms with a large portfolio have more incentive to launch directly and less incentive to form alliances when conducting business in new markets. This is consistent with Hypothesis 1 and Kyle (2006, 2007)'s argument, that firms with a large portfolio are unlikely to engage in licensing activities, because those products may cannibalize sales of their own products. This reveals the importance of dealing with multiproduct firms' strategies to investigate entry mode choice. As mentioned above, our firms' portfolio variable, which is the number of drugs that firms are associated with, may also be a proxy for scope economies. The estimation results suggest that firms with scope economies prefer direct launches. Our estimation results also show that scale economies are positively related to direct launches but have no relation to alliances. As scope economies are related to research productivity (Henderson and Cockburn, 1996) and scale economies to manufacturing productivity, this implies that firms with scope and scale economies are capable of engaging not only in research but also distribution activities. Therefore, as in the literature showing that productive firms self-select to export or FDI, here productive firms self-select to launch directly and not to form alliance. Heterogeneous firms use different foreign entry modes.

Firm size has a negative impact on direct launches and a positive impact on alliances; a positive effect on alliances has also been found by Nagaoka and Kwon (2006) in a context of cross-licensing. Our results are consistent with the view that large firms tend to form alliances to manipulate market competition and their dominant positions are not threatened by alliances in a market. The results also suggest that large firm size does not necessarily entail the ability to

**Table 3: Multinomial Logit Estimation**

	Direct	Alliance	Direct	Alliance	Direct	Alliance	Direct*	Alliance*
Distance	-0.976a (0.15)	-0.632a (0.137)	-1.073a (0.156)	-0.738a (0.145)	-0.986a (0.187)	-0.658a (0.141)	-0.028a (0.006)	-0.048a (0.011)
Subsidiary	0.817a (0.164)	0.674a (0.131)	0.89a (0.168)	0.728a (0.138)	0.721a (0.207)	0.353b (0.17)	0.021a (0.007)	0.025c (0.013)
Portfolio	0.967a (0.212)	-0.319b (0.13)	0.731a (0.219)	-0.658a (0.141)	0.833a (0.243)	-0.676a (0.152)	0.027a (0.007)	-0.054a (0.012)
Scale Econ	0.964a (0.176)	0.132 (0.139)	0.794a (0.181)	-0.039 (0.152)	0.796a (0.199)	-0.008 (0.163)	0.024a (0.006)	-0.003 (0.012)
Size	-1.292a (0.281)	0.362c (0.189)	-1.066a (0.292)	0.773a (0.211)	-1.095a (0.323)	0.82a (0.226)	-0.036a (0.01)	0.065a (0.017)
Non-Pharma	-0.672 (0.441)	-0.247 (0.324)	-0.525 (0.453)	-0.593c (0.348)	-0.502 (0.504)	-0.641c (0.371)	-0.014 (0.015)	-0.048c (0.028)
R&DINT	0.280 (0.222)	0.236c (0.126)	0.549b (0.217)	0.361a (0.13)	0.581b (0.238)	0.396a (0.14)	0.017b (0.007)	0.029a (0.011)
Drug Age			1.422a (0.17)	1.773a (0.123)	1.446a (0.186)	1.792a (0.132)	0.039a (0.006)	0.133a (0.01)
World Market Size			0.321a (0.083)	0.059 (0.062)	0.307a (0.091)	0.085 (0.066)	0.009a (0.003)	0.006 (0.005)
World Comp			-0.132 (0.365)	-0.291 (0.267)	-0.249 (0.388)	-0.267 (0.288)	-0.007 (0.012)	-0.02 (0.022)
Pop					0.193 (0.132)	-0.014 (0.104)	0.006 (0.004)	-0.002 (0.008)
GDP					0.146 (0.26)	-0.293 (0.194)	0.005 (0.008)	-0.023 (0.015)
Other Class Drugs					0.78a (0.245)	1.298a (0.218)	0.02a (0.008)	0.097a (0.016)
IPP					-1.588 (1.466)	2.283b (1.151)	-0.054 (0.044)	0.179b (0.088)
IPP <sup>2</sup>					0.2 (0.2)	-0.251c (0.152)	0.007 (0.006)	-0.02c (0.012)
Local Firms					-0.23c (0.132)	0.023 (0.100)	-0.007c (0.004)	0.002 (0.008)
Constant	-1.554 (2.503)	-2.773 (1.979)	3.524 (2.812)	-0.501 (2.151)	-0.042 (4.607)	-12.633a (3.427)	0.032 (0.139)	-0.965a (0.26)
Log-likelihood	-1972.712		-1799.591		-1522.805		-1522.805	
Num. of Obs.	3640		3640		3185		3185	

Note: The numbers in parentheses are standard errors. The letters a, b, and c indicate statistical significance at the 1, 5, and 10 percent levels. All estimations include therapy dummies, regional dummies, and a Japan dummy. \*: These two columns report marginal effects.

conduct distribution activities. Note that because we include a chemical and food firm dummy, this result is not caused by the presence of large chemical and food firms, but common characteristics of companies supplying drugs. Technological elements are also important factors for entry. R&D intensity is positively correlated with both direct launches and alliances. This implies that irrespective of entry modes, research-intensive firms tend to launch drugs. This reflects the importance of research activities in the pharmaceutical industry.

Columns 3 and 4 report the results for drug characteristics. Drug characteristics are also significant determinants to entry mode choice. Drug age is positively related to both direct

launches and alliances. When comparing the marginal effects reported in columns 7 and 8, the marginal effect on alliances is larger than that on direct launches. This can be attributed to less uncertainty about revenues of old drugs compared with those of new drugs, so it may be easy to reach a licensing agreement for older drugs (Rockett, 1990). In addition, because the patents of older drugs may expire in the near future, opportunity costs of alliances are low. This also makes alliance agreements easy to reach.

The world market size for a drug is positively related to direct launches. This implies that profits from promising drugs with large markets are large, so the benefit from directly launching high-quality drugs is larger than those from an alliance. This is consistent with Hypothesis 2 and the theoretical result of Katz and Shapiro (1985) that major innovations that can capture a large market are less likely to be licensed. This result also adds insight into the relationship between quality and trade (Schott, 2004; Hummels and Klenow, 2005). Firms are likely to supply high-quality goods through their own channels. Then, with firm characteristics, our estimation reveals the determinants of marketing and branding strategies. Marketing and branding activities are likely to be internalized as the originator firms' productivity and product quality are high, because their productivity and product quality affect revenues to a large extent. This is consistent with the residual rights theory view (Grossman and Hart, 1986; Hart and Moore, 1990) that residual rights should be allocated to the party contributing most to the value of the relationship, and direct launches allocate the rights to the originator firm. The effect of world competition is found to be negative for both direct launches and alliances. While these effects are insignificant, the negative effect on both direct launches and alliances may imply that if there are a large number of potential competitors, neither entry mode is likely to occur. This suggests the possibility that competitive pressure does not change firms' entry alternative strategies but suppresses the incentive to enter new markets.

Columns 5 and 6 report the results when we include market characteristics. The size of population and GDP affect direct launch positively but insignificantly. The effect of the number of drugs for other therapies (Other Class Drug) is positive for both choices. A local pattern of health and disease represents a particular demand for drugs. In addition, regulations may affect the availability of drugs. Because the number of drugs for other therapies is significant for both entry modes, we are to some extent able to control for the local determinants of demand side and the regulations for pharmaceutical entry mode.

Finally, we discuss the variables associated with IPP. Columns 5 and 6 show the effects of IPP. IPP is positively related to alliances, while it has no significant effect on direct launches. This is consistent with Hypothesis 3 and the findings of international transaction flows that IPP is positively correlated with licensing royalties (Smith, 2001; Yang and Maskus, 2001). IPP may be associated with strong enforcement of alliance contracts, encouraging alliance agreements. Moreover, we found that the quadratic term for IPP is negative, suggesting that moderate IPP most strongly encourages alliances. This finding is consistent with McCalman04 using movie company data. Because both the pharmaceutical and movie industries are intellectual property intensive, firm strategies with regard to IPP may be similar. As long as IPP is moderately strong, the risk of imitation is rather low, so the likelihood of alliance is high. However, in a stronger IPP market, consistent with theories on residual rights allocation (Grossman and Hart, 1986; Hart and Moore, 1990), alliances are unlikely to be chosen. Alliances allocate more residual rights to the partner firm than do direct launches. Thus, in a stronger IPP country, residual rights should be allocated to the originator firm, because its intellectual property is highly protected and thus contributes most to the value of a relationship.

The number of local firms is negatively correlated with direct launches. Hence, firms do not

tend to enter by themselves when there are imitation opportunities and competition from local pharmaceutical firms. Because it is not significantly related to alliances, the possibility of imitation and competition may not imply a change of mode choice from direct launches to alliances. In a high imitation and competition country, firms simply may have less incentive to launch in any form. Because we do not directly use regulation measures in the estimations, the significance of local firms suggests that this variable may capture local market conditions, as for Other Class Drug.

Columns 7 and 8 report marginal effects, because the estimated coefficients and marginal effects do not coincide in the multinomial logit models ( $\partial Pr(m) / \partial x_k = Pr(m)(\beta_k^m - \sum_{m'} \beta_k^{m'} Pr(m'))$ ). The results are qualitatively similar between the coefficients (columns 5 and 6) and the marginal effects. The marginal effects of distance and subsidiary do not substantially differ between direct launches and alliances. The effect of R&D intensity is larger for alliances than for direct launches. While the question of whether licensing opportunities decrease or increase an incentive for innovation is theoretically ambiguous (Katz and Shapiro, 1985), our result suggests that R&D is related to profitability from alliances more than direct launches. As mentioned above, the marginal effect of Drug Age is higher for alliances, implying that old drugs are more likely to be licensed.

To assess the fit of our empirical model, we compared the predicted choices from our estimation and choices from the data. In Table 4, the choices in the data are shown in the rows and the predicted choices are in the columns. The figures in the diagonal of the table are the numbers for which the predicted choices are the same as the observed choices. Our model predicts the emergence of fewer alliances than the data indicate. This may reflect the number of alliances being overcounted in our data, as described in Section 2. However, overall, about 81 percent of choices are matched.

**Table 4: Predictions**

Observations	Predictions			
	No launch	Direct launch	Alliance	Total
No launch	2434	27	36	2497
Direct launch	166	90	20	276
Alliance	309	37	66	412
Total	2909	154	122	3185
Matched Choice=81.3 percent				

While we focus on the mode choice of the distribution channels of pharmaceutical companies, the identification of determinants of entry is an important issue (Scott Morton, 1999; Danzon, Wang and Wang, 2005; Lanjouw, 2005; Kyle, 2006,2007). Table 5 reports the estimation results for choices of whether to enter. We employed probit and linear probability models. The results of these estimations are qualitatively similar to those in the previous estimations. For example, the effect of distance is negative and the presence of a subsidiary is positive. R&D intensive firms tend to launch drugs. These factors are significant not only for direct launches and alliances, but also for entry decisions.

By combining the results of the entry mode choice obtained in Table 3 with those here, we can derive several implications. The effect of portfolio size is negative here, whereas portfolio size is significantly and positively associated with direct launches and negatively with alliances. The negative effect of entry is similar to the results by Kyle (2006, 2007). Our estimations show that



large portfolios facilitate direct launches but discourage alliances, and thus seem to have a negative effect on entry as a whole, which provides insights additional to those of Kyle (2006, 2007)'s results. Similarly, scale economies have an insignificant effect on entry in the linear probability model estimations, while in the entry mode choice estimations, they have a positive effect on direct launches and are insignificant for alliances. This shows that considering entry alone may lead to the mistaken conclusion that scale economies are irrelevant. We must investigate entry modes in detail when considering the effects of these firm characteristics on drug launches.

In summary, our estimations show that firm characteristics affect entry channel choice: large portfolio encourages direct launches but discourages alliances and scale economies are positively related to direct launches. We also show that market and product characteristics are important for entry mode choice. Positive effects of drug quality on direct launches are found and alliances are facilitated in countries with moderately strong IPP. When firms have small portfolios and IPP is moderately strong, the risk that licensed-out products and imitations will cannibalize sales of their own products is low. In such a case, alliances are likely to be chosen. On the other hand, if the productivity of firms and quality of product are high, the contribution of the originator firm to increasing profits is high. Then, local marketing and branding activities tend to be internalized because direct launches allocate residual rights to the originator firm that contributes most to the value of the relationship.

## **5 Concluding Remarks**

This study has analyzed the pharmaceutical company strategies of local entry mode: the choice between direct launches and marketing alliances. We used data on Japanese pharmaceutical companies and investigated the determinants of their choices. Our estimations show that firm entry mode choices depend on drug-specific, firm-specific, and market-specific factors. Firm heterogeneity captured by product portfolio size and scale economies determine the differences in choice between alliances and direct launches. Thus, while many trade models use a single-product firm framework, it is important to consider multiproduct firm perspectives to study entry strategies. Drug quality captured by potential market size also affects entry mode choice, which has not been examined by studies of product quality patterns of exports. The empirical results are consistent with the residual rights theory, in which as the role of the originator firm becomes important, control rights are allocated to it. Finally, IPP is relevant to entry mode choices and it has a nonmonotonic relationship with the likelihood of alliances.

The results obtained in this study suggest several implications for understanding strategic alliance behavior. However, there remain important factors that have not been explored in this paper. First, because of data limitations, partner firm characteristics are not taken into account. Dealing with the matching process between the originator and partner firms explicitly is useful to find pair characteristics inherent in alliance agreements. The rise of alliances may depend on a certain combination of characteristics. Second, as mentioned in the introduction, marketing alliances are likely to have an effect on market competition. To address this issue, focusing on a particular drug market and estimating the demand function of differentiated products are appropriate to investigate the effects of alliances on drug market competition. These issues require future research.

**Table 5: Entry Decision**

	Linear	Probit	Linear	Probit	Linear	Probit
Distance	-0.124a (0.016)	-0.439a (0.061)	-0.124a (0.015)	-0.5a (0.065)	-0.125a (0.017)	-0.442a (0.072)
Subsidiary	0.138a (0.017)	0.443a (0.064)	0.134a (0.016)	0.476a (0.067)	0.098a (0.019)	0.3a (0.082)
Portfolio	-0.008 (0.014)	-0.042 (0.064)	-0.056a (0.014)	-0.219a (0.069)	-0.056a (0.015)	-0.217a (0.075)
Scale Econ	0.042a (0.016)	0.192a (0.065)	0.013 (0.015)	0.131c (0.068)	0.013 (0.016)	0.137c (0.074)
Size	0.001 (0.022)	0.003 (0.091)	0.053b (0.021)	0.158 (0.097)	0.059a (0.022)	0.182c (0.105)
Non-Pharma	-0.031 (0.034)	-0.226 (0.152)	-0.078b (0.033)	-0.389b (0.158)	-0.079b (0.035)	-0.395b (0.172)
R&DINT	0.039a (0.015)	0.148b (0.063)	0.056a (0.014)	0.241a (0.067)	0.056a (0.015)	0.253a (0.072)
Drug Age			0.168a (0.010)	0.939a (0.059)	0.166a (0.011)	0.949a (0.063)
World Market Size			0.015b (0.007)	0.063b (0.031)	0.015b (0.007)	0.067b (0.034)
World Comp			0.046c (0.026)	-0.114 (0.132)	0.045 (0.028)	-0.124 (0.142)
Pop					0.007 (0.01)	0.033 (0.048)
GDP					-0.021 (0.019)	-0.068 (0.092)
Other Class Drug					0.106a (0.017)	0.609a (0.092)
IPP					0.159 (0.119)	0.324 (0.536)
IPP <sup>2</sup>					-0.016 (0.016)	-0.031 (0.072)
Local Firms					-0.005 (0.01)	-0.021 (0.047)
Constant	1.075a (0.159)	2.002a (0.631)	0.406c (0.222)	0.984 (1.04)	-0.533 (0.343)	-3.789b (1.641)
R-squared	0.175		0.242		0.264	
Log-likelihood		-1566.872		-1391.589		-1185.897
Num. of Obs.	3640	3640	3640	3640	3185	3185

Note: The numbers in parentheses are standard errors. The letters a, b, and c indicate statistical significance at the 1, 5, and 10 percent levels. All estimations include therapy dummies, regional dummies, and a Japan dummy.

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