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TAKECHI Kazutaka Hosei University



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TAKECHI Kazutaka

Hosei University

Abstract

The negative effects of intellectual property protection (IPP) on trade volume were found in previous research findings in which market power effects dominate market expansion effects. Because both effects increase profits, IPP induces entry without ambiguity. However, using product-level entry data, negative effects on market supply are found after controlling for country-specific effects. An examination of entry mode choice (direct supply vs. licensing) reveals that while the direct supply mode is negatively related to IPP, licensing is not, implying that firms facing infringement risk or intense competition may avoid direct supply in IPP-stringent countries.

Keywords: Entry pattern; Intellectual property rights protection; Pharmaceuticals *JEL classification*: F23; L24; L65

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Faculty of Economics, Hosei University. Address: 4342 Aihara-machi, Machida-shi, Tokyo, Japan 194-0298. Tel: +81-42-783-2566 Fax: +81-42-783-2611 Email: ktakechi@hosei.ac.jp

1 Introduction

The effects of intellectual property rights protection (IPP) on trade have been explored in the trade literature (Maskus and Penubarti 1995; Smith 1999; Liu and Lin 2005; Ivus 2010). Whether IPP has a positive or negative impact depends on the trade-off between the market expansion effect and the market power effect. IPP has a positive effect on trade because property rights protection facilitates transactions; this is known as the market expansion effect. Conversely, however, IPP may have a negative effect on trade because protection increases the market power of property rights owners, and they will therefore reduce the quantity of supply. In this situation, IPP has no significant effect on trade when this effect cancels out the market expansion effect (Maskus and Penubarti 1995) or strong IPP may even reduce the volume of transactions (Smith 1999; Liu and Lin 2005).

Because both the market expansion effect and the market power effect will increase profits, if IPP has no significant negative impact on profits other than the market power effects, positive profitable opportunities caused by IPP increase market supply. Therefore, using entry-level data, I assess the effect of IPP on market supply. In other words, I examine the impact of IPP on extensive margin of supply. In the trade literature, the distinction between extensive margin and intensive margin has been made. In this study, it is appropriate to focus on extensive margin, because it enables us to investigate whether there exist other IPP related factors affecting market transaction negatively. I use product-level pharmaceutical supply data from large US and Japanese pharmaceutical companies. The empirical results show that IPP has a negative effect on market supply after controlling for country-specific effects. As neither the market expansion effect nor the market power effect has a negative impact on profits, my results suggest that there are other channels through which IPP causes a reduction in the number of transactions.

This paper then attempts to investigate other possible causes of reductions in the number of transactions.¹

¹The idea that IPP may reduce innovations and new entries has been considered theoretically and empirically (Gallini and Winter 1985; Lerner 2002). In particular, if an industry is characterized by sequential innovation, new innovations are subject to infringement risk from previous inventions (Scotchmer 1991). Forming licensing contracts or alliances resolves such a risk; however, it may be too costly (Heller and Eisenberg 1998). Therefore, strong IPP may have a negative effect on new innovations.

One of the presumptions in previous empirical studies is that an entrant's goods do not infringe other products' intellectual property rights (IPRs). If strong IPP increases the likelihood of an entrant's goods infringing other products' IPRs, firms are unlikely to enter strong IPP countries, as Smith (1999) pointed out. The existence of this effect cannot be examined using trade flow data, because both market power and infringement risk effects may affect transactions negatively. Another possible negative factor is intense market competition. This effect can be caused by weak IPP: local firms enter the market through imitation, thus foreign firms are not able to find profitable opportunities. However, in the long run, because technology itself can be easily transacted in a strong IPP country, strong IPP may encourage vertical separation and induce new technology-intensive entrants. If market competition becomes intense, then market share and profits from each product may decrease (Ivus 2011).

How can firms deal with these problems? Licensing or alliances can be used to alleviate infringement risks or product market competition (Eswaran 1994). If firms want to avert infringement of other firms' IPP, they can form licensing contracts to settle in advance. Therefore, entry mode choice is examined. I estimate a mixed logit model to examine the effects of IPP on supply mode choice (direct supply vs. licensing). The estimation results indicate that while IPP has a negative effect on direct supply, it does not affect licensing. The negative relationship between IPP and direct supply is also consistent with internalization (McCalman 2004): firms prefer direct supply in low IPP countries to keep their technology inside the firm. However, internalization does not necessarily have a negative effect on entry itself. Hence, these results suggest that firms may avoid direct supply because of infringement risk or significant market competition effects.

In the literature, market expansion effects and market power effects are separately examined by Ivus (2011), who decomposes price and quantity. She shows that IPP induces new variety expansion, but reduces the quantity and raises the price of existing products. This suggests the presence of both market expansion effects and market power effects. The presence of a variety expansion effect of IPP in the literature seems to contradict my results of negative entry effects. However, this may be because the sample in my study is concentrated on large pharmaceutical companies. IPP may encourage new entry of small firms, as mentioned, and thus help expand variety. This

will reduce large incumbent firms' extensive margins. The large incumbent firms that suffer from competition or infringement risk for new firms' technology may reduce their number of directly supplied goods and instead form alliances. In my study, this reduction effect of IPP on incumbents' own supply is incorporated into the analysis.

Controlling for country-specific effects is an important element in my empirical analysis. In previous studies, to control for country effects, for example, countries are grouped in terms of imitation abilities (Smith 2001; Liu and Lin 2005). However, country-specific unobservable factors that affect transactions may remain. Because better protection might be correlated with other country characteristics that affect entry, such as price regulations (Danzon, Wang and Wang 2005; Kyle 2007), without controlling for country-specific effects, the IPP effect may be biased. While this aspect is taken into account in several studies (Yang and Maskus 2001; Kyle 2007), it has not been incorporated fully in the IPP and trade literature (Maskus and Penubarti 1995; Smith 1999; Liu and Lin 2005). My analysis suggests that country-specific effects should always be accounted for when examining the IPP effect.

The next section introduces my data set and empirical specifications. Section 3 reports my empirical results and the final section concludes.

2 Data and Empirical Specifications

The data source I use in this study is *Pharmaprojects* by Informa. This data source includes data on about 36,000 drugs developed worldwide. I focus on the data relating to drugs launched by large US and Japanese pharmaceutical companies before 2007. This is because my focus is on the effects of IPP on product market supply, not innovations. Launched drugs have less uncertainty for supply decisions than those under development.

The data have the following categories: drugs, companies, and therapies. The data file contains detailed information on drugs. Pharmaprojects uses the therapeutic 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", whereas "A1A: Stomatological" is a narrow class. In addition, my data include the current status of drugs in 40 countries in 2007. Examples are "pre-clinical", "phase I", "launched", and "suspended". In this paper, I focus on "launched", because my focus is on market entry strategies, not on technological development strategies. In the previous literature, Kyle (2006, 2007) uses 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 US and Japanese pharmaceutical companies. I select those firms that launched new drugs between 1997 and 2007. I then identify the market in which a drug has been launched and the therapeutic area for which it is intended. Hence, I construct a drug–country pair and consider each pair as a unit of the sample. For firm characteristics, I use financial data taken from various financial databases (Pharmaprojects, NEEDS for Japanese firms, and World Scope for the US firms). After omitting firms without financial or R&D data, 49 sample firms with 236 launched drugs remain. Thus, the number of units in the sample is 236 drugs × 35 countries = 8260. The sample drugs fall into 48 therapeutic classes according to the narrow therapeutic classification.

I investigate not only the supply pattern, but also the supply mode choice. To ascertain whether a particular drug is supplied directly or through a licensing agreement in a particular country, I check the data file on each drug. As mentioned previously, the file contains information on drug status. 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", I consider it launched by a licensing agreement. Because I use a data file updated to 2007, I may consider cases in which licensing occurred at a clinical stage before 2007, the firms passed clinical trials, and then sold the drug jointly in 2007. Therefore, my sample data may include a broader class of licensing. I also consider the entry mode of a licensing agreement when firms not only launch a drug on their own, but also form licensing contracts to supply the same drug in the market, a practice known as second sourcing (for example, see Choi and Davidson 2004). On the other hand, I consider direct supply as where the drug is launched but there is no mention of a licensing agreement in the data file. This construction of the direct supply variable may make the likelihood of direct launches in my analysis a conservative assessment. There might be bias in the sample when the publisher does not report an alliance agreement, even though one exists.

Figure 1 depicts the pattern of drug supply and entry mode for my sample firms. Blue bars indicate the number

of drugs supplied directly and red bars indicate the number of drugs supplied through licensing. While the Japanese and US markets have the most entrants, numbers vary across countries. The number of licensing agreements also varies across markets, and the proportion of licensing agreements among the total number of drugs supplied is not small.

== Figure 1 Here ==

To estimate the probability of firm entry, I specify the payoffs from supplying a drug for firm k, product i, origin c, and destination d in linear form as follows: $\pi_{kicd} = X_{kicd}\beta + e_{kicd}$, where X represents the factors affecting the payoffs, β is a parameter vector, and e_{kicd} is an error term. The entry probability is expressed as: $Pr(entry) = Pr(X_{kicd}\beta + e_{kicd} \ge 0)$. By assuming that the error terms follow a normal distribution, I estimate the entry probability using probit estimation.

I also examine supply mode choice (direct supply or licensing). Using data on direct supply and licensing status, I employ a mixed logit model, because it avoids the independence of irrelevant alternatives problem and allows flexible substitution patterns between choices. The likelihood function is now:

$$L_k = \int \exp(X_{kicd}\beta_j) / (\sum_j \exp(X_{kicd}\beta_j)) d\Phi(\beta_j),$$

where j = no entry, direct supply, or licensing, and Φ is a normal distribution function. The base choice is no entry, and thus the coefficients are interpreted as the effect relative to the base choice. In my study, the most comprehensive estimation specification of $X_{kicd}\beta_j$ is:

$$X_{kicd}\beta_j = \beta_{j0} + \beta_{j1}\text{IPP}_{cd} + \beta_{j2}\text{Distance}_{cd} + \beta_{j3}\text{Subsidiary}_{kd} + \beta_{j4}\text{Portfolio}_k + \beta_{j5}\text{Scale Econ}_k + \beta_{j6}\text{R&DINT}_k + \beta_{j7}\text{Drug Age}_i + \beta_{j8}\text{World Market Size}_i + \beta_{j9}\text{World Comp}_i + \gamma W_{id} + e_m$$

where $\beta_j = \beta$ in the entry estimations and β_j will be $\beta_{direct \ supply}$ or $\beta_{licensing}$ in the entry mode choice estimations.

The covariates and summary statistics are briefly described in Table 1. These include country-specific variables (for example, the great circle distance between capital cities), product-specific variables (for example, drug age, which is the number of years since a drug was launched), and firm-specific variables (for example, R&D-assets

ratio).

== Table 1 Here ==

The main variable is IPP, which is an index measure of each country's IPP strength, ranging from 0 (lowest protection) to 5 (highest protection). While this index can be regarded as a broad measure, because the pharmaceutical industry is recognized as one of the most IPP intensive industries, the correlation between the broad measure of patent strength and its effect on the pharmaceutical industry is high enough to capture the pharmaceutical specific factors. The average score of the 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. I use the relative IPP measure, which is the origin (Japan or the USA) IPP relative to the destination IPP. This enables me to use country-specific effects in the estimations. One issue is the exogeneity of IPP. Because I use a 2000 IPP measure to examine the impact on 2007 supply status, it may be regarded as exogenous from the 2007 viewpoint.

The variables in *W* are dummies. I use country dummies to control for market-specific effects. As Danzon, Wang and Wang (2005) and Kyle (2007) show, a country's adoption of a price control policy affects entry decisions significantly. There may be other factors that influence entry strategy. For example, countries with better pharmaceutical regulations may tend to have better property right protection systems. Then, entry will be facilitated by efficient regulations, but not by IPP. I will show that controlling for country-specific effects influences my estimation results and interpretations. Therapy dummies are also included in *W* to control for therapy-specific effects.

3 Estimation Results

In this section, I report my estimation results. Table 2 shows the results of the market supply decisions. The first two columns show the results without controlling for therapy- and country-specific effects. Column 1 reports the results of the most parsimonious specification using only IPP as an explanatory variable. IPP is found to be

positively and significantly related to entry. This result is unchanged when including other covariates, as shown in column 2. However, these results may be caused by unobservable country-specific effects, which include the health care system, drug market characteristics, and regulations.

== Table 2 Here ==

Column 3 reports the results with therapy-specific effects taken into account. The difference in the results in columns 1 and 2 relates to the effect of market size. Without controlling for therapy-specific effects, market size affects entry negatively, as reported in columns 1 and 2. Market size effects turn out to be positive in column 3: there is more entry in a larger market. This reflects that market competition and product market characteristics are significantly different across therapies (Berndt, Danzon, and Kruse 2007); therefore, controlling for therapy-specific effects is important for analyzing pharmaceutical markets.

The effect of IPP is still positive in column 3. However, again without country-specific effects, the IPP term may pick up country-specific factors other than IPP. Therefore, country dummies are incorporated into my main results. Column 4 reports the results when therapy- and country-specific effects are accounted for. The effect of IPP turns out to be significantly negative. The empirical results of the other parameters are not significantly different from columns 1 to 3. Hence, country-specific effects capture unobservable factors positively related to IPP. After controlling for country-specific effects, IPP decreases market supply. Because both market expansion effects and market power effects increase profit from entry, the negative effects should result from other factors.

The results of the other covariates are intuitive. Distance has a negative impact on entry, which is consistent with the fact that trade costs are increasing in distance. Sales, which measure economies of scale, and R&D intensity affect market supply positively: large and research-intensive firms are able to enter markets. Portfolio, which is measured by the number of drugs that a company has, has a negative impact on supply. This suggests that firms may try to avoid cannibalization of their own product sales, and so they selectively enter markets. Firms also tend to enter markets when there are their own subsidiaries. World market size is positively associated with entry. Because profitability will be high for such products, they can enter a large number of markets. Drug age also has

a positive effect on supply. This may reflect the fact that it takes time for new drugs to enter markets because of clinical trials and regulations. It may also be because firms accumulate information about old drugs and thus there is less uncertainty about the sales and profitability of old drugs.

To examine a possible reason why entry is negatively related to IPP, entry mode choice is examined. Because if, in fact, stringent IPP creates a risk of infringement of other products or highly productive and innovative firms exist because of stronger IPP, firms will use a licensing agreement to alleviate possible risks. Table 3 reports the estimation results of mode choice between no entry, direct supply, and licensing. The base choice is no entry; therefore, the results of direct supply and licensing are reported. IPP is found to be negatively related to direct supply, which is consistent with the results of entry. On the other hand, licensing is not significantly related to IPP, while the point estimate is positive. This is not a direct test that licensing is motivated by avoiding infringement risks or competition. In fact, internalization may also create the negative relationship between IPP and direct supply (McCalman 2004), because it is easier to form external contracts rather than supply by itself. However, with respect to entry choice, internalization does not necessarily lead to a negative effect. Therefore, these results may support the idea that fears of infringement or intense competition induce firms to find a partner to enter the market.

== Table 3 Here ==

Other variables also affect the entry choice mode. Portfolio has a negative effect on licensing. This suggests that firms do not choose licensing because they avoid cannibalization of their own sales and it is more difficult to control sales activities in licensing than own supply. Firms tend to choose licensing when there are their own subsidiaries. This implies the importance of proximity for licensing. Because of gaining bargaining power or facilitating licensee monitoring activity, it is easy for firms with own subsidiaries to sign a licensing contract.

4 Concluding Remarks

This study analyzed the link between IPP and international entry patterns. My estimation results reveal that IPP is negatively related to pharmaceutical supply. Empirical analysis of entry mode choice shows that IPP is negatively

related to direct supply choice, while IPP is not related to licensing. Combined with the results of entry, this suggests that IPP has a negative effect on transactions apart from a market power effect. Strong IPP may increase the risk of infringement of other products or IPP can create innovative and competitive companies; thus, firms are unlikely to enter directly into stringent IPP countries.

My results have an important policy implication for IPP. IPP itself may not facilitate transactions because of litigation risks and intense competition. If litigation costs are large because of stringent IPP, IPP will have a perverse effect. Then, a package of policies, such as IPP protection and an efficient litigation system, will be required. Otherwise, as widely discussed in the case of innovation and IPP, it may not be desirable to have stringent IPP for market transactions. Note that, as mentioned in the Introduction, the negative effect I obtain here is for large pharmaceutical incumbents. The overall effect on entry may be different when using data on new pharmaceutical ventures. Because of data limitations, this issue is beyond the scope of this paper and requires future research.

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Figure 1: Number of Entries in Each Country

Variables	Mean	Std	Min	Max
Entry	0.337	0.473	0	1
IPP: IPP measure by Park and Wagh (2002)	3.693	0.71	2.18	5
Relative IPP: IPP in US or Japan - IPP in destination countries	-0.998	0.812	-2.82	0.81
GDP (bil USD) in 2006	1220.332	2269.529	93.269	13201.82
Distance: distance from Japan or the US (km)	8465.503	3963.503	0	18373.78
Subsidiary: presence of a subsidiary in a country	0.472	0.499	0	1
Portfolio: number of drugs associated with each firm	664.322	641.165	6	2000
Scale Econ: total sales (mil dollar)	17978.03	17700.5	87.691	61094.99
R&DINT: R&D intensity (R&D divided by total assets)	0.095	0.061	0.008	0.853
Drug Age: years since first launch	11.678	6.87	1	41
World Market Size: worldwide drug sales calculated by Informa	2.805	1.071	1	5
No. of Markets (Country) = 35				
No. of Companies $= 49$				
No. of $Drugs = 236$				
No. of Observations $= 8260$				
Year = 2007				

Table 1: Variables and Summary Statistics

	Probit	Probit	Probit	Probit	Probit
Therapy Dummies	No	No	Yes	Yes	Yes
Country Dummies	No	No	No	Yes	Yes
IPP	0.098***	0.112***	0.132***	-0.565***	-0.706***
	(0.018)	(0.021)	(0.022)	(0.063)	(0.081)
Distance		-0.148***	-0.151***	-0.181***	-0.173***
		(0.012)	(0.012)	(0.015)	(0.015)
Sales		0.220***	0.256***	0.148***	0.147***
		(0.022)	(0.023)	(0.027)	(0.027)
R&D Intensity		0.484***	0.509***	0.360***	0.360***
		(0.037)	(0.038)	(0.042)	(0.042)
Portfolio		-0.091***	-0.114***	-0.057**	-0.057**
		(0.024)	(0.026)	(0.028)	(0.028)
FDI		0.291***	0.275***	0.074*	0.079*
		(0.037)	(0.038)	(0.042)	(0.042)
World Market Size		-0.001	0.080***	0.118***	0.117***
		(0.014)	(0.019)	(0.019)	(0.019)
Drug Age		0.550***	0.633***	0.722***	0.722***
		(0.024)	(0.025)	(0.027)	(0.027)
GDP		0.154***	0.162***		
		(0.016)	(0.016)		
IPP^2					-0.084***
					(0.031)
Constant	-0.324***	-2.769***	-2.934***	-1.284***	-1.379***
	(0.022)	(0.312)	(0.371)	(0.307)	(0.309)
Log-likelihood	-5263.3375	-4433.0161	-4264.88	-3910.0599	-3906.2597
No. of Obs.	8260	8260	8260	8260	8260

Table 2: Entry Decision

Note: The numbers in parentheses are standard errors. ***, **, and * indicate statistical significance at the 1, 5, and 10 percent levels.

	Direct Supply	Licensing
Therapy Dummies	Yes Yes	
Country Dummies	Yes Yes	
IPP	-1.929*** 0.096	
	(0.165)	(0.099)
Distance	-0.747***	-0.311***
	(0.042)	(0.033)
Sales	0.493***	0.225***
	(0.074)	(0.077)
R&D	1.111***	0.811***
	(0.117)	(0.129)
Portfolio	-0.089	-0.588***
	(0.077)	(0.096)
FDI	0.111	0.215*
	(0.106)	(0.138)
World Market Size	0.258***	0.083**
	(0.045)	(0.062)
Drug Age	1.43***	1.762***
	(0.088)	(0.108)
Constant	-3.656***	0.302**
	(0.185)	(0.134)
Log-likelihood	-5203.1392	
No. of Obs.	8260	

Table 3: Entry Mode Choice (Mixed Logit Estimation)

Note: The base choice is no entry. The numbers in parentheses are standard errors. ***, **, and * indicate statistical significance at the 1, 5, and 10 percent

levels.