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Integration from Entry Games:
An Analysis of the Generic
Pharmaceutical Industry**

Kensuke Kubo *

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Keywords: vertical integration, vertical foreclosure, entry, generic pharmaceuticals

JEL classification: L10, L13, L22, L42, L65

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Inferring the Effects of Vertical Integration from Entry Games: An Analysis of the Generic Pharmaceutical Industry

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Abstract

This paper introduces a novel method for examining the effects of vertical integration. The basic idea is to estimate the parameters of a vertical entry game. By carefully specifying firms' payoff equations and constructing appropriate tests, it is possible to use estimates on rival profit effects to make inferences about the existence of vertical foreclosure. I estimate the vertical entry model using data from the US generic pharmaceutical industry. The estimates indicate that vertical integration is unlikely to generate anticompetitive foreclosure effects. On the other hand, significant efficiency effects are found to arise from vertical integration. I use the parameter estimates to simulate a policy that bans vertically integrated entry. The simulation results suggest that such a ban is counterproductive; it is likely to reduce entry into smaller markets.

Introduction

The effect of vertical integration on market outcomes—such as prices, quantities, and product quality in the final goods market—can be either positive or negative. For instance, an increase in the level of vertical integration can lead to higher prices or lower prices in the downstream market, depending on the underlying demand and cost function parameters (Salinger [1988]; Hendricks and McAfee [forthcoming]). This is because vertical integration has two countervailing effects: one is to decrease the integrating firm's costs through the elimination of double marginalization, and the other is to raise the intermediate input costs faced by other non-integrated firms. In addition, vertical integration is sometimes used to facilitate noncontractible investments in

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one of the segments of a vertical chain (Grossman and Hart [1986]), or to assure the supply of an intermediate good (Carlton [1979]; Bolton and Whinston [1993]). Integration based on these motives will also affect market outcomes, but the direction of such effects is generally indeterminate. Because of these inherent indeterminacies, the motives for, and the effects of vertical integration tend to be analyzed on an industry-by-industry basis. The results of such studies are then used to inform competition policy as well as corporate strategy (Lafontaine and Slade [2007]).

This paper presents a novel method for empirically examining vertical integration in an individual industry. The basic idea is to apply an econometric model of a static entry game to a vertical setting. By estimating firms' payoff functions in a vertical entry game, it is possible to recover vertical rival effects—the effect of upstream, downstream, and vertically integrated rival entry on profits. These estimates can then be used to make inferences about the effect of increased vertical integration on market outcomes. While the focus is on estimating the effects of vertical integration, the econometric model is also capable of shedding light on the motives for vertical integration.¹

To motivate the empirical analysis, I present a game theoretic model of simultaneous entry into an oligopolistic market consisting of an upstream segment that supplies an intermediate good and a downstream segment that uses the intermediate good to produce a final good. The players of the game are potential entrants who can enter into one of the vertical segments or both. After entry decisions have been made, vertically oligopolistic competition occurs within the post-entry market structure. Firms' entry decisions are based on their expectations of post-entry profits, which in turn are affected by the expected entry decisions of other firms. Put another way, potential entrants form profit expectations according to the market structure they expect in the entry equilibrium, as well as the position they foresee for themselves within that market structure. In my model, potential entrants are heterogeneous in both observable and unobservable ways, and the entry game is one of complete information.

My data consist of observations on vertical entry patterns in multiple markets. I interpret the entry patterns as the outcomes of a vertical entry game. By assuming a structural model such as the one described in the previous paragraph, I can use the entry pattern data to infer how vertical integration by one set of firms affects the profits of others. In other words, I can estimate vertical rival effects. The dataset comes from the US generic pharmaceutical industry. It covers multiple markets, each consisting of a distinct pharmaceutical product. The upstream segment of

¹Inferring the motives for vertical integration from entry games is the topic of a companion paper that is in progress.

each market supplies the active pharmaceutical ingredient (API), and the downstream segment processes APIs into finished formulations such as tablets and capsules. The clear demarcation between the upstream and downstream segments, as well as the existence of both vertically integrated and non-integrated firms make the generics industry an attractive setting for my analysis.

The object of estimation is the set of firm-level post-entry payoff equations corresponding to three different categories of entry: downstream-only, upstream-only, and vertically integrated. A given potential entrant chooses the entry category, or action, that yields the highest profit net of entry costs. Each payoff equation contains as arguments the variables that describe the actions of other potential entrants. The coefficient estimates for these variables provide the main results of the study. I find that vertical integration between a pair of firms has a significantly negative effect on independent upstream rivals. I also find that the effect of vertical integration on independent downstream rivals is positive. Taken together, these results suggest that vertical integration has large efficiency effects (i.e., cost reductions for the integrating firm), and that vertical integration does not reduce independent downstream firms' access to the intermediate good. I use the parameter estimates to simulate the effect of a policy that bans vertically integrated entry. Somewhat surprisingly, I find that, for smaller markets, prohibiting vertically integrated entry is likely to reduce the number of entrants in both the upstream and downstream segments.

The remainder of the paper is structured as follows. In section I, I explain how this study fits into the industrial organization literature on vertical integration as well as to the literature on market entry in the generic pharmaceutical industry. To my knowledge, the paper is novel on two fronts: it is the first empirical paper to exploit an entry game structure in order to analyze vertical integration; it is also the first econometric paper to investigate vertical integration in the generics industry.² In section II, I describe the vertical structure of the US generic pharmaceutical industry, and discuss the possible motives for and effects of vertical integration. In section III, I present the econometric specification along with the underlying model of a vertical entry game. In section IV, I describe the estimation strategy, followed by a description of the data in section V. Section VI presents the estimation results from the vertical oligopoly entry model together with the results of policy simulation. A concluding section follows.

²Elberfeld [2002] is a theoretical analysis of vertical market structure formation in which firms play an entry game before competing in vertical oligopoly.

I Relationship to previous studies

I.1 Empirical analysis of vertical integration

Empirical research on vertical integration can be classified into those that investigate motivations and those that look at effects. Studies in the former group, including Woodruff [2002], Baker and Hubbard [2004], and Ciliberto [2006] address the question: why do firms vertically integrate? A common approach is to identify the characteristics of products or industries whose producers tend to be vertically integrated. Studies in the latter group ask the following: what happens to market outcomes when firms vertically integrate? Most authors examine the direct impact on market outcomes (price of the final good, product quality, etc.). A few try to infer vertical integration’s impact on market outcomes by estimating its effect on competing firms’ profits.

This paper focuses on the effect of vertical integration on market outcomes. The parameter estimates can also be used to investigate the motivations for integration, but this topic is left for a companion paper. Like many other studies on the effects of vertical integration, my main interest is in the phenomenon known as vertical foreclosure—an increase in the final good price as a result of restricted access to an essential intermediate good. Before reviewing the empirical literature, let us briefly consider the economic theory.

Vertical foreclosure theory

Do vertically integrated firms restrict supply of the intermediate good with an aim to raise the final good price? If they do, what are the precise mechanics of their actions? These questions have been at the heart of a decades-long debate among scholars and practitioners, both legal and economic. Riordan’s [2008] review summarizes the notable theoretical models that have shaped this debate. The more recent studies are collectively known as the New Foreclosure Theory, and they identify the conditions under which vertical integration can give rise to foreclosure effects. The models are roughly divided into two groups: (i) models in which vertical integration is used to raise downstream rivals’ costs (Salinger [1988]; Ordoover, Salop, and Saloner [1990, 1992]; Riordan [1998]; Chen [2001]), and (ii) models where vertical integration allows upstream units to restrict the supply of the intermediate good and restore monopoly power (Hart and Tirole [1990]; Rey and Tirole [2007]).

The “raising rivals’ costs” theory is based on the idea that vertical integration between a pair of firms dampens competition in the upstream intermediate good market. This may raise the price that independent (i.e., non-integrated) downstream firms pay for the intermediate good. As an illustration, consider the two-by-two market configuration presented in figure 1. In panel (i) all

manufacturing units operate as independent firms, while in panel (ii) one pair of units is vertically integrated. In the quintessential raising-rivals'-costs model of Ordover, Salop, and Saloner [1990] (henceforth the "OSS model") the upstream units produce a homogeneous good and compete in prices, while the downstream units produce differentiated products and also compete in prices. The homogeneous good assumption implies that the price of the intermediate good in panel (i) is equated to its marginal cost of production. The question is how the intermediate good price is determined in panel (ii). OSS argue that the integrated firm has the incentive, as well as the ability, to raise the price substantially above marginal cost. This translates to a higher marginal cost for the independent downstream firm and a higher final good price.

The OSS model has been subjected to some criticism. First, Hart and Tirole [1990] and Reiffen [1992] raised doubts regarding the integrated firm's ability to raise the intermediate good price above marginal cost. Specifically, in a static game the integrated firm cannot commit not to undercut the independent upstream firm's price, and so the upstream price falls to the Bertrand level. Ordover, Salop, and Saloner [1992] argued that high prices can be maintained if the two upstream units compete in a descending-price auction to supply the independent downstream unit. Riordan and Salop [1995] and Normann [2006] showed that the OSS conclusions are valid if the firms engage in repeated play. As these examples show, OSS-type results do hold in some models, but only if the basic setup is modified. Another critique of OSS is that the assumption of linear pricing of the intermediate good is not realistic in many industries, and that foreclosure effects would be much weaker under nonlinear pricing (Hart and Tirole [1990]). While both critiques are quite valid, the OSS model continues to form a cornerstone of economic thought on vertical foreclosure. This may be because, as noted by Ordover, Salop, and Saloner [1992], "The notion that vertically integrated firms behave differently from unintegrated ones in supplying inputs to downstream rivals would strike a businessperson, if not an economist, as common sense" (p.698).

An alternative to raising rivals' costs theory is the "monopoly restoration" theory of Rey and Tirole [2007]. They showed how, in a one-by-two setting as in figure 2, downward integration by the sole upstream firm can have a foreclosure effect even if the intermediate good is priced nonlinearly. This is because vertical integration gives the upstream unit the ability to commit to a lower total quantity of the intermediate good. In other words, under vertical separation—panel (i) of figure 2—the upstream monopolist U supplies more of the intermediate good than the profit maximal (i.e., monopolistic) amount. This is because U cannot convince either D_1 or D_2 that it will restrict supply to the other firm. Under the two-by-two configuration of figure 1, vertical integration has no foreclosure effects unless the marginal cost of the integrating upstream

unit is substantially lower than that of the independent upstream unit (Hart and Tirole [1990]).

As this brief review suggests, the existence of vertical foreclosure is sensitive to model assumptions. Particularly important are the assumptions regarding pricing behavior (linear or nonlinear) and those regarding time horizon (one-shot or repeated pricing game). In addition, research focusing on the bargaining between upstream and downstream units indicates that the existence of foreclosure is sensitive to bargaining format (Hart and Tirole [1990]; de Fontenay and Gans [2005]). In studying individual industries, it is crucial that some idea is formed regarding the underlying theoretical model.

Empirics of vertical foreclosure

Most of the empirical analysis on vertical foreclosure looks directly at the effect of vertical integration on market outcomes (e.g., Hastings and Gilbert [2006], Hortaçsu and Syverson [2007], Ciliberto and Dranove [2006], and Suzuki [2008]). A general conclusion from this literature is that the effect of vertical integration varies across industries; higher final good prices (or lower product quality) due to vertical integration is found in some industries, but not in others. This could be because there are little or no foreclosure effects in certain industries, possibly due to commitment problems or nonlinear pricing. Alternatively, it could be that any foreclosure effects that do exist are offset by the efficiency effects of vertical integration that work to lower downstream prices. One such efficiency effect is the elimination of double margins that exist in vertically related oligopolies under linear pricing. Another is the improvement in incentives for productive noncontractible investment.

Martin, Normann, and Snyder [2001] and Normann [2007] are two important papers providing experimental evidence on foreclosure. Normann [2007] shows that, despite the criticism received by OSS, raising-rivals'-costs strategies do appear in one-shot vertical oligopoly games played in a laboratory setting by university students. Similarly, Martin, Normann, and Snyder [2001] demonstrate that the monopoly restoration model is partially supported by experimental data. Thus, the experimental literature provides support for vertical foreclosure theory, not least because efficiency effects can be assumed away.

Rosengren and Meehan [1994] and Snyder [1995] look at the effect of vertical integration on rival profits (i.e., rival effects) in order to say something about vertical foreclosure. Both papers focus on the effect of a vertical merger announcement on the stock prices of nonintegrated rivals. Rosengren and Meehan [1994] do not find that vertical mergers have a significant effect on independent downstream rivals. Thus, they find no support for foreclosure theory. In a study of the British beer industry described by Snyder [1995], it is found that an independent

upstream brewery was harmed by vertical integration between rival breweries and downstream pubs. Snyder [1995] interprets this as support of foreclosure theory.³

My study is closest in approach to the papers discussed in the previous paragraph in that I estimate rival effects to make inferences about the effects of vertical integration. This approach has two hurdles that must be overcome before meaningful tests can be constructed. The first is the choice of underlying theoretical model. The raising-rivals'-costs and monopoly restoration theories yield different predictions regarding the relationship between foreclosure effects and rival profit effects. That is, they disagree on what kind of rival effects are likely to be observed when foreclosure effects are present. As Snyder [1995] points out, vertical integration with foreclosure has a positive impact on independent upstream profits in the OSS model, but the impact is negative or neutral in Hart and Tirole [1990].

The second issue is the disentangling of foreclosure effects and efficiency effects. In many cases, foreclosure effects and efficiency effects move the profits of unintegrated rival firms in the same direction. This makes it difficult to identify the existence of foreclosure effects using only rival effect estimates. For example, Rey and Tirole [2007] suggest testing foreclosure theory by seeing if the profits of independent downstream firms fall in response to vertical integration by a monopolistic upstream firm.⁴ Yet at the same time, they admit that the test is “subject to the potential criticism that specific increases in the merged entity’s efficiency may hurt downstream rivals even in the absence of foreclosure intent” (p.2166). Snyder [1995] suggests addressing such concerns by using out-of-sample information. In the aforementioned beer study, he rules out efficiency effects by citing a UK government finding that “retail prices were higher for integrated pubs on average than for unintegrated pubs” (p.115). In general, however, it is difficult to find valid supporting evidence to rule out efficiency effects. The two issues above are further discussed in sections II and III.

I.2 Market entry in the generic pharmaceutical industry

In the pharmaceutical industry, new drugs are developed by originator—also called brand-name or innovator—pharmaceutical companies. After a new drug loses patent protection, generic pharmaceutical companies can enter the market, offering products that are equivalent to the originator’s. The generics industry consists of a number of markets, each defined by a particular

³It should be noted that in the OSS model independent upstream rivals *benefit* from vertical integration when foreclosure effects are present.

⁴The raising-rivals'-costs model predicts that independent downstream profits fall in response to vertical integration. The monopoly restoration model makes no prediction regarding the direction of change, because all downstream profits are extracted by the upstream firm through nonlinear tariffs and take-it-or-leave-it bargaining.

product, that open up to competition at different points in time as originator patents expire. It is one of the few industries where one can observe a large number of markets where near-simultaneous entry by multiple firms takes place. This feature makes it an attractive setting for studying entry and market structure formation. Previous studies look at the determinants of market entry by individual firms (Scott Morton [1999]; Gallant, Hong, and Khwaja [2008]) and the possibility of entry deterrence by originator pharmaceutical companies (Ellison and Ellison [2007]; Marco [2005]). Others investigate how market prices are influenced by market structure. A universal finding is that the price of generics is significantly lower than that of brand-name drugs (Caves, Whinston, and Hurwitz [1991]). Some studies, such as Grabowski and Vernon [1992] and Frank and Salkever [1997], find that the price of the brand-name drug sometimes increase in response to generic entry. Meanwhile, all studies agree that the price of generic drugs is decreasing in the number of generic entrants (e.g., Reiffen and Ward [2005]).

My study is closest in spirit to Scott Morton [1999] who focuses on entry in the downstream finished formulations segment. The theoretical model underlying her econometric analysis has the following feature: in the entry equilibrium for market m , all firms calculate the same “cutoff entry cost” F_m^* such that only those firms having entry cost below it enter the market.⁵ F_m^* is assumed to be a function of market characteristics and firm i ’s position relative to the cutoff level is a function of its own characteristics.⁶ Thus, the object of estimation in Scott Morton [1999]—the set of firms’ payoff equations—contains only market and firm characteristics as arguments; the number of rival entrants does not enter the payoff equation. Because of this simplified specification, Scott Morton’s [1999] analysis does not focus on rival effects. An important finding of her study is that a firm’s experience level—measured as the number of similar markets entered in the past, where similarity is defined as commonality in dosage form or therapeutic class—has a significantly positive effect on its propensity to enter. This suggests the existence of learning effects and/or economies of scope across similar products.

Gallant, Hong, and Khwaja [2008], who also examine downstream entry decisions, extend the econometric model of Scott Morton [1999] in two ways. First, they allow the number of rival entrants to enter the payoff equation so that horizontal rival effects can be estimated. Second, Gallant, Hong, and Khwaja [2008] recognize that different generic drug markets open up sequentially, so that the sequence of entry decisions by each firm should be thought of as the solution to a dynamic optimization problem. In fact, because firm interactions are incorporated,

⁵Quint and Einav [2005] show that such an equilibrium results from an entry game where entry costs are gradually sunk prior to the entry date.

⁶It may be more realistic to let F_m^* be a function not only of market characteristics, but also the characteristics of all potential entrants.

Gallant, Hong, and Khwaja [2008] estimate a dynamic game. In their model firms are allowed to be forward-looking; current entry decisions are made with the knowledge that future payoffs will be affected. My study is similar to Gallant, Hong, and Khwaja [2008] in that I estimate rival effects. I make an additional contribution by considering entry in the upstream segment as well as the downstream segment, allowing the possibility of vertically integrated entry. On the other hand, I do not incorporate dynamics. As Gallant, Hong, and Khwaja [2008] acknowledge, a dynamic and game theoretic specification leads to “severe computational difficulty in estimating the model” (p.2), which would be compounded by the consideration of vertical issues.

The estimation of a vertical entry model is a novel contribution to the empirical literature on static entry games. This field has been motivated by the technical challenge of how to handle the number of rival entrants—a key variable that is clearly endogenous. The earliest studies were Bresnahan and Reiss [1991a,b] and Berry [1992]. In Berry’s [1992] analysis of entry in the airline industry, each potential entrant’s post-entry profit is calculated from market and firm characteristics, candidate values for the number of other entrants, candidate parameter values, and simulated draws corresponding to unobserved fixed entry costs. The predicted payoffs are used to find the equilibrium market structure. The parameter point estimates are those that minimize the difference between the predicted market structure and the observed market structure.

Recently, Mazzeo [2002], Seim [2006], and Orhun [2005] extended this framework to markets with product differentiation. In these studies, firms decide not only whether or not to enter a market, but also how or where to enter. Mazzeo [2002] considers highway-exit motel markets where operators decide among different quality levels. In Seim [2006] and Orhun [2005], stores choose among different locations. In all cases, the parameters of interest are those describing the effect that different types of rival entrants have on post-entry profits. My vertical entry model can be thought of as a variant of the differentiated-product entry model, the results of which yield insights into the effects of vertical integration.

II Vertical structure of the generic pharmaceutical industry

The US generic pharmaceutical industry is characterized by a clear demarcation between the upstream and downstream segments. The upstream segment manufactures active pharmaceutical ingredients (APIs), using basic and intermediate chemicals, solvents, catalysts, etc. as raw material. The downstream segment manufactures finished formulations by combining the API with excipients and processing them into dose forms such as tablets, capsules, and injectables.

The US generics market has traditionally been characterized by vertical separation of the upstream and downstream segments. This is because when the industry began to grow in the 1980s, high quality and low cost active ingredients were available from Italy and other countries that had weak patent laws at the time (Bryant [2004]). American generic drug companies such as Mylan and Barr initially chose not to manufacture APIs in-house. However, firms began to exhibit vertical integration during the 1990s. Foreign firms who traditionally only supplied APIs increasingly entered the finished formulation market. Examples of such firms are Teva of Israel and Ranbaxy of India. In recent years, the traditionally non-integrated US firms have also begun to acquire upstream assets. Examples include the acquisition of Indian API manufacturers by Watson and Mylan, both large US finished formulation companies.⁷ As of the late 2000s, most of the large generic drug companies in the US market are vertically integrated to some extent. However, firms differ in the extent of vertical integration. Mylan and Barr continue to be predominantly downstream firms. On the other hand, Ranbaxy, Dr. Reddy's Laboratories, and other Indian firms have a larger presence in the upstream segment, while continuing to expand their downstream activities in the US.

Firms decide on their vertical integration status on a market-by-market basis. For example, Teva uses its in-house API for some of their finished formulation products but not for others, as seen in the first row of table 1. The upper panel of table 1 reveals the heterogeneity of firms' vertical entry strategies: Mylan, prior to its acquisition of Matrix in late 2006, only entered as an independent downstream producer. Meanwhile, the Indian API company Cipla only entered the upstream segment. Both Teva and Ranbaxy are vertically integrated, but it can be seen that Ranbaxy's activities are relatively more concentrated in the upstream sector.

The lower panel of table 1 presents the number of entrants per market. The number of independent upstream and independent downstream entrants both average around four, with some markets attracting more than ten entrants in a single segment. The average number of vertical entrants is only slightly below one, suggesting that vertically integrated entry is a common occurrence.

The motives for vertical integration have been reported in the industry press. A purchasing executive at Sandoz, one of the largest firms, mentions lower API costs, earlier access to APIs, and stability of supply as the advantages of vertical integration (Stafford [2006]). Others have mentioned the possibility that vertical integration allows better control over the information flow between segments, as well as better risk-sharing (Erdei [2004]; Hoffman [2004]). These point to

⁷Mylan acquired a majority stake in a large Indian API manufacturer called Matrix in September 2006. In the same month, Watson acquired a smaller firm called Sekhsaria (Roumeliotis [2006]; Barnes [2006]).

the existence of efficiency effects generated through vertical integration.

On the other hand, recent antitrust cases suggest that vertical integration can create anticompetitive foreclosure effects. In *Federal Trade Commission v. Mylan et al.*, the Federal Trade Commission (FTC) claimed that an exclusive dealing contract between Mylan and an upstream firm regarding the APIs for lorazepam and clorazepate tablets contributed to price increases of between 1,900 and 3,200 percent for the downstream products.⁸ The upstream firm, Profarmaco, terminated its supply of APIs to Mylan’s competitors, Watson and Purpac. These two downstream firms were forced to reduce their tablet production significantly. Mylan also convinced another upstream firm, called FIS, to raise its price of lorazepam API. As a result, a third downstream company called Geneva—a customer of FIS—raised the price of its tablets to match Mylan’s level. This is a classic example of pure vertical foreclosure described by the OSS model.⁹ An important aspect of this case is that the Mylan-Profarmaco combine was unable to extract the profits of downstream competitors through nonlinear pricing. This strongly suggests that in the generics industry, the raising-rivals’-costs theory of vertical foreclosure is more applicable than the monopoly restoration theory—a suggestion with implications for econometric analysis.

Unlike exclusive dealing contracts, vertically integrated entry is not subject to antitrust scrutiny. Moreover, the US government’s review of mergers within the generic pharmaceutical industry focus only on horizontal effects in the downstream segment (Silber [2007]).¹⁰ There is, however, no reason to assume that vertical integration cannot have the same anticompetitive effects as exclusive dealing. If it does, then future merger reviews for the generic pharmaceutical industry may have to include a vertical component.¹¹ This study provides the first formal and systematic analysis of the competitive effects of vertical integration in this industry.¹²

⁸See *Federal Trade Commission v. Mylan et al.*, DC District Court, 1999 (<http://www.ftc.gov/os/1999/02/mylanamencmp.htm>).

⁹For another case of vertical foreclosure through exclusive dealing, see *Geneva and Apothecon v. Barr et al.*, 2d Cir., 2004 (<http://cisgw3.law.pace.edu/cases/020510u1.html>).

¹⁰For an example, see Federal Trade Commission: *In the matter of Teva Pharmaceutical Industries and IVAX Corporation*, Docket No. C-4155. Analysis of agreement containing consent orders, filed January 20, 2006 (<http://www.ftc.gov/os/caselist/0510214/0510214analysis.pdf>).

¹¹Villas-Boas [2007], Hendricks and McAfee [forthcoming], and Manuszak [2010] illustrate the importance of incorporating vertical aspects into merger analysis.

¹²Unfortunately, exclusive dealing contracts are rarely observable and my econometric analysis does not take them into account. There is some reason to think that exclusive dealing contracts may have become more costly to implement after *FTC v Mylan*. As part of a settlement with the FTC, Mylan and its API suppliers (Cambrex, Profarmaco, and Gyma Laboratories) agreed, for a five-year period starting 2000, to notify the FTC before entering into any exclusive dealing agreement with any other firm. Moreover, the firms were prohibited from taking part in any exclusive dealing contract whose effect is to “unreasonably restrain trade” and “create an unlawful monopoly”. See *Federal Trade Commission v. Mylan et al., Order and Stipulated Permanent Injunction*, DC District Court, 2000 (<http://www.ftc.gov/os/2000/11/mylanordandstip.htm>).

III Econometric Specification

The basic econometric framework follows that of Berry [1992]. Each firm in the dataset is provided with a set of payoff equations corresponding to its possible actions. Given values for the explanatory variables, parameters, and error terms, the predicted payoff values define each firm’s best response given the actions of the other firms. For every market in the dataset, the system of best responses is solved for to yield the Nash equilibrium of the vertical entry game. The objective is to find the parameter values such that the predicted Nash equilibria of the entry games are as close as possible to observed entry patterns.

III.1 Entry game specification

The object of estimation is the set of firm-level post-entry payoff equations corresponding to three different categories of entry: independent downstream, independent upstream, and vertically integrated:

$$\begin{aligned} \pi_{mik} &= h(\mathbf{x}_{mi}; \omega_k) + g_k(\mathbf{N}_{mi}; \delta_k) + \epsilon_{mik}, \\ m \in \mathcal{M} &\equiv \{1, 2, \dots, M\} \quad i \in \mathcal{I}_m \quad k \in \mathcal{K} \equiv \{D, U, V\}. \end{aligned} \tag{1}$$

The subscripts m , i , and k denote market, firm, and entry category, respectively. M is the number of markets in the data and \mathcal{I}_m is the set of potential entrant firms in market m . \mathcal{K} , the set of entry categories, is also the firm’s choice set. Its elements D , U , and V are shorthand for “independent downstream”, “independent upstream”, and “vertically integrated”, respectively. The payoff for no entry is normalized to zero. \mathbf{x}_{mi} is a row vector of market and firm characteristics (including an intercept) and $\mathbf{N}_{mi} \equiv [N_{mi}^D \quad N_{mi}^U \quad N_{mi}^V]^\top$ is a three dimensional vector representing the number of entrants (excluding firm i) in each entry category. The function $h(\cdot)$ is common to all categories, but the $g_k(\cdot)$ functions are specific to each category. $g_k(\cdot)$ describes the competitive effects of rival entrants for a firm in category k , and additive separability between \mathbf{x}_{mi} and \mathbf{N}_{mi} is assumed. ω_k and δ_k are parameter vectors to be estimated, and ϵ_{mik} is a random error term.

Given values for \mathbf{x}_{mi} , \mathbf{N}_{mi} , ϵ_{mik} and the parameters, potential entrant i can figure out its optimal action. However, \mathbf{N}_{mi} is not observed until the actions of firms $j \neq i$ have been decided. By the time i observes the actions of its rivals, though, it will be too late for i to choose its own action.¹³ Here, game theory comes into play. We can assume that firms play an entry game,

¹³Recall that in the generics industry, market prices fall with the number of entrants. Given the delay between entry decision and actual entry, due to the Food and Drug Administration’s drug approval process, generic drug companies lose substantially by delaying entry.

and that the entry equilibrium is Nash in discrete actions. Thus, firm i forms an expectation of \mathbf{N}_{mi} and accordingly calculates its post-entry payoffs to make its entry decision. In equilibrium, it will turn out that the realized entry equilibrium is indeed \mathbf{N}_m (unlike \mathbf{N}_{mi} , \mathbf{N}_m —lacking a firm subscript—incorporates the actions of all firms including i). As Berry [1992] and others demonstrate, the econometrician can also use the Nash equilibrium concept during estimation. Specifically, different trial values for \mathbf{N}_m are plugged in until the firms’ optimal actions predicted by the fitted payoff values are consistent with the market structure defined by the trial value. The equilibrium conditions for the entry game are as follows:

- An entrant choosing action k finds it profit maximal to choose k , given the actions of others.
- A non-entering firm makes negative profits if it were to choose any other action k .

As I describe in section IV, an algorithm for equilibrium-finding can be incorporated into the estimation routine. One potential problem is the possibility of multiple equilibria in the entry game. There may be multiple trial values of \mathbf{N}_m that satisfy the equilibrium conditions. This is indeed the case in the vertical entry model, as I discuss in sections IV and VI.

III.2 Specification of rival effects

Estimates for $g_k(\mathbf{N}_{mi}; \delta_k)$, the functions containing the rival effects, form the key results. Hence, their specification must be thought out carefully. Many previous studies specify $g_k(\cdot)$ as being linear in \mathbf{N} . This has the benefit of being easier to estimate than nonlinear specifications when the underlying entry game is one of incomplete information (Seim [2006]). Linearity may be permissible in some applications of the entry model. However, in most markets the competitive impact of the first rival entrant is likely to be different from the impact of subsequent ones (Berry and Reiss [2007]). In models of vertical oligopoly or product differentiation, the impact of rival entry into one category is likely to vary according to the presence of entrants in the other categories. Thus, the studies on product differentiated markets by Mazzeo [2002] and Cohen and Mazzeo [2007] employ a multi-dimensional step function specification for $g_k(\cdot)$. I follow them in specifying $g_k(\cdot)$ as a partial step function in three dimensions.

The specification of $g_k(\cdot)$ must be capable of capturing the key implications of economic theory. As mentioned in section II, the appropriate theoretical framework for the generics industry is the OSS raising-rivals’-costs model and its variants discussed in Riordan [2008], Normann [2006], and Normann [2007]. An important implication of the OSS model is that foreclosure effects are more likely to be present under market structures with few upstream

firms. When there are many independent upstream firms, downward integration by one of them will not have a significant foreclosure effect. For instance, suppose that there are three upstream units and two downstream units in the market. Vertical integration by one upstream-downstream pair does not cause foreclosure, because the remaining upstream firms will carry on with their Bertrand price competition (Reiffen [1992]).

This suggests that our hypothesis tests should place emphasis on “small” market structures such as the two-by-two, one-by-two, and two-by-one configurations shown in figures 1, 2, and 3, respectively. One valid test would be to compare firm i ’s independent upstream profits in market m under the following market structures (note that N_{mi}^U does not account for firm i ’s entry decision):

$$\begin{bmatrix} N_{mi}^D \\ N_{mi}^U \\ N_{mi}^V \end{bmatrix} \in \left\{ \begin{bmatrix} 2 \\ 1 \\ 0 \end{bmatrix}, \begin{bmatrix} 1 \\ 0 \\ 1 \end{bmatrix} \right\}.$$

The vector $[2 \ 1 \ 0]$ describes the situation in panel (i) of figure 1, with firm i as either U_1 or U_2 facing two downstream customers and one upstream rival. $[1 \ 0 \ 1]$ is the situation in panel (ii) of the same figure, with U_2 facing one downstream customer and a vertically integrated rival. The prediction from the OSS model is that firm i ’s upstream profits are higher in the vertically integrated market—panel (ii)—than in the vertically separated market—panel (i)—when foreclosure effects are present. This is because the vertically integrated firm sets a high price for its intermediate product, giving the independent upstream firm room to raise its price. This prediction is testable with non-experimental data, because the foreclosure and efficiency effects work in opposite directions. Efficiency effects make the vertically integrated firm more competitive so that the independent upstream firm’s profit is pushed down. This does imply that foreclosure effects may be canceled out by efficiency effects. However, the more serious problem of confounding the two effects is avoided.¹⁴ Because independent upstream profits increase in response to vertical integration only in the presence of foreclosure effects, the test is capable of rejecting the null hypothesis of “no foreclosure”. On the other hand, it is not capable of rejecting the hypothesis that foreclosure effects exist.

Another test concerns the impact of vertical integration on independent downstream profits in the two-by-two setting. The OSS model with no efficiency effects predicts that independent downstream firms are harmed by vertical integration. Most of the other foreclosure models make the same prediction. However, there is one situation in which independent downstream profit

¹⁴The problem that foreclosure effects may be cancelled out by efficiency effects is also faced by researchers who measure the direct effect of vertical integration on market outcomes.

may *increase* as a result of vertical integration by the rival pair. It is characterized by: (i) a large efficiency effect from vertical integration, (ii) the inability of the vertically integrated firm to commit to a high intermediate good price (i.e., a clear absence of vertical foreclosure), and (iii) some degree of product differentiation between the intermediate goods produced by the two upstream units. In this setting, the vertically integrated firm might sell the intermediate good to the independent downstream firm at a lower price than what would have been charged under vertical separation. Thus, if we find that vertical integration in the two-by-two market structure is associated with higher independent downstream profits, then we can conclude that foreclosure effects do not exist. This is because vertical integration can benefit independent downstream firms only in the absence of foreclosure effects.¹⁵ In contrast to the test described in the previous paragraph, the test concerning upstream rival profits is capable of rejecting the hypothesis that foreclosure effects exist. It cannot, however, reject the null hypothesis that there is no foreclosure.

In order to capture vertical rival effects in small market structures such as the two-by-two, I specify the post-entry profit equations as follows:

$$\begin{aligned}
\pi_{miD} = & h(\mathbf{x}_{mi}; \omega_D) \\
& + \delta_{DD} \times \text{number of upstream entrants} \\
& + \delta_{DU1} \times \text{presence of first upstream entrant (no vertical entrants)} \\
& + \delta_{DU2} \times \text{presence of first upstream entrant (one vertical entrant)} \\
& + \delta_{DU3} \times \text{number of additional upstream entrants} \\
& + \delta_{DV1} \times \text{presence of first vertical entrant} \\
& + \delta_{DV2} \times \text{number of additional vertical entrants} \\
& + \epsilon_{miD}.
\end{aligned} \tag{2}$$

¹⁵For this reason, we do not have to worry about foreclosure effects being cancelled out by efficiency effects.

$$\begin{aligned}
\pi_{miU} = & h(\mathbf{x}_{mi}; \omega_U) \\
& + \delta_{UD1} \times \text{presence of first downstream entrant (no vertical entrants)} \\
& + \delta_{UD2} \times \text{presence of first downstream entrant (one vertical entrant)} \\
& + \delta_{UD3} \times \text{number of additional downstream entrants} \\
& + \delta_{UU} \times \text{number of upstream entrants} \\
& + \delta_{UV1} \times \text{presence of first vertical entrant} \\
& + \delta_{UV2} \times \text{number of additional vertical entrants} \\
& + \epsilon_{miU}.
\end{aligned} \tag{3}$$

$$\begin{aligned}
\pi_{miV} = & h(\mathbf{x}_{mi}; \omega_V) \\
& + \delta_{VD} \times \text{number of downstream entrants} \\
& + \delta_{VU1} \times \text{number of upstream entrants} \\
& \quad \text{(no downstream entrants; no vertical entrants)} \\
& + \delta_{VU2} \times \text{number of upstream entrants} \\
& \quad \text{(no downstream entrants; one or more vertical entrants)} \\
& + \delta_{VU3} \times \text{number of upstream entrants(one or more downstream entrants)} \\
& + \delta_{VV} \times \text{number of vertical entrants} \\
& + \epsilon_{miV}.
\end{aligned} \tag{4}$$

With these specifications, it is possible to compare firm profits under different market structures. For instance in the two-by-two market configuration, the impact of vertical integration on independent upstream rivals can be calculated as $(\delta_{UD2} + \delta_{UV1}) - (\delta_{UD1} + \delta_{UD3} + \delta_{UU})$. Such quantities will form the basis for hypothesis testing.

III.3 Choice of market and firm characteristics

The $h(\cdot)$ term in (1) represents the effect of various market and firm characteristics on profits. I refer to the existing literature for the choice of covariates to be included in \mathbf{x}_{mi} . Following Scott Morton [1999] and Gallant, Hong, and Khwaja [2008], I use the total market revenue for each drug (*MktRev*) as a measure of market size. It is measured for the year just prior to generic entry. Another important market characteristic is the height of entry barriers. I use the number of patents for each drug held by the originator pharmaceutical company (*OrigPat*) as a measure

of entry barrier height. I also use two sets of dummy variables: one for broad therapeutic classes (e.g., cardiovascular agents, central nervous system agents); another for the year in which first generic entry occurred (from 1997 to 2005).

In terms of firm characteristics, Scott Morton [1999] and Gallant, Hong, and Khwaja [2008] suggest that firm experience is an important determinant of entry behavior. For the downstream segment, I use as measures of experience the number of downstream markets entered by firm i during each of the five years prior to facing the entry opportunity in market m : $DownExp_{mi,-s}$, $s = 0, \dots, 4$. For the upstream, I use the number of upstream markets entered by firm i during each of the seven years prior to entry opportunity m : $UpExp_{mi,-s}$, $s = 0, \dots, 6$. I allow the learning effects of experience to deteriorate over time (Benkard [2000]). Thus, the past experience variables depreciate with constant factors ρ_D and ρ_U for downstream and upstream, respectively. Due to the allowance for experience depreciation, $h(\cdot)$ has the following nonlinear specification:

$$h(\mathbf{x}_{mi}; \omega_k) = \beta_{k0} + \beta_{k,MktRev} MktRev_m + \beta_{k,OrigPat} OrigPat_m + \beta_{k,DownExp} \sum_{s=0}^4 \rho_D^s DownExp_{i,-s} + \beta_{k,UpExp} \sum_{s=0}^6 \rho_U^s UpExp_{i,-s} \quad (5)$$

where $\omega_k \equiv (\beta_k, \rho_D, \rho_U)$. I assume that upstream experience has no bearing on the firm's profit as an independent downstream entrant. Hence, I set $\beta_{D,UpExp} = 0$. Similarly, I set $\beta_{U,DownExp} = 0$.

IV Estimation Strategy

IV.1 Equilibrium finding algorithm

The first step in estimation is to find the Nash equilibrium market structures under a given set of parameter candidate values. I restrict attention to pure strategy equilibria. The equilibrium finding routine involves plugging in various candidate market structures into each potential entrant's set of payoff equations (2)-(4), along with the parameter candidate values and a set of values for the error terms, and seeing whether or not the resulting payoffs satisfy the equilibrium conditions.

Comparing the fitted values for firm payoffs

For each candidate market structure vector $\mathbf{N}_c^{(0)} \equiv [N_c^D \quad N_c^U \quad N_c^V]^\top$, three additional vectors are generated:

$$\mathbf{N}_c^{(1)} = \begin{bmatrix} N_c^D - 1 \\ N_c^U \\ N_c^V \end{bmatrix}, \mathbf{N}_c^{(2)} = \begin{bmatrix} N_c^D \\ N_c^U - 1 \\ N_c^V \end{bmatrix}, \mathbf{N}_c^{(3)} = \begin{bmatrix} N_c^D \\ N_c^U \\ N_c^V - 1 \end{bmatrix}.$$

These four vectors are plugged into each potential entrant's payoff equations to generate fitted values for its payoffs. These fitted values are then compared with each other to predict each firm's action.

As a demonstration, firm i 's fitted payoff values in market m under $\mathbf{N}_c^{(1)}$, for a particular set of parameter candidate values and a particular set of values for the error terms, are:

$$\pi_{mik} \left(\mathbf{N}_c^{(1)}; \tilde{\theta}, \tilde{\epsilon} \right) = h(\mathbf{x}_{mi}, \tilde{\omega}_k) + g_k \left(\mathbf{N}_c^{(1)}; \tilde{\delta}_k \right) + \tilde{\epsilon}_{mik}, \quad k \in \mathcal{K}.$$

where $\theta \equiv (\omega, \delta)$ and the tilde indicates specific values for each object. For brevity, I suppress the arguments of the payoff function to use the shorthand: $\pi_{mik}^{(t)} \equiv \pi_{mik} \left(\mathbf{N}_c^{(t)}; \tilde{\theta}, \tilde{\epsilon} \right)$, $t \in \{0, 1, 2, 3\}$. Given the fitted payoff values, firm i finds it profit maximal to be an independent downstream entrant in market m if $\pi_{miD}^{(1)} > 0$ and $\pi_{miD}^{(1)} = \max_k \pi_{mik}^{(1)}$.

Firm i can also maximize its profit by being an independent *upstream* entrant if $\pi_{miU}^{(2)} > 0$ and $\pi_{miU}^{(2)} = \max_k \pi_{mik}^{(2)}$. Likewise, vertically integrated entry may be firm i 's optimal choice if $\pi_{miV}^{(3)} > 0$ and $\pi_{miV}^{(3)} = \max_k \pi_{mik}^{(3)}$. In fact, it is possible that *all* entry categories are profit maximal choices for firm i in an equilibrium characterized by market structure $\mathbf{N}_c^{(0)}$. In addition, "not entering" is a profit maximal choice for firm i if $\pi_{mik}^{(0)} \leq 0$, $\forall k \in \mathcal{K}$.

Checking if a candidate market structure satisfies equilibrium conditions

The preceding suggests that for each firm, multiple actions can be optimal under a given candidate market structure. This complicates the equilibrium finding procedure. For each market m , the following four steps are followed in order to find out if the candidate market structure $\mathbf{N}_c^{(0)}$ is an equilibrium.

1. Generate four matrices corresponding to the four vectors $\mathbf{N}_c^{(t)}$, $t \in \{0, 1, 2, 3\}$:

$$\mathbf{\Pi}_m^{(t)} = \begin{bmatrix} \pi_{m1D}^{(t)} & \pi_{m1U}^{(t)} & \pi_{m1V}^{(t)} \\ \pi_{m2D}^{(t)} & \pi_{m2U}^{(t)} & \pi_{m2V}^{(t)} \\ \vdots & \vdots & \vdots \\ \pi_{mID}^{(t)} & \pi_{mIU}^{(t)} & \pi_{mIV}^{(t)} \end{bmatrix}, \quad t \in \{0, 1, 2, 3\}$$

where I is the number of firms in the sample and firms are indexed by $i = 1, 2, \dots, I$. If firm i is not a potential entrant into category k of market m , then $\pi_{mik}^{(t)}$ is automatically set to zero for all t .¹⁶

2. From each of the three matrices $\mathbf{\Pi}_m^{(t)}$, $t \in \{1, 2, 3\}$, create a vector of length I called $\psi_m^{(t)}$.

This vector is equivalent to the t th column of $\mathbf{\Pi}_m^{(t)}$ except that the i th element of $\psi_m^{(t)}$ is

¹⁶The definition of potential entrants is discussed in section V.

set to zero if $\pi_{mi,\kappa(t)}^{(t)} \neq \max_k \pi_{mik}^{(t)}$ or if $\pi_{mi,\kappa(t)}^{(t)} < 0$, where

$$\kappa(t) = \begin{cases} D & \text{if } t = 1 \\ U & \text{if } t = 2 \\ V & \text{if } t = 3. \end{cases}$$

3. Merge the three vectors $\psi_m^{(t)}$ column-wise to form the $I \times 3$ matrix Ψ_m . It would look something like this:

$$\Psi_m = \begin{bmatrix} \pi_{m1D}^{(1)} & 0 & 0 \\ 0 & \pi_{m2U}^{(2)} & \pi_{m2V}^{(3)} \\ \vdots & \vdots & \vdots \\ 0 & \pi_{mIU}^{(2)} & 0 \end{bmatrix}$$

This particular example shows that D is a profit maximal action for firm 1, firm 2's optimal actions include U and V , and an optimal action for firm I is U .

4. The candidate market structure $\mathbf{N}_c^{(0)}$ is an equilibrium for market m if and only if there exists some vector \mathbf{e}_m of length I , with elements e_{mi} , $i \in \mathcal{I} \equiv \{1, 2, \dots, I\}$, such that the following four conditions are satisfied:

$$(a) \sum_i \mathbf{1}\{e_{mi} = \kappa^{-1}(k)\} = N_c^k, \quad \forall k \in \mathcal{K} \text{ and}$$

$$\kappa^{-1}(k) = \begin{cases} 1 & \text{if } k = D \\ 2 & \text{if } k = U \\ 3 & \text{if } k = V. \end{cases}$$

$$(b) \sum_i \mathbf{1}\{e_{mi} = 0\} = I - \sum_k N_c^k.$$

$$(c) \Psi_m(i, t) \neq 0 \text{ if } e_{mi} = t, \quad \forall t \in \{1, 2, 3\}.$$

$$(d) \Pi_m^{(0)}(i, t) \leq 0 \text{ if } e_{mi} = 0, \quad \forall t \in \{1, 2, 3\}.$$

\mathbf{e}_m is an equilibrium action profile characterized by market structure $\mathbf{N}_c^{(0)}$. Specifically, the i th element of \mathbf{e}_m provides a numerical code for the action of firm i , as follows:

$$e_{mi} = \begin{cases} 0 & \text{if } i \text{ does not enter} \\ 1 & \text{if } i \text{ enters as independent downstream} \\ 2 & \text{if } i \text{ enters as independent upstream} \\ 3 & \text{if } i \text{ enters as vertically integrated.} \end{cases}$$

Conditions (a) and (b) simply say that the market structure implied by \mathbf{e}_m must be $\mathbf{N}_c^{(0)}$. Condition (c) says the following: if \mathbf{e}_m indicates that firm i enters category k , then it must be the case that k is the profit maximal action for i , given that the actions of its rivals is summarized by $\mathbf{N}_c^{(\kappa^{-1}(k))}$. This condition guarantees that all entrants make positive profits, and that they are profit maximizing. Finally, condition (d) ensures that non-entering firms would make a loss if they were to enter.

Several different algorithms can be devised for finding the equilibrium action profile \mathbf{e}_m . The one I employ chooses equilibrium actions one firm at a time, starting with the element in Ψ_m with the highest value, and moving towards the element with the lowest value. Running this algorithm for every market in the sample, for every market structure candidate, is extremely time-consuming.¹⁷ Several simple-to-calculate criteria are used to screen out most market structure candidates before evaluating them rigorously. Still, the computational burden is quite high due to the large number of parameter iterations that I must go through during estimation. For this reason, I run the algorithm only for the market structures observed in the data. For instance, if the observed structure for market m is $\mathbf{N}_m = [4 \ 2 \ 1]$, I use the equilibrium finding algorithm to check whether or not $[4 \ 2 \ 1]$ is an equilibrium structure for market m under the given parameter values.

IV.2 Constructing the simulated likelihood

Exact likelihoods are difficult to compute for my model, because there is no analytical expression for the probability of observing a given market structure. Fortunately, simulated likelihoods can be constructed. This involves taking multiple sets of draws for the random error terms in the payoff equations.

I use a Halton sequence to generate R draws of the error term vector, which has length $\sum_m \#(\mathcal{I}_m) \times 3$ where $\#(\mathcal{I}_m)$ is the number of elements in \mathcal{I}_m . Each element of the vector is assigned to a specific category of a specific market, for a specific firm. The draws have a multivariate standard normal distribution and I assume zero correlation among the error terms.¹⁸ The number of draws, R , is set to 100.

Let \mathfrak{M}^o be the $M \times 3$ matrix of observed market structures, with each row corresponding to a market and each column corresponding to an element of $\{D, U, V\}$. Also, let $\mu(\tilde{\theta}, m, r)$ be a

¹⁷As described in the next subsection, my simulation-based estimator uses 100 sets of draws for the random error terms. Multiplying this by the number of markets in the data (91) and the number of possible market structures (more than 2,000), we find that the algorithm would have to be run more than 18 million times for each iteration of the parameter candidate values.

¹⁸At the cost of increasing the number of parameters, correlations among the elements of the vector can be introduced (Train [2003]).

correspondence that gives, for parameter candidate $\tilde{\theta}$, market m , and the r th draw of the error term vector the set of predicted equilibrium market structures. $\mu(\cdot)$ is essentially the equilibrium finding algorithm. Given $\tilde{\theta}$ and draw r , I obtain the value of an “equilibrium indicator function” for each market m , defined as:

$$q(\tilde{\theta}, m, r) = \begin{cases} 1 & \text{if } \mathfrak{M}_m^o \in \mu(\tilde{\theta}, m, r) \\ 0 & \text{otherwise.} \end{cases}$$

The simulated likelihood is then calculated as

$$SL(\tilde{\theta}) = \prod_m \frac{\sum_r q(\tilde{\theta}, m, r)}{R}. \quad (6)$$

The only information required for computing (6) is whether or not the observed equilibrium is included in $\mu(\tilde{\theta}, m, r)$ for all m and r ; it is not necessary to obtain all the elements in $\mu(\tilde{\theta}, m, r)$.

Before moving on, there are two issues that need to be addressed. The first pertains to the zero likelihood problem. This refers to the possibility that in some market, none of the draws yield the observed market structure as an equilibrium. The likelihood contribution of such a market is zero, which means that the entire likelihood is driven down to zero regardless of the value of other markets’ likelihood contributions. Several methods have been proposed to avoid this problem, such as discarding the observations that have a zero likelihood contribution, or altering the underlying theoretical model so that all outcomes in the data have some probability of occurring (El-Gamal, McKelvey, and Palfrey [1993]). The solution I adopt is somewhat ad hoc, but it is easy to implement and requires no change in the underlying model. I augment the likelihood contribution of each market with a value of $\frac{1}{R}$, thereby calculating the following modified simulated likelihood:

$$\check{S}L(\tilde{\theta}) = \prod_m \frac{1 + \sum_r q(\tilde{\theta}, m, r)}{R}. \quad (7)$$

This function does not satisfy the requirements of a likelihood; in particular, it does not integrate to one over the parameter space. It is even possible for the value of (7) to surpass one, if all draws correctly predict the observed market structure. However, these problems are likely to be less serious within the Bayesian framework that I adopt, because what matters for Bayesian inference is the ratio between densities at different points and not their absolute values. It is also hoped that near the center of the parameter vector’s distribution (either the sampling distribution or the posterior distribution, depending on whether one takes a frequentist or Bayesian stance), the simulated likelihood (6) will have a nonzero value, so that the zero likelihood problem goes

away.¹⁹

The second issue that needs to be addressed is that of equilibrium multiplicity. At its worst, the existence of multiple equilibria can render the econometric exercise useless. For instance, consider a bilateral vertical entry model with only one potential entrant in each of the vertical segments. Under a wide range of parameter values, the model predicts exactly two equilibria: *(enter, enter)* and *(not enter, not enter)*. The realized market structure will always be one of the two, and the observations provide little information about the parameters (Tamer [2003]). In other entry game situations, the problem is less serious. In the horizontal entry game with homogeneous firms, multiple equilibria do occur but the equilibria are generally characterized by the same number of entrants (Bresnahan and Reiss [1991a]). In the vertical entry model, multiple equilibria are sometimes characterized by different numbers of entrants. However, the set of multiple equilibria generally forms only a small subset of the set of possible market structures (Elberfeld [2002]). Thus, econometric analysis is useful in the sense that the set of likely outcomes is narrowed down substantially. Still, one must keep in mind that the model assigns probabilities not to an individual market structure, but to an outcome that contains the given market structure as one possible equilibrium (Ciliberto and Tamer [2009]).

IV.3 Bayesian procedures

I use the simulated likelihoods to conduct Bayesian inference. Specifically, I assume a prior distribution for the model parameters with density $p(\theta)$. The density of the posterior distribution of θ is proportional to the product of the (modified) simulated likelihood and the prior density:

$$p(\theta|\mathbf{Y}) \propto \check{S}L(\theta)p(\theta)$$

where \mathbf{Y} denotes the data, including market and firm characteristics as well as market structure outcomes. $\check{S}L(\theta)$ is derived from the data as described in the previous subsection. The posterior distribution is used to make inferences about the parameter values. Specifically, it is used to construct “highest posterior density (HPD)” sets for individual parameters and functions of parameters. The HPD sets are analogous to the confidence intervals in frequentist econometrics.

The first step of the Bayesian procedure is to define the prior distribution. I use an improper prior distribution in which the elements of β_k and δ_k , $k \in \{D, U, V\}$ are distributed

¹⁹Perhaps a better solution would be to utilize moment conditions, rather than the likelihood, to construct the criterion function. For instance, one can calculate the difference between the predicted market structure and the observed market structure, and interact it with the exogenous variables to construct a set of moment conditions. This method, used in the entry game context by Berry [1992] and Jia [2008], requires the econometrician to find all equilibria of the entry game, as well as to devise a rule for choosing a single equilibrium.

uniformly on the real number line.²⁰ The two remaining parameters, ρ_D and ρ_U , are given uniform priors on the interval $[0, 1]$. Because there is no analytical expression for the posterior density, I sample from the posterior distribution by utilizing the Metropolis-Hastings algorithm to construct a Markov chain. I choose the step size within the Metropolis-Hastings algorithm so that the acceptance rate is around 30 percent.²¹

V Data

The model is estimated using data for the US generic pharmaceutical industry. The data consists of drug markets, each having an upstream segment manufacturing active pharmaceutical ingredients (APIs) and a downstream segment manufacturing finished formulations. The markets are selected from a database of the US Food and Drug Administration (FDA) that contains the population of all drug approvals. I select a subset of drug markets that opened up to generic competition between January 1, 1997 and December 31, 2005. I further narrow down to markets in which the relationship between the upstream and downstream segments is relatively straightforward. This involves restricting the sample to the first dosage form to open up to generic competition for each API. I also restrict the sample to oral dosage forms—tablets and capsules, including extended-release versions. This leaves 91 downstream markets, each defined by a distinct combination of an API and a dosage form. There are 87 corresponding upstream markets, each defined by a distinct API. For four APIs (acyclovir, fluoxetine hydrochloride, gabapentin, and terazosin hydrochloride), two different dosage forms went generic on the same day. In these cases, I consider different dosage forms of the same API to constitute independent market observations, and allow each of them to be combined with data for their respective API markets. Thus, for the four APIs mentioned above, the same upstream market data are used twice.²² The Data Appendix contains further details on how the markets are selected, as well as a list of the drugs. The actual data was downloaded from a proprietary database called Newport SourcingTM, developed and maintained by Thomson Reuters.

V.1 Entry indicator

In order to define market entry, it is first necessary to define a date on which each drug market opens up to generic competition. Previous authors such as Scott Morton [1999] use the approval date of the first generic product as the market opening date. After comparing product approval

²⁰This is an improper distribution in the sense that it does not integrate to one.

²¹In the run used to construct the presented results, the acceptance rate is 31.3 percent.

²²Alternatively, I can choose to keep only one dosage form for each of the four APIs. Doing so does not alter the results.

dates with product launch dates, I find that this definition is not always appropriate.²³ In some cases, the first approved generic product is not marketed until several months after approval. During those months, the second and later generic products are not approved by the FDA. On the other hand, I find a few cases in which drugs that appear to be generics are launched before being approved. The former situation arises when pending patent litigation between the generic entrant and the originator firm, or an out-of-court settlement between the two parties, prevents the generic from entering immediately upon approval. The latter situation is related to a phenomenon known as “authorized generics”, whereby the originator firm licenses a generic company to sell the product under the originator’s own FDA approval. In order to accommodate such special cases, I define the market opening date as the first generic approval date or the first generic launch date, whichever is later.

Firm-level entry actions are defined on the basis of market opening dates. Specifically, a generic firm is considered to have entered the downstream segment if its application for approval to market a generic finished formulation, called an Abbreviated New Drug Application (ANDA), is approved by the FDA either before the market opening date, or not later than one year after the market opening date. The narrow window is justified on the grounds that entry timing is an important determinant of profits in generic drug markets; because prices fall rapidly in response to additional entry (Caves, Whinston, and Hurwitz [1991]; Reiffen and Ward [2005]), most firms enter in the beginning stages of the market.

In the upstream segment, a generic firm is deemed to have entered a market if it submits to the FDA a document, called a Drug Master File (DMF), that describes how the firm manufactures the API used in that market. To be considered as an entry event, the submission must be made before the market opening date, or no later than one year after the market opening date²⁴. A vertically integrated entry event is defined by the simultaneous occurrence of downstream entry and upstream entry.

V.2 Potential entrants

I identify potential entrants in market m as follows. Let us define $fdate_{il}$ as the first recorded entry date of firm i into segment $l \in \{D, U\}$ of any market, including those outside the sample but excluding market m itself. $ldate_{il}$ is similarly defined as firm i ’s last recorded entry date in segment l . Firm i is identified as a potential downstream entrant of market m if $fdate_{iD}$ is on or before the market opening date for market m and $ldate_{iD}$ is not more than five years before

²³Product launch dates were obtained from the Newport database.

²⁴Further details on DMFs and ANDAs are found in the Data Appendix.

the market opening date. Thus, I allow a firm to remain a potential downstream entrant for five years after its last entry. Similarly, firm i is identified as a potential upstream entrant of market m if $fdate_{iU}$ is on or before the market opening date and $ldate_{iU}$ is not more than seven years before the market opening date. Potential entrant status in the upstream segment is allowed to last for seven years after the last entry event. The reason for setting a wider window for potential upstream entrants is that upstream entry often occurs a few years before the market opening date. Firm i is a potential vertically integrated entrant of market m if and only if it is a potential downstream entrant as well as a potential upstream entrant.

Using the above definition of potential entrants, I obtain a dataset of 104 firms facing 8,127 choice situations. Each choice situation is a market-firm pair where a firm chooses whether or not to enter, and which segment(s) to enter. Not all choice situations involve the same choice set, because in a number of cases the firm is a potential entrant in only one of the segments. Table 2 classifies the choice situations according to the alternatives faced and the choices actually made. There are nine instances—three for potential downstream-only entrants and six for potential upstream-only entrants—where a firm enters a segment in which it is *not* a potential entrant. Such cases can be prevented by broadly defining potential entrants. However, such an adjustment substantially reduces entry probabilities and lowers the quality of the estimates. I consider the misclassification rates implied by table 2 to be acceptably low, and accordingly make adjustments to the data. Specifically, potential downstream-only entrants who enter as independent upstream and potential upstream-only entrants who enter as independent downstream are both deemed not to have entered. Potential downstream-only entrants who make a vertically integrated entry are deemed only to have entered the downstream segment, and their upstream counterparts are treated similarly.

V.3 Market size

Following Scott Morton [1999], I measure market size by the total revenue for a drug in the US market during the year prior to the first generic entry date. I calculate the revenue figures from a data source called the Medical Expenditure Panel Survey (MEPS). MEPS is a large-scale annual survey of households co-sponsored by the Agency for Healthcare Research Quality and the National Center for Health Statistics. It has been conducted since 1996, asking respondents detailed information about their medical expenditures and confirming those responses with the respondents' pharmacies²⁵. The MEPS data consists of several different files, and one of them,

²⁵See Cohen, Monheit, Beauregard, Cohen, Lefkowitz, Potter, Sommers, Taylor, and Arnett [1996]. Other economics articles using the MEPS data include Lichtenberg [2001], Rizzo and Zeckhauser [2005], and Acemoglu and Linn [2004].

called the Prescribed Medicines File contains information on the use and purchase of prescription drugs. As an example, in the 2004 Prescribed Medicines file (the latest year used in my study), there are a total of 317,065 records. Each record represents a single drug acquisition event, and contains data on drug characteristics such as active ingredient and strength. The quantity and value (including both insurance and out-of-pocket payments) of the transaction is also recorded. The same patient-drug pair appear more than once in the same file if the patient refills his or her prescription. Each record is assigned a weight based on the MEPS stratified sampling scheme. I apply such weights to estimate the national total revenue for each drug in my dataset, for the years 1996-2005.

Despite the large sample size, the national revenues estimated from MEPS data fluctuate significantly across years due to sampling variability. I therefore obtain smoothed estimates of market revenue by regressing the MEPS estimates on a time trend, after deflating the time series data using the consumer price index of the Bureau of Labor Statistics (base period 1982-84). The predicted value for the year prior to generic entry is used as the market size variable. Following Mazzeo [2002], the variable is transformed into the natural logarithm of the ratio to its mean (see the notes in table 3) and assigned the name *MktRev*. For smaller drug markets (i.e., those for which few drug acquisition events are recorded), the MEPS estimate for total revenue fluctuates so widely that it does not seem advisable to use it as data. Therefore, I set a cutoff level of market revenue such that drug markets with predicted market revenues below it are assigned a zero value for *MktRev*. I introduce a dummy variable (*NoRevData*) that equals one for markets with zero market revenue values, so in effect smaller markets are provided with a common intercept. The cutoff level is chosen as 30 million in 1982-84 dollars.

V.4 Originator patents

In the pharmaceutical industry, originator firms often file multiple patents for one product. In addition to the basic product patent covering the active pharmaceutical ingredient (API), there can be several secondary patents covering specific aspects of the drug, such as a process for manufacturing the active ingredient, a chemical form of the API, or a particular finished formulation. Such patents mostly arise during the drug development stage, after the drug compound has been discovered and patented, but prior to approval and marketing of the new drug. This implies that secondary patents generally expire at a later date than the basic patent, creating an entry barrier that the generic entrants must either accept, circumvent, or invalidate.

If a secondary patent covers a specific chemical form of the API, a generic entrant must either invalidate the patent or circumvent it by manufacturing a novel unpatented form or an

older unprotected form.²⁶ A secondary patent on a process for manufacturing the API can also pose a significant entry barrier. For instance, if the process disclosed in the basic patent is not suitable for commercial scale production, the originator (or its API supplier) develops and patents alternative processes, some of which are used for actual production (Mándi [2003]). The generic API manufacturer must circumvent or invalidate such process patents in order to sell its product without legal liability.

I count the number of patents held by the originator firm under the assumption that this measures the height of entry barriers created by secondary patents. In order to do so, I must first identify the originator for each drug. There are sometimes multiple firms involved in the development of a single drug, and it may not be possible to identify a single firm as the originator. Moreover, new drugs developed by foreign firms are sometimes licensed out to local pharmaceutical companies with better marketing infrastructure, so the sponsor of a new drug in the US may not necessarily be its innovator. To identify originator patents with as much accuracy as possible, I apply the following steps. First, for each drug I group all its associated US patents according to their assignees. This gives a list of patent holders as well as the number of patents held by each. Second, for each drug I identify the recipient of the first FDA approval—not the ANDA but the New Drug Application (NDA) approval—as well as the first launchers in the following markets: France, Germany, Japan, the UK, and the US. Lastly, I identify the first approval recipients and first launchers that are also US patent holders, and sum up their patent counts to form the originator patent variable. The patent variable is subjected to the same transformation as the market revenue variable, and it is assigned the name *OrigPat*. Of the 91 drug markets in the data, there are six for which no originator patent counts could be generated. For these observations, a value of 0.1 was assigned before applying the transformation.

V.5 Firm experience

The sole observable firm characteristic in my data is previous entry experience. Downstream entry experience is measured by the number of oral dosage form markets entered by the firm in each of the five years prior to the market opening date. The annual entry counts are denoted as *DownExp_{-s}*, $s = 0, 1, 2, 3, 4$. Upstream experience is measured by the number of distinct APIs for which the firm submitted a Drug Master File in each of the seven years preceding the market opening date. The variables are named *UpExp_{-s}*, $s = 0, 1, \dots, 6$. In constructing the two sets of

²⁶An interesting description of such secondary product patents is found in Judge Richard Posner's opinion in *SmithKline Becham v. Apotex*, District Court, Northern District of Illinois, filed March 3, 2003.

variables, the past entries to be counted are not restricted to the 91 drugs in the sample. Also, when measuring the firm’s entry experience variables for market m , entry into market m itself is not counted. Table 3 presents the summary statistics for the explanatory variables.

VI Results

I generate a Markov chain of 40,000 realizations from the posterior distribution of the parameters. The first 30,000 realizations are discarded as a burn-in period, and the last 10,000 are used for analysis. Table 4 presents some informal measures of goodness-of-fit when the modes of the marginal posterior distributions are used as parameter values, and 100 draws from the Halton sequence are used as simulated random error terms. The fitted payoff values are used to check if the market structures observed in the data are predicted as equilibria of the vertical entry game. The first row of table 4 shows that of the 91 markets in the dataset, 31 (34.07 percent) have at least one draw in which the observed market structure is contained in the (possibly non-singleton) set of equilibria. When we consider individual market-draw combinations separately, it is found that the rate of correct prediction is 4.26 percent (388 out of 9,100 market-draw combinations).

VI.1 Single parameters

Table 5 presents, for each parameter, the mode and 95 percent highest posterior density (HPD) sets of the marginal posterior distributions. Each HPD set is constructed by drawing a kernel smoothed density for the marginal posterior distribution, and finding a cutoff level such that the set of points with a density higher than the cutoff constitute 95 percent of the posterior distribution (Lancaster [2004]).²⁷

The coefficients on the three market characteristic variables mostly have the expected sign, but there are two exceptions: the coefficient on *MktRev* in the downstream payoff equation is negative, and that on *OrigPat* is positive in the upstream payoff equation. Otherwise, it is found that larger market size is associated with higher profits, while originator patents tend to reduce downstream profits. Firms’ entry experience is found to depreciate each year at a rate of between 34 and 54 percent, as seen from the estimates for ρ_D and ρ_U . The composite downstream experience term has a positive effect on both vertical and independent downstream profits. The composite upstream experience term also has a positive effect, but only for vertically integrated entrants.

²⁷For a graphical illustration, see figures 4 and 5.

The HPD sets for the δ parameters are quite illuminating. In all three equations, the effect of rival entry in the same category (δ_{DD} , δ_{UU} , and δ_{VV}) is significantly negative, as expected. Another expected result is that upstream entry and downstream entry are complementary; independent entrants in each vertical segment benefit when someone else enters the other segment independently. In other words, “matching” entry is universally welcomed.

For the other δ parameters, there is no *a priori* reason to expect a particular sign. One interesting result is that independent downstream entrants are not harmed by vertically integrated rivals, as can be seen from δ_{DV1} being significantly positive and δ_{DV2} not being different from zero. On the other hand, δ_{UV1} and δ_{UV2} are both negative, indicating that independent upstream entrants are hurt by vertically integrated rivals. These findings suggest that vertically integrated entrants compete with independent rivals primarily in the upstream segment. This is consistent with industry practice wherein vertically integrated firms such as Teva often sell active pharmaceutical ingredients (APIs) to their downstream rivals (e.g., Teva Pharmaceutical Industries [2005]). One reason for doing so may be the scale economies inherent in API production, something that is not incorporated into the simple theoretical models of vertical foreclosure.

Turning to the vertical payoff equation, it is found that independent rival entry in the downstream benefits vertically integrated firms. This is consistent with downstream rivals also being the buyers of the APIs produced by vertically integrated firms. The effect of independent upstream entry on vertically integrated profits is more ambivalent. Vertically integrated profits are not hurt by independent upstream rivals when there are no independent downstream firms. In fact, the profits of a sole vertical firm increases with upstream entry (i.e., δ_{VU1} is positive), presumably because the upstream firm offers an alternative source of API supply. These findings are not surprising, because upstream rivals in the absence of downstream customers pose no competitive threat to the vertical firm. Independent upstream entry does have a negative impact on vertical profits when downstream firms are also present (i.e., δ_{VU3} is negative). This is consistent with independent upstream firms and vertically integrated firms competing for the business of downstream customers.

VI.2 Testing foreclosure theory

Table 6 and figures 4 and 5 present the posterior modes and HPD intervals for specific linear combinations of the δ parameters. The linear combinations are designed to measure the impact, on independent firms, of vertical integration by a pair of firms in small market structures.

The first row of table 6 and panel (i) of figure 4 both show the impact of vertical integration

on independent downstream rivals in a two-by-two market. The effect is significantly positive. In terms of figure 1, firm D_2 is better off in panel (ii) than in panel (i). This is an important finding from the viewpoint of foreclosure theory. As discussed in section III, *vertical integration can benefit independent downstream firms only in the absence of foreclosure effects*. Thus, the finding allows us to reject foreclosure effects as a general tendency in the generic pharmaceutical industry. At the same time, this finding strongly supports the existence of efficiency effects through vertical integration.

Further support for efficiency effects is found in the second row of table 6 and panel (ii) of figure 4. They imply that in the one-by-two market structure (figure 2), the independent downstream firm is better off if the upstream unit is vertically integrated. This is surprising, given that vertical integration facilitates commitment by the upstream firm to restrict supply. While the monopoly restoration theory of Rey and Tirole [2007] cannot be rejected, any foreclosure effects that may exist are cancelled out by efficiency effects.

Rows three and four of table 6 and figure 5 present the effect of vertical integration on independent upstream profits in the two-by-two and two-by-one market structures. The effects are unambiguously negative. Although the results cannot be used to reject the hypothesis of “no foreclosure”, they lend further support to the existence of strong efficiency effects. These results also support the notion that vertically integrated firms compete vigorously against independent upstream firms in the API market. In the two-by-one market structure (figure 3), it is possible that the vertically integrated firm forecloses the upstream rival from access to the downstream market. However, it is more likely that the vertically firm uses the upstream rival as an additional supply source, as discussed in the previous subsection.

VI.3 Simulating a ban on vertically integrated entry

The preceding results indicate that firms’ entry actions are consistent with the existence of significant efficiency effects and the absence of foreclosure effects. This implies that vertical integration in this industry is unlikely to be anticompetitive from a static point of view. Vertical integration can have an anticompetitive dynamic effect, however, if independent upstream firms are deterred from entering when they anticipate tough competition from vertically integrated rivals. I examine this possibility by conducting a policy simulation. Specifically, I simulate the effect of a counterfactual policy that bans any firm from entering both vertical segments of the same market. To my knowledge, no such ban has been contemplated for the generic pharmaceutical industry, but policy makers may well consider it if the effects are found to be beneficial.

In order to simulate the effect of the policy, I run two sets of predictions on equilibrium market structures. In the first set, firms are allowed to enter as a vertically integrated entity. This is the status quo. In the second set, I simulate the policy by removing “vertically integrated entry” from the choice set of each potential entrant. For both sets, I make predictions for 100 draws of the error term vector (the same draws that are used to generate the simulated likelihoods), and for each draw I compute all pure strategy Nash equilibria of the entry game. The parameter values that I use are the modes of the marginal posterior distributions.

Before turning to the simulation results, table 7 presents statistics regarding the multiplicity and existence of equilibria for the simulation runs in which vertically integration was allowed. These give us some idea of the difficulties inherent in the estimation of a vertical merger game. Equilibrium multiplicity is widespread, with only six percent of the market-draw pairs exhibiting a unique Nash equilibrium. The average number of equilibria is 5.72, with some market-draws having as many as 20 equilibria. The prevalence of multiplicity is due to the strong complementarity between independent upstream entry and independent downstream entry. In other words, coordination problems appear to be a defining feature of the entry game. The non-existence of pure strategy Nash equilibrium is observed in only 0.2 percent of the market-draw combinations. It is likely that a unique mixed strategy equilibrium exists in such cases. In all of the markets, I was able to find a pure strategy Nash equilibrium for at least one of the draws. Thus, non-existence of pure strategy equilibrium does not appear to be a significant problem in my model.

Figure 6 presents the results of policy simulation. In order to compare the predicted equilibrium market structures with and without the ban on vertically integrated entry, I count the number of entrants that are predicted to be present in each vertical segment. Thus, a vertically integrated entrant is counted as both an upstream entrant and a downstream entrant. For the 91 markets in the dataset, I calculate the mean number of entrants in each segment, averaging over draws as well as over multiple equilibria. Each dot in figure 6 represents a market, with the horizontal axis measuring the number of entrants under free vertical entry, and the vertical axis measuring the number under the ban policy.

The results are illuminating. In panel (i) of figure 6, we see that in markets that are characterized by fewer entrants, the number of downstream entrants tends to be *smaller* when vertically integrated entry is banned. The opposite appears to be the case in markets characterized by many downstream entrants; the number of downstream entrants is somewhat larger under the ban. Turning to panel (ii) of the figure, we find that the effect of the policy is less clear-cut for the upstream segment. It seems that there are slightly fewer upstream entrants under the

ban in markets with less than five upstream units. On the other hand, in markets with six or more upstream units, the ban appears to slightly raise the number of entrants.

From a policy point of view, the effect of the ban in smaller markets (i.e., those with fewer entrants) is more important than its effect in larger markets. This is because the price reduction effect of additional entry falls with the number of entrants. What, then, accounts for the result that the ban reduces entry in smaller markets? One possibility is that because vertical integration has significant efficiency effects, banning it has a negative impact on the expected profits of potential downstream entrants. This reduces the firms' incentive to enter the downstream market. By depriving the opportunities for efficiency enhancement through vertical integration, the ban also has the effect of reducing entry in the upstream. A tentative conclusion that can be drawn from this exercise is that vertical integration does not appear to have any anticompetitive dynamic effects that would raise concerns among policy makers.

Conclusion

Vertical foreclosure has been a subject of intense theoretical and empirical research, but evidence supporting its existence or absence has been elusive. This study introduced a novel method for testing foreclosure theory that is based on the estimation of vertical entry games. The econometric model was applied to the US generic pharmaceutical industry, where markets open up to competition as drug patents expire, and where some firms are vertically integrated between the active pharmaceutical ingredient and finished formulation segments. The estimation results indicate that vertical foreclosure is not a prevalent feature of this industry. The parameter estimates were also used to simulate the effect of a counterfactual policy that bans vertically integrated entry. The results suggest that such a policy has the effect of reducing entry in smaller markets. Coupled with the finding of significant efficiency effects through vertical integration, the simulation results advise against instituting such a ban.

The success of the model at testing foreclosure theory arises from the careful consideration of two issues. First, the underlying theoretical model of vertical oligopoly was pinned down before specifying the firms' payoff equations. Second, the statistical tests were designed so that the results would more easily shed light on foreclosure theory. Specifically, care was taken in choosing the quantities on which to base the tests, so that the efficiency effect of vertical integration would not be confounded with the foreclosure effect.

Due to the computationally intensive nature of the equilibrium finding routine, the problem of equilibrium multiplicity and that of zero likelihood were not treated with the best available

econometric methods. The application of state-of-the-art techniques, particularly methods to resolve the equilibrium multiplicity problem, is expected to further advance the usefulness of the vertical entry model. There are other industries, such as the cement-concrete one, where entry into vertical segments can be observed across a large number of markets. It is hoped that the methodology presented in this study will be usefully applied to the study of vertical competition in such industries.

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Table 1: Distribution of Entries by Category

	Independent downstream	Independent upstream	Vertical
<i>Total number of entries by individual firms</i>			
Teva (Israel)	32	3	22
Mylan (USA)	38	0	0
Ranbaxy (India)	5	10	14
Cipla (India)	0	15	0
<i>Number of entries per market</i>			
Mean	3.923	4.220	0.901
Minimum	0	0	0
Maximum	12	14	6

Notes:

Counts are based on a sample of 91 pharmaceutical markets in the US that opened up to generic competition between 1997 and 2005. Definitions of downstream entry and upstream entry are provided in section V. Vertical entry implies both downstream and upstream entry.

For each firm, the country name in brackets denotes the location of its global headquarters. The entry counts for each firm do not include entries by acquired companies prior to acquisition.

Table 2: Classification of Choice Situations

Actual choice	Choice set		
	$\{NE, D\}$	$\{NE, U\}$	$\{NE, D, U, V\}$
<i>NE</i>	1,256	4,148	1,896
<i>D</i>	125	3	230
<i>U</i>	1	300	81
<i>V</i>	2	3	82
Total	1,384	4,454	2,289

NE: Not enter, D: Independent downstream, U: Independent upstream, V: Vertically integrated

The table shows the distribution of entry choices made by potential entrants. Firms are grouped according to the choice set they faced.

The sample consists of 91 markets that opened up to generic competition between January 1997 and December 2005.

Table 3: Variable Description and Summary Statistics

Variable name	Description	Mean	Min.	Max.
<i>MktRev</i> ^{a,b}	Market revenue in year before generic entry	-0.298	-1.982	1.501
<i>NoRevData</i>	Indicator for “no market revenue data”	0.407	0	1
<i>OrigPat</i> ^{a,c}	Number of originator patents	-0.565	-4.375	1.799
<i>DownExp</i> _{-s} ^d s = 0, 1, 2, 3, 4	Number of downstream entries in each of five previous years		0	25
<i>UpExp</i> _{-s} ^d s = 0, 1, 2, 3, 4, 5, 6	Number of upstream entries in each of seven previous years		0	43

^a These variables are transformed as follows. Let x_m be the level of the untransformed variable for market m . Then, the transformed value is $\ln \left[\frac{x_m}{(\sum_n x_n)/M} \right]$.

^b Before transformation, the average market revenue is 220 million in 1982-84 dollars. The maximum is 987 million dollars.

^c Before transformation, the average number of originator patents is 7.94, and the maximum is 48. Observations with zero patents are given a value of 0.1 before transformation.

^d The experience variables are interacted with the experience depreciation parameters to generate a scalar composite experience variable for each segment. The composite experience variables are transformed in the same manner as *MktRev* and *OrigPat*.

In the addition to the above, dummy variables for year (1997-2005) and broad therapeutic class are used. The broad classes, obtained from Thomson Reuters’ Micromedex directory, are the following: antineoplastic, blood modifier, cardiovascular, central nervous system, endocrine-metabolic, gastrointestinal, musculoskeletal, and respiratory.

Table 4: Informal Goodness of Fit

	Total Number	Number of Correct Predictions	Percentage
Markets	91	31 ^a	34.07
Market-draw pairs	9,100	388 ^b	4.26

Notes:

For each market, 100 sets of draws are taken from the multivariate standard normal distribution to simulate the error terms in the payoff equations.

^a The number of markets where there is at least one draw in which the observed market structure is an equilibrium (among a possible multitude of equilibria).

^b The number of market-draw pairs for which the observed market structure is one of the equilibria.

Table 5: Parameter Estimates

	Mode of Marginal Posterior Distribution*	95% Highest Posterior Density Set
Independent downstream payoff eq.		
β_{MktRev}	-2.465	[-3.536, -1.389]
$\beta_{NoRevData}$	-2.805	[-3.456, -2.344]
$\beta_{OrigPat}$	-1.345	[-1.913, -0.885]
$\beta_{DownExp}$	4.495	[3.238, 4.820]
δ_{DD}	-5.575	[-5.959, -4.898]
δ_{DU1}	2.275	[0.878, 2.764]
δ_{DU2}	1.655	[0.840, 3.169]
δ_{DU3}	6.675	[6.502, 7.785]
δ_{DV1}	5.135	[3.609, 5.441] #
δ_{DV2}	-0.995	[-1.143, 1.249] #
Independent upstream payoff eq.		
β_{MktRev}	1.745	[1.517, 2.956]
$\beta_{NoRevData}$	-1.025	[-1.443, -0.337]
$\beta_{OrigPat}$	0.925	[0.456, 1.286]
β_{UpExp}	-0.085	[-0.507, 1.021]
δ_{UD1}	4.215	[3.641, 4.948]
δ_{UD2}	1.735	[0.954, 3.624] #
δ_{UD3}	4.095	[3.319, 4.341]
δ_{UU}	-5.255	[-5.637, -4.139] #
δ_{UV1}	-2.105	[-2.926, -0.923] #
δ_{UV2}	-2.765	[-3.359, -2.190]
Vertical payoff eq.		
β_{MktRev}	2.525	[1.675, 3.564] #
$\beta_{NoRevData}$	-4.835	[-5.211, -3.784]
$\beta_{OrigPat}$	-0.285	[-0.768, 1.634]
$\beta_{DownExp}$	3.225	[1.747, 3.414]
β_{UpExp}	3.635	[3.130, 4.438]
δ_{VD}	1.905	[1.460, 4.107] #
δ_{VU1}	1.675	[0.438, 4.097] #
δ_{VU2}	0.255	[-0.492, 1.647] #
δ_{VU3}	-3.885	[-4.755, -1.647] #
δ_{VV}	-2.345	[-3.503, -1.959]
Experience Depreciation Rates		
ρ_D	0.545	[0.463, 0.617]
ρ_U	0.595	[0.535, 0.663]

Notes:

See table 3 for definitions of the variables corresponding to the parameters. The δ parameters are defined in equations (2), (3), and (4).

* The posterior modes were found using a grid with steps of 0.01. It is for this reason that the third decimal place is always 5.

indicates that the 95% highest posterior density set is disjoint.

Table 6: Payoff Impact of Vertical Integration by a Rival Pair

	Mode of Marginal Posterior Distribution*	95% Highest Posterior Density Set
Independent downstream in two-by-two market: $(\delta_{DU2} + \delta_{DV1}) - (\delta_{DD} + \delta_{DU1} + \delta_{DU3})$	2.935	[1.834, 3.917]
Independent downstream in one-by-two market: $\delta_{DV1} - (\delta_{DD} + \delta_{DU1})$	7.865	[6.658, 9.420]
Independent upstream in two-by-two market: $(\delta_{UD2} + \delta_{UV1}) - (\delta_{UD1} + \delta_{UD3} + \delta_{UU})$	-3.895	[-4.169, -1.340]
Independent upstream in two-by-one market: $\delta_{UV1} - (\delta_{UD1} + \delta_{UU})$	-1.065	[-1.981, -0.270]

Notes:

The δ parameters are defined in equations (2), (3), and (4).

* The posterior modes were found using a grid with steps of 0.01. It is for this reason that the third decimal place is always 5.

Table 7: Existence and Multiplicity of Pure Strategy Equilibrium

Multiplicity

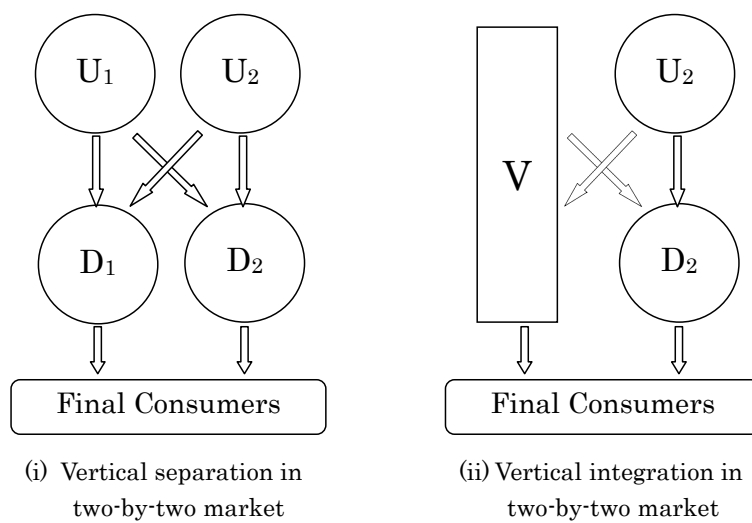
Average number of predicted equilibria per market-draw pair	5.722	
Maximum number of predicted equilibria per market-draw pair	20	
Number of market-draw pairs with unique pure strategy Nash Equilibrium (PSNE) predicted	542	(6.0%)

Non-existence of pure strategy equilibria

Number of market-draw pairs with no PSNE predicted	18	(0.2%)
Number of markets for which none of the draws have any PSNE prediction	0	

Notes:

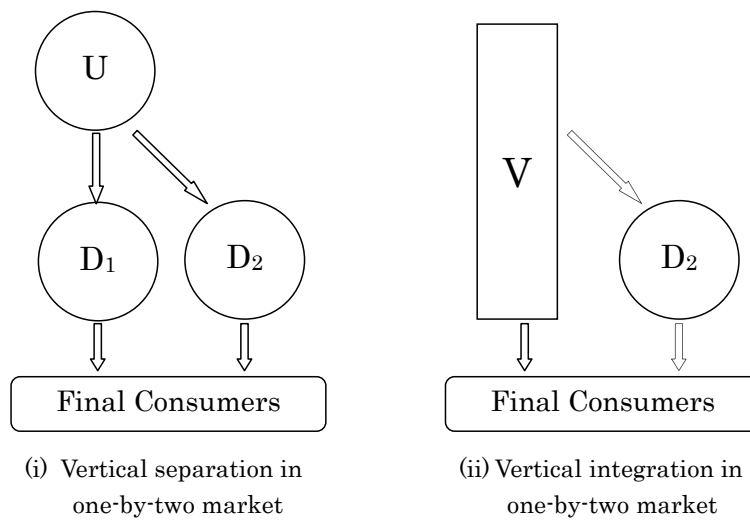
For each market, equilibrium market structures are predicted using the modes of the marginal posterior densities as parameter values. 100 sets of draws are taken from the multivariate standard normal distribution to simulate the error terms in the payoff equations. The total number of market-draw pairs is 9,100.



Notes

- (a) In panel (i), U_1 and U_2 are independent upstream firms who sell the intermediate good to the two independent downstream firms, D_1 and D_2 .
- (b) In panel (ii), V is a vertically integrated firm who may or may not trade the intermediate good with the independent firms, U_2 and D_2 .

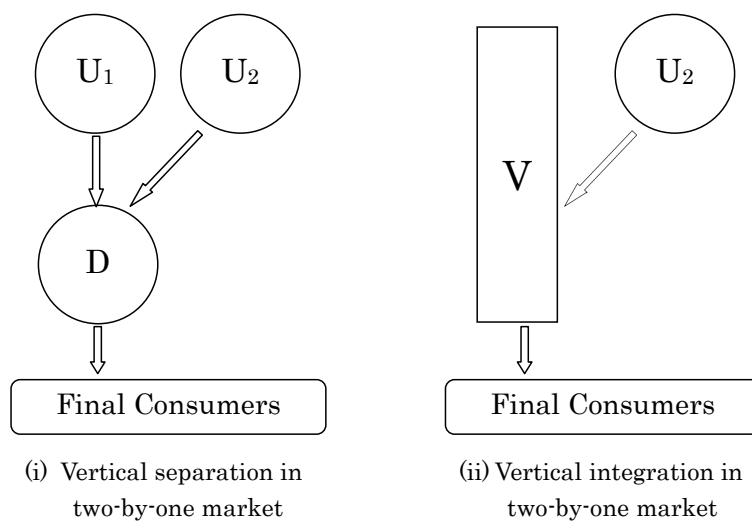
Figure 1: Vertical Structure in the Two-by-two Market Configuration



Notes

- (a) In panel (i), D_1 and D_2 purchase the intermediate good from the monopolist U_1 .
- (b) In panel (ii), V may or may not sell the intermediate good to D_2 .

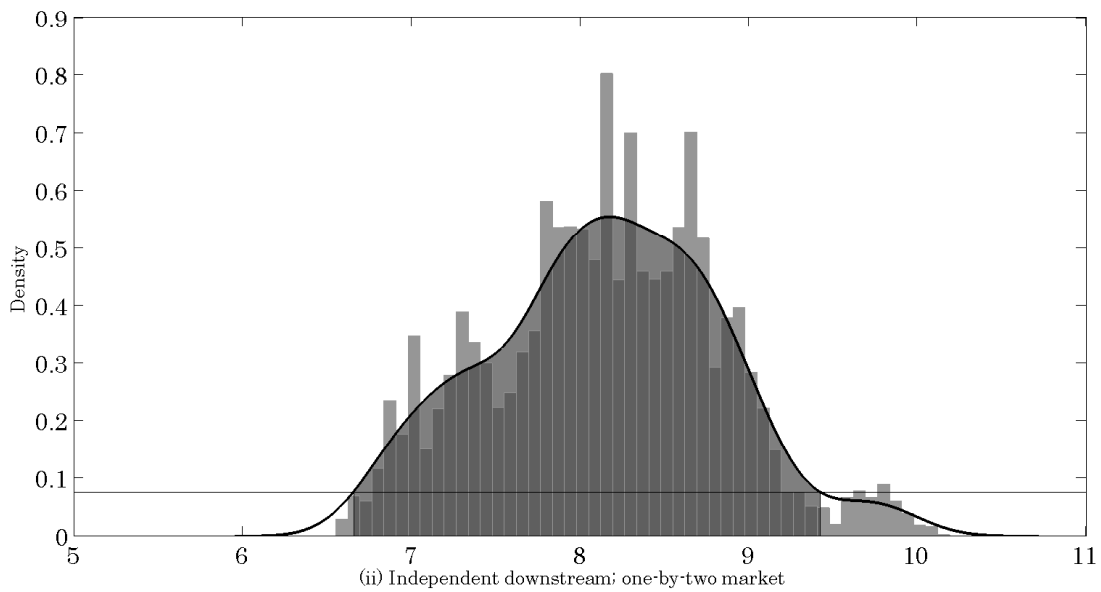
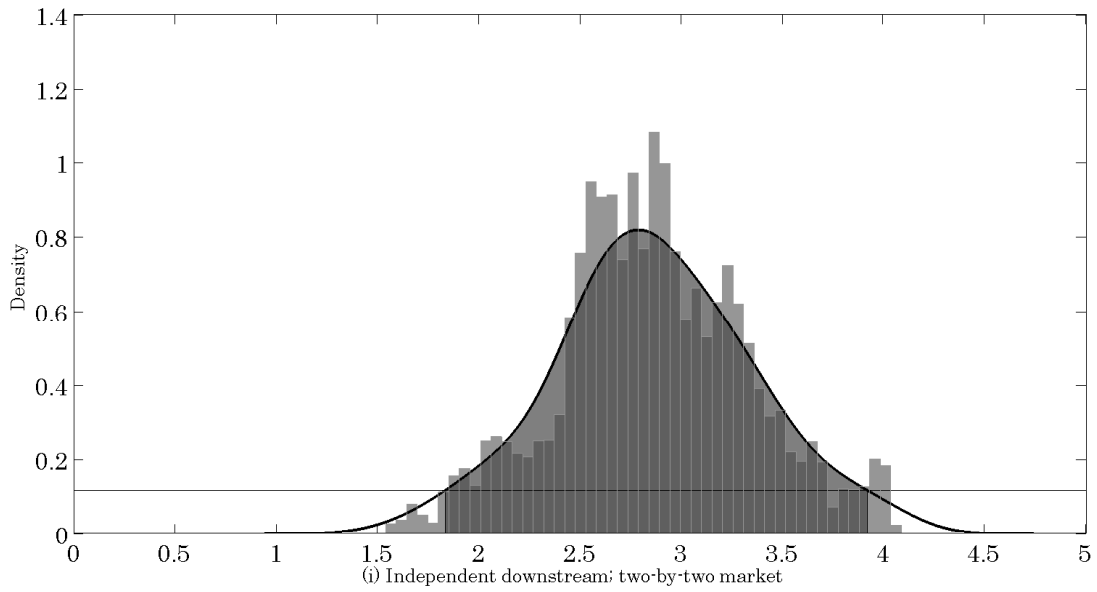
Figure 2: Vertical Structure in the One-by-two Market Configuration



Notes

- (a) In panel (i), U_1 and U_2 sell the intermediate good to the monopsonist D_1 .
- (b) In panel (ii), V may or may not purchase the intermediate good from U_2 .

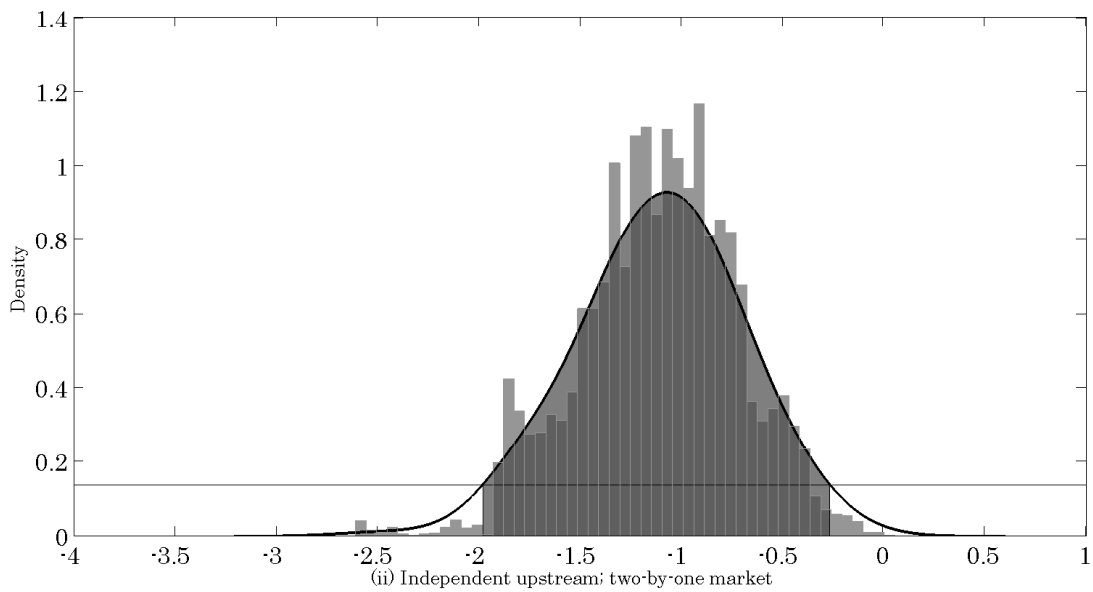
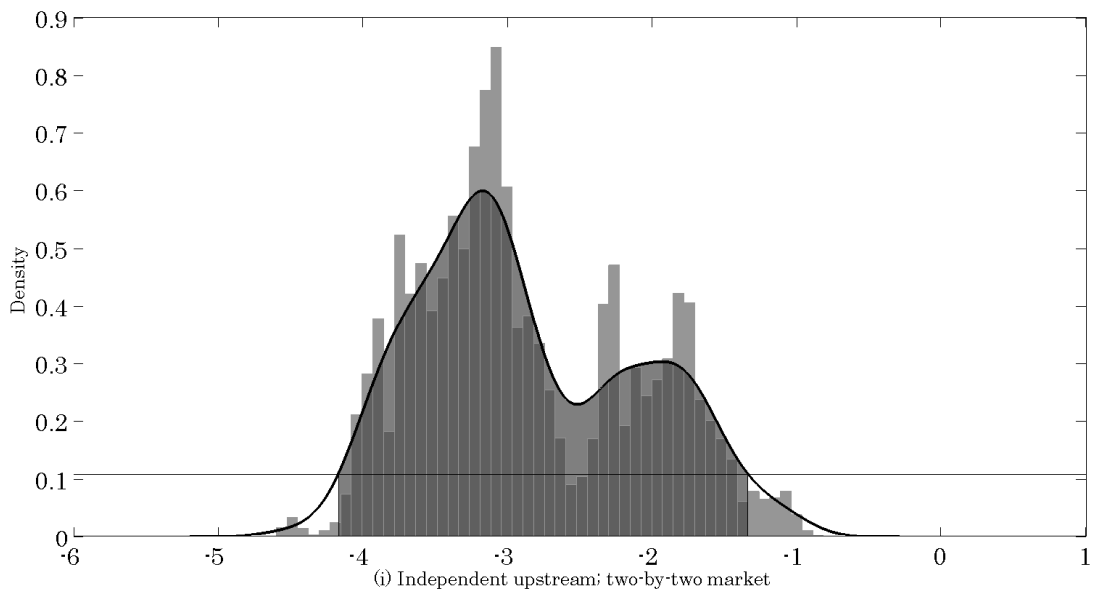
Figure 3: Vertical Structure in the Two-by-one Market Configuration



Notes

- (a) The bars form a density histogram of MCMC realizations for the impact of rival vertical integration on independent downstream payoffs.
- (b) The smoothed density is generated using a Gaussian kernel with bandwidth of 0.2 and 1,000 points of support.
- (c) The shaded area represents the 95% highest posterior density interval defined by the smoothed density.

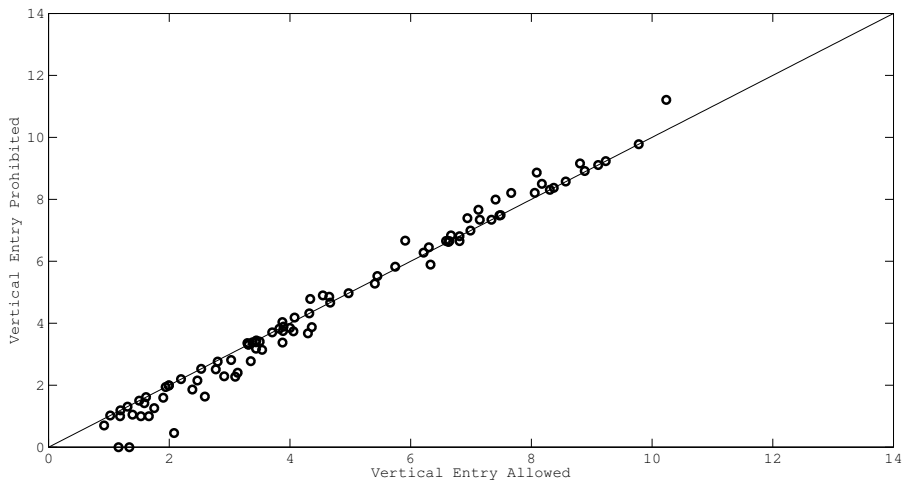
Figure 4: Highest Posterior Density Intervals of Downstream Payoff Impact



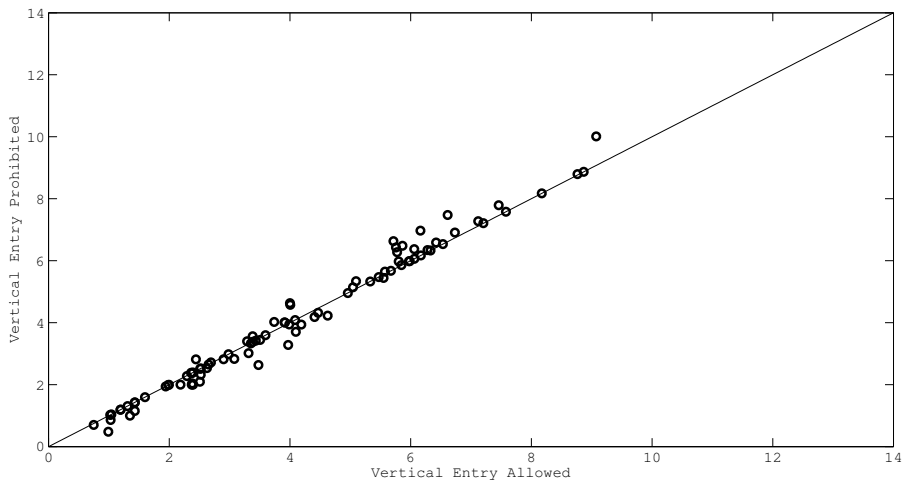
Notes

- (a) The bars form a density histogram of MCMC realizations for the impact of rival vertical integration on independent upstream payoffs.
- (b) The smoothed density is generated using a Gaussian kernel with bandwidth of 0.2 and 1,000 points of support.
- (c) The shaded area represents the 95% highest posterior density interval defined by the smoothed density.

Figure 5: Highest Posterior Density Intervals of Upstream Payoff Impact



(i) Mean Predicted Number of Downstream Entrants



(ii) Mean Predicted Number of Upstream Entrants

Notes

- (a) Each dot represents a market.
- (b) The marginal posterior modes are used as parameter values to predict the equilibrium market structure for each market under both “Vertical Entry Allowed” and “Vertical Entry Prohibited”.
- (c) For comparability, each vertically integrated entry in the “Vertical Entry Allowed” scenario is recounted as a pair consisting of one independent upstream and one independent downstream entry.
- (d) The predicted market structures are averaged, separately for each vertical segment, over multiple equilibria as well as over draws of the random error vector.

Figure 6: Simulated Effect of a Ban on Vertically Integrated Entry

Data Appendix

A.1 Market selection and entry indicators

The US Food and Drug Administration’s website provides a set of datafiles containing information on all pharmaceutical finished formulations that have ever been approved, including those that have been discontinued²⁸. Each approval is identified by a New Drug Application (NDA) number. From this database, known as the Orange Book, I first extract drugs that contain a single active pharmaceutical ingredient (API). This is because the relationship between the upstream API segment and the downstream finished formulation segment is simpler when there is only one API. Next, I keep drugs for which there is at least one generic approval—called an Abbreviated New Drug Application (ANDA) approval—and where the first generic approval occurs between January 1, 1997 and December 31, 2005²⁹.

Since many APIs are approved in multiple dosage forms, the relationship between the upstream and downstream segments is not always clear-cut even for single-ingredient drugs. For instance, the hypertension drug diltiazem hydrochloride is approved as a tablet as well as an injectable, but the API requirements for these two dosage forms are different (one is powder while the other is liquid); I am not able to discern from the data whether a given API manufacturer is supplying ingredients for tablets or for injectables.

I resolve this problem by limiting the downstream dataset to the first dosage form for which a generic is approved and launched, for each API. Moreover, I restrict the sample to tablets and capsules, including extended-release versions. This is because tablets and capsules are the two most common dosage forms, and are likely to make up a large proportion of the derived demand for active pharmaceutical ingredients. These restrictions lead to a downstream dataset consisting of 91 drugs. Table A.1 presents a list of the drug in the sample.

The upstream dataset for these drugs was constructed from the list of Drug Master Files (DMFs) published by the FDA on its website³⁰. A DMF is a dossier, submitted by an API manufacturer to the FDA, containing detailed information regarding the manufacture of a par-

²⁸These files are available from <http://www.fda.gov/CDER/orange/obreadme.htm>.

²⁹Identifying generic approvals in the Orange Book is no simple matter. One way is to refer to the FDA’s online database, called Drugs@FDA (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>) which identifies generic approvals with the term “ANDA”. However, I have reason to believe that the FDA’s own classification is not immune to misclassification; several drugs approved prior to the year 1984 are classified as ANDA, even though abbreviated applications were not practiced until after the passage of the Drug Price Competition and Patent Term Restoration Act of 1984. Therefore, I use the FDA’s classification in conjunction with another classification method which I term the “trade name rule”. Under this rule, an approved drug is classified as generic if its trade name is the same as the generic name of the drug. After applying both rules, I visually inspect all approvals in the database to correct obvious misclassifications.

³⁰The list is available at <http://www.fda.gov/cder/dmf/>.

ticular product. The FDA refers to the contents of a DMF only when it reviews a New Drug Application (NDA) for a finished formulation. An NDA—or an ANDA in the case of a generic product—contains the DMF identification number for the particular brand of API being used, so that the FDA’s reviewing officer knows where to find the relevant information. Each entry in the FDA’s list of DMFs contains the names of the API and the manufacturer, as well as the submission date.

According to industry experts, a DMF submission does not always imply that the submitting firm is able to supply the active ingredient to the US market (Stafford [2006]). This is because the FDA neither approves nor rejects a DMF. A manufacturer may file a DMF in order to advertise that it is willing to supply a particular active pharmaceutical ingredient, but may not actually produce for the US market until buyer interest is confirmed. On the other hand, filing a spurious DMF that is not backed by actual production capability is potentially damaging to a manufacturer’s reputation. Moreover, changing the content of a DMF—say, in order to scale up to commercial production—is time-consuming, and requires the consent of customers. I take a DMF submission to indicate upstream entry, but reduce the risk of picking up spurious DMFs by restricting the dataset to manufacturers with 10 or more submissions, including submissions for APIs outside the sample.

A.2 Identifying firms and treating mergers

By matching firms in the upstream and downstream datasets, it is possible to identify the vertical integration status of each entrant in each market. However, the FDA’s data on ANDAs and DMFs often contain multiple (sometimes erroneous) names for the same firm, and therefore must be cleaned extensively. Moreover, different firms belonging to the same corporate group are not identified as such.

To resolve this problem, I refer to the Newport SourcingTM database, which classifies finished formulation manufacturers and active ingredient manufacturers into uniquely defined corporate groups. I use Newport Sourcing’s corporate group classification to identify individual firms.

Since Newport Sourcing identifies the older ANDAs and DMFs in terms of their current corporate group affiliations, one must take into account the many mergers and acquisitions—both horizontal and vertical—that have taken place in the generics industry during the observation period and beyond. For instance, Teva and IVAX were rivals in both the API and finished formulation industries until IVAX was acquired by Teva in January 2006. Therefore, the two firms are treated as being separate before the acquisition. I gathered news information on

the timings of mergers and acquisitions involving all firms in the sample, and created new corporate groups to describe the pre-M&A entities. Merger histories are taken into account when determining the potential entrant status and counting the past entries of individual firms.

Table A.1: List of drugs in the dataset

Active pharmaceutical ingredient	Dosage form	Market opening	Active pharmaceutical ingredient	Dosage form	Market opening	Active pharmaceutical ingredient	Dosage form	Market opening
acyclovir	capsule	1997	fenofibrate	capsule	2002	naltrexone hydrochloride	tablet	1998
acyclovir	tablet	1997	fexofenadine hydrochloride	tablet	2005	nefazodone hydrochloride	tablet	2003
amiodarone hydrochloride	tablet	1998	flecainide acetate	tablet	2002	nizatidine	capsule	2002
anagrelide hydrochloride	capsule	2005	fluconazole	tablet	2004	norethindrone	tablet	2002
azithromycin	tablet	2005	fludrocortisone acetate	tablet	2002	norethindrone acetate	tablet	2001
benazepril hydrochloride	tablet	2004	fluoxetine hydrochloride	capsule	2001	ofloxacin	tablet	2003
betaxolol hydrochloride	tablet	1999	fluoxetine hydrochloride	tablet	2001	omeprazole	delayed-release capsule	2002
bisoprolol fumarate	tablet	2000	flutamide	capsule	2001	oxaprozin	tablet	2001
bromocriptine mesylate	tablet	1998	flvoxamine maleate	tablet	2001	paroxetine hydrochloride	tablet	2003
bupropion hydrochloride	tablet	1999	fosinopril sodium	tablet	2003	pentoxifylline	extended-release tablet	1997
bupirone hydrochloride	tablet	2001	gabapentin	capsule	2004	pergolide mesylate	tablet	2002
cabergoline	tablet	2005	gabapentin	tablet	2004	pitocarpine hydrochloride	tablet	2005
calcitriol	capsule	2001	ganciclovir	capsule	2003	propafenone hydrochloride	tablet	2000
cefepodoxime proxetil	tablet	2004	gimepiride	tablet	2005	quinapril hydrochloride	tablet	2004
cefprozil	tablet	2005	itraconazole	capsule	2005	ranitidine hydrochloride	tablet	1997
cefuroxime axetil	tablet	2002	ketoconazole	tablet	1999	ribavirin	capsule	2004
cilostazol	tablet	2004	ketorolac tromethamine	tablet	1997	rimantadine hydrochloride	tablet	2001
ciprofloxacin hydrochloride	tablet	2004	labetalol hydrochloride	tablet	1998	sotalol hydrochloride	tablet	2000
citalopram hydrobromide	tablet	2004	leflunomide	tablet	2005	tamoxifen citrate	tablet	2003
clarithromycin	tablet	2005	levorphanol tartrate	tablet	2000	terazosin hydrochloride	capsule	1999
clonazepam	tablet	1997	lisinopril	tablet	2002	terazosin hydrochloride	tablet	1999
clozapine	tablet	1997	lovastatin	tablet	2001	terbutaline sulfate	tablet	2001
diclofenac potassium	tablet	1998	mefloquine hydrochloride	tablet	2002	ticlopidine hydrochloride	tablet	1999
didanosine	delayed-release capsule	2004	metformin hydrochloride	tablet	2002	tizamide hydrochloride	tablet	2002
doxazosin mesylate	tablet	2000	methimazole	tablet	2000	torsemide	tablet	2002
enalapril maleate	tablet	2000	metolazone	tablet	2003	tramadol hydrochloride	tablet	2002
estazolam	tablet	1997	midodrine hydrochloride	tablet	2003	ursodiol	capsule	2000
ethambutol hydrochloride	tablet	2000	mirtazapine	tablet	2002	zidovudine	tablet	2005
etodolac	tablet	1997	misoprostol	tablet	2003	zomisamide	capsule	2005
famotidine	tablet	2001	moexipril hydrochloride	tablet	2003			
felodipine	extended-release tablet	2004	nabumetone	tablet	2001			