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Abstract

This paper explores the motives for vertical integration in the US generic pharmaceutical industry. There is some evidence of strategic complementarity: a firm is more likely to enter a generic drug market in a vertically integrated manner if it expects a higher degree of vertical integration among rivals. This suggests that vertical integration is characterized by bandwagon behavior. While bandwagon effects have been widely discussed in the vertical integration literature, this is one of the first studies to present empirical evidence on its existence. The analysis also indicates that vertical integration is driven by the need to promote a particular form of relation-specific investment – the early development of the intermediate good by upstream units to support patent challenges by downstream units. This explains why the increased prevalence of patent challenges – called "paragraph IV certifications" – has coincided with an increase in vertically integrated entry.

Keywords: Vertical integration, bandwagon effect, entry, generic pharmaceuticals, patent litigation

JEL Classification: L10, L13, L22, L65

Introduction

While vertical integration is a feature of many businesses, its incidence or prevalence varies across industries, across different markets in the same industry, and among firms operating in the same market. Explaining such variation in vertical integration has long been an active area of industrial organization research.

The motives for vertical integration identified in the theoretical literature can be grouped into two major categories: (i) improvement of efficiency for the integrating firm and (ii) foreclosure of rival firms

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from the supply of an input or from access to a market. Each category is further divided into subcategories. For instance, efficiency motives include the elimination of double margins, the facilitation of relationship-specific non-contractible investments, and the assurance of an input supply. In addition to these primary motives, firms may be led to vertically integrate in reponse to integration by rivals. In other words, vertical integration may be caused by bandwagon behavior.

Most empirical analysis on the determinants of vertical integration has focused on efficiency motives (Lafontaine and Slade, 2007). A common approach is to investigate the relationship between certain market characteristics – such as those associated with the importance of relationship-specific investments – on the one hand, and the incidence or prevalence of vertical integration on the other. Numerous studies have found a significant relationship between non-contractible investment requirements and vertical integration.[1] This has provided support to the transaction cost and property rights theories of vertical integration represented by Williamson (1971), Klein et al. (1979), and Grossman and Hart (1986).

In principle, the vertical foreclosure motive can also be explored through similar methodology – for instance, by examining whether markets that are more susceptible to foreclosure are characterized by higher rates of vertical integration. However, market characteristics associated with vulnerability to foreclosure, such as the level of market concentration, also tend to be related to the degree of relationship specificity in investments. Thus, studies that find a positive relationship between market concentration and vertical integration attribute those findings to efficiency rather than foreclosure motives (e.g., Caves and Bradburd, 1988; Lieberman, 1991). [2]

To date, the role of bandwagon effects as a motive for vertical integration has received little attention from empirical researchers. This is despite such effects often being discussed and documented in business and legal circles. For example, industry executives in the cement and ready-made concrete industries, which experienced a vertical merger wave during the 1960s, justified their vertical integration decisions as an inevitable response to increasingly integrated rivals (Federal Trade Commission, 1966). A more recent example is the acquisition of Kinko's by Fedex in 2004. The shipping company's acquisition of the office services provider, which enabled the former to access small-business owners and other customers more directly, was seen by commentators as a reponse to rival shipper UPS's acquisition of Mail Boxes Etc., another office services provider (Deutsch, 2003).

The dearth of empirical research on bandwagon effects may be traced to the difficulty of collecting data; suspected cases of bandwagon behavior such as Fedex/Kinko's are few and far between in most

[1] Recent examples include Woodruff (2002), Baker and Hubbard (2004), and Ciliberto (2006). Whinston (2003) provides a useful review.

[2] Much of the recent empirical literture on foreclosure effects take the form of impact analysis. For example, Hastings and Gilbert (2005) and Suzuki (2008) measure the effect of vertical integration on intermediate good prices and product quality, respectively. The methodogical focus of these studies is to find situations where the incidence or prevalence of vertical integration can be assumed to be exogenous. Aydemir and Buehler (2003) is a notable exception.

industries. A notable exception is the aforementioned cement-concrete industry, which is the subject of econometric analysis by Hortaçsu and Syverson (2007). Using a panel dataset dating back 1963, they find that unintegrated cement producers were more likely to exit from markets characterized by a higher prevalence of vertical integration. While this result is consistent with the existence of bandwagon effects, futher analysis lead the authors to conclude that it was actually caused by a selection effect: unintegrated cement companies tended to be less efficient, making them more likely to exit from markets dominated by vertically integrated firms.

This paper looks at the motives for vertical integration in the US generic pharmaceutical industry. This industry consists of a number of markets, each identified by a particular drug product. Each market starts off as a patent-protected monopoly served by an originator pharmaceutical company – also called an innovator or brand-name firm. New markets open up to competition by generic manfacturers at different points in time, following the expiration of patents and other exclusivities held by the originators. This competition has a significant impact on the market price of drugs. Berndt and Aitken (2010) find, in a sample of nine drug markets that went generic during 2006-2008, that the daily cost of drug treatment fell by 50.1 percent on average in the first two years after generic entry. The same study finds that since 2007, the average volume-based share of generic products has been higher than 90 percent in markets where they exist. By generating large cost savings for consumers and insurers, generic competition has successfully reversed an earlier trend – observed up to the early 2000s – in which pharmaceutical expenditure growth outstripped growth in the quantity of drugs being prescribed (Berndt and Aitken, 2010).

The generic drug industry is a suitable setting for investigating the motives for vertical integration because each market exhibits a clear demarcation between the upstream and downstream segments, and each entrant decides whether or not to vertically integrate. Upstream plants produce active pharmaceutical ingredients (APIs), which are chemical compounds with therapeutic properties, using raw materials such as basic and intermediate chemicals, solvents, and catalysts. The downstream segment manufactures finished formulations by combining APIs with inactive ingredients and processing them into dose forms such as tablets and injectables. There is a significant degree of vertical integration in generic drug markets and it has been rising over time. Since the late 1990s, markets opening up in later years have tended to exhibit a greater prevalence of vertical integration. Using a sample of 128 markets, I calculate the average proportion of vertically integrated entrants among all downstream entrants as 8.1 percent in markets that went generic during 1993-2000. The corresponding figure for markets that opened up during 2001-2005 is 24.2 percent.

Using firm-level data, I first investigate the existence of bandwagon effects, by testing whether firms' vertical integration decisions are influenced by the characteristics of other firms. I find that a po-

tential downstream entrant's propensity to vertically integrate in a market is higher if the other potential entrants have a higher level of experience in the upstream segment. This finding, combined with another result that a potential downstream entrant's own upstream experience makes it more likely to integrate, implies that vertical integration decisions are strategic complements. In the simultaneous-move environment that characterizes most generic drug markets, strategic complementarity of vertical integration decisions is equivalent to the existence of bandwagon effects.

The existence of bandwagon effects provides only partial explanation for the recent increase in vertical integration. There is likely to have been a trigger that led some of the firms to expand the practice of vertically integrated entry, and which set the bandwagon process in motion.[3] One possible trigger is the 1998 regulatory change that made it easier for generic drug companies to earn substantial profits by challenging the unexpired patents of originator pharmaceutical companies. I argue that in markets where generic entrants challenge the patents of brand-name companies, investments by upstream API suppliers tend to become specific to a particular downstream user. Vertical integration can be an effective way to facilitate such relationship-specific investments. Indeed, I find some indication that the returns to vertical integration are higher in markets characterized by patent challenges.

The remainder of the paper is structured as follows. In Section I, I describe the process of entry and vertical market structure formation in the generic drug industry. The section also examines how vertical integration patterns have evolved over time. Section II employs simple theoretical models to derive testable predictions. The first model shows that when vertical integration is characterized by strategic complementarity, one firm's probability of vertical integration rises as its rival's cost of integration falls. The second model demonstrates that in a market where generic companies engage in a patent-challenge race, investment into API development is characterized by relationship specificity. It also shows the advantage of being vertically integrated in such a market. In Section III, I present the econometric specification used to analyze the vertical integration behavior of individual firms. Section IV describes the data for the US generics industry and Section V presents the empirical results. Section V.2.3 concludes.

I Entry and Vertical Market Structure in the Generic Pharmaceutical Industry

I.1 Marketing Exclusivity of New Drugs

A pharmaceutical product market is born when an originator company receives approval from the Food and Drug Administration (FDA) to market a new drug. The approval process involves the submission of a New Drug Application (NDA) by the orignator, and the FDA's review of the NDA based on the

[3] In the cement and ready-made concrete case, the Federal Trade Commission (2002) and Hart and Tirole (1990) suggest that the build-up of overcapacity in the upstream cement segment was the original trigger of the vertical integration wave.

criteria of safety and efficacy. Included under the definition of new drugs are formulations containing entirely novel active pharmaceutical ingredients (called new chemical entities), formulations containing new combinations of existing APIs, new dosage forms of existing APIs, and existing drugs for use in previously unapproved indications.

Most newly approved drugs are awarded a period of marketing exclusivity by the federal government. For example, a drug containing a new chemical entity is usually protected by a patent on the API as well as by a five-year period of data exclusivity. The term "data" in data exclusivity refers to the clinical trials information generated by the originator and submitted to the FDA as part of its NDA. The data is protected in the sense that the FDA is not authorized to use it for the purpose of reviewing marketing approval applications submitted by generic manufacturers. In fact, the FDA is not even allowed to accept applications from generic companies until one year before the expiration of the originator's data exclusivity period if, as is normally the case, those applications rely on the originator's clinical trials data. New drugs that do not contain new chemical entities are also subject to data exclusivity: new combinations, new formulations, and new uses are all eligible for three years of data protection (International Federation of Pharmaceutical Manufacturers and Associations, 2005).

In many cases, a new drug is protected by multiple patents. Each patent basically has a minimum term of twenty years from the date of application so that patent protection usually outlasts the data exclusivity period.[4] The one covering the API is often called a basic product patent. In addition, there are patents that protect new formulations (including new combinations of existing APIs) and new uses for existing drugs. Originators also employ additional patents relating to the API, such as those covering new processes of manufacture and those protecting new chemical forms of the same compound (e.g., novel salts). Such additional patents, sometimes called secondary patents, are especially valuable when a new drug is not protected by a basic product patent. This was the case for the antiviral drug zidovudine, whose basic product patent had already expired when it was developed as a pioneering treatment for HIV infection (Grabowski, 2004). Even in cases where a basic product patent exists, secondary patents are often used to extend the exclusivity of a new drug beyond the life of the basic patent (Mándi, 2003). This is done by filing the secondary patents during or after the drug development stage, when the life of the basic patent has already been eroded by several years (Hutchins, 2003).

From the viewpoint of originators, a limitation of secondary patents as an entry barrier is that, unlike data exclusivities and basic product patents, they tend to provide incomplete protection against generic entry. It is sometimes possible for generic companies to produce and sell a drug without infringing any of its secondary patents. For example, if a drug is protected only by a process patent, a

[4]For patents whose applications were filed before June 8, 1995, the patent term is seventeeen years from the date of issue or twenty years from the date of first application, whichever expires later.

generic firm can avoid infringement by employing an altenative process. Moreover, the patentability of innovations that underlie secondary patents is often open to question even after the patent is granted. For instance, combining an anti-hypertension compound and a cholesterol-lowering agent into the same pill creates significant benefits for some consumers, given that physicians often prescribe such combinations. However, it is a challenge to argue that the combination satisfies the non-obviousness requirement of patentability. Thus, the validity of Pfizer's patent on Caduet, a combination of amlodipine besylate and atorvastatin calcium, has been challenged by several generic firms (Harrison, 2008).

In this way, many secondary pharmaceutical patents belong to the category of what Lemley and Shapiro (2005) call "probabilistic patents". Lei and Wright (2009) shed light on the question of why such patents are allowed to exist in the first place. Their empirical analysis indicates that while patent examiners at the US Patent and Trademark Office generally have the ability to correctly judge the patentability of an application, the pro-applicant rules and procedures within the organization drive them to issue more patents than they should.

The proliferation of secondary patents creates a potential "patent minefield" where generic firms face the risk of being sued by the originator for infringing a patent that they did not even know existed. Such litigation risks are harmful not only for the generic firms but also for consumers, because they may lead to the abrupt removal of approved generic products from the market. Partly in order to prevent such situations, the FDA requires originator firms to provide information on the patents covering new drugs as part of their NDA filings. In general, originators provide information on all relevant patents except for those that only claim manufacturing processes. Once an NDA is approved, a list of patents that are associated with the new drug is published in a FDA publication called "Approved Drug Products with Therapeutic Equivalence and Evaluations", commonly known as the Orange Book.[5] The Orange Book is used by generic companies to learn about the existence and duration of originator patents in every drug market that they contemplate for entry.

I.2 Process of Generic Entry

I.2.1 Downstream Entry Through Abbreviated New Drug Applications

The entry process for generic pharmaceutical has greatly evolved over the last three decades. Prior to 1984, generic firms seeking marketing approval had to provide the FDA with the same type of information as originator firms, including data on clinical trials conducted on a large number of patients. As a result of the substantial entry costs that this entailed, entry by generic companies was limited: in 1984, roughly 150 drug markets were estimated to have been lacking generic entrants despite the expiration of

[5] An electronic version of the Orange Book is accessible at `http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm`.

patents (Federal Trade Commission, 2002).

The Drug Price Competition and Patent Restoration Act of 1984, also known as the Hatch-Waxman Amendments, drastically changed the process of generic entry. Most significantly, generic companies were exempted from submitting complete NDAs.[6] Instead, a generic entrant could file an Abbreviated New Drug Application (ANDA) which replaces full-scale clinical trial results with data on bioequivalence. Bioequivalence tests – which compare generic and originator drugs in the way that the active ingredient is absorbed into the bloodstream of healthy subjects – are much smaller in scale and far cheaper to conduct than conventional clinical trials. When the FDA reviews an ANDA for a generic product, its decision is based on the bioequivalence test results as well as the clinical trial results contained in the originator product's NDA. The introduction of the ANDA system implied a huge reduction in product development costs, and generic entry surged after the mid-1980s; the volume-based share of generic drugs rose from 19 percent in 1984 to 51 percent in 2002, increasing further to 74 percent in 2009 (Grabowski, 2004; Berndt and Aitken, 2010).

ANDAs are prepared by downstream finished formulation manufacturers and submitted to the FDA some time before they plan to enter the generic market. In the case of a drug containing a new chemical entity, the earliest possible date for filing an ANDA is four years after the approval of the originator's NDA (one year before the data exclusivity expires), but typical filing dates are later. If a generic firm plans to enter after all patents listed in the Orange Book have expired, it begins the ANDA filing process two to three years before the patent expiration date (Scott Morton, 1999). This reflects the expected time it takes the FDA to review an ANDA; the median approval time was 16.3 months in 2005, increasing in recent years to reach 26.7 months in 2009 (Buehler, 2006; Karst, 2010).[7]

When unexpired patents are listed in the Orange Book at the time of ANDA filing, the generic firm must make a certification regarding each patent. The firm either indicates that it will wait until the patent expires to enter, or certifies that the patent is invalid or not infringed by its product. The first option is called a paragraph III certification and the latter is called a paragraph IV certification, named after corresponding passages in section 505(j)(2)(A) of the Federal Food, Drug, and Cosmetic Act. By filing an ANDA containing a paragraph IV certification, a generic firm pre-emptively counters any patent infringement claims that it expects from the orginator. The FDA cannot give full approval to an ANDA until all patents listed in the Orange Book have expired or have been determined to be invalid or not infringed; a tentative approval, which does not permit the ANDA applicant to enter, can be issued in the mean time. The filing of an ANDA by a generic firm is not publicized by the FDA until the latter

[6] Another important aspect of the Hatch-Waxman Amendments is that it introduced patent term restorations of up to five years, in order to compensate for the delay in drug marketing that arises from the FDA's regulatory process.

[7] The lengthening of generic approval times is due to a growing backlog of ANDAs. This backlog has been caused by a larger number of drugs going off patent and more firms entering the generics industry (Buehler, 2006).

announces a tentative or full approval. Therefore, generic firms generally do not observe their rivals preparing and filing ANDAs in real time.

I.2.2 Sourcing of Active Pharmaceutical Ingredients

The preparation of an ANDA involves the development of the generic drug product by the applicant, who uses it to conduct bioequivalence tests.[8] A physical sample of the product is submitted to the FDA along with documents pertaining to bioequivalence and quality. An important part of generic product development is the sourcing of APIs. Here, the ANDA applicant faces a make-or-buy decision. If the firm has a plant equipped with specialized machinery such as chemical reactors, it can choose to produce its own API. If the ANDA applicant decides to buy its API from outside, it must find a supplier from among the many suppliers located around the world. There is no centralized market for generic APIs, but international trade shows such as the Convention on Pharmaceutical Ingredients and Intermediates (CPhI) provide regular opportunities for buyers and suppliers to gather and transact. Once the API is obtained, the downstream firm develops the finished formulation and prepares documentation for the ANDA.

The ANDA documents, which are used by the FDA to evaluate the safety and efficacy of the generic product, must contain detailed specifications of the API, including information on manufacturing equipment and methods. When the API is purchased from outside, the required information must be supplied by the upstream manufacturer. Basic information on the processes used for synthesizing the API is usually shared between the seller and buyer, but there remain trade secrets – such as the optimal conditions for chemical reaction – that the upstream firm may be unwilling to fully disclose to the downstream buyer. This is because the buyer might misuse the trade secrets by divulging them to other upstream firms who are willing to supply the API at a lower price.

To address such concerns among API manufacturers, and to maximize the quantity and quality of API-related information that reaches the FDA, the agency uses a system of Drug Master Files (DMFs). DMFs are dossiers, prepared by individual manufacturers, that contain detailed information on manufacturing processes and product quality for APIs. By submitting the DMF directly to the FDA rather than to its downstream customer, the API manufacturer is able to convey all relevant information to the regulatory agency without risking the misuse of its trade secrets (Shaw, 2008).[9] Unlike ANDAs, the identities of submitted DMFs are published upon receipt by the FDA.[10]

[8] Section 271(e)(1) of the Patent Act, also known as the Roche-Bolar provision, enables generic firms to develop their products during the orignator's patent term without being sued for infringement.

[9] One impact of the DMF system may have been to promote vertical separation between the API and finished formulation manufacturing activities. The risk of expropriation of upstream trade secrets, had it not been addressed by the DMF system, may have motivated more firms to vertically integrate.

[10] The list of DMFs submitted to the FDA is available on the website of the FDA's Office of Generic Drugs at `http:`

If an ANDA applicant buys APIs from outside, it notifies the FDA about the source of the ingredient by referring to the serial number of a specific DMF. At the same time, the applicant contacts the DMF holder, who in turn informs the FDA that the ANDA applicant is authorized to refer to its DMF. In this way, the FDA reviewer knows where to find the API-related information for each ANDA. It is possible for the ANDA applicant to reference multiple DMFs at the time of filing, and for a single DMF to be referenced by multiple ANDAs. On the other hand, adding new DMF reference numbers after filing the ANDA is time-consuming. According to the Federal Trade Commission (FTC), it takes around eighteen months for an ANDA applicant to switch its API supplier by adding a new DMF reference.[11]

It would appear that a vertically integrated entrant has less of an incentive to use the DMF system than an unintegrated upstream firm. To the extent that the vertically integrated firm produces API exclusively for in-house use, concerns about the expropriation of trade secrets do not arise. In reality, however, many DMFs are filed by vertically integrated firms. One reason for this is that such firms often sell APIs to unintegrated downstream firms even if they are competing in the same market. For instance, Teva, a large Israeli generic drug company who is present in many US generic markets as a vertically integrated producer, sold 32 percent (in value terms) of its API output in 2008 to outside buyers (Teva Pharmaceutical Industries, 2009). Another reason is that generic companies often file separate ANDAs for multiple formulations containing the same API. By submitting a DMF to the FDA, an integrated firm can avoid the burden of including the same API information in multiple ANDAs. While one cannot rule out the possibility that vertically integrated firms sometimes refrain from submitting DMFs, the above discussion suggests that a DMF submission is a good indicator of upstream entry by both vertically integrated and unintegrated entrants.[12]

A final note regarding DMFs addresses the possibility that a DMF submission does not necessarily imply entry into the API market. As Stafford (2006) suggests, some API manufacturers may file a DMF in order to attract the attention of potential buyers, but may not begin actual product development for the US market until buyer interest is confirmed. Such cases do appear to exist, but the practice

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//www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/default.htm.

[11] See Amended Complaint for Injunctive and Other Equitable Relief, *FTC v. Mylan Laboratories, Inc., et al.* (D.D.C., 1999), available at http://www.ftc.gov/os/1999/02/mylanamencmp.htm.

[12] There are two possible reasons why a vertically integrated firm may want to avoid filing a DMF, but neither of them appear to be substantial. First, filing a DMF might alert the originator firm to the entry plans of the integrated generic firm, causing the former to take defensive action. However, the generic firm can avoid giving such early warning by submitting the DMF immediately before filing its ANDA (the latter act is immediately observed by the originator if a patent challenge is involved, as described later). Second, by filing the DMF and exposing its intent to enter, the vertically integrated firm may reveal private information about the profitability of a market to other generic companies. Such information asymmetries are, however, unlikely in the generics industry where markets tend to be mature by definition. In fact, a vetically integrated firm may gain strategically by using a DMF submission to credibly indicate its intent to enter, possibly deterring the entry of some of its rivals. By contrast, the FDA's policy of keeping ANDA receipts confidential until approval implies that an unintegrated downstream firm can at best engage in cheap talk – in the manner of Farrell (1987) – about its intention to enter a market.

is counterproductive for two reasons. First, a spurious DMF that is not backed by an actual product, while creating little real business for the firm, can be potentially damaging for an API manufacturer's reputation. Secondly, changing the content of an already-submitted DMF is time-consuming and requires notification to downstream customers (Food and Drug Administration, 1989). Thus, it seems safe to assume that a DMF submission by a relatively established API manufacturer indicates upstream market entry.[13]

I.2.3 Stylized Description of Vertical Market Structure Formation

In order to motivate the subsequent empirical analysis, I present a stylized description of the vertical market structure formation process in the generic industry. The process varies depending on whether or not a patent challenge is involved. I first consider the situation without patent challenges, and discuss the case involving patent challenges next.

When all generic entrants decide to wait until the expiration of originator patents (i.e., they make paragraph III certifications with respect to all unexpired patents), the vertical market structure of a given generic drug market is formed through a simultaneous entry game. We can envision a fixed number of potential entrants simultaneously choosing their modes of entry.

For the sake of simplicity, I assume for the remainder of this paper that the set of potential entrants can be divided into two groups: those that have the ability to enter the downstream segment and those that do not. The two groups will be called potential downstream entrants and potential upstream-only entrants, respectively. Each potential downstream entrant has a strategy space consisting of three elements: unintegrated downstream entry, vertically integrated entry, and no entry at all. It is assumed that a potential downstream entrant never enters as an unintegrated upstream firm. A potential upstream-only entrant, on the other hand, has two elements in its strategy space: unintegrated upstream entry and no entry. This separation of potential entrants into two groups is identical to that employed in Elberfeld's (2002) theoretical model. The reason for making these assumptions is that in the empirical analysis, we focus on the vertical integration decisions of potential downstream entrants, conditional on their decision to enter the downstream segment.

A firm's entry decision is not observed by the other players until the FDA announces the approval of its ANDA. This unobservability allows us to assume that firms make their downstream entry decisions simultaneously (Scott Morton, 1999). On the other hand, an entrant's submission of a DMF becomes observable when the FDA posts that information on its website. This creates the possibility that some

[13] In a 2007 suit in which a patent holder sought to prevent a generic API manufacturer from selling an infringing product, the plaintiff's attorney stated that "the act of filing a DMF indicates that the present intent of the DMF filer is to supply API in the United States". See Complaint for Declatory Judgement, *Teva Pharmaceutical Industries, Ltd. v. Lupin Ltd.* (D.N.J., 2007), available at `http://patentdocs.typepad.com/patent_docs/files/teva_v_lupin_621.pdf`.

firms choose their actions after observing the upstream entry decisions of other firms. However, since upstream manufacturers tend to submit DMFs later in the product development process, when they are already capable of producing the API on a commercial scale, it is reasonable to assume that upstream entry decisions are made simultaneously with downstream decisions.

Once the identities of the market entrants are fixed, a matching process takes place where downstream manufacturing units are matched with upstream units. Different matching processes and matching patterns can be envisioned. One possibility is that each unintegrated downstream firm is paired randomly with one unintegrated upstream firm, and that vertically integrated firms do not pair up with any other firm. Another possibility is that each downstream unit (including those belonging to vertically integrated entrants) is paired with every upstream unit. Actual matching patterns observed in the industry appear to fall somewhere in between these two extremes.[14]

After the matches are realized, firms invest in product development and document preparation. Upstream units develop their APIs and submit DMFs to the FDA, while downstream units develop finished formulations and file their ANDAs.[15] Downstream generic manfacturers market their products to consumers after the FDA approves their ANDAs and all patents and data exclusivities belonging to the originator expire. The payoffs of individual firms are realized when each downstream firm's revenue is split between itself and its upstream supplier, in the form of payment for APIs.

The payoffs realized in the investment and marketing stages can be expressed as functions of market characteristics, firm characteristics, and the actions of rivals. Denoting the action of firm i as a_i, the actions of potential entrants can be summarized into the number of entrants in each category. Thus, the number of unintegrated downstream entrants is calculated as $N_D = \sum_{i \in \mathfrak{P}_D} \mathbf{1}(a_i = D)$ where $\mathfrak{P}_D$ is the set of potential downstream entrants, $\mathbf{1}(\cdot)$ is the indicator function, and D denotes unintegrated downstream entry. The number of vertically integrated entrants is $N_V = \sum_{i \in \mathfrak{P}_D} \mathbf{1}(a_i = V)$ with V denoting vertically integrated entry. Similarly, the number of unintegrated downstream entrants is $N_U = \sum_{j \in \mathfrak{P}_U} \mathbf{1}(a_j = U)$ where $\mathfrak{P}_U$ is the set of potential upstream entrants and U denotes unintegrated upstream entry.

Let the vector $\mathbf{N} = (N_D, N_U, N_V)$ summarize a vertical market structure. Then, I assume that the payoffs of individual firms can be expressed by the following functions:

[14] Court records from *Geneva and Apothecon v. Barr et al.* (N.Y.S.D, 2002; 2d Cir., 2004) indicate that upstream-downstream groupings are one-to-one in some markets, while in others they are multilateral.

[15] The existence of a time gap between entry decisions and actual investments (due to the inclusion of the matching stage) suggests that some firms may cancel their entry plans after finding out that the outcome of the entry and matching processes is not in their favor. Such reversals would create transactional risks for other firms, which in turn may affect the entry behavior of all potential entrants. In order to avoid this problem, I assume that entry decisions are irreversible.

$$\text{Payoff of firm } i \text{ from unintegrated downstream entry} = \pi_D(\mathbf{w}_m, \mathbf{x}_i, \mathbf{N} - \iota_1)$$
$$\text{Payoff of firm } i \text{ from vertically integrated entry} = \pi_V(\mathbf{w}_m, \mathbf{x}_i, \mathbf{N} - \iota_3)$$
$$\text{Payoff of firm } j \text{ from unintegrated upstream entry} = \pi_U(\mathbf{w}_m, \mathbf{x}_j, \mathbf{N} - \iota_2)$$
$$\text{Payoff from no entry} = 0$$

where $\pi_k(\cdot)$ is the payoff function for entry action k, $\mathbf{w}_m$ is a vector consisting of the characteristics of market m, and $\mathbf{x}_i$ and $\mathbf{x}_j$ are vectors containing the characteristics of individual firms. ι_k is a three dimensional unit vector containing one as the kth element and zeros for the other elements. The reason for subtracting ι_k from the market structure vector is to avoid including a firm's own action as an argument of its action-specific payoff function. These payoffs are net of product development investments – i.e., sunk entry costs – which are functions of firm and market characteristics. Following common practice in the empirical entry literature (e.g., Berry, 1992), I assume that a firm's payoff is affected by a rival firm only through the latter's action, so that the payoff functions do not contain the characteristics of rivals as arguments. I also assume that the payoff impact of one rival's entry is identical to that of another's. This allows us to aggregate the payoff impact of rivals into a term involving the three dimensional vector $\mathbf{N}$.

Define $\mathfrak{E}_D$ and $\mathfrak{E}_V$ as the subsets of $\mathfrak{P}_D$ that enter as unintegrated downstream and vertically integrated manufacturers, respectively. Similarly, let $\mathfrak{E}_U \subseteq \mathfrak{P}_U$ denote the set of unintegrated upstream entrants. Then, a pure-strategy Nash equilibrium market structure $\mathbf{N}^*$ is characterized by the following set of equilibrium conditions:

$$\begin{aligned}
\pi_D(\mathbf{w}_m, \mathbf{x}_i, \mathbf{N}^* - \iota_1) &> \max[\pi_V(\mathbf{w}_m, \mathbf{x}_i, \mathbf{N}^* - \iota_1), 0], \quad \forall i \in \mathfrak{E}_D \\
\pi_V(\mathbf{w}_m, \mathbf{x}_i, \mathbf{N}^* - \iota_3) &> \max[\pi_D(\mathbf{w}_m, \mathbf{x}_i, \mathbf{N}^* - \iota_3), 0], \quad \forall i \in \mathfrak{E}_V \\
\max[\pi_D(\mathbf{w}_m, \mathbf{x}_i, \mathbf{N}^*), \pi_V(\mathbf{w}_m, \mathbf{x}_i, \mathbf{N}^*)] &\leq 0, \quad \forall i \in \mathfrak{P}_D \setminus \{\mathfrak{E}_D \cup \mathfrak{E}_V\} \\
\pi_U(\mathbf{w}_m, \mathbf{x}_j, \mathbf{N}^* - \iota_2) &> 0, \quad \forall j \in \mathfrak{E}_U \\
\pi_U(\mathbf{w}_m, \mathbf{x}_j, \mathbf{N}^*) &\leq 0, \quad \forall j \in \mathfrak{P}_U \setminus \mathfrak{E}_U
\end{aligned}$$

These conditions say that each firm earns a higher payoff by choosing its equilibrium action than by choosing any other action.

Entry games into vertical oligopoly such as the one considered here are generally characterized by multiple equilibria (Elberfeld, 2002). To simplify the analysis, I assume that potential entrants follow a common equilibrium selection rule such as one in which the equilibrium with the highest joint profits

is realized (e.g., Berry, 1992; Scott Morton, 1999). Therefore, the same unique equilibrium is always chosen for a given set of values for the exogenous variables. This implies that we can define a function that maps from the exogenous variables (market characteristics and firm characteristics of every potential entrant) to market structure outcomes. The existence of such a function allows us to rewrite the payoff equations in the following reduce form:

$$\begin{aligned} \text{Payoff from unintegrated downstream entry} &= \pi_D(\mathbf{w}_m, \mathbf{x}_i, \mathbf{X}_{-i}) \\ \text{Payoff from vertically integrated entry} &= \pi_V(\mathbf{w}_m, \mathbf{x}_i, \mathbf{X}_{-i}) \\ \text{Payoff from unintegrated upstream entry} &= \pi_U(\mathbf{w}_m, \mathbf{x}_j, \mathbf{X}_{-j}) \\ \text{Payoff from no entry} &= 0 \end{aligned} \tag{1}$$

where $\mathbf{X}_{-i}$ is a matrix containing the firm characteristics of all potential entrants excluding firm i.

We can envision firms as making entry decisions based on these reduced-form payoff functions. Linear approximations of these equations can be used in a discrete choice analysis of entry behavior. Scott Morton (1999) employs such reduced form payoff equations to analyze entry into the downstream segment of the generic drug industry. Unlike (1), however, her specification of the payoff equation does not include the characteristics of other potential entrants as covariates. As we shall see later, the payoff impact of rival firm characteristics contains information on bandwagon behavior.

I.2.4 Entry Process in the Presence of a Patent Challenge

When entry into a generic drug market involves a paragraph IV patent challenge, the process of market structure formation can no longer be described as a simultaneous entry game. There are two reasons for this. First, there is no fixed date on which generic firms can enter due to the uncertain nature of patent litigation outcomes. Second, there exist regulatory rules that reward the first generic firm to initiate a successful patent challenge against the originator. This causes potential entrants to compete to become the first patent challenger.

The system of rewarding patent challenges was introduced in 1984 as part of the Hatch-Waxman Amendments. The rationale for providing such an incentive to generic firms is that the outcome of a successful patent challenge – the invalidation of a patent or a finding of non-infringement – is a public good (Lemley and Shapiro, 2005). Suppose that one generic firm invests in research and spends time and money on litigation in order to invalidate an originator patent listed in the Orange Book. Suppose also that the patent is the only one protecting a particular drug market. Then, the act of invalidation benefits not only the generic firm who made the investment, but also others who seek to enter the market. Because such public goods tend to be undersupplied in a competitive market, Congress created a system

to reward the first generic firm to invest in a patent challenge.

The reward is given out through a complex process which I summarize here. When a generic firm files an ANDA containing a paragraph IV certification to the FDA, it must directly notify the originator (the holder of the NDA for the original product), as well as the other holders of the patents being challenged, about its filing. The originator must then decide within 45 days whether or not to initiate a patent infringement suit. If the originator decides not to sue, then the FDA is allowed to approve the ANDA and the generic may enter the market. If the generic firm is the first to have filed a substantially complete ANDA containing a paragraph IV certification, it is awarded a 180-day exclusivity in the generic market. This means that the FDA is not allowed to approve any other ANDA until 180 days have passed since the first generic product's commercial launch.

If the originator decides to sue the generic entrant, then the FDA is stayed from giving final approval to the ANDA until 30 months have passed or until a court decides that the patent in question is invalid or not infringed, whichever comes sooner. The FDA may review the ANDA in the mean time, but it can only issue a tentative approval. Thus, the 30-month stay functions as an automatic preliminary injunction against the paragraph IV ANDA applicant.

The main possible outcomes of the patent infringement suit between the originator and the paragraph IV applicant are the following: a victory for the generic entrant, a loss for the generic entrant, or a settlement between the two parties. If the generic applicant wins the patent infringement suit, its ANDA receives final approval from the FDA once the other patents listed in the Orange Book expire. If the generic firm is the first to have filed a substantially complete paragraph IV ANDA, it obtains the right to 180-day exclusivity. The exclusivity period starts when the first-to-file generic begins commercial marketing or when a court decides that the patent in question is invalid or not infringed, whichever is earlier.

If the generic firm loses the infringement suit for every challenged patent, then its ANDA is not approved until expiration of those patents or until the end of the 30-month stay. Even if the firm is the first-to-file paragraph IV applicant, it is not awarded the 180-day exclusivity, because the right to exclusivity disappears with the expiration of the challenged patents (Lietzan, 2004a).

If the generic and originator firms decide to settle the patent infringement suit, the generic firm's ANDA is approved only after the 30-month stay. If the generic firm is the first-to-file paragraph IV applicant, it becomes eligible for 180-day exclusivity, which is triggered by the generic product's commercial launch.

The right to 180-day exclusivity is given only to the first-to-file paragraph IV applicant. If the first-to-file applicant loses in patent infringement litigation or otherwise forfeits its right to 180-day exclusivity, the right disappears; it is not rolled over to the next-in-line applicant (Korn et al., 2009). If

multiple firms file ANDAs with paragraph IV certifications on the same day, and no prior ANDA has been filed, the right to generic exclusivity is shared between those firms.[16]

Although the Hatch-Waxman framework for rewarding patent challenges was introduced in 1984, it was not until the late 1990s that 180-day exclusivities began to be issued on a regular basis. Prior to 1998, the FDA's regulatory rules required a paragraph IV applicant to be sued by the originator, and to prevail in the ensuing infringement suit, in order to be eligible for generic exclusivity. This rule, called the "successful defense requirement", prevented most paragraph IV applicants from earning 180-day exclusivity because in many cases the originator did not sue and many patent disputes that were litigated ended in settlement. The Federal Trade Commission (2002) notes that between 1992 and 1998, not a single 180-day exclusivity was granted by the FDA. The system changed drastically following a pair of appellate court decisions: *Mova Pharmaceutical Corp. v. Shalala* (D.C. Cir., 1998) and *Granutec, Inc. v. Shalala* (4th Cir., 1998). These decisions struck down the FDA's successful defense requirement, and allowed paragraph IV applicants to be eligible for 180-day exclusivity even if they are not sued by the originator or if their suit ends in settlement (Lietzan, 2004b).

The regulatory change of 1998 had a dramatic impact. According to the Federal Trade Commission (2002), 180-day exclusivities were granted 31 times between 1998 and 2002. The generic exclusivity awarded to Barr Laboratories in 2000 for the antidepresant drug fluoxetine (Eli Lilly's Prozac) demonstrated the magnitude of profits at stake in the markets for so-called "blockbuster" drugs. Barr's stock price rose by two-thirds on the day of the appellate court decision invalidating the patent held by Eli Lilly. Barr proceeded to capture a 65 percent share of the market for fluoxetine within two months (Filson and Oweis, 2010).[17]

The large profits available from 180-day exclusivities have made generic firms more aggressive in their patent challenges. As Grabowski (2004) and Higgins and Graham (2006) note, the number of ANDAs containing paragraph IV certifications increased rapidly after the regulatory change: the average number of paragraph IV ANDA filings per year rose from thirteen during 1992-2000 to 94 in the 2001-2008 period. While this increase partly reflects the greater number of blockbuster drugs going generic in the latter period, observers agree that the regulatory change played a significant role (Grabowski, 2004; Filson and Oweis, 2010; Hemphill and Sampat, 2010). Table 1 presents the share of generic markets that were the subject of one or more paragraph IV ANDA filings in a sample of 128 markets that opened up during 1993-2005. As described more fully in Section IV, drug markets were selected for inclusion using the following criteria: (i) the drug product contains only one API; (ii) of the set of finished formulations

[16] Such "shared exclusivities" arise when multiple generic firms file on the first day that the FDA begins accepting ANDAs. For a drug containing a new chemical entity, that date is exactly four years after the approval of the originator's NDA.

[17] According to Garnett (2000), fluoxetine sold more than 2.5 billion dollars globally in 1999.

Table 1: Incidence of Paragraph IV Certification

Year	Number of markets	Share of markets with Paragraph IV Certification (%)
1993	8	12.5
1994	5	0.0
1995	10	20.0
1996	4	0.0
1997	9	11.1
1998	7	14.3
1999	6	66.7
2000	9	22.2
2001	12	50.0
2002	17	52.9
2003	14	42.9
2004	16	56.3
2005	11	18.2

The second column shows the number of markets in the dataset to experience first generic entry in each year. The selection of markets is explained in Section IV.

The third column shows the percentage of markets where one or more ANDAs containing a paragraph IV certification was filed.

containing the same API, the product is the first to experience generic entry; and (iii) there is at least one generic entrant in the market. The propensity of paragraph IV challenges suddenly jumps for markets that experienced first generic entry in 1999. This reflects expectations among generic firms that the FDA would give out more 180-day exclusivities following the 1998 court decisions. The share of generic markets with paragraph IV certifications remains high – at around one-half – in the subsequent years.[18]

Grabowski (2004) comments that the granting of more 180-exclusivities has, in some cases, turned the generic entry process into a race to be first. Higgins and Graham (2006) note that, as a result of more aggressive efforts by generic entrants, ANDA filings have come to take place earlier in a drug's

[18] Using a larger dataset of generic drug approvals, Hemphill and Sampat (2010) shows that new drugs approved during the 1990s were more likely to be the subject of paragraph IV patent challenges than those approved earlier. These drugs are likely to have experienced generic entry after the 1998 court decisions.

lifecycle. Indeed, there have been many markets where multiple generic firms filed their paragraph IV ANDAs exactly four years after the approval of the orignator's NDA – that is, on the earliest date allowed by the FDA (Grabowski, 2004). Also, Grabowski and Kyle (2007) show that drug markets with higher revenue tend to experience generic entry sooner, partly because they tend to be more heavily targeted by patent challenges. Interestingly, while ANDAs filings are being made increasingly early, Grabowski and Kyle (2007) find no evidence that generic product launches are occurring earlier in the drug's lifecycle in markets that opened up more recently. This may be because the Hatch-Waxman system has had an unintended side effect. As reported by the Federal Trade Commission (2002) and Bulow (2004), the system has been used by some orignators, somewhat paradoxically, to delay generic entry through the use of so-called "pay-to-delay" settlements.[19]

Given that the existence of a patent challenge turns the generic entry process into a race to be first, econometric analysis of generic firm behavior would ideally be based on a model that takes the timing of entry into account. Unfortunately, the data that I use does not contain accurate information on the timing of entry by each generic firm.[20] Also, I do not observe whether or not each ANDA filing contains a paragraph IV certification because this information is not disclosed by the FDA. On the other hand, the FDA publishes a list of drug markets that were the subject of one or more ANDAs containing a paragraph IV certification. Therefore, it is possible to distinguish between paragraph IV markets and non-paragraph IV markets, and to see if firm behavior differs across the two groups.

Our interest in this study is in seeing if a paragraph IV patent challenge is associated with a generic firm's vertical integration decision. How might such an association arise? As I argue in Section II, when generic entry involves a race to be first, investments made by upstream API manufacturers tend to become specific to a particular downstream buyer. If contracts between unintegrated upstream suppliers and downstream buyers are incomplete and payoffs are determined through *ex post* bargaining, this increase in relationship specificity could enhance the role of vertical integration as a way to facilitate investments.

[19]To see how such a settlement might be employed, suppose that an originator and a first-to-file paragraph IV ANDA applicant begin a patent suit and approval of the ANDA is stayed by 30 months. By settling or prolonging the trial, the two parties can prevent the FDA from approving the first-to-file applicant's ANDA for the duration of the stay. Under the regulations that were in place until 2003, the originator and the generic challenger could delay the approval of subsequent ANDAs even after the expiration of the stay and the approval of the latter's ANDA. This was because the first-to-file applicant's right to 180-day exclusivity was not triggered until the applicant began commercial marketing as long as a court decision could be avoided. Thus, orignators were able to delay generic competition indefinitely by convincing first-to-file applicants to hold off entry – often with the help of settlements involving payments to the generic side. While court decisions have been permissive of such pay-to-delay settlements (see, e.g.,*Schering-Plough v. FTC*, 11th Cir., 2005), their legality has been challenged by the FTC (Federal Trade Commission, 2002). Based on the FTC's recommendations, the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 introduced several amendments to the Federal Food, Drug, and Cosmetic Act to limit the scope for collusive delays. Under the MMA provisions, the first-to-file ANDA applicant forfeits its right to 180-day exclusivity if the right is not exercised within 75 days of a settlement in the patent infringement suit or a court decision of invalidity/non-infringment (Korn et al., 2009). In addition, whereas originators were previously able to use multiple 30-month stays to delay the approval of the first-to-file paragraph IV ANDA, the MMA alllows only one stay per drug product.

[20]This is because the FDA, whose data I use to measure entry, publicizes the approval dates of ANDAs but not not their filing dates.

In the empirical analysis, I employ a simple entry regression framework to see if the occurrence of paragraph IV certification at the market level is associated with higher incidence of vertical integration at the firm level.

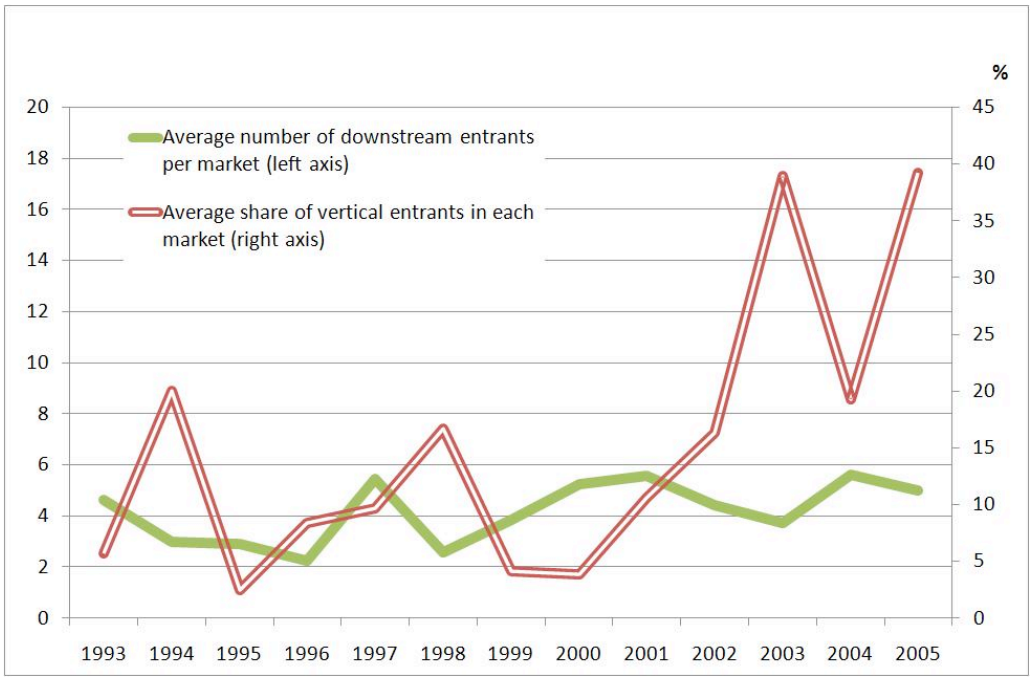
I.3 Trend in Vertical Integration

Before turning to the formal analysis, let us examine the pattern of vertical integration in the generics industry. Figure 1 shows how the prevalence of vertical integration at the market level has changed over time. It is based on the sample of 128 markets that opened up between 1993 and 2005. It can be seen that the average number of downstream entrants (including vertically integrated ones) per market has remained stable at around five. On the other hand, the share of those downstream entrants that are vertically integrated has increased over time. For markets that opened up in the 1993-2000 period, the average share of vertically integrated entrants, as a percentage of the number of downstream entrants, was 8.1 percent. In 2001-2005, the figure rose to 24.1 percent and the difference between the sub-periods is highly significant (the p-value is 0.001).

The incidence of vertical integration has similarly risen over time. In each of the years from 1993 to 2000, 24.0 percent of the sample markets opening up each year, on average, had one or more vertically integrated entrants. For the years 2001-2005, the average share of markets having any vertically integrated entry was 64.6 percent (the p-value for the inter-period difference is less than 0.001).

An interesting fact about the US generic pharmaceutical industry is that it started off as being vertically separated. When the industry began its growth in the 1980s, finished formulation manufacturers procured most of their API requirements from outside suppliers located in Italy, Israel, and other foreign countries. This was mainly due to differences in patent protection across countries: while strong patent protection in the US (and the lack of Roche-Bolar-type exemptions until 1984) made it difficult for domestic companies to develop APIs before the expiration of originator patents, the weak patent regimes in Italy and other countries at the time allowed firms located there to develop generic APIs early (Bryant, 2004).

In addition to these historical origins, the nature of the generics business also made vertical separation a natural outcome. Different downstream manufacturers of generic drugs produce near-identical products, because, by definition, they are all bioequivalent to the original product. Therefore, the APIs manufactured by different upstream firms are also expected to be homogeneous. This implies that in general, investments into API development by a upstream manufacturer are not specific to a particular downstream user. In other words, the investment facilitation effects of vertical integration are unlikely to be important in this industry under normal circumstances. This is analogous to Hart and Tirole's (1990) observation that the efficiency benefits of vertical integration were unlikely to have been strong in the



Notes
(a) The selection of markets is explained in Section IV.
(b) The number of markets opening up each year is presented in Table 1.
(c) For each year, the average number of downstream entrants (including vertically integrated entrants) and the average share of vertically integrated entrants in terms of entrant count are calculated for the sample markets that opened up in that year.

Figure 1: Market-Level Share of Vertically Integrated Entrants

cement and ready-mixed concrete industries during the 1960s when the vertical merger wave took place. Nevertheless, as Figure 1 demonstrates, vertical integration has become more prevalent over time in the generics industry. Several possible reasons for this can be found from industry reports.

One is that early development and procurement of APIs has become more important to the profitability of downstream manufacturers in recent years, particularly in markets characterized by paragraph IV patent challenges. For example, the annual report of Teva, the industry's largest firm, describes the motive for vertical integration as follows: "to provide us with early access to high quality active pharmaceutical ingredients and improve our profitability, in addition to further enhancing our R&D capabilities." (Teva Pharmaceutical Industries, 2008, p.15). Karwal (2006) mentions that "having access to a secure source of API can make a significant difference, particularly relating to difficult-to-develop API, when pursuing a potential Paragraph IV opportunity, and to secure sufficient quantities for development" (p.274). Similarly, Burck (2010) notes that "Access to API and control of the development and manufacturing process to support patent challenges has often been cited as a reason for backward

integration"(p.34). These comments suggest that vertical integration allows downstream manufacturers to obtain APIs sooner than they otherwise would, and that this aids them in attaining first-to-file status in paragraph IV markets. This would partly explain why the increased prevalence in vertical integration appears to have followed closely behind the increase in paragraph IV patent challenges.

A second possible reason for increased vertical integration pertains to bandwagon effects. A former purchasing executive at Sandoz, one of the largest firms, mentions that firms vertically integrate in order to "avoid sourcing API from a competitor" (Stafford, 2006, p.302). Karwal (2006) points out that "Many key API suppliers, especially from India, China and Eastern Europe, are moving up the value chain and decreasing their supply activities, becoming direct competitors in finished form generics" (p.274).[21] He suggests that this is one of the factors behind increased backward integration by downstream manufacturers.

In the mid-2000s, traditionally unintegrated US firms in the downstream segment began acquiring API manufacturing assets. Examples include the acquisition of Indian API manufacturers by Mylan and Watson, both large US finished formulation companies.[22] It is important that these actions, by two of the main players of the industry, took place *after* vertically integrated entry became common. It is unlikely that Mylan and Watson were slower than their rivals at noticing the efficiency effects of vertical integration, given their long histories and large scale of activities.[23] A more plausible explanation is that their decisions to vertically integrate were made in response to the increasingly integrated structure of their rivals.

The next section discusses how we can test the two leading explanations for the increase in vertical integration within the generic pharmaceutical industry: the existence of bandwagon effects and the importance of relationship-specific investments to support patent challenges.

[21] During the 1990s, traditional API suppliers from Italy and other south European countries lost market share to new entrants from India and Eastern Europe. A major reason for this shift was that stricter patent protection in Western Europe – most notably the term extensions given to pharmaceutical patents through the introduction of Supplementary Protection Certificates in 1991 – made it more difficult for firms located there to develop their generic APIs early (Bryant, 2004; Stafford, 2006). Meanwhile, Indian pharmaceutical firms – who honed their product development skills under a weak patent regime that lasted from 1972 to 2005 and who became more open to the outside world under the economic liberalization policies of the early 1990s – focused on the US generic market as a target for their exports. As Lanjouw (1998) documents, Indian drug companies initially entered the US and other Western markets as API suppliers. By the mid-2000s, several of them, including Ranbaxy and Dr. Reddy's Laboratories, had also become major players in the downstream segment.

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

[23] Mylan and Watson were founded in 1961 and 1984, respectively. As of 2006, both firms were among the top six firms in the global generic pharmaceutical industry in revenue terms (Stafford, 2006).

II Testing the Motives for Vertical Integration

II.1 Bandwagon Effects

II.1.1 Bandwagon Behavior and Strategic Complementarity

The theoretical literature on vertical integration is somewhat vague regarding the definition of bandwagon effects. In some models, where an *ad hoc* ordering of vertical integration decisions by firms is assumed, a bandwagon effect is deemed to exist if a firm finds it profitable to integrate given an earlier decision by a rival to integrate (e.g., Hart and Tirole, 1990). Under such a broad definition, bandwagon effects may be shown to exist even if a firm's incentive to integrate *decreases* as a result of its rival's vertical integration decision.

In order to consider bandwagon effects in an industry where vertical integration decisions are simultaneous – or, as in the case of paragraph IV generic entry, they are not necessarily simultaneous but still unobserved between firms – one must consider how a firm's incentive to vertically integrate changes with the expected actions of rivals. A reasonable definition in this case is the following: if a firm's incentive to vertically integrate increases with the probability of integration by a rival, or with the proportion of rivals who are expected to be integrated, then a bandwagon effect exists. In other words, we can equate the existence of bandwagon effects with the strategic complementarity of firms' vertical integration decisions. In some cases, the strategic complementarity may be so strong that a firm who would otherwise prefer to be an unintegrated downstream entrant finds it more profitable to vertically integrate if it expects its rival to do the same. Hart and Tirole (1990) call such a situation a "relucant bandwagon".

Buehler and Schmutzler (2005) point out that in most theoretical models, vertical integration decisions are strategic substitutes rather than complements. There are only a few exceptions in the literature, such as Ordover et al. (1990), Hart and Tirole (1990, p.227), and McLaren (2000) that demonstrate the possibility of strategic complementarity.[24] The theoretical literature's tilt toward strategic substitutability is not, however, necessarily supported by empirical evidence.

In fact, there is anecdotal evidence that vertical integration actions are strategic complements in some industries. For instance, one US cement company's annual report for 1963 mentioned that while it was not inclined to acquire assets in the ready-made concrete industry, the wave of vertical integration among its rivals was forcing the firm to follow suit.[25] While generic pharmaceutical companies have not

[24] Algebraic analysis of the Ordover et al. (1990) model shows that integration decision are strategic complements. Nevertheless, bandwagon behavior may not occur in their model because of an *ad hoc* ordering of integration decisions and strategic pricing behavior by the first mover. Specifically, the first firm to vertically integrate sets the intermediate good price low enough so that its rival will not find it profitable to integrate.

[25] Annual Report of Alpha Portland Cement Company for 1963 as quoted in Federal Trade Commission (1966).

been as candid about bandwagon behavior, it is possible that integration decisions in this industry are also strategic complements.

II.1.2 Incidence of Vertical Integration in Equilibrium

The simultaneity of vertical integration decisions in generic drug markets allows us to devise a simple test for the existence of bandwagon effects – or equivalently, a test for strategic complementarity of integration decisions. It is based on the observation that an individual firm's equilibrium vertical integration decision in a simultaneous-move game varies with its rival's cost of vertical integration. I show, using a simple two-firm model, that when vertical integration decisions are strategic complements, one firm's reduction in the cost of vertical integration leads to a higher probability of vertical integration by the other firm. When vertical integration decisions are strategic substitutes, the opposite result holds: one firm's reduction in vertical integration costs lowers the other firm's probability of integrating.

Consider a market consisting of an upstream and a downstream segment. Assume that there are two potential downstream entrants indexed by 1 and 2. The firms simultaneously choose between unintegrated downstream entry (D), vertically integrated entry (V), and no entry. When both firms 1 and 2 decide to enter as unintegrated downstream producers, I assume that two unintegrated suppliers enter the upstream segment. When one potential downstream entrant chooses unintegrated downstream entry while the other chooses vertically integrated entry, it is assumed that a single unintegrated upstream supplier also enters.

Each firm's payoff can be expressed as a function of its own action and the action of its rival. I assume for simplicity that the cost of unintegrated downstream entry is zero. On the other hand, the cost of vertically integrated entry for firm i is $K_i > 0$. Thus, firm i's payoff, net of entry cost, is $\pi(a_i, a_j) - \mathbf{1}(a_i = V)K_i$.

In the following, I employ the shorthand π_{mn} to represent the post-entry payoff function $\pi(m,n)$. I assume that post-entry payoffs are greater than zero under any market structure, so that both of the potential downstream entrants always enter in one way or another. Thus, all realized market structures are characterized by two upstream units and two downstream units. The following assumptions are made about the post-entry payoff function:

$$\pi_{VD} > \pi_{DD}, \tag{2}$$

$$\pi_{VV} > \pi_{DV}, \tag{3}$$

$$\pi_{VD} > \pi_{VV}, \tag{4}$$

$$\pi_{DD} > \pi_{DV}. \tag{5}$$

Inequalities (2) and (3) say that a firm's post-entry profit, conditional on its rival's action, is higher if it is vertically integrated, whether the other firm chooses unintegrated entry or vertical integration. Inequalities (4) and (5) say that a firm's post-entry payoff is decreasing in the other firm's vertical integration choice. Both sets of assumptions can be justified by the existence of efficiency effects due to vertical integration. I also assume the following:

$$\pi_{DD} > \pi_{VV} - K_i, \quad i = 1,2, \tag{6}$$

which says that firms prefer to be in a market where both entrants are unintegrated than in one where both are vertically integrated.[26]

Two separate cases are considered with regard to the magnitude of payoff differentials. In the first case, $\pi_{VV} - \pi_{DV} > \pi_{VD} - \pi_{DD}$, so that vertical integration decisions are strategic complements. In the second case, $\pi_{VV} - \pi_{DV} < \pi_{VD} - \pi_{DD}$, implying that vertical integration actions are strategic substitutes.

The payoff matrix in Table 2 can be used to find the Nash equilibrium market structures. To see how one firm's equilibrium behavior is affected by the other firm's cost of vertical integration, let us assume that K_1 is fixed at some value $\bar{K}_1$ that falls between $\pi_{VD} - \pi_{DD}$ and $\pi_{VV} - \pi_{DV}$ and see how the equilibrium changes as K_2 varies.

Table 3 presents the results when the firms' vertical integration decisions are strategic complements. When the value of K_2 is at or below $\pi_{VD} - \pi_{DD}$ so that vertically integrated entry is a dominant strategy for firm 2, firm 1 also chooses vertically integrated entry in equilibrium. On the other hand, when K_2 is greater than or equal to $\pi_{VV} - \pi_{DV}$ so that unintegrated downstream entry is firm 2's dominant strategy, firm 1 likewise chooses unintegrated downstream entry. For intermediate values of K_2, there are three possible Nash equilibria: the two pure strategy equilibria $(a_1^*, a_2^*) = (D,D)$ and (V,V), and the following mixed strategy equilibrium:

$$\begin{aligned}&(\mathit{Prob}(a_1 = V),\ \mathit{Prob}(a_2 = V)) \\ &= \left(\frac{K_2 - (\pi_{VD} - \pi_{DD})}{(\pi_{VV} - \pi_{DV}) - (\pi_{VD} - \pi_{DD})},\ \frac{K_1 - (\pi_{VD} - \pi_{DD})}{(\pi_{VV} - \pi_{DV}) - (\pi_{VD} - \pi_{DD})} \right).\end{aligned}$$

If we only look at the range of K_2 where the equilibrium is unique, firm 1's vertical integration probability is decreasing in firm 2's cost of vertical integration. As for the intermediate range characterized by multiple equilibria, we cannot say how firm 1's equilibrium probability changes with K_2 without

[26]This suggests that the equilibrium of the vertical integration game might be characterized as a Prisoner's Dilemma, a common result found in Ordover et al. (1990), Hart and Tirole (1990) and other representative models.

Table 2: Payoff Matrix of Vertical Entry Game

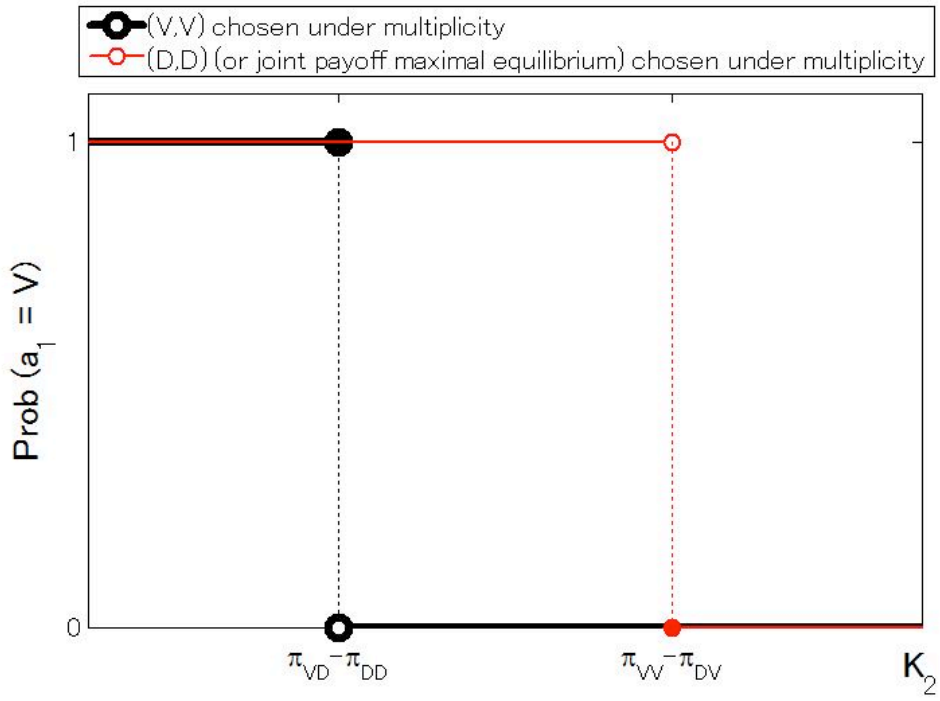
		Firm 2's action	
		D	V
Firm 1's action	D	$\pi_{DD},\ \pi_{DD}$	$\pi_{DV},\ \pi_{VD}-K_2$
	V	$\pi_{VD}-K_1,\ \pi_{DV}$	$\pi_{VV}-K_1,\ \pi_{VV}-K_2$

D denotes unintegrated downstream entry and V denotes vertically integrated entry.
In each cell, the first element is firm 1's payoff and the second element is firm 2's payoff.
The first subscript of π represents the firm's own action; the second subscript is its rival's action.

Table 3: Equilibrium Vertical Integration Probabilities Under Strategic Complementarity

Range of K_2	Firm 1's equilibrium vertical integration probabilities
$[\,0,\ \pi_{VD}-\pi_{DD}\,]$	1
$(\,\pi_{VD}-\pi_{DD},\ \pi_{VV}-\pi_{DV}\,)$	$\left\{0,\ \frac{K_2-[\pi_{VD}-\pi_{DD}]}{[\pi_{VV}-\pi_{DV}]-[\pi_{VD}-\pi_{DD}]},\ 1\right\}$
$[\,\pi_{VV}-\pi_{DV},\ \infty\,)$	0

Firm 1's vertical integration cost is fixed at $\bar{K}_1 \in (\pi_{VD}-\pi_{DD}, \pi_{VV}-\pi_{DV})$.
When $K_2 \in (\pi_{VD}-\pi_{DD}, \pi_{VV}-\pi_{DV})$, there is one mixed strategy equilibrium and two pure strategy equilibria: $(a_1^*, a_2^*) = (D,D)$ and $(a_1^*, a_2^*) = (V,V)$.



(a) The horizontal axis represents firm 2's cost of vertical integration.

(b) The graphs represent firm 1's vertical integration probabilities under different equilibrium selection rules.

Figure 2: Firm 1's Vertical Integration Probability Under Strategic Complementarity

specifying which equilibrium is realized. Firm 1's vertical integration probability in the mixed strategy equilibrium is increasing in K_2, but one cannot conclude from this that firm 1 is more likely to be vertically integrated when K_2 is high.[27]

A one-to-one mapping between K_2 and firm 1's vertical integration probability can be obtained by specifying an equilibrium selection rule. A simple rule is to let a particular pure stratgy equilibrium be chosen for all values of K_2 in the intermediate range. This rule yields two possibilities. The first is that (D,D) is always chosen for $K_2 \in (\pi_{VV}-\pi_{DV}, \pi_{VD}-\pi_{DD})$. The other possibility is that (V,V) is always chosen in the intermediate range. Figure 2 shows how firm 1's vertical integration probability can be presented as functions of K_2 under the two cases.

An alternative rule – one that is often employed in the empirical literature on entry games (e.g., Berry, 1992) – is to select the equilibrium (possibly one in mixed strategies) that yields the highest

[27] Firm 1's mixed-strategy vertical integration probability is increasing in K_2 for the following reason. When K_2 is low and vertically integrated entry is relatively more attractive for firm 2, firm 1's vertical integration probability must be low enough in the mixed strategy equilibrium so that firm 2 stays indifferent between vertical integration and unintegrated downstream entry. As K_2 rises, higher vertical integration probabilities for firm 1 become possible in the mixed strategy equilibrium.

Table 4: Equilibrium Vertical Integration Probabilities Under Strategic Substitutability

Range of K_2	Firm 1's equilibrium vertical integration probabilities
$[\,0,\ \pi_{VV}-\pi_{DV}\,]$	0
$(\,\pi_{VV}-\pi_{DV},\ \pi_{VD}-\pi_{DD}\,)$	$\left\{0,\ \frac{[\pi_{VD}-\pi_{DD}]-K_2}{[\pi_{VD}-\pi_{DD}]-[\pi_{VV}-\pi_{DV}]},\ 1\right\}$
$[\,\pi_{VD}-\pi_{DD},\ \infty\,)$	1

Firm 1's vertical integration cost is fixed at $\bar{K}_1 \in (\pi_{VV}-\pi_{DV}, \pi_{VD}-\pi_{DD})$.
When $K_2 \in (\pi_{VV}-\pi_{DV}, \pi_{VD}-\pi_{DD})$, there is one mixed strategy equilibrium and two pure strategy equilibria: $(a_1^*, a_2^*) = (D,V)$ and $(a_1^*, a_2^*) = (V,D)$.

joint payoffs. Using inequalities (4), (5), and (6), it can be shown that under this rule, the pure strategy equilibrium $(a_1^*, a_2^*) = (D,D)$ is chosen when $K_2 \in (\pi_{VD}-\pi_{DD}, \pi_{VV}-\pi_{DV})$.[28] In other words, firm 1's vertical integration probability stays at zero when K_2 is in the intermediate range.

Figure 2 demonstrates that, under each of the equilibrium selection rules considered, firm 1's vertical integration probability is a decreasing function of K_2 when the firms' vertical integration decisions are strategic complements. An intuitive interpretation of this result is that when firm 2's vertical integration cost rises, firm 1 expects less vertically integrated entry by its rival. Under strategic complementarity, this expectation is translated into a lower probability of vertical integration by firm 1 itself.

Table 4 shows how firm 1's vertical integration probability changes with K_2 when the firms' integration decisions are strategic substitutes. In this case, the unique pure strategy equilibrium is $(a_1^*, a_2^*) = (D,V)$ for low values of K_2 and (V,D) for high values of K_2. The intermediate values of $K_2 \in (\pi_{VV}-\pi_{DV},\ \pi_{VD}-\pi_{DD})$ are characterized by the two asymmetric pure strategy equilibria, (D,V) and (V,D), and the mixed strategy equilibrium

$$\begin{aligned}&(\,Prob(a_1 = V),\ Prob(a_2 = V)\,)\\ &= \left(\frac{(\pi_{VD}-\pi_{DD})-K_2}{(\pi_{VD}-\pi_{DD})-(\pi_{VV}-\pi_{DV})},\ \frac{(\pi_{VD}-\pi_{DD})-K_1}{(\pi_{VD}-\pi_{DD})-(\pi_{VV}-\pi_{DV})}\right).\end{aligned} \tag{7}$$

[28] Joint payoffs are greater under (D,D) than under (V,V) by (6). In the mixed strategy equilibrium, firm i's payoff, given that firm j's vertical integration probability is q_j, is $\pi_{VD} - q_j(\pi_{VD}-\pi_{VV}) - K_i = \pi_{DD} - q_j(\pi_{DD}-\pi_{DV})$. The equality indicates firm i's indifference between vertically integrated and unintegrated downstream entry. The left-hand side is greater than π_{VV} by (4), and the right-hand side is less than π_{DD} by (5). Therefore, the joint payoffs under the mixed strategy equilibrium are between that under (V,V) and that under (D,D).

As before, let us consider different equilibrium selection rules for the intermediate range. If (D,V) is always chosen for $K_2 \in (\pi_{VV}-\pi_{DV},\ \pi_{VD}-\pi_{DD})$, firm 1's vertical integration probability jumps from zero to one at $K_2 = \pi_{VD}-\pi_{DD}$, as seen in Figure 3. The jump occurs at $K_2 = \pi_{VV}-\pi_{DV}$ if (V,D) is always chosen instead. If we assume that the pure strategy equilibrium with the highest joint payoffs is chosen, then the function exhibits a jump from zero to one at $\bar{K}_1$. Thus, as long as we restrict attention to pure strategy equilibria, as do most of the existing empirical studies on entry games (e.g. Berry, 1992; Mazzeo, 2002; Ciliberto and Tamer, 2009), the function that maps from K_2 to firm 1's vertical integration probability is an increasing one when strategic substitutability holds.

The same function becomes more complicated if we allow for mixed strategy equilibria and apply the joint payoff-maximality rule. Let us simplify the analysis by setting firm 1's vertical integration cost at $\bar{\bar{K}}_1 = \frac{1}{2}(\pi_{VV}-\pi_{DV}+\pi_{VD}-\pi_{DD})$. First, consider the case where firm 2 has a vertical integration cost that is less than or equal to firm 1's so that $K_2 \in (\pi_{VV}-\pi_{DV},\ \bar{\bar{K}}_1]$. The joint payoff maximal outcome in this case is the pure strategy equilibrium $(a_1^*,a_2^*) = (D,V)$. The proof involves taking the difference between the joint payoffs under the mixed strategy equilibrium and that under (D,V), which is the pure strategy equilbirium with the highest joint payoffs. [29]

Next, consider the case of $K_2 \in (\bar{\bar{K}}_1,\ \pi_{VD}-\pi_{DD})$. It can be shown that the pure strategy equlibrium (V,D) maximizes joint payoffs for $K_2 \in (\bar{\bar{K}}_1,\ \bar{\kappa}]$, where

$$\bar{\kappa} = \pi_{VV}-\pi_{DV}+\frac{(\pi_{VD}-\pi_{VV})[(\pi_{VD}-\pi_{DD})-(\pi_{VV}-\pi_{DV})]}{2(\pi_{DD}-\pi_{DV})} > \bar{\bar{K}}_1.$$

The inequality follows from the strategic substitutability condition, $\pi_{VV}-\pi_{DV} < \pi_{VD}-\pi_{DD}$. For $K_2 \in (\bar{\kappa},\ \pi_{VD}-\pi_{DD})$, the mixed strategy equilibrium (7) maximizes joint profits. [30] As Figure 4 shows, firm

[29] The joint payoffs under the mixed strategy equilbrium can be written as

$$\Pi_{MS} = (1-q_2)\pi_{DD}+q_2\pi_{DV}+(1-q_1)\pi_{VD}+q_1\pi_{VV}-K_2,$$

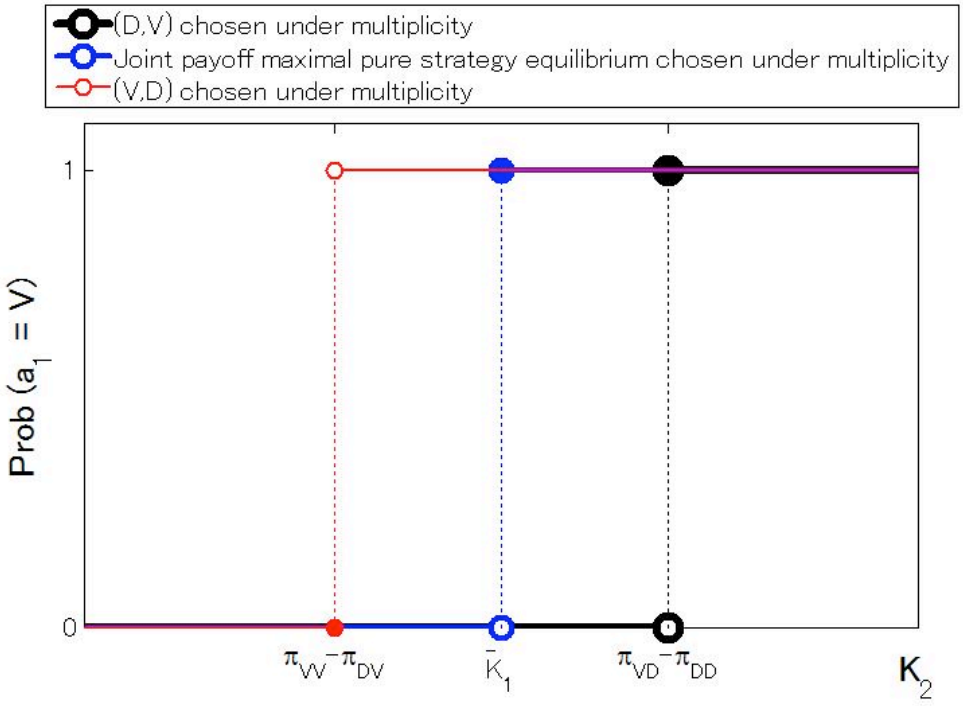
where q_i stands for firm i's vertical integration probability. Taking the difference with $\Pi_{PS} = \pi_{DV}+\pi_{VD}-K_2$, the joint payoffs under (D,V), and collecting terms gives

$$\begin{aligned}\Pi_{MS}-\Pi_{PS} &= (1-q_2)(\pi_{DD}-\pi_{DV})-q_1(\pi_{VD}-\pi_{VV}) \\ &= \frac{1}{2}(\pi_{DD}-\pi_{DV})-\frac{\pi_{VD}-\pi_{DD}-K_2}{(\pi_{VD}-\pi_{DD})-(\pi_{VV}-\pi_{DV})}(\pi_{VD}-\pi_{VV}) < 0.\end{aligned}$$

The second equality is obtained by plugging in the expressions for q_1 and q_2 and rearranging. The last inequality follows from $\pi_{DD}-\pi_{DV} < \pi_{VD}-\pi_{VV}$, which is derived from the condition for strategic substitutability, and $\pi_{VD}-\pi_{DD}-K_2 \geq \pi_{VD}-\pi_{DD}-\bar{\bar{K}}_1 = \frac{1}{2}[(\pi_{VD}-\pi_{DD})-(\pi_{VV}-\pi_{DV})]$.

[30] Let us rewrite the joint payoffs under the mixed strategy equilbrium as

$$\Pi_{MS} = (1-q_1)\pi_{DD}+q_1\pi_{DV}+(1-q_2)\pi_{VD}+q_2\pi_{VV}-\bar{\bar{K}}_1.$$



The graphs represent firm 1's vertical integration probabilities under different equilibrium selection rules.

Figure 3: Firm 1's Vertical Integration Probability in Pure Strategy Equilibria Under Strategic Substitutability

1's vertical integration probability is a non-monotonic function of K_2 in this case.

The monotonicity of firm 1's vertical integration probability with respect to firm 2's vertical integration cost under strategic substitutability depends on the choice of equilibrium selection rule. Nevertheless, there are grounds to expect the relationship to be increasing in practice. First, it is not very likely that in real world industries, firms actively switch between pure strategy entry equilibria and mixed strategy equilibria based on the criterion of joint profit maximality, as in Figure 4. Secondly, the range of K_2 in Figure 4 where firm 1's vertical integration probability is a decreasing function is narrow. Thus, we can state with some confidence that firm 1's equilibrium vertical integration probability is likely to be an increasing function of K_2 when vertical integration decisions are strategic substitutes. Intuitively,

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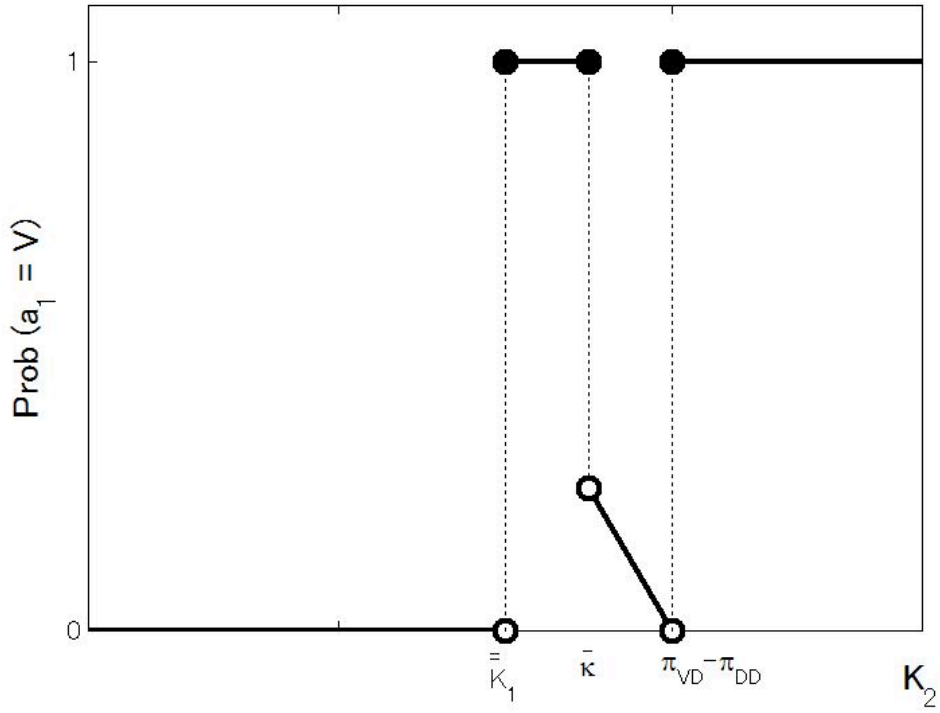
Subtract from it $\Pi_{PS} = \pi_{DV} + \pi_{VD} - \bar{\bar{K}}_1$, the joint payoffs under (V,D), which is the joint payoff maximal pure strategy equilibrium when $K_2 > \bar{\bar{K}}_1$:

$$\begin{aligned}\Pi_{MS} - \Pi_{PS} &= (1-q_1)(\pi_{DD}-\pi_{DV}) - q_2(\pi_{VD}-\pi_{VV}) \\ &= \frac{K_2 - (\pi_{VV}-\pi_{DV})}{(\pi_{VD}-\pi_{DD})-(\pi_{VV}-\pi_{DV})}(\pi_{DD}-\pi_{DV}) - \frac{1}{2}(\pi_{VD}-\pi_{VV}).\end{aligned}$$

Rearranging terms shows that this expression is negative if and only if $K_2 < \bar{\kappa}$.



The graph represents firm 1's vertical integration probability when the equilibrium with the highest joint payoffs is always chosen.

Figure 4: Firm 1's Vertical Integration Probability Under Strategic Substitutability When Mixed Strategy Equilibrium Is Possible

a higher vertical integration cost for firm 2 is interpreted by firm 1 as a lower probability of integration by its rival. Under strategic substitutability, this results in a higher probability of vertical integration by firm 1.

II.1.3 Testing for Bandwagon Effects

The main results represented by Figures 2 and 3 can form the basis for an empirical test of strategic complementarity or substitutability in vertical integration decisions. Suppose that one has data on multiple markets in which a number of firms make entry and vertical integration decisions simultaneously. Suppose also that one has prior information that a particular firm characteristic – call it z – affects the cost of vertical integration. Then, the test consists of measuring the effect of $\mathbf{z}_{-i}$, the vector containing the characteristics of firms other than i, on the probability that firm i chooses to enter vertically. If z_i has a cost-lowering effect and vertical integration decisions are strategic complements, we would expect the elements of the vector $\partial Prob(a_i = V)/\partial \mathbf{z}_{-i}$ to be positive. If vertical integration is characterized by strategic substitutability, the derivatives are expected to have a negative sign. This suggests that the

existence of strategic complementarity – and by association, bandwagon effects – can be tested in a reduced-form regression framework similar to the one used to analyze peer effects in youth behavior (e.g., Case and Katz, 1991; Evans et al., 1992).

A good candidate for z is the firm's previous entry experience. Earlier studies on the generic drug industry by Scott Morton (1999), Gallant et al. (2008), and others have shown that previous experience in entering similar markets has a significantly positive effect on entry probabilities. They conclude from this that previous entry experience lowers current entry costs. While these authors only examine downstream finished formulation markets, it is likely that previous entry experience lowers current entry costs in the upstream API segment as well.

If a firm's previous upstream entry experience is indeed associated with a lower cost of upstream entry, then it should also be associated with a lower cost of vertical integration for downstream entrants. In the subsequent empirical analysis, we use the potential downstream entrant's own upstream experience, as well as the upstream experience of the other potential downstream entrants, as covariates in order to test the existence of bandwagon effects.

II.2 Relationship Specificity of Investments to Support Patent Challenge

As discussed in Section I.2, generic entrants engage in a race to be the first-to-file ANDA applicant when a market is characterized by a paragraph IV patent challenge. In such markets, early access to APIs, which enables early ANDA filings, is particularly important for the profitability of downstream entrants. Here, we examine how vertical integration might provide downstream entrants with earlier access to APIs than would be possible under vertical separation. According to the transaction cost and property rights theories of the firm (e.g., Williamson, 1971; Klein et al., 1979; Grossman and Hart, 1986), vertical integration facilitates investments that are characterized by relationship specificity and non-contractibility. A relationship-specific investment is one that has a greater value within a particular vertical relationship than in others (Grossman and Hart, 1986). Using a simple model, I show that the development of APIs to support a paragraph IV patent challenge fits this definition. I then demonstrate how vertical integration may facilitate the early development of APIs when supply contracts are incomplete *ex ante*.

II.2.1 Product Development in a Paragraph IV Market

In the previous subsection, where we focused on the vertical integration decisions of downstream entrants, we implicitly assumed the timing and cost of product development to be fixed. Here, we take the potential entrants' entry and vertical integration decisions as given and focus on the process of product development. We allow both the timing and cost of development to vary.

The timeline of events for a particular generic drug market is depicted in Figure 5 where one period

is equal to one year. Activity begins at time 0 when the FDA approves the original product. The basic product patent for the drug expires at time T_b. The drug is also covered by a secondary patent that expires at $T_s > T_b$. Generic drug companies become aware of the product at time 0 and make plans for product development and regulatory filings. If a generic firm makes a paragraph IV patent certification with respect to the secondary patent, it aims to file its ANDA several periods before T_b. There are two reasons for the early filing. First, the target entry timing of a paragraph IV applicant is T_b; the ANDA must be filed a few periods prior to that in order to give the FDA sufficient review time. I assume that the ANDA review process takes two periods. Second, and more importantly, the paragraph IV applicant files the ANDA early in order to be ahead of its rivals.

A paragraph IV certification is met with a patent infringement suit by the originator, but it is assumed that the generic defendant invalidates the secondary patent and wins the suit with certainty. The FDA gives final approval to the first-to-file paragraph IV applicant's ANDA at T_b whereupon the firm begins commercial marketing. The first-to-file firm enjoys exclusivity in the generic market from T_b to $T_b + \frac{1}{2}$ (180-day exclusivity). If a generic firm plans to enter without a patent challenge, it files an ANDA at or near $T_b - \frac{3}{2}$. This gives the FDA two periods to review the ANDA and give final approval at $T_b + \frac{1}{2}$. Non-challengers begin commercial marketing at $T_b + \frac{1}{2}$, as do paragraph IV applicants who fail to be the first to file.

I assume that the timing of successful API development by upstream units is a random variable, and that downstream units are able to develop finished formulations immediately after the API becomes available. Following Loury's (1979) model of a patent race, the timing of successful API development by an upstream unit depends on the level of investment chosen by it at time 0. Let d_i be the level of investment by an unintegrated upstream entrant i. The probability that the timing of success, $\tau(d_i)$, is earlier than t is $Pr[\tau(d_i) < t] = 1 - e^{-h(d_i)t}$. Following Reinganum (1983), it is assumed that $h(0) = 0$, $h'(d) > 0$, and $h''(d) < 0$ for $d \in \mathbb{R}_+$. For the upstream unit of a vertically integrated entrant j, the corresponding hazard function is $g(\cdot)$, with $g(d) < h(d), \ \forall d \in \mathbb{R}_+$. That the vertically integrated entrant

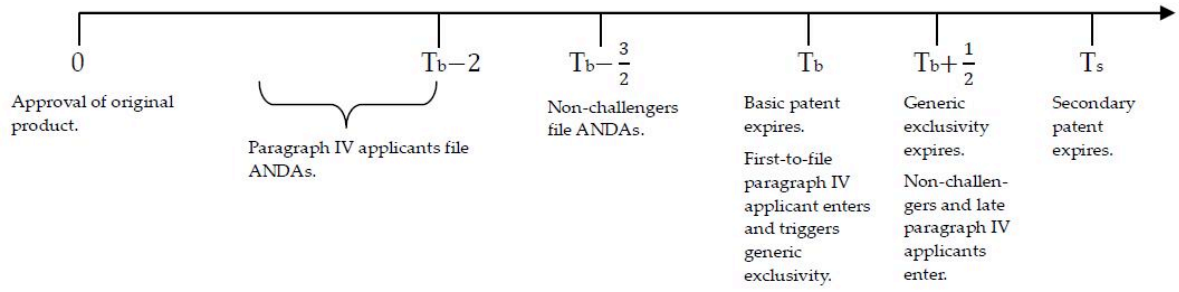


Figure 5: Timeline of Events in a Market Characterized by Patent Challenge

has a lower hazard rate than the unintegrated entrant at the same level of investment implies the lower efficiency of the former in API development. This reflects the organizational inefficiencies due to vertical integration. The random variable $\tau(d_i)$ is assumed to be independent across firms.

I also make the following assumption: the hazard functions are such that upstream units face little uncertainty with respect to investment outcomes when they are not involved in challenging the secondary patent. In other words, if an upstream unit invests to maximize its expected payoff from supporting a non-challenger's ANDA, the probability that its API is successfully developed by $T_b - \frac{3}{2}$, the time for filing the ANDA, is very close to one. This implies that upstream units supporting a paragraph IV applicant, who are likely to investment more into API development and who expect their downstream users' ANDAs to be filed by $T_b - 2$ at the latest, face a probability near one of successfully developing its API by $T_b - 2$. In other words, there is almost always some paragraph IV applicant who is successful at obtaining generic exclusivity. This assumption simplifies the subsequent analysis.

II.2.2 Firm Revenues

The expected revenue of a non-challenger in the finished formulation market, net of downstream processing costs, is

$$\pi_{pe}\left\{1 - e^{-[\sum_{i\in\mathcal{U}_c} h(d_i)+\sum_{j\in\mathcal{V}_c} g(d_j)](T_b-2)}\right\} + \pi_{ps}e^{-[\sum_{i\in\mathcal{U}_c} h(d_i)+\sum_{j\in\mathcal{V}_c} g(d_j)](T_b-2)} \approx \pi_{pe},$$

where π_{pe} and π_{ps} are the revenues receivable from entering at $T_b + \frac{1}{2}$ and T_s, respectively. Both revenue figures are in present values as of time 0. The subscript *pe* stands for "post-exclusivity" and *ps* stands for "post-secondary patent". $\mathcal{U}_c$ is the set of unintegrated upstream firms that are involved in a paragraph IV patent challenge (the subscript c stands for "challenger") and $\mathcal{V}_c$ is the set of upstream units belonging to vertically integrated paragraph IV applicants. $e^{-[\sum_{i\in\mathcal{U}_c} h(d_i)+\sum_{j\in\mathcal{V}_c} g(d_j)](T_b-2)}$ is the probability that none of the paragraph IV applicants succeed at developing their APIs by $T_b - 2$. The approximation follows from the assumption that this probability is close to zero.

The expected revenue of a paragraph IV applicant, after it finds out that it is not the first to file, is π_{pe}. On the other hand, the revenue of the first-to-file paragraph IV applicant is $\pi_e + \pi_{pe}$, where π_e is the revenue earned during the generic exclusivity period. In practice, π_e is several times larger than π_{pe} because the first-to-file firm enjoys both a larger market share and a higher product price during the exclusivity period.

A set of assumptions is employed regarding the way in which revenues and profits are shared between upstream and downstream units. For simplicity, let trades of API occur only within pairs consisting

of one upstream unit and one downstream unit. In the case of a pair consisting of two separate firms, downstream revenue is divided through *ex post* bargaining. The bargaining takes place immediately after revenues are realized, which occurs when the ANDA is approved or when the first-to-file status of a paragraph IV applicant is revealed. *Ex ante* contracts for the supply of API are ruled out. This assumption may require some justification. In particular, readers may wonder why the firms don't enter into a contingent contract – e.g., one that specifies a high payment to the upstream firm only in the event of the pair winning first-to-file status. The problem with a contingent contract in practice is that the upstream firm's investment performance (timing of successful API development relative to rivals) and its contribution to the final outcome (the timing of filing the paragraph IV ANDA) may be unverifiable. This is because in reality, unlike in the present model, the speed of generic product development depends to some extent on investment by the downstream unit. In addition, there is some anecdotal evidence, contained in court records, that buyers often breach API supply contracts without having to pay penalties.[31]

For a vertically integrated entrant, I assume that profit (revenue minus API development cost) is divided between the vertical units in fixed prorportions. This profit-sharing assumption, which is borrowed from Hart and Tirole (1990), essentially assumes that "under integration, profits of the parent and subsidiary are commingled in such a way that profit sharing is inevitable" (Hart and Tirole, 1990, p.217).

Let us consider the *ex post* division of revenue by an unintegrated upstream-downstream pair who do not make a patent challenge. Assuming that there is some other firm who succeeds in a patent challenge, π_{pe} becomes available to the pair at $T_b + \frac{1}{2}$ if the upstream firm succeeds at API development by $T_b - \frac{3}{2}$. In principle, bargaining over the division of this revenue can take a very complex form, involving all possible trading partners of the two firms (de Fontenay and Gans, 2005). For the sake of simplicity, however, I assume that the revenue is split evenly between the two firms. Thus, the upstream entrant – call it firm i – solves the following maximization problem when it chooses its investment level:

$$\max_{d_i} \frac{1}{2}\pi_{pe}\left[1 - e^{-h(d_i)\left(T_b - \frac{3}{2}\right)}\right] - d_i. \tag{8}$$

The earlier assumption that upstream entrants succeed at API development by $T_b - \frac{3}{2}$ with probability near one is equivalent to assuming that $1 - e^{-h(d_i^*)\left(T_b - \frac{3}{2}\right)} \approx 1$, where d_i^* is implicitly defined by the first order condition of (8).

Now, consider the divsion of revenue by an unintegrated pair who pursues a paragraph IV patent

[31] Many instances of API contracts being breached are described in the court's opinion for *Geneva and Apothecon v. Barr et al*. (S.D.N.Y., 2002). In one particular case in 1995, a downstream firm made a 1.8 million dollar purchase order for 2,500 kilograms of API from an upstream supplier. The purchase order was canceled eighteen months later, with more than 1,500 kilograms yet to be delivered.

challenge. When the pair loses in the race to be first-to-file, each firm's revenue is the same as when there is no patent challenge: both receive $\frac{1}{2}\pi_{pe}$. When the pair wins generic exclusivity, I assume that the extra revenue during the exclusivity period, π_e, is split according to the Nash bargaining solution.

Let us consider the firms' outside options. The downstream firm, who owns the first-to-file paragraph IV ANDA, can enjoy the generic exclusivity revenue even if it does not trade with its original partner. Between winning first-to-file status (some time before $T_b - 2$) and receiving final approval (at T_b), the downstream firm has sufficient time to find another API manufacturer who is willing to supply during the exclusivity period. It must cede some portion (say, γ ¡ 1) of revenue during the exclusivity period to the alternative supplier, but the downstream firm keeps the major share.[32]

Meanwhile, the original upstream partner has no claim on generic exclusivity except through its relationship with the downstream firm. Therefore, its outside option during the exclusivity period is zero. Note that the upstream firm's investment into API development is characterized by relationship specificity: its product generates a revenue of π_e if supplied to the first-to-file ANDA applicant during the exclusivity period, but if supplied to another user, it generates zero revenue. Investment by the upstream firm is crucial for winning the right to generic exclusivity. Yet, the firm has no ownership claim over this valuable asset.

Given the outside options, the Nash bargaining solution for the upstream partner's revenue when the pair wins generic exclusivity is $\frac{1}{2}[\pi_e - (1-\gamma\pi_e)] + \frac{1}{2}\pi_{pe} = \frac{1}{2}(\gamma\pi_e + \pi_{pe})$. The first term on the left-hand side is the revenue from supplying the downstream partner during the generic exclusivity period and the second term is the revenue during the post-exclusivity period. γ, the share of exclusivity period revenue that the downstream firm must pay to an alternative API supplier, is expected to be small (i.e., not much larger than zero). Therefore, the upstream firm's revenue from supplying the first-to-file paragraph IV applicant is only slightly larger than its revenue from supplying a non-challenger.

II.2.3 Equilibrium Investments

The equilibrium level of investments by upstream units can be derived as the solution of an investment race. For simplicity, I assume that two upstream units are present in the market. The first unit, labeled u, is an unintegrated firm who supplies API to an unintegrated downstream firm. The second unit is a subsidiary of a vertically integrated entrant labeled v. It produces API exclusively for in-house use. Both upstream units participate in a paragraph IV patent challenge. Following Reinganum (1983), the race outcome is derived as a Nash equilibrium with investment as the strategic variable.

[32]The existence of an alternative supplier is assured with near certainty if there are multiple upstream units pursuing a paragraph IV patent challenge, because given the earlier assumption, each successfully develops its API by $T_b - 2$ with probability close to one. Even if there is only one upstream firm that pursues a patent challenge (i.e., the downstream firm's original partner), the downstream firm can contract with other potential suppliers, at relatively low cost, to develop the API by $T_b - 2$.

Given the formula for the probability of successful API development, the probability density of firm u succeeding at time t is $h(d_u)e^{-h(d_u)t}$. The density for the probability of firm u winning the race at time t is therefore

$$h(d_u)e^{-h(d_u)t}\left[1-\left(1-e^{-g(d_v)t}\right)\right]=h(d_u)e^{-[h(d_u)+g(d_v)]t}.$$

Integrating from 0 to T_b-2 gives the probability that u wins the race:

$$\begin{aligned}Prob(u \text{ wins}) &= \int_0^{T_b-2} h(d_u)e^{-[h(d_u)+g(d_v)]t}dt \\ &= \frac{h(d_u)}{h(d_u)+g(d_v)}\left[1-e^{-[h(d_u)+g(d_v)](T_b-2)}\right].\end{aligned}$$

The probability of firm v winning the race is analogously derived.

The profit maximization problem for firm u is the following:

$$\max_{d_u}\ \frac{1}{2}\left\{\gamma\pi_e\,\frac{h(d_u)}{h(d_u)+g(d_v)}\left[1-e^{-[h(d_u)+g(d_v)](T_b-2)}\right]+\pi_{pe}\right\}-d_u.$$

Firm u's best response to firm v's investment is implicitly defined by the following first-order condition:

$$\begin{aligned}&\frac{1}{2}\gamma\pi_e\left\{\frac{h'(d_u)g(d_v)}{[h(d_u)+g(d_v)]^2}\left[1-e^{-[h(d_u)+g(d_v)](T_b-2)}\right]\right.\\ &\left.+\frac{h'(d_u)h(d_u)(T_b-2)}{h(d_u)+g(d_v)}e^{-[h(d_u)+g(d_v)](T_b-2)}\right\}=1.\end{aligned}$$

Applying the assumption that both upstream firms are successful at developing API by T_b-2 with probability near one, this expression simplifies to

$$\frac{1}{2}\gamma\pi_e\frac{h'(d_u)g(d_v)}{[h(d_u)+g(d_v)]^2}\approx 1. \tag{9}$$

The upstream unit of the vertically integrated firm v faces the following profit maximization problem:

$$\max_{d_v}\ \xi\left\{\pi_e\,\frac{g(d_v)}{h(d_u)+g(d_v)}\left[1-e^{-[h(d_u)+g(d_v)](T_b-2)}\right]+\pi_{pe}-d_v\right\},$$

where ξ is the upstream unit's share of profits. The first-order condition that implicitly defines firm v's best response to firm u's investment level is

$$\pi_e \left\{ \frac{g'(d_v)h(d_u)}{[h(d_u)+g(d_v)]^2} \left[1 - e^{-[h(d_u)+g(d_v)](T_b-2)}\right] \right.$$

$$\left. + \frac{g'(d_v)g(d_v)(T_b-2)}{h(d_u)+g(d_v)} e^{-[h(d_u)+g(d_v)](T_b-2)} \right\} = 1.$$

which simplifies to

$$\pi_e \frac{g'(d_v)h(d_u)}{[h(d_u)+g(d_v)]^2} \approx 1. \tag{10}$$

We assumed earlier that $g(d) < h(d)$ in order to represent the organizational inefficiency of a vertically integrated entrant in terms of API development. Let us simplify by assuming that $g(d) = \phi h(d)$ with $\phi < 1$. Equating the left-hand sides of (9) and (10) yields the following result regarding the equilibrium level of investment by the upstream units:

$$\frac{h'(d_v^*)/h(d_v^*)}{h'(d_u^*)/h(d_u^*)} = \frac{\gamma}{2} < 1. \tag{11}$$

where the inequality follows from the definition of γ. Inequality (11) and the assumption of $h(\cdot)$ being an increasing and concave function imply that $d_v^* > d_u^*$. Therefore, firm v invests more into API development than firm u in equilibrium.

In order to compare the two firms' probability of winning the race, we require knowledge regarding the functional form of $h(\cdot)$. For the purpose of illustration, let us assume that $h(d) = \sqrt{d}$. Then, (11) simplifies to $d_v^* = \frac{2d_u^*}{\gamma}$. The hazard rate defining firm v's success probability, $g(d_v^*)$, is equal to $\phi\sqrt{\frac{2d_u^*}{\gamma}}$. This is greater than $h(d_u^*) = \sqrt{d_u^*}$ if and only if $\phi > \sqrt{\frac{\gamma}{2}}$. Therefore, the vertically integrated entrant has a higher probability of winning the investment race than the unintegrated upstream entrant as long as the organizational inefficiency due to vertical integration is not too severe.

The result that the vertically integrated firm is likely to have a higher probability of winning is driven by the assumption of *ex post* bargaining between the members of the unintegrated pair. The relationship specificity of API development investments in the context of a patent challenge, combined with the fact that the ANDA is owned by the downstream firm, contributes to the weak bargaining position of the unintegrated upstream firm. Expecting lower profits than its vertically integrated counterpart, the unintegrated upstream firm invests less in equilibrium.

II.2.4 Implication for Empirical Analysis

The prediction that vertical integration facilitates early API development during a patent challenge can be tested by seeing if ANDA applicants who make a paragraph IV certification are more likely than other applicants to be vertically integrated. However, my dataset only records whether or not each market is subject to one or more paragraph IV certifications. I therefore construct a market-level variable that indicates the occurrence of a paragraph IV patent challenge. A somewhat blunt test of the theory can be carried out by including the paragraph IV indicator in a firm-level discrete choice model of entry and vertical integration. The focus is on whether the variable is associated with a higher propensity of vertical integration.

Inclusion of the paragraph IV indicator variable into the firm-level regression introduces a potential endogeneity problem: markets that are the subject of paragraph IV certification may be attractive to generic entrants in unobservable ways, and those unobserved factors may also influence entry and vertical integration decisions. This endogeneity can be taken care of by modeling the process of paragraph IV certification, and allowing the error term in the firm-level equations and that in the paragraph IV equation to be correlated.

Many authors note that paragraph IV patent challenges have become more common in recent years (Grabowski, 2004; Grabowski and Kyle, 2007; Higgins and Graham, 2006; Hemphill and Sampat, 2010). Patent challenges may also be more likely in larger markets that offer greater profits to the first-to-file entrant during the exclusivity period. In addition, Grabowski (2004) and Hemphill and Sampat (2010) find that certain types of secondary patents – particularly those that cover formulations and new uses – tend to be more vulnerable to patent challenge, presumably because it is easier to invalidate or avoid infringing such patents. This suggests the following as possible market-level determinants of paragraph IV certification: market size, the number of orignator patents of different types, and year dummy variables.

III Econometric Specification

The econometric analysis focuses on the behavior of a potential downstream entrant in a newly opening generic drug market. The reduced-form equations for the potential downstream entrant's payoffs from vertically integrated entry and unintegrated downstream entry, contained in (1), form the basis of estimation. While these equations can be directly employed in a multinomial discrete choice framework, they are modified to support a two-step decision structure. It is assumed that a potential downstream entrant first decides whether or not to enter the downstream segment of a market. Conditional on entering downstream, the firm then decides whether to enter the upstream segment as well – in other words, whether

to vertically integrate. This suggests the use of a bivariate discrete choice model with sample selection – for example, the censored probit model of Meng and Schmidt (1985). The selection equation is based on the potential entrant's payoff from entering the downstream market, either independently or as part of a vertically integrated firm. The outcome equation is based on the incremental payoff that the downstream entrant earns by vertically integrating.

The model is slightly complicated by the inclusion of an indicator for paragraph IV certification as a covariate. The potential endogeneity of this variable leads us to employ a trivariate discrete choice model with sample selection and endogeneity. By assuming a normal distribution for the error term vector, the following trivariate probit model is specified:

$$
\begin{aligned}
y^*_{1mi} &= \beta_1' \mathbf{x}_{1mi} + \alpha\, PF_m + \varepsilon_{1mi} \\
y^*_{2mi} &= \beta_2' \mathbf{x}_{2mi} + \varepsilon_{2mi} \\
y^*_{3m} &= \beta_3' \mathbf{x}_{3m} + \varepsilon_{3m},
\end{aligned}
$$

$$
\begin{aligned}
VI_{mi} &= \mathbf{1}(y^*_{1mi} > 0) \times DE_{mi} \\
DE_{mi} &= \mathbf{1}(y^*_{2mi} > 0) \\
PF_m &= \mathbf{1}(y^*_{3m} > 0),
\end{aligned}
\tag{12}
$$

$$
(\varepsilon_{1mi},\, \varepsilon_{2mi},\, \varepsilon_{3m}) \sim \mathcal{N}(0, \Sigma).
$$

The model contains three dichotomous endogenous variables. DE_{mi} is an indicator for firm i's entry into the downstream segment of market m. VI_{mi} indicates that firm i enters as a vertically integrated firm. It is observed only if firm i enters the downstream segment. PF_m is a market-level indicator of paragraph IV certification by one or more downstream entrants. The β vectors and α are unknown parameters to be estimated, and the covariance matrix of the error term vector is assumed to have the following form:

$$
\Sigma = \begin{bmatrix} 1 & \rho_{12} & \rho_{13} \\ \rho_{12} & 1 & 0 \\ \rho_{13} & 0 & 1 \end{bmatrix}.
$$

ρ_{mn} is the correlation coefficient between ε_m and ε_n and $\rho_{23} = 0$ is assumed.

The row vector of covariates in the outcome equation, $\mathbf{x}_{1mi}$, contains both market and firm characteristics. The market characteristics represent the revenue potential of the market as perceived by generic firms as well as the costs required for entering. They include measures of market size, the willingness of patients and other payers (e.g., insurers) to pay for the drug, and dummy variables for different therapeutic classes and dosage forms. The first two variables measure the market's revenue potential, while the

dummy variables capture both revenue potential and magnitude of entry costs. The sole firm characteristic contained in $\mathbf{x}_{1mi}$ is the firm's experience in entering the upstream segment of markets that opened up previously. We can expect higher values of this variable to be associated with lower vertical integration costs.

Another set of variables in $\mathbf{x}_{1mi}$ is generated from the characteristics of other potential entrants in the same market. The first variable is the mean level of upstream entry experience among potential downstream entrants $j \neq i$. Inclusion of this variable is motivated by the discussion in Section II.1. There, it was shown that lower vertical integration cost among rivals raises the probability of vertical integration by a potential downstream entrant if and only if bandwagon effects exist. To the extent that past upstream experience lowers vertical integration costs, the mean upstream experience of rivals can be used to test the existence of bandwagon effects. This test can be compared to the one in Hortaçsu and Syverson (2007), which examines whether the exit probabities of unintegrated firms are higher if their rivals, who are already present in their respective markets, have a higher propensity to be vertically integrated. The existence of selection effects preclude Hortaçsu and Syverson (2007) from detecting bandwagon effects: although unintegrated firms have higher exit probabilities when more of their rivals are vertically integrated, it appears to be due mainly to the lower productivity of unintegrated firms compared to their vertically integrated rivals. The test that I propose is free from such selection effects because the vertical integration status of firm i is treated as an endogenous outcome and the past upstream experience of rivals can be considered to be exogenous to firm i's vertical integration decision.

The second variable to be constructed from the characteristics of other firms is the number of potential upstream-only entrants, defined as firms who are capable of entering the upstream segment but not the downstream segment. This variable represents the stength of the unintegrated upstream industry. A greater number of potential independent upstream suppliers is expected to lower firm i's probability of vertically integrating.

The paragraph IV indicator enters the vertical integration equation as a potentially endogenous variable. A positive coefficient on this variable indicates support for the hypothesis that vertical integration facilitates the early development of API when pursuing a patent challenge.

$\mathbf{x}_{3m}$ consists of variables that influence the incidence of paragraph IV certification at the market level. In addition to the maket characteristics contained in $\mathbf{x}_{1mi}$, I include the following: the number of potential downstream entrants in market m, the mean level of upstream experience among potential downstream entrants, and the number of potential upstream-only entrants.[33] These three variables are

[33]The "mean level of upstream experience among potential downstream entrants" variable is slightly different from the "mean level of upstream experience among potential downstream rivals" contained in $\mathbf{x}_{1mi}$ in that firm i's upstream experience is excluded from the calculation of the latter.

expected to affect the post-entry market structure. To the extent that they also affect post-entry profits, the variables are also likely to affect the firms' paragraph IV decisions. For instance, a firm may be more likely to engage in a patent challenge if it expects stiffer downstream competition.

Two variables related to the number of originator patents are also included in $\mathbf{x}_{3m}$. The first one measures the number of patents pertaining to the API – namely, product patents and process patents. The second variable measures the number of formulation patents and new use patents which are more closely associated with the finished drug product. These variables can be used to check whether patent challenges are more likely when there are more patents to serve as targets for paragraph IV certification. Of particular interest is whether formulation and new use patents are more likely to attract challenges as suggested by Grabowski (2004) and Hemphill and Sampat (2010). The two patent-related variables are excluded from $\mathbf{x}_{1mi}$ based on the assumption that originator patents affect the vertical integration decisions of generic entrants only through their effect on the paragraph IV status of the market. This justification for this exclusion restriction is as follows. First, patents that are not the subject of paragraph IV certification are either those that are too strong to be challenged, or those that are clearly incapable of blocking generic entry.[34] In either case, they are unlikely to influence the vertical integration decisions of generic firms. Secondly, given that a market is subject to paragraph IV certification, the number of patents is unlikely to matter for the vertical integration decision.

The vector of covariates for the selection equation, $\mathbf{x}_{2mi}$, contains all of the variables in $\mathbf{x}_{1mi}$. Additional variables which are expected to influence the downstream entry decision, but not the vertical integration decision, are also included. First, the firm's downstream entry experience in past markets is included to represent its downstream entry cost. Secondly, the number of rival potential entrants in the downstream segment, representing the intensity of competition in the entry game, is included.[35] Although paragraph IV certification is expected to have an influence on the downstream entry decision, instead of including it in the selection equation, I put the two patent variables contained in $\mathbf{x}_{3m}$ into $\mathbf{x}_{2mi}$.[36] Thus, the selection equation can be thought of as being in a reduced form with respect to the effect of paragraph IV certification. Year dummy variables are included in $\mathbf{x}_{1mi}$, $\mathbf{x}_{2mi}$, and $\mathbf{x}_{3m}$ to control for unobserved time effects that may be correlated with some of the market and firm characteristics.

The inclusion of previous entry experience in the covariate vectors gives rise to two econometric

[34] The patent data that I use to construct the two variables contains both patents that are listed by the originator in the Orange Book as well as those that are not. While listed patents become the subject of paragraph IV certification even if they are clearly non-blocking, patents that are not listed and that are non-blocking can be ignored by generic entrants.

[35] The difference between "number of potential downstream entrants" in $\mathbf{x}_{3m}$ and "number of potential downstream rivals" in $\mathbf{x}_{2mi}$ is that the latter does not count firm i.

[36] By replacing the paragraph IV indicator with the variables in $\mathbf{x}_{3m}$, I can assume that ε_{2mi} and ε_{3m} are uncorrelated. This facilitates estimation by preventing numerical problems, similar to the one pointed out by Butler (1996), that arise in the estimation of correlation coefficients.

concerns. The first is the possible correlation between past entry experience on the one hand, and ε_{1mi} and ε_{2mi} on the other. This would arise, for instance, if the error terms contain the effect of the firm's unobserved proficiency at developing certain types of products (e.g., injectable drugs), which may be positively correlated with the firm's past entry experience. Ignoring the correlation may lead to upwardly biased estimates for the coefficients on the experience variables. The second concern is the possibility of forward-looking behavior by the firms. As Gallant et al. (2008, 2010) argue, generic drug manufacturers may consider, when making their entry decisions, how their actions in the current market affect their entry costs in future markets. For example, a firm may decide to enter a market this year, even though it earns no direct profit from doing so, just because the resulting accumulation of experience would lower its costs and raise the profitability of entering another market next year. Ignoring such forward-looking behavior may introduce bias into the coefficient estimates, but the direction of bias is not clear *a priori*.

By employing the specification in (12), which ignores the potential endogeneity of the experience variables as well as the possible dynamics in firm behavior, I am implicitly assuming that the above concerns are not severe. The grounds for doing so are the following. First, if a firm is especially proficient at developing a certain type of product, it is most likely due to the accumulation of experience in developing such products. In other words, the past entry experience variable can be interpreted as a proxy for unobserved proficiencies. Secondly, unless the managers of generic drug companies are compensated based on their firms' long-term performance, the entry decisions made by them are unlikely to reflect dynamic solutions that are optimal for the firms' shareholders. Given the large number of mergers and acquisitions in this industry and the resulting high rate of employee turnover, it is likely that managers' decisions are more myopic than what their shareholders would like them to be.[37]

Before deriving the estimator, it is important to note that the paragraph IV equation is defined at the market level whereas the other equations are defined at the level of individual firms. In addition, it is possible that the firm-level error terms are correlated within markets due, for instance, to the existence of unobserved market effects. In this setting, the true likelihood function must be based on likelihood contributions defined at the market level. Each market's likelihood contribution is calculatd by integrating over the joint distribution of ε_{3m} and all the elements of $\{\varepsilon_{mi}\}_{i\in\mathfrak{P}_{Dm}}$, where $\varepsilon_{mi} = (\varepsilon_{1mi}, \varepsilon_{2mi})$ and $\mathfrak{P}_{Dm}$ is the set of potential downstream entrants in market m. Thus, estimation based on the true likelihood function requires the calculation of complicated integrals with high dimensionality.

Fortunately, consistent estimates of the parameters can be obtained by maximizing a "partial likelihood" rather than the true likelihood (Wooldridge, 2002, p.401). The partial log likelihood function is

[37] Erdei (2004) notes that "the generics sector has been one of the most mergers and acquisitions (M&A)-driven subsectors within the pharmaceutical industry" (p.18). Karwal (2006) contains a list of the major M&A deals in the generics industry during 2004-2006.

based on likelihood contributions defined at the firm level, as follows:

$$
\begin{aligned}
\ell(\theta) = & \sum_{m=1}^{M} \sum_{i \in \mathfrak{P}_{Dm}} (1 - DE_{mi}) \ln \int_{-\infty}^{-\beta_2' \mathbf{x}_{2mi}} \phi(\varepsilon_2) d\varepsilon_2 \\
& + VI_{mi}\, DE_{mi}\, PF_m \ln \int_{-\beta_3' \mathbf{x}_{3m}}^{\infty} \int_{-\beta_2' \mathbf{x}_{2mi}}^{\infty} \int_{-\beta_1' \mathbf{x}_{1mi} - \alpha}^{\infty} f_3(\varepsilon_1, \varepsilon_2, \varepsilon_3; \Sigma)\, d\varepsilon_1 d\varepsilon_2 d\varepsilon_3 \\
& + VI_{mi}\, DE_{mi} (1 - PF_m) \ln \int_{-\infty}^{-\beta_3' \mathbf{x}_{3m}} \int_{-\beta_2' \mathbf{x}_{2mi}}^{\infty} \int_{-\beta_1' \mathbf{x}_{1mi}}^{\infty} f_3(\varepsilon_1, \varepsilon_2, \varepsilon_3; \Sigma)\, d\varepsilon_1 d\varepsilon_2 d\varepsilon_3 \\
& + (1 - VI_{mi}) DE_{mi}\, PF_m \ln \int_{-\beta_3' \mathbf{x}_{3m}}^{\infty} \int_{-\beta_2' \mathbf{x}_{2mi}}^{\infty} \int_{-\infty}^{-\beta_1' \mathbf{x}_{1mi} - \alpha} f_3(\varepsilon_1, \varepsilon_2, \varepsilon_3; \Sigma)\, d\varepsilon_1 d\varepsilon_2 d\varepsilon_3 \\
& + (1 - VI_{mi}) DE_{mi} (1 - PF_m) \ln \int_{-\infty}^{-\beta_3' \mathbf{x}_{3m}} \int_{-\beta_2' \mathbf{x}_{2mi}}^{\infty} \int_{-\infty}^{-\beta_1' \mathbf{x}_{1mi}} f_3(\varepsilon_1, \varepsilon_2, \varepsilon_3; \Sigma)\, d\varepsilon_1 d\varepsilon_2 d\varepsilon_3.
\end{aligned} \tag{13}
$$

where $\theta = (\beta, \alpha, \rho)$, M is the number of markets in the dataset, and $\phi(\cdot)$ is the standard normal probability density function. $f_3(\cdot; \Sigma)$ is the density for a trivariate normal distribution with zero mean vector and covariance matrix Σ.

The parameter point estimates can be obtained as if the firm-level observations were independent by maximizing (13). However, estimates of their standard errors must be adjusted to account for the clustering of firm-level observations into markets. Following Wooldridge (2002, pp.406-407), the cluster-adjusted asymptotic covariance matrix for the parameters can be written as $\text{Asy.Var}\sqrt{N}(\hat{\theta} - \theta_0) = \mathbf{A}_0^{-1} \mathbf{B}_0 \mathbf{A}_0^{-1}$, where θ_0 is the true parameter value and $\hat{\theta}$ its estimate,

$$
\begin{aligned}
\mathbf{A}_0 &= - \sum_{i \in \mathfrak{P}_{Dm}} \mathrm{E}\left[\nabla_\theta^2 \ell_{mi}(\theta_0) \right], \\
\mathbf{B}_0 &= \mathrm{E}\left\{ \left[\sum_{i \in \mathfrak{P}_{Dm}} \mathbf{s}_{mi}(\theta_0) \right] \left[\sum_{i \in \mathfrak{P}_{Dm}} \mathbf{s}_{mi}(\theta_0) \right]' \right\}, \\
\mathbf{s}_{mi}(\theta) &= \nabla_\theta \ell_{mi}(\theta)',
\end{aligned}
$$

and $\ell_{mi}(\theta)$ is the log likelihood contribution of firm i in market m. The expectation is taken over markets. I use the following estimators for $\mathbf{A}_0$ and $\mathbf{B}_0$, as suggested by Wooldridge (2002):

$$
\begin{aligned}
\widehat{\mathbf{A}} &= M^{-1} \sum_{m=1}^{M} \sum_{i \in \mathfrak{P}_{Dm}} \mathbf{s}_{mi}(\hat{\theta}) \mathbf{s}_{mi}(\hat{\theta})', \\
\widehat{\mathbf{B}} &= M^{-1} \sum_{m=1}^{M} \sum_{i \in \mathfrak{P}_{Dm}} \sum_{j \in \mathfrak{P}_{Dm}} \mathbf{s}_{mj}(\hat{\theta}) \mathbf{s}_{mi}(\hat{\theta})'.
\end{aligned}
$$

The scores, $\mathbf{s}_{mi}(\hat{\theta})$, are calculated numerically by a finite difference method. Asymptotic standard errors

are obtained by taking the square root of the main diagonal of $M^{-1}\widehat{\mathbf{A}}^{-1}\widehat{\mathbf{B}}\widehat{\mathbf{A}}^{-1}$.

Additional calculations are required to obtain the marginal effect of changes in the covariates on outcome probabilities. As noted by Greene (2008, p.821), several types of marginal effects can be defined for multivariate discrete choice models. The simplest one in the current setting is the marginal effect on the marginal probability that a potential downstream entrant vertically integrates. For continuous covariates, it is defined as

$$\frac{\partial Prob\left(VI=1 \mid \overline{\mathbf{x}}_1,\, \overline{PF}\right)}{\partial x_{1k}} = \phi\left(\beta_1'\overline{\mathbf{x}}_1 + \alpha\overline{PF}\right)\beta_{1k}, \tag{14}$$

where the bar shows that the variables are evaluated at their sample averages or some other representative values. x_{1k} is the kth element of $\mathbf{x}_1$, β_{1k} is the corresponding element of β_1, and the market and firm subscripts have been omitted for simplicity. For the dichotomous covariates in $\mathbf{x}_1$, the marginal effect on the marginal probability is calculated as $Prob(VI=1 \mid \overline{\mathbf{x}}_{1,-k},\, x_{1k}=1) - Prob(VI=1 \mid \overline{\mathbf{x}}_{1,-k},\, x_{1k}=0)$ where $\overline{\mathbf{x}}_{1,-k}$ consists of representative values for the covariates excluding the kth one. The marginal effect of PF, the paragraph IV indicator, is $Prob(VI=1 \mid \overline{\mathbf{x}}_1,\, PF=1) - Prob(VI=1 \mid \overline{\mathbf{x}}_1,\, PF=0)$.

Another type of marginal effect that is advocated by Greene (1996) relates to the conditional outcome probability. In the current setting, it is defined as the marginal effect of the covariates on the probability of vertical integration by a potential downstream entrant, conditional on the firm having entered the downstream segment and on the paragraph IV status of the market. The expression for this set of marginal effects is quite involved and it is contained in Appendix A. The standard errors for both sets of marginal effects are calculated by the delta method, using finite-difference numerical derivatives of the marginal effects with respect to the parameters (Greene, 1996).

IV Data

The generic drug markets used for analysis are selected from a database of the US Food and Drug Administration (FDA) called the Orange Book which contains the population of all drug approvals. I begin by selecting a subset of drug markets that opened up to generic competition between January 1, 1993 and December 31, 2005.[38] The set of markets is further narrowed down to those in which the relationship between the upstream and downstream segments is relatively straightforward. This is done by first restricting the downstream products to finished formulations containing only one API. When there are multiple single-ingredient formulations containing a given API, I choose only the first of these to open up to generic competition. This is based on the belief that when generic companies make their

[38] Appendix B explains how generic products are identified in the Orange Book.

entry decisions in the first downstream market for a given API, the upstream market structure is not yet formed. Therefore, it makes sense to view downstream and upstream entry decisions as being made simultaneously. By the time the other downstream markets using the same API open up, the upstream market structure may already be fixed. Because it is not realistic to assume that upstream and downstream actions are decided simultaneously in such markets, they are excluded from the analysis.

I also restrict the sample to the following dosage forms which constitute the majority of generic drugs: oral solids, injectables, and topicals. This leaves 177 downstream markets, each defined by a distinct combination of an API and a dosage form. 128 markets remain after removing observations for which market characteristics data could not be obtained. There are 125 corresponding upstream markets, each defined by a distinct API. For three APIs (acyclovir, fluconazole, and gabapentin), 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 markets, and combine each of them with data for their respective API markets. Thus, for the three APIs mentioned above, the same upstream market data are used twice. Table A.1 in the Appendix contains a list of the drugs in the sample. A processed version of the FDA data was obtained from a proprietary database called Newport Sourcing, developed and maintained by Thomson Reuters.

Table 1 and Figure 1 presented in Section I are constructed from the dataset of 128 markets. The econometric model is estimated using observations on 85 of those markets that opened up to generic competition between 1999 and 2005. The reason for restricting the time period in this way is as follows. Between 1992 and 1998, the FDA did not grant 180-day generic exclusivity to the first-to-file paragraph IV applicant. Therefore, during this period generic firms had little incentive to develop their products early in order to engage in patent challenges. Thus, the paragraph IV status of a market is likely to have been irrelevant for the decision to vertically integrate. By limiting the sample to the post-1998 period, we can analyze the role of paragraph IV certification more accurately.

IV.1 Entry Indicators and Potential Entrant Status

In order to record the two firm-level outcomes – downstream entry and vertical integration – it is first necessary to pinpoint the date on which each market opens up to generic competition. Previous authors such as Scott Morton (1999) define the market opening date as the approval date of the first ANDA. After comparing ANDA approval dates with the dates on which the generic products actually began to be marketed, I find that this definition is not always appropriate.[39] In some cases, the first generic product is not marketed until several months after its ANDA is approved. During those months, subsequent generic products are not approved by the FDA. I also find a few cases in which drugs that appear to be generics are

[39]The product marketing dates are obtained from the Newport Sourcing database.

marketed before their ANDAs are approved. The first phenomenon arises when pending patent litigation between the generic entrant and the originator firm, or a settlement between the two, prevent the generic from entering immediately upon ANDA approval. The latter phenomenon is related to a practice called "authorized generics": the originator gives the generic company a license to sell the product based on the former's New Drug Application rather than the latter's ANDA. In order to accomodate these special cases, I define the market opening date as the first generic approval date or the first generic marketing date, whichever is later.

Firm-level entry actions are defined on the basis of market opening dates. Specifically, a potential downstream entrant is considered to have entered the downstream segment if its ANDA is approved by the FDA either before the market opening date or not later than one year after the market opening date. The relatively 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, most firms enter in the first few months after market opening (Caves et al., 1991; Reiffen and Ward, 2005). As for actions in the upstream segment, a downstream entrant is deemed to have vertically integrated if it submits a Drug Master File (DMF) to the FDA before the market opening date or no later than one year after the market opening date.

I identify a potential downstream entrant in market m as a firm who has entered the downstream segment of any other generic market, including one outside the sample, on a date that is earlier than market m's opening date but that is no more than five years before that date. Thus, I allow a firm to remain a potential downstream entrant for five years after its last entry. Similarly, a firm is identified as a potential upstream entrant of market m if it has entered the upstream segment of another generic market prior to, but not more than seven years before, market m's opening date. Therefore, 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 DMF submissions sometimes occur a few years before the market opening date. Firm i is a potential upstream-only entrant in market m if it is a potential upstream entrant but not a potential downstream entrant.

In order to evauate the potential entrant status of a given firm, it is necessary to accurately identify its previous entries. This requires correct data on the names of ANDA applicants and DMF holders contained in the FDA data. Similarly, identifying firms' vertical integration actions, which involves matching the firms found in the downstream ANDA database with those in the upstream DMF database, requires accurate data on firm names. These tasks are complicated by the several mergers and acquisitions that took place in the generics industry during the observation period. As described in Appendix B, I use the Newport Sourcing database to attach accurate firm names to the FDA data. Changes in firm ownership are taken into account by assuming that the past entry experience of an acquired firm is fully carried over

Table 5: Distribution of Entry Actions in Dataset

		Vertical Integration	
		Not Integrate	Integrate
Downstream Entry	Not Enter	2,133	0
	Enter	330	76

The table shows the distribution of outcomes observed at the firm level. The dataset contains 2,539 firm-level observations from 85 markets that opened up to generic competition between 1999 and 2005.

to the acquiring firm.

Table 5 presents the distribution of actual entry actions taken by potential downstream entrants in the dataset. The data consist of 114 firms facing 2,539 choice situations spread across 85 markets. 406 of these choice situations (15.99 percent) result in downstream entry. 76 of the downstream entries (18.72 percent) lead further to vertical integration.

IV.2 Covariates

IV.2.1 Market Charactersitics

Table 6 presents summary statistics for the covariates. The first fourteen variables are market characteristics. "User Population" is a measure of market size, which is expected to have a positive impact on a firm's probability of downstream entry (Bresnahan and Reiss, 1991). However, its impact on a firm's propensity to vertically integrate is an open question: while Stigler (1951) hypothesizes that vertical integration would occur less frequently in larger markets, others note that under certain conditions, the incidence of vertical integration may actually rise with market size.[40] The user population variable is defined as the estimated number of users of each drug in the US during the period immediately before generic entry. It is constructed from results of the National Ambulatory Medical Care Survey (NAMCS) and the National Hospital Ambulatory Medical Care Survey (NHAMCS). These surveys are conducted by the National Center for Health Statistics (NCHS) to assess the use of ambulatory medical care in the

[40] Perry and Groff (1988), Elberfeld (2002), and Dufeu (2004) indicate that larger markets may be characterized by more vertical integration if entry does not increase in proportion to market size.

Table 6: Summary Statistics for Covariates

Variable Name	Unit	Mean	Min.	Max.
Market Characteristics				
User Population	1 million people	2.566	0.022	18.127
Per-User Expenditure	1,000 US dollars	0.979	0.018	10.726
Anti-infective	Dummy	0.235		
Cardiovascular	Dummy	0.247		
Central Nervous System	Dummy	0.200		
Gastrointestinal / Endocrine-Metabolic	Dummy	0.141		
Oncology	Dummy	0.082		
Other Therapeutic Class	Dummy	0.094		
Oral Solid	Dummy	0.824		
Injectable	Dummy	0.129		
Topical	Dummy	0.047		
Paragraph IV (*PF*)	Dummy	0.447		
Upstream Originator Patents	Count	3.353	0	24
Downstream Originator Patents	Count	3.506	0	24
Firm Characteristics				
Own Upstream Experience	Count (depreciated)	8.870	0	71.423
Own Downstream Experience	Count (depreciated)	8.407	0.616	55.162
Potential Entrants' Characteristics				
Potential Downstream Entrants' Mean Upstream Experience [a]	Count (depreciated)	7.964	5.198	19.461
Number of Potential Upstream-Only Entrants	Count	53.499	41	73
Number of Potential Downstream Entrants [b]	Count	35.973	6	42

Notes:
The data consist of 2,539 firm-level observations in 85 markets.
[a] In firm-level equations, the mean experience level of potential downstream entrants excluding firm *i* is used to construct the value for firm *i*.
[b] In firm-level equations, firm *i* is not counted when constructing the value for firm *i*.

US, through questionnaires sent to randomly selected hospitals and physicians' offices. One part of the survey asks for information on "drug visits" during a fixed reference period. A drug visit occurs when a patient visits a health care facility and a drug is prescribed. I estimate the total number of drug visits in the US for each drug in the sample for every year between 1992 and 2004, based on the number of drug visits recorded by the surveys.[41] Then, the total number of drug visits during the one- to five-year period before generic market opening is used to represent the size of the user population for each drug market.[42] Because the focus of NAMCS/NHAMCS is on outpatient services, drugs that are primarily used in inpatient settings (e.g., anesthetics) are not captured by the surveys. Such drugs are therefore excluded from the sample. The average user population for the drugs in the sample is 2.57 million people.

"Per-User Expenditure" is a measure of patients' and insurers' willingness to pay for a drug product. Willingness-to-pay varies greatly across drug products because medical conditions (illnesses and injuries) vary in terms of morbidity and mortality for the patient, while pharmaceuticals vary in their effectiveness at preventing or treating those conditions as well as in the number of available substitutes (e.g., different drugs that treat the same condition). Such variation may influence generic companies' incentive to enter a market because it is likely to affect the number of firms that can profitably enter. As a proxy for the willingness to pay for a drug, I use the per-user average annual expenditure on the drug, including out-of-pocket expenses as well as payments made by insurers and other payers, during the year immediately prior to generic entry. This is estimated in two steps. In the first, the average consumed quantity per user is estimated for each drug using data from the Medical Expenditure Panel Survey (MEPS). Co-sponsored by the Agency for Healthcare Research Quality and the NCHS, MEPS is a nationwide survey that collects data on households' use of medical goods and services, supplemented with information from the respondents' health care providers and pharmacies. Using MEPS data for the

[41] The NAMCS/NHAMCS data identifies drugs only by their APIs and not their dose forms. Therefore, drug visits are counted for each API. Because the reference period for collecting drug visit information is relatively short (one week for NAMCS and four weeks for NHAMCS), I assume that each drug visit represents a unique patient. Sampling weights provided by the NCHS are used when adding up drug visits across different facilities. Detailed information on the surveys is available at `http://www.cdc.gov/nchs/ahcd.htm`.

[42] Due to sampling error, drug visit estimates based on a small number of records in the NAMCS/NHAMCS data tend to be inaccurate. According to Hsiao (2010), the reliability of the estimates can be raised by pooling together multiple years to yield a large number of records. Thus, the following steps are taken to generate the user population for drug product m whose generic market opens up in year t. First, I construct the following estimates of total drug visits at the national level, using different numbers of years up to $t-1$:

$$TotVisit_{mt,\tau} = Pop_{t-1} \sum_{s=t-\tau}^{t-1} \frac{\sum_h \omega_{hs} Visit_{mhs}}{Pop_s}, \qquad \tau = 1,2,3,4,5.$$

The subscript s denotes year and h denotes health care facility. ω_{hs} is the sampling weight for facility h in year s, $Visit_{mhs}$ is the number of unweighted drug visits recorded for drug product m at facility h in year s, and Pop_s is the US civilian non-institutionalized population in year s. Then, the value of the user population variable is chosen as $TotVisit_{mt,\underline{\tau}}$ where $\underline{\tau} = \min \tau \ s.t. \ \sum_{s=t-\tau}^{t-1} \sum_h Visit_{mhs} \geq V_\tau$. In words, the value of τ, the number of years used for generating the data, is raised until the cumulative number of unweighted drug visit occurrences reaches a prespecified threshold. The threshold value V_τ is set at 25 for $\tau \in \{1,2\}$, 20 for $\tau \in \{3,4\}$, and 17 for $\tau = 5$.

period 1996-2005, I calculate the average quantity of each drug consumed by a user in one year. Instead of producing separate values for each year, ten years' worth of observations are pooled together to generate one figure for each drug to cover the entire observation period.[43] In the second step, the average wholesale price of each drug in the year immediately before generic market opening is obtained from different editions of the *Red Book*.[44] The per-user consumed quantity (rescaled to pricing units) is then multiplied by the average wholesale price to generate the average per-user annual expenditure. The mean of this variable for the drugs in the sample is 979 US dollars.

The drugs in the sample are grouped into six broad therapeutic classes: anti-infectives, cardiovascular agents, central nervous system agents, gastrointestinal and endocrine-metabolic agents (endocrine-metabolic agents include antidiabetic drugs), oncology drugs, and others.[45] The first three categories each make up between one-fifth and one-quarter of the markets in the sample. The drugs are also classified into three distinct dose form groups: oral solids, injectables, and topicals. Oral solids, which make up 82.4 percent of the in-sample drugs, consist of tablets and capsules including extended-release and other enhanced versions. Injectables are liquids which are usually contained in vials and ampoules. Topicals include creams, lotions, and gels.

There are two reasons for including indicators for therapeutic classes and dose form groups as covariates. First, they are expected to capture unobserved factors that are related to the revenue potential and product development costs for each market, and that may affect generic entry behavior. For instance, patients may be more willing to switch from originator products to generics in certain therapeutic classes than in others. Secondly, technological economies due to vertical integration may be stronger for certain drug types than for others. For instance, the production of injectables is subject to quality and manufacturing standards that are generally more stringent than the ones for oral solids (Surendar, 2009). Thus, the returns to vertical integration, which enables tighter control over manufacturing processes, may be higher for injectables.

The remaining market characteristics pertain to paragraph IV patent challenges. The paragraph IV indicator variable is equal to one if the market experiences paragraph IV certification by one or more ANDA applicants, and zero otherwise. This data is available from the FDA's website.[46] To construct the

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[43] For many of the drugs in the sample, the number of users contained in a single year's MEPS data is too small to serve as basis for estimation. By pooling observations from ten years, it is possible to obtain more accurate estimates. The procedure relies on the assumption that per-user consumed quantity does not vary greatly over time. Details of the MEPS data are available at `http://www.meps.ahrq.gov/mepsweb/`.

[44] The *Red Book* is a standard reference for drug prices. During the 1992-2004 period for which data was obtained, it was published by the Medical Economics Company, Thomson Medical Economics, and Thomoson PDR.

[45] The therapeutic class of each drug was obtained from Thomson Reuters' Micromedex database.

[46] A list of drugs that have been subject to paragraph IV certification is posted at `http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm047676.htm`.

two patent-related variables, I obtain a list of patents from the Newport Sourcing database for each drug in the sample. Using this data in conjunction with data on drug approvals and marketing, I identify the originator firms for each drug. Specifically, a firm is identified as an orignator of a drug if it fulfills one or more of the following criteria: (i) the firm holds a constraining patent for the drug,[47] (ii) the firm holds the earliest product patent (likely to be the basic product patent) for the drug, (iii) the firm is the applicant of the first New Drug Approval for the drug, (iv) the firm is the first marketer of the drug in the US, UK, France, Germany, or Japan. The "upstream originator patents" variable for market m is constructed as the number of product patents and process patents that belong to one of originators of product m and that cover the API used in the product. In addition, the application dates of the patents must be earlier than the generic market opening date, because otherwise they will not affect generic entry. The "downstream originator patents" variable is similarly constructed by counting the number of formulation patents and new use patents that cover product m, that belong to its originators, and whose application dates are earlier than the market opening date. The mean number of upstream originator patents in the sample markets is 3.353, and the mean number of downstream patents is 3.506.

IV.2.2 Firm Charactersitics

Following Scott Morton (1999) and Gallant et al. (2008), firm characteristics are generated from the same data source used to generate entry indicators and to determine the potential entrant status of firms. Specifically, a firm's past entry history is used to construct its experience variable for both the upstream and downstream segments. The value of firm i's upstream experience variable for market m which opens up in year t is constructed from the firm's DMF submissions during years $t-7$ to $t-1$. Let DMF_{is} be the number of DMFs, excluding the one for market m, submitted by firm i in year s. Then, the "own upstream experience" variable is constructed as $\sum_{s=t-7}^{t-1} \delta_U^{t-s-1} DMF_{is}$, where $\delta_U \in [0,1]$ is the depreciation factor for upstream experience. For constructing the downstream experience variable, the drug product's dose form type is taken into consideration. Suppose that drug m is an oral solid formulation. Then, the downstream experience variable counts the number of oral solid ANDAs, excluding the one for the current market, filed by firm i in years $t-5$ to $t-1$. Denoting market m's dose form type by f, and the number of firm i's ANDAs of the same type in year s as $ANDA_{ifs}$, the "own downstream experience" variable is constructed as $\sum_{s=t-5}^{t-1} \delta_D^{t-s-1} ANDA_{ifs}$. δ_D represents the depreciation factor for downstream experience.

I refer to Gallant et al. (2008) for the value of the depreciation factors. Using data from generic drug markets that opened up during 1990-1994, they estimate a dynamic model in which a firm's entry

[47] Constraining patents are defined in the Newport Sourcing database as those that are difficult to circumvent and are likely to prevent generic firms from entering.

into one market reduces its cost of entering future markets. Under the simplifying assumption that generic markets open up sequentially in fixed intervals of 1.5 months, Gallant et al. (2008) estimate that fixed entry costs have a persistence parameter of 0.985.[48] In other words, 98.5 percent of the stock of cost reductions realized through past entry is carried over from one market opening to the next. Here, I assume that the depreciation factor of entry experience is equal to the rate of persistence of costs. Therefore, the depreciation factor over a one year interval is caculated to be $0.985^{12/1.5} = 0.886$. I set $\delta_U = \delta_D = 0.886$ and use it to construct the experience variables.

The mean of the own upstream experience variable is 8.870 and that for the own downstream experience variable is 8.407. While the means are similar and both are positively skewed, the upstream experience variable has a higher variance and is more highly skewed. This suggests that firms are more strongly differentiated in terms of their vertical integration capabilities than in terms of their downstream entry capabilities. The mean upstream experience level among all potential downstream entrants, calculated separately for each market, has a sample mean of 7.964. The firm-level counterpart of this variable is the mean upstream experience level among rivals. For firm i, it is caculated as the mean upstream experience level among potential downstream entrants $j \neq i$.

The last two covariates in Table 6 count the number of potential entrants in each market. The mean number of potential upstream-only entrants (53.499) is greater than that of potential downstream entrants (35.973).[49] This is partly a reflection of the higher degree of globalization in the upstream API industry, which in turn may be due to stricter demands for product quality – both from the FDA as well as consumers – in the downstream finished formulation segment. When drug manfacturers from developing countries such as India first enter the generics markets of the US and other developed countries, they find it easier to enter the upstream segment than the downstream segment (Lanjouw, 1998; Chaudhuri, 2005). As a result, the generic API industry is characterized by a larger number of firms that are more geographically dispersed than in the generic formulation industry.

V Results

Table 7 presents the coefficient estimates for the trivariate probit model and Table 8 presents the corresponding marginal effects. The marginal effects are evaluated at representative values of the covariates. For a market characteristic variable that is continuous, the simple average across markets is used. The representative value of a continuous firm characteristic variable x_k is obtained as the sample average of the mean among potential downstream entrants in a market: $\bar{x}_k = \frac{1}{M}\sum_m \left(\frac{1}{\#(\mathfrak{P}_{Dm})}\sum_{i\in\mathfrak{P}_{Dm}} x_{mik}\right)$, where

[48] See the first column of Table 2 in Gallant et al. (2008).

[49] The number of potential downstream entrants, when used as a covariate in the firm-level equations, counts potential downstream entrants $j \neq i$.

$\#(\cdot)$ is a function that counts the number of elements in a set. For the two variables that are defined differently at the firm level and at the market level – namely, the mean upstream experience of potential downstream entrants and the number of potential downstream entrants – the sample average of the market-level variable is used as the representative value. Therefore, the mean upstream experience of all potential downstream entrants, averaged across markets, is plugged into the firm-level equations as well as the market-level equation. Similarly, the average number of potential downstream entrants is used in all of the equations.[50]

The dichotomous variables are given values that are most commonly observed in the data. With regard to therapeutic class, the cardiovascular category is chosen as the baseline for measuring marginal effects and the dummy variables for the remaining classes are set to zero. Accordingly, the coefficient on each therapeutic class dummy is recalculated so that it measures the difference between that category and the cardiovascular category.[51] Similarly, the oral solid dose form group is chosen as the baseline and the dummy variables for injectables and topicals are set to zero. The most common market opening year in the data is 2002. Therefore, 2002 is chosen as the baseline year and dummy variables for the other years are set to zero (and their coefficients adjusted accordingly). Finally, the paragraph IV indicator variable is set to zero.

The predicted probabilities evaluated at representative values of the covariates are as follows: the marginal probability of vertical integration, $Prob\left(VI = 1 \mid \bar{\mathbf{x}}_1, \overline{PF}\right)$, is 3.17 percent; the conditional probability $Prob\left(VI = 1 \mid DE = 1,\ PF = 0,\ \bar{\mathbf{x}}\right)$ is equal to 27.02 percent. The marginal effects in Table 8 are divided by these probabilities. Therefore, they represent changes in the outcome probability as a proportion to the predicted probability for the representative observation.

The bottom of Table 7 presents estimates for the correlation coefficients ρ_{12} and ρ_{13}. In practice, the inverse hyperbolic tangent of these parameters are estimated and transformed back to their original values.[52] ρ_{12} is estimated to be significantly positive with a large absolute value, indicating that ε_1 and ε_2, the error terms in the vertical integration and downstream entry equations, are strongly correlated. Thus, firms with a higher unobserved propensity for downstream entry tend to have higher unobserved returns from vertical integration. On the other hand, the estimate for ρ_{13} is negative with a smaller

[50] In other words, the values of these two variables for the representative firm are constructed *without* excluding the firm from the calculation. The reason for doing so is that when calculating their marginal effects on the conditional outcome probability, these variables need to move together inside the three equations.

[51] During parameter estimation, the coefficient on a therapeutic class dummy is defined to measure the difference between that category and the "Other Therapeutic Class" category.

[52] The inverse hyperbolic tangent of ρ, also known as Fisher's z transformation, is defined as $\text{arctanh}(\rho) = \frac{1}{2}\ln\frac{1+\rho}{1-\rho}$. This transformation has the benefit of lying on the real number line while ρ is confined to the interval $[-1,1]$. As a result, the transformation is simpler to estimate than ρ itself and its standard error is more easily obtained. Standard errors for the ρ parameters can be obtained from the standard errors of their transformations using the delta method. However, the practice is not advisable because the standard errors thus obtained may imply confidence intervals that go outside the $[-1,1]$ interval.

Table 7: Parameter Estimates of Trivariate Probit Model

	Dependent Variable		
	Paragraph IV (*PF*)	Downstream Entry (*DE*)	Vertical Integration (*VI*)
User Population	0.011	0.047 *	0.077 ***
	(0.069)	(0.027)	(0.018)
Per-User Expenditure	0.134	0.019	0.005
	(0.235)	(0.049)	(0.051)
Anti-infective [a]	−0.528	0.115	0.03
	(1.567)	(0.291)	(0.301)
Cardiovascular	0.07	0.398	0.147
	(1.479)	(0.301)	(0.298)
Central Nervous System	1.176	0.730 **	0.052
	(1.507)	(0.318)	(0.305)
Gastrointestinal / Endocrine-Metabolic	0.14	0.405	−0.425
	(1.498)	(0.284)	(0.320)
Oncology	2.783	0.530 *	0.104
	(1.979)	(0.307)	(0.478)
Injectable [b]	−0.858	−0.508	1.173 ***
	(2.070)	(0.379)	(0.308)
Topical		−0.371	1.175
		(0.676)	(0.976)
Paragraph IV (*PF*)			0.424 **
			(0.214)
Upstream Originator Patents	−0.153	−0.003	
	(0.133)	(0.018)	
Downstream Originator Patents	0.268 **	−0.013	
	(0.108)	(0.016)	
Own Upstream Experience		0.004	0.045 ***
		(0.004)	(0.006)
Own Downstream Experience		0.056 ***	
		(0.004)	
Potential Downstream Entrants' (Rivals') Mean Upstream Experience [c]	0.032	0.04	0.171 *
	(0.396)	(0.068)	(0.094)

(Table continued on next page.)

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	Dependent Variable		
	Paragraph IV (*PF*)	Downstream Entry (*DE*)	Vertical Integration (*VI*)
# Potential Upstream-Only Entrants	0.29	0.086 *	−0.091 ***
	(0.192)	(0.046)	(0.034)
# Potential Downstream Entrants (Rivals) [d]	0.203	0.006	
	(0.157)	(0.033)	
Year 2000 [e]	−0.482	0.089	0.441
	(0.915)	(0.307)	(0.671)
Year 2001	−1.614	−0.167	1.287 *
	(1.110)	(0.291)	(0.672)
Year 2002	−1.065	−0.247	0.883
	(0.982)	(0.291)	(0.655)
Year 2003	−0.960	−0.474	0.467
	(1.057)	(0.319)	(0.596)
Year 2004	−0.025	−0.084	−0.181
	(1.602)	(0.408)	(0.619)
Year 2005	−0.168	0.269	−0.694
	(2.458)	(0.626)	(0.875)
Constant	−0.630	−2.190 ***	−4.931 ***
	(3.395)	(0.640)	(1.032)
ρ_{12} [f]	0.886 ***		
ρ_{13} [g]	−0.300 *		
Number of observations	2,539	(85 markets)	

Notes:
***, **, and * represent significance at the one percent, five percent, and ten percent levels, respectively. The cluster-adjusted asymptotic standard errors are in parentheses.

[a] The baseline therapeutic class is "Other".
[b] The baseline dose form is "Oral Solid".
[c] For the vertical integration and downstream entry equations, the variable measures the mean upstream experience among rivals (potential downstream entrants other than the firm in question).
[d] For the vertical integration and downstream entry equations, the number of rivals is used.
[e] The baseline year is 1999.
[f] The inverse hyperbolic tangent of ρ_{12} is estimated as 1.404 with a standard error of 0.380.
[g] The inverse hyperbolic tangent of ρ_{13} is estimated as -0.310 with a standard error of 0.171.

Table 8: Marginal Effects of Trivariate Probit Model

	Marginal Effect on:	
	$Prob(VI = 1)$	$Prob(VI = 1 \mid DE = 1, PF = 0)$
User Population	0.164 ***	0.082 *
	(0.049)	(0.046)
Per-User Expenditure	0.011	0.014
	(0.112)	(0.099)
Anti-infective [a]	−0.224	0.063
	(0.376)	(0.449)
Central Nervous System	−0.186	−0.233
	(0.352)	(0.352)
Gastrointestinal / Endocrine-Metabolic	−0.743 ***	−0.715 ***
	(0.171)	(0.165)
Oncology	−0.089	0.927
	(0.847)	(1.413)
Other Therapeutic Class	−0.275	0.272
	(0.789)	(1.093)
Injectable [b]	5.816 *	1.878
	(3.310)	(1.468)
Topical	5.835	1.881
	(9.679)	(1.493)
Paragraph IV (*PF*)	1.279	
	(0.986)	
Upstream Originator Patents		−0.029
		(0.031)
Downstream Originator Patents		0.075
		(0.051)
Own Upstream Experience	0.096 ***	0.077 ***
	(0.014)	(0.018)
Own Downstream Experience		−0.072 ***
		(0.019)
Potential Downstream Entrants' Mean Upstream Experience	0.364 **	0.267 *
	(0.182)	(0.148)

(Table continued on next page.)

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	Marginal Effect on:	
	$Prob(VI=1)$	$Prob(VI=1\|DE=1,PF=01)$
# Potential Upstream-Only Entrants	−0.193 **	−0.214 **
	(0.079)	(0.097)
# Potential Downstream Entrants		0.036
		(0.070)
Year 1999 [c]	−0.892 ***	−0.871 ***
	(0.220)	(0.235)
Year 2000	−0.642 ***	−0.711 ***
	(0.225)	(0.152)
Year 2001	1.199	0.576
	(1.186)	(0.556)
Year 2003	−0.617 **	−0.393
	(0.259)	(0.404)
Year 2004	−0.937 ***	−0.915 ***
	(0.075)	(0.094)
Year 2005	−0.989 ***	−0.991 ***
	(0.037)	(0.029)

Notes:

Formulas for the marginal effects of continuous variables are given in (14) and (15). The marginal effects of dichotomous variables are calculated as the change in the outcome probability as the variable changes from zero to one. The marginal effects are evaluated at representative values of the covariates whose choice is explained in the beginning of Section V. Each marginal effect is divided by the predicted probability for the representative observation so that the figures represent changes in the outcome probability as a proportion of the base probability. The asymptotic standard errors, in parentheses, are obtained by the delta method. ***, **, and * represent significance at the one percent, five percent, and ten percent levels, respectively.

[a] The baseline therapeutic class is "Cardiovascular".

[b] The baseline dose form is "Oral Solid".

[c] The baseline year is 2002.

absolute value and a lower significance level. The negative correlation between ε_1 and ε_3 suggests that firms' unobserved returns from vertical integration are somewhat lower in markets that are more likely, in unobserved ways, to be the target of paragraph IV certification. This may be because such markets tend to attract a greater number of unintegrated upstream suppliers.

V.1 Paragraph IV and Downstream Entry Equations

Before turning to the vertical integration equation which is of primary interest, let us consider the other two equations. In the paragraph IV equation, the coefficient on the downstream originator patents variable is significantly positive. Thus, the observation by Grabowski (2004) and Hemphill and Sampat (2010) that patents on new formulations and new uses are more vulnerable to challenge by generic entrants is supported. This finding has interesting implications regarding the effectiveness of such patents as entry barriers. To the extent that formulation patents and new use patents induce more aggressive entry behavior by generic firms – in the form of paragraph IV ANDA filings – they may be ineffective at delaying generic entry. In fact, the existence of vulnerable secondary patents might make a drug market more attractive in the eyes of potential generic entrants because it creates an opportunity for 180-day exclusivity, and may induce more of them to enter.

In the downstream entry equation, the user population variable has a significantly positive coefficient, which agrees with the intuition that larger downstream markets attract more entrants. On the other hand, the coefficient on per-user expenditure is not significantly different from zero. This suggests that downstream generic entrants are attracted more by market size than by the willingness-to-pay of patients and other payers. Two therapeutic classes – central nervous system agents and oncology drugs – have a significantly positive coefficient, which implies that drugs in these classes tend to attract more generic entry than those in the "Other Therapeutic Class" category.

The coefficient on the firm's own downstream experience is positive and highly significant, confirming earlier results by Scott Morton (1999) and Gallant et al. (2008) that past downstream entry experience reduces firms' entry costs in current markets. On the other hand, the coefficient on the own upstream experience variable is not significantly different from zero, which suggests that the effect of upstream experience on downstream entry costs is small.

The number of potential upstream-only entrants has a significantly positive coefficient in the downstream entry equation. This implies that in markets where the number of potential unintegrated API suppliers is large, downstream entrants expect to earn higher payoffs. It may not be obvious why the number of *potential* entrants in the unintegrated upstream category, as opposed to the number of *actual* entrants, affects the expected payoffs of potential downstream entrants. A likely explanation is that when there are many potential unintegrated upstream entrants, downstream firms expect the equilibrium market struc-

ture to be characterized by a greater presence of unintegrated upstream suppliers – in other words, a lower degree of vertical integration. The payoffs of downstream entrants would be higher in markets with less vertical integration if such markets have lower API prices – in other words, if foreclosure effects exist.

Meanwhile, the coefficient on the number of potential downstream rivals is not significantly different from zero. Keeping the size and other characteristics of the market fixed, one would expect an individual firm's entry probability to fall with the number of rivals vying to enter the same market, because the equilibrium number of entrants is not expected to change. Therefore, it comes as somewhat of a surprise that this coefficient is not significantly negative.

V.2 Vertical Integration Equation

V.2.1 Effect of Market Characteristics

In the vertical integration equation, the user population variable has a significantly positive coefficient and its marginal effect on the probability of vertical integration is also positive and significant. An increase in the number of users by one million raises a potential downstream entrant's marginal probability of vertcial integration by 16.4 percent. Conditional on the firm entering the downstream segment and on the market not being subject to paragraph IV certification, the same increase in user population raises the probability of vertical integration by 8.2 percent. The finding of a positive relationship between market size and vertical integration, which runs counter to Stigler's (1951) hypothesis that vertical integration is less prevalent in larger markets, is somewhat puzzling. One possible explanation is that unintegrated upstream firms (whose behavior is not the subject of analysis here) are more efficient in the manfacture of APIs than vertically integrated firms. If the equilibrium selection process for the entry game is such that the more efficient API manufacturers are given higher priority in entry, then we are likely to see a higher share of the upstream market being taken up by unintegrated entrants in smaller markets.

Of the therapeutic class dummy variables, the one for gastrointestinal and endocrine-metabolic agents has a significantly negative marginal effect on the probability of vertical integration. This may be because for some drugs belonging to this class (e.g., antacids), tighter control over the upstream manufacturing process through vertical integration is not as important as it is for cardiovascular drugs, the baseline category. The dummy variable for injectable formulations has a significantly positive coefficient, and its marginal effect on the marginal probability of vertical integration is also positive and significant. This is consistent with the notion that control over manufacturing processes is more important for injectables than for oral solids, and that vertical integration enables firms to have better control.[53]

[53]The estimated coefficients on the dummy variables for injectables and topicals have extremely high absolute values. For instance, the marginal probability of vertical integration is shown to be 581.6 percent higher for injectables than for oral solids. This is an artifact of the low predicted probabilities at representative values of the covariates; the marginal probability of vertical integration for a representative oral solid observation is 3.17 percent, while that for an injectable observation is 21.61 percent.

The coefficient on the paragraph IV indicator variable is estimated to be significantly positive. This lends some support to the hypothesis that vertical integration is motivated by the need for early API development when pursuing a paragraph IV patent challenge. However, the marginal effect of the paragraph IV variable on the marginal probability of vertical integration is not significantly different from zero. The inability to detect a significant marginal effect may be due to the fact that the incidence of paragraph IV certification is measured for the market as a whole even though certifications are made separately by individual firms. The resulting measurement error for the paragraph IV variable may be causing a downward bias on the estimated marginal effect. A better test would use measurements of paragraph IV certification at the firm level to see if generic entrants that file paragraph IV ANDAs are more likely to be vertically integrated; unfortunately I do not have access to such data.

V.2.2 Effect of Own and Rival Firm Characteristics

A firm's past experience at entering the upstream segment of a market has a significantly positive impact on its probability of vertical integration. One additional upstream entry event during the previous year raises the marginal probability of vertical integration by 9.6 percent and increases the conditional probability of vertical integration by 7.7 percent. This finding indicates that the past upstream experience of a potential downstream entrant lowers its cost of vertical integration. In other words, past entry experience has a cost-lowering effect in the upstream API segment just as it does in the downstream finished formulation segment.

Meanwhile, the downstream entry experience of a firm has a significantly negative marginal effect on the conditional probability of vertical integration. Since the downstream experience variable appears only in the downstream entry equation (the selection equation), this is entirely attributable to an indirect effect (Greene, 2008, p.822). As the downstream experience variable rises, firms having a low value of ε_1 become more likely to enter the downstream segment (i.e., to be included in the selected group). Because such firms tend to have low values of ε_2 due to the positive correlation between the two error terms, their inclusion into the selected group lowers the conditional probability of vertical integration.

The mean upstream experience among potential downstream entrants (i.e., rivals) has a significantly positive coefficient in the vertical integration equation, and its marginal effect on the probability of vertical integration is also positive and significant. When the mean upstream experience of rivals increases by one unit (equivalent to one upstream entry event during the previous year), the representative firm's marginal probability of vertical integration rises by 36.4 percent and its conditional probability of integration increases by 26.7 percent.

Combined with the earlier result that a downstream entrant's own upstream experience increases its probability of vertical integration by lowering its cost of vertical integration, this finding implies the

following: lower vertical integration costs among rivals raises a firm's incentive to vertically integrate. According to the model presented in Section II.1, this implies that firms' vertical integration decisions are strategic complements, which, in the context of a simultaneous-move vertical integration game, implies the existence of bandwagon effects. Interestingly, increasing the mean upstream experience of rivals by one unit raises a firm's vertical integration probability by more than three times the amount caused by increasing the firm's own upstream experience by one unit. This suggests that the magnitude of bandwagon effects in the generics industry is quite substantial.

The number of potential upstream-only entrants, which was found to affect downstream payoffs positively, has a significantly negative coefficient in the vertical integration equation. The estimated marginal effects also indicate that increasing the number of potential upstream suppliers significantly lowers a firm's probability of vertically integrating. This finding can be interpreted as follows: when the number of potential unintegrated upstream entrants is large so that a lower degree of vertical integration is expected to hold in equilibrium, each downstream entrant has a lower incentive to vertically integrate. This provides additional support to the view that firms' vertical integration decisions are driven by bandwagon behavior.

V.2.3 Possible Causes of Bandwagon Behavior

The main finding from the econometric analysis is that vertical integration decisions in the generics industry exhibit bandwagon effects: a firm's incentive to vertically integrate is higher if it expects a greater prevalence of vertical integration among its rivals. What could be the cause of such strategic complementarity? One possibility is that in paragraph IV markets where generic firms race to be the first-to-file, the returns from vertical integration are greater when rivals are integrated. Unfortunately, however, we do not have sufficient information to tell how such returns might vary with the vertical integration status of rivals.[54]

A second possible explanation is that the strategic complementarity of vertical integration is caused by strong foreclosure effects in the post-entry market. Imagine a market where the foreclosure effects of vertical integration are severe relative to its efficiency effects. In such a market, an unintegrated downstream entrant earns a low profit when many of its rivals are vertically integrated, but it gains a high incremental profit by choosing to vertically integrate. On the other hand, when few of its rivals are vertically integrated, the firm's incremental profit from integrating is likely to be small. By comparison, when foreclosure effects are weak relative to efficiency effects, the firm's incremental profit from vertical integration is likely to be larger when fewer of its rivals are integrated (Buehler and Schmutzler, 2005).

[54] In the context of a paragraph IV patent challenge, the returns from integration can be thought to be proportional to the increase in the probability of winning that is brought about by vertical integration.

Another possibility is that firms in the industry learn from others about the benefits of vertical integration as suggested by Rosengren and Meehan (1994). The performance of a vertical integrated entrant in one market may inform others in the industry about the hitherto unknown benefits of vertical integration, and influence their actions in future markets. The existence of such learning spillovers would cause vertically integrated entry to become more prevalent over time; it would also create correlation between individual firms' probability of vertical integration and their rivals' upstream experience levels. However, while such inter-firm learning effects cannot be ruled out entirely, they are unlikely to be driving the estimated positive impact that rivals' mean upstream experience has on the probability of vertical integration. This is because the year dummy variables in the vertical integration equation are expected to pick up any learning spillover effects that exist. Turning to the marginal effects of the year dummies, we find that the probability of vertical integration was signficantly higher in 2001 and 2002. The rising trend during the first half of the observation period is consistent with the existence of learning spillovers. Somewhat puzzling is the decreasing trend during the second half. One possible explanation is that some of the vertically integrated entries in the former period were caused by fad behavior, which declined in importance during the latter period.

Conclusion

The US generic pharmaceutical industry has experienced a wave of vertical integration since the late 1990s. Industry reports suggest that this pattern may be associated with the increase in paragraph IV patent challenges that followed key court decisions in 1998. The 180-day market exclusivity given to the first generic entrant to file a patent challenge has turned the entry process in some generic drug markets into a race to be first; vertical integration may provide an advantage to race participants by promoting investments aimed at the early development of active pharmaceutical ingredients (APIs). Another cause of the vertical merger wave suggested by industry reports is the existence of bandwagon effects: increased vertical integration among rivals may have motivated firms to become vertically integrated themselves.

This paper employs simple theoretical models to demonstrate the validity of these two explanations and to derive emprical tests. In the context of a simultaneous-move vertical integration game such as the one seen generally in the generics industry, the existence of bandwagon effects is equivalent to the strategic complementarity of vertical integration decisions. The theoretical model in Section II.1 shows that under strategic complementarity, a firm's probability of vertical integration increases as its rivals' cost of integration decreases. This result leads naturally to a test of bandwagon effects based on a discrete choice analysis of entry and vertical integration. Another model presented in Section II.2 shows that vertical integration enables firms to develop their APIs early during a patent challenge, increasing their

chances of winning first-to-file status, when API supply contracts are incomplete and payment terms are determined through *ex post* bargaining. This prediction can be tested by seeing if markets characterized by paragraph IV certification are more likely to attract vertically integrated entrants.

The two tests are applied to data on 85 generic drug markets that opened up during 1999-2005, using a trivariate probit model that accounts for selection and endogeneity. The coefficient estimate for the paragraph IV indicator variable shows that vertical integration payoffs are higher in paragraph IV markets as the theory suggests, but the marginal effect evaluated at representative values of the covariates is not significantly different from zero. Thus, the hypothesis that vertical integration facilitates relationship-specific non-contractible investments is only partially supported by the data.

The past upstream entry experience of a downstream entrant is found to have a signficantly positive impact on its probability of vertical integration. This suggests that upstream experience lowers the cost of vertical integration. We also find that the mean upstream experience of rivals has a significantly positive effect on a firm's vertical integration probability. These two results combined indicate that vertical integration decisions are strategic complements – in other words, bandwagon effects are likely to exist.

There are several possible causes for bandwagon behavior. One possibility is that the returns to vertical integration in paragraph IV markets are higher when rivals are integrated, but there is insufficient evidence to support this claim. Another possibility is that vertical integration generates strong foreclosure effects in the post-entry market, which, according to Buehler and Schmutzler (2005), give rise to the strategic complementarity of vertical integration decisions. There is some empirical evidence to support the existence of foreclosure effects: the number of potential unintegrated upstream entrants has a postive effect on downstream payoffs but its effect on the returns to vertical integration is negative, which suggests that unintegrated downstream entrants are better off if the market is less vertically integrated. A final candidate cause of bandwagon behavior is inter-firm learning about the benefits of vertical integration. The marginal effects of the year dummy variables provide some indication of learning spillovers. However, learning effects are unlikely to be causing the estimated positive relationship between the mean upstream experience of rivals and the probability of vertical integration.

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Appendix

A Marginal Effects on Conditional Outcome Probability in Trivariate Probit Model

Here, I derive the marginal effect of changes in the covariates on the probability of vertical integration by a potential downstream entrant, conditional on the firm having entered the downstream segment and on the market not being subject to paragraph IV certification. The conditional probability is written as

$$Prob(VI = 1 \mid DE = 1,\, PF = 0,\, \bar{\mathbf{x}}) = \frac{Prob(VI = 1,\, DE = 1,\, PF = 0 \mid \bar{\mathbf{x}})}{Prob(DE = 1,\, PF = 0 \mid \bar{\mathbf{x}})},$$

where $\bar{\mathbf{x}} = \bar{\mathbf{x}}_1 \cup \bar{\mathbf{x}}_2 \cup \bar{\mathbf{x}}_3$ contains representative values of the covariates. The probabilities on the right-hand side are written out as

$$Prob(VI = 1,\, DE = 1,\, PF = 0 \mid \bar{\mathbf{x}}) = \int_{-\infty}^{-\beta_3' \bar{\mathbf{x}}_{3m}} \int_{-\beta_2' \bar{\mathbf{x}}_{2mi}}^{\infty} \int_{-\beta_1' \bar{\mathbf{x}}_{1mi}}^{\infty} f_3\left(\varepsilon_1, \varepsilon_2, \varepsilon_3; \Sigma\right) d\varepsilon_1 d\varepsilon_2 d\varepsilon_3,$$

$$Prob(DE = 1,\, PF = 0 \mid \bar{\mathbf{x}}) = \int_{-\infty}^{-\beta_3' \bar{\mathbf{x}}_{3m}} \int_{-\beta_2' \bar{\mathbf{x}}_{2mi}}^{\infty} \phi_2\left(\varepsilon_2, \varepsilon_3; 0\right) d\varepsilon_2 d\varepsilon_3,$$

where $\phi_2(\cdot;\rho)$ is the density of a standard bivariate normal distribution with correlation coefficient ρ. The marginal effect of a continuous covariate x_k, which may belong to one, two, or all three of the covariate vectors $\mathbf{x}_1$, $\mathbf{x}_2$, and $\mathbf{x}_3$, is derived as follows:

$$\frac{\partial Prob(VI=1 \mid DE=1,\, PF=0,\, \bar{\mathbf{x}})}{\partial x_k} = \frac{1}{[Prob(DE=1,\, PF=0 \mid \bar{\mathbf{x}})]^2}$$

$$\times \left\{ \frac{\partial Prob(VI=1,\, DE=1,\, PF=0 \mid \bar{\mathbf{x}})}{\partial x_k} Prob(DE=1,\, PF=0 \mid \bar{\mathbf{x}}) \right.$$

$$\left. -Prob(VI=1,\, DE=1,\, PF=0 \mid \bar{\mathbf{x}}) \frac{\partial Prob(DE=1,\, PF=0 \mid \bar{\mathbf{x}})}{\partial x_k} \right\}$$

$$= \frac{1}{\Phi(\beta_2'\bar{\mathbf{x}}_2)\Phi(-\beta_3'\bar{\mathbf{x}}_3)}$$

$$\times \left[\beta_{1k}\phi(\beta_1'\bar{\mathbf{x}}_1) \int_{-\infty}^{-\beta_3'\bar{\mathbf{x}}_3} \int_{-\beta_2'\bar{\mathbf{x}}_2}^{\infty} f_2\left(\varepsilon_2 + \rho_{12}\beta_1'\bar{\mathbf{x}}_1,\, \varepsilon_3 + \rho_{13}\beta_1'\bar{\mathbf{x}}_1;\, \Sigma_{23|1}\right) d\varepsilon_2 d\varepsilon_3 \right.$$

$$+ \beta_{2k}\phi(\beta_2'\bar{\mathbf{x}}_2) \int_{-\infty}^{-\beta_3'\bar{\mathbf{x}}_3} \int_{-\beta_1'\bar{\mathbf{x}}_1}^{\infty} f_2\left(\varepsilon_1 + \rho_{12}\beta_2'\bar{\mathbf{x}}_2,\, \varepsilon_3;\, \Sigma_{13|2}\right) d\varepsilon_1 d\varepsilon_3$$

$$\left. -\beta_{3k}\phi(\beta_3'\bar{\mathbf{x}}_3) \int_{-\beta_2'\bar{\mathbf{x}}_2}^{\infty} \int_{-\beta_1'\bar{\mathbf{x}}_1}^{\infty} f_2\left(\varepsilon_1 + \rho_{13}\beta_3'\bar{\mathbf{x}}_3,\, \varepsilon_2;\, \Sigma_{12|3}\right) d\varepsilon_1 d\varepsilon_2 \right]$$

$$- \frac{\beta_{2k}\phi(\beta_2'\bar{\mathbf{x}}_2)\Phi(-\beta_3'\bar{\mathbf{x}}_3) - \beta_{3k}\phi(\beta_3'\bar{\mathbf{x}}_3)\Phi(\beta_2'\bar{\mathbf{x}}_2)}{\left[\Phi(\beta_2'\bar{\mathbf{x}}_2)\Phi(-\beta_3'\bar{\mathbf{x}}_3)\right]^2}$$

$$\times \int_{-\infty}^{-\beta_3'\bar{\mathbf{x}}_3} \int_{-\beta_2'\bar{\mathbf{x}}_2}^{\infty} \int_{-\beta_1'\bar{\mathbf{x}}_1}^{\infty} f_3(\varepsilon_1, \varepsilon_2, \varepsilon_3;\, \Sigma) d\varepsilon_1 d\varepsilon_2 d\varepsilon_3, \tag{15}$$

where $\Phi(\cdot)$ is the standard normal cumulative distribution function and $f_2(\cdot;\Sigma)$ is the density of a bivariate normal distribution with zero mean vector and covariance matrix Σ. The conditional covariance matrices are written out as follows:

$$\Sigma_{23|1} = \begin{bmatrix} 1-\rho_{12}^2 & -\rho_{12}\rho_{13} \\ -\rho_{12}\rho_{13} & 1-\rho_{13}^2 \end{bmatrix}, \Sigma_{13|2} = \begin{bmatrix} 1-\rho_{12}^2 & \rho_{13} \\ \rho_{13} & 1 \end{bmatrix}, \Sigma_{12|3} = \begin{bmatrix} 1-\rho_{13}^2 & \rho_{12} \\ \rho_{12} & 1 \end{bmatrix}.$$

For the dichotomous covariates in x, the marginal effect on the conditional probability is calculated as

$$Prob(VI=1 \mid DE=1,\, PF=0,\, \bar{\mathbf{x}}_{-k},\, x_k=1) - Prob(VI=1 \mid DE=1,\, PF=0,\, \bar{\mathbf{x}}_{-k},\, x_k=0).$$

B Dataset Construction Details

Identifying Generic Products in the FDA's Database

The US Food and Drug Administration's Orange Book contains information on all pharmaceutical finished formulations that have ever been approved, including those that have been discontinued. [55] There are several methods to Identify generic approvals in the Orange Book data. One way is to refer to another database of the FDA, called Drugs@FDA, which identifies generic approvals with the term "ANDA".[56] However, the FDA's own classification appears to be imperfect. For instance, several drug approvals from before 1984 are classified as ANDAs, even though abbreviated new drug applications did not exist until after the passage of the Hatch-Waxman Amendments in 1984. Therefore, I use the FDA's classification in conjunction with another classification rule based on the trade name, or brand name, of a drug. Under this rule, an approved drug is classified as a generic if its trade name is the same as the generic name of the API contained in the drug. After applying both rules, I visually inspect all approvals in the database to correct obvious misclassifications.

Identifying Firms and Treating Mergers

The FDA's data on ANDAs and DMFs often contain multiple (sometimes erroneous) names for the same firm. Moreover, different firms belonging to the same corporate group are not identified as such. To resolve this problem, I refer to the Newport Sourcing ^{TM} database, which classifies finished formulation manufacturers and API manufacturers into uniquely defined corporate groups. A firm in my dataset is equivalent to a corporate group as defined by Newport Sourcing.

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 and around the observation period. For instance, Teva and IVAX were rivals in both the API and finished formulation industries until IVAX was acquired by Teva in January 2006. In the raw data from Newport Sourcing, however, the two firms are treated as being part of the same corporate group, even in markets that opened up prior to the acquisition. To fix this problem, I designate a separate corporate group for the observations for IVAX prior to the acquisition. Other ownership changes are similarly accounted for on the basis of news information on the timings of mergers and acquisitions that involve in-sample firms.

Merger and acquisition histories are also taken into account when determining a firm's potential entrant status on the basis of its past experience, or when constructing variables that measure a firm's

[55] The Orange Book files are available from the FDA's website: `http://www.fda.gov/CDER/orange/obreadme.htm`.

[56] Drugs@FDA is accessible online at `http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm`.

entry experience. In doing so, I assume that an acquired firm's past entry experience is carried over to the acquiring firm, and that the new entity's entry experience is calculated as the sum of the two firms' experience levels.

Table A.1: List of Drugs in the Dataset

Active Pharmaceutical Ingredient	Therapeutic Class	Dose Form	Market Opening
acebutolol hydrochloride	Cardiovascular	capsule	1995
acyclovir	Anti-Infective	capsule	1997
acyclovir	Anti-Infective	tablet	1997
alprazolam	Central Nervous System	tablet	1993
alprostadil	Endocrine-Metabolic	injectable	1998
amiodarone hydrochloride	Cardiovascular	tablet	1998
anagrelide hydrochloride	Blood Modifier	capsule	2005
azathioprine	Musculoskeletal	tablet	1996
azithromycin	Anti-Infective	tablet	2005
benazepril hydrochloride	Cardiovascular	tablet	2004
benzonatate	Respiratory	capsule	1993
betaxolol hydrochloride	Cardiovascular	tablet	1999
bromocriptine mesylate	Central Nervous System	tablet	1998
bumetanide	Cardiovascular	tablet	1995
bupropion hydrochloride	Central Nervous System	tablet	1999
buspirone hydrochloride	Central Nervous System	tablet	2001
cabergoline	Endocrine-Metabolic	tablet	2005
captopril	Cardiovascular	tablet	1995
carboplatin	Oncology	injectable	2004
cefotaxime sodium	Anti-Infective	injectable	2002
cefoxitin sodium	Anti-Infective	injectable	2000
cefpodoxime proxetil	Anti-Infective	tablet	2004
cefprozil	Anti-Infective	tablet	2005
cefuroxime axetil	Anti-Infective	tablet	2002
ciclopirox olamine	Dermatological	topical	2004
cilostazol	Blood Modifier	tablet	2004
cimetidine	Gastrointestinal	tablet	1994
ciprofloxacin hydrochloride	Anti-Infective	tablet	2004
cisplatin	Oncology	injectable	1999
citalopram hydrobromide	Central Nervous System	tablet	2004
clarithromycin	Anti-Infective	tablet	2005
clonazepam	Central Nervous System	tablet	1997
clozapine	Central Nervous System	tablet	1997
diclofenac potassium	Central Nervous System	tablet	1998
diclofenac sodium	Central Nervous System	ER tablet	1995
didanosine	Anti-Infective	ER capsule	2004

(Table continued on next page.)

(Continued from previous page.)

Active Pharmaceutical Ingredient	Therapeutic Class	Dose Form	Market Opening
dihydroergotamine mesylate	Central Nervous System	injectable	2003
doxazosin mesylate	Cardiovascular	tablet	2000
econazole nitrate	Dermatological	topical	2002
enalapril maleate	Cardiovascular	tablet	2000
estazolam	Central Nervous System	tablet	1997
ethambutol hydrochloride	Anti-Infective	tablet	2000
etodolac	Central Nervous System	tablet	1997
etoposide	Oncology	injectable	1994
famotidine	Gastrointestinal	tablet	2001
felodipine	Cardiovascular	ER tablet	2004
fenofibrate	Cardiovascular	capsule	2002
fexofenadine hydrochloride	Respiratory	tablet	2005
flecainide acetate	Cardiovascular	tablet	2002
fluconazole	Anti-Infective	injectable	2004
fluconazole	Anti-Infective	tablet	2004
fludarabine phosphate	Oncology	injectable	2003
fludrocortisone acetate	Endocrine-Metabolic	tablet	2002
fluoxetine hydrochloride	Central Nervous System	capsule	2001
flurbiprofen	Central Nervous System	tablet	1994
flutamide	Oncology	capsule	2001
fluvoxamine maleate	Central Nervous System	tablet	2001
fosinopril sodium	Cardiovascular	tablet	2003
gabapentin	Central Nervous System	capsule	2004
gabapentin	Central Nervous System	tablet	2004
ganciclovir	Anti-Infective	capsule	2003
gemfibrozil	Cardiovascular	tablet	1993
glimepiride	Endocrine-Metabolic	tablet	2005
glipizide	Endocrine-Metabolic	tablet	1994
glyburide	Endocrine-Metabolic	tablet	1995
guanfacine hydrochloride	Cardiovascular	tablet	1995
hydroxychloroquine sulfate	Anti-Infective	tablet	1995
hydroxyurea	Oncology	capsule	1995
indapamide	Cardiovascular	tablet	1995
itraconazole	Anti-Infective	capsule	2005
ketoconazole	Anti-Infective	tablet	1999
ketorolac tromethamine	Central Nervous System	tablet	1997

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Active Pharmaceutical Ingredient	Therapeutic Class	Dose Form	Market Opening
labetalol hydrochloride	Cardiovascular	tablet	1998
leflunomide	Musculoskeletal	tablet	2005
leuprolide acetate	Endocrine-Metabolic	injectable	1998
lisinopril	Cardiovascular	tablet	2002
lovastatin	Cardiovascular	tablet	2001
mefloquine hydrochloride	Anti-Infective	tablet	2002
metformin hydrochloride	Endocrine-Metabolic	tablet	2002
methazolamide	Ophthalmologic	tablet	1993
methimazole	Endocrine-Metabolic	tablet	2000
metolazone	Cardiovascular	tablet	2003
metoprolol tartrate	Cardiovascular	tablet	1993
mexiletine hydrochloride	Cardiovascular	capsule	1995
midazolam hydrochloride	Central Nervous System	injectable	2000
midodrine hydrochloride	Cardiovascular	tablet	2003
mirtazapine	Central Nervous System	tablet	2003
misoprostol	Endocrine-Metabolic	tablet	2002
moexipril hydrochloride	Cardiovascular	tablet	2003
mupirocin	Dermatological	topical	2003
nabumetone	Central Nervous System	tablet	2001
nadolol	Cardiovascular	tablet	1993
naltrexone hydrochloride	Central Nervous System	tablet	1998
naproxen	Central Nervous System	tablet	1993
naproxen sodium	Central Nervous System	tablet	1993
nefazodone hydrochloride	Central Nervous System	tablet	2003
nicardipine hydrochloride	Cardiovascular	capsule	1996
nizatidine	Gastrointestinal	capsule	2002
norethindrone acetate	Endocrine-Metabolic	tablet	2001
ofloxacin	Anti-Infective	tablet	2003
omeprazole	Gastrointestinal	ER capsule	2002
oxaprozin	Central Nervous System	tablet	2001
paclitaxel	Oncology	injectable	2002
pamidronate disodium	Endocrine-Metabolic	injectable	2001
paroxetine hydrochloride	Central Nervous System	tablet	2003
pentoxifylline	Blood Modifier	ER tablet	1997
pergolide mesylate	Central Nervous System	tablet	2002
propafenone hydrochloride	Cardiovascular	tablet	2000

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Active Pharmaceutical Ingredient	Therapeutic Class	Dose Form	Market Opening
quinapril hydrochloride	Cardiovascular	tablet	2004
ranitidine hydrochloride	Gastrointestinal	tablet	1997
ribavirin	Anti-Infective	capsule	2004
rimantadine hydrochloride	Anti-Infective	tablet	2001
selegiline hydrochloride	Central Nervous System	tablet	1996
sotalol hydrochloride	Cardiovascular	tablet	2000
sucralfate	Gastrointestinal	tablet	1996
tamoxifen citrate	Oncology	tablet	2003
terazosin hydrochloride	Cardiovascular	capsule	1999
terbutaline sulfate	Respiratory	tablet	2001
terconazole	Genitourinary	topical	2004
ticlopidine hydrochloride	Blood Modifier	tablet	1999
tizanidine hydrochloride	Musculoskeletal	tablet	2002
torsemide	Cardiovascular	tablet	2002
tramadol hydrochloride	Central Nervous System	tablet	2002
triazolam	Central Nervous System	tablet	1994
ursodiol	Gastrointestinal	capsule	2000
vinorelbine tartrate	Oncology	injectable	2003
zidovudine	Anti-Infective	tablet	2005
zonisamide	Central Nervous System	capsule	2005