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ABSTRACT

In this paper I use data on all generic drug approvals granted from 1984-1994 to examine whether heterogeneity among potential generic entrants can be used to predict which firms will choose to enter a particular market. The findings suggest that a firm's portfolio characteristics, namely, its previous experience with a drug or therapy reduces the cost of preparing an ANDA and increases the probability of entry. A subsidiary's *parent's* experience is not generally significant in predicting entry of the subsidiary. Firms also prefer entering markets that are similar, in terms of revenue and sales to hospitals, to markets already in their portfolios. On both scientific and marketing dimensions, the evidence shows that firms are specializing. I explore several different ways of constructing the set of potential entrants and find that the results are not affected by methodological variation. Standard IO theory suggests that profits per entrant will decline in the number of entrants. Previous research has found that generic prices depend on the number of generic entrants, and the results presented here show that the total number of entrants increases with the size of the market (revenue). These findings imply that generic firms face a negative competition externality which makes their expectations about who else might be planning to enter any given market important in the entry decision. The limited evidence on entrant beliefs supports this conjecture as do several features of a regulatory upheaval when firms began entering different markets than they had in the past.

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I. Introduction

A firm's decision to enter a particular market is one of the most important economic actions in a market economy. The number of firms in a market and distribution of market share have long been known to affect price levels and consumer welfare. Most research in this area uses the convenient assumption of symmetric firms, although this is of course not a good representation of reality. In contrast, this paper takes explicit account of heterogeneity among potential entrants to predict *which* firms are likely to enter which markets. In particular, it examines the entry choices of heterogeneous generic pharmaceutical firms and finds that they specialize along both scientific and marketing dimensions. The history and experience of a firm that lead it to enter particular markets can be thought of as firm 'capabilities,' in the sense that word is used in the business press. This industry provides a setting where a firm's capabilities can be explicitly measured and the result of using existing capabilities or developing new ones can be observed.

The entry decision is complex because the number of firms in a market affects the payoff to any one of them from entering that market; each entrant creates a negative externality for the others that can be severe. Profits earned by an entrant firm therefore depend on entry decisions of other firms. Entrants sink entry costs simultaneously because firms do not typically announce their entry plans and the FDA does not reveal whose application it has received. The timing of the game, combined with research showing generic prices (and presumably profits) depend on the number of generic entrants, implies that generic firms face the difficult problem of how to form expectations about where others will enter. Those expectations will affect its own entry decisions.

The question of which firms are expected to enter -- as well as do enter -- which markets in a simultaneous game is important. For a generic pharmaceutical manager making entry decisions for his or her firm, it is clearly a crucial problem. I discuss and examine how a generic pharmaceutical firm might form expectations of rivals' actions and what firm equilibrium strategies might be. I argue that repeat players may use an entry strategy that provides stability of expectations: specialization. Specialization based on both scientific and marketing characteristics is natural because it reflects lower costs and provides a well-understood way to form conjectures about where competitors will enter.

It is possible to conduct an empirical study of firm decision-making in the generic pharmaceutical industry because entry regulations create relatively good experiments and the regulatory agency, the Food and Drug Administration (FDA), generates data that are available to researchers. In this paper I use data on all generic drug entries from 1984 to 1994 to examine entry patterns and

specialization. In particular, I explore whether generic entrants are choosing markets based on past experience as measured by characteristics of their portfolios. I find that a firm's previous experience with a drug or therapy increases the probability of entry into a similar market. The experience of a firm's parent on various dimensions is generally not helpful in predicting entry, above and beyond the firm's (subsidiary) experience. Marketing similarities between the entry opportunity and characteristics of the firm's portfolio such as market revenue and hospital share are also important in explaining entry. Additionally, I show that larger markets, those that attract more entry, are markets with more sales to hospitals and those where the drug treats a chronic condition.

In 1989 a major scandal erupted when various illegal practices were uncovered in the generic drug industry. I present results showing that the subsequent regulatory upheaval re-weighted the components of entry cost and disrupted established industry practices, including the pattern of specialization. Firms began to enter markets that looked different, rather than similar, to markets they were already in.

II. Institutional Framework and Timing

A firm that invents a new drug must get approval from the FDA by showing the drug is safe and effective. A New Drug Application (NDA) reports tests showing safety and efficacy and is typically expensive to construct and takes many years to be approved. A firm taking this route is called an innovator and the product is typically promoted under a proprietary brand name. In 1984 the pharmaceutical regulatory regime was significantly altered by the Waxman-Hatch Act. This legislation, among other things, allowed generic firms to submit Abbreviated New Drug Applications (ANDAs) for drugs approved since 1962. A flood of new ANDAs was filed in response to the law. The advantages of the ANDA process are summarized in the quotation below.

> "The benefit of the ANDA process to generic manufacturers is that it does not require these companies to repeat costly clinical and animal research on active ingredients or finished dosage forms already found to be safe and effective. A generic drug must contain the same active ingredients; be identical in strength, dosage form, and route; be bioequivalent; and be manufactured under the same strict standards as the brand-name drug to gain FDA approval." (Frost and Sullivan report (1994))

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