Innovate or Imitate? Strategic Innovation Decision in the Pharmaceutical Industry

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Abstract
Although social welfare and firms’ strategic innovation decisions are closely related through firms’ innovation activities, their relationship is still left unexplored. By measuring their relationship, we unveil how firms’ strategic decisions shape the overall demand structure and consumer welfare. Consequently, we empirically emphasize the role of public policy in inducing and directing innovation and shaping social welfare.

We also suggest an empirical estimation structure for the study of firms’ strategic innovation behavior by adapting the model of endogenous choice of product quality. The empirical focus is on the pharmaceutical industry where technological innovation has huge impact on consumer welfare.

Keywords: Innovation; Firm Objectives, Organization, and Behavior; Health Policy

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I. Introduction

Firms’ strategic decisions on innovation is the origin of firms’ internal and external changes. Based on their strategic decisions, their profit enhances or depreciates, demand is created or cannibalized, and, accordingly, overall consumer benefit is restructured and redistributed. In other words, through the outcomes of their innovation activities, that is, product innovation, firms’ strategic innovation decisions fundamentally reshape social welfare as well as determine firms’ market performances.

The relationship between the outcomes of innovation and social welfare change has been considerably examined in economics over the decades. Following the pioneering work by Grilliches (1957) and Schmookler (1962, 1966), which demonstrated the important role of demand in stimulating firms’ innovation activities, economists looked closely into the impact of product innovation on its social rate of return in various industries, such as, the pharmaceutical industry, for example, Trajtenberg (1989). In addition, the impact of product innovation on firms’ market performance has been extensively examined in various literatures.

However, the sources which shape and determine firms’ strategic decisions on innovation and their impact on social welfare change is still left unexplored. What are the important elements of firms’ innovation decision? How significantly those elements affect firms’ market performance? How substantial the impact of firms’ innovation decisions is in reshaping social welfare? These questions have been, surprisingly, left unanswered, though they are critical for firms’ managerial decisions as well as the establishment of public policy.

In this paper, therefore, we examine the role of technological, as well as, market environmental factors, such as technological uncertainty, market competition, and institutional regulation, in firms’ strategic decisions on innovation. In addition, we explore how those sources of innovation decisions, subsequently, reshape firms’ market performance as well as social welfare.

We focus on the pharmaceutical industry where technological innovation, such as new drugs, has huge impact on firms’ profits and on consumer welfare. In this industry, earlier successful innovation strategies have altered not only consumer welfare, but also market structure and even science base to a large extent. Correspondingly, innovation strategies have been substantially changed over the decades in response. More specifically, by empirically applying our model to the antidepressant market initially, we uncover the determinants of pharmaceutical firms’ strategic innovation behavior and measure their impact on consumer welfare.

At this point, firms’ strategic decisions are defined as to whether firms try to innovate or imitate: whether to innovate and produce novel drugs or to imitate them and introduce non-novel drugs, such as me-too drugs and generics. Preliminary results
show that firms’ strategic innovation decisions can be skewed by incomplete information about potential demand, firms’ limited resources, uncertainty of innovation, and market competition resulting in suboptimal consumer welfare. In addition, the overall welfare gain from innovation on novel drugs is substantially higher than that from non-novel drugs.

Methodologically, the proposed empirical model encompasses the dynamic model of consumer demand for differentiated non-durable products. The dynamic model of consumer demand for differentiated product has been developed recently in the case of durable markets (Melnikov 2000, Carranza Romero 2004). In our study, we develop a dynamic model for non-durable products, specifically pharmaceuticals, with the assumption that consumers purchase a non-durable good repeatedly. In addition, we assume that, at each time of purchase, they face a sequence of static discrete choice problems over a non-stationary choice set. Although the dynamic setting and assumptions are different from the durable goods case, we find that the empirical structure is consistent with the durable goods case. In addition, we further extend our dynamic model of consumer choice by combining it with a random coefficients model and suggest a simulated estimation technique for the estimation of both static and dynamic parameters.

The suggested estimation structure for the dynamic model of consumer choice enables us to estimate the supply side parameters simultaneously under the assumption of market equilibrium. Therefore, we further examine a firm’s strategic pricing behavior corresponding to its market power and innovation capability, a function of variables such as the lag between market and patent approval, the lag between patent expiration and market withdrawals, the lag between patent expiration and introduction of generics (market power), and the percentage of successful applications (innovation capability). As far as it can be determined, our research is the first systematic empirical examination of the pricing behavior of pharmaceutical firms regarding their market power and innovation capability.

This paper also suggests an empirical estimation structure for the study of firms’ strategic innovation behavior by adapting the model of endogenous choice of product quality. In a recent study (Carranza Romero 2004) has incorporated the endogenous choice of product quality and expected behavior of firms and consumers, and the changing cost of technology into the entry problem. By annexing the condition of resource constraints, we suggest a novel model of firms’ strategic innovation behavior.

The rest of the paper organized as follows. Section II discusses the relevant literature and its relation to active public policy. Section III introduces and analyzes the theoretical model of the paper. Section IV analyzes the empirical application and discusses the results. Section V summarizes and concludes the paper.
II. Literature Review and Active Public Policy

Firms’ strategic behavior and its effect on social welfare have been out of focus in public policy research. With social welfare improvement in mind, public policy can be categorized into an active and passive approach depending on the targeting processes\(^1\) in innovation. The bulk of existing public policy has been following mostly the passive approach. Passive approach in public policy, in the form of demand-side regulations and subsidies, is executed to directly improve consumer welfare, especially in pharmaceutical markets, by changing consumer characteristics. For instance, including a new drug in Medicaid coverage can be accepted as a passive approach. Therefore, researchers evaluate patient welfare benefits arising from pharmaceutical innovation and, subsequently, suggest demand-side modifications to improve consumer welfare.

However, the active approach in public policy, which covers firms’ strategic behavior and its effects, has not been fully explored. Active policy, in the form of incentives and regulations for the supply side, is implemented to guide the behavior of decision makers and/or the overall direction of innovation and, ultimately, welfare. For instance, funding firm research for cures of neglected diseases can be viewed as an active policy. However, researchers have neglected long enough the fact that the strategic innovation behavior of firms is one of the major determinants of innovation direction and the outcomes of it. For example, we know little about what the determinants are for pharmaceutical firms’ strategic decisions, whether to invest enormous amounts of resources into a drug innovation project for long-term profit or into the development of several generics for short-term profit and, consequently, its effect on consumer welfare.

More importantly, active policy for firms’ strategic innovation decisions is especially important in the areas of neglected diseases. Since the innovation for neglected diseases is left behind in firms’ strategic innovation priorities and, in the perspective of public goods, it is urgently required to be actively pursued to meet the social need. For instance, less than ten percent of the global spending on healthcare R&D is dedicated to the major health problems of 90 percent of the world population\(^2\). Two of the main reasons why large numbers of neglected diseases have been outside of firms’ innovation scope is that the demand for each cure is relatively small and that for some cures demand is large only in third-world countries.

In addition to the small incentives of market demand, firms are being compelled to select such strategies that reduce the odds of innovation. Such strategies are generic imitation, serving more predictable niche markets with me-too proprietary products and specializing in elements of R&D with better odds, such as delivery technologies. The latter is exacerbated as the market environment becomes highly competitive and the process of discovering novelty drugs becomes increasingly difficult and costly. This idiosynchrasy of the pharmaceutical industry, that is, high risk and high reward,

\(^1\) That is, supply-side versus demand-side.
\(^2\) Pull Mechanism working Group 2004
drives more firms to rely on odds-reducing strategies that prosper long term. (Schmid et al. 2004) Therefore, it is important to actively guide their potentially and possibly skewed innovation activities and directions toward the direction supporting neglected diseases and, consequently, increasing overall social welfare.

There are a number of other studies related to our work. First, Trajtenberg (1989) pioneered the work on the effect of product innovation on welfare. Trajtenberg measures the social rate of return to R&D by analyzing the effect of tomography scanners innovation on consumer welfare. Lichtenberg (2001) estimates the contribution of pharmaceutical innovation to consumer welfare through reductions in mortality, and total medical expenditure. He provides that though cheaper generic drugs might seem as an effective way to reduce health expenditure expanding consumer welfare, branded drugs tend to be younger and, therefore, better so that their use reduces total treatment costs. More recently, Cleanthous (2003) empirically quantifies the patient welfare benefits from pharmaceutical innovation in the U.S. antidepressant market. The study estimates large patient welfare gains from innovation and helps explain the detected divergence between social and private patient benefits by the presence of prescription drug insurance. However, firms’ innovation has been treated as exogenous with an ex-post analysis of the market.

Second, regarding innovation incentives for firms, Kyle (2003) examines the use of price controls on pharmaceuticals, while controlling for both market structure and of firm and product characteristics in analyzing the extent and timing of the launch of new drugs around the world. She suggests that price control has a significant effect on pharmaceutical launches, although it has a non-uniform impact on firms in different countries. In addition, Acemoglu and Linn (2004) investigate the effect of potential market size on entry of new drugs and find a large effect of potential market size on the entry of non-generic drugs and new molecular entities. Moreover, Finkelstein (2004) studies whether and to what extent the demand-side incentives embodied in health policy affect the rate of technological change in the medical sector. She suggests the evident, that an increase in vaccine investment is associated with the increase in demand-side investment incentives. In other studies, she finds that public policy designed to increase utilization of existing technologies affect incentives to develop new technologies. These studies reveal the important market and policy elements, which compose firms’ innovation incentives.

Thirdly, concerning firms’ innovation decisions, Scott Morton (1999) and Reiffen and Ward (2004) study the relationship between the innovation decision of firms and market size. They find a positive relationship between the introduction of generic drugs and expected revenues in the target market. David, Grabowski, and Moe (2004) examine policies designed to increase incentives for research and development for diseases that primarily afflict people in developing countries. They consider push strategies, which fund inputs, such as R&D, and pull strategies which provide financial incentives for producing outputs, such as drugs and vaccines. Conclusively, they suggest a novel pull strategy in which a voucher is awarded for creating and licensing a drug that treats neglected diseases. However, none of these studies explore
the overall welfare change resulting from firms’ strategic innovation decisions, especially, in the perspective of active public policy.

III. Model

This section provides an overview of the firms’ strategic innovation decision model used in this paper. Before we describe our model, we briefly introduce our categorization of firms’ innovation strategies – horizontal and vertical innovation. The drugs are, then, categorized into horizontally and vertically innovated drugs based on the innovation strategies. Horizontal innovation is to introduce new and horizontally differentiated characteristics into a product expanding or substituting the scope of existing products’ variants. In contrast, vertical innovation is to introduce vertically differentiated characteristics into a product in order to cannibalize the demand for existing products. A more detailed explanation of horizontal and vertical innovation will follow in the application section.

We start by considering the decision problem faced by a firm in the evolving market for non-durable goods, specifically the pharmaceutical industry. In general, a firm that is deciding whether to innovate or imitate has to balance the expected flow of profits generated by horizontally (or vertically) innovated drugs by that of vertically (or horizontally) innovated drugs. If this net expected profit is greater than some reservation value, the firm will introduce the horizontally (or vertically) innovated drug. We will assume that the reservation value is zero and thus firms introduce a drug as soon as it is profitable.

More formally, the general problem of a firm deciding on the introduction of a drug $j$ with characteristics vector $x_j$ at time $\tau$ will be described as follows:

$$
\max_{I^+, I^-} \left\{ \max_{s_\tau} \left[ V^{I^+}(x_j, s_\tau) - V^{I^-}(x_k, s_\tau) \right] - RD^{I^+ - I^-} \right\}
$$

where $I^+ = h, v$ and $I^- = v, h$

Here $h$ and $v$ denote horizontal and vertical innovation, respectively, and $V(\cdot)$ is the expected discounted sum of profits from the production and sales of a drug during its product life, which depends on the characteristics vector, $x_j$, and the state space, $s_\tau$. $RD$ stands for the research and development cost difference between horizontal and vertical innovation.

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3 We could also categorize innovation strategies into radical and incremental innovation. However, the concept of radical and incremental innovation is too broad and general to apply to the pharmaceutical industry so as to complete the objectives of this paper. In pharmaceuticals, innovation can be very obscure to be categorized into radical or incremental.

4 This is reasonable in a monopolistic competition setting. As in Caranza Romero (2004), an endogenous reservation value is present in our model.

5 R&D costs can be endogenous or not. This will be discussed later.
The estimation of the structure of equation (1) will give us the deterministic parameters of firms’ strategic innovation behavior. In order to do that, we need the following assumptions:
(a) Drugs are innovated and introduced by monopolistically competitive firms.\(^6\)
(b) Prices are set optimally every period at no cost under a static pricing game.
(c) The fixed cost of innovation has stochastic properties depending on the innovation properties, that is, whether it is horizontal or vertical.\(^7\)
(d) Each firm decides on the optimal strategy, that is, whether to innovate or imitate, depending on its expected flow of profits and the reservation value protected by a patent.
(e) Marginal production costs are assumed to be constant and do not vary over time depending on drug characteristics.

Each of the above assumptions is discussed in detail in the following section while we introduce our model. In addition, by specifying demand, cost and price as a function of the transition probabilities of each state, we identify the function \(V(\cdot)\) and suggest an estimation structure.

1. Demand Structure

Demand for drug \(j\) at time \(t\) is described by the random coefficients model with heterogeneous consumers. In each period \(t\), consumer \(i\) has two options: (a) to buy one of the drugs \(j \in \mathcal{J}_t\) available on the market at this period and keep taking it or (b) to postpone the purchase by choosing an outside alternative. If option (b) is chosen, the consumer obtains a one period utility payoff of \(c\), but if the consumer was prescribed a drug, then \(c\) equals to 0. If consumer \(i\) buys a drug \(j \in \mathcal{J}_t\), his/her lifetime utility is given by:

\[
\begin{align*}
  u_{ijt} &= c_j + \beta \cdot x_j - \alpha \cdot \ln(y - (p_{jt} - \mu_{jt})) + mk_{jt} + \xi_j + \epsilon_{ijt} \cdot \mu_{jt} \\
  &= \delta_{jt} + \epsilon_{ijt} \cdot \mu_{jt}
\end{align*}
\]

where \(\epsilon_{ijt}\) is the time and drug specific logit disturbance. The mean utility \(\delta_{jt}\) depends on the observed characteristics vector of the drug \(x_j\), its price \(p_{jt}\), and an unobserved attribute \(\xi_j\), which is uncorrelated with the observed drug characteristics. However, the fixed brand-effect, \(c_j\), and the marketing effect, \(mk_{jt}\), capture some portion of unobserved characteristics effect on consumer choices.

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\(^6\) This assumption rules out any dynamic strategic interactions across firms. (Caranza Romero 2004).
\(^7\) The stochastic component of fixed costs captures the complex nature of pharmaceutical innovation. As described in the introduction, odds-reducing strategies in pharmaceutical firms explain the stochastic aspect of innovation and the corresponding R&D and other costs. However, the fixed costs do not change over time reflecting the nature of pharmaceutical innovation.
A consumer decides, in each period, whether to choose drug \( j \), which maximizes his/her utility among \( \mathcal{J} \), or to postpone his/her purchase until next period. If we denote the time of purchase for the consumer as \( \tau \), the optimal stopping problem of the consumer can be written as follows:\(^8\)

\[
U_{\tau} = \max \left\{ \sum_{k=0}^{\tau-1} \beta^{k-1} \cdot I + \beta^{\tau-\tau} \cdot E_{\tau} \max_{j \in \mathcal{J}} u_{\tau} \right\}
\]

\[
I = \begin{cases} 
0 & \text{if patient is prescribed} \\
1 & \text{o.w.} 
\end{cases}
\]

(3)

where \( \beta \in [0,1) \) is a common discount factor. The difference with the case of durable goods is that the consumer obtains zero payoffs if he/she is prescribed any drug. The zero payoffs of the consumer capture the lower probability of delaying the purchase of a drug if he is prescribed the drug by a physician at time \( t \). However, he/she can still delay his/her purchase of a drug, which makes the optimal stopping problem to be simple as the durable good case. In a standard framework of dynamic programming, we can rewrite equation (2) as follows:

\[
U(\Omega_t) = \max \left\{ \mathcal{J}_t, \min(c,0) + \beta E_t U(\Omega_{t+1}) \right\}
\]

where \( \mathcal{J}_t = \max_{j \in \mathcal{J}} u_{j} \)

(3)

As shown in Melnikov (2000), if \( \mathcal{J} \) is distributed type I extreme value with a cumulative distribution with some specific density\(^9\), the individual hazard rate of the drug purchase depends on the inclusive value as follows:

\[
h(r_t) = P(\mathcal{J}_t > \min(c,0) + \beta E_t U(\mathcal{J}_{t+1}))
\]

(4)

where \( r_t = \log \sum_{j \in \mathcal{J}_t} \exp(\delta_{j,t}) \)

The inclusive value, \( r_t \), is the state variable which enables us to have transition probabilities of each period. Consequently, given that the market potential at time \( t \) is \( M_t \), the demand for drug \( j \) at time \( t \) and aggregated demand at time \( t \) is given as follows\(^10\):

\[
q_{j,t} = M_t s_{j,t} = M_t h(r_t) \frac{\exp(\delta_{j,t})}{\exp(r_t)}
\]

(5)

\(^8\) The basic framework of the consumer’s optimal stopping problem, here, follows Melnikov (2003).

\(^9\) Melnikov (2000).

\(^10\) For a more detailed derivation, see Melnikov (2000).
\[ q_t = M_t s_t = M_t h(r_t) \]  

where \( s_t \) and \( s_{jt} \) are market share of the outside option and of product \( j \) at time \( t \), respectively. Finally, we can rewrite demand as a function of quality, price, marketing, and firm-specific variables as follows:

\[ q_{jt}(x_j, p_{jt}, r_i) = M_t s_{jt}(x_j, p_{jt}, r_i) \]  

The unobserved attribute \( \xi_j \) can be obtained numerically from equation (7) and moment conditions can be computed by interacting this vector with a set of appropriate instruments. The parameters that minimize this moment condition are the estimates of the demand function.

2. Horizontal and Vertical Innovation

Having obtained demand as functions of estimated parameters and the chosen quantities, we now turn back to the firm’s innovation decision problem. As described in the model introduction, the firm decides whether to innovate on a novelty drug – horizontal innovation – or imitate the existing one to produce generics or me-too drugs – vertical innovation. The firm’s profit function for horizontal innovation differs in two ways from that of vertical innovation in the following model. One difference is that the firm faces technological uncertainty, which inevitably comes along with the novelty drug innovation, when firm decides to pursue horizontal innovation. The other difference is that the fixed cost of horizontal innovation is greater than that of vertical innovation, reflecting the huge R&D costs involved in novelty drug innovation.

When we consider the success ratio of novelty drug innovations out of the applications for approval by the Food & Drug Administration (FDA) and the different phase trial, our assumption on technological uncertainty is necessary and reasonable. This technological uncertainty makes the firm’s expected profit on a novelty drug to be comparable to that of an imitated one. In addition, it gives the firm a dilemma to resolve before its innovation decision for profit maximization. Through the following model we unveil the process of resolution and the deterministic elements, which shape the firm’s innovation decision. We, first, define the firm’s profit function under horizontal innovation as follows:

\[ \Pi^h = \phi^h \left[ (p^h_mc^h(x^h, \phi^h)) \cdot q^h(x^h, p^h, mk^h, r^h) \right] - F_j(q^h) \]
where h denotes horizontal innovation and $F(q^h_j)$ is the fixed cost of innovation for drug $j^{11}$. Here, marginal cost $mc^h_j(\cdot)$ depends on the set of characteristics $x^h_j$ of horizontally innovated drugs and $\theta_t$ is a vector of exogenous parameters that changes over time. $\phi^v(\cdot)$ is the technological uncertainty parameter and will be specified in a later section.

In the case of vertical innovation, we define the firm’s profit function as follows:

$$\Pi^v_i = \phi^v_{it} \left[ \left( p^v_{it} - mc^v_i(x^v_i, \theta_t) \right) \cdot q_{it}(x^v_i, p^v_{it}, mk^v_i, r^v_i) \right] - F^v_i(q^v_i)$$  \hspace{1cm} (22)

where v denotes vertical innovation. Although, we dichotomize the drugs into horizontally and vertically innovated ones in the firm’s profit function above, we will allow continuous distribution of the degrees of innovation between horizontal and vertical innovation in the empirical application. By allowing for these degrees of innovation, we accommodate the complex features and degrees of innovation in the pharmaceutical industry.

3. Firm’s Pricing

Under the assumption that firms can change prices without cost, a firm’s pricing decision is the result of each period’s static optimization problem of profit functions as follows:

$$\max_{p^h_{it}} \left\{ \phi^h_{it} \left[ \left( p^h_{it} - mc^h_i(x^h_i, \theta_t) \right) \cdot q_{it}(x^h_i, p^h_{it}, mk^h_i, r^h_i) \right] - F^h_i(q^h_i) \right\}$$ \hspace{1cm} (23)

$$\max_{p^v_{it}} \left\{ \phi^v_{it} \left[ \left( p^v_{it} - mc^v_i(x^v_i, \theta_t) \right) \cdot q_{it}(x^v_i, p^v_{it}, mk^v_i, r^v_i) \right] - F^v_i(q^v_i) \right\}$$ \hspace{1cm} (24)

The subgame perfect Nash equilibrium of price can be obtained by deriving the static first order conditions of the pricing problem. Then, the obtained prices for each period are:

$$p^h_{it}(x^h_i, mk^h_i, r^h_i) = mc^h_i(x^h_i, \eta^h_i) + \frac{\phi^h_{it}}{\alpha^h}$$ \hspace{1cm} (25)

$$p^v_{it}(x^v_i, mk^v_i, r^v_i) = mc^v_i(x^v_i, \eta^v_i) + \frac{\phi^v_{it}}{\alpha^v}$$ \hspace{1cm} (26)

\footnote{Here, we assume constant and symmetric fixed costs for all horizontally innovated drugs for the simplicity of our model. Surely, the asymmetric structure of fixed cost is more realistic and we will allow variation of fixed costs depending on the drug later with observed data on fixed costs.}
Here, we assumed that the marginal costs are linear on \( x^l_i \), where \( i = h, v \) and \( l = j, k \). The technological uncertainty parameter \( \phi_j \) in equation (25) captures the firm’s strategic behavior of price discrimination for horizontally innovated drugs. Therefore, it captures the monopolistic pricing behavior of the firm during the patent periods of novelty drugs including the aspects of technological uncertainty mentioned in the previous section.

Based on the prices, which are endogenously determined, we can represent the demand functions as functions of drug characteristics and parameters as follows:

\[
q^h_{ji}(x^h_j, p^h_{ji}, m^h_{ji}, r^h_{ji}, \eta^h_j) = M^h_{ji} \frac{\exp(\delta^h_{ji})}{\exp(r_{ji})} = M^h_{ji} h(r_{ji}) \frac{\exp(\xi_j + c_j + \beta \cdot x_j - \alpha \cdot (y - (p^h_{ji}(x^h_j, m^h_{ji}, r^h_{ji}, \eta^h_j) - \mu_{ji}))) + m^h_{ji}}{\exp(r_{ji})} \tag{27}
\]

\[
q^v_{ki}(x^v_k, m^v_{ki}, r^v_{ki}, \eta^v_k) = M^v_{ki} \frac{\exp(\delta^v_{ki})}{\exp(r_{ki})} = M^v_{ki} h(r_{ki}) \frac{\exp(\xi_j + c_j + \beta \cdot x_j - \alpha \cdot (y - (p^v_{ki}(x^v_k, m^v_{ki}, r^v_{ki}, \eta^v_k) - \mu_{ki}))) + m^v_{ki}}{\exp(r_{ki})} \tag{28}
\]

4. Firms’ Strategic Innovation Decision

Having obtained the demand functions with only drug characteristics and their parameters, technological uncertainties, and state parameters, we can then obtain the expected sum of discounted profits from each innovation respectively as follows:

\[
V^h(x^h_j, m^h_{ji}, r^h_{ji}, \eta^h_j) = v^h(x^h_j, m^h_{ji}, r^h_{ji}, \eta^h_j) - F(q^h_j) = E_{r, \theta_j} \left\{ \sum_{i=1}^T \delta^h \phi^h_j \frac{q^h_{ji}(x^h_j, m^h_{ji}, r^h_{ji}, \eta^h_j)}{\alpha^h} \right\} - F(q^h_j) \tag{29}
\]

\[
V^v(x^v_k, m^v_{ki}, r^v_{ki}, \eta^v_k) = v^v(x^v_k, m^v_{ki}, r^v_{ki}, \eta^v_k) - F(q^v_k) = E_{r, \theta_k} \left\{ \sum_{i=1}^T \delta^v \phi^v_k \frac{q^v_{ki}(x^v_k, m^v_{ki}, r^v_{ki}, \eta^v_k)}{\alpha^v} \right\} - F(q^v_k) \tag{30}
\]

where \( V(\cdot) \) is net profit and \( v(\cdot) \) is revenue function, respectively. Here we assume that firms have perfect information about market potentials and the discount rate is the same for both horizontally and vertically innovated drugs. Expectations are taken
regarding \( r_i \) and \( \theta_i \), the estimated state parameters. The summation is up to period \( T \) when the drug is out of the market.\(^{12}\)

Now we turn to the firm’s innovation decision problem. As described in the introduction part of this section, the firm will create and introduce a new drug which is horizontally or vertically innovated with characteristics \( x_j \) and marketing effort \( m_k \) at time \( t \). The innovation decision depends on the difference between the expected sums of discounted profits from horizontal and vertical innovation. If the differences between the expected sums of discounted revenue between horizontal and vertical innovation is greater than that of the fixed cost from each innovation, the firm will innovate pursuing that strategy (horizontal or vertical) for which the expected revenue is greater than the fixed cost difference. Therefore, the firm’s innovation decision can be characterized as follows:

\[
\max_{r^*, r^-} \left\{ \max_{s_{j}} \left[ v^+ (N_j, s_j^+) - v^- (N_k, s_k^-), \quad RD^{r^*-r^-} \right] \right\}
\]

where \( RD^{r^*-r^-} = F(\Theta_j^+) - F(\Theta_k^-) \)

where \( r^* = h, v \) and \( r^- = v, h \), and \( h \) and \( v \) denote horizontal and vertical innovation, respectively. \( N_j \) is a vector of overall drug quality including not only the common characteristics for both horizontally and vertically innovated drugs, but also the idiosyncratic ones of each innovation. \( \Theta_j \) is a redefinition of the demand for drugs with \( N_j \) quality. We introduce \( N_j \) under the assumption that the overall drug characteristics, which encompass the characteristics of both types of strategies, are available for the firm’s strategic innovation decision. However, we will use the realized values of those characteristics in our empirical analysis. \( RD \) is the fixed cost difference between two different innovations. We further define the first term within the brackets in equation (31) as the incentive for strategic innovation, that is:

\[
I_{jkt}^{r^*} = v^+ (N_j, s_j^+) - v^- (N_k, s_k^-)
\]

Thus the firm will choose the optimal drug quality under the optimal strategic innovation decision – horizontal or vertical innovation – based on the first order condition of equation (32):

\[
\frac{\partial I_{jkt}^{r^*}}{\partial N_j} = \frac{v^+ (N_j, s_j^+) - v^- (N_k, s_k^-)}{\partial N_j} = 0
\]

\(^{12}\) Here we assume that firms’ innovation decisions have negligible effect on state variables. Therefore, \( V(\cdot) \) depends on the current state variables only, not on the future state variables, such as the characteristics of drugs that the firm introduces in the future or the effect of other firms’ decisions (Caranza Romero 2004).
Now, we impose the required constraints for the firm’s strategic innovation decision – resource constraints. Since a firm’s resources for innovation are limited, the firm has to balance their innovation behavior between horizontal and vertical innovation through drug quality and marketing efforts. In order to impose these constraints, we assume that the sum of quality levels and marketing levels are limited to a certain level within the firm as follows:

$$\sum_i q_{ij} + \sum_i m_{ik} = \bar{N}$$

$$\sum_i m_{ij} + \sum_i m_{ik} = \bar{MK}$$

Therefore, the firm’s strategic innovation decision becomes a choice of the optimal innovation strategy with the optimal quality level, which maximizes the expected sums of profits considering the resource constraints. Then, the incentive for strategic innovation can be rewritten using the characteristics’ variables and parameters, and state parameters as follows:

$$I_{jkt}^* = \frac{\phi^h M_j^i}{\alpha} \exp(c_j^* + \beta \cdot \bar{N}_j^* + \alpha \cdot p_j^* + \gamma \cdot m_j^* + \xi_j^*)$$

$$- \frac{\phi^v M_j^i}{\alpha} \exp(c_j^* + \beta \cdot (\bar{N} - \bar{N}_j^*) + \alpha \cdot p_j^* + \gamma \cdot (\bar{MK} - m_j^*) + \xi_j^*)$$

$$+ \frac{\phi^v M_j^i}{\alpha} \exp(c_j^* + \beta \cdot (\bar{N} - \bar{N}_j^*) + \alpha \cdot p_j^* + \gamma \cdot (\bar{MK} - m_j^*) + \xi_j^*)$$

$$\Delta^j = \xi_j^* + c_j^*$$. Therefore, by the first order condition of equation (33), we have the optimal condition for the incentive of strategic innovation decision as follows:

$$I_{jkt}^* = \frac{2\phi^h M_j^i h(r_j)}{\alpha \exp(r_j)} \exp(c_j^* + \beta \cdot \bar{N}_j^* + \alpha \cdot p_j^* + \gamma \cdot m_j^* + \xi_j^*)$$

Hence, the firm’s strategic innovation decision is made if the following condition is met:

$$R_{jkt}^* = I_{jkt}^* - RD_{jkt}^*$$

Although the constraints are appropriate in the case of vertical product differentiation, we can still apply these constraints in the case of horizontal product differentiation by using weighted sums of product quality, where consumers determine the weights.

We assume that the marginal price and marginal quality are the same across the markets for horizontally and vertically innovated drugs. However, by allowing consumer heterogeneity in our estimation of the demand function this will be relaxed in the empirical analysis.
where $RD^{t-i} = F(\Theta^{i}_t) - F(\Theta^{i}_i)$ is the difference in fixed costs between two different innovations. Now, by specifying the structure of $h(r_i)$, $M^{t}_i$, and $\phi^{h}_j$, we uncover the relationship between firms’ strategic innovation behavior and the rate of diffusion, market potential, and technological uncertainty, respectively.

First, we specify the function $h(r_i)$ with a logistic form\(^{15}\) as follows:

$$h(r_i) = \frac{a}{1 + \exp(r_i)}$$

(39)

where $a$ is the parameter which determines the rate of diffusion of a drug in the market. An estimated $a$ will capture the effect of drug diffusion on the firm’s innovation decision. If $a$ is high, this means that the diffusion rate is an important element of the firm’s innovation decision.

Second, we allow a random distribution of market potential, $M^{t}_i$, in order to uncover the relationship between market potential and the firm’s strategic decision as follows:

$$M^{t}_i = \overline{M}^{t}_i + m \cdot \sigma_{M} \quad \text{with} \quad \sigma_{M} \sim N(0,1)$$

(40)

where $\overline{M}^{t}_i$ is the mean of the distribution of $M^{t}_i$ and $m$ is the coefficient of market uncertainty distribution where $\sigma_{M}$ is distributed standard normal. Therefore, $m$ captures the importance of market uncertainty for the firm’s strategic innovation decision. If $m$ is high, this explains that the firm’s innovation decision depends on broad information about the market potential of the drug and vice versa. In other words, if $m$ is high, the market potential of an innovation substantially affects the firm’s innovation decision and, therefore, demand pull effects become important elements of the firm’s problem.

Third, we specify technological uncertainty, $\phi^{h}_j$, as follows:

$$\phi^{h}_j = \rho_0 + \rho_1 \cdot \Phi^{n}_j + \rho_2 \cdot \Phi^{p}_j + \rho_3 \cdot \Phi^{pe}_j + \rho_4 \cdot \Phi^{pg}_j + \nu_{\phi}$$

(41)

\(^{15}\) It has been shown that the function $h(\cdot)$ conforms to the general shape of a logistic form (Melnikov 2000).
where $\nu_\phi$ is the unobserved technological uncertainty with random error. Here, we consider the four aspects of technological uncertainty: the ratio of successful applications (RS), the ratio between patent approval and market introduction of novelty drugs (PI), the ratio between patent expiration and market withdrawal of novelty drugs (PE), and the ratio between patent expiration and introduction of generics (PG). The ratio of successful applications (RS) describes the major element in technological uncertainty, which exists during the late stage of drug innovation. This is a component that is both firm specific and innovation specific. That is, not only does past overall performance of the specific firm with regards to FDA applications matter, but also past performance of other firms with regards to FDA applications in the specific therapeutic area matter.

Concerning $RD^{i-\tau}$, we do not specify the its structure, rather we assume that all existing drugs have been introduced because the expected value of $R^i$ is positive for all $i$. Therefore, we can use the simulation methodology holding $RD^{i-\tau}$ to zero to find the set of parameters that best match the moment condition of the firm’s strategic innovation regarding $I^i$.

In addition, once we estimate all the variables of the strategic innovation decision, we further specify and substitute the state variable $r_i$ with the market competitive measure as follows:

$$r_i = \lambda_1 \cdot f(n_i) + \lambda_2 \cdot d_i + t + \epsilon,$$

where $f(n_i)$ is a function of the number of drugs in the market at time $t$ and $d_i$ is a dummy variable for the average remaining time of patents before they expire. By re-specifying the state variable as in equation (42), we can capture the market competition effect on the firm’s innovation decision. However, as already mentioned, we estimate equation (42) separately by substituting it into equation (38) when all the other parameters are estimated.

5. Estimation Strategy and Monte Carlo Experiments

In this section we perform a set of Monte-Carlo experiments to illustrate the applicability of our model. The estimation of the model requires two separate estimations depending on the set of parameters: demand and cost parameters, and strategic ones. We use random coefficients estimation methods for the estimation of demand and cost parameters (Berry, Levinsohn, and Pakes 1995) and simulation methods for that of the strategic ones.
Demand Side

Based on equations (5) and (6), we can obtain the market share functions for each drug with random coefficients considering patient characteristics as follows:

\[
\ln \left( \frac{s_{ji}}{s_{j}} \right) = \delta_{ji} - r_i \\
= c_j + x_{ji} \beta_i - \alpha_i \cdot \ln(y_i - (p_{ji} - \mu_{yi})) + mk_{ji} + \xi_j - r_i 
\]

with \( \left( \frac{\alpha}{\beta} \right) = \left( \frac{\alpha}{\beta} \right) + \Pi Ps_i + \Sigma \nu_i, \quad \nu_i \sim N(0, \sigma_i^2), \quad Ps_i \sim P_{ps}(Ps) \)

where \( Ps_i \) is a \( p \times 1 \) vector of patient characteristic variables, \( \nu_i \) captures the additional characteristics which is individual deviation from the average weight on the drug characteristics with mean zero and standard deviation \( \sigma_i \), and \( P_{ps} \) is a nonparametric distribution known from other data sources on patient characteristics. \( \Pi \) is a \((k+1) \times p\) matrix of coefficients and \( \Sigma \) is a \((k+1) \times (k+1)\) matrix of parameters. Then, the market share function can be decomposed as follow:

\[
\ln \left( \frac{s_{ji}}{s_{j}} \right) = \delta_{ji} + \mu_{ji} - r_i 
\]

where \( \theta_i = (\beta_i, ..., \beta_k, \gamma) \) is the set of parameters which is associated with consumer independent characteristics, \( \theta_2 = (\alpha, \sigma_1, ..., \sigma_k, \sigma_y) \) is the set of parameters associated with patient characteristics, and \( \nu_i = (y_i, \nu_{i1}, ..., \nu_{ik}, \nu_{iy}) \). Following Berry et al. (1995), the demand-side errors conditional on \( \theta_2 \) are,

\[
\xi_{ji} = \delta_{ji}(\theta_2) - [x_{ji}, mk_{ji}] \cdot \theta_1 - r_i 
\]

Cost Side

In order to estimate the cost function, we assume a log-linear marginal cost function. For a firm producing drug \( j \) with characteristics \( x_{ji} \) and marketing effort \( mk_{ji} \), the marginal cost is given by:

\[
\ln(c_{ji}) = [x_{ji}, mk_{ji}] \cdot \eta + \psi_{ji} 
\]

where \( \psi_{ji} \) is the unobserved idiosyncratic cost for drug \( j \). Therefore, we can rewrite the pricing equations of equation (25) and (26) with the functional form of the cost equation as follows:
\[
p_{ij}^* = \exp([x_{ij}^*, mk_{ij}^*] \cdot \eta + \psi_{ij}^*) + \frac{\tilde{\phi}_{ij}^*}{\alpha}
\]

Consequently, the errors from the supply side are given by

\[
\psi_{ij}^* = \ln \left( p_{ij}^* - \frac{\phi_{ij}^*}{\alpha} \right) - [x_{ij}^*, mk_{ij}^*] \cdot \eta
\]

\[
= \ln \left( p_{ij}^* - \frac{1}{\alpha} \left( \rho_0 + \rho_1 \cdot \Phi_{ij}^* + \rho_2 \cdot \Phi_{ij}^* + \rho_3 \cdot \Phi_{ij}^* + \rho_4 \cdot \Phi_{ij}^* + \nu_\phi \right) \right) - [x_{ij}^*, mk_{ij}^*] \cdot \eta
\]

However, since we have an unobserved technological uncertainty, \( \nu_{\phi} \), we rewrite the errors from the supply side as follows:

\[
\zeta_{ij}^* = \psi_{ij}^* - \ln(\alpha / \nu_{\phi})
\]

\[
= \ln \left( p_{ij}^* - \rho_0 - \rho_1 \cdot \Phi_{ij}^* - \rho_2 \cdot \Phi_{ij}^* - \rho_3 \cdot \Phi_{ij}^* - \rho_4 \cdot \Phi_{ij}^* \right) - [x_{ij}^*, mk_{ij}^*] \cdot \eta
\]

Since, price is correlated with the error term in the demand function (\( \xi_{ij}^* \)) and the error term in the cost function (\( \zeta_{ij}^* \)), we use instrumental variables for the estimation of parameters. In addition, we can gain efficiency from using a simultaneous-equations estimation method, because the error terms of demand and cost functions are correlated. Therefore, Generalized Method of Moments (GMM) is desirable to estimate the model following Berry et al. (1995). Let \( z \) be a set of valid instruments to be used. That is, \( z \) is exogenous and independent of the errors terms in the demand and price equations, \( \xi_{ij} \) and \( \zeta_{ij} \). Then, we can obtain a set of moment conditions as follows:

\[
\{ \xi_{ij}^*, z \} = 0 \quad (45)
\]

\[
\{ \zeta_{ij}^*, z \} = 0 \quad (46)
\]

After solving numerically for the unobserved \( \xi_{ij} \) and \( \zeta_{ij} \), the estimates of demand and cost parameters \( \theta = \{ \theta_1, \theta_2, r_{i=1..T}, \rho, \eta \} \) where \( \rho = (\rho_0, \rho_1, \rho_2, \rho_3, \rho_4) \) are obtained as follows. Let \( \zeta = (\zeta^*, \zeta^*) \). Then by minimizing the following GMM estimator, we can obtain the estimates \( \hat{\theta} \):

\[
\min_{\theta} \zeta' z (z' \Omega z)^{-1} z \zeta
\]

where \( \Omega \) is the standard weighting matrix given by \( E(\zeta \zeta') \).
Value Matrix Calculation

In order to estimate the strategic parameters in equation (38), we need to calculate the incentive for strategic innovation \( (I') \) for each of drug in the market. In order to do so, we first calculate the discounted sums of revenues for all drugs \( (v') \) using the estimated parameters of the demand and cost functions and create a value matrix. The value matrix contains the amount of incentive gains \( (I') \) of each drug compared to that of other drugs available in the market. In establishing the value matrix, we no more discriminate drugs into horizontally or vertically innovated ones. Rather, we allow the continuous and relative realization of the different strategic incentives for each drug. For example, if the amount of differences in innovation incentives between two drugs is large, we can recognize that the drug with higher incentive is closer to horizontally innovated drug comparatively and vice versa. Consequently, the value matrix reveals the overall structure of innovation incentive for all drugs in the market. The value matrix can be computed based on equations (29) and (30) using the estimated parameters.

Strategic Innovation Incentives

Once we obtain the value matrix, we estimate strategic parameters using equation (38). However, as we mentioned earlier, we assume that all drugs in the market are introduced right after they have positive incentive to innovate, \( \Re I > 0 \). Therefore, we will only consider the part of strategic incentive gains \( (I') \) in our estimation of strategic variables\(^\text{16}\). Therefore, in order to estimate the strategic parameters in \( I' \), we use a Simulated Method of Moments (SMM) with the realized and predicted gains of the innovation incentive \( (I') \). In order to do that, we rewrite equation (37) with the strategic variables as follows:

\[
\hat{f}_{j\mu} = \frac{2 \cdot \alpha \cdot (\hat{c}_j + v \cdot \sigma_v) \cdot (\hat{M}_{j\mu} + m \cdot \sigma_m) \cdot \exp(\hat{\Delta}_j + \hat{\xi}_j)}{\alpha \exp(\hat{r}_j)(1 + \exp(\hat{r}_j))}
\]

where

\[
v \cdot \sigma_v = \nu, \quad \sigma_v \sim N(0,1)
\]

\[
\hat{\Delta}_j = \hat{c}_j + \hat{B} \cdot \hat{V}_j + \hat{\alpha} \cdot p_{j\mu} + \hat{\gamma} \cdot m_k
\]

\(^\text{16}\) We can estimate the difference in fixed costs, \( RD_{j\mu}^{I' - \tau} \), for each drug pair in the value matrix using the simulated method of moments, after we specify the structure of \( RD_{j\mu}^{I' - \tau} \). However, we will only focus on the strategic part of the incentive gain for the simplicity of the estimation.
\[
\hat{\phi}_{jt} = \hat{\rho}_0 + \hat{\rho}_1 \cdot \Phi_{jt}^\nu + \hat{\rho}_2 \cdot \Phi_{jt}^{pl} + \hat{\rho}_3 \cdot \Phi_{jt}^{pe} + \hat{\rho}_4 \cdot \Phi_{jt}^{pe}
\]

where \( \Delta_{jt}^\ast \) and \( \dot{\phi}_{jt}^\ast \) are predicted values of mean utility and technological uncertainty from the estimation of the demand and cost functions. In order to make the estimation of equation (48) possible, we assume that \( \nu_{jt} \) has normal distribution with standard error \( \nu_{jt} \). Therefore, we can rewrite equation (48) as follows with a logarithmic form:

\[
\Theta_{jt} = \ln(2 \cdot a) + \ln(\dot{\phi}_{jt}^\ast + \nu \cdot \sigma_{jt}) + \ln(M_{jt}^\ast + m \cdot \sigma_{jt}) + \xi_{jt}^{\ast*}
\]

where

\[
\Theta_{jt} = \ln \left( \frac{\hat{\alpha} \cdot I_{jt}^\ast \cdot \hat{\epsilon}_t \cdot (1 + \exp(\hat{\epsilon}_t))}{\exp(\Delta_{jt}^\ast)} \right)
\]

Hence, \( \Theta_{jt} \) becomes

\[
\Theta_{jt} = \int \ln(2 \cdot a) + \ln(\dot{\phi}_{jt}^\ast + \nu \cdot \sigma_{jt}) + \ln(M_{jt}^\ast + m \cdot \sigma_{jt}) + \xi_{jt}^{\ast*} \right) P(\theta) \] P(\theta) \]

where \( P(\theta) \) is the joint distribution over all of the elements of \( \theta = (\sigma_{jt}, \sigma_{jt}) \). The equation above involves a log integral that has no closed form. Hence, we need to use simulation to compute the above integral. Drawing \( n \) vectors of \( \theta \) from \( P(\theta) \), we have the following moment conditions:

\[
\Theta_{jt} = \frac{1}{n} \sum_{\theta=1}^{n} \left[ \ln(2 \cdot a) + \ln(\dot{\phi}_{jt}^\ast + \nu \cdot \sigma_{jt}) + \ln(M_{jt}^\ast + m \cdot \sigma_{jt}) + \xi_{jt}^{\ast*} \right]
\]

Here, we have \( L \) number of moment conditions depending on the value matrix in which \( L \) numbers of drugs are innovated by same firms, although we have only three parameters to be estimated.

In addition, we further estimate the state variable \( \hat{r}_t \) with the market competitive measure as follows:

\[
r_t = \lambda_1 \cdot \ln(n_t) + \lambda_2 \cdot d_t + t + \epsilon_t, \quad (42)
\]

where we assume a logarithmic functional form for the number of drugs in the market at time \( t \).
Fixed Cost Estimation

Under fixed (estimated) $a$, $M^h$, and $\dot{r}^h$ we get:

$$F(q^h) = \varphi_q + \varphi_{DT} DT_{jk} + \varphi_{CN} \cdot NC_{jkt} + \varphi_{SB} \cdot SB_{jk} + \varepsilon_t$$

where $DT_{jk}$ is the Development Time for drugs $j$ before it is introduced into market, $NC_{jkt}$ is the Number of Corporative R&D activities for the development of drug $j$, $SB_{jk}$ is the Amount of R&D Subsidies from public institutes for the development of drug $j$.

Technological Uncertainty Estimation

$$\hat{\Phi}^h = \hat{\rho}_0 + \hat{\rho}_1 \cdot \Phi^* + \hat{\rho}_2 \cdot \Phi^{pe} + \hat{\rho}_3 \cdot \Phi^{pc} + \hat{\rho}_4 \cdot \Phi^{Pc}$$

Market Size and Outside Options

- Estimation of Market Potential
  - Market potential with market expansion and category cannibalization
Market potential Estimation

a) First competitive drug introduction: \( t = [j + 1, j + 2] \)

\[
\begin{align*}
    n_{0, t} &= M_t - n_{j+1,t} - n_{j,t} \\
    n_{j+1,t} &= q_1 n_{0,t-1} + w_1 n_{j,t-1} + \varepsilon_t \\
    n_{j,t} &= k_1 n_{0,t-1} + (1 - w_1) n_{j,t-1} + \varepsilon_t \quad \text{where} \quad q_1 + k_1 < 1 \\
    M_{j,t} &= n_{j,t} + k_1 n_{0,t} - \hat{w}_1 n_{j,t} \\
    M_{j+1,t} &= n_{j+1,t} + q_1 n_{0,t} + \hat{w}_1 n_{j,t}
\end{align*}
\]

b) Second competitive drug introduction: \( t = [j + 2, j + 3] \)

\[
\begin{align*}
    n_{0, t} &= M_t - n_{j+2,t} - n_{j+1,t} - n_{j,t} \\
    n_{j+2,t} &= q_2 n_{0,t-1} + w_2 (n_{j,t-1} + n_{j+1,t-1}) + \varepsilon_t \\
    n_{j,t} + n_{j+1,t} &= k_2 n_{0,t-1} + (1 - w_2) (n_{j,t-1} + n_{j+1,t-1}) \\
    n_{j+1,t} &= q_1 (1 - q_2) n_{0,t-1} + w_1 (1 - w_2) n_{j,t-1} - w_2 n_{j+1,t-1} + \varepsilon_t \\
    n_{j,t} &= k_1 (1 - k_1) n_{0,t-1} + (1 - w_1) (1 - w_2) n_{j,t-1} + \varepsilon_t \quad \text{where} \quad q_2 + k_2 < 1 \\
    M_{j,t} &= n_{j,t} + k_1 (1 - k_1) n_{0,t} - \hat{w}_1 (1 - \hat{w}_2) n_{j,t} - \hat{w}_2 n_{j,t} \\
    M_{j+1,t} &= n_{j+1,t} + \hat{q}_1 (1 - \hat{q}_2) n_{0,t} + \hat{w}_1 (1 - \hat{w}_2) n_{j,t} - \hat{w}_2 n_{j+1,t} \\
    M_{j+2,t} &= n_{j+2,t} + \hat{q}_2 n_{0,t} + \hat{w}_2 (n_{j,t} + n_{j+1,t})
\end{align*}
\]

c) Generalization for further entrance a la Lilien et al (1981) and Hahn et al (1994)
IV. Application

1. Horizontal and Vertical Innovation in Pharmaceutical Market

Before we estimate our model, we introduce our categorization of firms’ innovation strategies – horizontal and vertical innovation. The drugs are then, categorized into horizontally (HI) and vertically (VI) innovated drugs based on the corresponding innovation strategies. Horizontal innovation is to introduce new and horizontally differentiated characteristics into a product expanding or substituting the scope of existing products’ variants. For example, the innovation of Viagra® by Pfizer in 1998 is a pure horizontal innovation since at the time of introduction it involved the first pharmacological cure of erectile dysfunction. In contrast, vertical innovation is to introduce vertically differentiated characteristics into a product in order to cannibalize the demand for existing products. For example, the introduction of Prozac® Weekly™ by Eli Lilly in 2001 is an example of pure vertical innovation since, at the point of its introduction, Prozac®\textsuperscript{17} already existed; the differentiated characteristic being dosage frequency. A different example of vertical innovation would be the introduction of a generic counterpart of a branded drug, post patent expiration.

However, for many of pharmaceutical products their innovation has both types of features in its characteristics – vertical and horizontal. Therefore, we first categorize the antidepressants into horizontal and vertical innovation based on certain assumptions.

\textsuperscript{17} Prozac® was introduced by Eli Lilly in 1988.
References


