# Encyclopedia of Pharmaceutical Technology

# Volume 5

Editors

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# ENCYCLOPEDIA OF PHARMACEUTICAL TECHNOLOGY

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#### **VOLUME 5**

ECONOMIC CHARACTERISTICS OF THE R&D-INTENSIVE PHARMACEUTICAL INDUSTRY TO FERMENTATION PROCESSES

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# Economic Characteristics of the R&D-Intensive Pharmaceutical Industry

#### Introduction

This article presents a sketch of a theory of the economics of the R&D-intensive ethical pharmaceutical industry, highlighting its dynamic characteristics. The approach taken here minimizes the use of static analysis and thus avoids the use of pure or perfect competition as an analytical tool. In this theoretical discussion, certain empirical studies will be cited as support for aspects of the theory being developed. The theory that will be outlined is primarily descriptive and may not be applicable to rigorous mathematical or graphical exposition.

The theory discussed here will concentrate on allocative efficiency, but as with all discussions of allocative efficiency, elements of technical efficiency will automatically be involved and at least implicit recognition of these elements will be evident. The allocative efficiency concerns will be placed in a dynamic framework; we will be attempting to establish a notion of "dynamic pure competition" that has analytical and policy implications. The concept of dynamic pure competition will describe a hybrid form of workable competition as the term is used by industrial organization economists.

#### **An Outline of a Competitive Process**

Before we get into an outline of the theory of pharmaceutical economics, we need to establish pure dynamic competition as a competitive process. This is a process that has been recognized by many economists, and it is emphasized here in order to establish an analytical context for the pharmaceutical industry [1].

Traditional microeconomics has assumed implicitly that the "natural state" is one that is depicted by pure competition. Deviations from the natural state occur as a disequilibrium, by the establishment of monopoly, or through other often cited market failures. In cases of disequilibrium, the tatonnement will bring us to the equilibrium ideal of pure competition. Interestingly, the model of pure competition never really describes the process of the tatônnement (equilibration) but only the conditions necessary for the process to operate and the final equilibrium to result when the process has worked itself out.

The monopoly deviation arises because the nature of economic man\* causes him or her to attempt to break out of a pure competitive equilibrium, or the equilibrating tatonnement process, and maximize his or her own economic situation relative to the rest of the world. The economic man will attempt to establish a monopoly position through "entry barrier" means.

According to traditional microeconomics, then, the natural economic process

<sup>\*</sup>The term economic man as used throughout this article applies to males and females equally.

is one that proceeds from the natural state of pure competitive equilibrium, or from where the necessary conditions exist for the pure competitive tatonnement process to take place, to conditions of monopoly.

It seems that this "monopoly process" is really a "competitive process" turned on its head. The natural economic state may be one of monopoly, in the traditional sense, and the process that occurs is one in which economic forces are constantly operating to erode the naturally occurring monopoly (not to be confused with a natural monopoly) [2].

An example of this competitive process can be seen by going back to the beginning of humanity. When there were only two persons on earth, and given conditions of scarcity and unlimited wants, then a natural state of "monopoly" automatically occurred. This is because of the inherent comparative advantage that one person would have over the other in utilizing resources to produce goods and services. These comparative advantages generate a natural state of "monopoly." That this can cause a tending toward efficiency from the standpoint of society is evident when we consider that society must forego the benefits of the efficiencies of the individual with the comparative advantages. In addition, the "monopoly power" of the individual with the comparative advantage would serve as an incentive for others to engage in this activity as the population grew.

Entrepreneurship is very crucial in establishing a process, under this natural monopoly state, that generates a dynamic efficiency. Entrepreneurial ability is required for people to establish their initial comparative advantage—and it is required for those who observe the profit opportunities of the individuals with the initially established monopoly positions. The concept of the entrepreneur is important here in that he or she has the motivation to constantly seek out opportunities to improve his or her economic position. In doing this, the entrepreneur will seek ways to provide goods and services to consumers or "substitutes" for goods and services that represented initial monopolies. These substitutes provide the means of breaking up the temporary monopoly power of the individual providing the first good or service. Sometimes the new product may represent a less costly version of the initial product, but if the entrepreneur is particularly astute, it may also represent a good or a service that provides greater utility to consumers. That consumers will act upon these "innovations" from producers and thus reward entrepreneurship comes from the basic symmetry of economic man in that he or she attempts to maximize his or her economic position through both incomeproducing activities and consumer want satisfaction activities.

Economic man uses goods and services as inputs to produce satisfaction, and wants to economize on the use of these inputs [3]. It is the role of the entrepreneur to "exploit" this desire on the part of consumers to economize on the production of satisfaction. In doing this, the entrepreneur may establish a transitory monopoly position, but the consumer, in face of the alternatives, is better off, especially as other entrepreneurs will continue to seek this exploitation of opportunities through time.

Consumers maximize their positions through current consumption activities as well as through improved consumption possibilities in the future—in terms of lower costs and improved utilities [4]. To get these improved consumption possibilities, consumers must forego current consumption that may appear to be the static monopoly rents of producing entrepreneurs. These monopoly rents serve as the primary incentive and in many cases provide the wherewithal to generate even

further improved goods and services. Thus, these are the dynamic social opportunity costs of producing greater benefits in the future [5].

The competitive process that is relevant here is one in which a naturally occurring monopoly is systematically faced with a pressure that erodes this position. Remember that it is a process that occurs on a continuum and which must be considered on the basis of changes through time. Reverting to the static sense, the deadweight welfare loss is a representation of the social opportunity cost that is associated with having entrepreneurs invading previously held monopoly positions by providing new and improved products and services. This in turn represents the economic progress that generates welfare gains. Through time economic life is characterized as a continual process of monopoly establishment and systematic erosion via entrepreneurial activity. This entrepreneurial activity constitutes the observation of and action upon profit opportunities as evidenced by static monopoly rents.

We can think of dynamic pure competition as a process where naturally occurring monopoly is systematically eroded. It represents a kind of entropy that properly allocates resources in the production of current and future goods and services.

The underlying characteristics of the competitive process are that it recognizes that economic imperfections are inherent; that economic man realizes this as a matter of course; and he or she is willing to compensate economic agents who act to ameliorate these imperfections.

# Basic Assumptions for a Model of Pharmaceutical Industry Competition and a Theory of the Pharmaceutical Firm

Keeping in mind the somewhat incomplete and not necessarily new view of competition as a dynamic process that generates allocative efficiency through time, we will now attempt to outline the process of competition in the pharmaceutical industry. The description of this competitive process is Schumpeterian in spirit. An excellent summary of Schumpeterian competition has been given by Nelson and Winter [6], and this summary applies to the concepts we are trying to develop for the pharmaceutical industry.

In modern formal theory, the virtues ascribed to competition are the virtues of an achieved state of efficient allocation, an essentially static condition that can be "sustained" by prices and price-taking calculations. Joseph Schumpeter's version of competition, on the other hand, is a vision of an ongoing dynamic process, of a market system generating irreversible change in the course of historical time. The difference is profound; if it were not the case that both sets of ideas are presumably intended to illuminate the same reality, one would certainly regard them as belonging to separate subjects.

The key point is that in the modern competitive equilibrium story, what can be done is objectively and clearly defined. The question—both for the individual actor confronting his choice set, and in the analysis of the system as a whole—is what should be done. In the Schumpeterian scheme, the limits of what can be done are never fixed and never clearly in view. Discovering what can be done is part of the problem for the individual actor, and in analysis of the wider system, its performance as a social device for probing

and expanding the limits of the possible is the fundamental concern. (Of course, the question of what should be done remains, and becomes more difficult as a consequence of the vagueness of the opportunities.)

Because of this central difference, a number of specific features of economic reality and specific theoretical approaches are seen in a very different light. Information imperfections, and informational differences among the actors, are not complications of the basic structure, but are central to the Schumpeterian scheme. The gains obtainable by guessing better and acting sooner are not a mere will-o-the-wisp, luring the actors toward inevitable frustration in equilibrium, but are the crucial motive power and adaptive mechanism of a system that is permanently in disequilibrium. And, because it arises from a continual unfolding of unanticipated possibilities, the disequilibrium is disequilibrium in the fundamental sense: Expectations are not being realized; mistakes are being made and corrections attempted.

It is plausible that the task of developing formal models is intrinsically more difficult in Schumpeterian theory than in modern orthodoxy. As the above remarks should make clear, the most powerful abstractions and simplifications of orthodoxy are inappropriate or ineffective in the Schumpeterian context. As we have argued elsewhere, the absence of formal theory probably accounts for the relative neglect of Schumpeterian ideas, ideas that, at the informal "appreciative" level, many economists find productive and persuasive.

When discussing this competitive process, the essential point to keep in mind is that it attempts to establish that resources are being properly allocated for current pharmaceutical products as well as for the generation of new pharmaceutical products.

Thus, the descriptive model of the competitive process in the pharmaceutical industry that we will attempt to develop emphasizes change and adaptation to change as well as recognizes the existence of economic agents—both consuming and producing—who anticipate the future and act on the opportunities provided by their foresight.

Our model of the economics of the pharmaceutical industry has four basic assumptions:

- 1. There is price sensitivity on the part of pharmaceutical consumers or, in particular, their agents, for new products as well as for existing products.
- 2. Research and development (R&D) serves as the primary catalyst for change among drug firms and is the focal point of entrepreneurial activity that ensures dynamic welfare gains (a continuum of static welfare losses being offset by concomitant higher utility, yielding benefits from new products and systematic erosion of monopoly power through price pressures for older products). As an institutional consideration, there will be a substantial number of firms intensively engaged in R&D activity.
- 3. The utility benefits from even small improvements in therapy can theoretically offset substantial differences in the prices of the new improvement relative to existing drug therapies. (This is basically a corollary to assumption 2.)
- **4.** The economic profitability of the industry will reflect all dynamic opportunity costs and will through time tend toward normal returns. As such, economic profitability serves as the ultimate guide to the proper allocation of resources as it does with the pure competitive model.

It is necessary to elaborate further on assumptions 1 and 3. Assumption 1 is contrary to the conventional assumption that physicians are insensitive to the prices of pharmaceutical products and therefore demand is relatively price-inelastic.

The price sensitivity issue is partially and implicitly addressed in the works of Cocks and Virts [7] and Cocks [8], who show a significant lack of price rigidity in various drug markets and among individual drug products. But its clearest discussion is given by Brozen [9]:

The Cocks data also destroy the common fiction of rigid prices for drugs and the fiction of inelastic demands for each of these patented products. Prices are remarkably flexible, thus producing large effects on market position. Leading products in the anti-infective market, for example, suffered price declines from 1962 to 1971 ranging from 7 percent (for product number 8) to 67 percent (for product number 3). The average price decline in this inflationary period for these products was 32%, while the consumer price index rose 34%. The price of leading anti-infectives fell by 51% in constant dollars. That is a remarkable record.

Sales of these products also demonstrate what a complete fiction is the story that the average physician pays no attention to prices in writing prescriptions. Product 11 among the anti-infectives languished at 0.1% of the market for 5 years until it had cut its price by 47%. At that point, its market share rose to 0.7%, a sixfold increase. Another 14% price cut raised its market share another 170%. Still further cuts over the next three years amounting to 12% raised its market share by still another 68%. This would seem to demonstrate a remarkably high price elasticity of demand for a branded patented product; particularly in view of the price cuts of competitive products.

Product number 3 had a fading market position from 1962 through 1969 despite its price cuts, but then a 16% price cut in 1970 stopped the decline and added 14% to its market share. A further 27% cut in 1971 jumped its market share by another 40%. The market for ethical drugs responds remarkably vigorously to price changes, the myth of the price-insensitive prescribing physician to the contrary notwithstanding.

There appears to be competition among the products within each class despite whatever unique features each possesses. A product only singular enough to win 0.1% of the market over a five-year span won a 310 percent increase in market share when it cut its price relative to most of the other products in its market. A fading product turned itself around and reclaimed a major portion of its market position as it undertook similar price action.

A study by Reekie provides a more systematic analysis of pricing behavior regarding pharmaceutical products [10]. This study provides a statistically strong inference that physicians are indeed sensitive to drug prices. The paper provides statistical evidence on pharmaceutical product price elasticity in which the coefficient of elasticity is determined to be greater than 1. Schwartzman also provides significant evidence on the amount of price competition in the pharmaceutical industry, especially in the area of antibiotics [11].

It should be pointed out that physicians very likely do not know the exact prices of various products. Rather, it is likely that they know the relative prices of various products on an order of magnitude basis. This is enough to cause the relative price elasticity found by Reekie.

There may be at least two hypothetical reasons why physicians are sensitive to the prices of pharmaceutical products. One explanation is the entrepreneurial proclivity of the physician. Recall that we are applying the Kirzner concept of the entrepreneur as one who attempts to exploit consumers' desire to economize on their inputs in the production of satisfaction. The physician is possibly motivated to engage in this entrepreneurial activity because he or she acts as the patients' agent in choosing the inputs, and thus enhances economic position by maintaining and expanding his or her patient base. In this entrepreneurial activity as applied to prices of pharmaceuticals, the focal point of physicians' price sensitivity is hedonic prices. That is, they are aware of the price-quality (relative to various drug alternatives as well as other therapeutic alternatives), and thus their actions in this agency relationship fulfill the conditions of entrepreneurial behavior. This is especially crucial in a market environment when new product introduction is occurring on a continual basis.

The second reason that physicians may be sensitive to the relative prices of pharmaceuticals occurs because of the role of "detail people." Although individual detail people may or may not talk about the price of their own product, it is very likely that they will point out the relative price difference of their product compared to a newly introduced, higher-priced product or an already existing product. Detail people with new products will point out the hedonic price—the price—quality relationships—that actually represents a total cost saving even though the nominal price of the product may be higher. The symmetry of this price sensitivity on the part of physicians is embodied in the strong inferences that we can gain from empirical studies; drug firms behave as if they are aware of physician price sensitivity. This was also articulated by Brozen [12] and is implied through the price volatility and the price-volume volatility found in the Cocks and Virts [13] and Cocks [14] research. Likewise, the Reekie work yields the strong inference that drug firms respond to physicians' price sensitivity.

In looking at assumption 3, that the utility benefits from even small improvements in drug therapy can theoretically offset substantial differences in the prices of the new improvement relative to existing drug therapies, we can gain insight into its implications by resorting to static consumer theory [15]. Assume that it is possible for the consumer (or the agent, the physician) to choose between two products. To simplify, and to put the analysis in a general equilibrium framework, assume there are only two products in the economy; these products are pharmaceutical products, and there is one representative household. One of the products will be produced competitively with the necessary condition that price equals marginal cost. (The difficulty of the concept of marginal cost as it applies to pharmaceutical firms will be discussed later.) The other product will be a new product that is initially not available. We want to analyze the welfare implications of its introduction.

In addressing the welfare implications of a new product, we will place the analysis in the framework of Bergson [16]:

As J. R. Hicks taught us long ago, consumer's surplus is susceptible to diverse constructions. The particular construction need not be a practically very important matter, but we may conveniently consider the evaluations that have been made in relation to a concept of surplus corresponding to the compensating variation as understood by Hicks, . . . i.e., the compensatory change in income needed to assure that a household's utility is unaffected by a change in price.