

Strategic Under-utilization of Patents and Entry Deterrence:
The Case of Pharmaceutical Industry

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(2006)

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Abstract

This paper seeks to explain why some pharmaceutical companies are observed to withdraw their products before patents are expired and simultaneously introduce new patented (competing) products. Given the specific nature of drug markets, the companies in fact increase the entry cost of the potential generic drug manufacturers and thereby lessen competition for new drugs. The paper determines the optimal date of withdrawing the product and studies comparative static effects of the change of parameters underlying the model.

Keywords: Patent protection, patent expiry, pharmaceutical industries, generic drugs, entry cost.

JEL Classification Numbers: L1, O3.

1. Introduction

International patent rules have come into existence after the Uruguay Round of Multilateral Trade Negotiations under the GATT and are being enforced by the World Trade Organization (WTO). Before the GATT resolution, the norms and standards of intellectual property protection in the international context were governed by the World Intellectual Property Organization (WIPO). The WIPO, as contrary to WTO, had neither enforcing power nor dispute settlement mechanism; it gave the countries flexibility to design their own patent rules, and choose the coverage of patentability. As a result, there were various products like agricultural machinery, fertilizers, chemical products, food products, pharmaceutical products, etc. which were excluded from patenting in many developing countries. But the GATT based patent system has called for a uniform patent protection for all products including pharmaceuticals, genetically engineered organisms, plants and animal varieties for 20 years.

This has given rise to acrimonious debate between the developed and the developing countries.¹ In the present paper the issue at hand is pharmaceutical industry. In fact, the proposal requiring product patents for pharmaceutical innovations has been one of the most sensitive issues. This has evoked a considerable debate and differences of opinion among the economists and industrialists. While the developing countries think that the medical discoveries should be available free of patents, the developed countries call for a stronger international patent protection so as to ensure high prices and high profits in the pharmaceutical industry, given industry's uniquely high and risky expenditures on research, development and introduction of new products.²

In the context of pharmaceutical industry, problems usually dealt with in the literature reflect the concern over the impact of patent rights on the prices of generic products, rates of innovation, and welfare of the trading nations. For this literature one may look at, for instance, Frank and Salkever (1992), Grabsowski and Vernon (1992), Nogues (1993), Watal (1996) and Lanjouw (1997). However, this paper highlights a

¹ Already there is a large literature focusing on the north-south debate on IPRs. Interested readers may look at Chin and Grossman (1991), Maskus (1990), Diwan and Rodrik (1991), Deardorff (1992), Aoki and Prusa (1993), Helpman (1993), Taylor (1994), Grinols and Lin (1997), Yang (1998), Marjit and Beladi (1998), Kabiraj (2000), Grossman and Lai (2004), etc.

² Scherer (2002) discusses the question of whether global welfare is higher under uniform pharmaceutical patent standards or with free riding.

different problem. This is motivated from the survey results of Dutta (2003). It is found that some pharmaceutical companies withdraw patented drugs before the expiry of patent period and simultaneously introduce a new patented drug. Though this seems to be strange, as it cuts back the initial period of monopoly for the patent holder, we argue that this type of strategy has a deeper implication. In particular, such a strategy adversely affects entry of the potential firms who wait to introduce the generic drug once the patent period is over, and hence it has implication for drug prices.³

Entry in the drug market depends on the following consideration. The traditional system allowed process patenting and encouraged inventing around. This enabled the firms to develop commercial production capabilities for on-patent drugs before patent expiry and then compete in the world market as soon as the patent elapsed. Market entry by generics was limited only to the extent they would have to take pioneer's tests before gaining market approval. Thus the originator had to face a tough challenge from the imitators even during the patent period. And after expiry of the patent, its profits drop substantially due to competition from the generic substitutes. In the new patent system, process patenting as well as compulsory licensing has been almost scrapped. Hence the innovator, the patentee enjoys almost monopoly for the whole stretch of the patent period.

Theoretically, even under the new patent system, pioneer's profits should drop to an insignificant amount after the patent expiry with the entry of generics. In practice, this never happens because of the peculiar nature of the pharmaceutical products as a whole. Typically, pharmaceuticals are cited as an example of first-mover advantage. First-movers have natural product differentiation advantages that permit them to charge higher prices and retain substantial market shares (see Conrad (1983) and Schmalensee (1982), and Scherer and Ross (1990)). There is a strong brand loyalty in pharmaceuticals for innovative brands over generic competitors. Once physicians gain experience with a new drug during its period of patent exclusivity, then even when patents expire and cheaper substitutes become available, many physicians might remain insensitive to the lower-price opportunities, and therefore they continue to prescribe the branded product. In

³ For the literature on entry deterrence see, in particular, Dixit (1980), Milgrom and Roberts (1982), and Salop and Schiefman (1983).

pharmaceutical industry, the consumers and the consumption decision-makers (that is, physicians) are not the same, and sometimes the consumers are not the ultimate contributors due to existence of the third party reimbursement schemes. The combination of all these factors makes demand for the branded product stronger and less elastic. On the supply side entry of the potential firms is restricted to the extent they will have to incur costs on getting market access in the post-patent period. There are evidence showing that after patent expiry the price of the branded product has gone up and that there has been only marginal market share gain by generic entrants even several years after patent expiration (see, for instance, Statman (1981), Frank and Salkever (1992), and Grabowski and Vernon (1992)).⁴

This paper refers to the situation when the patent holder intends to deter by means of withdrawing the existing patented product from circulation and then introducing a new patented substitute. The withdrawal date is optimally chosen by the incumbent and is chosen earlier than the expiry date of the patent. The role of the prescribing medical practitioners is very important in this context since their prescriptions in a way determine the marketability of the medicines. The new drug is introduced with the pretext that it has new and interesting characteristics. It gets prescribed before the generic substitutes of the old drug have a chance to appear, since the patent period for the old drug is yet not over. Since doctors often are not fond of prescribing drugs that have gone out of fashion, the potential entrants of the generic drugs find it tough to compete after entry since the original drug itself is out of circulation for some time. There is no taker for their generic substitute and a newer form of the original drug already reaches the market. This is the case where deliberate withdrawal of patented drug even before the expiry of the patent period leaves the potential entrants at a disadvantage and acts as an entry deterring strategy.

The empirical support of our theory is drawn, as mentioned earlier, from the survey reported in Dutta (2003). For a molecule named *Nitrofurantoin*, initially the normal tablet was patented for twenty years. Close to the expiry, a new formulation naming, *Vincristine*, was introduced and a patent was again taken. Next, before

⁴ Indian case shows that in 1998 patented drugs constituted 84.7 % market share in anti-hypertensive, 70.3% in Quinolones and 56.7% in anti-ulcerants.

completing the term of twenty years, a new patent was taken on the solution form of Vincristine, saying that the new form is even more stable. The original drug was withdrawn while marketing the new drug. Another example is *Cyclosporin*. Close to the expiry of the patent, the patentee introduced a new micro-emulsion form of the drug. Doctors are usually not interested in prescribing drugs which are not vigorously marketed. The cause behind this is that they derive the knowledge of new drugs from the medical representatives, who constitute the backbone of pharmaceutical marketing. A survey on doctors from Calcutta and Bolpur, a district town in West Bengal, India, revealed that sixty per cent of the doctors surveyed collected information about new drugs from the representatives, though they seldom received any detailing about the chemical and biological characteristics from them. The pharmaceutical companies stress on heavy marketing of new molecules. If they decrease the marketing expenditure in the post patent expiry period, the market share of those drugs fall fast because the memory of the doctors is short. On the other hand, if the firms find that there is no new generation substitute in the pipeline, they increase promotional expenditures on them. This may increase their market share even after expiry of the patents. For example, market shares of *Sulphamides* and anti-depressants increased after patent expiry in early 70's due to the boost up in promotional expenditures (Slatter, 1977).

We construct a simple dynamic model of an entry game capturing the above facts. The key feature of the model is that early withdrawal of the patented drug increases the entry costs of the potential entrants with generic substitutes. Although we do not model the strategy of the prescribing doctor explicitly, early termination implies that the drug is out of circulation and the entrants have to spend more to influence the doctor to prescribe an out-of-circulation drug. But early termination is costly for the incumbent in the sense that it has to forego patent protected profit from the old drug and have to introduce a new drug early. Such a trade-off determines the optimal termination period. The termination date is sensitive to certain basic parameters of the model, such as the cost of introduction and promotion of the new drug, the length of the patent period etc.

The paper is laid out as follows. In the second section we discuss the model and the results. The third section concludes.

2. Model and Results

In this section we provide a model to show that the incumbent, the originator of a drug, will introduce a new competing drug before the patent of its earlier generation expires. Imitators can enter the market with generics of a drug only after its patent period is over. We focus on the stationary equilibrium where the patent holder withdraws the new patented drug before the old patent expires.

Let T be the length of patent of a drug available from the date it is introduced in the market. Then we are concerned with an equilibrium when the incumbent introduces a new substitute drug t years before the expiry of patent of its earlier generation; $t \in [0, T]$. We further show that introducing the new drug after the expiry of the patent will never be optimum. To make the analysis simple we assume zero discounting rate.

Let $D(0)$ denote the current generation drug. Then $D(-s)$ denotes the s -generation earlier drug and $D(r)$ is the drug to be introduced r generations later. We assume that demand for drugs over time remains unchanged and that the newer version of drugs will have no market demand effect. However, doctors will be more prone to prescribe the latest generation drug. In other words, the older generation drugs will have lower market share, as if, older generation drugs become obsolete in the minds of the doctors. To make the structure simple, we further assume that when the latest generation drug (which is presently protected by a patent) competes with the generics of older generations, only the last generation generic will survive and all older generation generics will have zero market shares. The doctors while prescribing the drug do not take into older generation generics except the one in the recent past. Thus when $D(0)$, $D(-1)$ and $D(-2)$ compete in the market place, $D(-2)$ will have no positive market share, and in competition between $D(0)$ and $D(-1)$, the drug $D(0)$ will have a larger market share.

Think of the period when $D(0)$ is not yet introduced but patent of $D(-2)$ has expired. Then $D(-1)$, which is now under patent protection, will compete with generics of $D(-2)$. Let the flow of gross payoffs of the originator of $D(-1)$ and that of each entrant producing generics $D(-2)$ be $B(n)$ and $G(n)$, respectively, which are decreasing functions of the number of entrants (n); therefore $B'(n) < 0$ and $G'(n) < 0$.

Consider now the period after introduction of $D(0)$. By our assumption, $D(0)$ is introduced t years before the expiry of patent of $D(-1)$. So these t years the patented $D(0)$ will compete with $D(-2)$ generics. Note that during first t years after launch of $D(0)$, the drug $D(-1)$ cannot be imitated. Let $A(n)$ and $\tilde{G}(n)$ be the flow of gross payoffs of the patentee of $D(0)$ and each $D(-2)$ generic producer, respectively. By our assumption, $A(n)$ will be larger than $B(n)$ and $\tilde{G}(n)$ is much smaller than $G(n)$.

But once t years are over after $D(0)$ is launched, generics of $D(-1)$ will enter (because by this time its patent is expired). Then by assumption, producers of $D(-2)$ generics will cease to operate. Then a next generation drug, $D(1)$, will be launched again t years before the expiry of patent of $D(0)$. Therefore, $D(0)$ and generics of $D(-1)$ will compete for $T - 2t$ years.

This framework suggests that any generic producer will enjoy a flow of gross profit $G(n)$ for $T - 2t$ years before the next generation drug is introduced and $\tilde{G}(n)$ for t years after the new generation drug is introduced. Similarly, for any new innovation, the incumbent will get a flow of gross payoff $A(n)$ for the first t years of the product and $B(n)$ for the next $T - 2t$ years. It is further understood that for $t \geq T/2$, $B(n) = 0$ and $G(n) = 0$.

Since we are assuming away any demand effect of a new drug, the payoff structure of the incumbent and the generic producers will remain the same as above. In other words, the same scenario will repeat every time after a new generation drug is introduced. The sequence of launching new drugs is depicted in *Figure 1*.

We shall now introduce the cost side. Assume that there is a cost to introduce a new drug by withdrawing the existing patented drug from the market before the patent expiry. This may also include the cost of advertising and marketing of the new drug. When the drug is introduced t years before the expiry of patent of its earlier generation, the corresponding cost is given by the function:

$$Z(t) \text{ with (i) } Z(t) = 0 \text{ for } t \leq 0, \text{ (ii) } Z'(t) > 0 \forall t > 0 \text{ and (iii) } Z'(0) = 0 \quad (1)$$

This cost is increasing in t , and is zero if the product is introduced after the expiry of patent of its earlier generation.

Similarly, the generic producers face an entry cost which directly depends on the length of the period the product goes out of the market before any generics can be introduced. This is given by

$$E(t) \text{ with (i) } E(t) = \bar{E} \text{ for } t \leq 0, \text{ and (ii) } E'(t) > 0 \forall t > 0 \quad (2)$$

Since the new product is to be innovated, it involves an R&D cost. Let the cost be given by the function

$$I(t) \text{ with (i) } I(t) = \bar{I} \text{ for } t \leq 0, \text{ (ii) } I'(t) > 0 \forall t > 0 \text{ and (iii) } I'(0) = 0 \quad (3)$$

This tells us that the earlier the product is innovated, the larger the cost of innovation is.

Given the structure of the model, we are now in a position to find the optimal number of entrants producing generic drugs and the optimal time of introducing a new product. If n generic producers enter the market, each firm's net payoff becomes

$$(T - 2t)G(n) + t\tilde{G}(n) - E(t)$$

Then the optimal n is solved from

$$(T - 2t)G(n) + t\tilde{G}(n) = E(t) \quad (4)$$

Eqn. (4) solves $n(\cdot)$ as a function of t . Given the restrictions⁵, we must have $n'(t) < 0 \forall t > 0$ and $n(0) = n^*$ with $n^* > n(t) \forall t > 0$. This is quite intuitive. As t goes up, on one hand the entry cost goes up and on the other the period of possible operation of each generic drug is shortened. Therefore, there will be lower number of entrants.

Now, given $n(t)$, define

$$\bar{A}(t) = A(n(t)) \text{ and } \bar{B}(t) = B(n(t)) \quad (5)$$

Since $\{A', B', n'\} < 0$, we must have $\bar{A}'(t) > 0$ and $\bar{B}'(t) > 0$ for all t .

The incumbent's problem is

$$\max_{t \in [0, T]} V(t) = R(t) - C(t) \quad (6)$$

where,

$$R(t) = t\bar{A}(t) + (T - 2t)\bar{B}(t) \text{ and } C(t) = Z(t) + I(t)$$

⁵ We have, $n^* = G^{-1}\left(\frac{\bar{E}}{T}\right)$ and $n'(t) = \frac{2G - \tilde{G} + E'}{(T - 2t)G' + t\tilde{G}'} < 0$.

To see that the above problem has an interior solution, note that $R(0) = T\bar{B}(n^*)$, $C(0) = \bar{I}$, $R(T) = 0$ and $C(T) > 0$. Therefore, $V(T) < 0$, and it is reasonable to assume $V(0) > 0$, that is,

$$T\bar{B}(n^*) - \bar{I} > 0 \quad (7)$$

This tells that the R&D cost associated with an innovation will be fully recovered by the existing patent system. Hence,

$$\exists t < T \mid V(t) > 0 \quad (8)$$

Now to ensure that the optimal t is indeed positive, consider the first order condition of the maximization problem (6), i.e.,

$$\begin{aligned} V'(t) &= R'(t) - C'(t) \\ \text{or, } \bar{A} + t\bar{A}' + (T - 2t)\bar{B}' - 2\bar{B} &= Z' + I' \end{aligned} \quad (9)$$

If t^* maximizes $V(t)$, then $t^* > 0$ if and only if $V'(0) > 0$, that is,

$$TB'(n^*)n'(0) - 2\bar{B}(n^*) > 0 \quad (10)$$

Eqn. (7) and (10) together ensure that

$$V(t^*) > V(0) > 0 > V(T) \quad (11)$$

Now we show that introducing the new drug at a date after the expiry of patent of the earlier generation drug will not be optimal. To do so, suppose that the innovation is introduced τ years after the expiry of patent of its earlier generation; $\tau > 0$. The sequence of introduction of new drugs is shown in Figure 2.

As the Figure 2 shows, here the number of generic entrants (\hat{n}) will be more than n^* , i.e., $\hat{n} > n^*$, because the patent of the existing drug expires before the current generation drug is introduced and hence entrants have low cost of entry. Moreover, these firms compete with the current generation for a period longer than T .

Therefore, the innovator of a drug will derive a flow of gross payoff $B(\hat{n})$ during the patent period; $B(\hat{n}) < B(n^*)$. And once its patent is expired, next τ years it will compete with its generics, and hence its payoff may be assumed to drop to zero due to entry of large number of generic producers. Hence the net payoff that the innovator is expecting to derive from introducing a drug τ years after the patent expiry of its earlier generation is:

$$\hat{V}(\tau) = T B(\hat{n}(\tau)) + \tau.0 - \bar{I} = T\hat{B}(\tau) - \bar{I} \quad (12)$$

Comparing (7) and (12), we have

$$V(0) > \hat{V}(\tau) \quad \forall \tau > 0 \quad (13)$$

We are now in a position to write the main result of our paper.

Proposition: *It is optimal for the originator of a drug to introduce a new competing drug before the expiry of patent of its earlier generation.*

Proof: Results (11) and (13) together imply that $V(t^*) > V(0) > \hat{V}(\tau)$, and hence the result. QED

The result can be explained as follows. If the new drug is introduced after the period of patent expiry of the earlier generation, then it will face more competition from the entrants producing generic drugs of the earlier generation, because generic entrants now face a lower cost of entry, and once patent of the current drug expires, the generics of the current generation drug enter. This will result in a drop of revenue almost to zero.

On the other hand, when the new drug is introduced at an earlier date before the expiry of patent of its earlier generation, the innovator, by doing so, successfully increases entry cost of the potential generic entrants. Although the innovator itself incurs some additional costs of innovating and introducing the product earlier, under some conditions this strategy is profitable. To see the effect of an increase in t on revenue of the innovator, note that as t goes up, the length of operation of the innovator with this drug is shortened to that extent, and hence there is some loss of revenue. On the other hand, during the period it operates, it faces less competition from generics of earlier generations. These two opposite forces give the necessary trade-off and determine the optimal $t > 0$.

Effects of a change in T

For comparative static analysis let us assume that t^* is unique and a stable equilibrium. From Eqn. (4) we shall get n as a function of t and T , i.e., $n(t, T)$ with $n_t < 0$ and $n_T > 0$. Then Eqn. (9) will solve for $t^* = t(T)$ satisfying $R_t = C'$ and $\Delta \equiv R_{tt} - C'' < 0$. Hence when T changes, it affects t^* directly (when n and n_t remain

unchanged) and indirectly through the change of n and n_t . Therefore, from the condition $R_t = C'$, we shall get:

$$\frac{dt^*}{dT} = \frac{1}{-\Delta} [R_{tT} + R_m n_T + R_{m_t} n_{tT}] \quad (14)$$

where,

$$\Delta = 2A'n_t + tA'n_{tt} + tA''n_t^2 + (T-2t)B'n_{tt} + (T-2t)B''n_t^2 - 4B'n_t - C''$$

$$R_{tT} = B'n_t$$

$$R_m = A' + tA''n_t + (T-2t)B''n_t - 2B'$$

$$R_{m_t} = tA' + (T-2t)B'$$

It is clear that $R_{tT} > 0$. Therefore, the direct effect of a change in T is positive, i.e., an increase in T will lead to an increase in t^* . Since a priori we cannot make any conclusion on the sign of n_{tT} , to make it simple we may assume that $n_{tT} = 0$, i.e., a change of T will lead to a parallel shift of $n(t, T)$ function. Moreover, it is not unreasonable to assume that if n goes up, it leads to a downward shift of the R_t curve,⁶ i.e., $R_m < 0$. Under this assumption the indirect effect of a change in T is negative. Hence the net effect of a change of T on t^* depends on two opposing effects. When the direct effect dominates the indirect effect, t^* will go up as T increases. Then if further $n_{tT} < 0$, this will reinforce our conclusion.

If there is a shift of E function, it has only indirect effect --- t^* will change through the shift of $n(t, \cdot)$. However, if there is a shift of either I function or Z function, to the extent it results in a shift of $C'(t)$ function, t^* will be affected. For instance, if $C'(t)$ shifts up, t^* must fall.

3. Conclusion

A strong argument in favor of granting patent rights has to do with encouraging innovations since the monopoly profit of the innovator is protected over the patent period,

⁶ We may generally presume that $A'' > 0, B'' > 0$. Then the sufficient condition for $R_m < 0$ is $A' - 2B' \leq 0$.

usually for twenty years. We argue that given a guaranteed patent period, pharmaceutical firms can also engage in further anti-competitive and entry deterring strategies by withdrawing the patented drug before the expiry of the patent period. Our analysis is based on some empirical evidence where early withdrawal of the drug makes the future generics less effective as competing products. We highlight the role of prescribing doctors who are likely to be influenced by the persuasion of the innovating firm. We develop a simple dynamic model to capture the effect of such an interesting entry-deterring strategy.

Our paper opens up the possibility of an interesting policy question. Should the organization such as the FDA allow the drug companies to withdraw the patented drug before the expiry of the patented period and to introduce a new drug earlier than what is expected? The generic substitutes which are supposed to come up right after the patent period is over, will be in a disadvantageous position if the doctors are somehow convinced of the “limitations” of the drug the generics are likely to substitute. If the producer of the existing patented drug A, reveals an “adverse side effect” and uses this as an excuse to prematurely introduce the new drug B, the generic substitute of A will be in a bad shape. We argue that the drug manufacturer/innovator might have all the incentive in the world to use such “revelations” as a profit-increasing strategy. However, the problem is that there is no obvious way to decipher the fact that whether the existing drug should really be replaced, because there is a sudden discovery of an unanticipated side-effect, or something needs to be improved upon immediately. Our paper proposes to take up this particular issue, the behavior of prescribing doctors, “influence-fees” to induce the doctors to prescribe the new drug etc., as inputs for further research. But at the end our point that strategic withdrawal of patented drug can lead to anti-competitive outcome, is quite a fresh insight so far as the economics of patent is concerned.

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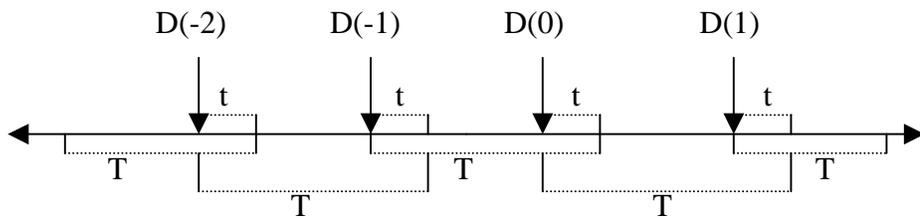


Figure 1

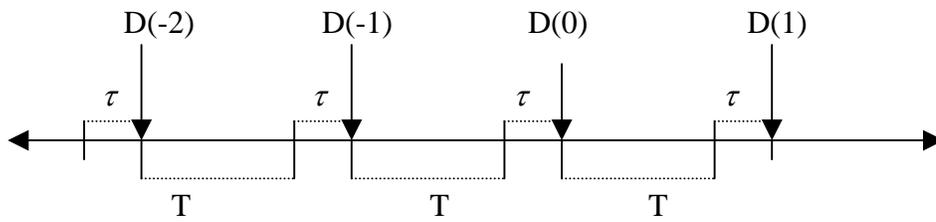


Figure 2