TIMING TO INVEST AND VALUE OF MANAGERIAL FLEXIBILITY. SCHERING PLOUGH CASE STUDY

by Alberto Micalizzi

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2. Introduction

This work investigates the timing of investments in developing new products and their problematic, irreversible nature. These two related issues are fundamental dimensions of firms' strategic decisions, especially in contexts of high environmental uncertainty.

The kind of investments that will be analyzed comply with two fundamental standards:

- a) the capital expenditures, or a part of them, are irreversible, and must be considered as sunk costs;
- b) the decision to invest can be postponed, so that waiting allows the company to collect new information about the key value drivers.

The objective of this paper is to demonstrate that pursuing methods to increase managerial flexibility in the structuring of investment projects can be an important source of value creation in the decision of timing to invest.

The case is taken from the pharmaceutical sector, where the concept of value creation is currently under significant reconsideration. Since pharmaceutical industry cannot afford the increases in R&D expenses observed in the last two decades, a key short term goal becomes the reduction of R&D investments without adversely affecting output.

In particular, the costs of the last phase of clinical trials necessary to bring new products to market are the most expensive ones, and are typically undertaken three to five years before the product launch so that these resource-intensive trials can significantly impact the total value of the project.

Therefore, this phase is perceived as the key area where there is a large scope for improvement over the next decade; In particular, the enabling technologies of genomics, combinatorial chemistry and rational drug design are considered as a means of optimization of stop-go decisions through which managers can improve the R&D efficiency and increase projects and candidates shedding.

It follows that more and more attention is being devoted to:

- □ increasing market opportunities for each product
- selecting the best candidates to further develop into the last stage of clinical trials
- □ boosting the customer satisfaction

This is the context of the Schering Plough case. The firm is faced with an irreversible decision of whether (and when) to invest in the third stage of clinical trials of a new anti-asthma product, Newprox. The investment required, I, is known, but the value of the project, V, is uncertain. The potential worldwide market for Newprox is approximately one billion dollars per year.

The case of Newprox is enriched by the fact that the firm plans the launch of a product, Minprox, designed to treat nasal congestion caused by allergies. This product uses the same molecule in Newprox but the market for Minprox could be significantly small, which would result in a negative NPV.

There are two important aspects worth considering about the Minprox project and its link to Newprox.

First, the launch of Minprox would underline the continuity of investments in company image and would represent a bridge between the anti-allergy segment (where Schering Plough has been present for over ten years) and the anti-asthma segment (where Schering Plough is a newcomer).

Second, Minprox represents an important source of information that allows SP to postpone and condition the launch of Newprox. As a matter of fact, SP bases the decision to invest in the last stage of clinical trials of Newprox on the potential success of Minprox.

The objective of this paper is twofold. Firstly, we want to calculate the value to invest in the third stage of clinical trials of Newprox, under the assumption that V evolves stochastically and the decision to invest can be postponed infinitely. Secondly, we want to assess whether the marketing strategy of presenting Minprox and Newprox as complementary products creates value.

3. The value of postponing irreversible investments: technical and economic uncertainties

To best define the problems related to the deferment of investment decisions under uncertainty, we must distinguish between economic and technical uncertainty¹.

Economic uncertainty depends on the factors exogenous to the project such as the evolution of market prices and the volatility of sales. This type of uncertainty can influence managers to postpone the implementation of a certain project until more information is available about the key value drivers. The economic uncertainty is often counterbalanced by heavily positive NPV values.

Technical uncertainty depends instead on factors endogenous to the project, such as the quantity of raw materials contained in a mineral glacier. Such factors can influence managers to anticipate the start of a project in order to collect additional information about the project's potential profitability. In this case, even negative NPV values can be considered satisfactory for starting a project.

The concept of economic uncertainty is important to assess the role of "timing to invest" as a critical variable of the strategic decision making process.

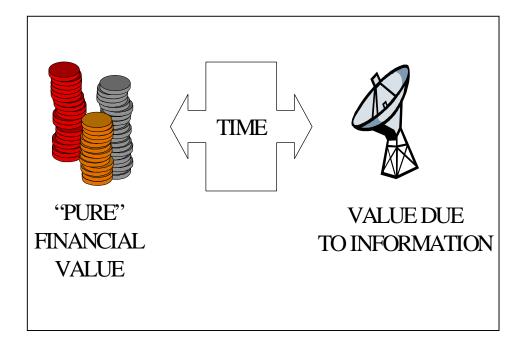
In order to explain the above concept, one must consider that if time has a "pure" financial value, there is also an additional value due to the new information revealed during the time interval. The "information value" of time is a very important resource in every sector where rapid technological

¹ This analysis is taken from A.K.Dixit and R.S. Pindyck, *The options approach to capital investment*, «Harvard Business Revue», May-June, 1995.

evolution and competitiveness force companies to make irreversible decisions.

It is precisely the information value that allows us to attribute a particular value to projects whose implementation can be postponed without compromising the project's feasibility. Likewise, as more information becomes known about the new strategic-competitive scenario, the company can either abandon the investment, or modify it accordingly in order to maximize the project value.

The "double value" of time



Some examples that illustrate the problematic nature of timing investment decisions can be taken from the oil industry and the real estate market.

In the United States, for example, companies operating in the oil sector receive exploitation rights for a certain period of time. The volatility of crude prices poses a significant problem with respect to the timing of mining projects. In a period of significant reduction of crude prices, a company may find it convenient to postpone the start of extraction in order to wait for more advantageous market conditions. In this case, the exclusive right guarantees the technical feasibility of the postponement within a certain timeframe.

In real estate, timing is crucial to the success of a building development project. In conditions of relative price volatility, it may be convenient to delay the project in order to maximize the market price of the properties. The following example is aimed at clarifying how the economic uncertainty referred to one of the decision making variables makes meaningless the result achieved with the application of deterministic approaches such as NPV.

Consider a case in which the opportunity to launch a new product requires an investment of 100 that will generate differential flows of 110 one year later.

Let's assume the following:

□ 1 year spot rate (S_{0,1}) = 10%
 □ risk premium = 200 basis points

If the investment opportunity follows the "now or never" approach, the NPV of the investment is:

$$[110 / (1.12)] - 100 = -1.79$$

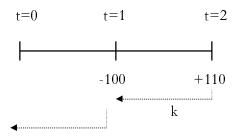
Let's consider the possibility to postpone the investment opportunity by one year. One year from now the company would present value the payoff of 110 at the one year spot rate (plus risk premium).

In order to demonstrate the effect of uncertainty, let's assume that next year's spot rate is a function of the current 2 year spot rate $(S_{0,2}) = 8.5\%$, and that $S_{0,2}$ follows a binomial process:

t = 0	t = 1
8.5%	11.5% (up)
	6.3% (down)

where the up-down jumps are derived from the risk-neutral probabilities, assuming σ =30%.

If the company decides to postpone the investment by one year, everything else being constant, the structure of the project would be the following:



where k is the future spot rate plus the risk premium, or the opportunity cost of capital.

The value of the investment opportunity, assuming risk-neutral valuation, is calculated as follows:

Cost of capital	Present value of	NPV of the	Max (NPV;0)	Value of the
	payoff in t=1	project in t=0		investment
				opportunity
13.5% (up)	96.9	-3.1	0	0.8
8.3% (down)	101.6	1.6	1.6	

In this simple example, the decision to invest is reversed: under uncertain market rates the value of the investment opportunity, considering the option to postpone, is greater than the traditional NPV.

More generally, if we assume that the discount rate is uncertain (i.e. follows a brownian motion) the traditional NPV approach would lead to sub-optimal decisions to invest.

As a matter of fact, the dependency on an uncertain variable transforms the investment into an opportunity because of the possibility of postponing the decision to a period in which interest rates are lower.

Because of the uncertainty of the interest rate, the investment competes against itself in time. In similar circumstances, the management can postpone the investment, conditioning the decision on a positive future outcome of relevant variables.

As a consequence, the company should invest when the value of the project exceeds the value of the initial investment in a proportion equal to the value represented by preserving the opportunity to invest.

This fundamental concept represents the key to interpreting this research, and will be further explained in paragraph 7.

4. The new competitive dimension in the pharmaceutical industry and the irreversible nature of decisions

For years, managers in the pharmaceutical industry have adopted value creation strategies based on strong efforts in the base research activity. These strategies were understood to be both instruments of product innovation and mechanisms through which to improve company image towards clients (physicians) and markets (investors).

This reasoning stemmed from the underlying notion that product innovation was the major key of success, and that the necessary and sufficient condition for market success was the degree of technical innovation of each compound. Therefore, the past two decades have seen a noticeable increase of the R&D expenditure for both US and European companies (see Figure 1).

16 20 R&D expenditures, \$bn 14 R&D as % of sales 12 10 Value 8 10 6 % of Sales 4 2 0 1975 1980 1985 1990 1995

Figure 1. Ethical pharmaceutical R&D expenditures for US-based companies, 1975-1995

(Source: Datamonitor)

This almost mechanical vision illustrates its limits when one observes that the increase in average R&D expenditure as a percentage of sales, from 12% in the early 1980s to almost 20% by 1997, has adversely affected the average return on capital invested. In addition, this increased investment has not resulted in proportionally greater numbers of product approvals².

² This statement is based on interviews and discussions with managers of pharmaceutical companies The statement is confirmed in various, recent articles appeared in specialized publications, and in particular: «Pharmabusiness- The International Magazine of Pharmaceutical Business», n° 18, November-December 1997, Euromoney Publications PLC.

A second important aspect worth considering is that university research centers and biotechnology firms increasingly adopt research methods based on combinatorial chemistry through which millions of new active compounds are developed for each single therapeutic area.

These factors lead to the development of a notable market for molecules in different phases of development. The R&D pipeline splits of the top 10 companies ranked according to the number of products in R&D are detailed in Table 1.

The presence of this market significantly reduces the large investments in base research that many pharmaceutical companies undertake internally and makes more crucial the development phase of each compound.

Table 1. R&D product status of the top 10 companies ranked by number of pharmaceutical products in R&D, 1997

Rank	Company	Preclinical	Clinical studies		FDA	Total	
		studies	P1	P2	Р3	filing	
1	Merck&Co	137	17	22	10	4	190
2	Hoechst	106	15	24	9	7	161
3	Novartis	82	27	33	12	5	159
4	Roche	82	21	36	10	8	157
5	Pharmacia and Upjohn	83	16	14	16	10	139
6	Americal Home Products	53	17	32	21	12	135
7	Lilly	84	11	12	7	0	114
8	Bristol Myers-Squibb	65	9	16	13	4	107
9	Glaxo Wellcome	56	11	25	6	4	102
10	SmithKline Beecham	45	14	19	18	6	102

(Source: Datamonitor, ADIS International)

The increasing role of biotechnological firms has also brought substantial similarities in the composition of the main competing products.

As a result, physicians find it increasingly difficult to determine the relative effectiveness of each product with respect to the product's composition. Consequently, they are becoming more and more sensitive to other factors such as the company image, the product shedding, the company's contribution to expanding the body of knowledge in the scientific community, the seriousness with which critical trials are conducted, and the attention paid to the evolution of the patients' pathologies.

All these factors lead one to believe that the competition in the pharmaceutical industry is being necessarily transferred from the product level to the market/client level. There is a consequent push for companies to become more market-oriented.

The emerging vision of the successful pharmaceutical company is a firm that variabilises its research costs by externally acquiring active compounds and molecules and

that reduces the costs of production as a result of the increased efficiency of modern compounds, that require fewer raw materials.

Decreased research and production expenses release funds, and allows managers to focus on development, marketing and distribution. In particular, the third stage of clinical trials appear to be the most critical in terms of irreversible investment decisions.

It is at this level that managerial flexibility assumes a role of fundamental importance. The most significant investment necessary for the launch of a product is mainly composed of the clinical trials. Only by doing extensive clinical trials can a company receive authorization from the FDA or EMEA to bring the product to the market. These clinical trials require, on the average, from one to five years of fixed investments. During the trials, the product will be administered to thousands of patients, at the cost of between 5,000 to 10,000 dollars per patient. The last stage of clinical trials is responsible for more than 50% of the total costs of product as the following Table 2 clearly shows.

Table 2. Efficiency of the drug development process, 1999

Stage	Preclinical	Clinical studies			FDA	Total
	Studies	P1	P2	P3	Review	
Avg. Duration	5-7	1	2	3	1.5-2.5	12-15
(ys)						
% success at	<0.01%	70%	47%	75%	80%	<0.001%
each stage						
Avg. Cost per	6	12	12	100	40	170
stage (\$m)						

Source: Datamonitor, Lehman Brothers 'New Drug Discovery Technologies' 3/97)

We can further consider that the third stage of clinical trials is even more critical in that it requires an accurate evaluation of the after launch options. As a matter of fact, after the initial launch, usually in one geographical location, the company might decide to seek for further product approval, as well as for widening the breadth indications for which the product is licensed, thus expanding the initial market size (for example, many companies seek to increase the patent lifetime by producing new versions of the product).

To this regard it is worth noticing that optimization of product launch must be seen as a means of increasing cost efficiency in $R \mathcal{L} D$ and maximizing the returns on new products, therefore improving the Revenues/ $R \mathcal{L} D$ expense ratio.

Lastly, the trend towards the maximization of R&D returns throws a new light to the issue of patent expiry and generic competition analysis.

5. "The value of allergy", the interaction between Newprox and Minprox

Schering Plough has produced for approximately ten years the well-known anti-histamine product, Claritin. Due to the success of this product, the company enjoys a very strong image especially in the area of anti-histamine products.

Since Claritin's patent will shortly expire, the company is currently occupied with preparing a new product that will be able to supplant Claritin's role as a major source of the group's profits.

This is the context in which the company, in the early 1990's, started the development of Newprox. The key characteristics of Newprox are:

- □ it uses the same molecule as Claritin, Loratadine, so that Schering Plough can take advantage of the positive brand image constructed over the years by the success of Claritin, with notable advantages especially in the uptake phase of the product;
- □ it focuses on Asthma, a therapeutic area with notable growth potential. As a matter of fact the company can expect gross earnings around one billion dollars within five years from the product launch.

Newprox is, therefore, a leading product for Schering Plough, and will underpin the company's development strategy for the next decade. Newprox, however, poses two basic problems.

The first problem is of a marketing nature. Although the product contains the same molecule as Claritin, the company does not have significant experience in the pathological area of Asthma (currently, Glaxo Wellcome and Astra are the major competitors with significant experience in the area of anti-asthma medicines). Moreover, physicians are well aware of the substantial differences between anti-histamines and anti-asthma medicines.

As a consequence, Schering Plough is faced with the challenge of bridging the "cultural gap" between Claritin and Newprox so as to convince physicians that Schering Plough's past success in the area of anti-histamines is of significant value for a successful penetration of the anti-asthma market niche.

Schering Plough identifies the following key success factors in the area of anti-asthma medicines:

- pointing out the link between allergy and Asthma;
- □ developing a wide portfolio of products;
- managing actively the products' life cycle;
- □ being strongly committed on distribution;
- deepening the interaction with customers and opinion leaders.

The second problem is related to the length required by the FDA and EMEA for the experimentation program. The company is required to conduct tests on approximately 10,000 patients, at a cost of nearly 5,000 dollars per patient. The company expects the tests to take four years, beginning in 1997.

The total investment in clinical trials can be divided as follows. The *first* and second stages of clinical trials are mainly based on healthy volunteers (people not suffering from any pathology), and are aimed at analyzing the tolerability of the product for the human body. The third stage of clinical trials is addressed to patients suffering from the specific pathology, and aimed at assessing the therapeutic properties of the new compound.

The present value of the total investment, also considering structural fixed costs, amounts to approximately 275 million dollars.

It is in this context that the issue of irreversible investments assumes critical importance. As a matter of fact, SP might be better off postponing the third stage of investment in clinical trials, conditioning it to the positive evolution of the key value drivers.

Along these lines, the strong commitment of the company to its new product is highlighted by the words of one of Newprox's greatest supporters: "Our competition owns the asthma market today. We need a committed investment in every market to prepare a foundation for success. This means advocate meetings, physician launch meetings and other service offerings need to be implemented. All components of the promotional mix need to be employed. This is a new market, not a line extension".

One feasible answer to the above two problems lies in Minprox, a product designed to treat nasal congestion due to allergies. Minprox requires fairly contained fixed costs. The experimentation phase will require tests on 2,000 patients at the cost of approximately 5,000 dollars per patient, and requires an experimentation period of just a few months.

With regard to the first problem associated with the Newprox project, Minprox is presented as the "bridge" that links allergies with asthma. Along these lines, the company will emphasize that asthma is nothing more than the result of a poorly cured, or an incurable allergy. In this way, Minprox is the mechanism through which Schering Plough can manage the transition phase between the two pathologies.

The message that Schering Plough conveys is: "SP could use our Clarityne and Minprox products to the benefits of Newprox. Costs of asthma therapy are much higher if comorbid patients allergy symptoms are left untreated or poorly treated. Allergy symptoms are asthma cost drivers. We will be able to treat the upper and lower airway disorders with our products."

In terms of the directions for the usage of Minprox, the messages that link Claritin and Minprox are eloquent: "Clarityne: first line symptom, relief for allergic rhinitis and urticaria; Minprox: when nasal system are problematic, add on Minprox".

Regarding Newprox's second problem, Minprox represents an important market test to verify the sales potential of Newprox, in that it

provides an important source of data for forecasting Newprox potential sales.

6. The project structure and the flexibility option

In terms of evaluation model, the adoption of the NPV rule for Newprox would implicitly assume that the decision should be made "now or never," without contemplating, however, the possibility of postponing some stages of the clinical trials.

In order to account for the role of flexibility, the value of the investment postponed must be seen as a "price" to be paid to conclude the investment program, and get the benefits of the market upside potential. To this regard it is worth noticing that target elucidation projects which are not developed further should not necessarily be seen as wasted expenditure as they have the potential to be reinvestigated at a later stage when market conditions and enabling technologies may make it a more favorable option.

In light of the above information, we can define with precision the entire structure of the project, and identify the flexibility option.

Under uncertainty, we assume that Minprox evolves stochastically and that Newprox market potential is based on Minprox results so that SP might be better waiting rather than launching Newprox in 1999. Therefore, the uncertainty over Newprox makes valuable the managerial flexibility to postpone the launch.

To this regard we also assume that the decision to invest in Minprox follows the "now or never" rule so that it is either launched in 1997 or definitely abandoned.

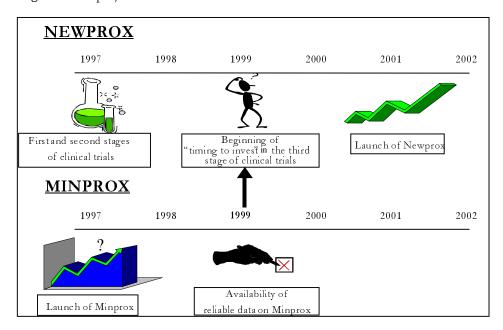
Figure 2 shows the project structure that considers the flexibility option. In 1997, Schering Plough begins clinical tests of Newprox. In the same year, the company concludes the tests on Minprox and launches it.

At the end of 1999, Schering Plough will have available two years of observations resulting from the Minprox launch. Starting from that time, the company will begin assessing the opportunity to invest in the third stage of clinical trials of Newprox.

As a consequence, the whole project entails a real option, represented by the possibility to postpone the investment required for the third stage of the clinical trials and take the decision based on the new market information due to Minprox; such an option allows SP to condition irreversible capital investments to the positive evolution of the critical decision making variables.

To evaluate the option to invest in Newprox, we will assume an infinite-time horizon.

Figure 2. The project's structure



7. The reference model: Dynamic Optimization

Let N be the gross value in 1997 of the expected cash inflows from Minprox. Let V be the gross value of the cash flows from Newprox (V and N are gross of fixed investments, comprised mainly of clinical testing and structural fixed costs), whose values are represented by (compare table 5 and table 7):

$$V = 10 N \tag{1}$$

The company, therefore, estimates that the market value of Newprox is equal to ten times the market value of Minprox. This is justified by two considerations: a) the link between the two products explained in paragraph (5); b) the assumption that the structure of the annual costs (costs of goods sold, sales and distribution expenses, promotional costs) of the two products is similar, as shown by comparing tables (3) and (6).

Let F(V) be the market value of the investment opportunity in Newprox. In this case, F(V) becomes the objective function to maximize in order to evaluate the flexibility option under the hypothesis of active management, where³:

³ The following model is taken from A. K. Dixit and R. S. Pindyck, "Investment Under Uncertainty", Princeton University Press, 1994, p. 137-142.

$$F(V) = \max E\left[(V_T - I)e^{-\rho T}\right]$$
 (2)

where:

T = unknown future time to invest

 ρ = risk-adjusted discount rate

E = expected value

I = investment required to support the third phase of clinical trials

The maximization of F(V) refers to the Bellman equation:

$$F_{t}(V) = \max_{u_{t}} \left\{ \pi_{t}(V_{t}, u_{t}) + \frac{1}{1+\rho} E[F_{t+1}(V_{t+1})] \right\}$$
(3)

where:

u = control variable

 π = immediate profit flow

 ρ = risk-adjusted discount rate

E = expected value

The above symbols must be interpreted as follows.

As far as the control variable "u" is concerned, this is a scalar binary variable which represents "waiting" if SP decides to postpone the investment decision, and "investing" if SP finds it convenient the immediate exercise of the investment opportunity.

As a consequence, the immediate profit flow, π , must be considered as 0 if the firm postpones the investment, and (V-I) if the company decides to invest.

In continuous time, equation (3) becomes:

$$\rho F(V,t) = \max_{u} \left\{ \pi_{t}(V_{t},u,t) + \frac{1}{dt} E[dF] \right\}$$
(4)

Let's suppose that V evolves according to the following geometric Brownian motion:

$$dV = \alpha V dt + \sigma V dz \tag{5}$$

where:

 α = drift rate

 σ = standard deviation of percentage changes in V, determined exogenously

dz = increment of a Wiener process, with ε random variable normally distributed and standardized

Given the expression (5), (4) can be solved by referring to Ito's Lemma:

$$E(dF) = \alpha V F'(V) dt + \frac{1}{2} \sigma^2 V^2 F''(V) dt$$
 (6)

Thus, (4) becomes:

$$\rho F(V,t) = \max_{u} \left\{ \pi_{t}(V_{t},u,t) + \alpha V F'(V) + \frac{1}{2} \sigma^{2} V^{2} F''(V) \right\}$$
 (7)

This formulation of the Bellman equation underlines how the investment opportunity is comparable to an asset that generates a normal return per unit of time equal to $\rho F(V,t)$, and which is equivalent to the sum of the two terms present in the braces: the first, identifiable by π , represents the asset's immediate payout or dividend, while the second, that starts from α , identifies the asset's expected appreciation or capital gain. Therefore, the term on the right of equation (7) identifies the total expectation of the asset return per unit of time.

The reference to the control variable "u", that we use to maximize the objective function, serves to indicate that the project is managed in an optimal way, considering at the same time both the immediate profit opportunities and the growth expectations of the project's value.

Equation (7) implies also that there will be critical values of V, referred to as V^* , that identify the boundary between two regions. On the one side $(V < V^*)$, there will be those values for which postponing the investment is optimal (*Continuation region*); on the other side $(V > V^*)$ there are values of V for which the company would be best off to immediately exercise the investment opportunity (*Stopping region*).

It's worth reminding that the opportunity to invest in the third stage of clinical trials can be exercised in any moment after 1999, when the first reliable results on Minprox are available.

In other words, (7) (and therefore all the formulas that derive from it) refers to the period that starts two years after the launch of Minprox. As a matter of fact, it's only from 1999 that SP can "acquire" the market potential

of Newprox by paying the "price" represented by the investment needed to execute the third stage of clinical trials.

If the time horizon is infinite, π , α , and σ are independent of t:

$$\rho F(V) = \max_{u} \left\{ \pi(V, u) + \alpha V F'(V) + \frac{1}{2} \sigma^{2} V^{2} F''(V) \right\}$$
(8)

Since the investment opportunity, F(V), produces no cash flow up to the time the third stage of clinical trials is undertaken, the return from holding the asset is equal to its capital appreciation.

Therefore, in the continuation region equation (7) becomes a differential equation with V as the independent variable:

$$\frac{1}{2}\sigma^{2}V^{2}F''(V) + \alpha VF'(V) - \rho F = 0$$
 (9)

In addition, F(V) has to satisfy the following boundary conditions:

$$F(0) = 0 \tag{10}$$

$$F(V^*) = V^* - I \tag{11}$$

$$F'(V^*) = 1 \tag{12}$$

where V* represents the minimum value of V for which it is convenient to invest immediately; in the case of the clinical testing, this means completing the experimentation program and executing the final two investment installments.

The condition expressed by equation (10) is based on the logic that if the value of the investment becomes zero, there are not other possible actions. Economically, this is justified by the fact that if the gross value of the project (not considering the fixed investments in clinical trials) approaches zero, then the project should be certainly stopped.

Equation (11) is referred to as value-matching condition. For the value of V for which it is best to invest immediately, the value of the investment opportunity is equal to the difference between the gross present value of the investment and the initial required investment. Equation (12) describes the smooth pasting condition. It ensures that once V* is determined, there are no better investment possibilities than those derived from the rule of optimal investment fixed by equation (8).

If equations (11) and (12) did not hold, then there would be values of V different from V* that would allow the opportunity to further optimize the investment decision.

8. The problem data

The input data for the calculation of the expanded value of the project are listed below.

The calculation of the project value (V) is done employing a deterministic method. In this case, the project value is represented by the NPV of Newprox. Next, the value of the investment opportunity F(V) is calculated according to the Dynamic Optimization method presented in the preceding paragraph.

Table 5 shows the NPV of Newprox. The calculation is based on data provided by table 3 and 4.

Table 3. Newprox data

Cost of product sold as % of revenues	10%
Sales and Distribution expenses (US\$/millions)	462.4
Promotion as % of revenues	20%
Net working capital	Unchanged
No. of patients needed for clinical trials	10,000
No. of years of clinical trials	4
Cost of clinical per each patient (US\$)	5,000
Other capital investment (US\$ millions)	90 per year

Table 4. Financial data

2 Wolf II I III II					
Financial structure	100% equity				
SP systematic risk (β) ⁴	1.27				
Risk free interest rate (1)	5%				
Average market return ⁵	14%				
Market premium for risk	9%				

^{(1) 1} year T-Bond total return

It's worth pointing out that we assume that revenues and cash flows of Newprox will remain at the level achieved in 2005 for all the periods beyond it. To this regard, in 2006 we calculate a residual value of the project equal to: (cash flow of 2005 / k), where k is the discrete-time risk-adjusted opportunity cost of capital.

The same procedure is followed for Minprox, whose cash flows are supposed to remain constant at the level achieved in 2003. The residual value is calculated as: (cash flow of 2003 / k).

The opportunity cost of capital can be determined from table (4), corrected for the Schering Plough's systematic risk factor:

⁴ See attachment 5

⁵ See attachment 6

$$k = r + \phi \rho_{SP, m} \sigma_{SP} \tag{13}$$

where:

$$\phi = \frac{(r_m - r)}{\sigma_m} \tag{14}$$

represents the market premium for risk, whereas $\rho_{SP,m}$ represents the coefficient of correlation between SP security and the whole market portfolio.

Schering Plough's opportunity cost is, therefore, equal to k = 16.4%.

Table 5. NPV of Newprox

(US\$ million)	<u>199</u> 7	<u>199</u> 8	<u>199</u> 9	<u>200</u> 0	<u>200</u> 1	<u>200</u> 2	<u>200</u> 3	<u>200</u> 4	<u>200</u> 5	<u>200</u> 6
					260	350	650	8 00	1000	=
Revenues (M) Cops					-26	-35	-65	-80	-100	=
Distribution & Sales (DS)					-462	-462	-462	-462	-462	=
Promotion (PRO)					-52	-70	-130	-160	-200	=
Gross cash flow (GCF)	0	0	0	0	-280	-217	-7	97	237	1446
PV(GCF)	215		291							
Fi <u>rst and</u>	second:	stage <u>T</u> h	urd stage							
Clinical trials	5	8.5	16.5	20						
Other Capex	45	50	100	120						
Capital Investments (CI)	50	58.5	116.5	140						
PV(CI)	275		237	140						
NPV = PV(GCF) - PV(CI)	-60									

Table 6. Minprox data

Revenues (as % of Newprox)	10%		
Cost of product sold as % of revenues	10%		
Sales and Distribution expenses (US\$/millions)	49.5		
Promotion as % of revenues	20%		
Net working capital	Unchanged		
No. of patients needed for clinical trials	2,000		
No. of years of clinical trials	1		
Cost of clinical per each patient (US\$)	5,000		
Other capital investment (US\$ millions)	60 per year		

Table 7. NPV of Minprox

(US\$ million)	<u>1997</u>	<u>1998</u>	<u>1999</u>	<u>2000</u>	<u>2001</u>	<u>2002</u>	2003	<u>2004</u>
Revenues (M)	26	35	65	80	100	100	100	_
. ,		-3.5	-6.5		-100			_
Cops (COPS)	-2.6			-8		-10	-10	
Distribution & Sales (DS)	-49.5	-49.5	-49.5	-49.5	-49.5	-49.5	-49.5	=
Promotion (PRO)	-5.2	-7	-13	-16	-20	-20	-20	=
Gross cash flow (GCF)	-31.3	-25	-4	6.5	20.5	20.5	20.5	125
PV(GCF)	20.4							
Clinical trials	10							
Other Capex	25							
Capital Imestments (CI)	35							
PV(CI)	35							
NPV = PV(GCF) - PV(CI)	-15							

Table (5) shows the calculation of the NPV relative to Newprox. Regarding Minprox, the input is reported in table (6). Using the opportunity cost k = 16.4%, table (7) shows the NPV calculation of Minprox.

Considering the result achieved with the NPV approach, in 1997 SP should neither invest in Minprox nor in Newprox.

9. The value of the investment opportunity

Referring to equation (9), let's consider the following input.

Table 8. Input

V =	291	Present value at 1999 of expected cash flows due to Newprox
I =	237	Value of the capital investment required to execute the third stage
		of the clinical trials of Newprox (see table 5)
σ =	30%	Standard deviation of V, determined as exogenous ⁶
ρ =	15.2%	Risk adjusted discount rate, based on: $\rho = \ln (1+k)$
α =	10%	Average percentage growth of V
δ =	ρ - $\alpha = 5.2\%$	Dividend paid by the underlying asset

As far as the specific meaning of α and δ is concerned, it's worth making a parallel with the financial markets. Considering the investment in a

⁶ The assessment of volatility is not the object of the present work. It's just the case to suggest that this parameter can be calculated as the standard deviation of the percentage changes on the units sold in the last three years by two of the SP major competitors in the anti-asthma field, which are Glaxo Wellcome and Astra.

stock, ρ is the total expected return from holding it; such a return can be split into two different components: $\rho = \alpha + \delta$, where α represents the expected capital gain, whereas δ the dividend yield.

If the dividend were zero, a call option on the stock would never be exercised prior to expiration, since the total return of the asset would coincide with the price movements.

If the dividend were positive, keeping the option alive would imply an opportunity cost, represented by the dividend lost.

Adopting the same approach to investments in real assets, δ still represents the opportunity cost of postponing the decision to invest. Such a cost may coincide, for instance, with the cash flow generated by the project (which would be lost in case of postponement), or with any other payout (even intangible) due to the project.

Therefore, if δ were zero, it would be always convenient to postpone the investment, whereas an unacceptably high δ would make the option to delay almost worthless due to the elevated opportunity cost.

This would lead to the same results as those resulting from a traditional NPV analysis, where the decision to invest follows the "now or never" rule.

In the following parts of this paper we will analyze the sensitivity of F(V) to a change in δ , and therefore in α .

In the case of Newprox, these considerations explain the fundamental assumption that $\delta > 0$.

As for α , we can refer to the average growth of revenues, in a period of 15 years.

In a 15-year period, the average growth of Newprox can be calculated as follows:

$$\alpha = \left(\frac{1000}{260}\right)^{\frac{1}{14}} - 1 \approx 10\%$$

Given α , δ is simply defined as $\delta = \rho - \alpha = 5.2\%$. As far as δ is concerned, it's worth mentioning two aspects. First of all the calculation of δ assumes that α and ρ are known; secondly, δ must be interpreted as the opportunity cost related to the cash flows lost due to the decision to postpone the investment.

In order to satisfy the boundary condition given by equation (10), the solution must take the form:

$$F(V_0) = AV_0^{\beta_1} \tag{15}$$

Substituting equation (15) in equation (9) and considering the boundary conditions (10), (11) e (12) we obtain:

$$A = \frac{(V^* - I)}{(V^*)^{\beta_1}} \tag{16}$$

$$V^* = \frac{\beta_1}{\beta_1 - 1} I \tag{17}$$

$$\beta_{1} = \frac{1}{2} - \frac{(\rho - \delta)}{\sigma^{2}} + \sqrt{\left[\frac{(\rho - \delta)}{\sigma^{2}} - \frac{1}{2}\right]^{2} + \frac{2\rho}{\sigma^{2}}}$$
(18)

By referring to the input reported in table 8, the value of the investment opportunity F(V) is equal to 148.

Considering an incremental investment needed of I=237, the value of the investment opportunity plus the investment required (I+F(V)) exceeds the present value of expected inflows by an amount (OV):

$$OV = 237 + 148 - 291 = 94$$

where OV represent the net option value.

10. Comments on the results

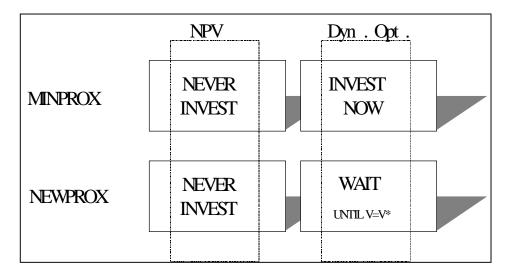
First and foremost, the total value of the opportunity to invest in Newprox is higher than the value obtainable by following a deterministic approach, and the difference is the value of the option to postpone the decision to invest.

Secondly, it's worth noticing that the negative value of the NPV of Minprox is more than compensate by the value of the opportunity to invest in Newprox.

This offers an important numerical support to the marketing strategy of presenting Minprox as the bridge that links allergy to asthma and, therefore, as the means for preparing the market for Newprox.

Such a result also leads to modify the investment rule. Under uncertainty (σ >0) the company should invest in Minprox immediately, and should wait to invest in Newprox until V reaches a floor equal to V*=963, whereas according to the assumption that σ =0 neither Minprox nor Newprox should be exercised.

The map on investment decisions



The exercise level of $V^* = 963$ is the consequence of considering an infinite horizon for the decision to invest in Newprox.

This suggests that NPV does not consider the opportunity cost of investing today rather than waiting. This opportunity cost is given by F(V).

When V < V*, it follows that
$$F(V) > (V - I)$$
, thus,
$$V < I + F(V),$$
 or $291 < 237 + 148$

We can consider I and F(V) as the two components of the "total cost" of the project where I represents the "explicit" cost and F(V) the "implicit" cost or opportunity cost. Since the value of the project (V) is less than the sum (the total project cost) of the explicit cost and the opportunity cost, Schering Plough should postpone the decision to invest in the third stage of clinical trials.

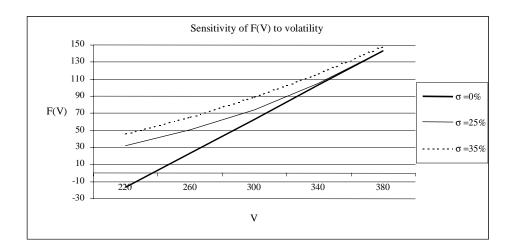
11. Sensitivity of the results to the main valuation parameters

An initial sensitivity analysis should be conducted on σ . Graph 1 and the relative table 7 show the values of F(V) for variations in volatility.

Table 9

V	σ=0%	σ=25%	σ=35%
220	-17	31.6	45.6
260	23	50.2	65.4
300	63	74.5	89,0
340	103	105.3	116.5
380	143	143.2	148.1

Graph 1



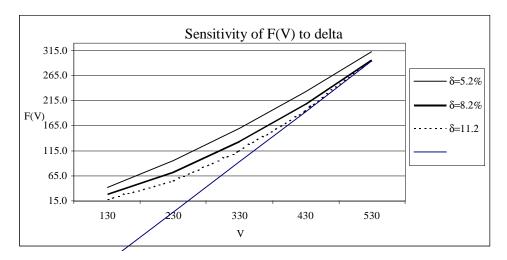
For values of σ equal to 0, the value of the investment opportunity equals the difference between V and I, which confirms the NPV rule. For increasing values of σ , F(V) and, therefore, OV, grow. This shows that the value of any real option is proportional to the level of uncertainty (calculations are available in attachment 1).

Another area of analysis has to do with the relationship between F(V) and δ , based on table 10 and graph 2.

Table 10

V	δ=5.2%	δ=8.2%	δ=11.2%
130	42.4	28.1	17.9
230	95.5	73.0	55.9
330	159.6	133.5	115.0
430	232.6	207.9	195.1
53 0	313.3	295.0	296.2

Graph 2



Graph 2 shows that as δ increases, the expected growth rate of V decreases, and so does the expected growth rate of the option value.

Under these circumstances, postponing the investment becomes costlier, and more convenient to exercise the option to invest earlier, so that the company can take advantage of the "acquisition" of Newprox market (calculations are reported in attachment 2).

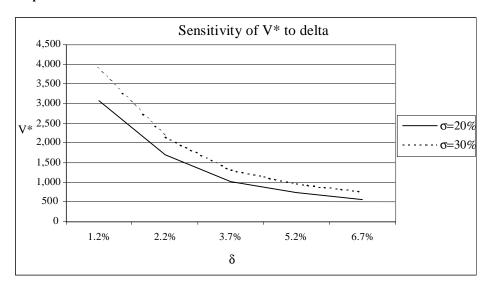
The analysis of V^* as δ changes is of great interest.

As δ changes, the critical values V* change in the same way as F(V) does. See table 11 and graph 3.

Table 11

δ	σ=20%	σ=30%
1.2%	3,081	3,911
2.2%	1,692	2,171
3.7%	1,013	1,321
5.2%	725	963
6.7%	567	767

Graph 3



From graph 3, we see that other things being equal, as δ increases, V* decreases and viceversa.

The higher cash flows generated by the underlying project diminish the critical values of V* which makes it convenient to exercise the investment opportunity.

To this regard, it's worth noticing the combined effect of σ and δ . δ being constant, the higher the volatility the more convenient it is to wait to invest, and therefore, the higher the critical values of V^* .

In terms of the SP case, the meaning is the following: the lower (and more distant from present) the cash flows generated by the project and the higher the uncertainty, the more convenient it is to postpone the investment, in order to wait for new information about the relevant variables.

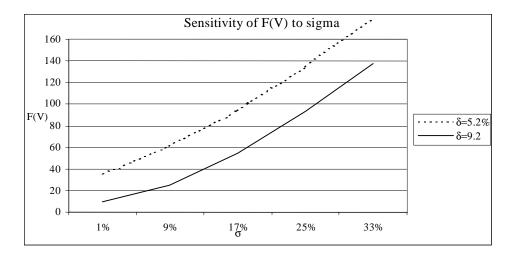
Big cash inflows (impending) lead the company to exercise the investment opportunity, and make the postponement more expensive. In extreme cases, when σ =0, the decision to invest goes back to the "now or never" form (calculations are available in attachment 3).

An alternative way to express the same concept is shown by graph 4, and table 12, that illustrate the values of F(V) as σ changes, for different values of δ . The value of the option to invest is proportional to the volatility: other things being equal, a higher δ makes more valuable the option to invest (calculations are available in attachment 4).

Table 12

σ	δ =5.2%	δ=9.2
1 %	36	9
9%	61	25
17%	94	55
25%	135	93
33%	180	138

Graph 4



Attachment 1

V=	220	260	300	340	380	220	260	300	340	380
E=	237	237	237	237	237	237	237	237	237	237
σ=	25%	25%	25%	25%	25%	35%	35%	35%	35%	35%
ρ =	15.2%	15.2%	15.2%	15.2%	15.2%	15.2%	15,2%	15.2%	15.2%	15.2%
α=	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%
$\delta = \rho - \alpha$	5.2%	5.2%	5.2%	5.2%	5.2%	5.2%	5.2%	5.2%	5.2%	5.2%
β =	2.76	2.76	2.76	2.76	2.76	2.15	2.15	2.15	2.15	2.15
. V*	371	371	371	371	371	442	442	442	442	442
V*-I	134	134	134	134	134	205	205	205	205	205
V*^ β	12,556,292	12,556,292	12,556,292	12,556,292	12,556,292	498,392	498392	498,392	498,392	498,392
A =	0.0000	0.0000	0.0000	0.0000	0.0000	0.0004	0.0004	0.0004	0.0004	0.0004
F(V) =	31.6	50.2	74.5	105.3	143.2	45.6	65.4	89.0	116.5	148.1
V-É =	-17	23	63	103	143	-17	23	63	103	143
OV =	48.6	27.2	11.5	2.3	0.2	62.6	42.4	26.0	13.5	5.1

Attachment 2

ſ	V=	130	230	330	430	530	130	230	330	430	530	130	230	330	430	530
	E=	237	237	237	237	237	237	237	237	237	237	237	237	237	237	237
	$\sigma =$	18%	18%	18%	18%	18%	18%	18%	18%	18%	18%	18%	18%	18%	18%	18%
	ρ =	15.2%	15.2%	15.2%	15.2%	15.2%	15.2%	15.2%	15.2%	15.2%	15.2%	15.2%	15.2%	15.2%	15.2%	15.2%
	$\alpha =$	10%	10%	10%	10%	10%	8%	8%	8%	8%	8%	6%	6%	6%	6%	6%
	$\delta = \rho - \alpha =$	5.2%	5.2%	5.2%	5.2%	5.2%	7.2%	7.2%	7.2%	7.2%	7.2%	9.2%	9.2%	9.2%	9.2%	9.2%
	$\beta =$	1.42	1.42	1.42	1.42	1.42	1.67	1.67	1.67	1.67	1.67	2.00	2.00	2.00	2.00	2.00
	V*	797	797	797	797	797	589	589	589	589	589	475	475	475	475	475
	V*-I	560	560	560	560	560	352	352	352	352	352	238	238	238	238	238
	V*^β	13,489	13,489	13,489	13,489	13,489	43,183	43,183	43,183	43,183	43,183	221,706	221,706	221,706	221,706	221,706
	A =	0.04	0.04	0.04	0.04	0.04	0.01	0.01	0.01	0.01	0.01	0.00	0.00	0.00	0.00	0.00
	F(V) =	42.4	95.5	159.6	232.6	313.3	28.1	73.0	133.5	207.9	295.0	17.9	55.9	115.0	195.1	296.2
	V-E =	-107	-7	93	193	293	-107	-7	93	193	293	-107	-7	93	193	293
	OV =	149.4	102.5	66.6	39.6	20.3	135.1	80.0	40.5	14.9	2.0	124.9	62.9	22.0	2.1	3.2

Attachment 3

V=	130	230	330	430	530	130	230	330	430	530
E=	237	237	237	237	237	237	237	237	237	237
σ =	10%	10%	10%	10%	10%	30%	30%	30%	30%	30%
ρ =	15.2%	15.2%	15.2%	15.2%	15.2%	15.2%	15.2%	15.2%	15.2%	15.2%
α =	14%	13%	12%	10%	9%	14%	13%	12%	10%	9%
$\delta = \rho - \alpha =$	1.2%	2.2%	3.7%	5.2%	6.7%	1.2%	2.2%	3.7%	5.2%	6.7%
β =	1.08	1.16	1.31	1.49	1.72	1.06	1,12	1.22	1.33	1.45
V*	3,081	1,692	1,013	725	567	3,911	2,171	1,321	963	767
V*-I	2,844	1,455	776	488	330	3,674	1,934	1,084	726	530
V*^ β	6,017	5,679	8,387	17,723	53,586	6,669	5,566	6,356	9,068	14,951
A =	0.47	0.26	0.09	0.03	0.01	0.55	0.35	0.17	0.08	0.04
F(V) =	92.2	142.9	179.5	224.6	293.9	98.0	155.6	200.0	249.2	310.4
V-E =	-107	-7	93	193	293	-107	-7	93	193	293
OV =	199.2	149.9	86.5	31.6	0.9	205.0	162.6	107.0	56.2	17.4

Attachment 4

V=	130	180	230	280	330	130	180	230	280	330
E=	237	237	237	237	237	237	237	237	237	237
σ =	1%	9%	17%	25%	33%	1%	9%	17%	25%	33%
ρ =	15.2%	15.2%	15.2%	15.2%	15.2%	15.2%	15.2%	15.2%	15.2%	15.2%
α =	10%	10%	10%	10%	10%	6%	6%	6%	6%	6%
$\delta = \rho - \alpha =$	5.2%	5.2%	5.2%	5.2%	5.2%	9.2%	9.2%	9.2%	9.2%	9.2%
β =	1.52	1.49	1.43	1.37	1.30	2.53	2.33	2.03	1.79	1.62
V*	692	719	786	886	1,015	392	416	467	536	618
V*-I	455	482	549	649	778	155	179	230	299	381
V*^ β	20,860	18,239	13,985	10,569	8,365	3,677,830	1,240,133	263,751	78,498	33,534
A =	0.02	0.03	0.04	0.06	0.09	0.00	0.00	0.00	0.00	0.01
F(V) =	35.8	61.1	94.5	134.6	179.6	9.5	25.5	54.6	93.3	137.8
V-E =	-107	-57	-7	43	93	-107	-57	-7	43	93
OV =	142.8	118.1	101.5	91.6	86.6	116.5	82.5	61.6	50.3	44.8

Attachment 5: Beta Schering Plough

Index	SPX
Period	Weekly
Range	15/11/94 – 13/11/96
Alpha (intercept)	0.61
R2 (correlation)	0.47
St. Dev. error	2.83
St. Dev.beta	0.12
Observations.	104
β adjusted	1.08
β	1.27
σ(SP)	0.48
σ(market)	0.2

Source: Bloomberg

Attachment 6: Average market return

Dow Jones Inc	dustrial Average	
(% of annual to	otal return)	
1997	22.64	
1996	26.01	
1995	33,45	
1994	2.14	
1993	13.72	
1992	4.17	
1991	20.32	
1990	-4.34	
1989	26.96	
1988	11.85	
1987	2.26	
1986	22.58	
1985	27.66	
1984	-3.74	
1983	20.27	
1982	19.61	
1981	-9.23	
1980	14.93	
Average	14.0 (Rm)	

Source: our calculation