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Eduardo S. Schwartz

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### **ABSTRACT**

This article develops and implements a simulation approach to value patents and patent-protected R&D projects based on the Real Options approach. It takes into account uncertainty in the cost-to-completion of the project, uncertainty in the cash flows to be generated from the project, and the possibility of catastrophic events that could put an end to the effort before it is completed. It also allows for the possibility of abandoning the project when costs turn out to be larger than expected or when estimated cash flows turn out to be smaller than anticipated. This abandonment option represents a very substantial part of the project's value when the project is marginal or/and when uncertainty is large.

The model presented can be used to evaluate the effects of regulation on the cost of innovation and the amount on innovative output. The main focus of the article is the pharmaceutical industry. The framework, however, applies just as well to other research-intensive industries such as software or hardware development.

Eduardo S. Schwartz  
Anderson School at UCLA  
110 Westwood Plaza  
Los Angeles, CA 90095-1481  
and NBER  
[eschwart@anderson.ucla.edu](mailto:eschwart@anderson.ucla.edu)

## 1. Introduction

The pharmaceutical industry has become a research-oriented sector that makes a major contribution to health care. The success of the industry in generating a stream of new drugs with important therapeutic benefits has created an intense public policy debate over issues such as the financing of the cost of research, the prices charged for its products and the socially optimal degree of patent protection.<sup>1</sup>

There is a trade-off between promoting innovative efforts and securing competitive market outcomes. The expected monopoly profits from ethical drug sales during the life of the patent compensate the innovator for its risky investment, while the onset of competition after the expiration of the patent limits the deadweight losses to society that arise from monopoly pricing under the patent. The research-oriented sector of the pharmaceutical industry relies heavily on the patent system.

“Because regulation has had important effects on the cost of innovation in the pharmaceutical industry, a great deal of research has been done on the innovation end of the trade-off between innovation and competition. The cost of innovation, the effect of regulation on cost and innovative output, and the dependence of pharmaceutical manufacturers’ rents on innovation have been much studied.”<sup>2</sup>

In this article I take the regulatory environment as given and concentrate on the valuation of an R&D project that is patent protected. I also present a methodology to determine the value of a patent to develop a particular product (e.g. a drug). The model presented, however, can be used to evaluate the effects of regulation on the cost of innovation and the amount on innovative output. This can be accomplished by analyzing

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<sup>1</sup> This discussion is based on Caves et al. (1991).

<sup>2</sup> Caves et al. (1991), page 2.

the effect on valuation and optimal abandonment policy of changes in the regulatory parameters in the model. The focus of this article is the pharmaceutical industry. The framework, however, applies just as well to other research-intensive industries such as software or hardware development.

The analysis of R&D projects is one of the most difficult investment problems. The development of a drug, for example, can take ten or more years to complete. During all this period, investments have to be made without reaping any of the possible benefits of the investment, and with a significant probability of having to put an end to the effort for technical or economic reasons. In addition, even for successful efforts, there is uncertainty about the actual costs of development. Further, after the drug has been successfully developed and approved by the Federal Drug Administration (FDA) there is substantial uncertainty about the sales and cash flows that it will generate. To value the R&D project or patent, these cash flows have to be assessed long before they are realized.

The approach taken in this article is to treat the R&D project or the patent as a complex option on the variables underlying the value of the project, which in this case are the expected costs to completion and the estimated cash flows after completion. Uncertainty is introduced in the analysis by allowing these variables to follow stochastic processes through time. This type of approach, generally known as the Real Options approach, has been successfully applied to value mines (Brennan and Schwartz (1985)), oil leases (Paddock, et al. (1988)), and many other real assets.<sup>3</sup>

Several papers in the economics and finance literature study the issue of investment in patents and R&D. For example, Pakes (1985) provides an empirical

characterization of the dynamic relationship among the number of successful patent applications of industrial firms and the stock market valuation of the firm. Pakes (1986) looks at the annual renewal fee patent-holders must pay in order to keep their patents in force, and develops and estimates a model which allows to recover the distribution of returns for holding patents at each age over the lifespan of patents. Bloom and Van Reenen (2000) look at the impact of patents on productivity and market value using patent citations as a proxy for innovation. Parry, Rose and Smith (1999) study the appropriate sources of financing for biotechnology firms and conclude that, contrary to the pecking order theory of capital structure, equity or equity-type securities issues are at the top of the pecking order.

Childs and Triantis (1999) examine dynamic R&D investment policies and the valuation of R&D programs in a real options framework. They focus on the interactions across projects and look at optimal policies for a firm with multiple R&D projects that can run in parallel or sequentially. They also introduce capital rationing constraints and competition into the analysis. Myers and Howe (1997) present a life cycle model of investments in pharmaceutical R&D programs. Uncertainty is explicitly accounted in the model, which is solved using Monte Carlo simulation.

There are two papers that are closest to this one. The first one is Schwartz and Moon (2000) which deals with some of the same issues discussed in this paper. There are important differences, however, both in the formulation of the problem and in the solution procedure between Schwartz and Moon and this article. In Schwartz and Moon, once investment in R&D is completed, the owner of the project receives the value of the

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<sup>3</sup> There is a large and growing literature on Real Options. See for example Dixit and Pindyck (1994) and

approved drug in the form of a single cash flow. In that framework calendar time does not enter into the solution of the problem. In this paper, more realistically, upon approval the owner starts receiving cash flows with timing, and possibly duration, depending on the duration of the R&D investment. If a patent is obtained before the completion of the R&D investment, the duration of the cash flows will depend critically on the duration of the investment; that is, it will be path dependant. Since now both the duration of the investment and the duration of the cash flows are random variables, the problem cannot be easily solved directly from the partial differential equation. In this paper, the problem is solved by Monte Carlo simulation adapting the procedure developed by Longstaff and Schwartz (2001) for valuing American type options. This provides for the option to abandon the project if investment costs turn out to be higher and/or cash flows turn out to be lower than anticipated. The simulation approach used is not only easily applied to multifactor and path dependant problems, but it is also very intuitive, flexible and transparent. In addition, it provides insights that are lost in the more complex numerical solution to the partial differential equation.

The second paper that is closely related is Berk, Green and Naik (2003). They also focus on the development of a single R&D project and take as exogenous the process describing the cash flows the project will generate. However, since the focus of this paper is patent-protected R&D projects, not only the level of cash flows is uncertain but also the duration of these cash flows. They assume that the cash flows last for ever which simplifies the value of the completed project to the continuously compounded version of the growing perpetuity formula. In addition, they take as exogenous the technology for randomly advancing through stages of the project whereas I take as exogenous the

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Trigeorgis (1996).

stochastic process for the expected cost to completion of the project (as in Pindyck (1993)). While their formulation is more fundamental in this respect, it makes it harder to employ in practice to value R&D projects.

The theoretical model is developed in Section 2. Section 3 gives a detailed implementation of the approach using data that is representative of the pharmaceutical industry to value a particular drug development project. Sensitivity of the project value to the key parameters in the model is also presented. Section 4 discusses some possible extensions of the model to take into account more realistic situations that were omitted in the simple model developed in Section 2. Finally, Section 5 gives some concluding remarks. The details of the Monte Carlo simulation methodology are presented in the Appendix.

## **2. Model**

Consider an investment in R&D that takes time to complete. The maximum rate at which the owner of the project can invest is  $I_m$  and the total cost to completion is a random variable  $\tilde{K}$  with expected value  $K = E[\tilde{K}]$ . When, and if, the project is completed the owner starts receiving the benefits of the investment represented by the net cash flow rate  $C$ , which follows a stochastic process to be described below.

Assume that a patent protecting the R&D project expires at time  $T$ , after which a successful project will be subject to a more intense competition such that cash flows will decrease substantially. In this framework, both the time to completion of the project and duration of the cash flows protected by the patent are random variables.

To reflect the fact that many R&D projects fail, assume that during the period of investment there is a Poisson probability  $\lambda$  per unit of time that the project will fail and

its value will jump to zero. This probability of failure is what Schwartz and Moon (2000) call catastrophic events, such as the situation where another firm wins the race to obtain a patent on the product, or the drug turns out to have a terrible side effect. In the framework below we concentrate on another reason to stop the project: the optimal exercise of the abandonment option when costs turn out to be higher than expected and/or cash flows turn out to be lower than anticipated. This abandonment option can have substantial value when the project is marginal, or when uncertainty is large as is the case for most R&D projects.

## 2.1 Investment Cost Uncertainty

The dynamics of the expected cost to completion of the R&D project is described by the controlled diffusion process:<sup>4</sup>

$$(1) \quad dK = -I dt + \sigma(IK)^{\frac{1}{2}} dz$$

where  $dz$  is an increment to a Gauss Wiener process that is assumed to be uncorrelated with the market portfolio.<sup>5</sup> The first term is the control of the diffusion process: as investment proceeds, the estimated remaining cost to completion decreases. The second term corresponds to what Pindyck calls *technical uncertainty* which is related to the physical difficulty of completing the project and therefore can only be resolved by investing in the project. More complex specifications of the expected cost dynamics can easily be incorporated in the analysis, such as including *input cost uncertainty*.<sup>6</sup> The advantage of the simple specification in equation (1) is that it gives rise to a bang-bang solution for the optimal control (optimal investment is either at the maximum possible rate or at zero)

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<sup>4</sup> See Pindyck (1993) and Schwartz and Moon (2000). Note that any alternative process could be used without major changes in the analysis that follows.

<sup>5</sup> The implication of this is that cost uncertainty will not have a risk premium associated to it.



when the cost and cash flow processes are uncorrelated, and that the variance of the cost to completion has a simple analytical expression<sup>7</sup>:

$$(2) \text{Var}(\tilde{K}) = \frac{\sigma^2 K^2}{2 - \sigma^2}$$

This expression, which relates the variance of the project's total cost and the volatility parameter  $\sigma$ , can be used to infer reasonable values for this volatility parameter.

## 2.2 Cash Flow Uncertainty

The dynamics of the net cash flow rate is described by the Geometric Brownian motion:<sup>8,9</sup>

$$(3) dC = \alpha C dt + \phi C dw$$

where  $dw$  is an increment to a Gauss Wiener process which is correlated with the market portfolio and which may also be correlated with the uncertainty in the expected cost to completion of the project. The drift in the cash flow process reflects the characteristics of a particular R&D program. Note that these cash flows start to be received by the owner of the project only after the investment has been completed. Before that time they represent the current cash flow the project would have produced if it were completed. These cash flows change as more information is obtained through investment and through an increased knowledge of the market for the product. The correlation between cost and cash flow uncertainty,  $\rho$ , also reflects the characteristics of a particular R&D program. In some cases, for example, higher than predicted investment costs may also translate

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<sup>6</sup> Input cost uncertainty will be discussed in Section 4.

<sup>7</sup> See Pindyck (1993).

<sup>8</sup> This is the stochastic process used in Schwartz and Zozaya (2001a and 2001b). Other processes, such as an Arithmetic Brownian motion, could be used without changing the nature of the analysis.

<sup>9</sup> These cash flows are net of production and marketing costs to be made once the R&D is complete.

into lower than predicted cash flows: this would imply a negative correlation between costs and cash flows.

Equation (3) represents the dynamics of the true process for the cash flows. For valuation purposes, however, the risk neutral or risk adjusted process for the cash flows will be used:

$$(4) dC = (\alpha - \eta)Cdt + \phi Cdw = \alpha^* Cdt + \phi Cdw$$

where  $\eta$  is the risk premium associated with the cash flow process (to be defined below) and  $\alpha^*$  is the risk adjusted drift.

### 2.3 Value of Project once Investment has been Completed

When the investment in the R&D project has been successfully completed, the value of the project depends only on the net cash flows to be generated from the project. Let  $V(C,t)$  be the value of the project at time  $t$  for cash flows  $C$ , and assume that the patent for the product expires at time  $T$ . Also assume that the residual value of the project, represented by the possible cash flows generated after the patent expires, is a multiple  $M$  of the cash flows at time  $T$ <sup>10</sup>. Different specifications of the post-patent cash flows will be discussed in Section 4.

Standard arguments imply that the value of the project must satisfy the partial differential equation:

$$(5) \frac{1}{2} \phi^2 C^2 V_{CC} + \alpha^* C V_C + V_t - rV + C = 0$$

with boundary condition:

$$(6) V(C,T) = M \cdot C$$

It can easily be verified that the complete solution to this PDE is given by:

$$(7) V(C, t) = \frac{C}{r - \alpha^*} [1 - \exp(-(r - \alpha^*)(T - t))] + MC \exp(-(r - \alpha^*)(T - t))$$

The first term in Equation (7) represents the present value of the cash flows up to the expiration of the patent and the second term represents the present value of the terminal value of the project. Note that the value of the project after the investment is completed is linear in the cash flows and does not depend on the volatility of the cash flows. This will not be the case, however, during the period of investment, which is the main focus of this paper.

Applying Ito's Lemma to Equation (7) and using (3), after some manipulation the (true) stochastic process for the value of the successful project can be shown to be:

$$(8) \frac{dV}{V} = (r + \eta)dt + \phi dw$$

Equation (8) verifies that the volatility of the total return on the successful project and its risk premium are the same as the volatility of the cash flows and the risk premium associated with the cash flow process, respectively. The returns on successful R&D projects can then be used to estimate cash flow volatility and the risk premium parameter.<sup>11</sup> Assuming the Intertemporal Capital Asset Pricing model of Merton (1973) applies, the risk premium is equal to the beta of the successful project times the risk premium on the market portfolio:

$$(9) \eta = \beta(r_m - r)$$

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<sup>10</sup> If the market becomes perfectly competitive after the patent expires, M would be equal to zero.

<sup>11</sup> It should be pointed out that this is not a trivial matter since traded "pure play" successful R&D projects would be needed. But, even when traditional discounted cash flow methods of valuation are used, risk adjusted discount rates are required.

Equation (9) provides for an easy way for estimating the risk premium in the model. The assumptions employed here would be the same ones used when the CAPM is used to determine the risk adjusted discount rate in NPV calculations.

## 2.4 Value of the Investment Opportunity

Before the investment is completed, the value of the R&D project at time  $t$ ,  $F(C,K,t)$ , depends both on the cash flow rate the project would have produced if it were completed and on the expected costs to completion, and calendar time. This value must satisfy the following partial differential equation:<sup>12</sup>

$$(10) \text{Max}_t \left[ \frac{1}{2} \phi^2 C^2 F_{CC} + \frac{1}{2} \sigma^2 (IK) F_{KK} + \phi \sigma \rho C (IK)^{\frac{1}{2}} F_{CK} + \alpha * CF_C - IF_K + F_t - (r + \lambda)F - I \right] = 0$$

subject to the boundary condition:

$$(11) F(C,0, \tau) = V(C, \tau)$$

where the left-hand side of the boundary condition comes from Equation (7) and  $\lambda$  is the Poisson probability per unit of time that the project will fail.

The difficulty with boundary condition (11) is that the completion date of the investment,  $\tau$ , is a random variable. The value of the R&D project at completion depends not only on the cash flows at that time, but also on how long the investment took place, because the duration of the cash flows is limited to the expiration of the patent. In this case, Equation (10) cannot be easily solved by conventional numerical methods.

In the Appendix, a simulation method is proposed that solves Equation (10) with boundary condition (11) under two simplifying assumptions:

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<sup>12</sup> Schwartz and Moon (2000) derive a similar equation but with the fundamental difference that it is independent of calendar time. The resulting elliptic partial differential equation can then be solved by standard finite difference procedures.

- (a) The investment strategy takes two possible extremes values: to invest at the maximum possible rate or not to invest at all. This bang-bang policy is exactly optimal only for the case where the cost and cash flow processes are uncorrelated. The possibility of investment at a lower level than the maximum possible rate, however, is unlikely to have a significant effect for low correlation values.
- (b) Once the project is abandoned, it will not be started again. That is, only the abandonment option is considered in the analysis, not the options to delay investing and to stop and restart investment in the future if future cash flow estimates improve.<sup>13</sup> It is important to consider, however, that as time passes, the duration of the cash flows decreases since there is an expiration date for the patent. This makes delaying investment extremely costly.

## **2.5 Critical Values for Costs and Cash Flows**

The solution to (10) and (11) also gives the critical values for the state variables which separates investment from abandonment. For every level of the cash flow rate there is a critical cost to completion,  $K^*(C)$ , above which it is not optimal to invest in the project. Equivalently, for every level of cost to completion there is a critical cash flow rate,  $C^*(K)$ , below which it is not optimal to invest in the project. The value of the project or patent when it is not optimal to invest is zero. These functions define a critical curve in the K-C space. This curve would naturally be a function of time and of all the other fixed parameters of the valuation problem.

## **2.6 Valuation under Certainty**

Traditional NPV valuations discount the net cash flows to a project at a risk-adjusted discount rate. For comparison purposes, the R&D investment problem described above

can be analyzed in this framework by setting the cost and cash flow volatilities equal to zero. The relevant risk premium and the probability of failure can then be incorporated in the discount rate. This analysis would correspond exactly to the traditional NPV valuation.

Under certainty, the time to completion of the investment would be deterministic and equal to:

$$(12) T_K = \frac{K}{I_m}$$

and the NPV of the project would be:

$$(13) NPV = V(C, T_K) \exp(-[(r + \lambda) - (\alpha - \eta)]T_K) - \frac{I_m}{r + \lambda} [1 - \exp(-(r + \lambda)T_K)]$$

The first term represents the present value of the cash flows at time  $T_K$  (from Equation (7)) discounted at the appropriate risky rate, and the second term represents the integral of the (discounted) investment costs until completion.

## 2.7 Volatility and Beta of R&D Project

Using Ito's Lemma and stochastic processes (1) and (3), it is easy to derive the volatility and the beta of the investment opportunity:

$$(14) \sigma_F^2 = \left(\frac{\phi CF_C}{F}\right)^2 + IK \left(\frac{\sigma F_K}{F}\right)^2 + 2(IK)^{\frac{1}{2}} \left(\frac{\phi \sigma \rho CF_C F_K}{F^2}\right)$$

$$(15) \beta_F = \beta \left(\frac{CF_C}{F}\right)$$

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<sup>13</sup> In Section 4 I discuss this in more detail.

The beta of the project equals the beta of the successful project times the elasticity of the project's value to changes in cash flows. The volatility of project depends on the volatilities of the two stochastic processes and their correlation.<sup>14</sup>

### **3. Implementation of the Approach**

#### **3.1 Data for Drug Development Project**

To illustrate the implementation of the methodology proposed in this article, I evaluate an R&D project for the development of an ethical drug using, as much as possible, typical parameter values from the pharmaceutical industry. A typical self-originated new drug introduction requires over US\$100 million of out-of-pocket expenditures<sup>15</sup>, so I will take \$100 million to be the expected cost to completion of the project. Since the average time to complete is 10 years<sup>16</sup> I will assume that the maximum investment rate is \$10 million per year. This is a simplification of reality since different phases of the R&D project require different levels of investment<sup>17</sup>.

DiMasi et al. (1995, pp. 204) find that “only 23% of the new drug candidates that enter phase I clinical trials will eventually be approved by the FDA”. But this success rate takes into account both the failures due to catastrophic events and the optimal exercise of the abandonment option. Assuming that one half of the projects fail due to catastrophic events, and considering an average time to completion of the investment is 10 years, the Poisson probability of failure can be computed as:

$$\begin{aligned}\exp(-\lambda T_K) &= \exp(-10\lambda) = 0.50 \\ \lambda &= 0.07\end{aligned}$$

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<sup>14</sup> Apart from the covariance term these formulas are the same as those found in Schwartz and Moon (2000).

<sup>15</sup> See DiMasi et al. (1991).

<sup>16</sup> See DiMasi et al. (1995).

<sup>17</sup> This issue will be discussed in more detail in Section 4.

The volatility parameter in equation (1) is inferred from the variance of the costs to completion in equation (2). For a volatility parameter equal to 0.5, the standard deviation of the cost to completion is \$37.8 million (for an expected costs to completion of \$100 million)<sup>18</sup>.

The Uruguay Rounds Agreements Act (Public Law 103-465), which became effective on June 8, 1995, changed the patent term in the United States. Before June 8, 1995, patents typically had 17 years of patent life from the date the patent was issued. Patents granted after the June 8, 1995 date now have a 20-year patent life from the date of the first filing of the patent application.<sup>19</sup> However, innovative pharmaceutical products undergo, on average, more than 10 years of development and regulatory approval before coming to market. This reduces the effective patent life of innovative pharmaceutical products to less than 10 years. I assume that the total life of the project is 20 years of which, on average, 10 years will be devoted to the development of the drug and 10 years will be generating cash flows. Note that the choice of the starting point of the life of the patent to evaluate the project is arbitrary. The project can just as well be evaluated, with the necessary adjustments in costs and time to completion, a few years into the patent or even before the patent has been obtained.

The estimated cash flows of the project are assumed to be \$20 million per year<sup>20</sup> and growing stochastically at 2% per year (the rate of inflation) according to Equation (3). The cash flow volatility parameter in (3) and (8) is obtained as the average implied volatility for traded call options of nine pharmaceutical companies (0.35). The beta to be

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<sup>18</sup> This standard deviation is smaller, but of the same order of magnitude, than the standard deviation reported in Table 2 of DiMasi et al. (1991) for 93 randomly selected new chemical entities.

<sup>19</sup> U.S. Food and Drug Administration – Center for Drug Evaluation and Research Website.

<sup>20</sup> This is consistent with the average cash flows reported in Grabowski and Vernon (1994).



used to compute the risk premium in Equation (9) is also obtained as the average beta of the same pharmaceutical companies (0.6).<sup>21</sup> Using a risk premium on the market portfolio of 6%, the resulting risk premium associated with the cash flow process is 3.6%.

The correlation between the stochastic processes for cost and cash flows depends on the characteristics of the R&D project, and, in general, it is probably small<sup>22</sup>. Since more successful projects take a shorter time to develop and cost less, cash flows from these projects might be larger. In this case a negative correlation might be reasonable. In the base case I assume a correlation of  $-0.1$  and in the comparative statics section I analyze the sensitivity of the results to changes in this parameter.

At the expiration of the patent, the entry of generic drug products significantly decreases the cash flows to the patent-holder.<sup>23</sup> To take into account the cash flows generated after the expiration of the patent, I assume that the terminal value of the project is five times the terminal cash flow rate.

In the simulation approach developed in this article it would be relatively easy to include stochastic interest rates, but, for simplicity, I assume that the risk-free rate of interest is constant and equal to 5%. Finally, the step size for the simulations and the evaluation of the abandonment option is one quarter of a year, and the number of simulations performed is 100,000. Table 1 summarizes the parameters described above.

### **3.2 Valuation of Drug Development Project**

Figure 1 shows a randomly selected path of costs and (true) cash flows using the parameters in Table 1. For this particular path, investment takes 8.5 years to complete.

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<sup>21</sup> Clearly, more accurate estimates of the volatility of the cash flows and the beta coefficient could be obtained from pure equity firms that produce only one drug.

<sup>22</sup> The fact that all drugs must go through the same general regulatory process might suggest a low correlation.

Estimated cash flows at the evaluation time (time 0) are \$5 million per quarter. At the time they start to be generated in year 8.5, however, they are only \$2.74 million per quarter. During the duration of the investment, the cash flows represent the cash flows that would occur if the project was completed. At the expiration of the patent, cash flows grow to \$6.60 million. It should be pointed out that Figure 1 illustrates only one of the 100,000 paths generated for the evaluation, and might not represent a typical or average path.

Table 2 displays the valuation results for five different seeds for the random number generator. The first row gives the value of the project with the abandonment option, the second row gives the proportion of paths in which it is optimal to abandon the project, and the third row gives the value of the project using the same simulations but not allowing abandonment.

The real options value of the project (with the abandonment option) lies between \$12.9 and \$14.0 million, with a mean of \$13.4 million. The standard deviation of the mean in all cases is very close to \$0.4 million, so all values lie well within two standard deviations from the mean. The proportion of paths abandoned lies between 39.9% and 42.5% with a mean of 41.0%. The value of the project without the option to abandon lies between \$4.8 and \$5.7 million, with a mean of \$5.2 million (again the standard deviation of the mean is around \$0.4 million). The approximate value of the abandonment option is \$8.2 million, which in this case represents a very large proportion of the value of the project. In 41% of the paths this option is optimally exercised.

The percentage of paths abandoned each quarter for the first four years is shown in Table 3. At the end of the first quarter 2.58% of the paths are optimally abandoned.

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<sup>23</sup> See Grabowski and Vernon (1992).

Conditional on not having been abandoned before, 5.85% are abandoned at the end of the second quarter, and so on. Most of the abandonment decisions are taken in the first two years, but some reduced percentages occur well beyond the fourth year. Note that all these abandonment decisions correspond to the risk-neutral paths. The proportion of abandonment using the true paths would be somewhat smaller.

The net present value of this project, assuming certainty, and computed using Equation (13) is -\$7.4 million. A simple NPV calculation used to value the project would suggest that it should not be undertaken. It is rather surprising to see the big difference that exists between the value of the project without the option to abandon and the simple NPV: \$12.6 million. The reason for this is Jensen's inequality: the expected value of a convex function is larger than the function of the expected value. Figure 2 shows that the NPV of the project is a convex function of the cost to completion. This effect is magnified when there is a negative correlation between cash flows and costs to completion since more extreme valuations are possible.

The simulated cost distribution is depicted in Figure 3. Note that approximately 2.3% of the paths get to the expiration of the patent without being completed. These would certainly be abandoned much earlier in the respective simulation. The mean of the simulated costs is \$99.8 million, very close to the \$100 million assumed ex-ante, but the standard deviation is \$34.8 million, somewhat smaller than the \$37.8 million assumed ex-ante.<sup>24</sup>

### **3.3 Sensitivity Analysis**

#### **3.3.1 Uncertainty Parameters**

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<sup>24</sup> This is due to the truncation of the distribution at 20 years.

Table 4 shows the effect of the uncertainty parameters (volatilities and correlation) on the value of the R&D opportunity. The top panel shows the effect of changing the cost uncertainty parameter while keeping all the other parameters as in Table 1. As is typical in option pricing, the value of the project unambiguously increases with cost uncertainty. The probability of abandonment goes down with increased cost uncertainty since in this framework the only way to “learn” about the project costs is by investing: with more uncertainty there is more to learn by investing. Interestingly, the value of the project without the option to abandon increases even more in value with increased uncertainty. The result of this is that the value of the option to abandon actually slightly decreases in value with increased cost uncertainty. The option to abandon is less valuable because it is used less often.

The middle panel in Table 4 gives the same information as the top panel, but for changes in cash flow uncertainty. The value of the project also increases with cash flow uncertainty, but in this case the probability of abandonment increases. More uncertainty in the cash flows increases the probability of good outcomes, but it also increases the probability of bad outcomes and therefore, the probability of abandonment. The option to abandon, then, is more valuable as indicated in the last column of the table.

The above analysis indicates that cost uncertainty and cash flow uncertainty have a different effect on the project. Though increases in both lead to increases in the value of the project, the probability of abandonment and the value of the option to abandon move in the opposite direction. Another way of presenting this result is that higher cash flow (value) uncertainty leads to delay investment (as is traditional in option pricing),

whereas higher cost uncertainty leads to advance investment (since you only learn by investing).

The bottom panel in Table 4 presents the effect of changes in correlation. The higher is the correlation between costs and cash flows, the lower is the value of the project, with or without the option to abandon. This is because a negative correlation implies that when costs are low, cash flows tend to be high, and vice versa: this leads to a wider distribution of values. The reverse is true when the correlation is positive. As the correlation increases the project becomes more marginal, the probability of abandonment increases and the option to abandon becomes more valuable.

All the values in Table 4 are directly comparable (without simulation error) because the same random numbers were used in all the simulations.<sup>25</sup> They correspond to those used in the last column of Table 2. Since uncertainty does not affect the net present value of a project, the net present value of the project without uncertainty for all the cases in the table is -\$7.4 million.

### **3.3.2 Cost and Cash Flow Parameters**

The effects on project values and probabilities of abandonment of changes in expected costs to completion, maximum investment rate, cash flow rate and terminal cash flow multiple are presented in Table 5. All of them have predictable effects: values increase and probabilities of abandonment decrease when expected cost to completion decrease, when the maximum investment rate increases, when cash flow rate increases, and when the terminal cash flow multiple increases. The value of the option to abandon, however, is more valuable the more marginal the project and the higher the probability of abandoning it.

The level of expected investment costs has a large effect on the value of the project since they are all paid before cash flows start to be generated. The effects are also asymmetric: a 10% increase in costs decreases the value of the project by \$6.24 million, whereas a 10% decrease in costs increases the value by \$8.53 million. The main reason for this is that when costs increase, the option to abandon is used more often preventing additional losses.

The value of the project increases with the investment rate because cash flows will start earlier since investment will be completed faster. Since the patent expires in 20 years, the duration of the cash flows will also be longer.

The value of the project is somewhat less sensitive to the cash flow rate and the cash flow multiple at the expiration of the patent than to the total investment costs. The reason for this is that cash flows are to be generated in a distant future. This is especially true for the terminal cash flow.

### **3.3.3 Parameters that Affect Compounding and Discounting**

There are three parameters in the model that affect the compounding and discounting of costs and cash flows. These are the drift of the cash flow process<sup>25</sup>, the Poisson probability of failure during investment, and the risk-free rate of interest. Table 6 shows the effects of changes in these parameters on valuation and probability of abandonment.

The top panel of Table 6 shows the effect of changes in the drift of the cash flow process. These are substantial, but these results should be interpreted with caution, since a higher cash flow drift would probably be due to a higher expected inflation, which

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<sup>25</sup> The same applies to the next two subsections and to Tables 5 and 6.

<sup>26</sup> Actually only the risk adjusted drift affects valuation, so changes in the risk premium have exactly the same, and opposite, effect on valuation that changes in the true drift of the cash flow process.

would also affect in similar fashion the risk-free rate (bottom panel in Table 6). These two effects would, to a large degree, mitigate one another.

As expected, a higher probability of catastrophic failure decreases the value of the project and increases the probability that it will be abandoned. These results are shown in the middle panel of Table 6.

### **3.3.4 Time to Expiration of the Patent**

Table 7 reports the sensitivity of the value of the project with respect to changes in the time to expiration of the patent. This is an important parameter since it depends on public policy. Changes in the time to expiration of the patent have significant effects on the value of the project. Extending the duration of the patent by 10% increases the value of the project by 35%.<sup>27</sup>

The model can also be used to analyze issues of public policy such as the tradeoff between the duration of a patent and the allowable competition by generic drugs at the expiration of the patent. For example, assume that the degree of allowable competition can be represented by the multiple of cash flows that the patent-holder receives at the expiration of the patent. Then a 10% reduction of the life of the patent (from 20 to 18 years) would require an increase of this multiple from 5 to 7.6 to approximately maintain the same value of the R&D project.

## **3.4 Critical Values**

For any given level of the cash flow rate we can increase the cost to completion until the project is immediately abandoned and its value is zero. This is the critical cost to

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<sup>27</sup> In comparing the results reported in Table 7 it should be noted that they are subject to simulation error since, given their different duration, each row uses different random numbers.

completion above which it is not optimal to invest in the project. For the base case cash flow rate of \$20 million the critical cost is \$125 million.

Alternatively, for any given level of cost we can decrease the cash flow rate until abandonment is optimal at the initial period. This is the critical cash flow rate below which it is not optimal to invest. For the base case cost of \$100 million the critical cash flow rate is \$13.6 million.

Figure 4 shows the critical cash flows rates (critical costs) for costs between \$80 and \$100 million (cash flow rates between \$9 and \$18 million). Above (or to the left of) the curve, when cash flows are high and/or cost are low it is optimal to invest. Below (or to the right of) the curve it is optimal to abandon the project.<sup>28</sup>

### **3.5 Risk Measures of the R&D Project**

To compute the volatility and the beta of the project using Equations (14) and (15), we need first to compute the derivatives of the project's value with respect to expected costs and cash flows. These derivatives are computed numerically applying the same simulation procedure, perturbing these variables (by 1%) using the same seed in the random number generator.

The risk measures for the R&D project are substantially higher than those of the successful project. The volatility of the project computed using Equation (14) is 1.51, which is more than 4 times larger than the average volatility (0.35) of the nine pharmaceutical companies used as a proxy for the successful project. The beta of the project computed using Equation (15) is 2.01, which is more than 3 times larger than the average beta (0.60) of the same nine companies.

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<sup>28</sup> The results reported in Figure 4 were done using 10,000 simulations.



This high level of risk is to be expected since at the start of the project approximately \$100 million have to be invested over a period of ten years before starting to receive the benefits of this investment. Expected returns on the investment, however, should be commensurate to its risks.<sup>29</sup>

#### **4. Extensions of the Analysis**

The model developed and discussed in the previous sections is a simplified description of the real world. In this section some important features of the pharmaceutical industry are presented, and I discuss how the simple model developed can be modified to deal with these features. There are two stages in pharmaceutical research and development: drug discovery (the research stage) and drug development. The goal of the research phase is to find a chemical compound that has the desirable effect in a “screen” that mimics some aspect of a disease state in man, while the goal of the drug development process is to ensure that compounds identified through the research process are safe and effective in humans (Henderson and Cockburn (1996a), page 34).

##### **4.1 Drug Development Process**

New drug development is a sequential process. At several points in the process a pharmaceutical firm will review the status of testing on the drug and make a decision on whether to continue with its development or abandon the project. The decision will depend on factors such as potential therapeutic benefits, expected frequency and severity of adverse reactions, projected additional development, marketing, distribution, and production costs and estimates of the future revenue stream.<sup>30</sup>

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<sup>29</sup> According to Grobowski and Vernon (1990, 1994) realized returns on new drug introductions in the 1970s and early 1980s have not been of an order of magnitude to justify this high level of risk. It should be taken into account, however, that they include the cost of failed projects in the cost of successful ones.

<sup>30</sup> This discussion is based on DiMasi et al. (1991), pages 109 and 110.

Once a new compound has been identified and is considered a promising candidate for further development the firm will file with the FDA an Investigational New Drug Application. The firm may begin clinical (human) testing of the drug thirty days after the filing unless the FDA places a hold on the application. Clinical testing normally occurs over three distinct phases, each of which contributes different amounts and types of information on safety and efficacy.

In phase I, testing is performed on a small number of usually healthy volunteers. The main purpose of these trials is to obtain information on toxicity and safe dosing ranges in humans. In phase II the drug is administered to a larger number of individuals consisting of patients for whom the drug was intended to benefit. The purpose of these trials is to provide the first significant evidence of efficacy, and additional safety information. Phase III involves large-scale trials on patients. The purpose of these trials is to find definitive evidence of efficacy and any possible adverse reactions.

A New Drug Application is submitted to the FDA for review once the clinical development phases have been completed and the firm believes it has sufficient evidence for approval. Marketing for the new drug can only begin upon notification from the FDA. The FDA review can be considered as a fourth phase in the cycle.

The simulation approach can readily be adapted to deal with different phases of investment. The expected cost to completion, the maximum rate of investment, the cost volatility, and the probability of failure would, in general, be different for different phases. The correlation between costs and estimated cash flows could also be different for the different phases. Then, for each phase  $j$ , the dynamics of the expected cost to completion (from Equation (1)) would be:

$$(16) dK_j = -I_j dt + \sigma_j (I_j K_j)^{\frac{1}{2}} dz_j$$

Phase  $j$  would have to be completed before the start of phase  $j+1$ .<sup>31</sup> Moreover, the approach allows for the cost variables (expected cost to completion, maximum investment rate, volatility of costs and probability of failure) in phase  $j+1$  to depend on the realized cost variables in phase  $j$ . For example, if the realized total investment costs in a given phase turn out to be lower than expected, it seems likely that the expected costs in the subsequent phase would also be lower than originally expected. It would be very unlikely that any other method of solution, other than simulation, would be able to deal with this complex type of path dependency.

Given that for every new chemical entity that is approved, there are several others that are abandoned at some point in the development process, most of the literature dealing with the cost of innovation in the pharmaceutical industry<sup>32</sup> include the costs of failed projects with those of successful projects. In addition, the investments costs are usually capitalized (at the cost of capital of the pharmaceutical firm) to the point of marketing approval. This is an ex-post assessment of the costs (and returns) of successful pharmaceutical products.

The purpose of my analysis is to determine the value of the R&D project (or the patent) before investment starts. In this context the expected cost to completion represent an ex-ante assessment of the costs of the project. Some projects are successful, some fail (probability of failure), and some are abandoned (optimal exercise of the abandonment option). The value of the project today takes into account that there is some probability

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<sup>31</sup> This framework would even allow for phase  $j+1$  to start before the completion of phase  $j$ , which is sometimes the case in the drug development process.

of failure and abandonment, but the expected costs are not increased to take into account this possibility. The expected costs to completion in my analysis are related to what the literature calls “out-of-pocket cost per approved new chemical entity”.

#### **4.2 Patent Term Restoration**

As mentioned earlier: “The 1994 Uruguay Round Agreements Act changed the way in which the term of a U.S. patent has been calculated since 1861. Unlike the former seventeen-year term, which was measured from the date that the patent issued, a patent that issues from an application filed on June 8, 1995, and thereafter has a term of twenty years measured from the date that the earliest U.S. patent application was filed.”<sup>33</sup> The new twenty-year term is subject to patent term extension for a period of time related to the regulatory period review. To compensate for the regulatory review period by the FDA, an extension for up to five years can be obtained. Extensions can be granted only if the remaining term of the patent is less than fourteen years after regulatory approval for market, and the remaining patent term and the extension combined cannot exceed fourteen years beyond the date of market approval.

This patent extension feature can also be incorporated in the simulation approach developed in this article. For every path in the simulation, once the investment is completed and the drug approved, the regulatory review period is known. Then, if the remaining time to the expiration of the patent is less than fourteen years, the period where cash flows are generated can be extended to fourteen years. This modification would certainly increase somewhat the project values reported in Section 4.

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<sup>32</sup> See for example Di Masi et al (1991, 1995), DiMasi, Grabowski and Vernon (1995), and Grabowski and Vernon (1990, 1994).

<sup>33</sup> Marks (1996), page 445.

The discussion above is a somewhat simplistic description of how patents actually operate in practice. The reality is that there is much more fuzziness around these patent issues. For example, litigation over intellectual property is frequent when competitors have developed similar new drugs, and even if a firm may think it has patent protection for a particular drug, it is always possible that it may end up having a key patent declared invalid.<sup>34</sup> This type of issue is difficult to incorporate explicitly in the model developed. The probability of failure during the investment period, however, can implicitly take into account all those events that could put an end to the project.

### **4.3 Cash Flows and Product Life Cycle**

In the development of the model, I have assumed that the cash flows process follows a Geometric random walk. In reality pharmaceutical sales and cash flows start very low at the introduction of a new drug, then grow to a maximum close to the expiration of the patent, and decrease dramatically once the patent has expired<sup>35</sup>. One possible way to add this product life cycle to the analysis would be to superimpose a deterministic life cycle variable to the stochastic cash flows to be able to more closely mimic actual sales and cash flows. This modification would somewhat change the timing of the cash flows, but would not change significantly the nature of the analysis.

### **4.4 Patent Expiration and Entry**

The “1984 law Drug Price Competition and Patent Term Restoration Act facilitated the entry of generic drug products after patent expiration while it also restored part of the patent life lost during the pre-market regulatory process for new introductions.”<sup>36</sup> Before

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<sup>34</sup> For a discussion of these issues see Lanjouw and Schankerman (2001) and Schankerman and Scotchmer (2001). For some Japanese evidence see Sakakibara and Branstetter (2001).

<sup>35</sup> See Grabowski and Vernon (1990, 1994).

<sup>36</sup> Grabowski and Vernon (1992), page 331.

1984 market entry by generics was limited due to the costly requirements imposed by the FDA for imitative products (i.e. duplicate many of the pioneer's tests). The 1984 law required generic products to demonstrate only bio-equivalence to the pioneer's brand. As a consequence, generic entry has increased significantly.

The post-patent competitive process in which entry erodes patent-protected monopoly rents and eliminates the associated deadweight losses to society, has received relatively little attention in the literature<sup>37</sup>. To simplify the analysis of post-patent cash flows, the model developed in the previous sections assumed that the present value of these cash flows at the expiration of the patent is equal to a multiple of cash flows at that point in time. This is similar to assuming that the terminal value of a firm is a multiple of earnings at a given horizon. Alternative assumptions are possible. For example, the life of the project could be extended into the post-patent period (i.e. five or ten years longer) and declining cash flows consistent with recent experience could be modeled.

#### **4.5 Tax Considerations**

Clearly, for valuing any project the relevant cash flows are the ones after taxes. For simplicity, the model developed has completely abstracted from tax considerations and has implicitly assumed that all relevant cash flows are on an after tax basis. For any particular project, however, tax distortions can be significant.

The tax situation of a particular project would depend on the fraction of the investment costs that can be expensed immediately, and the fraction that has to be capitalized for future depreciation, on whether the firm has other profitable projects for offsetting losses, etc. However, for a given known situation, the simulation approach is

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<sup>37</sup> Notable exceptions are Caves et al. (1991) and Grabowski and Vernon (1992).

especially suited to deal with the path dependencies of capital expenditures and capital cost allowances.<sup>38</sup>

#### 4.6 Input Cost Uncertainty

The dynamics of the expected cost to completion of the R&D project specified in Equation (1) assumes that all the uncertainty in the costs are of a *technical* nature, that is, it can only be resolved by investing. Pindyck (1993) suggests the possibility of including in the stochastic process for the cost to completion also *input cost uncertainty* (e.g., prices of labor and materials) that are external to what the firm does and might be partially correlated with the overall economic activity.

Adding input cost uncertainty to the cost process, Equation (1) would be written as:

$$(17) \quad dK = -Idt + \sigma(IK)^{\frac{1}{2}} dz + \gamma K dy$$

where  $\gamma$  is the input cost uncertainty and  $dy$  is an increment to a Gauss Wiener process that may be correlated with the return on the market portfolio and with the cash flow process.

A cost specification as in (17) could be easily incorporated in the simulation procedure described in Appendix.<sup>39</sup> The difficulty in adding input cost uncertainty would be that, if it is correlated with the return on the market, it would have a risk premium associated with it which might be difficult to estimate in practice.

#### 4.7 Options to Delay Investment, Stop Investment, and Restart the Project

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<sup>38</sup> See Schwartz and Moon (2001) for a discussion of these issues.

<sup>39</sup> A third standard normal variate, correlated with the other two, would have to be generated and Equation (A1) would have another term in the right hand side to deal with input cost uncertainty. The rest of the procedure would be the same.

The model discussed in the previous sections takes into account the option to abandon the project, but not the option to delay investment or the option to restart a project that has been previously stopped. This is a reasonable framework for situations in which the product to be produced in the future is protected by a patent, since delaying investment shortens the duration of the future cash flows making it very unlikely that a stopped project would be restarted later on.

For situations in which the duration of the cash flows is independent of the duration of the investment, these options can become more important. Delaying investment does not shorten the duration of cash flows, though it still has the effect of generating cash flows more distant in the future. In this case the value of the investment opportunity depends on the cost to completion,  $K$ , and the value of the asset obtained at the completion of the project,  $V(C,t)$  given by Equation (7), but not on calendar time since now  $T-t$  has a fixed duration independent on when the investment is completed. This problem generates an elliptical partial differential equation which can be solved by numerical methods to give the value of the project and the optimal investment strategy.<sup>40</sup> This case is simpler since the duration of the cash flows is deterministic.

## **5 Conclusions**

In this article I have developed and implemented a simulation approach to value R&D projects and patents that is based on the Real Options approach. It takes into account uncertainty in the cost to completion of the project, uncertainty in the cash flows to be generated from the project, and the possibility of catastrophic events that could put an end to the effort before it is completed. It also allows for the possibility of abandoning the project when costs turn out to be larger than expected or when estimated cash flows



turn out to be smaller than anticipated. This abandonment option represents a very substantial part of the project's value when the project is marginal or/and when uncertainty is large.

Even though this article looks at R&D projects from the private point of view, the analysis has important public policy implications. Regulation can affect not only the life of the patent, but also the cost of development and/or the prices charged for the product produced. All of these will affect the profitability of R&D projects and, therefore, the amount of innovative output. The model developed in this article should be of help to policy makers for analyzing the trade-off between promoting innovative efforts and securing competitive market outcomes.<sup>41</sup>

In the development and analysis of this article, it has been taken for granted that development costs and the cash flows generated by the project are independent of the owner of the project. As in many other types of projects this is not necessarily the case. There is some recent evidence that the R&D cost per new drug approved in the US decrease with firm size, while the sales per new drug approved increase with firm size.<sup>42</sup>

New regulatory initiatives in the United States have provided valuable opportunities for pharmaceutical developers to improve efficiency.<sup>43</sup> For example, the Prescription Drug User Fee Act of 1992, which authorized the collection of user fees by the FDA, resulted in a sharp decline in new drug approval times, and the FDA Modernization Act of 1997 established the "Fast Track Process" for speeding the development and approval of drugs that address unmet medical needs. The model

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<sup>40</sup> See Schwartz and Moon (2000).

<sup>41</sup> It should be pointed out that intellectual property is not the only mechanism for rewarding R&D. Prizes and contract research of various types are also common. For a discussion of these issues see Gallini and Scotchmer (2002).

developed in this article is well suited to deal with economic effects of these types of issues.

There are important factors about the decision to invest in R&D that are not incorporated in the analysis of this article. For example, recent theoretical work has stressed strategic interaction among rivals as a primary determinant of investment decisions. This approach has suggested some powerful insights into the dynamics of competition in R&D.<sup>44</sup>

The pharmaceutical industry appears to have suffered a decline in productivity over the last twenty years. Henderson and Cockburn (1996b) use disaggregated data at the research program level to explore that decline. They conclude that “the decline is probably not a function either of a shift to research in more difficult areas or of an increase in racing behavior in the industry. Rather, our results are consistent with the hypothesis that rising real costs of research in the industry reflect decreasing returns. The switch to more science-intensive methods of drug research appears to be a major contributor to increasing costs, but the most important driver of cost escalation appears to be the rocketing costs of developing clinical drugs. We speculate that this probably reflects both a shift to the treatment of conditions that require more complex clinical trials and increasing regulatory stringency, but we have no data about those issues.”<sup>45</sup> As the investment process in R&D becomes more complex, tools as those suggested in this article will become more important in the evaluation and decision making processes.

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<sup>42</sup> See DiMasi, Grabowski and Vernon (1995).

<sup>43</sup> See Kaitin and DiMassi (2000).

<sup>44</sup> See Cockburn and Henderson (1994), Reinganum (1989) and Miltersen and Schwartz (2002).

<sup>45</sup> See Henderson and Cockburn (1996b), page 184.

## **Summary**

This article develops and implements a simulation approach to value R&D projects and patents that is based on the Real Options approach. It takes into account uncertainty in the cost to completion of the project, uncertainty in the cash flows to be generated from the project, and the possibility of catastrophic events that could put an end to the effort before it is completed. It also allows for the possibility of abandoning the project when costs turn out to be larger than expected or when estimated cash flows turn out to be smaller than anticipated. This abandonment option represents a very substantial part of the project's value when the project is marginal or/and when uncertainty is large.

Even though this article looks at R&D projects from the private point of view, the analysis has important public policy implications. Regulation can affect not only the life of the patent, but also the cost of development and/or the prices charged for the product produced. All of these will affect the profitability of R&D projects and, therefore, the amount of innovative output. The model developed in this article should be of help to policy makers for analyzing the trade-off between promoting innovative efforts and securing competitive market outcomes.

## Appendix: Solution Procedure

The appendix describes the Monte Carlo simulation procedure used to solve the problem. The option to abandon the R&D project is computed using a variation of the least-squares method proposed by Longstaff and Schwartz (2001) for valuing American options. The decision to abandon the project is evaluated at discrete points in time, instead of continuously. This would seem to be a more reasonable assumption when analyzing R&D projects. In the simulations, the following discrete approximations to Equations (1) and (4) are used:

$$(A1) \quad K(t + \Delta t) = K(t) - I\Delta t + \sigma(IK)^{1/2}(\Delta t)^{1/2} \varepsilon_1$$

$$(A2) \quad C(t + \Delta t) = C(t) \exp((\alpha * -0.5\phi^2)\Delta t + \phi(\Delta t)^{1/2} \varepsilon_2)$$

where  $\varepsilon_1$  and  $\varepsilon_2$  are standard normal variates with correlation  $\rho$ .

If  $T$  is the time to the expiration of the patent and  $\Delta t$  is the step size,  $NT = \frac{T}{\Delta t}$  is the number of periods per path in the simulation. Equations (A1) and (A2) are used to generate  $N$  paths of  $NT$  periods each of costs to completion and cash flow rate. Each path  $i$  is then described by two  $NT$  vectors  $K(i)$  and  $C(i)$ . After the cost to completion reaches zero, the  $K(i)$  vector is filled in with zeros.

The Longstaff and Schwartz (2001) least-squares Monte Carlo algorithm (LSM) is used to provide a path-wise approximation to the optimal stopping rule that maximizes the value of the project. I assume that the option to abandon the project can only be exercised at the  $NT$  discrete times in the simulation and consider the optimal stopping policy at each exercise date. The option to abandon the project has value only during the period of investment in R&D, since once the investment is completed the net cash flows

are assumed to be positive and abandonment is never optimal. At each possible exercise date, the value of the project is zero if abandoned. The value of continuation can be obtained by taking the conditional expectation of the remaining discounted cash flows with respect to the risk-neutral measure. The LSM approach uses least squares to approximate the conditional expectation function at each exercise date. The project is abandoned if the expected value of the project next period is smaller than the marginal investment required this period.

Conditional on not having abandoned the project before, at the final expiration date of the patent (time  $NT$ ), the value of the project for any path  $i$  is given by the boundary condition:

$$(A3) W(i, NT) = M \bullet C(i, NT)$$

At any date  $j$  the value of the project, conditional on not having been abandoned before, for those paths for which the investment has been completed is computed recursively by:

$$(A4) W(i, j) = \exp(-r\Delta t)W(i, j+1) + C(i, j)\Delta t$$

For all those paths for which investment is not completed and optimal abandonment is possible, the conditional expected value of continuation is estimated by regressing the discounted value of the project,  $\exp(-(r + \lambda)\Delta t)W(i, j+1)$ <sup>46</sup>, onto a set of basis functions of the state variables at time  $j$ <sup>47</sup>. The fitted value of this regression,  $\hat{W}(i, j)$ , is the best linear unbiased estimator of the conditional expectation. For those paths for which this fitted value is smaller than the additional investment required in period  $j$ , abandonment is optimal and I set:

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<sup>46</sup> Note that during the period of investment the discount rate is equal to the risk free rate plus the Poisson probability of failure.

<sup>47</sup> In the implementation of the algorithm I use polynomials with nine terms.

$$(A5) W(i, j) = 0$$

For those paths for which the fitted value is larger than the additional investment required, abandonment is not optimal and the expected value of the project at time  $j$  is:

$$(A6) W(i, j) = \hat{W}(i, j) - I\Delta t$$

The recursion proceeds by rolling back in time and repeating the procedure until the exercise decisions at each possible exercise time along each path have been determined. The value of the R&D project is then computed by starting at time zero, moving forward along each path until the expiration of the patent or until the first stopping time occurs, discounting the resulting cash flows to time zero, and taking the average over all the paths. When the optimal stopping time is time zero, the value of the project is zero. Note that the value of the project obtained by this procedure is generally not equal to the average of the  $W(i,0)$ 's, since only the optimal stopping times generated by the algorithm are used, and not the expected values.

The value of the R&D project without the abandonment option can be easily computed as a byproduct of the procedure described above. Note that this value will be in general different from the net present value (Equation (13)) since, even though it does not take into account the option to abandon, it does take into account the volatilities and the correlation of costs and cash flows.

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<b>Parameter</b>	<b>Value</b>
Total Cost to Completion	\$100 million
Maximum Investment Rate	\$10 million per year
Cost Uncertainty	0.5
Cash Flow Rate	\$20 million per year
Cash Flow Uncertainty	0.35
Cash Flow Drift	0.02
Terminal Cash Flow Multiple	5
Annual Probability of Failure	0.07
Time to Expiration of the Patent	20 years
Correlation between Costs and Cash Flows	-0.1
Risk Premium Associated with Cash Flows	0.036
Risk-free Rate of Interest	0.05
Time Step Size in Simulations	0.25 year
Number of Simulations	100,000

**Table 1: Parameters used in Simulations for the base case**

Value with abandonment option (\$ million)	13.9	12.9	13.1	14.0	13.3
Proportion of paths optimally abandoned (%)	40.8	39.9	42.5	40.4	41.3
Value without abandonment option (\$ million)	5.7	4.8	4.8	5.7	5.0

**Table 2: Values and Proportion Abandoned for Different Seeds**

Quarter	% Abandoned
1	2.58
2	5.85
3	5.18
4	4.07
5	3.40
6	2.56
7	2.22
8	1.66
9	1.42
10	1.16
11	1.11
12	0.82
13	0.79
14	0.65
15	0.66
16	0.55

**Table 3: Percentage of Paths Abandoned in First Four Years**

Cost Uncertainty	Value with Option	% Abandoned	Value Without Option	Option Value
0.40	9.658	43.9	1.263	8.395
0.45	11.370	42.4	3.055	8.315
0.50	13.291	41.3	4.992	8.299
0.55	15.241	40.0	7.035	8.206
0.60	17.186	38.5	9.198	7.988
Cash Flow Uncertainty	Value with Option	% Abandoned	Value Without Option	Option Value
0.25	10.926	40.2	4.221	6.705
0.30	12.128	40.8	4.607	7.521
0.35	13.291	41.3	4.992	8.299
0.40	14.433	42.1	5.392	9.041
0.45	15.401	43.6	5.830	9.571
Correlation	Value with Option	% Abandoned	Value Without Option	Option Value
-0.10	13.291	41.3	4.992	8.299
-0.05	12.040	42.5	3.611	8.429
0.00	10.737	43.9	2.221	8.516
0.05	9.515	45.5	0.823	8.692
0.10	8.265	47.4	-0.581	8.846

**Table 4: Comparative Statics with respect to Volatilities and Correlation**

Expected Cost	Value with Option	% Abandoned	Value Without Option	Option Value
80.00	32.812	18.6	30.060	2.752
90.00	21.818	28.1	16.691	5.127
100.00	13.291	41.3	4.992	8.299
110.00	7.047	56.0	-5.252	12.299
120.00	3.273	71.4	-14.116	17.389

Investment Rate	Value with Option	% Abandoned	Value Without Option	Option Value
8.00	5.315	59.3	-5.935	11.250
9.00	9.160	49.1	-0.483	9.643
10.00	13.291	41.3	4.992	8.299
11.00	17.415	34.5	10.298	7.117
12.00	21.430	29.1	15.354	6.076

Cash Flow Rate	Value with Option	% Abandoned	Value Without Option	Option Value
16.00	5.488	60.2	-7.072	12.560
18.00	9.036	49.3	-1.040	10.076
20.00	13.291	41.3	4.992	8.299
22.00	17.955	35.2	11.024	6.931
24.00	22.878	30.7	17.057	5.821

Cash Flow Multiple	Value with Option	% Abandoned	Value Without Option	Option Value
3.00	9.633	49.1	-0.555	10.188
4.00	11.396	45.1	2.218	9.178
5.00	13.291	41.3	4.992	8.299
6.00	15.271	37.9	7.767	7.504
7.00	17.307	34.8	10.540	6.767

**Table 5: Comparative Statics with respect to Cost and Cash Flow Parameters**

Cash Flow Drift	Value with Option	% Abandoned	Value Without Option	Option Value
0.00	4.166	66.8	-10.320	14.486
0.01	7.734	52.3	-3.273	11.007
0.02	13.291	41.3	4.992	8.299
0.03	20.699	31.7	14.700	5.999
0.04	30.487	24.7	26.121	4.366

Probability of Failure	Value with Option	% Abandoned	Value Without Option	Option Value
0.05	18.757	34.8	10.920	7.837
0.06	15.888	37.9	7.793	8.095
0.07	13.291	41.3	4.992	8.299
0.08	11.041	45.0	2.485	8.556
0.09	9.057	48.9	0.243	8.814

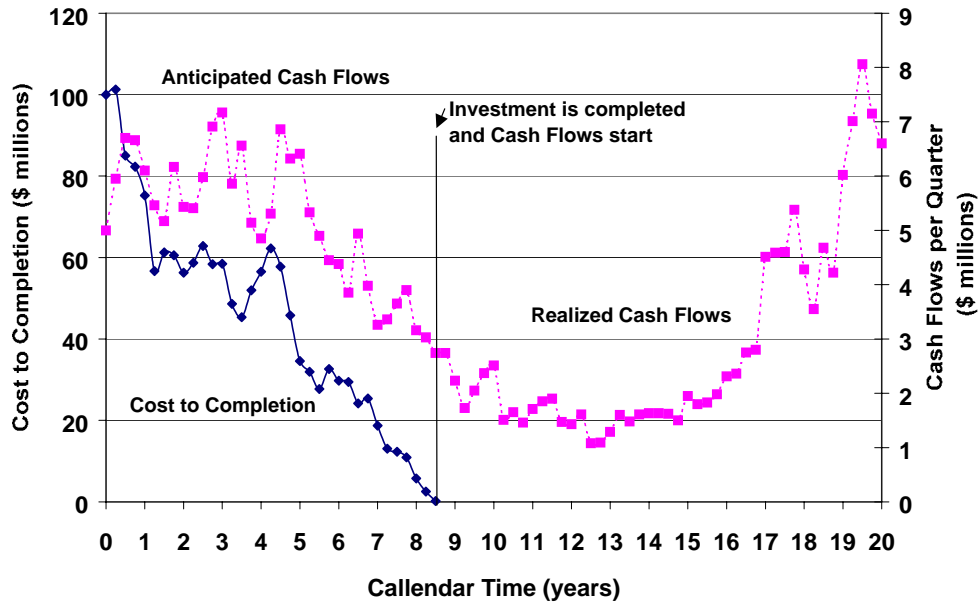
Risk Free Rate	Value with Option	% Abandoned	Value Without Option	Option Value
0.03	27.415	28.9	21.133	6.282
0.04	19.489	34.3	12.290	7.199
0.05	13.291	41.3	4.992	8.299
0.06	8.522	50.0	-1.017	9.539
0.07	5.152	60.3	-5.951	11.103

**Table 6: Comparative Statics with respect to Compounding and Discounting Parameters**

Expiration of Patent	Value with Option	% Abandoned	Value Without Option	Option Value
18.00	9.037	49.3	-1.040	10.077
19.00	11.077	45.0	1.976	9.101
20.00	13.291	41.3	4.992	8.299
21.00	15.611	38.1	8.008	7.603
22.00	17.955	35.2	11.024	6.931

**Table 7: Comparative Statics with respect to Time to Expiration of the Patent**

Figure 1  
 Simulated Paths of Cost to Completion and Quarterly Cash Flow



**Figure 2:**  
**Net Present Value of Project for Cash Flow Rate of \$20 Million**

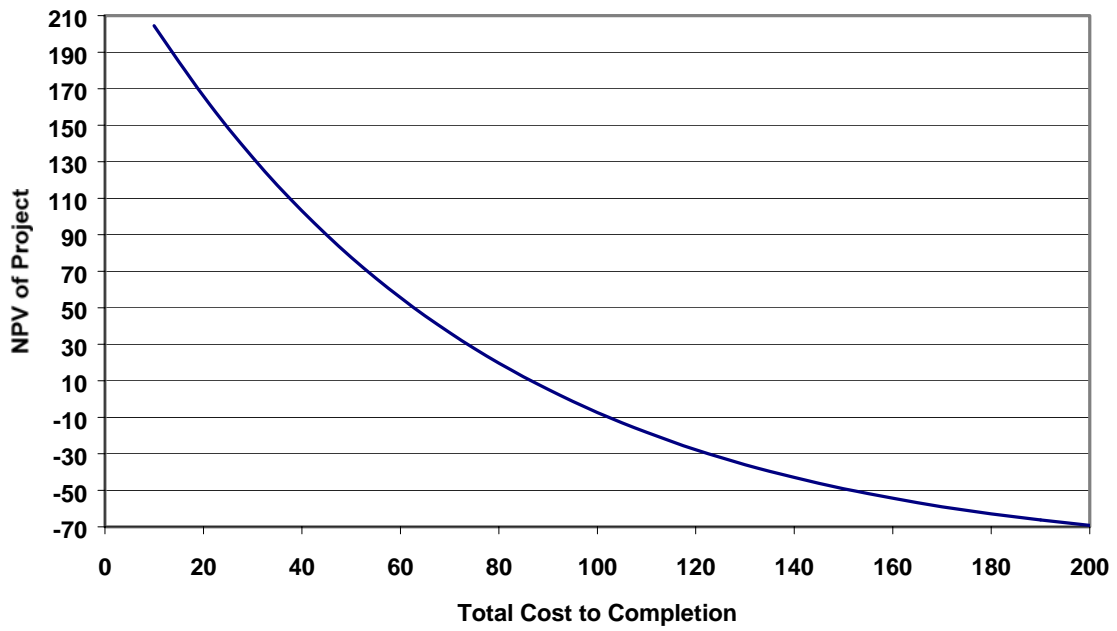
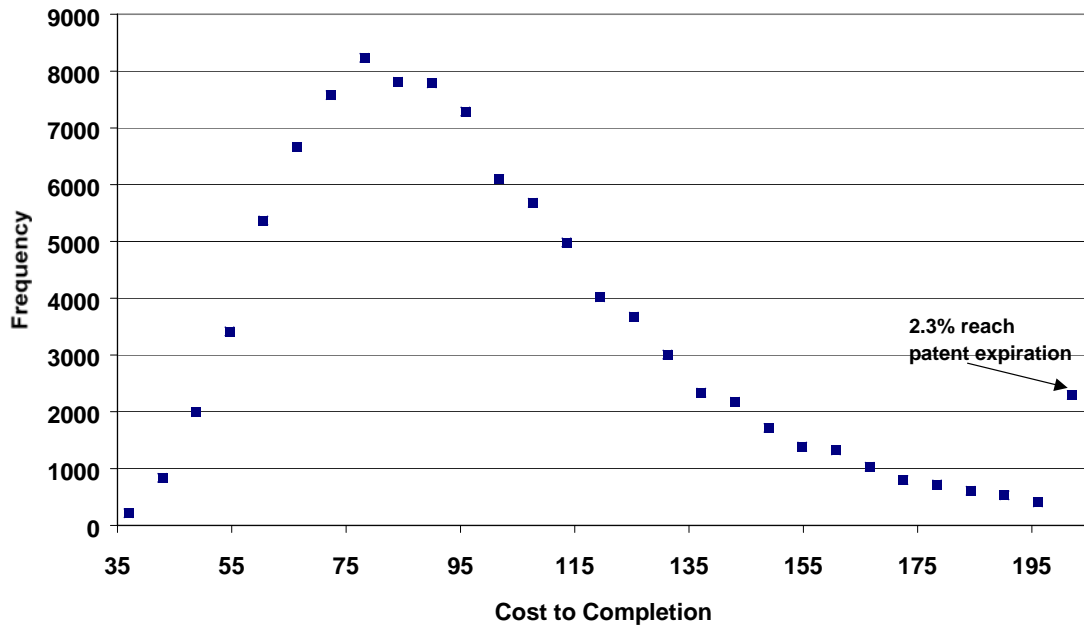




Figure 3  
Cost to Completion Distribution



**Figure 4:  
Critical Values for Investment**

