PART 6

Economics and Safety Issues

11

Beyond Bayh–Dole and the Lambert Review: an Initial Product Development and Transaction Model for the Interface between Universities and Business[1]

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> Full many a gem of purest ray serene,
> The dark unfathom'd caves of ocean bear;
> Full many a flower is born to blush unseen,
> And waste its sweetness on the desert air.
>
> In: Elegy in a Country Churchyard. Thomas Gray (1716–1771)

Introduction: the economics of value creation

Despite advances in the life sciences, the discovery and development of drugs, diagnostics, and medical devices are facing obstacles on all fronts. Pharmaceutical companies face pricing pressures, relatively empty product pipelines, increasing costs of development, patent expirations, and a dismal record of regulatory approvals (*The Economist*, 2003a,b). *Innovation*, rather than mergers, *is the solution* (Editorial, 2002). Universities are confronted with a different set of problems that include increased costs for research and education, coupled with a decrease in government funding (Bok, 2003; Eisenberg, 2003; Rai and Eisenberg, 2003; Thursby and Thursby, 2003; Walsh *et al.*, 2003). In the US, there is a negative relationship between R&D investment and the introduction of new drugs into the market (*Figure 11.1*). In order to capture and leverage returns in the knowledge economy,

[1]Although this model has general applicability, the focus here is on the technology–product continuum relative to biotechnology and genetic engineering, namely drugs, diagnostics, and medical devices.

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Abbreviations: EMEA, European Agency for the Evaluation of Medicinal Products; FDA, Food and Drug Administration; ICH, International Conference on Harmonization; NIH, National Institutes of Health; PD&TO, Product Development and Transaction Office; TTO, Technology Transfer Office; USPTO, United States Patent and Trademark Office.

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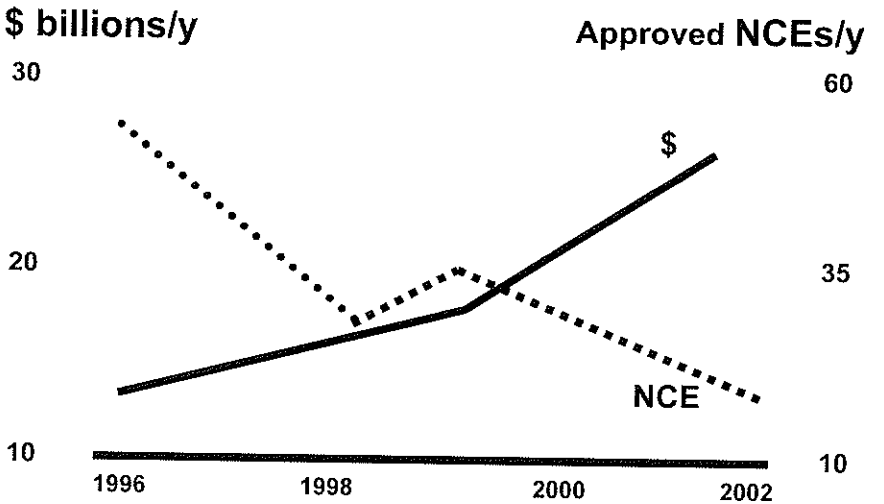

Figure 11.1. The US drug industry. Innovative advances in biotechnology and genetic engineering in universities are not being translated into clinically useful products, NCE = new chemical entity (modified from Hall, 2003; *The Economist*, 2003a).

focus needs to be directed to the translation of advanced science and technology into high-value marketable products, and therefore attention and encouragement should be directed to universities, the proximate source of innovation.

Innovation is the successful commercialization of good ideas. For successful commercialization, the idea has to be protected and entered into a product development process. Although collaboration is essential, the academic inventor, rather than the industry scientist, is best qualified and positioned to transition an idea into a product prototype that can satisfy a defined market need. By decreasing risk, this transformation can add major value to the invention. In essence, *alignment of capabilities, expectations, and knowledge of the market* are essential to productive transactions at the university–business interface.

The 25th anniversary of the Bayh–Dole Act of 1980 is approaching, and it is perhaps time to pause and reflect on this pioneering legislation. The Act sought to enable the transfer of technology from universities in the United States to business, providing incentives for the former. Today, *there is a weak demand from business for the knowledge created in universities* (Lambert Review of Business–University Collaboration, 2003a,b). Although patents continue to be filed in US universities at a record pace (Staedter, 2003), few make the transition to commercially successful products (Allison *et al.*, 2003). This discrepancy may be related to a *perceived lack of commercial relevance*, *relative immaturity of the product concept*, or *problems related to patent law (Figure 11.2).*

Although all are in favour of closer university–business collaboration and the attendant economic benefits, none desire the 'commercialization' of the mission of institutions of higher education. For knowledge transfer to be effective, the gap between non-directional technology and a specific product architecture needs to be bridged in a manner that is fair to universities and business, and relevant to market need. Economically, this should be relatively easy since the gap represents definable

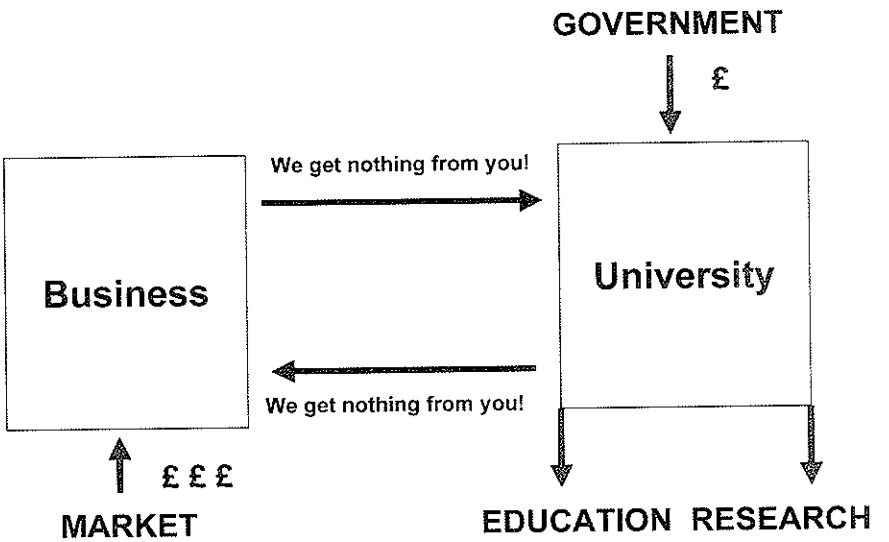

Figure 11.2. Who is at fault? Analysis of supply and demand is the key to valuation. Alignment of interests between business and universities and appropriate valuation of transactions can result in new, improved, and affordable products to society, coupled with invigoration of the national and regional economies while rationalizing government outlays to universities. The major obstacles are information asymmetries relative to the valuation of technologies and products, and the necessity for predictable application of patent law. Everything considered, a detailed description of a *product* concept facilitates better recognition of value than mere opinions of the market potential of a technology. (*Answer*: In keeping with the Lambert Review (2003b), there are *two* correct answers. It depends on which box you are in!)

and surmountable risk. And although the bridging process will require investment, a value proposition based on supply and demand can be structured to assure appropriate capitalization, as well as an attractive outcome (Dixit and Pindyck, 1994; Stewart *et al.*, 2001; Arnold *et al.*, 2002).

According to Eisenberg, one reason for the slow entry of economists into this area may be the indeterminacy of economic analysis in evaluating the patent system (Eisenberg, 2000). Valuation of technology cannot be reached in isolation. Granted protection, factors determining the supply and demand of technology, have to be examined in a product–market context in order to approximate value and price. In this construct, valuation reaches an asymptote when there is a *qualitative alignment and a quantitative mismatch* between supply and demand (demand exceeds supply). By definition, an analysis that is limited to either the *supply-side* (universities) or the *demand-side* (business) of the exchange is incomplete, and cannot lead to an understanding of transactional dynamics and prescriptive solutions (Medbase, 2003). This may represent a limitation of the Lambert Review (2003a), the main focus of which was on the *demand-side* – the *wants* of business in terms of university R&D, and in the transfer of technology and skills. Overall, business currently operates in the manufacturing mode (not the knowledge economy). Here, competitive advantage is a lower cost structure, and its 'wants' are facilitated by globalization (cheaper labour and technology), not innovation. Innovation thrives in an academic setting that allows for independent research, and in a market economy; it can be facilitated

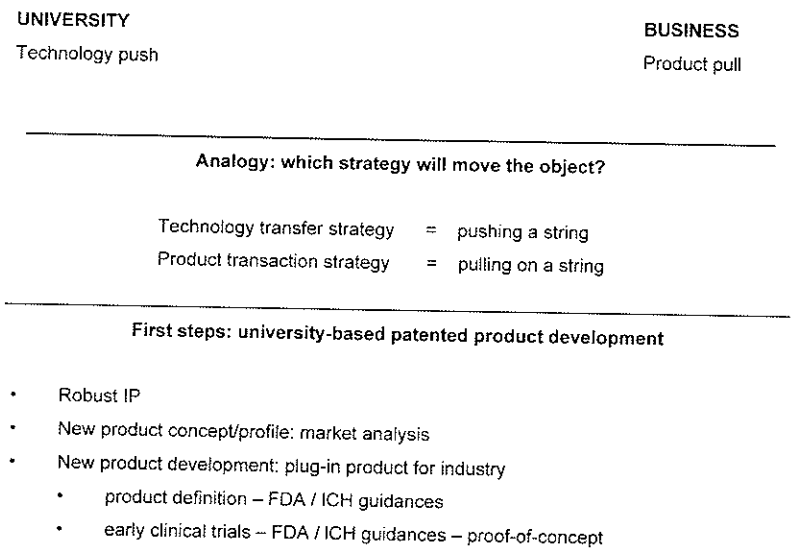

Figure 11.3. Context shift: from technology transfer to product development and transaction. The university–business interface is not a club – it is a market between a buyer (business) and a seller (university). In most cases, the subject of transaction is a patented intangible. If the seller does not construct and justify appropriate valuation of the invention, it is quite unlikely that the buyer will do so. Markets are not in the technology business, and it is difficult to value technology prospectively. As a first step, it is best to transform technology into defined product concepts, and then place this in the development/market context.

by appropriate legislation (Fernandes and Miska, 2002a) but probably cannot be created nor accelerated by central planning (Editorial, 2003).

Universities produce *patentable technologies*, while business is looking for promising *early-stage products (Figure 11.3)*. The central mechanism coordinating this transaction is the university Technology Transfer Office (TTO). TTOs have rendered a superb service in the evaluation and patenting of technologies, but have fallen short in negotiating and closing on licensing deals at appropriate valuations (Edwards *et al.*, 2003). We attribute the latter to a lack of product focus, an imperfect understanding of relevant downstream development, regulations and markets, and scant attention to the due diligence process on intellectual property (Gogoris and Clarke, 2001a,b). With critical information asymmetries, a win–win agreement with business cannot be reached. *The real outcome is loss–loss–loss, for universities, business, and society.* Recently, the legality of 'use' patents has been questioned, and there is a fear that this may become a trend (Shuster *et al.*, 2003). Basic science is central to the discovery of new drug classes (Kirschenbaum, 2002). The initial output is usually a blueprint for product development and use. If early, important and valuable discovery cannot be protected, then conventional technology transfer becomes a moot point – *why buy a cow when milk is free*?

Historically, discoveries were never protected. Patents were devised to protect novel technical solutions to technical problems, either in the form of a specific and

well-defined novel product or a novel process. Accordingly, the goal was to promote innovation in business by conferring limited property rights to the inventor. The trend to cover *de facto* discoveries or general ideas is a recent one, and parallels developments in genomics, software, and business methods. And it is questionable whether this trend promotes or inhibits innovation (The Royal Society, 2003), although it is likely that overly broad patents inhibit rather than promote progress. But, as in all schemes, there are always fuzzy boundaries between a discovery, a problem, and a derivative technical solution. Other issues – the experimental use exception does not exempt universities from patent infringement – are equally serious (Eisenberg, 2003; Walsh *et al.*, 2003), but will not be considered here.

Universities are in a bind – between increasing research costs, decreased funding for education and research, and decreasing revenue generation from the successes. Universities have all the resources to transform technology into products and, in addition, to conduct proof-of-concept clinical trials. Accordingly, and under the Bayh–Dole Act, it makes both legal and business sense for universities to focus on the 'last critical step' of conventional 'use' patents, and as a policy, consider initial product development for promising inventions. Excellent arguments have been advanced to 'keep science open' (The Royal Society, 2003) and, although Bok disapproves of the commercialization of higher education (Bok, 2003), Baltimore reminds us that universities sit within the same capitalistic framework as the rest of American life (Baltimore, 2003). It serves a high ideal – the discovery and dissemination of understanding and skill – but it does so with the same concerns of any business striving to stay solvent (Baltimore, 2003). Specifically, three major trends characterize the ongoing transformation of the role of universities in the US R&D system: *a decline in the federal share of funding*, *the growth of self-financed R&D*, and *an increase in biomedical research to a position of dominance* (Mowery, 2002).

The purpose of this review is to explore the causes and loci of transactional asymmetries and bottlenecks in technology transfer, and propose a model that could alleviate the problems in universities and business alike. In an admittedly imperfect and complex landscape that includes science, medicine, law, economics, and the market, the desired effect would be assured support for scientific endeavour and the delivery of expected results: new, improved, and affordable medicines, diagnostics, and medical devices to society (Blumenthal, 2003). Several elements of our proposal are consistent with recent, major, national and international initiatives (The Sainsbury Report, 2002; Academy of Medical Sciences, UK, 2003; Committee on Large-Scale Science and Cancer Research, 2003; European Commission, 2003; Lambert Review, 2003a,b; OECD, 2003; The House of Commons, 2003; Zerhouni, 2003). We will also discuss the problems and opportunities relative to patentability in the life sciences, since *invention is a subset and pre-requisite of innovation* (Lemley and Burk, 2002).

Patentability: necessary, but not sufficient for valuation and transaction

Patenting is central to ownership, and thereby valuation (Meltzer *et al.*, 2002), and because industries are different, patents are not created equal (Allison *et al.*, 2003). The general impression is that fewer than 1 in 20 patents are licensed, and that fewer than 5% of licensing deals generate appreciable royalties. The key to licensing and royalties is

not just an allowed patent, but one with a persuasive case for marketability. *Accordingly, the potential for improvement in outcomes is huge, and self-evident.*

As noted, broad claims related to pioneering discoveries may promise a 'dominant' role, but risk invalidation, while narrow product claims, though easier to construct and defend, run the risk of being by-passed. The best patent is one that is able to withstand challenge, and rewards the inventor (Gogoris and Clarke, 2001a,b). Accordingly, no activity is more important than a sound and comprehensive intellectual property strategy that covers R&D points, regulatory issues, and market considerations (Daizadeh *et al.*, 2002; Meltzer *et al.*, 2002; Duxbury and Mellett, 2003). All vulnerabilities should be addressed at inception since a successful challenge nullifies the entire venture (Shuster *et al.*, 2003). These vulnerabilities may be rather difficult to identify and evaluate – patent offices and attorneys tend to consider patent data only, whereas general ideas may be published in the non-patent literature, including grant applications and conference abstracts, that are legitimate sources of prior art. Serious asymmetry characterizes the interaction at the university–business interface. In order to arrive at the appropriate valuation, the licensor should understand the requirements and costs of the development, and the market potential of the product to a similar, or preferably greater, extent than the potential licensee. This should not pose a problem for the inventor – *although the fox may know many things, the hedgehog knows one big thing*! (Berlin, 1953).

The basic principles of patentability are listed in *Table 11.1*. Detailed information and guidance can (and should) be obtained from national patent offices and accredited counsel. The interested reader is directed to Pila (2003) for a comprehensive treatment of patent law and modern biotechnology. For scientists contemplating commercialization of their inventions, the story of the rise and fall of CellPro is required reading (Valoir, 2000; Bar-Shalom and Cook-Deegan, 2002).

According to Thomas Edison, *the value of an idea lies in the using of it*, and this value is best protected and realized by the patent process. In brief, to be patentable, an invention has to be *novel, non-obvious* – the inventive step, and *useful* – capable of industrial application. Evaluation of the inventive step is central to the process and includes: definition of the underlying problem, the insight upon which the solution relies, the means constituting the solution, and the effect obtained. To

Table 11.1. Patentability – principles

PATENTABLE SUBJECT MATTER
Product or process that relates to a new and useful function – *the invention*
• **Product** – composition of matter, machine
• **Process** – manufacture, method of treatment/use (business methods)
CRITERIA
• **Novelty** – an *undisclosed difference* between the invention and the state of the art
• **Non-obviousness** – the difference is *not obvious* – *the inventive step*
• **Utility** – the invention is *useful* and capable of *industrial application*
SPECIFICATIONS
• **Written description** – clear description of invention which is in existence at filing
• **Enablement** – guidance to make and use the invention without undue experimentation
• **Best mode** – indicates preferred method to make the invention
CLAIMS
• **Claims** – define the boundary of *desired, justifiable,* and *defensible* intellectual property

Source: The US Patent and Trademark Office, The Patent Office, UK, and the European Patent Office, Luxembourg.

qualify for non-obviousness, the inventive step should be clearly differentiated from current knowledge – *prior art*. The proof, or more likely, the promise of utility must be specific, substantial, credible, and relevant to the market. The patent application must contain an adequate written description of the invention, which verifies possession at the time of filing, as well as an enabling description, which teaches how to make and use the invention (Webber, 2003). There should be a strict linkage between the *claims* and the *written description* in order to assure that what is claimed was actually invented (Goldschmidt, 2002). In biotechnology, fulfilment of the written description requirement has come under close scrutiny by both the USPTO and the courts (Blaug *et al.*, 2003).

Usually, inventions with physical and/or chemical attributes (composition of matter, articles of manufacture) can be more easily and precisely described than those without them (method of treatment, use). Although the 'written description' and 'enablement' requirements appear rational and reasonable, they allow for wide interpretation not only in different technology contexts (Burk and Lemley, 2002), but also within the same industry (Hasson, 2002). Wide interpretation of the requirements for patentability undermines predictability both at the USPTO and in the courts.

Although patent law gives the impression of transparency, respect for precedence, and common-sense rules, the reality is quite different, and especially between the US and Europe. In the US, the concept of 'non-obviousness' is ascertained by patent attorneys, who have a very different frame of reference than scientists or engineers. In our experience, a patent on almost any trivial submission can be obtained in the US if it is worded properly (Doctrine of the Magic Words); it is more difficult in the UK, Germany, or Japan, where patent officers have a much deeper technical background (Stoy, 2003). Lemley at UC Berkeley has provided an elegant and amusing explanation and justification of 'rational ignorance' at the USPTO: *the office doesn't do a very detailed job of examining patents but we probably don't want it to*. In view of the large and increasing number of applications, the USPTO is 'rationally ignorant' of the objective validity of patents because it is too costly to discover those facts (Lemley, 2001). The default outcome? *Let the courts decide*.

Further, there is a wide schism between technical and legal language. In the US, claims are often allowed for specifications that are vague and poorly defined (*The Economist*, 2003c). Rarely do specifications describe realistic instructions for implementation of the invention. Finally, when challenged, especially on appeal, the interpretation of claims is argued in front of a judge with no specialized training in patent law. This makes the protection of intellectual property a virtual lottery, and a rich source of legal revenue. Currently, the system discriminates against individual investigators, universities, and small companies – the real and proximate source of innovation (Allison *et al.*, 2003).

There are differences between patenting a broad and perhaps vague idea, structured as a method for instance, and protecting a *specific* method or product. Broad claims have the potential of including prior art, and are therefore more vulnerable to invalidation or challenge. On the other hand, narrow and specific claims are safer but more likely to inspire alternative solutions, which is actually a benefit of the patent system. Patenting on the basic level of knowledge necessarily leads to broad claims that have to be defended or enforced by very expensive legal action. This is

	TECHNOLOGY TRANSFER	PRODUCT DEVELOPMENT AND TRANSACTION
Patent		
• emphasis	protection only	protection and valuation pitch: product concept and utility performance: initiate 'last critical step'
Negotiations		
• participants	seller – buyer	development and commercialization partners
• subject matter	standard requirements	plus 'plan to FDA and market'
• decision-maker	R&D	marketing
• time-to-decision	slow	real time – competition
• structure of contract	complex, customized	standard
Market		
• time-to-market	slower	faster
• cost-to-market	higher	lower
Return on investment		
• deal valuation	low	much higher
• deal number	single	multiple products
• revenue stream	smaller and delayed	appropriate and not discounted
Overall process	quagmire lose – lose	transparent, rational, low-risk win – win

Figure 11.4. Downstream strategy – from technology to products. Publications and patents are a natural outflow of university work but this does not effortlessly extrapolate to market value. By adapting to business requirements and needs, it may be appropriate for universities to adopt, in addition, a product focus. 'Transfer' conjures the image of effortless movement from the underground to the bus to the train on one ticket, while transaction implies a cash exchange between participants who understand the value of the deal within the context of product, regulations, and market risk. If there is an agreement on assumptions, the potential, and the risk, then there should be an agreement on the price range.

probably one of the main factors inhibiting investment. In our proposed model, appropriate valuation and demand from business would be a consequence of a product vision (beyond technology *per se*), risk reduction, and reliable patent protection. The Product Development and Transaction Office (PD&TO) would reflect the new mission (*Figure 11.4*). It would be structured to implement the suggested changes, and its performance would be measured by the *rate of product development* rather than patent output, and by *revenue generation* rather than the number of licensing deals and start-up companies.

The Birch Bayh–Bob Dole Act of 1980: innovation's golden goose

The growing problems surrounding the inefficiency of federal research funding in the US relative to the commercialization of discoveries were recognized decades ago and the enactment of Bayh–Dole in 1980 was designed as a comprehensive remedy. The major policy objectives of this act provided for:

- universities to file patents on inventions they elect to own, and license them to business
- universities to allocate returns to the inventor and other research or educational projects

- a close collaboration between universities and business in order to ensure public availability of the benefits

Bayh–Dole is an example of well-intentioned legislation, and has been credited for the remarkable growth of knowledge-intensive industries in the US over the past two decades, and is now serving as a global model for technology transfer (*The Economist*, 2002; OECD, 2003). In essence, it was incentive driven: it aimed to transfer ownership of an invention from the government to the university, and provide for rewards to the inventor, university, small business entities, and society (Nelsen, 1998; *The Economist*, 2002). Many countries have initiated similar legislation in order to enhance the collaboration between universities and business, notably Germany, France, Japan, India, and Australia (Fernandes and Miska, 2002a; Kilger and Bartenbach, 2002; Schmiemann and Durvy, 2003; Schwartz and Vilquin, 2003). The Third Report of the European Commission details the problems and opportunities that have to be addressed in order to capture the benefits of the knowledge economy (European Commission, 2003). The problem is simple, clear, important, and immediate: *European industry faces a disconnect between R&D and the results from innovation* (Short, 2003). It is hoped that the work being performed by the Trade and Industry Committee (The House of Commons, 2003) and by Richard Lambert may direct interest to the advisability of a Bayh–Dole-type initiative for the UK (Lambert Review, 2003b).

The verdict on Bayh–Dole: value not proven?

Judging the success of legislation depends on the criteria set for evaluation (Fernandes and Miska, 2002a). The most common cause for disagreement is that different yardsticks are used to measure productivity and valuation in universities and in business. When judged by the creation of university technology transfer offices, patent filings, and start-up companies, Bayh–Dole has been a remarkable success (Kneller, 2001; Thursby and Thursby, 2003). But when judged by revenue generation to the university and the transfer of the benefits of inventions to society, it has fallen far short of expectations. In fact, there may even be support for the opinion that an unintended (read: intended) consequence of Bayh–Dole was the possibility of universities subsidizing business for R&D. Technology transfer of publicly funded research may not even be revenue neutral; universities incur considerable costs in setting up TTOs and absorbing patent expenditures. A major segment of the unlicensed intellectual property represents early-stage technology which, though promising, may not qualify for risk financing. This situation may have been justifiable and workable in an earlier era of stable and assured R&D funding, but is, perhaps, not desirable or expected today, or in the future (*Table 11.2*).

Intellectual property is competitive advantage in the form of information, an intangible asset (Medbase, 2003). As such, it is subject to 'Information Rules' related to product positioning, protection, valuation, pricing, and commercialization (Shapiro and Varian, 1999). Intangible assets are the basis of an enterprise's innovation power, the raw material from which the bulk of its future economic and

Table 11.2. Bayh–Dole: a rethink

Viewpoint	Benefits	Issues
1. University	Opportunity for revenue generation	Will TTOs ever be profitable? Could the possibility of infringement hinder academic research?
2. Business	Improved access to early technology	Could the possibility of infringement hinder product development?
3. Inventor	Possibility of benefit from research	Opportunity to participate in product development Patent law reform?
4. Rewards	Innovation is recognized and rewarded	Equitable distribution of rewards
5. Society	Possibility of benefit from federally funded research	After 24 years, are we there yet?
6. Overall impression	Superb legislation	Failure in implementation? Possible adjustments: – university policies – demand from business – patent law reform

financial returns are made (Daum, 2003). In 1999, intangible assets accounted for 80% (40% in 1982) of total market value of S&P (Standard and Poor's 500 companies) companies with market value exceeding book value by 15 to 20 times – e.g. Microsoft, Coca-Cola, SAP. Here, the key required action is the maximization of value of intellectual property, not just its protection (Daum, 2003).

Without action, a patent is worthless; a passive licensing effort should not be mistaken for a commercialization strategy, a product development plan is. As we will note later, technology transfer offices have directed much effort towards intellectual property definition and protection, but little has been directed towards valuation and development. This is admittedly unfair criticism since TTOs were set up as service centres/cost centres, and not as profit centres. If TTOs were set up as profit centres, the focus would be on the relationship between costs and revenue generation. This would result in a lesser attention towards technology transfer (non-selective patent filings, low-value equity contracts) and a greater emphasis on high-value revenue generation, especially in the near-term.

The Bayh–Dole record does not measure up to expectations. Although it is tempting to attribute the dramatic growth of research-intensive industries and the increase in licensing activity in the 80s and 90s to the Bayh–Dole Act, Mowery *et al.* (2001), in a careful study of three universities, could not find evidence to support a causal connection. The University of California and Stanford were active in patenting and licensing before Bayh–Dole, while Columbia started only after its passage. Technology flow has always followed the steep down-gradient from university laboratories to industry, and it is difficult to provide a single example of a federally funded technology that could not get transferred on account of a patent/ownership complication. Therefore, it is interesting to note that no one queried the premise of

Bayh–Dole in 1980: *does one need a pump to send water down the hill?* Specifically, the 1975 discovery of hybridoma technology, which was not patented, led to the creation of an entire industry based on monoclonal antibodies with therapeutic potential (Kohler and Millstein, 1975; Brekke and Sandlie, 2003). Penicillin is an example from an earlier era. Overall, patents do not appear to inhibit or encourage innovation; they relate primarily to the property rights that are claimed and granted to the inventor. Ownership is moot if the protected solution is not relevant to commercial problems or needs. Therein, lies the rub.

Interestingly, the diligent student (read: visitor from Mars) may arrive at a novel, and non-obvious conclusion: federally funded technology was under-utilized by business on account of its perceived low commercial value. And the Bayh–Dole engineered patent flood has not improved the situation. In fact, Bayh–Dole may be likened to good medicine, but for the wrong disease. In this case, the disease is lack of protection and low valuation for excellent, but amorphous and untested (early-stage) technology. Although better product selection and patent submissions would facilitate better valuation, recent trends in patent practice (the '850' patent, University of Rochester) indicate that protection will not be assured without performance of the 'last critical step' – *initial product development*. Theory alone may not be adequate; it has to be accompanied by a tangible – *reduction to practice*. This case clearly demonstrates that the 'transfer' of federally funded technology to business may have, in an unintended way, reached the asymptote of desired efficacy, and in the most quixotic and cost-efficient manner – *with the focus on technology only, the*

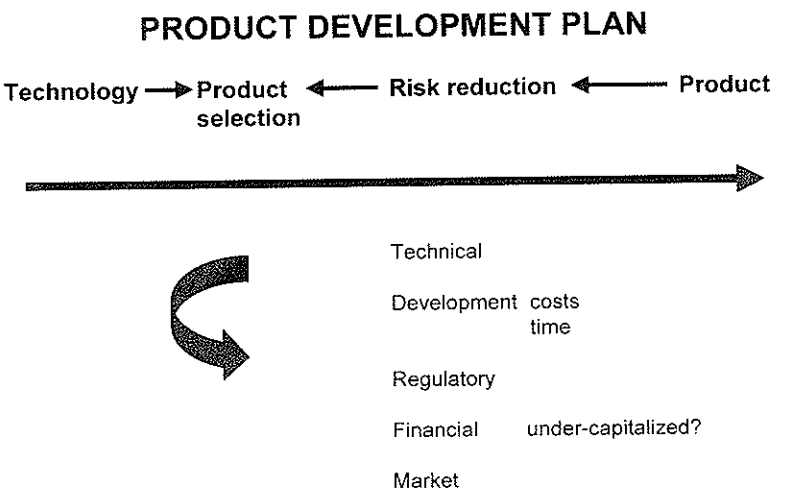

Figure 11.5. Value creation in a surprise-free mode. The product development plan is central to the creation of value. The pharma landscape is littered with predictable, and thereby preventable setbacks and market recalls. In this scheme, decision-making proceeds from right to left, and implementation from left to right. The product has to be visualized, and product selection should be made only *after* risk has been addressed. Early failures are less expensive than late failures, reflecting the importance of regulatory risk and predicted market performance.

transfer is made at low valuation, or the rewards due the inventor and the university risk being nullified by the courts. In reality, the rewards to the inventor or the university are miniscule at best.

In universities, value is placed on patentable and published inventions, while business is more concerned with the likelihood that the derived product will represent a solution that is rewarding and risk (technical, regulatory, market)-free (*Figure 11.5*). *Defining risk in an early-stage setting is risky business*, and it is understandable that decision-making will be difficult, and if possible, concluded at low valuations and weighted towards (i.e. discounted by) distant milestones. *The impact on cash flow is obvious.* Accordingly, suggestions to remedy this problem will have to address the key concern of the customer: *at this stage, what evidence has been presented that this proposal will deliver as described?* Therefore, it is best that the inventor chart a 'real options map' to regulatory approval and to the market (Amram and Kulatilaka, 1999; Copeland and Tufano, 2004), and have this available at the first meeting with business. Contrary to conventional wisdom, valuation is critically influenced by qualitative considerations (Arnold *et al.*, 2002), and we only have *one* opportunity to make the *first* impression. The price is related to the benefits of exercising defined options, and by definition, is what the customer is willing to pay.

Bayh–Dole: market focus is the key to value creation

The desired outcome of Bayh–Dole depended on a multitude of factors that could not be controlled, the most important being the setting of objectives and implementation. Although it is difficult to discipline and align market forces, the best instrument is *incentivization*, but even here with Bayh–Dole it appears to have failed. It is a sad fact that many well-intentioned legislative initiatives have a tendency to fail, and the common cause usually results from problems related to implementation and a lack of market focus. In this case, a logical candidate is the failure of universities to recognize that TTOs had to be staffed by both professionals in intellectual property management as well as professionals with relevant business experience. *Since the buyer has a product focus, it is essential for the seller to have product knowledge.* In the future, an alignment in subject matter and intent will do much in furthering the flow of knowledge, and at the appropriate valuation.

The ideal university technology transfer officer is unaware of any company that has built a path to a TTO in order to buy a *design* for a better mouse-trap. (The first statement will be '*Show me how this here gadget will catch the mouse I'm chasing?*') He is aware that a patented invention, though necessary, is not sufficient to reach a deal at appropriate valuation. He would therefore conduct an analysis of objective validity of the patent ('prior art'), applicable product regulations and commercial potential, especially future competition and pricing, and request plans for product development – costs and time (Moscho *et al.*, 2000; Stewart *et al.*, 2001; Davis, 2002; Shuster *et al.*, 2003). He realizes that he is a seller of valuable intangibles, and is in a buyer's market, and needs to strategize the value drivers relevant to the licensing deal (Arnold *et al.*, 2002). The reader interested in the creation of value from intangible assets through financial engineering and enterprise management is directed to Daum (2003). In our opinion, perfunctory attention to this 'sales' role at the TTO is primarily responsible for Bayh–Dole not to have recorded success.

Patent law: is it fair to biotechnology?

Burk and Lemley (2002) have detailed the consequences of a unified patent system that provides technology-neutral protection for diverse technologies. In this construct, there is an increasing divergence between the rules, and the application of the rules to different industries, especially between biotechnology and software. In biotechnology, as compared to software, there is a lesser emphasis on non-obviousness, but stricter requirements for enablement and the written description. The enablement requirement is relative to the theoretical and legal construct of PHOSITA – person having ordinary skill in the art. The greater the skill of PHOSITA, the lesser the requirements for enablement and written description, but the higher the expectations for the non-obviousness requirement. In biotechnology, courts hold that uncertainty in predicting the structural features of inventions renders them non-obvious, even if the prior art demonstrates a clear plan for producing the invention. The courts believe that computer programmers are extremely skilled, while biotechnology and genetic engineering experts know very little about their art (Burk and Lemley, 2002). But Mr. Bumble comes to our defence: *if the law supposes that, then the law is an ass* (In: *Oliver Twist,* by Charles Dickens, 1837).

'850' (US Patent 6, 048, 850) refers to a use patent issued to the University of Rochester, after a 7-year prosecution, involving the selective inhibition of cyclooxygenase-2 – Cox-2 (Young *et al.*, 2000).

US Patent 6, 048, 850: Method of inhibiting prostaglandin synthesis in a human host

INVENTORS: Donald A. Young, Michael K. O'Banion, and Virginia D. Winn.

ABSTRACT: The invention relates to the gene encoding the mammalian prostaglandin H synthase-2 and its product. More specifically, the invention relates to the diagnosis of aberrant PGHS-2 gene or gene product; the identification, production, and use of compounds which modulate PGHS-2 gene expression or the activity of the PGHS-2 gene product including but not limited to nucleic acid encoding PGHS-2 and homologues, analogues, and deletions thereof, as well as antisense, ribozyme, triple helix, antibody, and polypeptide molecules as well as small inorganic molecules; and pharmaceutical formulations and routes of administration for such compounds.

Issued 11 April, 2000

Cox-2 inhibitors represent a new class of drugs (Celebrex®, celecoxib, Pfizer; Vioxx®, rofecoxib, Merck) that have the ability to relieve pain and inflammation without causing the side effects of stomach ulcers and bleeding typical of aspirin, an inhibitor of Cox-1 and -2 (Hawkey, 1999). Following allowance of the patent in April 2000, the university promptly sued Searle, the manufacturer of Celebrex®, for infringement because this drug works by inhibiting the patented Cox-2 enzymatic pathway. On March 5, 2003, Judge Larimer of the US District Court for Western New York ruled against the University of Rochester and invalidated the use patent (Larimer, 2003; Malakoff, 2003; Shulman, 2003).

Reasons provided for the invalidation included:

- *written description requirement*: not indicating possession of a defined chemical entity (structure) to inhibit activity of the referenced enzyme. The only way to 'make and use' this invention is to find a specific chemical entity. And this can only be obtained by an onerous trial and error process
- *enablement requirement*: not providing sufficient guidance towards selecting a specific chemical entity without the need for undue experimentation

It appears that both items centre on the absence of a description and availability of a defined chemical entity that could have been used to test the hypothesis. One could justifiably ask a few simple questions:

- In biotechnology, is a novel, non-obvious blueprint for a product, *within the specific context of the standard drug discovery process*, patentable?
- In biotechnology, is 'reduction to practice' a mandatory requirement for patentability?

Gogoris and Clarke have stated that, in recent case law, the written description requirement has been applied stringently to biotechnology patents, requiring specific disclosure of the compounds claimed in the patent (Gogoris and Clarke, 2001b). Today, a biotechnology patent that is based on a functional description, without a description of structural attributes, will fail the written description requirement. *To us, this requirement, applied selectively to biotechnology, does not appear necessary, rational, or equitable.*

Evaluation of patents is technology-specific, and not a generic exercise (Burk and Lemley, 2002), and in this case, it would have been appropriate to consider the context of drug discovery. In drug discovery, enzyme inhibition has been the most successful tool of medicinal chemists. A majority of marketed drugs have mechanisms based on the inhibition of specific enzymes in defined metabolic pathways. In order to identify putative drug candidates by standard screening methodologies, key information needed includes a metabolic pathway, the characteristics of the reference enzyme, and an assay/signal to measure effect. *This is standard pharmacology, and there is no unpredictability here.* Contrary to conventional wisdom, and with rare exceptions, as with Gleevec® (imatinib, Novartis), drug discovery, and screening in particular, is a trial and error process, *but not unduly so.* The rapid identification of me-too Cox-2 inhibitors by a host of companies indicates that, at least in this case, inadequacy in the written description and enablement specifications were not limiting factors precluding validity of the patent. It is self-evident that scientists skilled in the art, after studying the blueprint, did not have to perform *undue* experimentation in order to reach the specified goal. In February 2004, the US Court of Appeals for the Federal Circuit in Washington DC affirmed the district court decision invalidating the '850' patent. The university will now request a hearing before the court's full panel of judges (US Court of Appeals, 2004).

The '850' patent, which was allowed by the USPTO after a 7-year prosecution, has self-evident statutory merit (novel, useful, and non-obvious). Accordingly, invalidation of the patent by the Federal District Court, and affirmation by the Appeals Court has serious and immediate implications for biotechnology, academic researchers, as well as the USPTO. University programmes involved in product

development will need to involve allied disciplines, including marketing, intellectual property law, regulations, and end-users, early in the process. The objective will be to generate relevant information to cover standard requirements – regulations, marketing, and to further assure patent validity – enablement, written description, and the justification of claims (Kunin *et al.*, 2002). Although these requirements will increase organizational complexity, and necessitate increased funding, it is not necessarily a bad outcome. It will force stricter upstream selection, facilitate accelerated development, and assure stronger patents. In retrospect, a modest investment (read: a rounding error in comparison to the injunctive and monetary relief sought for the alleged infringement), could have easily produced data to satisfy the written description and enablement key requirements. Valuable patents will be contested, and *vice-versa* (Allison *et al.*, 2003).

Cherchez le creneau: target the market gap

'Technology transfer' implies a smooth, pain-free extrapolation of science from the bench to the market and to the bedside: inventions are disclosed, processed, patented, and licensed to commercial partners at an appropriate value. In an ideal world, the USPTO would diligently check prior art, the inventive step, enablement, and the written description; and an issued patent would have the status of a Treasury Security – backed by the full faith and credit of the US government. In this optimistic scenario, clinical development would be problem-free, the FDA would promptly approve all submissions, and no one would complain about the high price of medicines. Also, in this context, the law is clear, fair, predictable, and invariant: issued patents with commercial potential are never invalidated, infringed upon, or challenged.

Within reason, the value of the patent bears no direct relationship to the elegance of the science or the technology. The stated utility must be specific, substantial, and credible. The context is simple and pragmatic – *does the product represent a solution to a major, immediate, and crying need*? In universities, the vast majority of issued patents are not licensed, or if so, revenues are minimal and in most cases do not cover patenting and administrative costs of the TTO. Value creation is a time-dependent process. Universities are generally unaware of this element, and many licensing deals forego payments related to 'milestones' and 'downstream alliance agreements' (Edwards *et al.*, 2003). Good patents invite, as well as survive, attempts at invalidation, and by definition, are central to the commercial success of derived products. Accordingly, technology transfer should be judged not by the number of patent filings, issuances, and licensing contracts (as in a cost-centre, or controlled economy), but by revenues from the commercial successes (as in a profit-centre, or market economy). Critical success factors for this function include: *the ability to predict the commercial worth of a scientific invention, a multidisciplinary and structured selection of the most promising ones, appropriate investment in the patent process in order to effectively immunize the submission against invalidation, and professional guidance in licensing deals* (Moscho *et al.*, 2000; Duxbury and Mellet, 2003; Edwards *et al.*, 2003; Shuster *et al.*, 2003). The keys to success are *product selection* and *appropriate funding*. For optimal product selection, the decision will have to be multi-disciplinary, and address risk-reduction and market

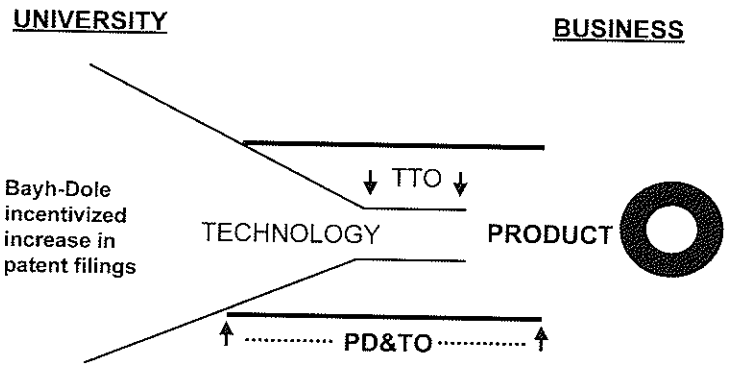

Figure 11.6. The 'bottleneck strategy' towards improved valuation. Bayh–Dole was responsible for incentivizing academic scientists to commercialize their research, as well as prompting universities to create technology transfer offices (TTOs). Overall, this scheme has resulted in a surge of patent filings (and attendant expenses), and only a trickle of technology into the market. Our proposal, the Product Development and Transaction Office (PD&TO) model, is designed to widen the bottleneck and allow for product development and improved valuation, *not increased patent throughput*. Upstream selection would reduce the number of patent filings, while downstream development would improve patent validity and increase the attractiveness of the product to business and the market. Essential to this exercise would be identifying the market *creneau*, and targeting it with relevant technology and development resources, and a solid patent.

predictions, not technological elegance alone. And, although there is nothing like scarcity of funds to stimulate the creative juices, the first five causes of new venture failure is under-capitalization.

Technology should be used to visualize and position new and improved products in the targeted future market space; and the new mantra for university scientists and business alike should be '*cherchez le creneau*' (*Figure 11.6*). Look for the gap, then fill it, in science and in the market (Reis and Trout, 1981). Within reason, and despite Bayh–Dole, the number of patent filings by TTOs is *inversely* related to net revenues and future gains. The diagnosis is obvious: there is poor selection, or if not, context is perhaps misplaced.

If a persuasive case for a 'method' (i.e. a blueprint) can be made, it may be prudent to pursue a 'composition-of-matter' claim and re-structure the entire programme from technology transfer to product transaction. It should be noted that several factors should be considered here, and that although 'methods' have had a better record of commercial transactions than composition-of-matter claims (Eisenstein and Resnick, 2001), this may not be so today. A product strategy would involve: selection of the therapeutic indication, and an analysis of regulatory requirements, including clinical trial endpoints (Miska, 2002, 2003). The drug product would have to be synthesized, optimized, formulated, and, after regulatory clearance, entered into early clinical trials in order to provide proof-of-concept in man. For initial definition, two clinical trials are sufficient; one to estimate the maximum tolerated dose, and the other to construct a dose–response relationship in order to obtain a testable range of doses for the defined clinical indication. The applicable disciplines would include medicinal chemistry and metabolic studies, including

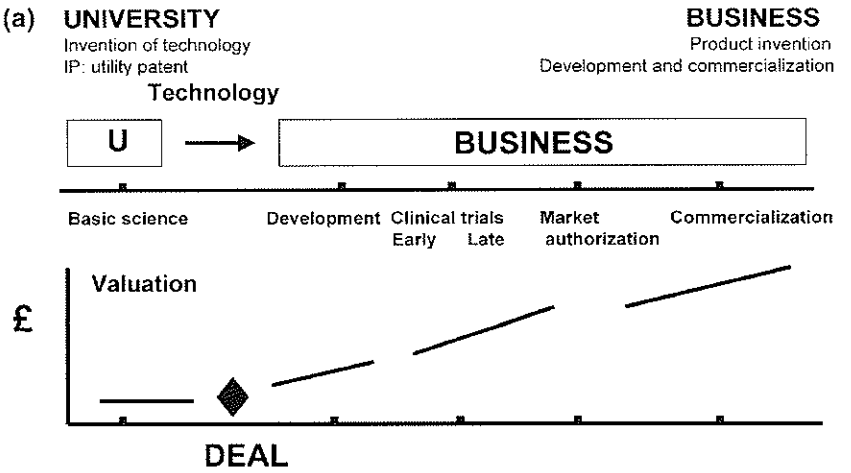

Figure 11.7a. Conventional technology transfer. The subject of transaction is usually an *intangible* – intellectual property. In order to compensate for uncertainties in product development, even a successful license can only obtain a low valuation and distant royalties.

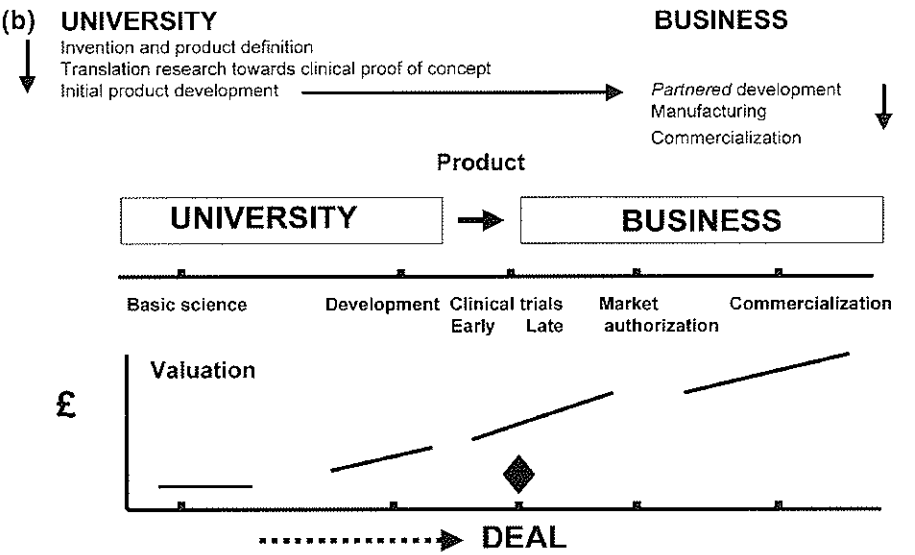

Figure 11.7b. Product development and transaction. The subject of transaction is a *tangible* – a well-patented product. Appropriate valuation is justified by prior work related to product selection and initial studies that further define and reduce risk and time-to-market. The timing of the deal is shifted to the right in order to accommodate initial product development. All resources necessary for product selection and development exist within university departments.

pharmacokinetics and toxicology, pharmaceutical sciences, clinical research, regulatory guidance, and marketing (*Figures 11.7a, b, c*).

Most major universities have established departments that are experienced in these disciplines, and could, with appropriate funding, provide product for translational studies and initial clinical trials (Academy of Medical Sciences, 2003;

(c) **University-originated pharma products – deal split based on future sales**

Stage	% University	% Business
Patented discovery lead	<1	>99
Phase I	2–5	95–98
Phase II	5–10	90–95
Phase IIB – proof of concept	25	75
Phase III – approval	50	50

Figure 11.7c. Deal split. For pharma products, the deal split on profits from future sales is based on the stage of development at acquisition. Steep valuation ramps are: entry into clinical trials, a positive proof-of-concept trial, and the demonstration of safety and efficacy in Phase III trials. The increase in value follows a non-linear progression and reflects continuing validation of human safety and efficacy, and product quality, as well as nearness to the market.

Schwartz and Vilquin, 2003). More importantly, the methodologies for these studies are codified by national and international regulatory agencies, and this makes the results transferable to a partner, and to an eventual regulatory submission (FDA – US Food and Drug Administration, EMEA – European Agency for the Evaluation of

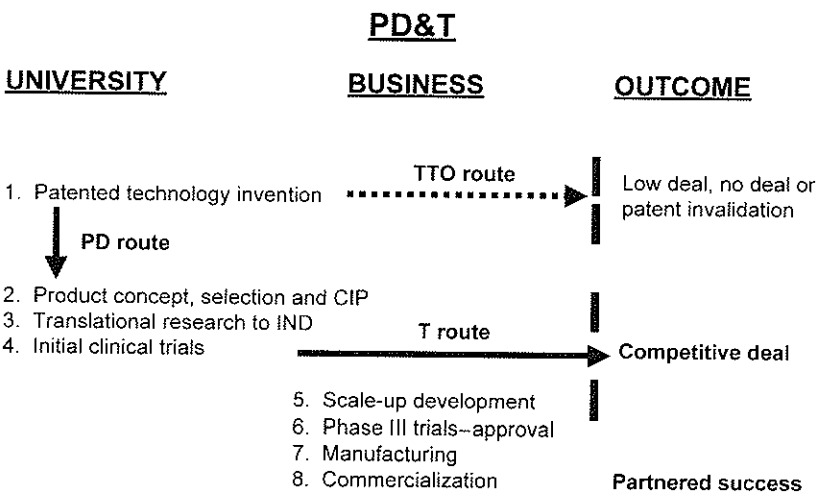

Figure 11.8. The 'bottleneck strategy' in action. Although the product development and transaction protocol implies up-front work and expense, it is basically a research plan that serves an important function. It indicates that the inventors and the universities have evaluated the prospects in a *clear, objective,* and *unbiased* manner, and deem it worthwhile to proceed on their own – if it is really outstanding, why do we have to sell it at a discount? Even if a deal is reached before step 4, the 'map' provides valuable context that can enhance dialogue, strengthen the partnership, and automatically support pricing of the deal. (CIP = continuation-in-part patent filings, PD = product development, T = transaction, IND = investigational new drug, application to FDA).

Medicinal Products, ICH – International Conference on Harmonization). In this construct, project management would merit an important role. Here, problems can be avoided by creating an environment of fairness and singleness of purpose, and where sharing between investigators, universities, and business is equitable, linked to effort, and results, and formalized. The development task as outlined is not *onerous*, as evidenced by the rapid flood of 'me-too' products that predictably follow an innovation. *The blueprint is the thing.* This, in a nutshell, incorporates the elements and mechanics of a university-originated 'later-phase, plug-in product' for business – Product Development and Transaction (*Figure 11.8*).

US and UK initiatives in translational research

In October 2003, NIH (National Institutes of Health) Director, Elias Zerhouni, unveiled the NIH roadmap directed to a more rapid translation of basic research into clinical practice (Zerhouni, 2003). The three elements cover: *new pathways to discovery*, *research teams of the future*, and *re-engineering the clinical research enterprise*. The NIH's fiscal year 2003 budget is $27 billion, of which $8 billion is targeted towards clinical research. Translational research centres will be established to help university scientists and physicians to conduct pre-clinical and clinical research. These centres will provide access to biopharmaceutical manufacturing capacity for clinical-grade material, along with consulting services for drug development regulations. At present, the US Congress is in appropriations negotiations directed to amending the Bayh–Dole Act in order to obtain a more perfect balance between market incentives and the public good (Bruckbauer, 2003).

In October 2003, The UK Academy of Medical Sciences proposed the creation of an NHS-funded National Network for Clinical Research that would focus on six therapeutic areas: vascular diseases (ischemic heart disease, stroke), respiratory diseases, mental health, neurodegenerative diseases, diabetes, and bone and joint disease. The emphasis would be on the translation of biomedical research into clinically useful products that are validated by controlled clinical trials (Academy of Medical Research, UK, 2003; Blakemore and Chalmers, 2003).

In March 2004, the US Food and Drug Administration issued a report detailing the problems and solutions of translating innovation in the biologic sciences into reliable medical treatments – drugs, biologics, and medical devices (FDA, 2004). The report focused on the critical path between discovery and product development and concluded that there is a lack of attention towards product development in contrast to the increasing emphasis on the discovery process. This imbalance will have a negative impact on investments, society, in the context of higher education and employment, and on the health and welfare of patients (FDA, 2004).

The Richard Lambert Review

In November 2002, HM Treasury, the Department for Education and Skills, and the Department for Trade and Industry requested Richard Lambert, former editor of the *Financial Times*, to examine how the relationship between business and universities could be *aligned* to the benefit of universities, business, and the national economy. The context of the review was a sense that the UK performs superbly in terms of

academic quality of its science and technology base, but is deficient in commercializing this knowledge to business in comparison to other countries – notably the USA. Richard Lambert took a comprehensive and structured approach to this review that involved nationwide consultation with universities, businesses, and intermediary organizations.

The Lambert Review of Business–University Collaboration, UK

I think that the big question is whether there is scope to manage universities in a different way – for the Government to specify some measures of success, which if met by the universities would mean that they could be given greater freedoms to behave in a more entrepreneurial way.

There is a weak demand for the knowledge created in universities.

Richard Lambert, July 2003

In the absence of empiric information and in the presence of uncontrollable factors, it will be interesting to note the Lambert opinion on a Bayh–Dole initiative for the UK. In view of the US experience, more attention may have to be directed to implementation and patent reform, especially for biotechnology. Without a market

Table 11.3. From the bench to the market: the transubstantiation of biotechnology

CRITERIA FOR ADVANCEMENT TO PATENT

- reasoned and annotated opinion of commercial interest and valuation
- assurance of protection against invalidation, circumvention
- product focus: product development plan
- regulatory focus: address safety, efficacy and quality requirements
- market focus: roadmap to the market

STRATEGY TOWARDS INCREASED PROTECTION

- **For invention resulting from pioneering science explore dual pathway to establish dominating status of patent**
  'Method of use' is the primary instrument. Supported by 'composition of matter'
  Based on technology, initiate search/synthesis for defined entity to provide example of utility – initial/surrogate evidence of reduction to practice
  Cascade the process – continuation-in-part filings
- **Technology to 'method of use' patent**
  Reason: attempt dominant status
  Risk: broad claims and weak description/enablement may result in invalidation
- **Technology to 'composition of matter' patent**
  Reason: support 'method of use' patent
  Risk: narrow claims may be circumvented

STRATEGY TO JUSTIFY APPROPRIATE VALUATION

- **Risk reduction**
  Nominate advisory committee – cover governance, management, industry practice
  Expand research group to include: medicinal chemistry/toxicology
  pharmaceutical sciences
  regulatory affairs/project management
  Finalize development plan – regulatory and commercial considerations
  Initiate *standard* studies required for *standard* product development
- **Positioning for product transaction**
  Publish and publicize proof-of-concept, and its significance
  Describe proven and/or potential product attributes relevant to competitive advantage
  Create a forum for competitive bidding – a market for intangibles

orientation, universities, as sellers of 'intangibles' (intellectual property), will find it difficult to attain equal partnership with business. This is the single, most important factor limiting technology transactions at the appropriate valuation (*Table 11.3*).

The Lambert Review (2003b) includes six major recommendations aimed at optimizing the collaboration between universities and the business community:

- **Knowledge transfer.** A greater role for the Regional Development Agencies in facilitating knowledge transfer from universities to industry.
- **Governance.** Universities to develop a code of governance and to demonstrate good management and strong performance.
- **Patents.** Development of model contracts and a protocol for intellectual property.
- **Networks.** Encouraging new forms of networks between business and universities.
- **Employment.** Universities to provide more information on student employability, and businesses to take a greater role in influencing university courses.
- **Rewards.** A new funding stream for business-relevant research and knowledge transfer. And a lighter regulatory touch from Government.

The Lambert Review in a real-life context

Industry is rapidly transitioning from a domestic manufacturing base to a global knowledge economy. In the manufacturing context, competitive advantage relates primarily to a low cost structure, while the knowledge economy depends on a continuous introduction of patented innovative products with a vastly improved or unexpected utility (disruptive technologies) that delight the customer. Innovation, the successful commercialization of new ideas, is the primary requirement in the knowledge economy. Since universities are the proximate source of innovation, the Lambert process should have included attention to the supply side (university output) rather than restricting analysis to the wants of business.

To an economist, the only way to increase demand is to focus on the supply: improve the quality, lower the price, or do both. Since academic output is already world-class, and the price is next to free, one wonders how this wish could be realized? The statement that: *public funding for universities should support new knowledge – it should not be a way of making some universities rich* is to ignore the power of economic incentives, and makes little sense for university-based entrepreneurial ventures in a market economy. Rewards do not come without addressing risks, and it is pointless to expect universities to shift resources and emphasis to applied research if the rare upside is denied. In this context, and in view of the sorry state of business R&D governance, especially in pharmaceuticals (Fernandes and Miska, 2002b; *The Economist*, 2003b), the request for universities to emulate business practices is to ask for a central planning, a de-emphasis of academic discipline, a lowering of standards, and will be an invitation to predictable failure.

In response to the Lambert Review, The Economist (2003d) commented: *Universities have talent but no money. Companies need new ideas. A deal?* We advise 'No deal'. Richard Lambert should have analysed university supply and the *needs* of the market, rather than the *wants* of companies, i.e. a highly skilled, low cost work force. Overall, business is still in the manufacturing mode and *wants* technically compe-

tent and cheap labour and technology in order to be profitable today (lower cost structure). However, it *needs* to attract innovative minds and technology in order to be successful tomorrow (value creation). Universities are well positioned to satisfy these *needs* of industry at the appropriate valuation, but may (read: should) not de-emphasize innovation-related R&D in order to comply with the current *wants* of business, especially in cost-competition with globally outsourced vendors in science and technology (Fox, 2003; Kripalani and Engardio, 2003), manufacturing (Aiyar *et al.*, 2003), and in pharmaceutical R&D (GlaxoSmithKline, 2003). Substantial and sustainable national benefit in the knowledge economy, namely revenues and employment, will happen only when the government realizes the need for a 'partnership of equals' between universities and business. In the ideal scenario, powered by the novel Product Development and Transaction Office, government involvement, *in its present form*, will be unnecessary at best (The Economist, 2003d), or counterproductive, at worst (Fernandes and Miska, 2002a).

A Bayh–Dole Act for the UK?

Today, Bayh–Dole does not allow for entrepreneurial activity within the university. However, in our opinion, universities may need to consider a more independent business office (PD&TO) to upgrade the current intellectual property dominated academic department (TTO). The PD&TO will benefit from staff with experience in business who would be better able to communicate and negotiate with industry. Independence would allow for entrepreneurial initiatives – allowance to conduct initial product development in the university, penalties for failures, and rewards for successes. Several university business schools have already adopted entrepreneurialism as a subject within their educational mission, and this course is usually oversubscribed. And 'Yes' – we do see merit for a new and improved Bayh–Dole Act for the UK (The House of Commons, 2003), and also for the US!

Conclusion: entrepreneurialism is education in action

Universities and business have a long and successful record as partners in science and product development (Edwards *et al.*, 2003; Hall, 2003; Lawler, 2003). However, with the passage of time, changes in the ecology of science, patent law, and the market, especially globalization, necessitate adjustments to earlier relationships. The time for change is past due when bottlenecks threaten to shut the entire system down (*The Economist,* 2003a,b).

The UK Biotechnology Industry. Twelfth Report of Session 2002–2003

The UK's research expertise in biotechnology has made its relative prominence in commercial biotechnology possible. The strength of the commercial biotechnology sector cannot be guaranteed merely by putting ever greater sums of public money into higher education and academic research. However, given the integral links between education and research and commercial biotechnology, it is hard to see how strength can be achieved and sustained in the latter without the former being adequately resourced.

The House of Commons. Trade and Industry Committee, July 2003

Evidence of bottlenecks are clearly visible in the empty pipelines in pharma, and the overcrowded shelves of 'orphan', but expensive, patent filings in university Technology Transfer Offices. By delaying the initial commercial contact until a product concept has matured, an appropriate valuation can be obtained for the patented technology. The higher valuation will reflect a reduction of risk, and time-to-market, consequent upon the availability of a map that addresses regulatory risk and commercial potential. Not every patent filing will a successful product make. But a transparent and a rational mechanism of selection and advancement will at least provide assurance that universities, business, and society will benefit from the transformation of science to innovative products and a better life for all (Schwartz and Vilquin, 2003). Burk and Lemley (2003) have recently addressed important policy initiatives directed to the refinement of patent law and efficiency in implementation in several technologic contexts, including biotechnology and the pharmaceutical industry. Here, there is a need for *clarity, fairness, predictability, and a bias towards innovation*. The recent Federal Trade Commission report, *To Promote Innovation*, represents a careful balance between competition, patent law and policy, and includes several initiatives directed towards these objectives (Federal Trade Commission, 2003).

Economic, strategic, and scenario analyses performed by Medbase (2003) on the consultation data (Lambert Review, 2003a,b) lead us to conclude that academic, rather than business, leadership is a pre-requisite for success in the knowledge economy. We find support in the comments on the Lambert Review.

The Lambert Review: comments

Gordon Brown, Chancellor: While good at pure research, we have, for decades, been poor at its application.

Patricia Hewitt, Secretary of State for Trade and Industry: Scientific excellence is at the heart of a competitive economy.

Charles Clarke MP, Secretary of State for Education and Skills: Our universities are a major national economic asset.

Professor Ivor Crewe, President of Universities UK: It is very easy to engage in optimistic fantasies about how much could be earned from commercializing research.

Sir Richard Sykes, Rector, Imperial College: To keep encouraging technology transfer, research-intensive universities need money for the phase of experimentation in which they prove that the basis of their research is sound, before they move to license their intellectual property or create spin-out companies.

Sir Christopher Evans, Merlin Biosciences: Incentives are lacking. If the issue is getting more private finance in, universities have to make themselves as seductive and attractive as possible. You have to make it easy to invest.

Lambert Review of Business–University Collaboration. Final Report, 4 December, 2003
The Financial Times, 4, 8 December, 2003

Our proposal for a PD&TO is in keeping with Chancellor Brown's comment on the shortcomings of business in failing to recognize and capitalize on academic research.

Secretaries Hewitt and Clarke emphasize the potential of universities in the knowledge economy: *innovation is the successful development and commercialization of good ideas*. Neither Bayh–Dole (Mowery *et al.*, 2001) nor corporate benevolence made MIT or Stanford rich; independent research did. Professor Crewe is pragmatic; based on the two decade US experience, there is no cause for optimism, but good reason to explore market-based mechanisms. Importantly, our proposal for a Product Development and Transaction Office is congruent with the comment from Sir Richard (Sykes, 2003). The PD&TO may represent the mechanism that could make universities, in Sir Christopher's terms, 'seductive and attractive' to business, and also to global private financing. It is now up to universities to formally declare a business interest, and allocate resources to leverage 'bridging' research towards industrial applications (Morrissey, 2003; The House of Commons, 2003). The appropriate context for innovation, whether incremental or disruptive, is *market need*, rather than the *wants of companies*.

A drug, diagnostic, or a medical device is an information product – knowledge is the scaffold that supports the discovery, development, commercialization continuum, patenting, and also appropriate usage as therapy. The future mission of universities will be the furtherance of knowledge and its translation into products that are useful and affordable to society. Although the process may appear difficult, the '850' lesson to universities is simple, short, and sensible: *initial product development is essential to valuation, commercialization, and most importantly, patent validity*. The exposure to product development, the generation of intellectual property, and market strategy will position students in biotechnology and genetic engineering as *new and different leaders in the knowledge economy* – the creation and commercialization of novel, value-based products. All elements are in place, and if the plan is implemented with independence and discipline, success is likely. This initiative has the potential of actually enhancing the academic mission of universities (The Royal Society, 2003), and by generating new business initiatives, making the costs and outcomes of higher education understandable to students and society.

The Economist (2002) has likened the Bayh–Dole legislation to 'innovation's golden goose'. *The Economist* got it half-right; on closer examination, this bird is a gander. We look forward to a new and improved Bayh–Dole for the United Kingdom, a proletarian goose that lays *gold eggs*, especially for universities, which are the proximate source of innovation, university–business collaborations, and society at large.

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