

Commercializing Biotechnology

**Critical Business & Legal Issues
for a Start-up Venture**

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Contents

INTRODUCTION.....	1
CREATING YOUR INTELLECTUAL PROPERTY RIGHTS (IPR)	1
Pre-empting Adversarial Negation of Your IPR.....	1
Developing Your Biotechnology IPR	3
Trade Secrets.....	3
Patents	5
Patentability of the Subject Matter of the Application.....	6
Patent Filing Strategy	6
Litigation Issues.....	8
COMMERCIALLY EXPLOITING YOUR BIOTECHNOLOGY IPR	9
Business Model	9
Technology Transfer Mechanisms	10
Financing	12
Human Resources.....	13
Production.....	14
Regulatory Approval.....	14
Process Know-How	15
Marketing and Sales.....	16
Packaging and Promotion	16
Product Liability	16
Product Pricing	17
CONCLUSION	18
REFERENCES.....	19

“Knowledge, competence and related intangibles have emerged as the key drivers of competitive advantage in developed nations... It is no longer in product markets but in intangible assets where advantage is built and defended. There is no such thing as a privileged product market position – unless it rests on some upstream intangible asset.”¹

Introduction

As was the case for the information technology industry two decades ago, the biotechnology industry is beginning to show the promise of sustained high growth. The challenges faced by the industry’s entrepreneurs are also similar – notably a lack of funding for a poorly understood field of endeavour, and a dearth of people whose talent encompasses both the technology and the business.

However, it appears that several factors have conspired to make biotechnology ventures more risky and difficult to render commercially successful:

- a greater degree of arcane specialization that is required of those who seek to make breakthrough discoveries;
- a much longer average product development cycle;
- a product market that is ruled not only by market forces but also by a plethora of government agencies; and
- a consequently more reticent capital market.

In this demanding and competitive environment, it's important for the start-up biotechnology venturer and his or her legal advisor to understand one another well, and for the lawyer to truly add value to his or her typically cash-strapped client.

Many are the perils a diligent solicitor can help the venturer avoid or overcome, and these perils generally disregard the boundaries of traditional areas of legal practice.² The purpose of this paper is therefore to help you, the biotechnology entrepreneur, deal with some of the more important business and legal issues that arise in the commercialization of your new technology.

Creating Your Intellectual Property Rights (IPR)

Pre-empting Adversarial Negation of Your IPR

The vast majority of biotechnological advances result from a combination of basic research sponsored mainly by the public sector and subsequent product development sponsored mainly by

the private sector.³ In any such partnership between academia and industry, there's an inherent conflict between the academic's desire to publicize his or her research findings and the financial sponsor's desire to prevent public disclosure of information that may later undermine intellectual property claims to the fruits of that work.⁴

In Canada and the US, if disclosure of information regarding an invention is made by the inventor or anyone who received the information from the inventor, a patent may still be granted if the application was filed within one year of the disclosure.⁵ However, other patent jurisdictions do not grant such leniency, and instead require the filing of an application before *any* disclosure occurs.⁶ You should therefore take heed of the disclosure rules that apply to your jurisdictions of economic interest before making public any information about your discovery or invention.

Restraint from disclosure applies particularly to trade shows, lectures, presentations, and publications. Even an indication in an academic paper as to how to proceed in further investigations of the subject at hand might render the results of such further investigations unpatentable by reason of obviousness.⁷ Discretion and the use of comprehensive confidentiality agreements become even more critical when disclosing information that's intended to be protected by means of trade secrecy.⁸

At a very early stage in the development of a new biotechnology, you should conduct a literature search and have a preliminary patent search done by a registered patent agent, in order to determine:

- the extent, if any, to which the invention has already been patented or is founded on other patented technology; and
- whether the invention is sufficiently novel to justify continuing the patenting process.⁹

The importance of this preliminary search is highlighted by the fact that roughly 10% of all R&D conducted in Canada ultimately duplicates already patented technology.¹⁰ In addition, many large R&D firms routinely file patent applications of questionable validity simply to discourage the commercialization, or at least encourage the cross licensing, of any breakthrough innovation whose exploitation might infringe those dubious patent claims.¹¹

It's been said that "It is far preferable to be the owner of what may ultimately be an invalid patent that it is to be an infringer of one."¹² You should therefore at least consider the merits of others' patents or disclosed filings before proceeding to possibly infringe them.

Thanks to information technology, you can perform an internet search of all Canadian patents and laid open applications since 1989.¹³ However, for a search of all patent documents dating back to 1920, the Canadian Intellectual Property Office (CIPO) TechSource system must be used at the Patent Search Room in Hull, Quebec.¹⁴

If your developing technology incorporates someone else's invention that has been patented in Canada, you don't automatically gain the commercial benefit of that prior invention.¹⁵ Your options in this situation therefore consist of:

- fitting your small-scale, non-commercial activity within the “experimental use” exemption of the *Patent Act*;¹⁶
- securing a license to commercially exploit some aspect of the prior invention;
- buying the prior patent outright;
- manufacturing and selling your new invention in a jurisdiction in which the prior invention has not yet been patented; or
- arguably infringing the prior patent and possibly defending a court action.¹⁷

If you choose to secure a license of another’s patented invention, then you should also seek a license to future enhancements, improvements or follow-on inventions.¹⁸ It is also important to stipulate in the agreement that royalties payable by you will be reduced if the licensor's patent application fails, if the patent is subsequently invalidated, or if it becomes the subject of a third-party suit for infringement, and to state that you're entitled to sue infringers and offset litigation expenses against those royalties payable.¹⁹

If the agreement contemplates you receiving a sample of a self-propagating patented organism, there will also be a natural tension between the parties as to whether the licensor's rights to the organism are exhausted upon the sale of that organism to you.²⁰ This should be a subject of discussion between you and your lawyer well in advance of the situation arising.

Developing Your Biotechnology IPR

Several forms of IPR normally apply to a biotechnology firm. Your firm’s original business documentation, proprietary software, and even its advertising jingle are automatically the subject of copyright.²¹ The firm’s logo and slogans may be trademarked or protected by the common law doctrine of passing off. Industrial design or trademark protections may apply to your firm’s commercial products and their packaging.²² If your product is a new, visually distinct and generationally stable multi-cellular plant variety, then the sale or propagation for sale of that variety’s propagating materials may be governed by the patent-like provisions of the *Plant Breeders’ Rights Act*.²³

Among all these forms of IPR, however, patents and trade secrets are usually by far the most valuable for a start-up biotechnology firm. Since the desirability and applicability of these forms of IPR can be quite fact-specific, what follows are practical guidelines to help create, use and protect trade secrets and patents.

Trade Secrets

The essential elements for a trade secret to be recognized and protected in law are as follows:

- the information is secret when it is transmitted, meaning that it is not “generally known among or reasonably accessible to persons that normally deal with the kind of information in question;”²⁴
- the information is transmitted to a receiver who is at that time in an express or implied relationship of confidence with the transmitter; and
- unauthorized disclosure would result in actual or potential detriment to the original transmitter.²⁵

Trade secrecy is therefore best maintained by the selective disclosure of information to a limited number of people, each of whom is contractually sworn to secrecy.

Trade secrecy protection is useful for an invention that is:

- not patentable;
- likely to become obsolete too quickly for patenting to be economical;
- unlikely to be independently conceived; or
- is too difficult for others to reverse-engineer to justify public disclosure during a patent prosecution.

Advantages of trade secrecy protection are that:

- it applies to all categories of valuable information;²⁶
- the duration of the protection is indefinite (subject to contractual provisions and actual disclosure); and
- the process of its creation does not involve litigation or government officials.

As an example of the suitability of trade secrets, a significant number of people in the industry have concluded that the genetic structure of a biological receptor, intended for use solely as an assay target, is best protected as a trade secret because that way the secrecy of that knowledge is not time-limited.²⁷ By contrast, a patent application ensures that the knowledge disclosed in the application will become public in 18 months unless you withdraw the application before then.²⁸

Weaknesses of trade secrecy are that:

- its continued existence depends on sustained compliance with their obligations of confidentiality by those to whom the information has been disclosed;
- the protection does not apply to strangers who receive the information without knowledge of its confidentiality; and

- it does not prevent the economic encroachment of others who have independently developed the same information.²⁹

In addition to these drawbacks, there is the practical reality that it can be a considerable evidentiary challenge to prove that the defendant misappropriated your secret.

If you delay filing a patent application in favour of trade secrecy protection, then you risk losing both forms of protection if your secret becomes public before that filing. However, trade secrecy is a useful fall-back position in case your patent application is rejected before the point in the process where it is disclosed to the public.³⁰ So in preparation for that possibility, you will be well served by continuing to avoid disclosure of his or her invention to the public even if you've filed a patent application.

Patents

Because of the very large and protracted investment that is normally involved in commercializing a biotechnology product, your ability to subsequently prevent others from appropriating the economic benefit of that investment is often paramount. More specifically, a patent can be used to simultaneously satisfy:

- the desire of academics and their supporting institutions to publicize research findings while also benefiting financially from the transfer of resulting technologies; and
- the desire of industry to commercially exploit such leading-edge research and outsource its product development while preventing pre-emption in the product market.³¹

It has also been said that “Healthcare inventions tend to be among the most licensable”³² of technologies, for which a patent is clearly a key enabler. For all these reasons, the patent plays a uniquely vital role in the biotechnology industry.

A patent in Canada grants to the holder a 20-year exclusive right³³ to use, make, sell, and import for sale³⁴ the patented invention. Related regulation can further bolster the value of your patent since prospective copiers will face a contingent series of additional barriers (such as approval by Health Canada or by the U.S. Food and Drug Administration) before being able to place a competing product in the market.

Essentially, a patent can serve as a key into the bureaucratic labyrinth and scarce resources of government, and once entered you may be able to effectively shut the door behind you.

On the downside, a patent is expensive to secure, and its value to the holder is highly dependent on the extent to which its infringement can be detected and prosecuted: that may turn on such subtleties as how obviously a finished product betrays the use of a patented process during its manufacture,³⁵ how likely it is that the primary infringers will be your own customers,³⁶ or even how agreeable patent lawyers in a particular jurisdiction are to litigating on a contingency fee basis.³⁷

As well, the automatic public disclosure of a patent application (18 months after the earliest of the filing date in Canada or the filing date elsewhere under an international treaty³⁸) enables others to use that information for the purpose of designing a competing technology which either skirts your patent claims or outperforms your technology for which the patent remains pending.

Patentability of the Subject Matter of the Application

In Canada, the subject matter of a patent must be an “art, process, machine, manufacture or composition of matter”³⁹ – or an improvement on any of these – which features three essential characteristics:

- it's *novel*, meaning that it has not been publicly disclosed in the past;
- it's *useful*, meaning that it has at least one practical application; and
- it's *non-obvious*, meaning that a person who is very knowledgeable in the applicable field of endeavour would not have conceived of the invention or application based on the information that was publicly available at the time.⁴⁰

The law in Canada currently allows you to patent among other things a new use of a widely known compound,⁴¹ a simple micro-organism that has been isolated or purified out of its natural environment,⁴² or an innovative medical product or an innovative process by which that product is created. But you can't yet patent a method of medical treatment⁴³ or a complex life form any of whose characteristics you can't reliably reproduce.⁴⁴ Unlike in the U.S. and to a limited extent in Europe, the only patent protection that's currently available for complex life forms in Canada is a process patent or a patent on the products that are used to create that life form. This juridical dichotomy between Canada and the U.S. may influence your patent filing strategy depending on the nature of your invention.

Patent Filing Strategy

A patent protects your invention only within the geographic boundaries of the jurisdiction that issued the patent.⁴⁵ Because it costs roughly \$15,000 to prosecute a patent application⁴⁶ – depending on translation fees, the number of Patent Office Actions and amendment letters, and issuing fees – a typically cash-strapped entrepreneur must be selective regarding where and when to patent his or her invention.

Relevant considerations include which jurisdictions present the most promising markets for your invention, which jurisdictions most rigorously enforce their patent protection laws, and how difficult the nature of the invention renders enforcement of the patent.⁴⁷ You should also note which countries revoke patents if the invention is not worked in that country within a specified time from patent grant or if the inventor fails to license the invention to nationals of that country.⁴⁸ As well, patent filings should be considered for the jurisdictions in which your invention could most efficiently be manufactured and exported to the many other markets in which a patent application has not yet been filed.⁴⁹

An advantage of filing the application first in one of the 89 countries (including most developed nations) which are signatories of the Patent Convention Treaty (PCT)⁵⁰ is that your priority date protects your patent in all other PCT countries for up to 30 months, during which time each of those markets can be assessed and patent applications filed as your economic analysis dictates.⁵¹ This benefit of the PCT considerably reduces the economic risk that would be involved in paying for a number of patent applications before you've had a chance to sufficiently assess the associated product and input factor markets. Note that applications to non-PCT countries must be filed within 12 months of the PCT priority date.⁵² Alternatively, applications made to jurisdictions that are signatories not of the PCT but of the Paris Convention must be filed within one year of the first filing to receive priority under the latter convention.⁵³ A patent application filing in Canada automatically entitles the applicant to the priority date benefit of the Paris Convention.⁵⁴

In Canada, Europe and Japan, a patent is granted to the first person to file an application at the national or treaty-associated patent office, so it's vitally important to file a patent application as quickly as possible.⁵⁵ Although the U.S. uniquely issues its patents by priority of invention, the evidentiary burden of establishing which claimant first created the invention confers even in that jurisdiction a significant practical advantage to the person who is the first to file a patent application.⁵⁶ Your incentive to file quickly is further heightened by the risk of prior disclosure by an independent inventor who may be more interested in publicity than in commercial profit.

You face something of a quandary:

- your invention must be kept relatively secret until a patent application is filed;⁵⁷
- you need time to study your invention's characteristics, identify promising markets, license the technology, or raise alternative financing before you commit to an expensive patent application campaign; and
- you need to conceive as fully as possible your invention's utilitarian possibilities before finalizing your submitted patent claims.

It's therefore fortunate that, in addition to recognizing the priority date of a filing in other patent treaty countries, several jurisdictions have enacted means by which you can further reconcile these conflicting demands.

In Canada, you can request – within four months of filing an initial, incomplete patent application – that your application be accorded priority for the purpose of establishing a claim date.⁵⁸ This filing must be followed by a finalized submission within 15 months of the initial filing.⁵⁹

In the U.S., you can file a provisional application to preserve your patent priority date for up to 12 months before the submission of a finalized application.⁶⁰

A similar device named an informal application is available in the U.K., but the priority date of each amendment to the application is the date on which the amendment is filed. Although the

U.K.'s priority date system is not as generous as the U.S.'s, the advantage of a U.K. informal is that the initial application need not be as complete as a U.S. provisional.⁶¹

A further means of reducing the venture's up-front expenditures, and of securing more time to conduct preparatory business activities, is to delay requesting an examination of the patent application after you've filed the application. In Canada, an applicant may delay his or her request for examination for up to 5 years from the Canadian filing date,⁶² and once underway, the examination process normally takes 2-3 years to complete.⁶³ As a result, several years may pass before you must pay the fees associated with office actions and a patent grant. Between the time that the application is laid open to public view and the time that a patent is granted, the incentive which encourages competitors not to use the disclosed information for their own commercial gain is that once the patent is granted, the inventor will be entitled to retroactive damages for infringement during that period.⁶⁴

You can also apply to broaden or amend your patent's claims through a reissue within 4 years of patent grant,⁶⁵ which is a useful course of action if certain benefits of the invention did not become apparent until after the patent was issued.⁶⁶

Since a patent has a term of only 20 years, and since a large proportion of that time may be consumed just bringing your invention to market, an ideal exploitation strategy for a biotechnology would consist of a staggered series of patents on the following inventions:

- the genetic sequence of the product;
- the product;
- the process by which the product is put to use;
- an improvement on the product;
- an improvement on the process; then
- continued improvements to both product and process.⁶⁷

Although the applicability of such a succession of patents depends on such factors as the nature of the core biotechnology involved, the incremental non-obviousness and novelty of each successive invention, and the ease with which competitors may produce non-infringing alternatives, it's clearly possible to effectively extend the exclusiveness of a fundamental platform technology beyond the 20 years that are provided by a single patent.

Litigation Issues

Despite concerted efforts by the bench to develop technological proficiency, it's been said that "[p]atent cases are the only cases argued by professionals and decided by amateurs."⁶⁸ You need to realize that litigation can be a major feature of patent prosecution and maintenance, and that the protection afforded by a patent is both uncertain and imperfect.

During examination of your application, anyone may file a protest against the granting of the patent or may attack the scope or validity of your claims.⁶⁹ If the Examiner rejects your application, you may need to appeal the decision at up to three consecutive levels of adjudication, including the Supreme Court of Canada.⁷⁰ Even once a patent has been granted, the Commissioner of Patents or a third party may at any time during the term of the patent attack the validity of one or more claims on the basis of “prior art.”⁷¹ Each of these challenges may also involve subsequent appeals to the courts.

It's worthy of note that of 294 patents contested in all US federal appellate courts during the period 1966-1971, only 89 (a mere 30%) were found to be valid.⁷² The apparent low quality of issued patents may have arisen because the Examiner has fewer resources available and less incentive to thoroughly scrutinize the validity of a patent application than does a sophisticated commercial party seeking to break into a lucrative monopoly.

The low rate of litigation success for the patent-holder also suggests that he or she may often find advantage in structuring a collaborative arrangement with the alleged infringer rather than litigating the dispute.⁷³ Should you find your patent to be the subject of litigation, a collaborative resolution with the attacker presents the added benefit of keeping secret from other potential entrants the profitability of your existing monopoly market.⁷⁴ Of course, that advantage must be weighed against the undesirably conciliatory signal that may be perceived by other prospective competitors who are already intent on entering your market.

Commercially Exploiting Your Biotechnology IPR

Business Model

“Seizing [commercial] opportunities frequently involves identifying and combining the relevant complementary assets needed to support the business. Superior technology alone is rarely enough upon which to build competitive advantage.”⁷⁵ As one such complementary asset, a patent can be used to assist business strategy in ways that have been described as blocking, running, and teaming up.⁷⁶

Your firm can *block* the entry of competitors by patenting and reserving to itself alone one or more technologies that are essential to commercial activity in your firm’s particular niche. This strategy is generally more successful in the shorter term because motivated competitors will over time find a way around the barrier to entry that the patent represents.

A *running* strategy involves continual innovation by the firm to produce and patent subsequent generations of technology before the competition does. This aggressive strategy can give your firm significant first-mover advantages including enhanced control over your business environment.⁷⁷ However, the costs of cannibalizing your own markets can also be very high since your firm has less opportunity to harvest the fruits of its large and prolonged investment in each successive technology.

Alternatively, your firm can *team up* with its competitors by cross-licensing its critical technology to them. The resulting collective may then establish the ensuing technology as an effective industry standard through coordinated marketing and distribution, lower prices from economies of scale, and enhanced customer confidence in the longevity of the standard.⁷⁸ If a formal standards-forming body exists in your field of competition, then you will first need to consider the relative merits of disclosing your intellectual property to that standards-forming body so as to dominate the formal standard.⁷⁹

In highly arcane fields of endeavour such as biotechnology, and particularly in the biopharmaceutical industry where a handful of large players dominate the available distribution channels, the teaming up strategy is often the most appropriate for nascent firms.

Another essential element of business planning in biotechnology is not to rely on the successful commercialization of one proprietary technology but rather to develop successive generations of related products whose lifecycles overlap significantly.⁸⁰ Although easier said than done, such a product migration strategy generates a more stable cash flow, diversifies technological and market risk, increases your firm's mindshare in the product market, and correspondingly increases your firm's perceived value in the capital markets.

Technology Transfer Mechanisms

A transfer of your proprietary technology to other commercial entities can take place for a variety of reasons, including gaining access to complementary technologies, accelerating the penetration of your firm's target market, and generating cash to develop subsequent product offerings.⁸¹ Variations on the arrangement by you transfer your technology to others include an outright sale of the technology and associated IPR, distributorship, franchise, joint venture, or a value-added reseller relationship.⁸² However, all of these arrangements but the first are essentially licensing agreements that are customized to the needs of the parties involved, and license relationships characterize the vast majority of technology transfers.

In a licensing arrangement, the licensor's primary interest is normally to ensure that the licensee has compatible business goals and that the licensee has the capability to fulfil his obligations under the licence.⁸³ By contrast, the licensee's primary interest is normally to ensure that the licensed technology is effective and legally protected from competition, and that the economics of its production, marketing and distribution are sound.⁸⁴ Clearly, licensing agreements need to explicitly manage foreseeable risks in order to prevent disputes between the parties and to allocate the relative burden of any future liability to third parties. To that end, two unique characteristics of biotechnology must be taken into account when structuring a license agreement.

First, the living matter which either helps to produce the patented invention or is itself the patented invention contains within its DNA all the information necessary to reproduce and work that matter. What's more, that reproduction may take place with little or no effort on the part of the licensee. In other words, providing a sample of biological material to a licensee is less akin to giving the licensee instructions on how to build a mousetrap than it is to giving the licensee a mousetrap factory complete with an endless supply of mousetrap parts.⁸⁵

Second, the natural or assisted replication of living matter is an imperfect process since artificially introduced genes may be ejected and any gene may be randomly mutated. The result is a replicated organism whose characteristics may differ from the licensed organism in a way that can be either detrimental or beneficial to either party.⁸⁶

Entire treatises have been written about structuring technology licenses.⁸⁷ Suffice it to say that, in light of the above two distinguishing characteristics of biotechnology, critical issues which must be clearly addressed in biotechnology license agreements include:⁸⁸

- clearly defining the scope of property (both tangible and intellectual) to be covered by the agreement;
- allocating rights to derivatives of licensed biological materials and to improvements on them;
- specifying ownership of transferred biological materials and controls on the transfer of those materials to third parties;
- detailing restrictions on the use of the materials, including those which may be imposed by a patient from whose living tissue the technology in question was developed,⁸⁹ those imposed by a government agency which helped finance the development of the technology, or those imposed by the owner of living material with which the licensed material is to be commingled;
- licence term, exclusivity, and the ability to sub-license; and
- compensation, which may consist of an up-front lump sum, subsequent periodic and performance milestone payments, and continuing royalties.⁹⁰

Determining appropriate royalties is something of a black art, but it ultimately depends on the cash flow needs of the parties, their relative time horizons and aversions to risk, and the economic context of the technology. Calculation methodologies are usually based on any of the following:

- a margin added to the cost of developing the technology;
- comparable transactions or comparable profit margins;
- an allocation of profits based on the licensee's and licensor's respective contributions to the technology in question;
- accounting-based valuation ratios; or
- the residual market value of a reference public company's intellectual property.⁹¹

Each method ultimately produces only a best guess based on its particular set of assumptions, and needs to be combined with the results of the other methods to arrive at a reasonable range of appropriate royalty rates with which to enter into negotiations.

Playing as they do such a critical role in the accrual of wealth to the licensor, licensing agreements are clearly devices to which your lawyer's application of ingenuity and foresight can add tremendous value.

Financing

It reportedly takes on average \$93M US to bring a drug from concept to the U.S. Food and Drug Administration for regulatory consideration,⁹² and some estimates put the average cost of taking a drug from concept all the way to market at \$300M US.⁹³

Public capital markets are rarely supportive of fledgling biotechnology ventures: the high risk of technological failure, combined with average waits as long as 12 years⁹⁴ for a technologically successful product to even reach its intended market, renders biotechnology enterprise reliant on extraordinarily patient capital rather than the type of capital that is sustained by quarterly earnings announcements.

Consider for example the failure rate of pharmaceutical products. In 1995, the relevant statistics in the U.S. were as follows:⁹⁵

Table 1: Pharmaceutical Product Success Rates

Development Phase	Years to Complete the Phase	% Survival Rate in the Phase
Basic research	3	0.2%
Preclinical testing	2	50%
Phase I clinical testing	2	50%
Phase II clinical testing	1	40%
Phase III clinical testing	2	50%
Regulatory approval	2	N/A
Total	12	0.01% or less

When the investment conditions in biotechnology are compared to those in information technology – where product development cycles are generally less than one year, the investment is often relatively small, and the cost of sales can be negligible – it is not difficult to understand why biotechnology venturers face relative difficulty in attracting and retaining investor loyalty. The reality of this difficulty has been reflected in a report that, “As a rule, publicly traded companies that have their first drug in the lab are being valued far more cheaply than the average Internet company that has yet to turn a profit.”⁹⁶

As for the private capital market, even venture capitalists that possess characteristic deep pockets and high risk tolerance are biasing their investment portfolios heavily in favour of information technology at the expense of biotechnology.⁹⁷ The result of these financing conditions has been

a “venture gap” between the discovery of biological insight and the development of ensuing technology.⁹⁸ You're therefore likely to face great difficulty in raising a large amount of cash to be invested in your high-risk enterprise on a long-term basis, particularly if the venture's sole product is still at the conceptual stage.

In the early going, a biotechnology venture should look primarily to government, friends and family for the cheapest and least restrictive money available. Government assistance may take the form of grants, repayable loans, or low-interest loans from a multitude of federal and provincial programs, or lease subsidies provided by a municipality. The venture may capitalize on such government-supplied income tax incentives as the refundable Scientific Research and Experimental Development investment tax credit.⁹⁹

Once these sources of funding no longer meet the needs of your enterprise, your general financing strategy should be to undertake staged rounds of financing over time, each successive round featuring a progressively smaller risk premium if your venture's performance meets stated milestones and the historical development of comparable firms.¹⁰⁰

The first few rounds of financing are normally private placements¹⁰¹ of equity in which the key issue is how much ownership of the firm should be traded for each infusion of cash.¹⁰² Target investors in these stages are normally wealthy individuals and venture capitalists.¹⁰³ Key to your ability to raise equity capital from these sources as a private company is the provision of an explicit exit strategy, in the absence of which the implied liquidity premium may be prohibitive.¹⁰⁴ Because the ability of an investor to liquidate his or her securities depends not only on market forces but also on any hold period imposed by the applicable securities legislation,¹⁰⁵ which may last until the later of 18 months or when – if ever – the firm becomes a public company, the most likely exit strategies are a contractual share buy-back, a takeover by a competitor, or an initial public offering of shares.

It's important to realize that the more commonly employed prospectus exemptions require that no advertisement¹⁰⁶ or invitation to the public¹⁰⁷ be made in preparation for a distribution of securities. You and all your staff should therefore be careful not to approach prospective investors without first having verified with legal counsel the propriety of your intended overtures.

Additional forms of financing for your budding biotechnology venture include licensing,¹⁰⁸ trade credit, asset-backed financing, bank debt, and eventually the sale of part or all of your firm to a private buyer or to the public.¹⁰⁹ The appropriateness of each form of financing at any given time will depend on the current state of your venture and of the capital markets.

Human Resources

For cash flow reasons during the early stages of your venture, you'll likely contract out what work you can't perform yourself, rather than hire salaried employees to do that work. You're your finances allow you to hire employees, you'll need to formulate appropriate personnel attraction and retention mechanisms.

You should bear in mind that employees with the greatest intellectual capital are essentially volunteers. Since they have their pick of well-paying prospective employers, they ultimately select their employers more on the basis of consequent personal satisfaction than strict economic return.¹¹⁰ Being highly mobile, key employees require tailored incentives to rent their services to your firm. Essential conditions in the modern workplace include:

- a meaningful vision for your firm;
- gain sharing (“skin in the game”);¹¹¹
- an enjoyable work culture;
- collaboration and communication;
- a high degree of personal autonomy within the overall aims of the firm;
- intellectually demanding work;
- labour-reducing technology; and
- ongoing professional development.¹¹²

In addition to maximizing the upside value of each employee to your firm, you should establish the necessary controls to prevent a disgruntled or opportunistic employee from harming your venture. Essential components of those controls include well-crafted confidentiality and non-competition agreements which govern the employee’s term of employment and a reasonable period of time thereafter. It's been said that, “More technology has been stolen by employees and business associates than by [existing] competitors... because too much reliance is placed on the traditional methods of protection (patents, trademarks, industrial design and copyright) and not enough on confidentiality and employment agreements.”¹¹³ Comprehensive and enforceable confidentiality agreements are particularly vital to sustaining the value of a venture that relies heavily on trade secrets.¹¹⁴

Production

Regulatory Approval

The eventual arrival of a biotechnology product among the very few that actually reach the marketplace depends not only on the technological characteristics of that product but also on its approval by the applicable regulatory agencies. In Canada, federal agencies are the primary gatekeepers for the introduction of biotechnology products into the marketplace, and they generally weigh the benefits to be derived from the product against the risks posed by that product in the context of its environment.¹¹⁵ The testing procedures are conceptually no different from those long used for new chemicals made by a non-biological synthesis, and they are applied on a case-by-case basis.¹¹⁶

In Canada, agricultural products of biotechnology are regulated by Agriculture Canada pursuant to the *Feeds Act*, *Fertilizers Act*, *Pest Control Products Act*, *Plant Protection Act*, *Health of Animals Act*, *Agricultural Product Standards Act*, *Livestock and Livestock Products Act*, *Meat Inspection Act*, and the *Seeds Act*¹¹⁷

The impact of biotechnological products on our ecology is regulated by the Environment Canada under the *Canadian Environmental Protection Act*, *National Parks Act*¹¹⁸ and related statutes, the Federal Environmental Assessment Review Office's Guidelines, and the *Pest Control Products Act*.¹¹⁹

The impact of ingested biotechnological products on people is regulated by the Canadian Food Inspection Agency under the *Food and Drugs Act*¹²⁰ and the *Pest Control Products Act*¹²¹ among other statutes. Health Canada is mandated to advise the Department of Consumer and Corporate Affairs on the advertising, sale or importation of biotechnological products under the *Hazardous Products Act*.¹²² The latter department also regulates the labelling and other information requirements of hazardous products under the *Consumer Packaging and Labelling Act*.¹²³

The health and safety of workers under federal jurisdiction is regulated by Labour Canada under the *Canada Labour Code*,¹²⁴ and similar provincial agencies and legislation govern workers who fall under provincial jurisdiction. It should be noted that Parliament has recently shifted more of the regulatory burden onto industry,¹²⁵ thus reducing the opportunity for a biotechnology firm to rely on government agencies to detect dangerous characteristics of a product before it reaches the market.¹²⁶

Process Know-How

A source of value which is often tremendously underrated in the early stages of an enterprise, and which is vital to leveraging a superior technology into a formidable commercial enterprise, is the knowledge that's embedded in the venture's business processes.

The value in sophisticated business processes lies in the difficulty of their imitation by competitors. These processes are likely to be founded on tacit rather than explicit knowledge, the supporting processes may be difficult for an outsider to perceive, and there may be uncertainty even within the business itself regarding the organizational matrix of personnel that supports any given process.¹²⁷ For this reason, an innovative production or related business process that is complex, poorly documented, under continual refinement, or unobservable to the firm's outsiders may best be protected as a trade secret rather than by a patent.

By contrast, if a production process is critical to your firm's business success, and if independent development, unprovable misappropriation, or reverse engineering are realistic possibilities, then you should consider patenting that process. A Canadian process or machine patent presents the additional benefit of prohibiting the importation into Canada of intermediate or final products whose creation abroad is significantly attributable to that process or machine.¹²⁸

Marketing and Sales

Packaging and Promotion

A mark stating “Patent Pending” or the numbers of any already issued patents should be placed on both your product and its packaging to alert potential infringers that they may attract penalties for their use, manufacture or sale¹²⁹ of the product following the issue of the patent. The importance of this mark is highlighted in the U.S., where actual notice to the infringer is essential to the recovery of damages for infringement.¹³⁰ The use of the packaging or product mark should also be demanded of any licensee to whom the technology has been transferred.¹³¹

The trademark of a product, service, firm name or logo, or of the shape of a product or its packaging, can be a valuable asset to encapsulate and protect the goodwill associated with the sale of business output. The value of this asset can be inexpensively boosted by registering it with the Trade-marks Office.¹³² Although several criteria must be satisfied for registration, the key ones are distinctiveness (either inherent or acquired)¹³³ and “use” as it is defined in the *Trade-marks Act*.¹³⁴

After registering your trademark, you will need to diligently tend to the continuing existence of that asset by, among other things, ensuring the quality and character of a licensee’s product or service,¹³⁵ suing competitors whose marks are confusing,¹³⁶ and renewing registration every 15 years.¹³⁷ The importance of this continuing diligence¹³⁸ is highlighted by the fact that, unlike most assets, the value of a trademark generally increases with use and time.

Product Liability

Damages caused by a hazardous product can very quickly turn a profitable enterprise into the commercial equivalent of a smoking hole in the ground.

Your venture’s biological raw materials, products, and by-products may each present risks to:

- your employees, sub-contractors and distributors;
- the end-users of your product; and
- the ecology into which these materials may be deliberately or unintentionally introduced.¹³⁹

Assuming that you've assiduously minimized the potential hazards of your end product, additional means to manage the risk of product liability include:

- incorporating a separate subsidiary for the development and marketing of a particularly high risk product;
- liability exclusion clauses in your sale or licensing agreements;

- effective containment breach and content monitors in processing facilities;¹⁴⁰
- rigorous documentation of all measures that have been taken to prudently manage process and product risk,¹⁴¹
- an effective system to fully inform learned intermediaries and end users of all material product risks;
- precise and complete labelling of transgenic foods so as to prevent allergic reactions;¹⁴² tamper-resistant and child-proof packaging; and
- an effective feedback system to monitor and respond to the effects of your product in the marketplace.¹⁴³

Another very effective but too frequently overlooked means to avert litigation is to simply treat an aggrieved consumer well rather than poorly. Too often, the straw that breaks the nascent plaintiff's back is an intensely personal resentment of how he or she has been treated by the emerging defendant in response to his or her complaints.¹⁴⁴ A sincere excuse and appropriate compensation can be a very small pro-active price to pay in comparison to the consequences of failing to take such progressive action.

When defending an action for product liability, you'll need to consider the relative desirability of a negotiated settlement versus going to trial. A settlement avoids the uncertain constraints on future business decisions that might arise from a court decision, but a well-publicized substantial settlement may also signal to the marketplace that your firm is not averse to sharing its profits with those who threaten court action. A trial may also reveal information to the public that you'd rather not disclose. If the outcome of a trial is highly indeterminate, the value of certainty will rise to a degree that may render settlement the only viable solution.

Product Pricing

If your venture manufactures a biotechnology product for which it holds a patent, it will need to charge prices that (1) the market can bear, and (2) will generate a risk-adjusted profit on sunk costs by the time the patent expires. That deadline exists because once a patent expires, generic producers tend to flood the market with their own versions of the product that feature prices which don't reflect your R&D costs. In fact, the patent term is likely too generous an economic profit deadline since one or more competitors might leapfrog your technology and render it obsolete before your patent expires.¹⁴⁵

The significance of that deadline will also be exacerbated if the product in question is normally paid for by a third party insurer, because the insurer may effectively remove from the ultimate consumer the choice of purchasing your more expensive, formerly patented product. In this context, a strong product or business trademark will truly demonstrate its value by slowing the loss of market share that will inevitably follow patent expiry.

Conclusion

The commercialization of biotechnology by a start-up venture is characterized by a succession of opportunities to either bolster the probability of eventual commercial success or inadvertently increase the obstacles that may jeopardize such success.

The close interdependence of the business and legal decisions that are involved in biotechnology commercialization demands that your legal advisor take an active and well-informed role in favourably influencing the likelihood and degree of your venture's commercial success.

Although such an enterprise will invariably face many legal and business issues for which no unambiguously ideal solution is apparent, I hope that the above discussion has provided some useful perspective on some of the more critical among those decisions.

May your next challenge be how to optimally invest or distribute the positive cash flows that your venture has begun to generate!

References

- ¹ David J. Teece, “Capturing Value from Knowledge Assets: The New Economy, Markets for Know-How, and Intangible Assets,” 40 *California Management Review* (Berkeley: 1998) 55 at 77.
- ² Areas of law which can reasonably be expected to affect a start-up biotechnology venture include intellectual property law, contract law, securities law, tax law, corporate law, employment law, real estate law, international trade law, environmental law, and tort law.
- ³ Helen Gavanagh, “From Research to Commercial Benefits,” 395 *Nature* (1998) 413 at 413.
- ⁴ *Ibid.* at 414.
- ⁵ *Patent Act*, R.S.C. 1985, c. P-4, s.28.2(1)(a), as amended.
- ⁶ David S. Wainright, “Patent Filing Strategy – Consider Filing More Often, Faster, and in Canada First,” (1997) 14 C.I.P.R. 61 at 65.
- ⁷ *Ibid.*
- ⁸ See the discussion of Trade Secrets below.
- ⁹ The services of a registered agent are recommended to have the job done properly, since the work involves a substantial degree of judgment and experience: Canadian Intellectual Property Office (CIPO), *A Guide to Patents* (Ottawa: Industry Canada, 1998) at 5.
- ¹⁰ *Ibid.* at 15. However, it may be that this figure is more attributable to perverse incentives in our income tax legislation and to the inadequate diligence of get-rich-quick investors than it is attributable to naïve or ignorant researchers.
- ¹¹ Wainright, *supra* note 6 at 64. See for example *ICN Pharmaceuticals, Inc. v. Canada (Patented Medicine Prices Review Board)* (1996), 66 C.P.R. (3d) 145.
- ¹² Wainright, *supra* note 6 at 63.
- ¹³ At <http://cipo.gc.ca>, or <http://strategis.ic.gc.ca/patents>.
- ¹⁴ CIPO, *supra* note 9 at 6.
- ¹⁵ *Patent Act*, *supra* note 5 at s.32.
- ¹⁶ *Ibid.* at s.55(6), as interpreted in *Micro Chemicals Ltd. v. Smith Kline and French International American Corp.* [1972] S.C.R. 506. See Linda M. Kurdydyk and Shone S. McDiarmid, “Patent Infringement Issues Relating to Biotechnology” (1993), 10 C.I.P.R. 175 for further discussion of the experimental use exemption.
- ¹⁷ CIPO, *supra* note 9 at 4.
- ¹⁸ Michael Lytton, “Avoiding Common Pitfalls,” 18 *Pharmaceutical Executive* (Eugene: 1998) 68 at 70.
- ¹⁹ *Ibid.* at 70.
- ²⁰ Kurdydyk and McDiarmid, *supra* note 16 at 177. To be enforceable, any restrictions on post-sale use of the organism must be explicit at the time of the sale: *Eli Lilly & Co. v. Novopharm Ltd.* (1998), 80 C.P.R. (3d) 321 (S.C.C.) at para 100.
- ²¹ *Copyright Act*, R.S.C. 1985, c.42 at s.3.
- ²² See the discussion of Packaging and Promotion below.
- ²³ S.C. 1990, c.20.

- ²⁴ *North American Free Trade Agreement*, Art. 17.11.1, as a fair encapsulation of Canadian and U.S. case law: John T. Ramsay, *Technology Transfers and Licensing* (Canada: Butterworths Canada Ltd., 1996) at 107.
- ²⁵ *LAC Minerals Ltd. v. International Corona Resources Ltd.*, [1989] 2 S.C.R. 574.
- ²⁶ Martin P.J. Kratz, *Canada's Intellectual Property Law in a Nutshell* (Scarborough: Carswell, 1998) at 109.
- ²⁷ Lytton, *supra* note 18 at 69.
- ²⁸ *Patent Act*, *supra* note 5 at s.10.
- ²⁹ Lita Nelsen, "The Rise of Intellectual Property Protection in The American University," 279 *Science* (1998) 1460 at 1461.
- ³⁰ Disclosure of confidential information to the Patent Office in a patent application arguably negates the protection of trade secrecy. However, it appears to the author that s.10(2) of the *Patent Act* imposes on the Patent Office staff the necessary obligation of confidentiality to perpetuate the trade secrecy of that information for 18 months from filing. Section 28.2(2) of the Act further reinforces the notion that the filing of an application does not constitute sufficient disclosure to negate trade secrecy.
- ³¹ Brendan Horton, "Taking Knowledge from Bench to Bank" 395 *Nature* (1998) 409.
- ³² Clay Boswell and Pamela Sauer, "Maximizing Yield in the Technology Harvest," 254 *Chemical Market Reporter* (New York: 1998) 28 at 28.
- ³³ *Patent Act*, *supra* note 5 at s.44.
- ³⁴ *Apotex Inc. v. Merck & Co.* (1995), 60 C.P.R. (3d) 352 (F.C.A.) at 364.
- ³⁵ David Waver, *Intellectual Property Law* (Canada: Irwin Law, 1997) at 154.
- ³⁶ Ramsay, *supra* note 24 at 44.
- ³⁷ Presentation by Mark Butler to University of Calgary Business School class, February 1, 1999.
- ³⁸ CIPO, *supra* note 9 at 3.
- ³⁹ *Patent Act*, *supra* note 5 at s.2 definition of "invention."
- ⁴⁰ *Ibid.* at ss.2, 28.2 and 28.3.
- ⁴¹ *Shell Oil Co. v. Commissioner of Patents* [1982] 2 S.C.R. 536.
- ⁴² *Re Application of Abitibi Co.* 62 C.P.R. (2d) 61 (1982).
- ⁴³ *Tennessee Eastman Co. v. Commissioner of Patents* [1974] S.C.R. 111. "Medical treatment" has since been confined to the treatment of a pathological condition rather than of physical symptoms in general: *Re Senetek plc Patent Application*, [1997] 77 C.P.R. (3d) 321.
- ⁴⁴ *Harvard College v. Canada (Commissioner of Patents)*, [1998] 79 C.P.R. (3d) 98. This case is under appeal at the time of writing.
- ⁴⁵ Ramsay, *supra* note 24 at 36.
- ⁴⁶ University of Guelph Collaborative Research and Development Office (CRDO) website, at <http://www.uoguelph.C.A./Research/crd/patprot.html>.
- ⁴⁷ *Ibid.*
- ⁴⁸ *Ibid.*

- ⁴⁹ *Wainright*, *supra* note 6 at 67.
- ⁵⁰ CIPO, *supra* note 9 at 10.
- ⁵¹ Kratz, *supra* note 26 at 136.
- ⁵² University of Guelph CRDO, *supra* note 46.
- ⁵³ CIPO, *supra* note 9 at 10.
- ⁵⁴ *Ibid.*
- ⁵⁵ *Wainright*, *supra* note 6 at 66.
- ⁵⁶ Stephanie Drouin, “Filing of Biotechnology Patent Applications in USPTO: Considerations for Canadians” (1993) 10 C.I.P.R. 109 at 118.
- ⁵⁷ See Avoiding the Negation of One’s Own IPR above.
- ⁵⁸ *Patent Act*, *supra* note 5 at s.28.4, and *Patent Rules* SOR/96-460-01 at s.88(1)(b).
- ⁵⁹ *Patent Rules*, *supra* note 58 at s.94. For the more complex provisions governing PCT national phase applications, see *Patent Rules* s.62(2).
- ⁶⁰ Ramsay, *supra* note 24 at 34.
- ⁶¹ University of Guelph CRDO, *supra* note 46.
- ⁶² *Patent Rules*, *supra* note 58 at s.96.
- ⁶³ CIPO, *supra* note 9 at 8.
- ⁶⁴ *Patent Act*, *supra* note 5 at s.55(2).
- ⁶⁵ *Ibid.* at s.47.
- ⁶⁶ CIPO, *supra* note 9 at 9.
- ⁶⁷ Presentation by Roseann Caldwell to the University of Calgary Law School on April 8, 1999, in reference to Monsanto’s demonstrated patenting strategy.
- ⁶⁸ Jay Pil Choi, “Patent Litigation as an Information-Transmission Mechanism,” 88 *The American Economic Review* (Nashville: 1998) 1249 at footnote 2.
- ⁶⁹ CIPO, *supra* note 9 at 8.
- ⁷⁰ *Ibid.* at 9.
- ⁷¹ *Ibid.*
- ⁷² Choi, *supra* note 68 at 1250.
- ⁷³ See “teaming up” in the discussion of Business Model below. Such a settlement arguably constitutes a restraint of trade because a potentially invalid legal monopoly is maintained by collusion among competitors: Choi, *supra* note 68 at footnotes 31 and 32. Obviously, the economic incentives that operate in a minefield of questionable patent applications favour the interests of collusive large corporations and seriously threaten the continued independence of start-up ventures.
- ⁷⁴ Choi, *supra* note 68 at 1257.
- ⁷⁵ Teece, *supra* note 1 at 59.

⁷⁶ Allan Afuah, “Strategies to Turn Adversity into Profits,” 40 *Sloan Management Review* (Boston: MIT, 1999) 99 at 100.

⁷⁷ *Ibid.* at 102.

⁷⁸ *Ibid.*

⁷⁹ Mary Petrosky, “Don’t Let Competition Stifle Cooperation,” 15 *Network World* (Framingham: 1998) at 33.

⁸⁰ Denzil Doyle, *Making Technology Happen: How to Find, Exploit and Manage Innovative Products, Services and Processes* (Ottawa: Silvan Communications Inc., 1997) at 54.

⁸¹ *Ibid.* at 68.

⁸² Vijay K. Jolly, *Commercializing New Technologies: Getting from Mind to Market* (Boston: Harvard Business School Press, 1997) at 250.

⁸³ Joy D. Morrow, “Biotechnology Licensing,” (1993) 10 C.I.P.R. 277 at 278.

⁸⁴ *Ibid.*

⁸⁵ *Ibid.* at 279.

⁸⁶ *Ibid.*

⁸⁷ See especially the World Intellectual Property Organization’s *Guide on the Licensing of Biotechnology* (Geneva: WIPO, 1992), and Ramsay, *supra* note 24.

⁸⁸ Morrow, *supra* note 83 at 281-285.

⁸⁹ *Moore v. University of California* (1990), 15 U.S.P.Q. 2d 1753.

⁹⁰ Boswell and Sauer, *supra* note 32 at 28.

⁹¹ Glenn DeSouza, “Royalty Methods for Intellectual Property,” 32 *Business Economics* (Washington: 1997) 46.

⁹² Andrea Orr, “Venture Capitalists Bypassing Biotech Ideas,” *The Financial Post* (March 8, 1999) E4.

⁹³ Presentation by Martin P.J. Kratz at the University of Calgary Law School, January 1999.

⁹⁴ Caroline Dorsa, “Evaluating Investment Opportunities: A Pharmaceutical Firm Case Study,” *Corporate Financial Decision Making and Equity Analysis*, ed. by Randall S. Billingsley (Charlottesville: AIMR, 1995) at 22.

⁹⁵ *Ibid.*

⁹⁶ Orr, *supra* note 92.

⁹⁷ *Ibid.*

⁹⁸ Boswell and Sauer, *supra* note 32 at 29.

⁹⁹ *Income Tax Act*, R.S.C. 1985, c.1 (5th Supplement), ss.37, 127 and Reg. 2900.

¹⁰⁰ Jeffrey A. Timmons, *New Venture Creation: Entrepreneurship for the 21st Century*, 4th ed. (USA: Irwin/McGraw-Hill, 1994) at 449.

¹⁰¹ Usually under the sophisticated purchaser (s.107(d)), seed capital (s.107(p)), common bonds (s.107(z)), or private company (s.115) prospectus exemptions in the Alberta *Securities Act*. The otherwise popular private company exemption (s.115) is unlikely to be used since most biotechnology companies understandably decline to include in their constating documents the required prohibition against offering securities to the public: Eric Elvidge, “Financing Biotechnology Companies” (1993) 10 C.I.P.R. 291 at 315.

¹⁰² Elvidge, *supra* note 101 at 311.

¹⁰³ Timmons, *supra* note 100 at 455.

¹⁰⁴ Doyle, *supra* note 80 at 74.

¹⁰⁵ *Securities Act*, S.A. 1981, c.S-6.1, ss.109-112.

¹⁰⁶ In the case of the seed capital exemptions, under ss.107(p) and (q) of the Alberta *Securities Act*, *supra* note 105.

¹⁰⁷ In the case of the common bonds exemption, under s.107(z) of the Alberta *Securities Act*, *supra* note 105.

¹⁰⁸ See the discussion of structuring licensing agreements in Technology Transfer Mechanisms above.

¹⁰⁹ Timmons, *supra* note 100 at 455.

¹¹⁰ Dave Ulrich, “Intellectual Capital = Competence x Commitment,” *Sloan Management Review* (Boston: MIT, 1998) 15 at 16.

¹¹¹ Equity is normally distributed to employees through an exempt offering of equity securities [Alberta *Securities Act* s.107(1)(n) or s.107(1)((z)(i)], or an exempt offering of rights that are convertible into equity securities [s.107(1)(h)] followed by an exempt exercise of those rights [s.107(1)(f)(iii)].

¹¹² Ulrich, *supra* note 110 at 21.

¹¹³ Doyle, *supra* note 80 at 66.

¹¹⁴ Todd Harrold and Michael Michalyszyn, “Confidential Information and Technical ‘Know-How’ ” (1998) 13 I.P.J. 1 at 19-22.

¹¹⁵ John S. Macera, “The Metamorphosis of Canadian Biotechnology Regulatory Law” (1993) 10 C.I.P.R. 255 at 258.

¹¹⁶ John S.L. Fowler, “Consideration of Aspects of Safety of Biotechnology-Derived Products,” *Issues in the Commercialization of Biotechnology* (Vienna: United Nations Industrial Development Organization, 1993) 211 at 214.

¹¹⁷ Macera, *supra* note 114 at 260-266. The statutes are to be found at R.S.C. 1985 c.F-9, R.S.C. 1985 c.F-10, R.S.C. 1985 c.P-9, S.C. 1990 c.22, S.C. 1990 c.21, R.S.C. 1985 c.A-7, R.S.C. 1985 c.L-9, R.S.C. 1985 c.25, and R.S.C. 1985 c.S-8 respectively.

¹¹⁸ R.S.C. 1985 c.16 and R.S.C. 1985 c.N-14 respectively.

¹¹⁹ *Ibid.* at 267-270.

¹²⁰ R.S.C. 1985 c.F-27

¹²¹ *Ibid.* at 270-272.

¹²² R.S.C. 1985 c.H-3.

¹²³ R.S.C. 1985 c.C-38.

124 R.S.C. 1985 c.L-2.

125 *Ibid.*

126 See the discussion of Product Liability below.

127 Teece, *supra* note 1 at 72. Of course, the competitive advantage provided by such “bounded chaos” within the firm may quickly be outweighed by the handicaps of high employee turnover and reduced productivity among those who remain in the firm.

128 *Halocarbon (Ont.) Ltd. v. Farbwerke Hoechst AG*, [1979] 2 S.C.R. 929.

129 Subject to the exhaustion of selling rights by the first authorized sale of the product: *Gillette v. Rea* (1909), 1 O.W.N. 448.

130 U.S. *Patent Act*, 35 U.S.C., s.287.

131 Ramsay, *supra* note 24 at 43.

132 Waver, *supra* note 35 at 178.

133 *Trade-marks Act*, R.S.C. 1985, c. T-13 at s.2 definition of “distinctive.”

134 *Ibid.* at ss.2 and 4 definitions of “use.”

135 *Ibid.* at s.50.

136 *Ibid.* at ss.20(1) and 6(5).

137 *Ibid.* at s.46.

138 Notwithstanding that invalidation or expungement becomes unlikely after 5 years from registration: *Trade-marks Act*, *supra* note 133 at s.17(2).

139 Emergency Preparedness Canada, *Managing Biological Risk* (Ottawa: Minister of Supply and Services, 1995).

140 I.W. Stewart and G. Leaver, “Detection of Containment Breach in Bioprocess Plant Using Aerobiological Monitors,” *Risk Assessment for Deliberate Releases: The Possible Impact of Genetically Engineered Microorganisms on the Environment*, ed. by Walter Klingmuller (Berlin: Springer-Verlag, 1988) at 137.

141 This documentation may however have the unintended effect of substantiating the negligence of particular decisions or actions.

142 Eric S. Grace, *Biotechnology Unzipped: Promises & Realities* (Joseph Henry Press, 1997) at 209.

143 Presentation by Donald Cranston, Q.C. at the University of Calgary Law School on March 18, 1999.

144 *Ibid.*

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