Intellectual Property Rights in Biotechnology: The Economic Argument

Prepared for

The Canadian Biotechnology Advisory Committee Project Steering Committee on Intellectual Property and the Patenting of Higher Life Forms

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March 2001

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Intellectual Property Rights in Biotechnology: The Economic Argument*

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Revised March, 2001

*The authors gratefully acknowledge the helpful comments and suggestions provided by Christina Sampogna of the Special Projects Directorate, Corporate Governance Branch. The views expressed are those of the authors.

Executive Summary

Intellectual property laws are a core component of the broad policy framework the government has put in place to foster a more innovative economy that will support continuing improvements in Canadians' living standards. In the absence of government intervention, firms would have a limited incentive to invest in the production of knowledge since many of the benefits accrue to others. Intellectual property laws attempt to remedy this market failure by granting property rights that recognize an inventor's exclusive right to make, use or sell an invention for a fixed term. Besides stimulating the production of new knowledge, the IP system facilitates its dissemination. In return for a period of market exclusivity, for example, patentees must provide a clear and complete description of their invention in the patent application, which, in Canada, is published 18 months after the filing date.

Governments face a number of difficult policy decisions in the design and employment of IP policy. They must determine to what extent to rely on IP as opposed to other policy instruments, such R&D tax incentives and public subsidies to promote innovation. They must also decide how provisions with respect to such matters as the scope, length and nature of IP rights can be set so as to maximize the benefits and reduce the costs of IP policy. A highly protective regime that restricts access to new technologies could reduce follow-on developments and slow the pace of innovation. On the other hand, a weak regime may be ineffective in promoting R&D and also impair a country's ability to license foreign technology and attract foreign investment. For Canada, the design of IP policy must be made with particular attention to this country's strong economic ties with the U.S. There is a need to consider how changes in IP policy will affect the commercial connections - including the strong trade and investment links and the other well-developed mechanisms facilitating access to the results of U.S. innovation - that have played such an important role in Canada's growth.

Over recent decades, broad forces that have transformed the overall economic environment have also brought important changes to the IP system. First, since the early 1980s, there has been a strong growth in patenting activity in industrialized economies. Research suggests that a main explanation is the expansion in research opportunities created by the technological revolution in high-technology sectors, especially biotechnology, information technology and software. Secondly, low-cost, increasingly powerful information technologies have made patent application information much more widely and easily accessible. And thirdly, as part of broad international efforts to enhance and spread the benefits of globalization, the disparity in global IP standards has been reduced. WTO member countries must now respect the TRIPs agreement that establishes minimum standards for intellectual property protection and sets out enforcement requirements.

The biotechnology sector, and particularly the health care segment of the industry, is a heavy user of the IP system. This is partly a result of the high rate of innovation in this industry. In Canada, the U.S, Japan and the EU, biotechnology is one of the most research-intensive sectors of the economy. With biotechnologies, it is generally relatively easy to define a new invention with the clarity needed to meet requirements under the

Patent Act and to permit an effective defence against infringement. Patents are especially important to biotechnology companies because of their highly skewed returns from investment in R&D. Patents help firms generate the high returns on successful biotechnology innovations that are needed to compensate for the losses on unsuccessful R&D investments - although, in some cases, the period of market exclusivity of a patent, and consequently investment returns, may be substantially reduced by regulatory approval delays and the lack of patent term restoration. Policy developments that have facilitated the application of patent policy to biotechnology and that have attempted to address abuses in the use of IPRs have also contributed to the growing importance of biotechnology patents.

Canada has a modest, but rapidly growing biotechnology industry. Most of the approximately 300 companies are small firms, employing 50 or fewer workers. The industry employed just under 10,000 workers in 1997 and generated $1.1 billion in sales, half of which came from health care products. R&D investment amounted to over 50% of sales revenue in 1997. Canadian firms are highly dependent on outside financing to cover R&D and sustain operations through long product development cycles. Patent protection is crucial in helping firms raise needed capital. Successful biotechnology firms have effectively used patents to attract financing, especially important venture capital support. Patents have also provided a basis for establishing alliances that help firms share R&D costs or that provide the latter-stage support firms need as they approach commercialization. Biotechnology firms generally patent first in the U.S. and then in Canada, which is a reflection of the greater size and importance of the U.S. market.

Among the different segments of the Canadian biotechnology industry, patent protection is most important to health care companies, which accounted for almost 90% of biotechnology R&D in 1997. Environmental and aquaculture companies rely mainly on other less costly forms of protection, including trade secrecy. Agricultural biotech firms also utilize the *Plant Breeders' Rights Act*, under which they may gain the exclusive right to sell and produce a specific plant variety *for the purpose of selling its propagating material.*

There are unique challenges in protecting biotechnology products against infringement. Canadian biotoech firms have to contend with the difficulties of enforcing claims on inventions that are reproducible and thereby simpler and cheaper to copy than traditional technologies. Another issue of increasing importance to Canadian biotech companies is the "transaction costs" of negotiating and collecting licensing royalties. As both significant buyers and sellers of intellectual property, biotechnology have an interest in strategic alliances, collectives and other arrangements with the potential to reduce the costs involved in negotiating and collecting royalties and enforcing IP rights.

There remains considerable scope for debate about the features of an optimal IP policy for the Canadian biotechnology sector. Recent surveys and reports have focussed on issues such as the application of patent protection to higher life forms, the scope of the research use defence and the methods of medical treatment exemption**,** and the appropriate interface between the *Patent Act* and the *Plant Breeders' Rights Act.* Canada's current IP

policy is different than that of its main trading partners on some of these issues, such as the patenting of higher life forms and patent term restoration. The resolution of questions that have arisen with respect to these and other matters requires a careful weighing of economic tradeoffs, along, in some cases, with an assessment of social and other public policy considerations.

Introduction

The purpose of this paper is to provide an overview of the economics of intellectual property (IP) and to examine the importance of IP in general and patents in particular for the Canadian biotechnology industry. It begins with a general discussion of how IP fits into the framework of government policies aimed at promoting innovation. The first section also contains a brief discussion of the factors that must be considered in designing an IP regime to meet the needs of a small open economy. The second section focuses on the importance of IP protection to biotechnology and examines recent efforts to extend the application of IP laws to this sector. In the third section, general considerations pertaining to IP are related to the specific circumstances facing the Canadian biotechnology industry. Following a brief review of key data on the Canadian industry, there is a discussion of evidence shedding light on the role and importance of patents in the development of Canadian biotechnology firms. The final part of Section 3 reviews some of the specific issues that have arisen in discussions on how to improve the application of Canadian IP law to the biotechnology sector.

Section 1: The Economics of IP

Intellectual property laws are a core component of the broad policy framework the government has put in place to foster a more innovative economy that will sustain continuing improvements in Canadians' living standards. Economists have long recognized the important contribution of technological progress to the productivity growth that has been the key to the sustained increases in average income that industrial economies have enjoyed over the past two centuries. Among the recent economic studies highlighting the importance of innovation are so-called "endogenous" growth models. These theoretical studies explain why, because of its unique characteristics, the new knowledge that results from research is a particularly important source of economic growth. The critical role of technological progress is supported by a variety of empirical evidence. For example, one historical study, which reviews evidence dating back to 1820 for 21 countries and back to 1950 for another 22 economies, concludes that "… the major engine of growth has been advancing knowledge and technical progress, which needs to be embodied in human and physical capital in order to have an impact".[1]

Economists have also long understood that, left to their own, markets will not lead to adequate innovation. The main source of market failure is the inability of individuals and firms to prevent others from making use of the new knowledge they produce. If firms cannot appropriate the full returns from producing knowledge, they will have less incentive to invest in knowledge-producing activities. R&D with potentially high social returns but with low expected private returns will not be undertaken.

Knowledge further qualifies as a public good because of its non-rival quality; it doesn't lose its utility as it is used and re-used. Since knowledge remains intact as it is used and it can be transmitted at close to zero cost, there are public benefits from the widespread sharing of knowledge. Profit-maximizing firms, however, have no incentive to contribute

to knowledge spillovers that benefit other firms. Studies suggest that private returns, which are the basis for research investments, are no more than half of the social returns to R&D.[2]

Intellectual property laws attempt to remedy the market failure in R&D markets by granting property rights that recognize the inventor's exclusive right to make, use or sell an invention. Inventors can apply for a patent, for example, that will provide up to 20 years of protection for eligible inventions that meet the tests of novelty, utility and non-obviousness. Intellectual property rights (IPRs) increase the extent to which the benefits of innovation can be appropriated and thus help strengthen the incentive for private firms to undertake R&D. This gain in dynamic efficiency[3] comes with a cost because IP protection leads the prices of goods and technology to rise above their efficient level based on the costs of production (or more precisely their marginal costs). There is a loss to the economy due to the resulting underutilization of knowledge and underproduction of goods. IP laws are beneficial because, in general, the dynamic efficiency gains from greater innovative activity exceed the losses in static efficiency[4] from higher product and technology prices.

Besides stimulating the production of new knowledge, the IP system facilitates its dissemination. In return for the grant of a period of market exclusivity, for example, patentees must disclose their invention. A clear and complete description of the invention must be provided on the patent application, which, in Canada, is published 18 months after filing. Such information dissemination is an important source of the dynamic efficiency benefits produced by IP. The information disclosed in patents enables other to build on earlier inventions. It also helps avoids costly and wasteful duplication in research efforts.

IP law is only one of the instruments Canadian policymakers employ to support the creation of knowledge and help build a more innovative economy. The creation of IP rights is inappropriate for basic research findings, such as new discoveries in physics, which are important building blocks in the advancement of human knowledge. Basic research findings generally do not have direct industrial applicability, but they lay a foundation for further research and subsequent inventive activity with potentially far-reaching implications for various aspects of human wellbeing. In this case, where there is a strong public interest in the free distribution of research findings, the government uses subsidies to supplement existing academic incentives for discovery and publication.[5]

To encourage R&D by business, in addition to IP law, the government employs tax incentives. Indeed, Canada has a very generous system of R&D tax incentives relative to other OECD countries.[6] With tax incentives and business subsidies, however, part of the cost of poor investment decisions are borne by the public at large. Under IP, by contrast, private investors bear all the investment risk. Entities who have invested their own funds to acquire an IP right or who are accountable to shareholders have a strong incentive to identify the most promising opportunities for the development of new products and processes.

Determining the Features of an Optimal IP Regime

Policymakers face a number of difficult decisions in their efforts to design a regime that maximizes the economic gains and minimizes the potential economic losses from IP protection. The economic impact of IP will be significantly influenced by the standards the government establishes to define the legal structure of IP rights. In the case of patents, for example, there is a need to determine: the scope of patentable subject matter; patent term; the breadth of patents; the nature of the patent rights; and the nature of any exceptions that are needed to protect the public interest. The strength of patent protection depends on the legislative standards established for these factors and on jurisprudential and administrative decisions that determine how these standards are interpreted and enforced. Administration and enforcement are affected by a variety of factors, including patent examination procedures, patent rules affecting onus of proof, patent opposition rules, court rulings regarding innoculary injunctions, infringement awards, and custom enforcement at the border.

Strong IP protection increases the value of patents and other IP rights, but it reduces access to patented goods and it could significantly reduce the contribution of the patent system to the dissemination of new research findings. Innovation involves both the development and the adaptation of new product and process technologies. By increasing the strength of IP protection - by, for example, extending the duration of patents - policymakers increase the potential returns from innovative activity, but they make it more costly to acquire protected technologies. The innovation that results from the spread of new technologies and their modification and adaptation by subsequent users is likely to be reduced.

Moreover, in designing an IP regime that effectively promotes innovation, policymakers must take account of the incremental and cumulative nature of the innovative process; existing innovations are key inputs into the production of future knowledge. As discussed above, the IP system contributes to the dissemination of knowledge. The disclosure that occurs when firms patent their inventions contrasts with the lack of information when firms chose to instead protect their innovations through trade secrecy. The benefits provided by the patent system, however, will be reduced where governments establish stringent tests and costly application processes that encourage firms to rely on trade secrecy rather than patent protection. The IP system's role as a mechanism of information dissemination can also be reduced by the creation of strong rights that result in excessively high prices for the information that is needed for follow-on innovations.

Of relevance to the latter issue are concerns that have been raised regarding the scope of patent rights. Concerns about the impact of broad patent claims have been highlighted by the U.S. government's allegation that Microsoft is leveraging its dominance of computer operating systems to exercise control over application software. Many industry experts believe that Microsoft's market power, which is partly attributable to its strong patent rights, may have retarded the pace of innovation in the computer industry.

The establishment of a positive innovation environment requires that decisions with respect to such matters as patent scope and duration reflect a careful balancing of the incentives for initial and follow-on inventors. It also requires the supportive application of competition policy. While, historically, anti-trust authorities have viewed the exclusionary rights conveyed by patents as being at odds with competition objectives, there has come to be a gradual appreciation that the dynamic efficiency gains pursued through IP policy contribute to enhancing consumer welfare, which is the ultimate objective of competition policy. In Canada, as in the U.S., however, competition authorities are concerned about possible abuses resulting from overly-broad patents, especially in network industries, and from firms' use of IP rights to extend their market power. [7] Abuse of patents may be addressed through S. 65 of the *Patent Act* and S. 32 of the *Competition Act*, but these provisions have been used infrequently.

IP Policy in a Global Economy

In a global economy characterised by growing trade and investment and the increasing importance of multinational enterprises (MNEs), there are additional factors that influence the role of objectives of IP policy. In general, small open economies that are heavy net importers of technology and goods embodying new technologies have an interest in weaker IP standards than countries that are major exporters of intellectual property.[8] It is also important to consider, however, that a country's ability to imitate and adapt foreign technologies depends on its innovative capabilities. Countries that are importers of technology must still build a significant R&D infrastructure through IP and other innovation policies if they are to be in a position to take advantage of inflows of foreign technology.

There are other potential costs from inadequate IP laws and enforcement mechanisms. Weak IP protection can impact on a country's trade, foreign investment and its ability to license foreign technology. While it is difficult to isolate IP from all the other factors that influence trade, investment and technology licensing, some studies focusing on the experience of developing countries suggest that inadequate IP policies do negatively impact on foreign commerce.[9] One study, for example, found that stronger patents contribute to increased trade by developing countries, especially larger and wealthier developing nations.[10] In the case of foreign direct investment, weak IP laws could reduce investment inflows into a country, but they could also result in an increase in investment because the alternative of technology licensing becomes an especially risky and unattractive option. The latter result would be consistent with research indicating that foreign direct investment is often a response to government policies that make it difficult for MNEs to realize the value of their strategic assets through market transactions. Evidence has found, however, that U.S. multinationals are discouraged from investing in countries with weak IP laws. The World Bank study found that strong patent rights are particularly important in the R&D and manufacturing investment location decisions of multinationals in the chemical and pharmaceutical sectors. [11]

For Canada, IP policy must be framed with particular attention to this country's strong economic ties to the U.S. As a small country, Canada's perspective on IP policy will

differ from the U.S., which is the world's most innovative economy by most measures. Strong IP protection will result in increased profits for a number of U.S. manufacturers of new products and increased prices for some goods consumed by Canadians. Decisions on a Canadian policy, however, need to be made in a broad context that takes account of the considerable benefits this country enjoys from its strong trade and investment links with the U.S. and its favourable access to the results of U.S. innovation. These benefits have been documented in a number of studies, including, for example, one recent report that found R&D spillovers from the U.S. were the major factor behind the productivity growth of eight out of eleven manufacturing industries examined over the period 1966 to 1991.[12] Technological progress in this country would have been slower without significant inflows of U.S. knowledge and, also, without the stimulus provided by the large U.S. market. Canadian inventors recognize the importance of penetrating the U.S. market and, in any given year, they file first with the U.S. Patent and Trademark Office (USPTO) and file more patents with the USPTO than with the Canadian Intellectual Property Office (CIPO). [13] An IP regime that reflects Canada's interest as a small, technology-importing country within the North American economic region will support the commercial connections that have played a major role in this country's long-term growth.

Recent Developments

Broad forces that have transformed the overall economic environment, especially globalization and the information technology revolution, have also brought important changes to the IP system. Three developments in IP are particularly noteworthy. First, since the early 1980s, there has been a strong growth in patenting activity in industrialized countries. Patent applications received by the USPTO, which were relatively stable for much of the postwar period, have doubled since 1984.[14] A number of explanations have been offered for the jump in patenting, including changes in business attitudes and practices and the emergence of more patent-friendly courts in the U.S.[15] A recent study examining Canadian experience finds that, while a number of factors have led to the growth in patenting activity, the most important explanation is the expansion of technological opportunities.[16] Canadian evidence supports the "fertile technology hypothesis", which argues that recent developments are due to the research opportunities created by the technological revolution in high-technology sectors, especially biotechnology, information technology and software.

Secondly, the information disclosed in patent applications has become more accessible, thereby strengthening the role of the IP system as a mechanism for disseminating information and helping to accelerate the diffusion of new technologies. With more countries requiring the publication of a patent application, patent information is available to the public earlier than in the past. Individuals can generally access patent application data 18 months from the filing date. More importantly, as a result of new, low-cost and increasingly powerful information technologies, patent application information is widely and easily accessible. From their home, using the Internet, Canadians can search the CIPO database and also check out the more than one hundred thousand patent applications that are filed annually in the U.S. and other major industrial countries.

Thirdly, IP protection in developing economies has been strengthened and the disparity in global IP standards has been reduced.[17] The changes in IP are part of a broader global development that has included reductions in trade and investment barriers and other international policy reforms aimed at enhancing and spreading the benefits of globalization. The major vehicle for the international changes in IP has been the 1994 WTO Agreement on Trade-Related Aspects of Intellectual Property (TRIPs). The TRIPs agreement requires signatories to apply the principles of national treatment and most-favoured nation (MFN) to intellectual property protection. It establishes minimum standards of protection for all forms of intellectual property - patents, copyright, trademarks, geographical indications, industrial designs and layout designs for integrated circuits - and sets out measures to address enforcement. TRIPs became applicable in 1996, but developing countries were allowed a 4-year transition period and the least-developed countries were granted an extension until 2006.

Section 2: IPRs and Biotechnology

The Importance of IP to the Biotechnology Sector

Biotechnology is one of the high-technology fields that has seen an exceptionally strong rise in new innovations and experienced rapid growth in recent years. Using new biological tools, researchers have developed a wide range of possibilities for using living organisms, or parts of living organisms, to produce new products or processes. Biotechnology has applications in many sectors, including healthcare, agriculture, environmental protection, and aquaculture. In healthcare, for example, research based on biotechnology has resulted in new diagnostic tools and treatments for cancer, atherosclerosis, osteoporosis, asthma and AIDS.[18] In agriculture, the industry has created disease resistant plants that are helping developing economies respond to the food needs of their growing populations.

Biotechnology, like information technology, is an enabling or general purpose technology. Enabling technologies open up important avenues of research that spawn further innovations and ultimately result in products and processes that may significantly affect individuals' lives. The application of steam power and electrification are example of such major innovations with long-term and far-reaching implications for the way economic activities are performed and organized. There is debate about whether recent advances in information technology and biotechnology are breakthroughs of a similar order of magnitude and whether they will have impacts on the growth of industrial economies comparable to steam power, electricity, and other past transformative technologies.[19] There is no question, however, that recent developments in information technology and biotechnology have contributed to an acceleration in the pace of innovation and that they have resulted in a multitude of important new products and processes.

A well-developed patent system is important to the biotechnology sector in part because of the industry's high rate of innovation. Studies that have attempted to understand the

substantial differences across industries in the use of intellectual property protection point to "innovativeness" as a key explanatory factor.[20] Industries that are major users of the patent system invest heavily in R&D and are proficient at developing marketable products. Biotechnology has the highest research intensity of any industry. The ratio of R&D spending to total sales is estimated at 48% in the U.S., 53% in Canada and 59% in the EU.[21] By comparison, R&D expenditures as a percentage of value added for all manufacturing is only about 8% in the U.S., and is under 7% for 14 major OECD industrialized countries.[22] The top five biotechnology companies in the U.S. spent an average of $121,400 per employee on R&D compared with an average of $30,600 per employee for the top pharmaceutical companies.[23] A high proportion of biotechnology workers (estimated at around 40% for Canada) is involved in basic and applied research.[24] Accordingly, much of the industry's workforce consists of highly skilled scientists and engineers with expertise in fields such as biology, protein chemistry, immunology, computer modelling and bio-process engineering.[25]

A high rate of innovation is a necessary but not sufficient condition for a firm to be a heavy user of the IP system. First, not all innovations qualify for IP protection. To be eligible for a patent, the innovation must be novel, non-obvious to a person skilled in the field, and have industrial applicability (i.e it must possess "utility"). A 1996 Statistics Canada survey of new, smaller firms in goods and services industries - the business population that is often the source of major new product developments - found that many firms are engaged in innovation, but only a small portion of this activity is directed to producing entirely new products or processes.[26]

Second, not all innovations that are eligible for IP protection are protected. Firms will only seek IP protection if the return from their investment in obtaining and enforcing patents or other IP rights is likely to exceed the return from investing in alternative means to appropriate the benefits from their inventive activity. There is some survey evidence suggesting that firms in many industries rely less on patents than other sources of protection such as their R&D lead or their possession of specialized knowledge or assets.[27] Secrecy is often favoured as the means for protecting process innovations. However, in a large number of industries, firms have indicated they are likely to patent their patentable inventions. One survey found that over 80% of patentable inventions were patented in the pharmaceutical, chemical, petroleum, machinery and electrical equipment industries.[28]

With biotechnologies, as with chemicals and pharmaceuticals, it is generally relatively easy to define a new invention with the clarity needed to meet requirements under the *Patent Act* and to permit an effective defence against infringement. Like the pharmaceutical industry, much of the biotechnology sector is characterized by high-risk research that may require several hundred million dollars and many years to complete. In the biopharmaceutical sub-sector, substantial further investment is required to take a new drug through the Phase I, II and III clinical trials and prepare it for commercialization. First-mover advantages and secrecy are ineffective appropriability strategies in this environment where firms must comply with a lengthy regulatory process involving significant disclosure.

In both the pharmaceutical and biopharmaceutical industries, most revenues come from a small number of highly successful products. One study found, for example, that ten "blockbuster" entities were responsible for a major share of the profits that pharmaceutical companies earned from the introduction of new drugs into the U.S. market over the 1970s.[29] Patents help generate the substantial returns pharmaceutical and biopharmaceutical firms need on their successful innovations to recoup their total investment in R&D. The extent of these returns may be affected, however, by whether additional patent protection is available to compensate for time lost in the regulatory process. In some cases, the period of market exclusivity of a patent may be substantially reduced by regulatory approval delays and the lack of patent term restoration

There are some differences in the role and importance of IP within different segments of the biotechnology sector. IP protection is most important in healthcare, which includes biopharmaceuticals. This is the largest segment of the industry, accounting for almost 70% of output in the U.S., which is the world's largest producer of biotechnology products.[30] Firms in agriculture, aquaculture, environmental protection and other industry segments are less research intensive and their inventions tend to generate much less revenue than innovations in medical biotechnology. In these smaller segments of the industry, firms are more likely to be discouraged by IP costs and to rely significantly on other forms of protection, such as first-mover advantages.

In the biotechnology industry generally, however, there is recognition that intellectual property rights are valuable assets that have a significant influence on firms' competitive prospects. Patents are important in helping biotechnology companies, especially smaller firms, raise needed capital. They also provide emerging companies with the secure ownership rights over new technologies that they need to enter into joint ventures and alliances. Patents help biopharmaceutical firms attract the interest of major drug firms that are looking for new opportunities to exploit technology synergies and strengthen their competitive position. In the early 1990s, when multinational drug companies, who were concerned about declining revenues, went shopping for acquisitions and partnerships, it was those biotechnology companies with strong IP rights capable of replacing their expiring patents that they targeted.[31]

Applying IP Policy To Biotechnology

Patent filings by biotechnology firms have increased rapidly in recent years and biotechnology has become one of the most patent-intensive of all industries.[32] In 1999, for example, the importance of the biotechnology industry as measured by its share of U.S. employment amounted to only about 0.1%. However, the 16,882 patents examined by PTO's Technology Center 1600, which handles biotechnology patents, represented 10 percent of all patents issued by the PTO in that year.[33] While these results are largely due to the industry's high rate of innovation and its other characteristics described above, they also reflect the impact of important developments in IP policy.

To respond to the needs of the biotechnology sector, IP protection is being extended to new subject matter and existing IP laws are being strengthened. The 1991 International Convention for the Protection of New Varieties of Plants (1991 UPOV Convention), for example, strengthened protection for plant varieties. While no country permits the patenting of human beings, inventions involving human organs and tissues are eligible for patenting in the U.S., Japan and Australia. Many of Canada's trading partners, including the U.S., Japan, Australia and the EU, patent plants and animals. Biotechnological processes - such as the basic technique for creating recombinant DNA - are patentable. In the EU, new sui generis database protection has allowed gene sequencers to contract for access to their genomic information.

In most countries, special steps have been taken to facilitate disclosure of patent information. For biological inventions that cannot be adequately described through words, the inventor may deposit a sample of the genetic material in a facility so the physical entity can be made available to interested parties. To facilitate examination of gene sequences, these organisms are disclosed in an electronic format using specialized software. Some countries have also introduced special rules to address infringement concerns raised by such provisions. In Europe, for example, patentees can restrict access to biological samples to experts approved by either themselves or the European Patent Office (EPO). In addition, samples from the deposit, which can only be obtained through a formal request to the EPO, can be used solely for experimentation and testing and cannot be transferred to other parties.

Through IP policy, and also through competition law, countries have been attempting to respond to concerns about overly broad biotechnology patents that could threaten follow-on innovation in the field. Where licensing is difficult or costly, overly-broad patents may effectively limit competitive entry into a number of market segments. Overly-broad patents can be challenged in the courts and can also be reviewed through re-examination. In the U.S., for example, the Federal Trade Commission (FTC) has focussed attention on the role of broad biotechnology patents in facilitating anti-competitive cross-licensing and patent pool arrangements. The FTC is also concerned about the recent more aggressive assertion of infringement claims, which it believes may be part of a strategy by some biotechnology companies to slow competitive entry into the industry.

For the biotechnology industry, one of the most significant recent policy developments has been the agreement among WTO countries to establish minimum standards of IP protection. With their very high R&D costs, its is important for biotechnology firms to market their innovations in as many markets as soon as possible. Global strategies, involving some combination of exports, foreign direct investment and foreign licensing, help firms realize the substantial economies of scale associated with their investment in developing new biotechnology-based products and processes. The TRIPs agreement has made it less risky and more feasible for biotechnology firms to pursue market opportunities in a number of rapidly emerging economies. As a result, the focus of major producers is increasingly shifting from exploiting patents in national and regional markets to developing strategies aimed at maximizing global revenues.

Section 3: Implications and Challenges for Canada

The Canadian Biotechnology Industry

The Canadian biotechnology industry consists of some 300 mainly small, research-intensive companies. In 1997, the year of the latest Statistics Canada survey, the industry employed just under 10,000 workers and generated $1.1 billion in revenue, of which 90% came from biotechnology sales. While biotechnology companies are located in all regions, firms in Ontario and Quebec account for 70% of sales. One quarter of the firms in the industry are publicly traded. Over 70 percent of Canadian biotechnology firms are small enterprises that employed 50 or fewer workers in 1997 (Figure 1). Most of these companies are still at the research and development stage and not yet earning revenues. About 60% of the industry's 1997 sales were due to five firms and virtually all sales were attributable to 50 firms.

Table 1 The Biotechnology Industry: Key Data by Company Size, 1997

	No. of employees			*Total*
	1-50	*51-150*	*over 151*	
No. of Firms	204	43	35	282
Revenue ($ millions)	231	183	721	1,135
R&D ($ millions)	192	153	240	585
Exports ($ millions)	95	43	275	413
Employees	3,125	2,397	4,302	9,823

Source: BIOTECanada, *Canadian Biotechnology '98: Success from Excellence*, 1999.

The rapidly growing Canadian industry is a small, but increasingly important, player in global biotechnology markets. The United States' industry is the world's largest, employing over 160,000 workers and earning revenues of over $C 34 billion (in 1999). Other significant participants are Japan and the EU, whose member countries employed over 53,000 workers in biotechnology in 1999. Biotechnology firms in all countries devote a very high proportion of revenue - close to or over 50% - to research and development. Canadian firms have a higher R&D intensity (R&D/revenue) than U.S. firms, but, this partly reflects the lower sales of Canadian firms, which tend to be positioned at an earlier stage in the product development and commercialization process. In terms of R&D per employee, Canadian spending is only about 60% of the U.S. industry average.

Health care is the largest segment of the Canadian biotechnology industry, accounting, in 1997, for almost half the number of companies, 68% of employment and 50% of biotech sales. Agriculture is the next largest segment of the industry, followed by food processing. While agriculture and food processing together account for almost 45% of biotech sales, their combined share of industry employment is only 19%. The other

segments of the industry - environment, aquaculture, bio-informatics - are significantly smaller in terms of output and production (Table 2).

Table 2 The Biotechnology Industry: Importance of Main Industry Segments, 1997
(*Percentage Share)*

	Companies	*Biotech Sales*	*Employment*	*R&D*
Health Care	46	50	68	87
Agriculture	22	23	17	5
Environment	11	3	3	1
Food Processing	7	21	2	2
Aquaculture	4	1	1	0
Bio-Informatics	3	0	2	2
Other	7	2	7	3
Total	100	100	100	100

Source: BIOTECanada, *Canadian Biotechnology '98: Success from Excellence*, 1999.

The relatively small biotechnology industry accounts for a significant portion of all R&D spending by Canadian business - over 5%. Most of the industry's approximately $600 million in annual R&D spending is undertaken by the health care sub-sector. Biotechnology firms are reliant on outside sources of capital to finance R&D and carry them through extended product development cycles that may last ten years or more.[34] Private placements and venture capital have been the two most important sources of outside financing. In 1999, $315 million in venture capital was invested in Canadian biotechnology firms.

The Role of IP in the Canadian Biotechnology Industry

The Canadian biotechnology industry benefits from a range of government policies supporting innovation. The federal government makes significant ongoing investments in programs to build the country's science and technology infrastructure (e.g. Canadian Foundation for Innovation), to develop skilled human resources (e.g. Millenium Scholarships, NSERC research grants) and to support public sector R&D (e.g. the work of the National Research Council). About 10 percent of the federal government's overall research budget is devoted to biotechnology. In addition, the sector has been able to take advantage of various initiatives to encourage applied and commercial research including, the federal program of R&D tax credits, the Industrial Research Assistance Program (IRAP) and Technology Partnerships Canada (TPC).

Among the various forms of support available to the Canadian biotechnology industry, IP protection plays a unique and especially significant role. Over a 5 year period, 57% of all Canadian biotechnology firms used patents to protect their proprietary technology, and 48% either licensed IPRs to or acquired IPRs from another firm.[35] A recent survey of 46 Canadian biotechnology companies found that almost all use patents to protect their most valuable technologies.[36] Senior biotech executives reported that acquiring a strong

intellectual property portfolio was crucial to their efforts to raise capital and achieve competitiveness.

A recent Statistics Canada research study found that patenting activity was one of the factors underlying the success of those Canadian biotech companies that experienced very rapid growth over the 1994 to 1998 period.[37] The author explains that patenting signals to the financial community, "the novelty of [firms'] future products, thus their exclusivity". Patents allowed companies to raise venture capital, which helped the more successful firms by providing them not only with needed funds, but also management and financial services and increased credibility.

Surveyed biotech CEOs confirm that attracting outside investment is critical and that investors are strongly influenced by the strength of the company's IP assets. Patents also provide a basis for forging alliances, which are particularly important in biotechnology. In 1997, over two-thirds of Canadian biotech firms had entered into R&D partnerships and almost half had entered into marketing alliances.[38] R&D alliances allow companies to exploit complementarities in knowledge and skills and to share the substantial costs and risks associated with the development of new biotechnology products. Later stage alliances enable biotech companies with strong patents to join forces with firms possessing the financial, manufacturing and marketing resources that are needed for successful commercialization. Canadian firms place importance, as well, in the strategic advantages they may gain from strong intellectual property rights that may dissuade other firms from developing competing products. [39]

Most biotechnology firms file their patent applications first in the U.S., and then, afterwards, in Canada. This is similar to the pattern in other industries and is a reflection of the greater size and importance of the U.S. market. U.S. patent protection is seen as essential for firms to generate a significant return on their large investment in research and product development.

Among the different segments of the Canadian biotechnology industry, patent protection is most strongly and consistently pursued by the health care companies. Biopharmaceutical and other health care companies are sensitive to the importance of patents to their financial viability and growth. They are especially aware of the relationship between acquiring patents on their innovations and recouping the high R&D costs typically associated with their area of business**.** On the other hand, it seems that environmental and aquaculture companies rely mainly on other forms of protection, including the entry barrier provided by regulatory standards.[40] The high cost of patent protection, which discourages the filing of applications for less important technologies or processes, is more of a deterrent outside of health care. As compared to other industry segments that look initially to the U.S., however, agricultural firms with patentable technologies place greater importance on a Canadian patent because Canada is a significant agricultural market.

Along with patents, Canadian biotechnology firms protect their intellectual property with trademarks, trade secrecy, and plant breeder's rights (PBRs). Trademarks are generally

not important assets for biotechnology companies and most small and medium-sized firms only register their corporate brands or domain names.[41] Product trademarks are more important to larger companies that have products that are being marketed or approaching commercialization. All biotechnology companies rely to some extent on trade secrecy. For certain process-related and secondary technologies, confidentiality agreements with employees, other firms, and potential investors constitute the main form of property right protection.[42] In other cases, secrecy agreements are a temporary measure to prevent disclosure until a patent is filed.

Agricultural biotech firms that are involved in developing propagating materials, such as seeds, can apply for protection under the Canadian *Plant Breeders' Rights Act,* which falls under the responsibility of the Minister of Agriculture and Agri-food (unlike the *Patent Act* which is the responsibility of the Minister of Industry). Holders of PBRs rights gain the exclusive right to sell and produce a specific plant variety *for the purposes of selling its propagating material*. An exemption under the Act, however, allows farmers to save the seeds from protected plant varieties and replant them in subsequent years.

There are unique challenges in protecting biotechnology products against infringement. Canadian biotech firms have to contend with the difficulties of enforcing claims on inventions that are reproducible and thereby simpler and cheaper to copy than traditional technologies. Enforcement problems have been of particular concern to plant breeders because of the so-called "brown-bagging" problem. Brown-bagging occurs when a crop grown from a pedigreed seed produces new seeds that are saved and subsequently resold. In response, biotech firms have begun turning to "terminator technology", which produces harvested seeds that cannot be sown, and entering into licensing agreements that provide farmers with access to protected seed technology on condition that they not sow harvested seed.

Another issue of increasing importance to Canadian biotech companies is the "transaction costs" of negotiating and collecting licensing royalties. Biotechnology firms have an interest in minimizing transaction costs from their perspective as both significant buyers and sellers of intellectual property. In the 1997 Statistics Canada survey, 37% of the respondents had assigned IP rights outside of the company over the previous 3 years, and 61% had acquired IPRs.[43] One area where transaction costs have become an important factor is in the material transfer agreements that are commonly negotiated between scientists and research institutes prior to exchange of plant material. These contractual arrangements, which have replaced the former practice of freely exchanging materials, have raised transfer costs and reduced the amount of material that is exchanged. In the future, contracting may become more costly. New plant varieties under development may contain ten or more patented genes, each of which will have to be licensed by those wanting to use the new plant technology. In coming years, biotechnology companies may have an added incentive to pursue strategic alliances and other arrangements that reduce transactions costs. There may also be a role for collectives, similar to those that operate in the copyright area and that help individual creators negotiate and collect royalties and enforcing their IP rights.

Improving the Design of Canadian IP Policy

While IP protection plays an important role in the biotechnology industry, there remains room for debate about the contribution of specific provisions of Canadian law. Indeed, a number of questions have been raised about the way Canadian patent law has been adapted to the special characteristics of biotechnology. Divergent opinions expressed in recent surveys and reports partly reflect differences in view about how to achieve an appropriate balance among the tradeoffs identified in the first section of the paper.[44] They involve different perspectives on the specific legislative changes that are needed to maximize the benefits that Canadians derive from both a highly innovative domestic biotechnology industry and the availability of reasonably priced biotechnology products. Differences in view, however, only revolve partly around economic issues; the application of IP policy to the biotechnology sector also raises important social and public policy questions that are beyond the scope of this paper. Among the specific issues that have been a focus of discussion are the following:

The Patenting of Higher Life Forms:
Until recently, plants and animals were not patentable in Canada. A recent Federal Court of Appeal decision allowing a patent on the "Harvard onco-mouse" challenges Canada's approach in this area. The Attorney General of Canada has sought leave to appeal this decision to the Supreme Court of Canada. Canada's policy differs from that of its major trading partners such as the United States, Japan, the European Union and Australia which permit the patenting of higher life forms. The patenting of higher life forms raises important social and public policy questions. For example, Canada could be faced with economic consequences, such as becoming a less desirable location for biotechnology activities and investment, should it choose a course completely different from that of its major trading partners with respect to the patenting of higher life forms.

The Method of Medical Treatment Exemption:
As a result of court decisions, methods of medical treatment cannot be patented in Canada while diagnostic methods are patentable. A significant consideration has been the importance of ensuring unrestricted access to methods of medical treatments for all members of society. This exemption, however, raises questions about the patentability of certain biotechnology inventions, such as gene therapies, that might be regarded as treatment methods as well as medicines. Some have argued that there is a need to develop statutory provisions that will clarify policy in this area.

The Research Use Defence
Jurisprudentially-created, the research use defence enables anyone conducting research of a non-commercial nature to defend themselves against a suit for infringement. The policy consideration underlying this defence is that pure, academic research should not be impeded. For example, the use of a patented gene by a university researcher to determine its other functions could be covered by the research use defence. Some have argued that there is a need for statutory provisions codifying this defence.

Interface Between Plant Breeders' Rights Act and Patent Act:
Given the more limited protection available under the PBR system, some have argued for an expansion of the patent system to include plants. An extension of patents to cover plant varieties would be of concern to agricultural researchers and workers who may no longer have free access to the varieties that they need for breeding. Although there is a research exemption under the *Patent Act*, it is not as broad as the one under the *PBR Act.* A related issue is whether compulsory licenses should be created to provide plant breeders with access to patented plant technology and patentees access to varieties protected under plant breeders' rights.

Third-Party Procedures:
There are some issues pertaining to patent practices that are important to the biotechnology sector while also being of general interest. One procedural issue is whether Canada should allow third parties to oppose patent applications. Japan and Australia have pre-grant opposition procedures, under which individuals may file a notice of opposition within a specified period of time. In the EU, there is a post-grant opposition procedure, allowing a notice of opposition to be filed within a specified period of time after the patent has been granted. Opposition procedures, depending on the manner in which they structured, may add to the time and expense of the patenting process. These costs must be weighed against the benefits that may come from providing for a fuller representation of interests in the patent-granting process.

Conclusion

Intellectual property laws are a response to the failure of markets to generate adequate incentives for innovation. By allowing firms to more fully appropriate the benefits from their investment in R&D, IP protection stimulates innovation. Since patent laws require firms to disclose their invention, they also contribute to the dissemination of information on new technologies. Governments face a number of difficult policy decisions in the design and employment of IP policy. They must determine to what extent to rely on IP as opposed to other policy instruments, such R&D tax incentives and public subsidies to promote innovation. They must also decide how provisions with respect to such matters as the scope, length and nature of IP rights can be set so as to maximize the benefits and reduce the costs of IP policy. A highly protective regime that restricts access to new technologies could reduce follow-on developments and slow the pace of innovation. On the other hand, a weak regime may be ineffective in promoting R&D and also impair a country's ability to license foreign technology and attract foreign investment. The design of an appropriate IP policy raises a number of complex issues that are likely to be addressed differently by various countries. The WTO TRIPs agreement, however, has removed some of the scope for countries to adopt independent standards and distinct approaches toward IP policy.

The biotechnology sector, and particularly the health care segment of the industry, is a heavy user of the IP system. This is partly a result of the high rate of innovation in this

industry. In Canada, the U.S, Japan and the EU, biotechnology is one of the most research-intensive sectors of the economy. In addition, with biotechnology, as with pharmaceuticals, patents are important because the of the highly skewed returns from investment in R&D. Patents help firms generate the high returns on successful innovations that are needed to compensate for the losses on unsuccessful R&D investments. The importance of biotechnology patents is also the result of important policy developments.

Canada has a modest, but rapidly growing biotechnology industry. Most of the approximately 300 companies are small firms, employing 50 or fewer workers. The industry employed just under 10,000 workers in 1997 and generated $1.1 billion in sales, half of which came from health care products. R&D investment amounted to over 50% of sales revenue in 1997. Canadian firms are highly dependent on outside financing to cover R&D and sustain operations through long product development cycles. Patent protection is crucial in helping firms raise needed capital. Successful biotechnology firms have effectively used patents to attract financing, especially important venture capital support. Patents have also provided a basis for establishing alliances that help firms share R&D costs or that provide the latter-stage support firms need as they approach commercialisation. Biotechnology firms generally patent first in the U.S. and then in Canada, which is a reflection of the greater size and importance of the U.S. market.

There remains considerable scope for debate on the best and most appropriately balanced IP policy for the Canadian biotechnology sector. Recent reports have focussed on issues such as the application of patent protection to higher life forms, the scope of the research use defence and the methods of medical treatment exemption**,** and the appropriate interface between the *Patent Act* and the *Plant Breeders' Rights Act.* Resolution of these issues requires a careful weighing of economic tradeoffs, along, in some cases, with an assessment of social and other public policy considerations.

Endnotes

[1] A. Maddison in W.J. Baumol, R.J. Nelson and E.N. Wolff (eds.), *Convergence of Productivity: Cross-National Studies and Historical Evidence* (New York: Oxford Univ. Press),1994.
[2.] Based on his review of the evidence, Lester Throw estimates the social rate of return on R&D at 66%, almost three times the average private rate of return of 24%. See "Building Wealth" in the *Atlantic Monthly*, June 1999.
[3.] Dynamic efficiency gains result from innovation and investment that increase productivity growth and help raise real income per capita over time.
[4.] Static efficiency requires that the economy's resources are allocated to generate maximum social welfare. For static efficiency, product prices should be set to allow purchases to be made by all who place value on units of a good or service that exceeds its cost of production (i.e. marginal cost).
[5.] Some economists have identified generic research as another area where IP laws are inappropriate and alternative incentives for innovative activity are needed. Generic or basic technology research has been described in one report as "need-driven, creative research on new kinds of materials, new processes or new ways of exploring or measuring, and new ways of doing and making thing". Lewis Branscomb et al., *Investing in Technology: Towards a Consensus Strategy for Federal Technology Policy*, John F. Kennedy School of Government, Center for Science and International Affairs, April 1997.
[6.] This is discussed in *Report of the Technical Committee on Business Taxation*, December 1997.
[7.] There remains an ongoing debate about how competition policy should treat these and related concerns. See R.D. Anderson and N.T. Gallini, *Competition Policy and Intellectual Property Rights in the Knowledge-Based Economy* (Calgary: Univ. of Calgary Press) 1998.
[8.] See Y. Kotowitz, *Issues in Patent Policy with Respect to the Pharmaceutical Industry*, Commission of Inquiry into the Pharmaceutical Industry (Ottawa: Supply and Services) 1986.
[9.] The potential impacts may extend to exports, imports, inward and outward foreign direct investment, technology licensing, and alliances and joint ventures with foreign-based firms.
[10.] K.E. Maskus and M. Penubarti, "How Trade-Related Are Intellectual Property Rights?" *Journal of International Economics*, 39, 1995.
[11.] E. Mansfield, "Intellectual Property Protection, Foreign Direct Investment and Technology Transfer," Discussion Paper No.19, The World Bank and International Finance Corporation, 1994.
[12.] J. Bernstein, "Inter-Industry and U.S. R&D Spillovers, Canadian Industrial Production and Productivity Growth," Industry Canada Working Paper No. 19, 1998.
[13.] WIPO, *World Intellectual Property Statistics, Industrial Property Statistics,* various years.
[14.] This is discussed in Iain Cockburn and Paul Chwelos, "Intellectual Property Rights and the Transition to the Knowledge-Based Economy," paper prepared for Industry Canada/CERI Conference on *Doing Business in the Knowledge-Based Economy*, Mont Tremblant, Sept 1998..
[15.] The most important development was the creation of the U.S. Court of Appeals of the Federal Circuit (CAFC) in 1982 to handle IP litigation. Between 1982 and 1990, under the CAFC, patentees were successful in around 90% of cases, which compares with the success rate of around 62% they experienced between 1953 and 1978 in appearances before the U.S. Federal Circuit Court.
[16.] M. Rafiquzzaman and L. Whewell, "Recent Jumps in Patenting Activities: Comparative Innovative Performance of Major Industrial Countries, Patterns and Explanations," Industry Canada, Working paper No. 27, 1998.
[17.] UNCTAD, *World Development Report, 1998/99.*
[18.] This is discussed in National Biotechnology Advisory Committee, *Leading in the Next Millenium*, Sixth Report, 1998.
[19.] For example: R.J. Gordon, "Has the `New Economy' Rendered the Productivity Slowdown Obsolete?" Northwestern Univ. Department of Economics Discussion Paper, Evanston Ill., 1999.
[20.] This is discussed in John Baldwin, *Innovation and Intellectual Property,* Statistics Canada and Industry Canada, Statistics Canada Cat. No. 88-515, 1997.
[21.] Data sources are: for Canada, BIOTECanada, *Canadian Biotechnology '98: Success from Excellence*;

for the U.S., Ernst & Young, *The 13th Biotechnology Industry Annual Report - Bridging the Gap 99*; and for the EU, *Ernst & Young's Seventh Annual Life Sciences Report 2000.*

[22.] These numbers, which are based on data for the mid-1990s, come from OECD, *Science, Technology & Industry Outlook 1998* (Paris: OECD) 1998.

[23.] M-A. Oliva and L.A. Rivera-Batiz, "Innovation, M&As and International Competition in Technology-Intensive Industries with an Application to Pharmaceuticals and Biotechnology," paper prepared for Industry Canada/CERI Conference on *Doing Business in the Knowledge-Based Economy*, Mont Tremblant, Sept 1998.

[24.] Industry Canada, *Sector Competitiveness Frameworks: Bio-Industries*, *Part 1 -Overview and Prospects*, 1997.

[25.] Ibid.

[26.] This is discussed in J. Baldwin and G. Gellatly, "A Firm-Based Approach to Industry Classification: Identifying the Knowledge-Based Economy," paper prepared for Industry Canada/CERI Conference on *Doing Business in the Knowledge-Based Economy*, Mont Tremblant, Sept 1998.

[27.] This evidence is quite dated and does not reflect the impact of recent technological developments and increased globalization. R. Levin, A. Klevorick, R. Nelson and S. Winter, "Appropriating Returns from Industrial Research and Development," in M. Baily and C. Winston (eds.), *Brookings Papers on Economic Activity*, No. 3 (Washington: The Brookings Institution) 1987.

[28.] E. Mansfield, "Patents and Innovation: An Empirical Study," *Management Science*, 32, 1986.

[29.] Ten entities were found to account for over half the quasi-rents realized from the introduction of 99 drugs over this period. Henry J. Grabowski and John Vernon, "A New look at the Returns and Risks to Pharmaceutical R&D," *Management Science*, Vol. 36, July 1990.

[30.] This is based on data in Industry Canada, *Sector Competitiveness Frameworks: Bio-Industries*, *Part 1 - Overview and Prospects*, 1997.

[31.] M-A. Oliva and L.A. Rivera-Batiz, "Innovation, M&As and International Competition in Technology-Intensive Industries with an Application to Pharmaceuticals and Biotechnology," paper prepared for Industry Canada/CERI Conference on *Doing Business in the Knowledge-Based Economy*, Mont Tremblant, Sept 1998.

[32.] This comes from U.S. General Accounting Office, *Deposits of Biological Materials in Support of Certain Patent Applications*, GA-01-49, October 2000.

[33.] Ibid.

[34] Life Sciences Branch, Industry Canada, "Economic Profile of the Canadian Biotechnology Sector," March 31, 2000

[35] From presentation by Manuel Trajtenberg at Industry Canada's "Distinguished Speaker Series", 1999.

[36.] Donahue, Ernst & Young, "Canadian Biotech and intellectual Property Report 2000," report prepared for Industry Canada, 2000.

[37.] Jorge Niosi, "Explaining Rapid Growth in Canadian Biotechnology Firms," Research Paper No. 8, Science and Technology Redesign Project, Statistics Canada, Feb. 2000.

[38.] BIOTECanada, *Canadian Biotechnology '98: Success from Excellence*, 1999.

[39.] Donahue, Ernst & Young, "Canadian Biotech and intellectual Property Report 2000," report prepared for Industry Canada, 2000.

[40.] Ibid.

[41.] Ibid.

[42.] Ibid.

[43.] BIOTECanada, *Canadian Biotechnology '98: Success from Excellence*, 1999.

[44] The reference is to surveys, such as those by BIOTECanada and Donahue, Ernst & Young, referred to above, and also recent studies with implications for the design of IP law. The latter include: D. Foray, "Production and distribution of Knowledge in the New Systems of Innovation: The Role of Intellectual Property Rights," *STI Review,* OECD, No. 14, 1994; and P. Cohendet, D. Foray, D. Guellec et J. Marisse, "La gestion publique des externalités positives de recherche," paper prepared for Industry Canada/CERI Conference on *Doing Business in the Knowledge-Based Economy*, Mont Tremblant, Sept 1998.