Impact of Canada's Patent System and Public Sector Technology Transfer System on the Growth of the Biotechnology Industry in Canada

Prepared for

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

By

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IMPACT OF CANADA'S PATENT SYSTEM

AND

PUBLIC SECTOR TECHNOLOGY TRANSFER SYSTEM

ON THE GROWTH OF THE BIOTECHNOLOGY INDUSTRY IN CANADA

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INTRODUCTION

There can be no doubt that biotechnology is having a great impact, and in the near future will have an even greater impact, on the economies of leading industrial nations. It is estimated that biotechnology is one of the world's fastest growing industries with global demand for biotechnology-based products and services expected to reach $50 billion by 2005. In the area of life sciences, for example, Stephen Byers, U.K. Trade and Industry Secretary stated in November, 2000 that "Advances in biotechnology offer the opportunity to change medicine fundamentally, moving from diagnosis and treatment to detection and prevention" (UK "Science Budget - 2001-02 to 2003-04; www.dti.gov.uk). Governments around the world are focussing their attention on what they can do to encourage the growth of their biotechnology-based industries, and the adoption of biotechnology-based products and services. In doing so, they are, at the same time, taking social and ethical considerations into account.

Canada is no different in its goals to encourage the creation and growth of new biotechnology firms. Unfortunately, we do not appear to be keeping up with our international competitors. The Sixth, and last report, of the National Biotechnology Advisory Committee (NBAC) pointed out that "in the early 1990s, Canada had as many biotech companies as Japan and as many as the whole of Europe" (NBAC, 1998, p.9). This, according to the NBAC Report, "has abruptly changed" (NBAC, p. 9). Canada is now third behind the U.S. and Europe in terms of the number of biotechnology companies (p. 10). To improve this situation, the NBAC report called for public policies that are consistent, effective and supportive of the biotech industry in Canada if it is to achieve a world leadership position (p. 11).

An earlier 1997 Ernst and Young study entitled, "Canadian Biotech'97: Coming of Age", conducted for the Department of Foreign Affairs and International Trade, placed Canada fourth behind the U.S., U.K. and Australia in a list of countries with a business climate that encouraged the development of biotechnology. The report also noted that Canada underinvests in biotech R&D relative to its U.S. and European competitors.

One of the important elements of a supportive environment for biotechnology, or indeed any technology-based industry, is a strong patent system. In the area of biotechnology, Canada's patent system differs from those of our competitors in a number of important aspects. The NBAC report (p. 51) noted the following differences between what is patentable in Canada and what is patentable in other jurisdictions in the areas of:

- *patenting of multicellular life forms (e.g., plants and animals)*;*
- *patent term restoration to compensate for regulatory delays in marketing approval; and*
- *lack of administrative procedures for opposing patents once they have been issued.*

[the status of this is awaiting an appeal to the Supreme Court of Canada to challenge a Federal Court of Canada ruling in 2000 that the higher life form (HLF) called the "Harvard Mouse" was patentable]*

Many of these "shortcomings" were reiterated during a briefing in September, 2000 on the patenting of higher life forms to the CBAC steering committee by Presidents and CEOs of Canadian biotech firms (Gold, (a), 2000). The Presidents and CEOs believed very strongly that Canada's patent system was conveying a message that Canada was unsupportive of, or even hostile to, biotechnological innovations. They feared that this would influence potential investors in Canadian firms. They also considered that Canada was five years behind the U.S. in establishing rules and regulations with respect to genetically modified animals.

Another important element in the supportive environment for biotechnology firms is the efficiency and effectiveness of the technology transfer activities of universities and government departments. These organizations can be an important source of biotechnological discoveries/inventions that can be exploited by Canadian industry. If the transfer process is flawed, however, these inventions may remain on the shelf or opportunities to create new businesses might be lost.

Thus, this background paper was commissioned to determine what policy/program initiatives might be recommended to the federal government so that patent and technology transfer environment are more supportive of the creation and growth of biotechnology firms in Canada. This background paper will draw heavily on previous reports and studies, and on the results of interviews with twenty-seven key, knowledgeable individuals in government, university, biotech associations and IP patent offices/associations that took place in November and December of 2000.

CANADIAN BIOTECHNOLOGY INDUSTRY

In order to place the discussion of the Canadian patent protection system into context, the following are highlights drawn from "Economic Profile of the Canadian Biotechnology Sector" prepared by the Research and Analysis Team of the Life Sciences Branch of Industry Canada (March 31, 2000). According to this profile:

- *in 1997, the Canadian biotechnology sector consisted of 282 firms of which 204 employed less than 50 people;*
- *Quebec had the largest number of companies (31%), followed by Ontario (25%), British Columbia (20%); and the Prairie provinces (18%);*
- *biotech sales in 1997 were $1,017 billion on R&D expenditures of $585 million (90% in the health area);*
- *exports accounted for 37% of sales which were primarily agri-food (58%) and health care related products (39%);*
- *the industry employed 9,823 people with 1,899 positions going unfilled; and*
- *health care, agriculture, and environmental companies accounted for 46%, 22% and 11% of the sector respectively.*

This report notes that one of the major hurdles to growing the biotech industry in Canada is the human resources and skills gap. Industry leaders have identified the lack of senior skilled managers with an understanding of science, marketing, financing, and regulatory systems as a challenge. The report also voices concern over a possible "brain-drain" to the U.S. due to the strong growth of their biotechnology sector. It warns that "a large flow of highly skilled Canadian workers moving to the United States would have serious consequences on the biotechnology industry in Canada"(p. 16).

The sectoral report states that in 1997/98, the Federal Government spent $314 million on biotech R&D with the largest players being the Medical Research Council (now the Canadian Institute of Health Research - $104 million), Natural Sciences and Engineering Research Council ($90 million), the National Research Council ($60 million), and Agriculture and Agri-Food Canada ($40 million).

PATENT REGIME DIFFERENCES

> *"One cannot build a world class innovative biotechnology sector on intellectual property (IP) protection that is less robust than the protection offered by Canada's major competitors and trading partners" - 1998 NBAC Report, p. 46.*

Information for this section is drawn mainly from a report previously commissioned for the Canadian Biotechnology Advisory Committee entitled, "Patenting Life Forms: An International Comparison" by E. Richard Gold [(b), 2000)].

Canada, like the European Union members, the United States and Japan, is a signatory to the World Trade Organization (WTO) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The purpose of TRIPS is to establish minimum standards of protection among countries in the area of intellectual property rights, including patents. TRIPS sets forth rules that each WTO member must follow in operating its country's patent regime. TRIPS does, however, include an exception (Art. 27.3(b)) which allows WTO members to exclude from patentability certain biological material (e.g., plants and animals other than micro-organisms and essentially biological processes for the production of plant and animals other than non-biological and micro-biological processes), provide protection over plant varieties either by patent or an alternative system (i.e., plant breeders rights). The Agreement also provides in Art. 27.3(a) WTO members with the option of excluding patents on certain processes related to medical diagnostics and treatment of humans or animals (e.g., surgical procedures, therapeutic methods).

Canada provides patent protection on fewer types of higher life forms than any of its major competitors. In Canada, (subject to the forthcoming Supreme Court decision on whether to hear the appeal of the Harvard Mouse case) an inventor cannot get patent protection on animal organs, whole animals, animal varieties, human organs, whole plants, and plant varieties. Both the U.S. and Europe issued their first plant and animal patents in the 1980s (Martin and Amanor-Boadu, January, 1997). Unlike Europe, in Canada inventors can obtain patents on processes using higher life forms involving animal and human diagnostic procedures but, like Europe, not on animal or human therapeutic and surgical therapies.

Plants and plant varieties are protected in Canada under Plant Breeders Rights (PBR); not under patents. PBRs are considered by many to be a much weaker form of protection given the extent of the significant exemptions which have no counterpart in patent law. For example, under what is commonly called "farmer's privilege", a farmer can save the seeds from a previous year's crop and plant them in the following years. It is estimated that 70% of the grain on the Prairies is grown from producers' bin seed (OAG, 1999, pp 8 & 10). If plants were patentable, barring a similar exemption under the Patent Act, the use of the seeds might be considered patent infringement. According to Gold (b,2000), the European Union, through the implementation of the

"Directive on the Legal Protection of Biological Innovation", has expanded the concept of "farmer's privilege" to cover both genetically modified plants and animals subject to patent rights. Gold notes that the exact form that the "farmer's privilege" exemption will take is still to be determined (p. 10).

Another difference between the U.S. and Canada, is that U.S. law prohibits anyone from making generic versions of biologics; Canada has no such restriction.

In general, the U.S. and Australia have the most open patent systems in that they allow patenting of almost anything involving higher life forms. In fact, the Australian patent system is in full harmonization with the United States on what is patentable.

One must be careful, however, when interpreting the impact of patent protection. For example, in the U.S., "methods of medical treatment" on humans is considered patentable subject matter. This does not imply, however, that only the inventor can use the treatment. If the patented method of medical treatment does not involve a pharmaceutical, but is strictly a technique, US courts have determined that the patent holder cannot collect damages for infringement.

Another area in which Canada differs from its European counterparts is in the use of morality or public order exemptions to the issuing of patents. Under TRIPS, countries must grant patents over all categories of inventions (subject to the exceptions noted above) despite the possible different natures of the inventions. Once a country decides to grant patents over a particular class of higher life form, it can only single out particular inventions within that class for exclusion in limited situations. A country may only exclude a particular invention from patent protection where the sale of that invention must be prohibited in order to protect political order (ordre publique) or morality of that country, to prevent harm to human, animal, or plant health, or to prevent serious prejudice to the environment. These moral exclusions have been used to prevent, for example, the patenting of contraceptive devices in some countries. A paper by Schrecker, et al (1998) delves into some of these ethical issues in more detail.

The U.S. and Australia believe that morality clauses should not be part of the patent system. They believe that issues of morality and public order should be dealt with in other ways or venues outside the patent system. Canada has not yet made any definitive statement on this issue but appears to go along with the U.S. in this matter.

One of the key questions to be addressed in this study is what effect do these differences have on the ability of Canadian organizations to transfer and/or commercialize biotechnological inventions.

IMPORTANCE OF PATENT PROTECTION

> *A patent can be the most valuable asset a biotechnology company owns.- Venture Capitalist*

Section 2 of the Patent Act defines invention as "Any new and useful art, process, machine, manufacture, or composition of matter, or any new and useful improvement in any art, process, machine, manufacture, or composition of matter".

New inventions are rarely in any state where they can be put to immediate use. It is not uncommon that 100 times the costs of the "invention stage" must be spent in order to produce the final product or process. Any investor in the new invention will require some guarantee that he/she will reap the benefits of their considerable cash outlay to bring the invention to market. Patents provide such protection by giving the inventor/developer a monopoly for a particular period of time on the sale and/or use of the patented product or process. The patent system is a major encouragement of technological innovation. Numerous surveys have noted that investors place more value on patent protection than on any other form of intellectual property protection. Having a patent also increases the ability of a firm to attract partners.

In addition, the strength of a country's patent system in protecting the rights of the inventor has an impact on the degree to which that country is viewed as a "good place to do business".

Schrecker et al. (1998, p. 4) note the following three arguments have been made in favour of patenting higher life forms:

- *patenting is a necessary incentive to motivate the profit-oriented private sector to meet public needs;*
- *countries that offer weak or limited patent protection can expect to suffer economic losses as investors in the biotechnology industry simply look elsewhere; and*
- *fairness or justice is valued in and of itself and people deserve the fruits of their intellectual work.*

Martin and Amanor-Boadu (1997), in their review of patenting in the animal and agri-food sector in Canada, conclude that the ability to patent farm animals, especially for non-traditional uses (e.g., transgenic animals for xenotransplants), would have a moderately positive impact on the Canadian agri-food sector. "Biotechnology firms would benefit from improved IP protection, while public institutions (government researchers and universities) will benefit from the potential of generating revenue from their research effort...."(p. 6). They go on to state that, "Under a stronger

IP system, processors and retailers would benefit from innovation leading to cheaper and/or more improved food products and/or new products such as pharmaceutical products and chemicals from animals". They noted that very few inventors are choosing Canada as the priority country (country of first filing) when filing for patents (p. 4).

They warn that "if Canada is not among the first countries to provide IP protection for farm animal biotechnology, it stands the chance of further worsening its trade balance in such products. If Canada is a laggard, Canadian producers may also suffer trade sanctions from countries that strengthen their farm animal biotechnology IP using patents..."(p. 6). They believe that the patenting of farm animals "would increase investment in agri-food biotechnology and, in the process, accelerate innovation in that industry".

In the briefing by CEOs and Presidents of Canadian biotech companies to the CBAC committee, corporate participants stated that Canada's IP policies with respect to agricultural biotechnology are significantly behind those of the U.S. and Europe (Gold, (a), 2000). For example, many of Canada's major competitors have in place a system which provides different forms of plant protection and allows "plant" inventors to choose the type of protection they wish to invoke (e.g., patents, plant breeders rights, or trade secret) and double protection is possible. Canada has not yet adopted the 1991 UPOV Convention that allows this choice. (The International Convention for the Protection of New Varieties of Plants (UPOV) was developed in 1961 to provide protection for plant varieties and underwent a major revision in 1991). Plant breeders rights are not considered by many to be strong enough, and so inventors choose the "trade secret" route, thus reducing the sharing of information among breeders about the underlying science. This lack of sharing of information is thought by some as an impediment to the advancement of science in this area.

Heller (1996), in his economic study of the Canadian biotechnology industry, found that "U.S. federal government support for biomedical R&D, technology transfer policies and ***strong IP protection*** *have created an environment conducive to discovery and commercialization of new therapeutic advances" (p. 5). In testimony to the U.S. Federal Trade Commission in the mid 1990s, representatives of pharmaceutical and biotechnology industries emphasized the importance of patents in protecting the large, up-front investments needed to research and develop new drugs and medical devices.*

As one venture capitalist who was interviewed for this paper stated, patents are critical in commercializing any activity and especially in the biotechnology industry where it takes a long time to develop a product. "You cannot rely on first-mover advantage in the marketplace. You still need patent protection".

In summary, most people believe that a strong patent system is a critical element in the growth of a vibrant biotechnology industry.

IMPACT OF CANADA'S LACK OF HARMONIZATION IN PATENTABLE SUBJECT MATTER WITH OTHER JURISDICTIONS

> *The Harvard Mouse controversy is a real show stopper.We are out of step with the rest of the world. - CEO*
>
> *What technology are we not getting access to because we do not provide patent protection for it? - Patent Lawyer*
>
> *From an economic point-of-view, Canadian patents are not relevant.- Snr. Univ. TT Advisor*

Information in this section is drawn from interviews conducted for this paper, and from previous reports that expressed the views of Canadians who are involved in the transfer and/or commercialization of biotechnology in Canada.

There are two schools of thought about what effect our lack of harmonization on what is patentable in Canada versus what is patentable in other jurisdictions is having on the ability of Canada to grow a vibrant biotechnology industry.

Insidious Impact

> *Studies have shown that strong IP protection encourages investment. - Martin and Amanor-Boadu, 1997, p. 5*

One school believes that Canada's stance on the patenting of higher life forms, in particular, is having a long-term deleterious effect on Canadian companies' ability to attract investment and R&D dollars. Some felt that it was making it difficult to do business smoothly across the Canada-U.S. border. One interviewee believed that "the differences cause a more insidious impact because they undermine our ability to be a world leader".

Sharing this view, Dr. John Rudolph, in his review of issues related to the patentability of biotechnological subject matter, believes that Canada's refusal to patent higher life forms is a factor in preventing Canada from becoming a world leader in biotechnology (Rudolph, 1997).

The CEO briefing to the CBAC also voiced concern that Canada's lack of harmonization with other countries' patent rules was sending a negative message to foreign investors and senior managers of foreign multinational companies in Canada that would result in reduced investment. "Our lack of harmonization is having a chilling effect on the international perception that Canada is a good place to invest in biotechnology". Pharmaceutical firms were especially concerned that Canada's patent policies would reduce their ability to convince their head offices that Canada was a good place to conduct R&D. This position was echoed by a government interviewee who said, "it sends a signal to the international research community that if you are doing research in genetically modified higher organisms, Canada may not be the place to do it".

The fact that the Commissioner of Patents was fighting the Federal Court decision in the Harvard Mouse case was felt by some as signalling that Canada is hostile to biotechnological inventions. This could reinforce the concern expressed during the CEO's briefing to CBAC (Gold, (a), 2000), that by failing to harmonize what is patentable with internationally accepted patent standards, Canada was discouraging foreign investors. Two interviewees noted that the outcome of the Saskatchewan court case involving Monsanto over the exercise of the "farmer's privilege" with seeds could have a major effect on R&D investment in the plant biotechnology area if Monsanto were to lose.

Many people interviewed consider that Canada's reluctance to quickly harmonize what is patentable subject matter is sending a very negative message out to the rest of the world about our technological sophistication. One government technology transfer officer thought that our unwillingness to harmonize our patent rules was "making us look parochial". The differences were simply forcing their organization to patent plants in the U.S. and to obtain only plant breeders rights in Canada.

Several respondents were concerned that the lack of patent protection for transgenic animals was discouraging the development of that industry in Canada despite the ability for transgenic firms to patent elsewhere. Another felt that it was discouraging R&D investment in plant research. Several agricultural interviewees thought that our lack of HLF protection was making it harder for Canadian organizations to compete for research dollars.

A university technology transfer interviewee felt that the inability to patent animals (i.e., research mice) was making it very difficult for them to enforce their patents on animal models in Canada. "We can patent the use of the animal, but it is very hard to enforce the patent if you can't patent the whole animal".

This interviewee also commented that the differences cause irritants in doing business across the Canada-U.S. border. "Really, we shouldn't be different from the U.S.; it makes it very difficult for people trying to do business fluidly across the US-Canada border. These differences are a pain in the neck".

A patent lawyer interviewee pointed out that our unwillingness to move quickly on the patent

protection scene was going to have an adverse effect in a newly emerging area of biotechnology, bioinformatics. "It is not clear that the computer models developed can be protected under our existing patent rules". This person felt that this uncertainty would drive this branch of activity outside of Canada into a patent jurisdiction that did offer solid protection.

The reality is that everyone who was interviewed for this study had no qualms about the patenting of HLFs and did so whenever and wherever necessary to protect their inventions. This raises the question of what the government's rationale is for operating under the existing policy on this important issue and, in doing so, making the Canadian patent system less relevant in the marketplace.

*When asked why they thought the government and CIPO were not moving quickly enough to harmonize what is patentable subject matter with our competitors, most thought it was for reasons of Canadian sovereignty. The sovereignty issue defence raises the question, "**How can we, as Canadians, claim pride in our sovereignty when we force our citizens to obtain the patent protection they need to build a strong industry for the benefit of Canadians, from foreigners**?".*

Little Direct Economic Impact

The other school, while not dismissing the concerns mentioned above, believed that the economic effects of the differences in what is patentable were not major. "Patenting in other jurisdictions gives us the protection we need".

CIPO's refusal to provide patent protection similar to that provided by other jurisdictions has made Canada's patent system less relevant in the strategic planning of many, if not most, Canadian biotechnology firms. One university technology transfer interviewee who believed that the differences in what was patentable had no impact went on to say, "People will do what they have to do to commercialize their inventions in other jurisdictions based on the law that is in place in those other jurisdictions".

The bottom line for these interviewees was that Canada was a relatively small market for biotech products and processes and it was much more important to protect inventions in the larger markets. As most of those markets allow for the patenting of higher life forms, companies file first in those jurisdictions for economic reasons, and file in Canada for patriotic reasons. Because other jurisdictions do not insist on reciprocal patenting arrangements, Canadian companies can develop new HLF-based products and patent them elsewhere. Thus their ability to commercialize is not seriously jeopardized. One interviewee wondered, however, how long it might be before other countries did retaliate and refuse to patent Canadian developed HLF biotechnologies.

In summary, the impact on Canadian firms of the differences in terms of what is patentable in Canada versus other major patent jurisdictions is likely having a negative long-term effect on Canada's image as an advanced nation interested in growing a strong biotechnology industry. With

respect to day-to-day operations, however, the effect is relatively minor given that most Canadian organizations, universities and companies, patent first in the countries with the larger market (e.g., U.S., Europe, Japan) and only secondarily in Canada, and they patent in Canada mainly for patriotic, not economic reasons.

This would change dramatically if other countries, especially the U.S., decided to retaliate, despite international agreements, against countries that did not match what they allowed as patentable subject matter. This might arise if the U.S. was successful in any future round of WTO Agreement negotiations in its efforts to amend TRIPS to eliminate the present exceptions under Article 27, and Canada were not to change its regime within a reasonable time.

IMPACT OF THE CURRENT CANADIAN PATENT PROCESSING SYSTEM

> *Little, it is a global activity - CEO*
>
> *A patent system is an economic tool; it has to function in harmony with the rest of the global economy or it will not work.- Interviewee*

As noted above, a Canadian patent is not considered to be as economically valuable as a U.S. or European patent because of the small size of the Canadian market, and therefore the Canadian patent system appears to have minimal impact on Canadian organizations' ability to commercialize their biotech inventions.

In general, most of the interviewees were critical of the level of service provided by CIPO. "CIPO doesn't have the resources or the people to get the job done". Many felt that the U.S. was making better progress at providing sufficient numbers of staff, and with the needed expertise.

In particular, everyone mentioned the slowness of the CIPO in examining and issuing patents as a major problem. This reinforced the economic reasons to file first for patent protection in other jurisdictions. It has been estimated that a two year delay in getting a product to market will reduce a biotechnology firm's rate of return by over 5% (Heller, 1997, p. 7). Company representatives believe that delays in the granting of patents results in:

- *a risk of unprotected exposure of technology to a competitor;*
- *undermining a company's competitive position; and*
- *undermining the firm's ability to obtain financing.*

According to a CIPO representative, there are approximately 18,000 patent applications in the system of which 6,000 are "active" (i.e., are being examined or that applicants have asked to be examined). 98% of these applications come from outside of Canada. There are 15 biotechnology examiners at present. CIPO hopes to hire 3-4 more in the next few months. In 1990, the U.S. Patent and Trademarke Office (USPTO) had 140 patent examiners in this area and still felt understaffed.

The biotechnology CEOs, in their briefing to CBAC, stated that delays in getting a patent reduces the inventor's ability to approach investors as they do not have a firm asset, and the life of the patent is running out. Unlike the U.S., Canada does not guarantee the patent holder at least 17 years of patent protection, regardless of how long the patent is in USPTO (Dickinson, 2000, p 10).

That Canadian patents tend to be valued less, and the service is slower, places into question the role of a Canadian patent office. Several interviewees questioned the need for CIPO, as presently structured.

Several respondents said that because of the slower service, they use the U.S. or European patent offices to obtain timely patent art searches. If CIPO could improve service levels, these searches could be conducted more cheaply in Canada since the charges would be in Canadian dollars. In order to save American firms from investing in R&D that has already been explored, the USPTO has put their databases on the internet. The European Patent Office estimates that over $22 billion dollars a year is wasted on research that has been done before (Dickinson, 2000, p. 4)

Another technology transfer patent agent pointed out that a firm cannot sue for infringement until the patent is issued, even though it sees a competitor capturing its market. Delays in issuing the patent might allow the competitor firm to cement its hold on the market, even if it has to pay royalties in the end.

Although most interviewees had no problems with the quality of the work CIPO does, one did feel that CIPO examinations were perfunctory and resulted in the granting of too broad a set of patent claims. One respondent stated that from his extensive experience, CIPO produced patents that were considered good by international standards, but on occasion, "you get some examiners approving too broad claims". Another interviewee stated that CIPO sometimes allows a different set of claims than those granted by other patent jurisdictions and this has the potential of undermining the claims of existing patents. This interviewee felt that CIPO was less predictable on what claims would be granted than the USPTO. "They allow some things no one else will, and deny some things other people will allow with the result that CIPO decisions can result in overlapping rights".

Several respondents considered CIPO's actions in regard to the Harvard Mouse case to be incomprehensible given the importance of the U.S. market. "To have different patent laws between the two countries seems insane". Some of this reaction was based on the fear that the U.S. would close its patent system to Canadians, despite any international agreements.

In addition to the HLF issue, several interviewees and others quoted in previous consulting reports mentioned the following as being irritants to the growth of the biotechnology industry in Canada:

- *lack of patent restoration to compensate for regulatory delays;*
- *lack of an opposition appeal process at CIPO to challenge broad blocking patents;*
- *lack of any mention in the Canadian Patent Act of what constitutes legitimate "research exemption" from charges of patent infringement;*
- *lack of clear guidelines on expressed gene sequence tags (ESTs);*

- *lack of a Canadian law prohibiting the manufacture of generic versions of biologics;*

- *lack of information on the front page of a patent giving the name and address of the patent applicant so that further information can be sought from the patent holder;*

- *Canada is not a signatory to the 1991 UPOV Convention that gives plant breeders choice in the form of protection they wish to have; and*

- *lack of fast tracking of patent claims that are identical to those approved in other jurisdictions which results in delays in issuing patents.*

It appears that because the Canadian patent system is in need of additional resources, and revision, it is contributing to a drag on the growth of the Canadian biotechnology industry.

RECOMMENDED CHANGES TO IMPROVE THE CANADIAN PATENT SYSTEM

> *To be competitive, we must be in harmony with the rest of the world.- Venture Capitalist*
>
> *We cannot be inconsistent with the U.S. if we want to be competitive.*

These two quotes from interviewees capture the general feeling of those interviewed during this study. The following recommendations, starting with some specific recommendations that could be acted upon immediately, are generally in line with the spirit of harmonization that Canadian industry and other organizations believe are absolutely necessary to promote the biotech industry in Canada.

Patent Higher Life Forms

The respondents overwhelmingly called for the immediate harmonization of what is patentable subject matter with our major trading partners, as did the industry representatives taking part in the CBAC briefing.

Immediate approval of the 1991 UPOV Convention concerned with plant varieties is also supported.

Patent Term Restoration

Another area of agreement was the establishment of patent term restoration to compensate for delays in regulatory approval in the biopharmaceutical area, as is available in Europe and the U.S.

The lack of patent term restoration was felt by some as reinforcing the impression that Canada does not understand the new product development process as it applies to biotechnology.

Research Exemptions

"Freedom to Operate" was voiced by many interviewees as a major concern. Because of uncertainty and lack of any explicit guidelines, many big biotechnology companies do not believe that research organizations such as university or government laboratories have any right to use patented research tools without the express approval of the patent holder. There is some concern that "hoarding" these research tools could be a major inhibiting factor in the advance of science. One university technology transfer officer said that more and more patents for "research tools" are being controlled by seven or eight large firms. "Tools of research are being tied up".

Concern over whether intellectual property rights are discouraging research, its communication and use is not unique to Canada. The Science, Technology and Economic Policy Board of the National Research Council in the U.S. in September of 1999, launched a 33 month study on the impact on IPR policies on performance and communication of academic research, mobility of highly trained personnel, initial and subsequent innovation, and competition and industry structure (http://www4.nationalacademies.org/pd/). The issues to be addressed include:

- *whether expressed gene sequences (EST) and other biological material patents will make it prohibitively complicated and expensive to conduct research using these tools or, alternatively expose research investigators to infringement suits;*
- *whether arguments between universities and industrial research sponsors about IPRs will discourage corporate support of academic research;*
- *the uncertainty of the scope of IPRs;*
- *high litigation uncertainties and costs, both financially and in terms of the time of scientists, engineers and managers; and*
- *licensing terms that will bar probing the intellectual content of software or genomic material and making modifications and improvements (i.e., decompilation).*

Several Canadian interviewees believed that patents that are far too broad are being granted in the U.S. and Canada, and that these are having the effect of inhibiting innovation (i.e., these are known as blocking patents).

In their review of the patenting of human genetic material, Caulfield and Gold (2000) suggest that possible solutions to the "hoarding of research tools" include mandatory licensing, at a reasonable price, and/or reduction of the power of the patent holder to exclude others from using their patented invention in research aimed either at discovering new genetic secrets or directed at finding other gene-based therapies.

For these reasons, many interviewees called for an explicit statement in the Canadian Patent Act to clarify when a researcher can safely use another's patent for the purposes of advancing science and developing future innovations. The European patent system provides such guidelines.

Establish a Patent Opposition Process

Several interviewees voiced concern over the fact that CIPO did not have any administrative procedure in place to allow for challenging patent applications prior to issue. Forcing companies to challenge patents in the Federal Court was felt to cause financial problems, particularly for smaller Canadian firms. The USPTO has a re-examination system, for example, that provides for re-examination if unconsidered or newly discovered prior art surfaces.

Creation of a North American Patent System

> *The availability of a North American patent, just like they have in Europe, makes a lot of sense. - Government Official*

One recommendation that has been made before, and was supported by most of the interviewees in this study, is to create a North American, or even a NAFTA patent system, along the lines of the European patent system. In the extreme, some respondents felt that once a patent has been issued in the U.S., a Canadian patent should be automatic. This would put into question the need for a Canadian patent office.

A major concern among many of the proponents of the North American patent system was the number of concessions that would have to be made to the U.S. to achieve a harmonized North American system. There was no suggestion of going back to a "first-to-invent" system. Several interviewees acknowledged that, in reality, a person in another country who wishes to file a U.S. patent must be able to prove when the invention was made. One university technology transfer officer stated that "Canada has saved itself a lot of grief and a lot of litigation and has become more stream-lined by going to a first-to-file system".

Several interviewees thought that a North American patent system might save time and money for patent applicants. Others thought that the lack of a North American patent was a major factor in discouraging patenting in Canada.

Under a North American patent system it was suggested that CIPO could take on the patenting of a few areas of technologies of interest to Canada (e.g., agricultural/plant biotechnology) for all of North America and become expert in those specific areas. The U.S. Patent and Trade Mark Office (USPTO), with its larger budget would handle the rest. Given the fact that most inventors patent in the U.S. in any event, this approach would not result in any increased load for the USPTO. Quite the contrary, it should reduce the workload for the USPTO.

Overall, there was general agreement that the North American or NAFTA patent model should be explored.

Reduce CIPO's Patent Processing Time

If Canada is to retain an independent patent processing activity that means something on the world stage, CIPO must reduce the time it takes to process patent applications. Slowness in processing patents can arise from at least two independent sources: lack of personnel to perform patent application examinations; or having personnel who require more training in order to quickly assess today's more complex biotechnological patent applications. Most respondents felt that most of the delays associated with processing patents came from a lack of personnel although a few did question whether CIPO staff were up-to-date on the latest biotechnologies.

Several respondents questioned CIPO's ability to attract first-rate talent because of the relatively low salaries it offers. Several interviewees commented on the low fees that CIPO charges. They suggested that an increase in fees to enable CIPO to hire additional competent people which hopefully would result in faster turnaround times would be acceptable to the biotechnology community.

Faster response times would encourage Canadian firms to make use of CIPO rather than spending their patenting dollars in other jurisdictions to obtain a search and preliminary opinion on the patent status of their invention. One interviewee thought that faster processing by CIPO could have a positive impact on Canadian companies in that they would be able to say that they had a Canadian patent, while their applications in other patent jurisdictions were still pending.

Fast-tracking, whereby the decisions of one patent agency are accepted by another to reduce duplication of activities, was also suggested as a way to speed up the process. "Prior art is a fact, and is not as prone to subjective interpretation. It should be possible to cooperate on identification of prior art".

The overall recommendation of interviewees was to put more resources into CIPO so that it can hire the personnel required in order to service clients in a timely manner and improve the quality of patents issued.

CIPO Should Conduct More Outreach Activities

Several interviewees felt that CIPO was interpreting its mandate much too narrowly and should be taking a more active role in meeting with the public, as well as patent agents. CIPO is perceived as being insular. Possibly as a result of this opinion, CIPO is planning on re-establishing a Management Advisory Board (MAB) that will be composed of "members of the private sector with senior experience and expertise". The MAB's mandate will be to provide strategic advice to CIPO's Chief Executive Officer on the mission, objectives and programs of the agency, as well as on its management and business strategies.

In a similar vein, the USPTO has recently established two committees to provide advice to the Office. The Patent Public Advisory Committee (P-PAC) and the Trademark Public Advisory Committee (T-PAC) each held their inaugural meetings on August 23, 2000. These Committees were created under the American Inventors Protection Act of 1999 in order to advise the Director of the USPTO on the agency's operations, including its goals, performance, budget, and user fees. Each Committee has nine voting members who are appointed by, and serve at the pleasure of, the Secretary of Commerce. Appointments include independent inventors, lawyers, corporate executives, small entrepreneurs, and academics with significant experience in management, finance, science, technology, labour relations, and intellectual property issues. Advisory Committee meetings ***are open to the public****. Since the inaugural meeting, the Committee has met once in October, 2000.*

From the limited information available, it appears that the U.S. initiative is much more open and potentially less professionally incestuous than the Canadian approach.

In addition to the new Committees, interviewees noted that the USPTO holds quarterly public meetings that anyone can attend. This allows people to meet examiners, find out what is going on, and to ask questions of the patent examiners. The meetings also allow people to voice concerns over particular procedures and ask that any problems be rectified. According to one respondent who has attended the meetings, the USPTO appears to listen and make corrections where necessary.

The USPTO also has educational programs where they go into the school system to describe what they do, and the importance of the patent system. One respondent stated that in contrast, CIPO personnel are often unavailable or reluctant to participate as guest speakers at IP seminars held in Canada.

NEW GOVERNMENT INITIATIVES TO PROMOTE THE GROWTH OF CANADA'S BIOTECHNOLOGY INDUSTRY

As much has been written on the relationship between the adequacy of venture capital at the early stage of a new firm's life and the growth of an industry, this study did not explicitly examine the adequacy of the biotechnology venture capital market in Canada. A few respondents mentioned that shortage of venture capital was a serious impediment at the moment. "Seed financing is in short supply". A few thought that Canadian venture capitalists were more risk averse than their American counterparts. Several interviewees found dealing with lending institutions that do not understand the value of patents to be very frustrating.

In addition to the changes to Canada's patent system mentioned above, interviewees thought that consideration should be given to the following:

Patent Infringement Insurance

Firms entering the U.S. market, or any other important market, face the possibility of their patented product or process being challenged by another firm claiming patent infringement.

A large predatory firm can use the patent courts to bleed a small company dry by simply filing an infringement case, regardless of the merits of their own patents. At the moment, the usual recourse or defence when this happens is for the smaller firm to align itself with a larger firm with financial pockets deep enough to fight the infringement charge in court. This usually means the smaller firm giving up ownership of its product/process in return for financial assistance.

In order to help prevent the sell-off of Canadian patents, many of which were supported by the Canadian taxpayer, and subsequent stunting of the growth of Canadian biotechnology firms, several interviewees agreed that the establishment of an "infringement insurance" program by the government would be useful.

There is, however, patent infringement insurance available from private sector firms. It is a relatively new "insurance product" and many people do not appear to know of its existence. Information about one such offering can be found at http://www.binks.ca/patent.htm. Marsh Canada Limited is another source. This raises the question of whether the private sector insurance offerings are sufficient and/or whether small biotechnology firms can afford the cost of the policy. If the cost of the policy from the private sector is beyond the financial reach of most biotechnology firms, then for all intents and purposes, patent infringement insurance is not available to an important segment of the industry.

There may still be a need to establish a government insurance program that would be similar to the "accounts receivable insurance program" operated by the Export Development Corporation. This program protects Canadian companies that do business in foreign countries from catastrophic loss if the foreign buyer refuses or cannot otherwise pay for goods/services received. One insurance agent contacted stated that accounts receivable insurance is also available in the private sector.

If a large foreign company decides to challenge a small Canadian firm entering its market, it would know that it could not wear down the Canadian firm in the courts because the Canadian firm would have the financial resources of the Canadian government behind it. This would be especially important if the Canadian firm is promoting a technology whose origin was in a Canadian government or university laboratory.

ETHICAL AND SOCIAL CONSIDERATIONS AS AN INTRINSIC ELEMENT OF THE PATENT SYSTEM

> *Hard for a patent office to play a role as ethical watchdog. - Gov. TT officer*
>
> *There is a serious risk of social engineering forcing biotech companies out of Canada.- Univ. Professor*
>
> *Patents are an economic tool. There are other fora to deal with social and ethical issues. - Gov. TT Officer*

Having social, moral or ethical considerations as an intrinsic part of the patent system was almost uniformly rejected by most of the interviewees. "Ethical and moralistic considerations should be kept out of the patent system". Many people remarked that if the federal election had gone a different way, a Canadian patent system that incorporated the European approach (i.e., morality and public order elements) might be under pressure to reject patents on religious grounds.

Most believed that our continued harmonization with the U.S. in this area was necessary. Issues of morality or ethics and what should be patentable was felt by many to be the domain of parliament, not the patent office or the courts. "If we had a challenged based system that operated through the patent system, it might be open to abuse by special interest groups. Most non-government organizations are not, in themselves, democratic organizations". Another interviewee commented, "Ethics policy must be in line with commercialization opportunities, otherwise research will be impeded".

One interviewee did believe that areas such as "methods of medical treatment" should remain exempted from patentability or, as in the case of the U.S., should not be subject to infringement damages. This allows medical practitioners to use the latest methods of medical treatment without fear of any financial consequences, while allowing the inventor to gain recognition from peers and the public by having their name associated with the new medical treatment method (e.g., Heimlich Manoeuver).

Another respondent said that the Canadian patent system should respect the traditional medicines of cultures that in the past relied solely on oral traditions for passing down information on medical products (e.g., herbal remedies). "There are companies that are trying to get patents on these ancient medicines". "Bio-piracy" should not be supported as it takes unfair advantage of people who might otherwise reap financial benefits from their knowledge and customs.

Several people who did favour Canada adopting an approach closer to the European stance

specifically mentioned the ethical issues associated with cloning human organs or humans. They believed that the patent system should deal with these types of issues.

In summary, most of the interviewees did not believe that the CIPO was equipped to deal with moral or ethical issues and that these should be handled by other institutions. The regulatory system was mentioned as a possible venue, if not parliament.

IMPROVING THE TRANSFER OF BIOTECHNOLOGY FROM PUBLICLY FUNDED INSTITUTIONS

> *UILOs are an obsolete model; they are under-resourced and are resented by the faculty.- CEO*

While the following suggestions are not unique to the biotechnology area, they were felt to be very important in the creation and growth of the biotechnology industry in Canada as universities are a major source of biotechnological inventions.

Develop Multi-University Technology Transfer Offices

> *Why don't we pool the IP work in a regional office? - Univ. Professor*

Most of the interviewees focussed their opinions on the transfer of technology from Canadian universities. Each university with its own technology transfer office (university industrial liaison office - UILO) was considered to be an outmoded approach and not very efficient. "With each public organization having its own IP office, we have created a system that is counterproductive".

One interviewee stated, "the present system of UILOs at universities is a terrible system; salaries are uncompetitive with people staying only long enough to get some training (9-12 months) and then go out and get 2-3 times the university salary". Another noted that we "need to worry about the 'Berlin Wall' around each of our institutions". At one university, for example, there were two distinct business development/technology transfer offices in competition with each other.

Another felt that the lack of more centralized offices prevents the effective bundling of individual patents into a stronger patent portfolio. "Everyone treats their small bundle of technology as their own, and they don't pool them to create a more substantial IP package".

One university professor, who was very familiar with technology transfer activities, was quite critical of many of the UILOs and believed that they had a higher opinion of their abilities than their

clients had. "Many companies don't like to negotiate with universities because the university UILO personnel don't know what the real world is like".

There was wide-spread support for a system whereby universities in a geographical region develop IP management specialties and provide services in particular technology areas to other nearby institutions. This would avoid the problem of a single UILO having to cover technologies for which it has little understanding of the marketplace. It is understood that universities need to have people "on-the-ground" to work closely with faculty and to encourage and guide disclosures, but other aspects of IP management could be more centralized and assigned to specialists.

Several people thought that an examination of the Québec model of business development units serving several universities might suggest ways it could be copied in other parts of Canada. A centralized service is also used in Nova Scotia by Dalhousie and other nearby institutions (Daltech).

Another interviewee stated that because each Canadian university has its own IP policies, it is difficult to negotiate license agreements when several university/research hospitals are involved in the development of a biotechnological invention. Working with a centralized business unit should reduce this problem.

Both provincial and federal government support should be aimed at increasing real cooperation and collaboration among the individual UILOs at the operational level, and should not be just a "smoke and mirrors" form of cooperation, which one respondent said has usually been the case with past initiatives. Several knowledgeable interviewees, for example, questioned the true degree of cooperation that was taking place within Alberta's Technology Commercialization Network.

While thinking that a multi-university model might be a good idea, several respondents did not have much faith in the willingness of universities to voluntarily cooperate to make such a model work.

While the above has focussed on universities, there is no reason that this model could not include the servicing of nearby federal and provincial government laboratories.

Increased Resources for University Technology Transfer Offices

Many university technology transfer officers commented on the lack of resources to hire additional staff, to provide proper protection for their intellectual property, and for prototype development.

Money for prototype develop was considered critical by one interviewee in order that additional experiments could be conducted after provisional filing to allow for data to be added in that first year thereby increasing the depth and strength of the patent application.

One respondent said that, "none of the [university] technology transfer professionals has enough money for proper patent protection; they do the skimpiest of patent protection on a piece of IP and they think they are covered. One patent will not give the licensor the tools to work with". Universities need the resources to provide global protection. This scope of coverage is usually too expensive, unless they have a local licensee lined up who is willing to share the costs.

Lack of resources and competent people can also result in UILO's limiting their activities to patenting and trying to sell licenses. They don't participate in the value-added development of the IP. They don't manage the process for a period of time so as to be able to show potential licensees or venture capitalists that there is value in the IP (e.g., conduct marketing studies, etc.).

Several interviewees noted that there is pressure on the UILO's operations to be at least cost neutral to the university. This forces the UILOs to focus their attention on licensing, which will generate funds faster, rather than on company creation that will result in slower returns to the university in the short-term but potentially better returns to both the university and economy in the long-term.

Several interviewees felt that the funding issue could be alleviated if grants from the major granting councils included a small percentage (e.g., 1%) which could be used to cover technology transfer expenses. "The end point of research is no longer just a publication, so the councils should fund the technology transfer". One respondent noted that requests that technology transfer funding be an explicit part of granting council funds have been made before. To date, no action has resulted. This recommendation is similar to Recommendation #3 of the report to the Advisory Council on Science and Technology entitled, "Public Investments in University Research: Reaping the Benefits" (Fortier, May, 1999).

The Natural Science and Engineering Research Council's Intellectual Property Management program, which does support university UILOs, was thought to be inadequately funded thereby compromising its effectiveness. One respondent believed that the new CIHR should also be supporting technology transfer activities through a 1% levy on its grants. One respondent reported that the UK granting councils budget a percentage of their grants for technology transfer activities.

With increased resources, UILOs or more centralized business development units could offer competitive salaries to technology transfer officers and provide them with the tools to protect and market their technologies more effectively, taking into account longer time horizons..

Training of New and Existing Technology Transfer Personnel

There was uniform agreement that Canada was lacking in qualified, well-trained technology transfer personnel and that more resources were required to fill this gap.

While several people mentioned the technology transfer workshop held recently in Montebello, Québec (sponsored by the Association of University Technology Transfer Managers), it was recognized that more effort and resources are required to produce a cadre of well-trained technology transfer personnel. Only the University of Alberta, through its MBA program, offers a graduate degree that includes technology transfer and intellectual property management in its program. A few other universities, through their extension programs or their engineering or law faculties, offer single courses on IP management. Some workshops are available from private consultants that deal with the transfer and commercialization of intellectual property from government laboratories to industry.

Better trained technology transfer officers, in both university and government business development offices, would help avoid the "over valuation" problem mentioned by one interviewee. "There is an unrealistic expectation of what the inventor or the institute should get".

One government respondent felt that Canada's lack of adequate training for new technology transfer officers, including patenting personnel, coupled with retirements in the near future of the few skilled people we had in the patent examination and regulation area, could stop the expansion of the biotechnology industry in Canada.

Because of concern over the training issue, the Federal Partners in Technology Transfer is commissioning a study to identify the training requirements of technology transfer officers, and another study to develop an inventory of the resources available in Canada and the U.S. to provide such training.

Differences in University IP Ownership/Management Policies

At present, Canadian university policies on ownership of an invention made by a faculty member ranges from the institution owns (e.g., University of British Columbia), to co-ownership (e.g., University of Toronto) to creator/inventor owns (e.g., Queen's University).

While inventor owned approaches are said to encourage more disclosures, they carry with them the danger of great conflict further down the commercialization chain. It has been the experience of some universities that even when the identified inventor has assigned ownership to the university in return for assistance in getting his/her invention to market, another "rogue" co-inventor has surfaced later on to claim partial ownership and a share of the royalties. Even if the "rogue" inventor's claims are weak or invalid, some have been known to threaten a licensee company, which in good faith, has spent considerable amounts of money on what it thought was an exclusive or sole license, to bring the product to market.

In Canada, if their claims are valid, "rogue" inventors have the right to practice the invention themselves. They do not have the right to license it to a third party. This is not the case in the U.S. A "rogue" inventor can therefor threaten the Canadian firm with licensing the technology to an American competitor.

According to one university technology transfer officer, big pharmaceutical firms are especially nervous about this situation. "The last thing big pharma wants is someone saying 'you do not have full title', I am taking this invention down the road [to a competitor]". This respondent added that the pharmaceutical companies will pay "rogue" inventors serious money to make she or he go away. The result is that some Canadian biotechnology firms will not license from inventor-owned universities for fear of downstream "blackmail".

The solution to this difficulty is for the institution to own any inventions developed by its faculty (and graduate students) so that it can transfer clear ownership or a clear license to the adopting company. This, of course, may generate other problems.

Another interviewee said that the transaction costs of dealing with universities was high because of the variation in how they managed their IP. Problems increase in universities where the creator has an ownership position and wants to play an active part in the business negotiations. Over valuating their "baby" can cause serious roadblocks to reaching a business agreement. This respondent felt that the granting councils should be enforcing more uniformity in IP management at universities.

Government Technology Transfer Activities

Like their university colleagues, technology transfer officers in government departments are running their operations on minimal budgets. This, according to one interviewee, limits their ability to file for protection in key countries, and to do strategic planning. It also limits their ability to hire good patent agents who can word claims carefully to meet the requirements in a particular country. Canadian companies need IP to be well-protected, otherwise they cannot be competitive. "There needs to be greater appreciation given to supplying sufficient resources to public research organizations for protection of their IP".

Several respondents noted that government laboratories have a mixed mandate when it comes to technology transfer. One mandate is to strengthen the Canadian economy, and the other, more immediate and mercenary concern, is to generate revenues that are needed to sustain their research activities. The situation can arise in which the short-term survival of a government laboratory (i.e., revenue generation) takes precedence over the economic development of a Canadian firm, when it cannot compete with what is being offered by a foreign competitor.

Adding to the challenges of managing intellectual property in the government context is the newly revised Treasury Board (TB) policy on "Title to Intellectual Property Arising Under Crown Procurement Contracts" (2000). This policy retains the presumption of contractor ownership of any new IP developed during the course of a contract, unless the government invokes one of six exceptions as stated in an earlier 1991 TB policy. The 1991 policy and the 2000 revision are based on the belief that when a contractor owns the IP, they will be more willing to invest the often considerable funds necessary to fully exploit the technology and develop new products or services (i.e., encourages job and wealth creation in Canada). The decision on whether to invoke an exception and for the Crown to retain ownership must be made before any contract solicitation

documents (e.g., Request for Proposal) are issued. This policy puts the government official in the unenviable position of having to decide whether to keep any resulting IP that might have commercial potential and have revenues come back to the department, or to allow the contractor to retain the IP ownership and have the department receive only contracted for deliverable. Past practice has been that the departments have used the exceptions liberally to retain any IP with commercial potential. The new revised policy is intended to make it more difficult for departments to invoke the exceptions for purely financial reasons.

The reluctance of some government departments to award exclusive licenses to firms was considered to be an impediment to the commercialization of technology. Without such a license, firms are reluctant to make the considerable investment often needed to bring the technology to market.

"Canada First" Exploitation of Publicly Supported Technology

Universities that are recipients of federal funds are not under any obligation to try to have their IP commercialized by a Canadian company. In addition they are not required to provide the government with any records on commercialization activities, as suggested in the Fortier Report. Some academics seem to consider that such reporting arrangements infringe on their academic freedom. It could be suggested that they are free not to accept government support if they do not like the conditions.

At least with IP generated by the National Centres of Excellence, there is an understanding that NCE managers will try to partner with or commercialize their IP from a Canadian base, and there are some sanctions if they break the spirit of the understanding.

However, if best efforts to work with or through a Canadian firm are unsuccessful, the IP should not sit on the shelf. The organization should then be free to offer the IP to the highest bidder.

One interviewee suggested that the extensive network of NRC's Industrial Research Assistance Program (IRAP) officers was an underutilized mechanism for identifying possible Canadian partners.

On a positive note, federal government laboratories do generally make considerable efforts to locate a Canadian partner in the commercialization of their technologies and only venture outside Canada if this approach proves to be impractical.

ISSUES FOR THE FORTHCOMING ON-LINE WORKSHOP

> *It is important that Canada not be perceived internationally as a country that falls behind in the development of advanced technologies.*

This short study has identified many intellectual property/technology transfer-related issues that affect the creation and growth of a vibrant biotechnology industry in Canada. As the purpose of this paper was not to make any recommendations or conclusions but to identify issues that could be discussed at a forthcoming on-line workshop, the following key issues that directly impact the biotechnology industry are put forward for consideration:

What structural changes are required in the Canadian patent system to prevent Canada from lagging behind in the protection of biotechnologial inventions and retarding the growth of the industry?

What are the pros and cons of Canada being part of a North American patent system, and what should CIPO'S role be it?

What are the pros and cons of the government establishing a patent infringement insurance program?

What incentives are needed to encourage greater cooperation among universities and government in the transfer and commercialization of their intellectual property?

Should the existing granting councils set aside a percentage of their grants to support the technology transfer activities of university and government recipients?

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