Summary Report of the President/CEO Industry Hearing to CBAC

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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Final Draft

CANADIAN BIOTECHNOLOGY ADVISORY COMMITTEE
PRESIDENT/CEO INDUSTRY HEARING
to the
Intellectual Property/Patenting of Higher Life Forms Project Steering Committee

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Rapporteur's Summary

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1. The President/CEO Briefing to CBAC brought together representatives from the pharmaceutical, biopharmaceutical, animal biotechnology, and plant biotechnology industries as well as intellectual property lawyers and a social scientist to discuss industry needs with respect to biotechnology patents. As the two Co-Chairs of the Briefing made clear, CBAC is interested in examining ways in which to foster biotechnological innovation in a way that is both consistent with Canadian values and contributes to the Canadian economy.

2. Although the Briefing was organised to give an overview of industry needs in the area of biotechnological innovation, it was not designed to solicit all views from all industry sectors. While several industries were not in attendance at the Briefing--including genetic testing companies, genetic therapy companies, producers of non-pharmaceutical bioproducts in the health care area, and bio-informatics companies–those selected represented a cross-section of the biotechnology industrial community.

3. Industry participants did not address in any detail the social and ethical context in which biotechnological research is or ought to be conducted in Canada, the respective roles of the public and private sectors in conducting this research, the role of the Canadian public in setting biotechnology policy, or the economic or social effects of patents either in general or in relation to biotechnology. Several industry participants did state, however, that they supported public research and some believed that industry-university research collaborations represented one means that their companies used to assist public sector research. They also believed that the biotechnology industry had salutary social effects such as increased employment opportunities in Canada and the training of future management personnel.

4. Ted Schrecker, the invited social scientist, pointed out that biotech patenting involved important social and ethical questions. He warned that it was "cognitively irresponsible" for policy-makers to look at life forms as equivalent to machines and cautioned against an overly technical approach to formulating patent policy. He suggested that, before proceeding with biotech patents, we first examine the economic effects that these patents have on health care and health care costs. He also argued that CBAC should undertake a consultation on biotechnology patents with university-based researchers at various stages of their scientific careers.

5. The industry participants focussed their presentation on three main areas of concern. The first involved the manner in which international investors and affiliates perceive the Canadian climate for biotechnological research and development. The second involved the need for efficiency in obtaining, using, and enforcing patent rights. The third area of concern related to particular industry needs in the fields of pharmaceuticals-biopharmaceuticals, animal biotech, and plant biotech.

CANADA'S INTERNATIONAL PERCEPTION

6. One of the strongest and most uniform messages that the industry representatives conveyed was that Canada is viewed internationally as being unsupportive of, or even hostile to, biotechnological innovation. This perception is based on a variety of Canadian policies of which

intellectual property protection is one. According to the industry representatives, those who make decisions about investing in Canadian research view Canadian patent laws as being less broad, more difficult to enforce, shorter, and longer to obtain than those in the United States, Europe, and Japan. Canada also has the reputation of being unwilling to live up to its international obligations with respect to patent protection.

7. While industry representatives pointed to the fact that Canada does not meet current standards set by the United States, Europe, and Japan with respect to patents, they acknowledged that, given the small size of the Canadian marketplace, this fact has little economic significance. In fact, Canada only accounts for approximately 2.5% of the worldwide pharmaceutical market. Since patent protection is worldwide and is particularly valuable in the major world markets–in particular in the United States and Europe–patent protection levels in Canada have little direct economic effect on decisions as to where to conduct research and development. This is because an invention developed in Canada can, despite Canadian patent laws, be patented and exploited in the United States and in Europe on identical terms to inventions developed in those regions.

8. Despite the fact that the strength of Canadian patent rights lack any direct economic impact on Canadian biotechnological research and development, Canadian industry is concerned about the indirect message that failure to meet international patent standards has on foreign investors and affiliates. This is because investors and affiliates often do not make decisions about where to invest based solely on measurable economic factors. They also take into account less quantifiable perceived innovation climates.

9. The representatives from the Canadian branches of the international pharmaceutical industry pointed out, for example, that it was difficult to convince their head offices to invest in research and development in Canada because of the perception that Canada does not treat these companies fairly in its patent policies. The Canadian representatives did not share the opinion that Canada was unsupportive of biotechnological innovation. In fact, Canada's publicly funded health care system and universities make Canada, in some respects, an ideal place to conduct research. Nevertheless, the negative perception that Canada is hostile to biotechnological research prevents Canada from capitalizing on this advantage.

10. Canadian-based industry had similar views about the attitudes of international biotechnology investors contemplating investments in Canada. Industry representatives believed that these investors would at least hesitate before investing in a Canadian biotechnology company because of the view that Canada was unsupportive of biotechnological innovation as exemplified in its patent policies.

11. Because of the relatively small economic impact that the Canadian market has on investment decisions, industry, other than the pharmaceutical companies, generally file their patents first in the United States. This is so for a number of reasons. First, patent protection in the major markets is required to attract investment. Venture capitalists and other investors care little about a company's patent position in Canada but care deeply about patent positions in the United

States and Europe. Second, the companies themselves are more interested in selling into the United States' market than the Canadian market because of the former's size. Third, there has been, up to now, greater secrecy governing patents in the United States than those filed elsewhere. This will change in November 2000 when the United States will open patent applications to public view 18 months after the earliest filing date or priority date of the application unless the patent is being filed solely in the United States. The pharmaceutical industry generally follows the rule that patents are first filed in the country in which the invention takes place and, following that, internationally.

12. In the past, when Canada increased its level of patent protection, industry increased its investment in Canadian research and development. Industry representatives stated that international pharmaceutical companies increased their research staffs significantly after changes to Canada's patent laws in 1987 and 1993. There has also been a two to threefold increase in research and development in the agricultural biotechnology sector in Canada since 1996 but this does not seem to be tied to any significant change in the scope of Canadian intellectual property rights.

13. Most industry representatives stated that there exists a robust investment climate in Canada with an increasing number of sophisticated and knowledgeable venture capitalists. One industry representative reported, however, that this robustness is not uniform. He stated that investors tend to look for technologies that enter niche markets and are suspicious of technologies with wide application. His company, which produced a product of broad application, had encountered difficulty in finding investors.

EFFICIENCY IN THE ADMINISTRATION OF THE PATENT SYSTEM

14. Industry representatives were uniform in calling for an easier to use and more transparent patent system in Canada. They voiced several concerns over the present administration of the Canadian patent system. First, they stated that the review of patent applications in Canada is too slow. Second, they pointed to the lack of patent term restoration periods as exists in the United States, Europe, and Japan to compensate patent holders for regulatory delays in getting an invention to market. Third, they noted particular areas where the Canadian patent system can be made more efficient.

Patent Review Periods

15. While industry representatives were happy with the quality of the Canadian Intellectual Property Office's (CIPO) review of their patent applications, they felt that the length of time that patent applications sit unexamined in the patent office is unacceptable. It takes, on average, 22 months after a request by an applicant for CIPO to formally respond to the application (the first office action). Since most patent applications arriving in Canada come through the Patent Cooperation Treaty (PCT)–an international convention that provides for a mechanism to file patent applications in many countries at once–most applications will already have been in process for approximately 30 months prior to this 22 month period. This means that the applicant does not

usually receive a first office action from CIPO before four years after the initial filing. While industry representatives acknowledged that applicants may seek special orders to have their applicants reviewed on a more urgent basis, they felt that this procedure is unfair to other applicants who, as a result, have to wait longer for the review of their applications.

16. Timeliness of patent application review would assist industry in several ways, according to the representatives. First, it would make it easier to attract investors and business partners earlier in the patent term. Since investors and potential partners are less interested in investing in technology without a firm patent, delays in patent prosecution mean that an inventor will have to wait longer before approaching these investors and partners. Nevertheless, since the 20 year period of exclusivity continues to run during the patent prosecution period, the invention becomes less valuable with every passing day. Thus, not only is production and distribution of the invention delayed, but it may never take place if so much of the 20 year period has expired that the patent no longer has sufficient value to justify an investment.

17. To remedy this problem of patent review delays, industry representatives recommend active recruitment of new patent examiners and increased training of those hired. In addition, they recommend that CIPO rely more on patent examinations conducted in other countries, particularly in the United States, so as to simplify the Canadian portion of the review.

Patent Term Restoration

18. The pharmaceutical and biopharmaceutical industry representatives raised another concern related to timeliness: regulatory delays in gaining approval to new medications. These industries, as opposed to most biotechnology companies including most in the health care sector, require regulatory approval by the Health Protection Branch of Health Canada before placing their products on the Canadian market. They require similar regulatory approvals elsewhere (for example, approval from the Federal Food and Drug Administration in the United States). On average internationally, this approval takes between 10 and 12 years. Small biopharmaceutical companies may find that it takes longer to get approval since they are, generally, less experienced with the approval process. The end result of the need for health-related review is that the effective life of a biopharmaceutical patent is only eight years as compared to closer to 17 years (assuming a three year delay in obtaining a patent) for other biotechnological and other technology patents.

19. In addition to the short effective lifespan of pharmaceutical patents, the cost of bringing these products to market is much larger than for most inventions including most biotechnological inventions. This again is because of regulatory review. In order to comply with the regulatory review process, pharmaceutical and biopharmaceutical companies must conduct expensive trials and tests. On average, it costs approximately U.S.$500,000 to bring one medication to market. With only eight years to recoup these costs, the pharmaceutical and biopharmaceutical industries feel that the Canadian patent system does not provide a fair return for their investments.

20. All of the United States, Europe, and Japan address the concern over regulatory delays in the

approval of medications by granting patent term extensions. Under these patent term restoration rules, patent terms may be extended by the relevant patent office for up to five years. Canada does not have similar rules. The pharmaceutical and biopharmaceutical industries believe that Canada's lack of patent term restoration rules contributes to the international perception that Canada is unsupportive of biotechnological innovation.

Other Suggestions

21. In addition to industry concerns over the timeliness of patent reviews and the request, in the pharmaceutical and biopharmaceutical sectors, for patent term restoration rules, industry raised a number of other issues related to the efficiency of the Canadian patent system.

22. One area in which improvement is needed is in the clarity of the patent process. Industry representatives pointed to the policy of the United States Patent and Trademark Office (PTO) of making the procedures to file and obtain patents as clear and straightforward as possible. For example, the PTO issues guidelines on filing applications and in assisting would-be applicants in understanding such concepts as description and utility requirements. To date, CIPO has not issued any guidelines of a similar nature.

23. While industry participants did not address the issue of the respective roles of the public and private sector in advancing biotechnological innovation, they acknowledged the need to encourage university research and to bring the products of that research to market. They pointed to the need for a more developed institutional infrastructure to patent university research and to create university-industry partnerships to move the products of that research to market. The industry representatives believed that industry has an important role in this area. In fact, one of the representatives from the pharmaceutical industry pointed out that her company engaged in partnerships with universities in order to further develop university research and research capacity.

24. Several of the participants pointed to the lack of any clear rules in Canada (or in the United States) on the type of research that is permitted to be conducted using patented inventions without infringing a patent holder's rights. The so-called experimental use exception is ill-defined in Canada and the United States as opposed to in Europe. This lack of clarity results in a grey zone for researchers in which they face the risk of being sued for patent infringement.

25. While the industry representatives agreed on the need to clarify the experimental use exception in Canada, they did not agree on the appropriate scope of the exception. The pharmaceutical and bio-pharmaceutical industries called for a narrow exception–one narrower, in fact, than current practice in Canada, Europe, and the United States. By statute in the United States and by judicial interpretation in Europe and Canada, rival companies are permitted to conduct clinical trials on generic versions of a patented medication without infringing on the patent holder's rights. The pharmaceutical industry believes that this is unfair and that experimental use ought to be limited to truly innovative research.

26. Other industry representatives favoured a wider approach to the experimental use exception

probably closer to the European standard where any research conducted on the subject-matter of a patent–even if the research is conducted for commercial purposes–is permitted. Some patent analysts believe that this is also the *de facto* standard in the United States even though there is no clear jurisprudence to this effect. A more generous research exception prevents any one company from holding back future rounds of innovation.

27. The agricultural industry is, in particular, concerned that patents not block access to platform technologies. Although the industry's preferred route to have access to this technology is through licensing and cross-licensing arrangements, there is a perceived need to ensure that no one company can block access to new germ plasm as it is developed.

28. Industry representatives generally supported the ability to patent higher life forms–plants and animals more complex than microorganisms. From a commercial point of view, they stated that there was nothing different between higher life forms and existing patentable material. They stated that Canada ought to harmonize its laws with those of the United States and Europe in which higher life forms are patentable. This is necessary in order to further develop our expertise in transgenic animals. Ted Schrecker pointed out, however, that there are vast moral and social differences between property rights in higher life forms and those in other inventions.

29. There was general consensus that the utility and description guidelines for biotechnological innovation ought to be harmonized internationally. The proposed guidelines on these points issued by the PTO in December 1999 found general favour among the industry representatives.

30. One of the lawyers invited to the Briefing stated that one of the ways that the United States had achieved uniformity and clarity in its patent laws was through the formation of a specialized court, the Federal Court of Appeals for the Federal Circuit, to deal with patent issues. He suggested that Canada consider establishing a specialized patent court, perhaps within the existing Federal Court of Canada structure.

31. In addition to these general proposals, industry representatives strongly recommended that Canada continue some of its current practices that are viewed as beneficial to the biotechnology community. These include Patent Act provisions (s. 52) permitting an individual to challenge an issued patent without having to first infringe on the patent. This is an advantage of the Canadian patent system over that in the United States. Similarly, the introduction in 1996 of a procedure (sections 93 and 94 of the Patent Rules SOR 96-423) under which applicants can file "provisional" applications to protect a priority date over an invention was seen as positive. This procedure matches the provisional patent application procedure in the United States.[1]

32. On the other hand, industry viewed Canada as falling behind in conforming to international

[1]The industry representative who raised this point actually stated during the Briefing that Canada ought to implement a procedure similar to the provisional patent application procedure in the United States. As the 1996 amendments only affected patent applications made after October 1, 1996, this representative may not have known that Canada had already done so.

standards on the filing of genetic sequences. One industry representative also suggested that Canada implement a continuation practice procedure–under which patent applicants can revive dormant patent applications–as in the United States. Another innovative proposal was that, where some of the claims in a patent application were in dispute while others were not, that CIPO issue a patent over the undisputed claims while the disputed claims continue through the court system.

PARTICULAR INDUSTRY CONCERNS

33. Although there was much uniformity in the views of the industry representatives, there were also substantial differences. Each industry sector put forward suggestions as to changes that would, in the opinion of the representatives, foster innovation in that sector.

Pharmaceutical and Biopharmaceutical Industries

34. There was little difference in the positions of the pharmaceutical and biopharmaceutical industries. This was due, in part, to the absence of any generic biopharmaceutical industry given that regulations and bioequivalence standards have not yet been established for biopharmaceuticals.

35. The pharmaceutical industry is very concerned, according to their representatives, about the protection of their research data. As discussed earlier, clinical trials are expensive to conduct. The pharmaceutical industry wants to ensure that, when a company submits clinical trial data to Health Canada, that this information remains confidential. In particular, companies do not want their competitors or generic companies to have access to this information. Currently, the industry feels that there is insufficient protection given to this information. The representatives called for amendments to the Food and Drug Act to strengthen the confidentiality of submitted research data.

36. The industry has not encountered difficulties with confidentiality when sharing information with university researchers. The industry representatives stated they they respect the need of university researchers to publish their research findings. When pharmaceutical companies share information with these researchers, they impose restrictions on the further dissemination of this information but not the information produced by the researchers. They accomplish this by incorporating a short delay period prior to publication so that the pharmaceutical company can review the proposed publication. The company would only not agree to the publication of the material if it contained confidential information supplied by the company or where one research group in a muti-centre trial attempted to publish ahead of the other research teams.

37. Where a pharmaceutical company has highly sensitive information, it generally will not share that information with university researchers, preferring to either conduct the research in-house or to contract the research out to the private sector under a strong confidentiality agreement. While the effect of this practice may be to reduce university researchers' access to some information, it preserves the freedom to publish research results.

38. The industry complained that Canada was reluctant to fully enforce pharmaceutical patents. This

is most clearly demonstrated, according to the representatives, in the so-called linkage regulations that are, in principle, designed to restrict a generic company's ability to gain approval to market a medication until the patent over that medication expires. In fact, according to the pharmaceutical industry, these linkage rules are not strong enough to prevent the generic companies from getting a significant lead on the approval of generic medications during the life of the patent.

39. Industry representatives were supportive of an orphan drug law in Canada. Under such a law, industry would receive certain benefits–including exclusivity in the market and tax incentives--to develop and market medications that affect only a small number of individuals in Canada. This legislation is needed to encourage research and development into ameliorating rare diseases. While the pharmaceutical industry does, on occasion, investigate rare diseases, it normally only does so where it can learn from that investigation knowledge of wider application. Orphan drug laws would encourage others, particularly small biotechnology companies, to conduct research on rare diseases.

Animal Biotechnology

40. The largest problem facing the animal biotechnology sector is not related to intellectual property protection: it is the lack of regulation. According to the industry representative from this sector, there is a complete vacuum of regulation in the animal biotechnology area, for example, with respect to environmental, animal care, and similar laws and regulations that apply to the care of, disposition of, and waste produced by genetically-modified animals. Almost any regulation would be better than the current absence of rules. As it stands, industry cannot assess its liabilities and cannot engage in any long-term planning about genetically-modified animals since no regulatory framework exists.

41. Canada is significantly behind other countries in establishing its rules and regulations with respect to genetically-modified animals. According to the industry representative, Canada is at least five years behind the United States in this area.

Agricultural Biotechnology

42. The international agricultural biotechnology industry relies on several different intellectual property regimes ranging from patents, to trade secrets, to plant breeders rights. As in other sectors, Canada's policies with respect to agricultural biotechnology is viewed by industry as being significantly behind those of the United States and Europe.

43. Most developed nations permit inventors to choose between intellectual property regimes. That is, a creator can select whether to protect a plant through a patent, plant breeders rights, or trade secret. As Canada does not permit patent protection over plants, creators only have the choice between trade secret protection and plant breeders rights. According to the industry representative, this limited choice has negative implications for research in Canada as more and more plant creators choose trade secret protection.

44. Historically, plant developers openly shared their technologies. With the advent of genetic

engineering, which the industry feels is inadequately protected through plant breeders rights, these developers have resorted to trade secret protection. Since, in order to maintain trade secret protection, developers must maintain the secrecy of their inventions, they can no longer maintain this open sharing of technology.

45. The industry representative stated that if patents were available over plants, the plant developers would resume their tradition of openness. This is because patented plants would be freely disclosed through the patent process itself. Thus, developers could more easily share ideas without fear of losing protection.

46. Given that many of the developments in plant biotechnology tend to produce platform technologies, it is extremely important that the tradition of sharing be maintained. Nevertheless, since patent rights are so much broader than plant breeders rights, there remains a danger that a particular plant developer will not conform to industry norms of openness. Patent law ought, according to the industry representative, to contain mechanisms to prevent this hoarding of technology. A broad experimental use exemption would help. Other options should also be investigated.

47. According to the industry representative, the best way for Canada to move forward in respect of plant biotechnology is to re-introduce and pass former Bill C-90 (An Act to revise and consolidate certain Acts respecting food, agricultural commodities, aquatic commodities and agricultural inputs, to amend the Canadian Food Inspection Agency Act, the Agriculture and Agri-Food Administrative Monetary Penalties Act, the Health of Animals Act, the Plant Protection Act and the Plant Breeders' Rights Act, and to repeal and amend other Acts in consequence). This Act would have the effect of harmonizing Canadian plant breeders rights laws with those of the United States and Europe.

48. Canada currently conforms to the 1978 UPOV Convention dealing with plant breeders rights. Other developed nations have moved to the standards set out 1991 UPOV Convention which not only permits patenting of plants, but enlarges the scope of plant breeders rights protection. Bill C-90 was designed to move Canada to the 1991 UPOV Convention standard.

49. Bill C-90 addressed important issues covered by the 1991 UPOV Convention. First, as already stated, it permitted patenting of plants. Second, it defined what constitutes experimental use within plant breeders rights. Third, it expanded protection by not only including plant varieties themselves, but plants derived from those varieties (through the introduction of the concept of essentially derived varieties) and material harvested from those plant varieties. The latter protection is particular important in respect of ornamental plants and horticulture. Fourth, the bill maintained the existence of farmers' privilege under which a farmer could plant the seeds harvested from a previous year's crop. Fifth, the bill would have permitted a developer to gain plant breeders rights protection even if a version of the plant had previously been sold in Canada.

CONCLUSION

50. The President/CEO Briefing to CBAC illustrated both the commonalities between the different biotechnology industry sectors and some of the differences. While all pointed to the need to rehabilitate the perception of the Canadian biotechnology climate held internationally and of the need to make the Canadian patent system more efficient, the different industry sectors had clearly different needs, some of which conflicted. The largest area of conflict surrounded which types of use others could legitimately make of a patented invention without infringing on the patent. In those industries where there is no tradition of sharing information, industry representatives asked for narrow exceptions. In those industries with a greater tradition of sharing, the representatives asked for wider exceptions.