Bureau de la coordination des politiques

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PATENTING LIFE FORMS & PROCESSES

Consommation et Corporations Canada

Consumer and Corporate Affairs Canada

PATENTING LIFE FORMS & PROCESSES

Consumer and Corporate Affairs Canada
in collaboration with
Science and Technology Canada
and
Agriculture Canada

Addendum

Since this study was printed, the Government has released proposed amendments to the Patent Act. If these proposals are enacted, certain statements in the study will no longer hold, in particular, as regards the following paragraphs:

(1) Paragraphs 20 and 64 refer to the two-year period of grace now provided for under Sections 28 and 29 of the Patent Act. The proposed amendments would amend these sections, reducing this period to one year.

(2) Paragraph 65 refers to provisions in Section 41 of the Act which at present limit claims on chemical substances intended for food or medicine to claims to the substance as produced by a described process. The proposed amendments would remove this product-by-process dependency by repealing subsections 41(1) and also consequentially 41(2) of the Act. Paragraph 65 also refers to the compulsory licensing provisions in subsection 41(4) of the Act, applicable to pharmaceutical patents. The proposed amendments would delay licences to import under this subsection and relate them to a guaranteed period of market exclusivity for patent-holders; they would similarly delay licences to manufacture where the patentee began to manufacture in Canada within two years; they would exempt pharmaceutical patents from licensing, other than licensing to manufacture, where the drug involved was discovered and developed in Canada; and they would exempt these patents from licensing to manufacture as well where the patentee manufactured in Canada within two years. The amendments would provide for removal of these restrictions and exemptions where excessive prices were found to have been charged for patented drugs.

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EXECUTIVE SUMMARY

This paper is being distributed to representatives of the Canadian biotechnology community in order to generate a discussion about patenting biotechnology in Canada. It is hoped that readers will come forward with their reactions to the paper as well as other comments they might wish to make on this important subject.

Most industrial countries now recognize the great growth potential in biotechnology. Many countries are already investing heavily in this field and some governments have adopted programs specifically intended to promote the exploitation of biotechnology within their territories.

Canada cannot afford to fall behind in this expanding new field. Certain steps have already been taken to promote biotechnology in this country, notably the adoption of the National Biotechnology Strategy. However, major decisions remain to be made, particularly on the application of our patent legislation to biotechnology.

Serious questions have been raised about the quality of patent or patent-like protection now available for biotechnology in Canada:

- Is the Canadian law in this area sufficiently clear and well established that biotechnology researchers can ascertain their rights as inventors with confidence?

- Does our *Patent Act* cover a suitable range of biotechnological inventions, or does its protection extend either too far or not far enough?

- Will the *Patent Act* in its present form work in harmony with the plant breeders' rights legislation now under consideration by the government?

These are difficult issues that must be faced soon.

Several policy options for addressing these issues are available. First, the *Patent Act* could be left basically as it is, and the development of our law left to the process of judicial interpretation. Second, the Act could be amended to include more explicit rules on

patenting biotechnology. The Act could be made to provide clear and positive protection for specified classes of biotechnology, perhaps by adopting the European Patent Convention rules delimiting patentable subject matter or by declaring that patentable subject matter can consist of or involve the use of living matter. Alternatively, if it is decided that Canada should not grant exclusive rights over living matter, the Act could be amended to deny such patent rights explicitly.

Whatever option is eventually chosen, its impact on the development of biotechnology in Canada could be significant.

This paper was prepared by the Department of Consumer and Corporate Affairs and is based on a study done by an interdepartmental working group headed by the Ministry of State for Science and Technology and including officials from the Departments of Consumer and Corporate Affairs and Agriculture.

I INTRODUCTION

1. The exploitation of biotechniques offers great potential for economic growth to Canadian industry, agriculture and medicine. This fact has led Canada and other industrial countries to include biotechnology in their "grand economic strategies." However, there are concerns about the quality of the protection available for biotechnology under the Canadian patent system.

2. The purpose of this paper is to outline how proprietary rights to inventions in biotechnology are being protected in Canada, review the national patent and plant breeder's rights laws of various industrialized countries, note the international arrangements for their recognition, identify important issues regarding protection of biotechnology in Canada and examine policy options to address those issues.

II THE NATURE OF BIOTECHNOLOGY

3. Biotechnology is not an industry but a grouping of technologies. Formal definitions aside, the term "biotechnology" as used in this paper refers to the controlled uses of biological systems: that is, the use of intact biological organisms such as bacteria, yeasts, fungi, algae, etc. (or isolated cellular components of such organisms), as well as biological systems or processes, to solve problems or obtain benefits. This definition encompasses many of the techniques employed in applied biology.

4. Some biological processes and properties of organisms have been exploited by mankind for centuries. Notable milestones in applying biotechnology include the use of fermentation techniques and those of classical genetics. Fermentation was used in the production of alcoholic beverages and foods and the detoxification of human and animal wastes, while genetics was applied to the selective breeding of organisms for desired characteristics, i.e. cows for increased milk production or crop plants for increased yield or resistance to certain adverse conditions. More recently, advances in fermentation technology have been used in the production of vaccines and several processes for the production of organic acids and solvents. Subsequently, after a period of rapid developments in microbiology, biotechnology made possible the production of

a variety of new products including antibiotics, amino acids and vitamins.

5. In recent years, however, spectacular advances in various fields of science and engineering, from biochemistry and biochemical engineering to molecular and cellular biology, have vastly magnified the range of applications to which biological processes and organisms can be directed. Most notable is molecular genetics which includes technologies of genetic engineering that involve man-controlled manipulation of the genetic material itself. Genes are the hereditary units controlling the characteristics of all life forms. Technologies such as recombinant DNA and the chemical synthesis of genes can increase the size of a gene pool for any one organism by making available genetic traits from many different populations. This newly developed capability represents a revolutionary advance over classical genetics in which the pool of genes available for selection was confined to those that cause natural differences among individuals in a population and those obtained by mutation. Molecular genetics also includes technologies in which manipulations occur at a level higher than that of the gene, namely at the cellular level (e.g. cell fusion and *in vitro* fertilization).

6. These advances in biotechnology now permit the development of various micro-organisms and other forms of life with pre-selected features, characteristics and properties and the programming of such novel living entities for particular tasks in manufacturing, mining, agriculture or medicine. These advances are already replacing or radically changing certain industrial processes presently in use. They also make possible the production of new substances, including some which to date had not been available in quantities large enough to be of practical use.

III THE INDUSTRIAL POTENTIAL OF BIOTECHNOLOGY

7. The potential of biotechnology has been addressed by a number of international bodies, including the Organization for Economic Co-operation and Development (OECD) and surveyed by several countries,

including Canada[1] and the United States.[2] It was found to be very impressive indeed.

8. For the purposes of examining its industrial potential, biotechnology may best be thought of as the application of micro-organisms and biological systems or processes to the production of goods and services. Bacteria, yeasts, fungi algae, cells and tissues of higher plants and animals or enzymes isolated from them provide starting points for new products and industries and the replacement of existing industrial processes with new or improved biological ones. It is a composite technology encompassing five major technical areas: genetic engineering, enzymes and enzyme systems, fused-cell technologies, plant-cell cultures and process and systems engineering. The exploitation of these techniques is expected to have a major impact on health care products, food production, agriculture and forestry, energy, recovery of metals, production of chemical raw materials, fisheries and the environment.

9. The major impact of biotechnology will not be felt for a decade or so since much of the present state of the art, though successfully demonstrated in the laboratory, has yet to be scaled up to a level appropriate for industrial exploitation. Many applications of biotechnology have yet to be invented. Moreover, the industrial exploitation of biotechnology will involve a massive changeover from existing production processes and facilities. For example, a study

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1. MOSST Background Paper, *Biotechnology in Canada*, 1980; Science Council Report, *Biotechnology in Canada, Promises and Concerns*, 1980. The Report of the Task Force on Biotechnology to the Minister of State for Science and Technology, *Biotechnology: A Development Plan for Canada*, 1981. In addition, *Biotechnology & Plants: Policy Concerns for Canadian Agriculture"* is the title of a forthcoming study by the Science Council of Canada.

2. See, for example, *Biotechnology, International Trends and Perspectives: A State of the Art Report*. Allan T. Bull, Geoffrey Holt, Malcolm D. Lilly, OECD, SPT(82)4, 1982; and *Impact of Applied Genetics, Micro-organisms, Plants and Animals*. Congress of the United States, Office of Technology Assessment, 1982.

entitled *Opportunities in Biotechnology* by T.A. Sheets Company of Cleveland, Ohio estimates that world sales from the new applications of biotechnology, which totalled $25 million in 1980, will rise to $25 billion in 1988-1990. Nearly 80 per cent of this increase in sales will likely result as a consequence of the changeover from current technology to the new biological processes in industrial sectors such as energy, agriculture, food production, drugs, chemicals and plastics.

10. In these circumstances predictions of future trends in biotechnology and its market potential are considerably more hazardous than usual. Nevertheless, a partial indication of direction in biotechnology may be found in the analyses of patents, including that referred to in *Biotechnology, International Trends and Perspectives: A State of the Art Report*[3] published by the OECD. Moreover, a number of estimates concerning the likely size of future markets for selected products of biotechnology together with the likely timetables for their commercial production may be found in the report of the Office of Technology Assessment entitled *Impacts of Applied Genetics, Micro-organisms, Plants and Animals.*[3]

11. These reviews and assessments of advances in biotechnology and of their potential for industrial and other societal exploitation have led some countries to regard it as one of the "locomotive technologies" that will pull their economies into the future. These evaluations have caused governments and industries worldwide not only to invest heavily in the continuing development of biotechnology but also to create conditions favourable to its exploitation, including protection of proprietary rights under both national and international patent laws. In Canada, the federal government has adopted the National Biotechnology Strategy, which is intended to expand, strengthen, focus and accelerate Canadian R&D in biotechnology and make sure that the economy and society take advantage of its opportunities and benefit from its exploitation.

12. "Biotechnology-related" industries are already an important segment of the Canadian economy. And their prospects for the future can only be enhanced by the National Biotechnology Strategy. To the extent they could be identified as such within the Canadian system of national accounts, these industries accounted

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3. *Op. cit.*

for more than 7 per cent of the Real Domestic Product in 1983. Industries identified as "biotechnology-related" are now largely dependent on the techniques of classical genetics which are yet to be enhanced or replaced by those of molecular genetics. They do not include firms established in recent years for producing new life forms and related systems and making such new biological agents and processes available for exploitation by others (or exploiting them themselves).

IV PATENTING BIOTECHNOLOGY IN CANADA AND SELECTED INDUSTRIAL COUNTRIES

A. Introduction

13. In the industrialized countries, patent systems, although they involve certain social costs, are nevertheless considered by many to be an effective incentive mechanism for applied research, inventions and innovations. Indeed, insufficient protection of the rights to intellectual property or lack of it is held by some to be no small impediment to technological development and industrial growth.[4]

14. In most of these countries, proprietary rights to new processes and products of biotechnology involving micro-organisms, cell lines and plants, are

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4. A patent is a form of property right granted by a state in respect of an invention. It is legally enforceable for a specified period of time by its owner against unauthorized exploitation by others. Patent systems are perceived to provide two basic social benefits. First, by giving, for a time, exclusive proprietary rights for an invention to a patentee, the patent system enables the inventor to capture the returns from his investment in the invention and thus provides an incentive to inventive activities. Second, by providing for the disclosure of various technical possibilities to the public, the patent system offers opportunities for the development of such known technological prospects for the benefit of society. The perceived social costs of patent systems arise out of the monopoly power they confer on patent holders in respect of the patented inventions.

protected either under the ordinary patent laws or separate "plant patents" legislation, or both. They are also recognized under the international patent system, including the special international convention regarding patent-like provisions for plant varieties.

15. All patent jurisdictions appear to require that an innovation for which a patent is sought must meet the following criteria to obtain patent protection. It must be new (not known, disclosed or used before). It must involve a genuine inventive step (not be obvious to those skilled in the art). It must be useful and it must fall within a defined class of patentable subject matter (i.e. it must qualify as a "machine", "manufacture", "process" or some similar class). Finally, before a patent is granted, a patent applicant must make a full disclosure of the innovation to the patent authorities for the use of the public.

16. These requirements have been well defined by jurisprudence over the years; for most innovations the application of the patentability criteria present no serious problems. In recent years, however, the subject matter of biotechnical inventions has come to include novel life forms and novel ways of using life processes for practical results and these unique features have presented new and difficult problems in all jurisdictions having to do with the application of the patentability criteria as set out in the patent laws.

17. In the last twenty years there has been considerable progress in resolving these problems. Both the national patent legislation and jurisprudence of many countries and some of the international patent treaties and conventions now contain explicit provisions for the patenting of new biotechnology. These provisions represent major changes in the laws hitherto in effect, whereby patenting of biological inventions was largely confined to processes using metabolic properties of micro-organisms and their results, providing these met the patentability conditions applicable to chemical processes and substances and were allowed for under the statutory provisions for patentable subject matter. One of the major changes was the extension of patent protection to novel micro-organisms as such, including cell lines and cellular material and the processes for their production. Another was the accommodation whereby the traditional requirements for disclosure could be met by depositing the claimed novel micro-organisms in an approved depository. At the international level, the Treaty on the International

Recognition of the Deposit of the Micro-organisms for the Purposes of Patent Procedure (Budapest Treaty of 1977) provided for the designation of certain national depository facilities as international depository authorities available for the purpose of international patenting in biotechnology. These changes in patent laws and practice have occurred in one of two ways. Some were the result of judicial decisions or administrative interpretation of what constitutes patentable subject matter under the existing patent legislation. Others were brought about by explicit statutory changes in the national patent laws and ratification of complementary conventions of the international patent systems.

B. Canada

18. The Canadian *Patent Act* provides that patents may be obtained on "inventions," as defined in Section 2 of the *Patent Act* as follows:

> "invention" means 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.[5]

Thus Section 2 contains three key criteria for deciding whether or not an innovation is patentable (i.e., is an "invention"). It must be new; it must have utility; and it must fall within one of the specified classes of subject matter (i.e., an "art", "process", etc.). These criteria have been developed and refined by the jurisprudence.

19. Perhaps it should be pointed out at the beginning that Canadian patent law parallels that of other industrialized nations in requiring that a genuine inventive step be involved. In other words, the subject matter of the patent application must be sufficiently different from the prior art that its production was not obvious to those of ordinary skills in the pertinent field.

20. In order to comply with novelty requirements, the invention for which a patent is being sought must not have been known or used by any other person before

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5. Adopted from a similar provision in Section 101 of the U.S. *Patent Act* (Title 35 of the *U.S. Code*).

the inventor invented it; described in any patent or application; in public use or sale for more than two years prior to the patent application in Canada. The Canadian approach differs from that in other countries where patents are granted and patent conflicts resolved by reference to the date of filing the patent claim (first to file system). In Canada and the United States patents are granted and conflicts resolved on the basis of first to invent. Moreover in allowing for a two years' grace period, Canada departs from the norm. Most countries require absolute novelty. The United States allows a one year's grace period.

21. Over the years, the types of biotechnology which qualify as "arts", "processes", "machines", etc. have become more clearly defined. Under the Canadian *Patent Act* as administered to date, new and useful processes employing micro-organisms and their products have been considered patentable subject matter and routinely granted Canadian patents for many years. Since the Patent Commissioner's decision in the Abitibi application, Canadian patents are also available for certain new and useful micro-organisms per se and for processes for making them. Indeed the September 1982 amendment to the *Manual of Patent Office Practice* explicitly states:

> In a decision dated March 18, 1982 (in *re Abitibi)* the Commissioner of Patents has indicated that inventions for new microbial life forms such as bacteria, yeasts, molds, fungi, actinomycetes, algae, cell lines, viruses, protozoa and processes for preparing them may be patentable. To be patentable, such inventions must relate to new man-made life forms which previously did not exist in nature; they must be reproduceable by others by the method used by the inventor or from publicly available culture collections; and they must satisfy the other requirements of the *Patent Act*. Processes which utilize microbial life forms may also be patentable if they meet the usual requirements of a patentable process.

22. Still not considered patentable subject matter and thus not eligible for Canadian patents are certain "agricultural processes and products thereof."

It has been held that certain agricultural processes such as those for soil treatment, plant growing or crop rotation are not patentable because they do not constitute "manners of manufacture." Also mentioned in this connection are processes pertaining to "animal husbandry, poultry care and similar farming procedures."[6] Similarly, to be patentable, an end product must be the result of a "manner of manufacture and these requirements have not been thought to apply to plants."

23. The judicial precedents to which this exclusion refers are presumably those mentioned in the PAB finding in the Etsuo Naito case rendered in 1979.[7] They consist of a series of British court decisions which date from 1935 to 1958. Judicial decisions handed down since that time indicate that a broader concept of "manner of manufacture," encompassing some agricultural inventions, may have been adopted. The 1961 judgement of the High Court of Australia, for example, has ruled in the N.R.D.C.[8] case that the claimed method of preparing a particular chemical and spraying it on specified crops to destroy weeds is a "manner of new manufacture" and explicitly stated that "...the fact that the relevance of the process is to agricultural and horticultural enterprises does not itself supply or support any consideration ... for denying that the process is a patentable invention." Similar reasoning appears to have prevailed in the 1961 judgement of the Supreme Court of New Zealand in *Swift and Co.'s Application* for a method of tenderizing meat by injecting enzymes into the animal before slaughtering. Furthermore in 1962 the High Court of Justice, Queen's Bench Division, quashed the decision of the Patent Appeal Tribunal which denied Swift and Co.'s patent in Britain.[9] In all three cases the determining criteria were whether the process involved was "man-controlled" and whether the product involved was "the inevitable result of natural process." The N.R.D.C. decision, for example, distinguishes between horticultural processes where the result is an

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6. 107 *Canadian Patent Office Record*, August 7, 1979, p. IV.

7. *Ibid.*

8. National Research Development Corporation [*N.R.D.C.* (1961) RPC 134].

9. *Swift and Co.'s Application* (1962) RPC 37.

"inevitable result of that which is inherent in the plant," and processes involving micro-organisms which are held to be "analogous to a chemical process."

24. As mentioned above, Section 2 of the *Patent Act* requires that a patentable innovation be useful. Generally this requirement presents no special problem for biotechnology. However, the notion of utility under the *Patent Act* has some significance for agricultural products and processes. The *Canadian Manual of Patent Office Practice* states that "utility, as related to inventions, means industrial value" and that for an innovation to be patentable it must have "practical application in industry, trade or commerce." Unlike some other jurisdictions, the Canadian law does not state explicitly that industry includes agriculture, so that the extent to which agricultural innovations may be held to have "industrial value" as required by the Act is not clear.

25. The Manual also states that processes for producing new genetic strains or varieties of plants or animals or their products are not patentable. This exclusion does not include micro-biological processes or their products.[10] In fact the "natural" (or "essentially biological", in European Patent Convention, or EPC terminology) processes for producing new varieties of plants (or animals, for that matter) -- i.e., processes involving the natural mutation and ensuing selection that occurs in the traditional breeding practice -- are considered unpatentable in all of the patent jurisdictions studied. Now however, there are micro-biological processes available to produce new varieties of plants and the advent of genetic engineering enables one to artificially transfer genes in a more directly controlled manner than in the natural breeding processes;[11] it may also permit the transfer to plants of useful genes not found in any plant species. It is not clear whether these micro-

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10. *Manual of Patent Office Practice*, Section 12-03-1.

11. According to *Business Intelligence Program of Fall 1984*, a report (No. 707) published by a consulting firm, SRI International, "Agrigenetics has acquired from Oregon State University the rights for the isolation, cloning and transfer of a part of the hydrogen-uptake (HUP) genes using a DNA technique. HUP genes, which strains of Rhibozium contain, regulate the plant's intake and recycling of hydrogen."

biological processes could receive Canadian patents or whether the products of these processes, e.g. new plants, could be protected by product-by-process patent.

26. In Canada, as in the other patent jurisdictions studied, discoveries are not patentable. This rule applies in biotechnology as in other fields of technology. For example the Patent Appeal Board (PAB), which reviewed the Abitibi application prior to the Patent Commissioner's decision on the matter, stated that the organism, to be claimed, should not have existed previously in nature, for in that event the "inventor" did not create it and his "invention is old." The September 1982 amendment to the *Manual of Patent Office Practice* which followed the Abitibi decision affirms that products found in nature are not patentable and that "to be patentable [such] inventions must relate to new man-made life forms which did not exist in nature." The rule has proved difficult to apply to biotechnology, however, where it can be difficult to determine whether living matter which is the subject matter of a patent application is simply a product of nature (i.e. a mere discovery and not patentable) or whether it can be said to be essentially man-created. The Patent Commissioner approved the application in *Abitibi*, yet that case involved a known biological culture from samples containing known species of yeast. An important basis for allowing it to be patented was the fact that the claimed organisms differed from those "found in nature." In effect what mattered was not that the subject matter was known to have existed in nature but that in the claimed form or state it was no longer "as found in nature;" it contained properties not previously known. In light of the language of *Abitibi*, the distinction between non-patentable discoveries and patentable inventions involving living matter still appears to be somewhat vague in Canada.

27. The PAB's review in the Abitibi application also raised the possibility of product patents for new plants *per se* (and animals, for that matter) but gave no opinion upon this issue. The Board suggested that it might not be illogical to extend the patent protection given to certain micro-organisms to higher forms of life (e.g. plants, insects and animals), declaring that it "can see no justifiable reason for distinguishing between these life forms when deciding the question of patentable subject matter." Whether the patentable subject matter reaches "up to higher life forms -- plants (in the popular sense) or animals

-- is more debatable." This is largely because it is less likely that the inventor will be able to reproduce the particular higher form of life at will and consistently. "But if it eventually becomes possible to achieve such a result, and other requirements of patentability are met [the Board] do not see why it should be treated differently." Some of the biotechnological processes, e.g. those involving genetic engineering, can accomplish just that. On that basis there is no reason why the Patent Commissioner, at the next opportunity, should not declare that such "not essentially biological" processes for producing new plants and the plants produced thereby are patentable subject matter under the *Patent Act*.

28. The statutory conditions for patent grants include the provisions for disclosure which, as given in Section 36 of the *Patent Act* require that the claimed invention be described in such a manner as to enable others to repeat and use it. In Canada and elsewhere these traditional requirements for disclosure were found to need adjustment to accommodate the unique features of an invention in the field of biotechnology. Mere descriptions of its nature may not give a reader what he needs to work the invention or to work it in the best way. The relevant organism may not be available. It may be necessary to isolate it from various sources or to alter its genetic structure and it may not be possible to do this with certainty or to do it as successfully as the inventor did. The resolution of this problem was found in the practice whereby the disclosure requirements could be met by depositing the pertinent organisms in a culture collection either on a voluntary basis or as an official requirement of the patent offices concerned. In most of the countries reviewed in this paper such deposits are now part of the legal requirements for disclosure of inventions involving micro-organisms.

29. Making deposits of micro-organisms in partial fulfilment of the disclosure requirements under Section 36 has been allowed in Canada for process claims for more than twenty years. The Abitibi decision sanctioned the use of culture deposit in making the required disclosure on claims for patentable micro-organisms *per se*. One of the PAB's conclusions in that case was that the deposition of a sample of the claimed living matter should meet both the specification and the disclosure requirements of Section 36 of the *Patent Act* and that, when possible, both the written description and the sample deposition should be used. The

Patent Office practice in this matter is that either written description or deposit of a sample will qualify when the claim is for micro-organisms *per se*. Such samples may be deposited in a recognized collection either in Canada or abroad by the time the patent application is filed and must remain on deposit at least for the life of the patent; they must be available to anyone requesting access after the patent is issued. From the patentee's point of view the main condition is that he must be notified of anyone's obtaining a sample.

C. The European Patent Convention

30. In Western Europe, special provisions for patenting microbiological inventions were agreed upon under the European Patent Convention (EPC) of 1973 and subsequently included in the national laws of the European countries which ratified the Convention and revised their patent laws to conform to its definition of patentable subject matter and other conditions of patentability. In the countries which ratified the EPC the national patents may be obtained either from the EPC's European Patent Office (EPO) or the national patenting authority.

31. Under Article 52 of the Convention, except for certain listed matters which are not considered patentable subject matter (i.e. discoveries, etc.), a European patent may be granted for any invention that is new, involves an inventive step and is susceptible of industrial application. The requirement for industrial application is modified by Article 57 which extends it to include agriculture.

32. The patentability of microbiological inventions is explicitly provided for under Article 53(b) whereby European patents are not granted in respect of:

> Plants or animal varieties or essentially biological processes for the production of plants or animals; *this provision does not apply to microbiological processes or the product thereof* (emphasis added).

33. This wording of the substantive law on patents in microbiology removes microbiology from the field of biology so that for the purposes of patent laws harmonized with EPC, micro-organisms are not regarded as plants (or animals). It also reflects the view first embodied in the pertinent provisions of the Convention on the Unification of Certain Points of Substantive Law on Patents of 1963 (Strasbourg Conven-

tion) to the effect that protection of plant and animal varieties should be provided under legislation other than the patent laws.

34. It should be noted that the provisions in Article 53(b) of the EPC, which allow for patenting of microbiological processes or products, apply not only to processes using the metabolic properties of the micro-organisms and their products (which were previously patentable) but also to processes for modifying micro-organisms by way of the selection and induced mutation as well as by the new genetic manipulation techniques. Moreover, they apply to the micro-organisms *per se*, including those isolated from soil samples.

35. Indeed, as noted in the *Guidelines for Examination in the European Patent Office* (Part C, Chap. IV, Section 3.5):

> ... The term microbiological process is to be interpreted as covering not only industrial processes using micro-organisms but also processes for producing new micro-organisms e.g. by genetic engineering. The product of microbiological processes may also be patentable per se (product claim). Propagation of the micro-organisms itself is to be construed as a microbiological process for the purposes of Article 53(b); consequently, the micro-organism can be protected per se as it is a product obtained by a microbiological process ... The term micro-organism covers plasmids and viruses."

36. Under the EPO Guidelines, a patentable invention must have a "technical character," it must relate to a technical field, it must be connected to a technical problem and have technical features. Furthermore,

> [the] requirement of "technical character" may be decisive in determining whether or not an invention is excluded from patentability under Article 52(1) and 53(b).

It may be noted that both articles list exclusions to patentability: 52(1) refers to discoveries, etc., 53(b) to plants and animals and the biological processes for their production.

37. In the EPC, as in all patent jurisdictions, mere discoveries are not patentable (Article 52). The

EPO Guidelines elaborate on this concept of discoveries, stating : "If man finds out a new property of a known material or article, that is mere discovery and unpatentable. If, however, a man puts that property to practical use he has made an intervention which may be patentable .... To find a substance in nature is also a mere discovery and therefore unpatentable. However, if a substance is found in nature and a process for obtaining it is developed, that process is patentable, as is the substance when produced by that process. Moreover, if the product can be properly characterized without reference to the process by which it is obtained and it is "new" in the absolute sense of having no previously recognized existence, the product per se may be patentable."

38. Article 83 of the EPC requires that inventions be disclosed in such a way as to allow those skilled in the art to reproduce them by themselves. The statutory regulations on this matter, Rules 28 and 28(a)[12] recognize certain unique difficulties with inventions involving living matter when it comes to complying with the disclosure requirements appropriate for patenting in the inanimate universe. They provide that in the case of patentable inventions in the field of biotechnology, the disclosure requirements may be met by deposits of the micro-organisms involved. Section 3.6 of the EPO Guidelines states:

> In the case of microbiological processes, particular regard should be had to the requirements of repeatability ... As for micro-organisms deposited under the terms of Rule 28, repeatability is assured by the possibility of taking samples (Rule 28(3)) and there is thus no need to indicate another process for production of the micro-organisms.

D. European States

39. The EPC definition of patentable subject matter including the exclusions areas are, as of the time of preparation of this paper, incorporated in the revised national patent laws of the United Kingdom, West Germany, France, Italy, the Netherlands and Sweden. There were some harmonizing amendments to the Swiss patent law of 1954 and revisions of the Austrian,

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12. These rules deal with arrangements for deposits of micro-organisms involved in patent claims and access to them.

Belgian, Irish, Norwegian and Finnish patent laws along the lines of the EPC provisions are pending.

40. In the United Kingdom, even under the *Patent Act* of 1949, the Patent Office was accepting claims to microbiologically produced compounds, micro-organisms per se, processes for producing mutants and the mutants so produced. The *Patent Act* of 1977 not only provides the legal basis for this practice but, among other things, establishes statutory requirements for its implementation along the lines envisaged by the provisions and regulations of the EPC. It also empowers the Minister responsible for its administration to vary exceptions to patentability "... for the purpose of maintaining them in conformity with developments in science and technology."

41. It may be of interest to note that in West Germany (under the *Federal Patent Act* of 1981) and France (Law No. 78-742 of July 13, 1978), in a departure from the EPC exclusion concerning plant and animal varieties, plant varieties are unpatentable only with respect to those which are protected under separate national laws.

42. In West Germany, the views of the Federal Supreme Court of what constitutes sufficient disclosure differ from those of the EPC under which the deposit of the micro-organism involved in the patent claim is considered adequate. According to West German case law (the Federal Supreme Court's decision in a number of cases), if the application seeks protection for a micro-organism *per se*, the mere deposit of the organism is not sufficient to satisfy the requirement for disclosure. "Indeed, patent protection for a new micro-organism is allowable but only if the inventor shows a reproductible way to produce the new micro-organism."[13]

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13. *Patent Protection in Biotechnology: An International Review*, OECD, SPT (84) 12, July 6, 1984, p. 19. It may be noted that the Court's requirement is no doubt intended to ensure that the aim of contributing to the state of the art by fully disclosing the invention is actually realized. Such a strict view of the law, however, makes it extremely difficult, if not impossible, to patent new strains of micro-organisms resulting from a chance mutation or isolated from soil and other sources. It is also questioned on a number of other grounds.

43. It should of course be pointed out, that the German Federal Supreme Court also held (in *Rote Taube)* that "it is not only permissible but, according to the character of the patent law, even imperative" to interpret the term "invention" in the light of actual scientific knowledge. This philosophy, plus the entry into force of the *Federal Patent Act 1981* which includes patentability conditions as found in the EPC and the Budapest Treaty, may well lead to a reconsideration of the Court's position.

44. In Sweden, in addition to microbiological processes and their products, product claims for foodstuffs and pharmaceuticals as well as new chemical products are now patentable for the first time, without restriction to a particular use. Microbiological processes and their products, as well as pharmaceuticals are also patentable for the first time in Italy (Law No. 338 of June 22, 1979).

E. Japan

45. The national patent legislation in Japan does not contain explicit provisions for patenting inventions in biotechnology including micro-organisms per se. Nevertheless under Japanese administrative decisions, the existing statutory definitions of patentable subject matter have come to be interpreted in such a way as to extend patent protection to novel micro-organisms developed as the result of advances in biotechnology.

46. Arrangements for patenting micro-organisms, cell lines and related processes in Japan have been in effect since 1975. These include (translation) "Examination Standards for the Micro-organism Industry" published by the Japanese Patent Office in 1975 and the (translation) "Procedures for Deposit of Micro-organisms in Japan" established in 1979. It should be added that in 1980 Japan also acceded to the Budapest Treaty of 1977. The Japanese patents available for biotechnology and the patenting procedures employed parallel those of the United States and the EPC countries. Plant varieties may be patented in Japan either under the *Patent Law* or protected under separate *Agricultural Seeds and Seedling Law* as revised in 1978.

F. The United States

47. As in Japan, patent legislation in the United States does not contain explicit provisions for patenting biotechnology. However, the existing legislation has been interpreted to cover novel micro-organisms. In *re: Chakrabarty*,[14] decided in 1980 (patent issued in 1981), the U.S. Supreme Court ruled for the first time that claims to compositions of living matter such as the bacterium produced by the respondent constitute statutory subject matter under the provisions of Section 101 of the U.S. *Patent Act* (Title 35 of the *U.S. Code)*.

This clause defines patentable subject matter as follows:

> Whoever invents or discovers any new and useful process, machine, *manufacture or composition of matter*, or any new useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title. (Emphasis added to show the Court's view that micro-organisms may be considered as "manufacture" or "composition of matter.")

48. The question of whether biologically pure cultures of micro-organisms found in nature are patentable in the United States appeared in *re: Bergy* and for a brief time remained unresolved. After the Chakrabarty decision, however, the Patent and Trademarks Office (PTO) issued administrative guidelines for claims directed to composition of matter involving micro-organisms, including claims of the type involved in the Bergy case. These guidelines state that the PTO considers "that the production of articles for use from new materials prepared by giving to these materials new forms, qualities, properties or combinations whether by hand, labor or machinery is a manufacture under section 101." Since then the PTO has granted numerous patents claiming various biologically purified cultures.

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14. It may be of interest to note that the Chakrabarty patent in the United Kingdom was granted on May 19, 1976 when the *Patent Act* of 1949 was still in effect.

V PLANT VARIETY PROTECTION IN CANADA AND SELECTED INDUSTRIAL COUNTRIES

A. Introduction

49. In order to support plant breeding as a vital economic activity governments of many countries have either allowed for patenting new varieties of plants under their ordinary patent laws or, far more often, provided patent-like protection of proprietary rights to them under separate "plant breeders rights" laws.

50. In comparison to that available under ordinary patent laws, the protection for new plant varieties provided under the plant breeders' rights laws is much narrower and the conditions for obtaining it (including procedures) are considerably different.

51. In terms of the scope of patentable subject matter, the protection offered under plant breeders' rights is confined to claims to new varieties of plants. It does not include the processes for their generation. It also does not cover new species of plants. Unlike under the patent laws, the claimed varieties may, however, include plants "as found in the wild." Under the patent laws the patentee of a new plant obtains exclusive right to reproduce, sell or use his "invention." In the case of a plant protected under the plant breeders' rights laws the rights granted are restricted to the control of commercial exploitation of reproductive materials only, such as seeds for growing, cuttings for planting, etc. as opposed to "consumption" material such as grain for milling or vegetables, etc., used as food or industrial material. Plant breeders' rights laws do not apply to the use of seeds saved from current crops for subsequent sowing or reproduction and propagation of plants of the protected variety for pleasure. They consist of two categories of rights: a) the basic or fundamental rights which give the plant breeder the exclusive right to sell (and to authorize others to sell) the reproductive material of the protected variety and to produce that material for the purpose of sale; and b) in the case of ornamental plants, of secondary breeders' rights. The latter provide, in addition, that the holder shall have the exclusive right to use commercially, for the production of ornamental plants or cut flowers, such plants or parts thereof which are normally commercialized for purposes other than propagation.

52. The conditions for obtaining proprietary rights under plant breeders' rights laws are also different in some important respects from those of the patent laws. Under the patent laws an organism must, among other things, be a) new, in the sense that it did not exist in the claimed form in nature; and b) non-obvious, that is, sufficiently different from known species in that its creation involved the necessary inventive step. The plant breeders' rights laws, on the other hand, require that the claimed variety be new in the sense that it has not been sold before contrary to legislation. It must also be *distinct* in one or more characteristics from other known varieties; *uniform*, which means that apart from a limited number of divergencies, individual plants must be identical in all their essential characteristics; and *stable*, that is, each plant must remain sufficiently true to its description when multiplied through such numbers of generations as necessary to produce seeds for commerce. There is no requirement for an inventive step and the proprietary rights may also be claimed for mere discovery of a new variety. Each claimed variety must have its varietal name and be registered under that name in the records listing "patented" varieties.

53. The global trend toward plant "patents" is reflected in the International Convention for the Protection of New Varieties of Plants. The Convention was negotiated at the initiative of France in 1961, came into force in 1968 and was revised in 1972 and 1978. The states to which this Convention applies constitute the Union for the Protection of New Varieties of Plants (UPOV). At this time, the Union comprises 17 states.[15] The Convention applies to all botanical genera and species and defines the minimum requirements and conditions for granting plant breeders' rights and the substance of such rights within their minimum scope. These rights must be provided for in the national legislation so that those rights could be recognized by the Members of the Union.

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15. Belgium, Denmark, France, the Federal Republic of Germany, Israel, Italy, the Netherlands, Spain, South Africa, Sweden, Switzerland, the United Kingdom, Japan, New Zealand, the United States, Ireland and Hungary.

B. Canada

54. Canada has no plant breeders' rights legislation at present. However a Plant Breeders' Rights Bill (Bill C-32) with provisions along the lines discussed above, and conforming to the provisions of the International Convention for the Protection of New Varieties of Plants, should Canada decide to ratify it (Canada already signed this Convention, in 1981), was introduced in Parliament in May 1980, but was never enacted.[16] The Minister of Agriculture has indicated his intention to introduce a new Plant Breeders' Rights Bill in the near future. The legislation will protect new varieties of plants designated by regulations and will grant breeders rights to control the commercial exploitation of the reproductive material of the protected varieties.

C. European States

55. Arrangements for protecting plant breeders' rights by way of legislation other than patent laws were adopted in the sixties and seventies by a number of Western European countries (and others). In Western Europe they are exemplified in a complex of national "patent" systems and certification procedures such as those established under the British *Plant Varieties and Seeds Act* of 1964 (Part 1), the West German *Law on the Protection of Plant Varieties* of 1968 as revised and in effect on January 4, 1977, the French *Law on the Protection of New Plant Varieties* (No. 70-489) of June 11, 1970, as well as similar legislation in Belgium, Switzerland, the Netherlands, Denmark, Sweden and Ireland.[17]

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16. The Provisions in Bill C-32 are reviewed in more detail in *Plant Breeders' Rights: Some Economic Considerations*. Preliminary Report, Pamela Cooper, Agriculture Canada, March 1984.

17. As noted in *Patent Protection in Biotechnology* p. 73: "Italy is unusual in the entire group of European countries in that it has opted for the patent law as the only means of protecting new plant varieties. [Since] Italy has ratified the European Patent Convention, therefore, its national law presents an anomalous position with regard to EPC Article 53(b)."

56. Plant breeders' rights in those countries are available to whoever breeds or discovers a plant variety; being any culture, class, line, stock or hydrid, whatever the origin, whether artificial or natural, of the variation from which it resulted, provided the variety for which the protection is being sought belongs to a species or group of species to which the relevant law has been extended. In France and West Germany, as noted before, plants not protected under plant breeders' rights law can be protected under ordinary patent law. In the United Kingdom, for example, the application of the 1964 Act is progressively extended by specific regulations. By 1980, these regulations covered more than 350 operational schemes, each covering the protection provided to a species or other convenient group of plants. It should be noted that (as indicated by the German court) the "discovery" referred to above can be of a plant growing in the wild or occurring as a genetic variant, whether artificially induced or not.

D. Japan

57. In Japan, the development of a new variety of plant was formally recognized as an invention under the revised *Patent Law* in effect from January 1, 1976. The related (translation) "Examination Standards for New Variety of Plants" permits patenting an invention of the variety of plant per se "produced by means of breeding" regardless of the manner of the plant's reproduction, as well as patents for the invention of the method for breeding the variety of plant "produced by means of breeding." The term "produced by means of breeding" is said to mean "bred" or "created." Subsequently new plant varieties have also become protectable under the plant breeders' rights type of legislation, namely, the *Agricultural Seeds and Seedlings Law*, revised in 1978.

E. The United States

58. In the United States specific provisions for plant patents were enacted by the Patent Law Amendment (Plant Patent Act) of 1930. In their current version they are contained in the *U.S. Code*, Title 35, Chapter 15, Sections 161-164, and provide that a patent may be granted to whoever invents or discovers and *asexually* reproduces any distinct and new variety of plant,[18]

18. For the purposes of this law the term "plant" includes fungi but does not include bacteria.

including cultivated spores, mutants, hybrids, and newly found seedlings, other than a tuber-propagated plant or a plant in an uncultivated state. Section 162 states that the claim in the specification shall be, in formal terms, for the plant shown and described. The plant patent granted gives "the right to exclude others from asexually reproducing the plant or selling or using the plant so reproduced for the term of 17 years from the date of issue."

59. The protection for sexually reproduced plant varieties is provided by the *Plant Variety Protection Act* of 1970, as revised in 1980. Expressly excluded from protection under this legislation are "fungi, bacteria or first-generation hybrids." The Act provides for a specialized review procedure and awards of "Certificates of Plant Variety Protection" with effective meaning of a patent for up to 18 years (from the date of issue) to a protectable variety defined by its distinctness, uniformity and stability (d.u.s.). Since hybrids are not stable they are not "patentable." Effective protection for hybrids however, is provided by allowing for control of the direct use of "patentable" inbred lines in the production of hybrids. The legislation explicitly limits the rights of certificate holders to those needed to prevent unauthorized sale of the protected seed for seed purposes or for use in producing hybrids.

VI PROTECTION FOR BIOTECHNOLOGY IN CANADA: THE ISSUES

A. Introduction

60. There appear to be three major issues surrounding protection for biotechnology in Canada. One concerns the degree of uncertainty as to just what protection is provided for various types of biotechnology under the *Patent Act* in Canada. A second issue, related to the question of uncertainty, is whether the scope of protection, so far as it can be determined, is appropriate. The third major issue concerns the interrelationship between patent (the *Patent Act)* and plant breeders' rights legislation (under consideration). Assuming a Plant Breeder's Rights Act (PBRA) is enacted, could the two pieces of legislation be expected to work together in harmony or would additional and specific legislative delimitation of their respective fields of operation be required? In addition there are a number of minor technical issues

regarding the working of the *Patent Act* in the area of biotechnology.

B. Uncertainty

61. There is substantial uncertainty in Canadian patent law as it applies to biotechnology.

First, the bounds of patentable subject matter in this area are not clear. For one thing, the status of products of nature remains uncertain. As indicated above, the Abitibi decision and ensuing guidelines in the *Manual of Patent Office Practice* have not cleared up this matter, since on the one hand they appear to deny the patentability of organisms which previously existed in nature, while on the other hand *Abitibi* itself found in favor of a known biological culture containing known organisms. Also, the patentability of plants remains uncertain in some respects. As previously noted, while the Patent Office excludes processes for the production of new genetic strains or varieties of plants and animals from patentability, the exclusion does not include microbiological processes or their products. It may well be that a new variety of a plant could be protected under the *Patent Act* by way of a product-by-process patent where the plant is the product of a patentable microbiological process or genetic engineering technique. This possibility has not yet been tested. *Abitibi* simply raised the possibility of plant patentability, leaving the question unanswered.

Second, there is uncertainty about the disclosure requirements for biotechnology inventions under Canadian patent law. Despite the existence of Patent Office procedures and practices respecting disclosure and deposit of samples, it is by no means clear whether and in what circumstances such deposits are optional or mandatory and whether only organisms which otherwise would not be obtainable need be deposited and held available to the public (after the patent grant). This is what is required under the EPC and the national patent laws of various countries.

Third, *Abitibi*, which provides the basis for the current presumptions as to what Canadian patent law is in the biotechnology area, does not positively affirm the patentability of the microbial culture involved. Rather, the PAB in its review would go only so far as to say that the subject matter of the application was not clearly unpatentable, stating, "We can no longer be satisfied that at law a patent for a micro-organism or

other life form would not be held allowable by our own courts." In effect, the Patent Commissioner, in accepting the PAB's recommendation, said that the claim involved might actually be invalid, but that he was not sure that it was and that therefore he was obliged to allow it.[19]

Fourth, the authority of the Abitibi decision is itself subject to doubt. Until its declaration that a) certain forms of life and processes to produce them are patentable subject matter and b) that deposits of cultures of the claimed organisms constitute sufficient disclosure are confirmed by the courts, the validity of patents granted under it appears uncertain.

Thus the scope of patentable subject matter is not clear. At this time, as indicated in the recent amendments to the Canadian *Manual of Patent Office Practice*, only claims for man-modified life forms specifically listed in the Abitibi ruling may be patented. Even then it is not at all certain that such patents will prove to be valid.

C. The Scope of Protection for Biotechnology

62. Apart from the question of uncertainty, there is some concern that, even after *Abitibi*, the scope of protection provided by Canadian patent law is less comprehensive than in other patent jurisdictions, in particular for agricultural products and processes. This concern is based partly on the fact that the Canadian patent law concept of utility (in the sense of utility in industry) does not explicitly include agriculture, in contrast to the EPC and European states individually. The result may be a narrower scope for agricultural products and processes in Canada than in

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19. The form the Patent Commissioner's decision took in *Abitibi* was in large part dictated by Section 42 of the Patent Act, which reads:

> 42. Whenever the Commissioner is satisfied that the applicant is not by law entitled to be granted a patent he shall refuse the application and, by registered letter addressed to the applicant or his registered agent, notify the applicant of such refusal and of the ground or reason therefor.

Europe.[20] In addition, U.S. and Japanese patents are being issued for new types of agricultural processes resulting from man's increasing ability to intervene in "natural" biological processes. Instead of growing plants from seeds or roots, for example, such cellular techniques as tissue culturing allow whole plants to grow from either excised plant tissue or single cells. These techniques are receiving process patents. In some instances these processes are being exploited for producing secondary metabolites such as in perfumes and flavours or dyes (e.g. a red dye, shikonin, produced by Mitsui Petrochemical Industries in Japan). In other instances they are used for the propagation of plants (e.g. orchids under U.S. Patent No 3514900 or clonal multiplication of hybrid seeds of certain plants patented in 1982 by Agrigenetics Research Associates of Denver, Colorado). The exploitation of some of the recent advances in biotechnology also results in methods for using micro-organisms to combat plant pests or soil-borne diseases. In Canada such "not essentially biological" processes may be denied patents because they relate to agriculture.

63. The uncertainty about disclosure requirements in Canada has been mentioned. Another issue respecting disclosure is related to the scope of protection given to patentees. It involves disclosure by deposit of samples and concerns public freedom of access to these deposits. Upon the patent grant Canada as well as all the reviewed patent jurisdictions provide for free access to deposits of patented micro-organisms. Such free acess is still a contentious issue and is objected to. It is pointed out that in the case of inventions involving micro-organisms, in releasing them to third parties the inventor is giving away much more than in any other invention. He gives away a ready working, complete "factory" and cannot control what is done with it from that point on. In genetically engineered strains the "know-how" contained in a deposit is not limited to structural gene coding for a specific product but includes also DNA sequences regulating the expression of the gene. The latter are often of great practical value and may be used for the expression of various structural genes. Yet another question that

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20. It has been argued, however, that while the concept of utility is not explicitly defined in the Canadian *Patent Act*, there is no explicit exclusion of agricultural innovations either, and that these innovations can expect to receive the same treatment as other types of innovations in Canada.

has been raised in this connection is whether such deposits should be freely available to, say, "patent free" countries. In Germany, Japan and under EPC there are prohibitions on such "exports" and restrictions on unauthorized reproduction (sub-culturing, i.e. mutating). Perhaps these issues should also be considered in Canada.

D. The Patent Act: Technical Issues

64. Questions have been raised concerning the two-year grace period after the publication of an invention during which inventors can apply for a Canadian patent. There are conflicting views as to whether the existence of a grace period is beneficial to Canada. On one hand, its existence should help to alleviate many of the problems which arise in the university sector with regard to dissemination of biotechnological knowledge, but it may also cause problems to Canadian inventors wishing to pursue an international patenting strategy. Indeed, Canadians have, at times, found that while they could obtain patents in Canada, they could not do so in other countries where novelty requirements are stricter. The OECD observation on this problem is that its resolution is "...quite simply a matter of education. Any proposals to do away with such provisions as is being mooted in Canada, may be an over-reaction to a problem which can be cured in other ways. The European Patent Convention reflects the official thought of the 1960s as to the kind of law best suited to industrial needs. It took little account of the academic inventor."[21] Of course, this issue has relevance for all types of inventions, including biotechnology inventions.

65. Questions have also been raised about the impact of Section 41 of the *Patent Act* on biotechnology. It should be noted that the present Canadian provisions for patenting in biotechnology may well be qualified by the fact that many products of biotechnological processes are intended for food or medicine and thus come under Section 41. Subsection 41(1) of the Act provides that in the case of a substance prepared or produced by a chemical process and intended for food or medicine, the substance itself shall not be claimed except when prepared by the method or process of manufacture particularly described and

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21. *Patent Protection in Biotechnology*, p. 47.

claimed or by its obvious chemical equivalent.[22] In effect, while some of the organisms or their products may be patented as products *per se*, others may be granted patents only if they result from a patented process. Perhaps the need to retain this restriction should be examined. To the extent that they are intended or capable of being used for medicine, biotechnological inventions are also subject to compulsory licensing provided for under Section 41(4) of the *Patent Act*. These provisions are now under review.

E. The Relationship between the Patent Act and the Plant Breeders' Rights Act

66. An important issue surrounding the protection of plants and plant parts concerns the interface between patent and plant breeders rights legislation. On one side there is the emerging view, given voice in *Abitibi*, that the Canadian *Patent Act* in its present form, does not rule out the possibility of patenting new plants (or animals for that matter), although, as has been indicated, the current Patent Office practice is to deny applications for patents on processes to produce the plant parts or the plants themselves. Moreover, this practice is reflected elsewhere. Further, even in France, Germany and Japan where some or any novel plants may receive full patent rights under the same conditions as any other biological inventions, the experience is that the number of claims submitted and patents granted are quite insignificant as compared to those under the special plant breeders' laws. The patent authorities in all three countries are of the view that the requirements for patent grants under ordinary patent laws are too demanding to be readily met by traditional plant breeders. However they do not consider them unsuitable for patentable plants produced by genetic engineers.

67. On the other side, a Plant Breeders' Rights Act would provide clear protection for plant varieties, albeit of a special type designed and adopted for plant breeders when the only method of producing new

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22. Whether biotechnological processes are equivalent to chemical processes referred to in Section 41 is not certain. Some judicial precedents suggest that biotechnological processes are not chemical processes within the meaning of Section 41, while others have held biotechnological processes to be chemical processes within that section.

varieties of plants was by way of "natural" biological processes, which to this day are not considered patentable. (It should be noted that although new and faster methods of producing new varieties, or even species, of plants are becoming available through biotechnology, these will become powerful adjuncts to but not replace the traditional breeding practices).

68. The rights granted under the plant breeders' rights legislation are much more restricted than those under the traditional patent laws and take account of the interests of the farmers and traditional plant breeders. The conditions for obtaining protection under the plant variety protection legislation are significantly different from those under the traditional patent laws, which, as the experience of certain countries indicates, cannot be readily complied with by the traditional plant breeders. This raises the possibility that an extension of Patent Act coverage to plants, however unlikely, could lead to a displacement of plant breeders' rights legislation. The question arises whether a clear demarcation should be established between plant innovations covered by each type of legislation, in effect ensuring a specific field of coverage for plant breeders' rights legislation.

69. The problem of the relationship between the *Patent Act* and plant breeders' rights legislation arises in connection with the protection of plant parts *per se* as well as whole plants. The Plant Breeders' Rights Act would grant proprietary rights to the "propagating material" of the protected variety, e.g. seeds for sowing, cuttings for planting, etc. It is by no means clear it would provide protection for all parts of plants. On the other hand, the more esoteric plant parts such as cells, segments of DNA, plasmids, genes and combinations thereof are eligible for patents under the traditional patent laws, including the Canadian *Patent Act*. A finding that new plants are eligible for patents could lead to patenting of new species of plants (but not many, if any, of the new varieties of existing species, which would be protected under the plant breeders' rights legislation). The following questions could be asked in this context: Should patenting of cell lines or genes, for example, which may be used to develop new plants, be denied? Would the proprietary rights granted under the *Patent Act*, if applied to plants, provide the patent holder with more protection than may be appropriate and acceptable for agriculture in Canada? Again, should a line of demarcation between the coverage of the respective legislation be established, and at what point?

VII POLICY OPTIONS

A. Introduction

70. In the preceding section issues have been raised concerning the adequacy of protection for biotechnology. Taking into account the existing provisions of the *Patent Act*, the Abitibi decision of the Patent Commissioner and the proposed Plant Breeders' Rights Bill, these issues relate to:

a) the degree of uncertainty in Canadian patent law as it applies to biotechnology;

b) the adequacy of the scope of protection provided, given the existing limitation of patentable subject matter and current disclosure requirements; and

c) the degree of compatibility between the *Patent Act* and the proposed Plant Breeders' Rights Act.

71. To address these issues there are two basic options available: (a) the status quo or case law approach and (b) the legislative approach. The first of these leaves it to the administrators of the *Patent Act* and ultimately the courts to establish which biotechnical inventions may be eligible for patents and how such claims may obtain patent grants under the existing provisions of the *Patent Act*. The second envisages asking Parliament to decide and provide accordingly whether and which living matter and processes involving it ought to be considered eligible for patents (or patent-like protection) and what ought to be the terms and conditions under which they may be obtained. Under this approach there are various

courses one may pursue. Both basic approaches and certain options thereunder are discussed below.[23]

B. The Status Quo Approach

72. The first of the basic options is to make no changes to the *Patent Act* and let the law respecting patent claims involving life forms continue to be developed on a case-by-case basis through decisions of the Patent Office, the Commissioner of Patents and the courts. In the immediate future what in biotechnology may be patented in Canada would follow the Abitibi ruling.

73. One advantage of this approach would be its flexibility in allowing patent administrators and the courts to develop the law in response to new and, in many cases, unforeseeable needs as they arise. It would allow the question of which biotechnological inventions may be patentable to be answered over time, and would avoid the drawbacks inherent in imposing a rigid statutory framework in advance of developments and on the basis of anticipated (and in many respects uncertain) future developments. This option would maintain continuity in our patent law and avoid the disruption which accompanies statutory reform and the uncertainty which prevails after the new legislation is brought in, pending its clarification through practice and interpretation. This approach towards the develop-

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23. In order to deal with the question of what level of protection for biotechnology, if any, is appropriate for Canada, it would be well to have a rigorous analysis of costs and benefits of extending or contracting its scope. Such an analysis should take account of the nature of the international patent system, in particular the fact that it operates, for the most part, on the principle of national treatment as opposed to the principle of reciprocity; of Canada's position as a country in which technology is largely imported and of the impact of the perceived "climate" for doing research in Canada on the attitudes and actions of potential innovating companies and other inventors and innovators. Such a complex assessment was beyond the scope of this paper. The discussion which follows shall confine itself to outlining in brief the basic options available and suggesting the major advantages and disadvantages of each without any attempt at quantification.

ment of our patent law is certainly valid and generally applicable whatever categories of inventions may be involved. Can Canada afford to let this process take its course in the matter of patenting in biotechnology, however?

74. In the particular case of patenting life forms, the "disruption" is already an accomplished fact in the form of the historic decision in the Abitibi appeal and the proposed Plant Breeders' Rights Bill. It is this very element of uncertainty that is the dominant negative factor in the present situation. Only an early judicial or statutory declaration on the patentability of living matter and the passage of the Plant Breeders' Rights Bill could change the present state of affairs. The Patent Office or the Commissioner of Patents can alter their views on the patentability of particular classes of subject matter fairly quickly in response to new developments; but it may take a long time before such administrative rulings are either confirmed or rejected by the courts.

75. In addition to its unpredictable nature in terms of time and outcome, another important disadvantage of the status quo or case law approach is that the labour and cost of clarifying our patent law would fall on the inventors, who in many cases can hardly afford it. Only institutional inventors (e.g. General Electric in the Chakrabarty case) are likely to have sufficient funds to undertake the necessary litigation and will do so only in cases of commercially important and readily exploited inventions. Uncertain validity of Canadian patents in biotechnology may induce some inventors to protect their proprietary rights via the trade secret route and the resulting lack of public disclosure of the particular invention may not best serve the public interest. These circumstances may also tip the scale in favour of patenting abroad rather than in Canada.

76. It should also be pointed out that the case law approach may result in rulings that could adversely affect the proposed plant breeders' rights legislation. If protection under the *Patent Act* is extended to cover new varieties of plants, it would not only overlap the coverage provided for under the proposed Plant Breeders' Rights Bill, but also create the situation in which the protection available to some plant breeders would be greater than that obtainable under the proposed PBR Act and acceptable in the interest of Canadian agriculture. Judging from the objections raised in connection with the PBR Bill it is very like-

ly that such a ruling would not remain unchallenged and the resolution of the issue may well involve prolonged litigation.

C. The Legislative Approach

77. A statutory approach to the resolution of the issue of patenting novel life forms and processes for their generation and exploitation would require changes to the present definition of patentable subject matter (Section 2 of the *Patent Act)* and possibly changes to the disclosure provisions.

Option in Favour of Patenting Life Forms

78. One way to provide a definitive statutory basis for patenting biotechnology in Canada would be to replace the present definition of patentable subject matter with one derived from the EPC and EPC countries. Another way this option could be accommodated is to retain the present definition of a patentable invention, and explicitly indicate within it that the fact that the subject matter of such an invention is, or involves, living matter does not bar it from eligibility for patents.

79. The first solution along the European model was in fact recommended in the 1976 proposals for the revision of the *Patent Act*. With regard to patenting in biotechnology, it would (as done under EPC) refer to plant or animal varieties or essentially biological processes for their production and to microbiological processes and their products, and expressly declare that only the latter are patentable. It should also indicate that inventions eligible for patents are not confined to those "susceptible of industrial application" but also include those exploitable in agriculture.

80. Such a definition of patentable subject matter would remove much of the present uncertainty regarding the limits of patentability for living matter. It would provide clear statutory confirmation of the Abitibi decision and decrease the present obscurity in the administration of the *Patent Act* in the matter of "agricultural" processes. It would also clearly rule out the possibility of obtaining product patents *per se* for new varieties of plants and thus resolve one of the problems of interface between the *Patent Act* and a Plant Breeders' Rights Act. There are, of course, other options for the wording of the European derived definition of patentable subject

matter to allow for the possibility that the proposed PBR legislation may not be passed, or should it be passed, that it may not be advisable that novel plants be also eligible for protection under the patent law.

81. The problems at the interface between the *Patent Act* and plant breeders' rights legislation could be minimized by holding against the patentability of any plants, including those produced by patented processes. (Product-by-process protection does exist under EPC and it is not positively ruled out by the "European" definition of patentable subject matter alone.) Nevertheless, even if no plants were to receive patents, certain problems would still remain between a Plant Breeders' Rights Act and the *Patent Act* under this option. For example, "not essentially biological" processes for producing new plants would remain patentable, opening the way for the control of such plants by the process patent-holder. Also, the genetic material resulting from biotechnological processes for producing plants (e.g. genes, cell lines etc.) would remain patentable. This would mean that if a variety carried a patented gene, it could not be used as a parent in further breeding without the permission of the gene's patent holder. To prevent the encroachment of the *Patent Act* on subject matter intended to be governed by the Plant Breeders' Rights Act, it might be necessary to deny patentability to these types of processes and products. The UPOV Convention (Section 5, paragraph 3) prohibits the restriction of a variety for further breeding. (It must be noted that the above and other problems between the patent laws and plant breeders' rights laws generated by the advent of biotechnology have not been fully resolved in any of the countries reviewed.)

82. It is worth noting in this connection that the 1980 Plant Breeders' Rights Bill contains explicit provisions that the plant varieties protected under it are to be "prescribed by regulations." Similar provisions for the implementation of the patent legislation are found in the United Kingdom's *Patent Act* of 1977 which, among other things, empowers the Minister responsible for its administration to vary exceptions to patentability "... for the purpose of maintaining them in conformity with developments in science and technology." If a similar clause is included in our *Patent Act*, the procedure established there would allow that certain matters related to the patenting of new technologies need not be resolved on an *a priori* basis and provided for in detail in the patent legislation, but could be attended to when and if they become a

problem requiring a resolution. Questions about the "demarcation" and "complementarity" between the *Patent Act* and the yet to be passed Plant Breeders' Rights Bill could be resolved in this way.

83. Adaptation of the European model to the Canadian definition of patentable subject matter would reduce the likely demand on the judiciary to determine what is patentable under Canadian patent law and would involve some loss of flexibility.[24] It would also entail a break in continuity in our patent legislation and some divergence between Canadian and U.S. patent law. By the same token it would bring Canadian protection for biotechnology closer to that afforded under the EPC and the break in legislative continuity would be attenuated by the fact that Canada could make use of the practice and jurisprudence developed under the EPC patent system. This practice and jurisprudence would, among other things, provide clearer guidance on not only what, for patent purposes, is regarded as a "biological process" but also what is considered to be "a product of nature." Neither of these would be patentable.

84. The alternative way to provide statutory accommodation for patenting in biotechnology (including life forms and processes for their generation) would be to revise our present "North American" definition of patentable subject matter by adding that it extends to claims to or involving living matter. Such definition would reflect in a statutory form the recent interpretation of the U.S. definition of patentable subject matter from which ours originates, as given in the U.S. Supreme Court decision in the Chakrabarty case (1980).

85. The definition of patentable subject matter revised in this way could well promote *de facto* conformity of Canadian patent law with that of the U.S. in this area. It would certainly provide firm legal grounds for *Abitibi* but no clear confirmation as to its details. It would allow the present trend in the Canadian Law toward the level of patent or patent-like protection for living matter, as now provided under EPC and in the United States, to continue.

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24. The European approach requires that in each particular case, a decision be made as to whether the subject matter involved is "essentially biological" or whether it is microbiological. The difficulties for the judiciary in making such a distinction should not be down-played.

86. Such a definition would, however, set no statutory bounds as to what processes of life and what living matter could be patented and leave many of the present uncertainties, including those pertaining to patenting "agricultural" processes. It would not contribute towards the clarification of the relationship between the *Patent Act* and a Plant Breeders' Rights Act. Finally, the adoption of such a definition of patentable subject matter would reduce only marginally the scope for administrative or judicial law-making pertaining to patents. Except for foreclosing the denial of patentability to life forms and processes for their generation, it would amount to the status quo option with all its advantages and disadvantages, including unpredictability of outcome (e.g. when the issues may come up for resolution and when and how they may be resolved).

87. Legislative confirmation of the presently sanctioned practice of accepting deposits of living matter to satisfy the requirements for disclosure could be achieved by changes to Section 36 of the *Patent Act*, to the effect that in specified circumstances deposition of living matter (e.g. micro-organisms) involved in the claim will satisfy requirements for sufficient disclosure.

Option to Deny Patents to Novel Life Forms

88. One of the options under the legislative approach is to deny patentability to any living matter and to revise the definition of patentable subject matter accordingly. In effect, *Abitibi* would be rendered invalid. Claims to processes using living matter and their patentable products would continue to receive Canadian patents to the extent they did so in the past. It is not clear, however, whether or not processes for producing novel life forms would be considered eligible for patent grants. Moreover, it is not entirely clear whether this option would also require a statutory confirmation of the existing practice whereby disclosure requirements may be met by deposits of the micro-organisms involved in the patent claims.

89. Adoption of this course would not allow the development of Canadian patent law to accommodate biotechnology to proceed much further than the stage it had reached prior to the Abitibi decision. It would run counter to the developments in the national patent laws of all important industrialized countries where novel forms of life (up to the level of plants in some countries) and "not essentially biological" processes

for making them are eligible for and receive patent grants. (It may be added that such patents are recognized and provided for under the international patent systems to the point that there are internationally designated facilities authorized to accept and maintain deposits of micro-organisms involved in the prosecution of patent claims.)

90. The option in favour of denying patents for life forms would not rule out the passage of a Plant Breeders' Rights Bill. The case for such legislation is that it is especially designed for one unique group of "inventors" of particular importance to agriculture. These "inventors," that is, breeders of new varieties of plants, are offered restricted proprietary rights to "patentable" results of their work sufficient to reward them and encourage them to continue, but not so all-inclusive as to constitute or involve an unreasonable burden on agricultural activities and operations. Thus, on the grounds that it is a special case, the passage of a Plant Breeders' Rights Bill would not be inconsistent with the version of the *Patent Act* that would not allow for patenting of micro-organisms and higher forms of life.

91. Consideration would have to be given, even under this option, to denying patentability to "not essentially biological" processes for producing plants, to ensure against encroachment on a Plant Breeders' Rights Act.

CONCLUSION

Canada is faced with three basic issues regarding the patentability of biotechnology.

The first is whether biotechnology research and investment is significantly affected by the uncertainty of our law in this area, to the extent that legislative changes should be made to remove it.

Second, while the scope of protection extended to biotechnology in Canada appears to be roughly comparable with that of other industrial countries (owing to the uncertainty in our law, it is difficult to make a firm comparison), it does seem to differ in some areas, notably as regards agricultural processes. The issue here is whether our law should be brought closer into line with that elsewhere, or whether, given Canada's position in the world economy, we would be better off with more, or less protection than that provided in other countries.

Third, the government is considering passing a Plant Breeders' Rights Act. The issue is whether the *Patent Act* needs to be changed to ensure compatibility beteween the two Acts.

A number of policy options for addressing these issues have been presented. Whatever option is eventually chosen, the impact on biotechnological development and the use of biotechnology products in Canada could be significant. Therefore, it is essential that a thorough discussion of the issues and policy options take place within the Canadian biotechnology community before a choice of option is made. The input of the patent profession, the universities and other research faculties, the biotechnology industry, and interested agencies in both levels of government will be most valuable in weighing the issues and assessing the options. Hopefully, this paper will help to generate discussion of these important matters.

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