

## Biotechnology Law: Corporate-Commercial Practice

by Mark J. Fecenko

Canada: Butterworths Canada Ltd. 2002. Pp. 316.

THE MATTER OF INTELLECTUAL PROPERTY and its protection is a continuing concern for established and growing companies. Mark Fecenko's book entitled *Biotechnology Law: Corporate-Commercial Practice*<sup>1</sup> speaks to this topic effectively. Fecenko offers insight and sound advice on how to address a complicated area by condensing it into a "user's guide" for the following matters: a basic primer on business associations; identifying and assessing biotechnology innovation; financing biotechnology companies; and, biotechnology agreements such as nondisclosure and confidentiality agreements, research and development agreements, licensing agreements, joint venture and collaboration agreements.

The book is intended to provide some background to lawyers and their clients who may have had limited exposure to biotechnology. The first four chapters of the book attempt to review various biotechnology terms, provide an overview of the biotechnology industry and demonstrate how to negotiate and draft biotechnology-related agreements. Although the "Introduction" is a respectable attempt at providing a broad overview of the area of biotechnology including definitions of scientific terminology and the techniques that have been applied therewith, (for example, there are sections that describe recombinant DNA technology, gene therapy, monoclonal antibodies, xenotransplantation and data mining), it falls short of being current. Unfortunately, some information is already outdated, as the field of science can progress rapidly. The latter is a common problem with any text that attempts to take a snapshot of the area of biotechnology at a given time. Areas such as nanotechnology, bioinformatics, stem-cell research and proteomics are some of the areas that readers will need to explore on their own. There are a number of journals that are readily accessible and add value to a lawyer's general pool of knowledge including *Biotechnology Focus*, *BioScan*, *Nature*, *Science* and the *Harvard Business Review*, to mention a few.

The definition of biotechnology also varies. Fecenko has defined it broadly as "...the use or exploitation of biological systems, or parts thereof, for a productive end".<sup>2</sup> He rightly points out that it is a dynamic system that is multidisciplinary by nature. "Biotechnology" has also been defined as the systemic industrial use of biological processes and organisms to manufacture medical, agricultural and consumer products.<sup>3</sup> The National Research

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1. Mark J. Fecenko, *Biotechnology Law: Corporate-Commercial Practice* (Markham: Butterworths, 2002) [Fecenko].

2. *Ibid.* at 4.

3. See Microbix Educational Systems, online: <<http://www.nsta.org/microbix/bioprime.htm>>

Council Canada (NRC) defines "biotechnology" as techniques that use living organisms to make or modify products, improve plants or animals, and develop microorganisms for specific purposes.<sup>4</sup> "Biotechnology encompasses the activities in science as they relate to living organisms."<sup>5</sup> Biotechnology is an important area of research, development and enterprise. The prospects of protecting and commercializing biotechnology are substantial considering the number of sectors of the economy that are affected by biotechnology.

Canada is a leader in biotechnology. There are a number of industry clusters in Canada. They include agriculture in Guelph, Saskatoon and Winnipeg; aquaculture in Halifax and St. John's; environment in Montreal, Toronto, Vancouver and Winnipeg; health in Halifax, Quebec City, Montreal, Ottawa, Toronto, London, Edmonton and Vancouver; and industrial processes in Vancouver.<sup>6</sup> These clusters are supported and fostered by the NRC by way of funding.

By keeping in mind the broad scope of the industry, Fecenko has dedicated a number of chapters to the negotiation and drafting of specific types of agreements including licensing, non-disclosure and confidentiality agreements, and research and development agreements. In addition, he has dedicated a chapter to identifying and assessing biotechnology innovations. The latter is of particular importance in protecting intellectual property.

A patent will issue in Canada and other jurisdictions when the invention is patentable; however, not all inventions are patentable. Only those inventions that meet the statutory requirements of the Canadian *Patent Act*<sup>7</sup> will be patentable in Canada. In Canada, there are no clear guidelines as to what is patentable in the area of biotechnology and the case law is also limited.

At this time in Canada, patents are granted for the following matters:

RNA, DNA, oligonucleotides including protein encoding sequences such as promoters, linkers, probes and vectors and polypeptides. Unicellular life forms and viruses are patentable including transformed cells, cells in culture, hybridomas, cell culture media and diagnostic methods and kits. In addition, a process to prepare, isolate, modify or manipulate biological products and living matter including plants and seeds is patentable. Therefore, the Canadian Intellectual Patent Office (CIPO) will grant patents for biological compounds, microorganisms, peptides, nucleic acid molecules and uses therefrom.<sup>8</sup>

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(this is a pay for service site).

4. See National Research Council Canada, online: <[www.nrc-cnrc.gc.ca](http://www.nrc-cnrc.gc.ca)> [NRC].
5. Nika V. Ketis, "Pharmaceuticals and Patents" (Paper presented to the Canadian Pharma Summit Insight Conference, Montréal, November 25-26, 2002) (Toronto: Insight Press, 2002) at 701.
6. See National Research Council Canada, online: <[http://www.nrc-cnrc.gc.ca/aboutUs/corporatereports/fact\\_sheets/factsheet\\_canada\\_e.html](http://www.nrc-cnrc.gc.ca/aboutUs/corporatereports/fact_sheets/factsheet_canada_e.html)>.
7. R.S.C. 1985, c. P-4.
8. Nika V. Ketis "Managing a Drug Patent Portfolio in Hard Economic Times" (Paper presented to the Insight Conference on Drug Patents: The Latest Developments and Strategies, Toronto, March 27-28, 2003) (Toronto: Insight Press, 2003) at 188-189 [Ketis, "Managing Drug Patent"].

The Canadian *Patent Act*, as the United States legislation, makes very few references to biotechnological materials. In the United States, one can obtain a plant patent, although it is not a true “utility” patent. In Canada, the equivalent falls under the Canadian *Plant Breeders’ Rights Act*.<sup>9</sup>

Section 2 of the Canadian *Patent Act* defines “invention” as:

any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter.

Section 2 has been interpreted to include naturally occurring gene sequences, proteins and microorganisms provided they are newly discovered, have a use, and are not claimed to occur in nature. Claims for such naturally occurring matter are rejected. DNA, RNA and proteins are considered as chemical compounds and not living matter. No distinction is made by the Patent Office between substances that are isolated from human sources and those isolated from non-human sources. In addition, patents are granted for new uses of a known biological product. However, multi-cellular organisms<sup>10</sup> (such as plants, seeds and animals), methods that occur according to the laws of nature without significant human intervention, and methods of medical and surgical treatment are not patentable in Canada.

In light of the aforementioned, Chapter five of Fecenko’s book is of particular importance. He effectively takes the reader through the key factors that need to be solicited from the “Form on Inventor’s Disclosure” in order to provide the basic information that an organization needs to:

- (a) understand the basic technology and determine its patentability;
- (b) assess potential commercial applications of the protectable elements of the invention (whether it be through patent protection or trade secret); and
- (c) consider potential partners who may have an interest in the intellectual property.<sup>11</sup>

Fecenko clearly lays out the matters that are required to effectively meet the need to identify and assess biotechnological inventions and to audit for existing intellectual property holdings of a company or individual.

The latter part of the book deals with what the key elements involved in drafting and negotiating agreements are that involve the biotechnology sector, including focusing on key clauses in the agreement that may present a challenge. For example, with regard to licensing agreements, the following are noted as being subject matters that should be considered: (a) subject matter of the license; (b) scope of the license; (c) ownership of improvements; (d) use of biological materials; (e) warranty respecting right to use; (f) maintenance of intellectual property rights; (g) limitation of liability; (h) obtain-

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9. S.C. 1990, c. 20; Ketis “Managing Drug Patent,” *supra* note 8 at 189.

10. See *Harvard College v. Canada (Commissioner of Patents)*, [2002] 4 S.C.R. 45; 219 D.L.R. (4th) 577.

11. Fecenko, *supra* note 1 at 151–155.

ing regulatory approvals; (i) initial and ongoing provisions of assistance; (j) term and termination; (k) compensation; (l) accounting and auditing; (m) taxes; and, (n) boilerplate provisions. There is an appendix to the chapter that provides an illustration of a basic form of a license agreement. In fact, various agreements referred to in the book's chapters have a sample agreement in their appendix. The latter are a useful tool for those dealing with the biotechnology industry.

The last two chapters deal with making the right strategic alliances and obtaining financing for the biotechnology sector. Strategically, these two later chapters are key to having marketable innovations and to achieving financial success:

The creation of an invention begins with a concept. The concept may be developed into a prototype. This prototype can evolve into a revenue-generating product. Thereafter, sales may provide for continued growth. In order to achieve these milestones, the inventor and subsequent teams/company needs to be able to finance the various endeavours.<sup>12</sup>

Fecenko takes the reader through such sources as "Angle Investors" and "Venture Capitalists" who can assist with the financing. However, there is a lack of description of resources that are available for funding and investment opportunities as listed by Strategis (Industry Canada)<sup>13</sup> or provided by the NRC;<sup>14</sup> the research and development (R&D) tax incentives;<sup>15</sup> the business service centers;<sup>16</sup> or Opportunity Match and the National Technology Index.<sup>17</sup> These are valuable business resources.

Chapter 10 reviews equity and debt financing but fails to include government financing and research and development tax incentives. Government financing is particularly useful for early stage companies. Government funding is often provided where there is a public purpose or benefit to the enterprise. Such funding provides for certain economic and social needs. It will often be directed to such endeavours as research and development of technology, improving Canada's trade relations and strengthening business opportunities in certain regions of Canada. In addition, Canada has one of the most attractive scientific research and experimental development (SR&ED) tax incentives in the world. SR&ED incentives are generally given in the form of deductions and refundable or non-refundable tax credits. Such incentives are available both at the provincial

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12. Ketis "Managing Drug Patent," *supra* note 8 at 197.

13. See Industry Canada, online: <<http://strategis.ic.gc.ca/epic/internet/incbc-gccb.nsf/vwGeneratedInterE/Home>>.

14. NRC, *supra* note 4.

15. See Industry Canada, online: <[http://strategis.ic.gc.ca/epic/internet/ineas-aes.nsf/vwapi/wp06e.pdf/\\$FILE/wp06e.pdf](http://strategis.ic.gc.ca/epic/internet/ineas-aes.nsf/vwapi/wp06e.pdf/$FILE/wp06e.pdf)>.

16. Canada Business Service Centres, online: Business Start-Up Assistant <<http://bsa.cbasc.org/gol/bsa/interface.nsf/engdoc/0.html>>.

17. See Industry Canada, online: <<http://strategis.ic.gc.ca/ssG/te01150e.html>>.

and federal level.<sup>18</sup> There is also some general and useful information regarding securities law issues for biotechnology companies. In addition, the appendix to the chapter provides an outline of a term sheet.

*Biotechnology Law: Corporate-Commercial Practice* by Fecenko is a useful user's guide that lawyers dealing with biotechnology companies should have as a resource. Although the author missed some references, the book is a must-read for an overview of what needs to be considered when dealing with biotechnology clients. The chapters are relatively self-contained and as such are an easy read and helpful regarding the topic at issue.

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18. *Supra* note 15.

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