Pin-Stripes, Test Tubes, and Patents: Is the Commercialization of University Research Consistent with the Fundamental Tenets of the *Patent Act*?

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AN EFFECT OF THE SHIFT TO A KNOWLEDGE-BASED ECONOMY is the advent of the "entrepreneurial university," whereby universities are recognized as incubators of knowledge products. Accordingly, issues surrounding the commercialization of university research are addressed, with specific focus on the following: an overview of trade secrecy and patent law as applicable to the university setting, and why patents are typically viewed as the appropriate mode of protection; different patent ownership policies adopted in the university setting and the effect of such policies; the success of the commercialization of university research in Canada; analysis of the Recommendations from the Expert Panel on the Commercialization of University Research with specific focus on the effects of their recommendation to mandate both disclosure and the university ownership model—two aspects rooted in the *Bayh-Dole Act* of the United States; examination of the *Bayh-Dole Act*, and the flawed notion that its implementation has resulted in the successful commercialization of university research in the United States; an examination of the conflict between the commercialization of university research and traditional university ideals; and an examination of the demise of the experimental use exception. Conceding that the commercialization of university-generated research is well ingrained into the structure of the modern university and will inevitably remain, recommendations to minimize the negative consequences of commercializing university-generated innovation and ensure compliance with the fundamental tenets of our patent regime are provided.

UN EFFET DU PASSAGE VERS UNE ÉCONOMIE DU SAVOIR est l'éclosion de l'« université entrepreneuriale », l'université perçue comme berceau des produits du savoir. Nous examinons donc les questions liées à la commercialisation de la recherche universitaire. En particulier, nous faisons un survol du droit en matière du secret commercial et des brevets applicable au milieu universitaire. Nous cherchons à déterminer pourquoi les brevets sont habituellement perçus comme le mode de protection approprié. Nous examinons les politiques relatives aux diverses formes de propriété de brevets en place dans le milieu universitaire et les effets de ces politiques. Nous évaluons le succès de la commercialisation de la recherche universitaire au Canada. Nous analysons les recommandations du Comité d'experts sur la commercialisation de la recherche universitaire et en particulier les effets de ses recommandations en matière de l'obligation de divulgation et du modèle de propriété de l'université – deux aspects inspirés de la loi Bayh-Dole Act des États-Unis. L'analyse de cette loi américaine et les conceptions erronées résultant de sa mise en œuvre a entraîné une commercialisation infructueuse de la recherche universitaire aux États-Unis. Enfin nous jetons un regard sur le conflit entre la commercialisation de la recherche universitaire et les idéaux universitaires traditionnels ainsi que sur la question de l'abolition de l'exception à des fins d'utilisation expérimentale. Tout en admettant que la commercialisation de la recherche issue des universités est bien ancrée dans la structure de l'université moderne et le restera inévitablement, nous formulons des recommandations afin de minimiser les conséquences négatives de la commercialisation de l'innovation de source universitaire et d'assurer le respect des principes de base de notre régime des brevets.

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1. INTRODUCTION

KNOWLEDGE HAS SHIFTED FROM A PUBLIC GOOD to intellectual property, which is "produced, accumulated, [and] traded like other goods and services in the so-called Knowledge Society."[1] Accordingly, intellectual property has become one of the most important instruments in the commercial world,[2] and is considered "the new wealth" in this knowledge-based economy.[3] One of the effects of this knowledge-based economy is the advent of the "entrepreneurial university," whereby universities are recognized as incubators of knowledge-products;[4] university agendas now include identification, generation, and commercialization of knowledge products.[5] Universities have become an integral component in the production of marketable products,[6] and are viewed as profit-generating enterprises[7]—and these shifts have fundamentally altered the nature of the university.[8] Consequently, intellectual property has become an increasingly important issue in the university setting, resulting in university intellectual property issues shifting to the forefront of discussion in academia.[9]

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1. Peter Scott, "The Ethical Implications of the New Research Paradigm," (2003) 9:1 Science and Engineering Ethics 73 at p. 73 [Scott, "Ethics of New Research Paradigm"].
2. Casey P. August & Michael J. Buchenhorner, "Strategies for Developing Intellectual Property Portfolios in the Global Environment: Protection of Intellectual Property in Hostile Environments," (1995) 21 Canada-United States Law Journal 261 at p. 261 [August & Buchenhorner, "Strategies for Developing IP Portfolios"].
3. David Vaver, *Intellectual Property Law* (Toronto: Irwin Law, 1997) c. 1(A) [Vaver, *Intellectual Property Law*].
4. Henry Etzkowitz *et al.*, "The future of the university and the university of the future: evolution of ivory tower to entrepreneurial paradigm," (2000) 29 Research Policy 313 at p. 313 [Etzkowitz, "Future of the University"].
5. *Ibid.* at p. 314.
6. Ann S. Jennings & Suzanne E. Tomkies, "An Overlooked Sight of Trade Secret and Other Intellectual Property Leaks: Academia," (2000) 8:2 Texas Intellectual Property Journal 241 at p. 243 [Jennings & Tomkies, "Trade Secret and IP Leaks"].
7. Jerrold L. Kachur, "Whose Intellectual Property? Whose Rights? GATS, TRIPS and Education in Canada," (2003) 1:3 Globalization, Societies and Education 375 at p. 376 [Kachur, "Whose Intellectual Property"].
8. *Ibid.* at pp. 385–386.
9. Canadian Association of University Teachers, "Intellectual Property & Academic Staff—Part One: What is Intellectual Property and Who Owns It?" (2003) 4 CAUT Legal Review 1, <http://www.caut.ca/uploads/LegalReviewVol4No3.pdf> at p. 1.

Having been identified by the federal government and the private sector as a generator of commercially exploitable research,[10] universities are now facing increasing pressure to enhance their commercialization capabilities.[11] As a result, irreconcilable incompatibilities with the traditional academic model exist, which have the potential to fundamentally alter the nature and structure of universities in a negative manner, as well as to impair economic and scientific progress. The increasing demands being placed on universities and the negative impact that the commercialization of university research can have on both the academy and the advancement of scientific progress[12] undoubtedly has the potential to undermine the fundamental tenets of our patent regime: namely, ensuring technological and economic advancement.[13] Conceding that the commercialization of university-generated research is well ingrained into the structure of the modern university and will inevitably remain, recommendations to minimize the negative consequences of commercializing university-generated innovation and to ensure compliance with the fundamental tenets of our patent regime are provided.

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2. CANADIAN INTELLECTUAL PROPERTY LAW AS RELEVANT TO UNIVERSITY-GENERATED RESEARCH

2.1. The Appropriate Vehicle: Trade Secrecy or Patent?

BEFORE DELVING INTO THE INTRICACIES of university commercialization processes, it is appropriate to begin by addressing the form of intellectual property protection available in the university setting with respect to knowledge-based products: namely, trade secrecy or patent.

2.1.1. Trade Secrecy

Through contract or trust, the common law of trade secrecy is a possible mechanism for protecting information.[14] Protection is achieved by preventing those possessing this information[15] from disclosing or using it[16] for as long as it remains confidential, perhaps indefinitely.[17] Accordingly, the requirements of trade secrecy are that:

10. Canadian Association of University Teachers, "Intellectual Property & Academic Staff—Part Three: Intellectual Property: Responding to the Challenges," (2004) 5:2 CAUT Legal Review 23, <http://www.caut.ca/uploads/5.2Intellectual_property_3.pdf> at p. 24 [CAUT, "Intellectual Property Part 3"].
11. Canada, *Public Investments in University Research: Reaping the Benefits—Report of the Expert Panel on the Commercialization of University Research* (Ottawa: Industry Canada, 1999) (Chair: Pierre Fortier) [*Report of the Expert Panel*].
12. Support for these conclusions will be provided.
13. Thomas E. Roberts, "Life Forms as Patentable Subject Matter: Is a Divergence in Canadian and U.S. Laws Warranted?" (1999) CSALE Occasional Paper No. 7, <http://www.csale.usask.ca/PDFDocuments/lifeFormsPatentableSubject.pdf> at p. 3 [Roberts, "Life Forms as Patentable Subject Matter"].
14. August & Buchenhorner, "Strategies for Developing IP Portfolios," *supra* note 2 at p. 264.
15. *Ibid.* at p. 264.
16. George S. Takach, *Computer Law*, 2d ed. (Toronto: Irwin Law, 2003) at c. 2(B)(1).
17. Vaver, *Intellectual Property Law*, *supra* note 3 at c. 3(A)(1).

> [t]rade secrets must not be generally known in the industry, their nondisclosure must give some advantage over competitors, and attempts to prevent leakage of the information must be made (such as pledges of secrecy in employment contracts or other company security policies).[18]

Anything that falls within the scope of patent protection can also be the subject matter of a trade secret; however, not everything capable of being the subject matter of a trade secret is necessarily capable of being afforded patent protection.[19] Advantages of trade secrecy over patenting include, but are not necessarily limited to, the ability to refrain from disclosure, indefinite protection, and reduced costs.[20] Nevertheless, protection via trade secrecy is also unpredictable.[21] Trade secrecy does not protect against reverse engineering, nor does it protect against discovery by another entity.[22] And as trade secrecy depends on secrecy, once the protected subject matter is no longer secret, the protection ceases to exist.[23]

Notwithstanding that trade secrecy is an effective mechanism for allowing companies to protect innovation, the need to signify an invention's commercial potential to capital markets is best addressed via intellectual property protection under the *Patent Act*.[24] Universities attempting to commercially exploit inventions generated in their institution are no exception. In addition to commercial realities, however, there are also practical and theoretical reasons why universities would elect to obtain protection using the patent regime as opposed to trade secrecy.

As a matter of practicality, academic institutions are composed of inherent characteristics that render trade secrecy difficult to maintain,[25] if not render it entirely unfeasible. Specifically, research conducted in the university setting often includes graduate and undergraduate students at some stage of the research process. This, of course, has the ability to significantly compromise the effectiveness of trade secrecy, as these same individuals are also encouraged to be mobile through the course of their academic training.[26] The confluence of a high number of such persons involved in any given research project, who are also likely to migrate to other institutions, decreases the probability that a trade secret could be maintained.

Practicality aside, trade secrecy is in essence the antithesis to information sharing, which is an important theoretical underpinning to the academic institution.[27] Although intellectual property protection under the *Patent Act* is in many respects also considered incongruous with many of the aspirational ideals of academia, it is arguably the lesser of two evils. For example, as full disclosure

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18. Edwin C. Hettinger, "Justifying Intellectual Property," (1989) 18:1 Philosophy and Public Affairs 31 at p. 33 [Hettinger, "Justifying Intellectual Property"].
19. *Ibid.* at p. 33.
20. *Ibid.* at p. 33.
21. Vaver, *Intellectual Property Law*, *supra* note 3 at c. 3(A)(1).
22. Hettinger, "Justifying Intellectual Property," *supra* note 18 at p. 33.
23. Vaver, *Intellectual Property Law*, *supra* note 3 at c. 3(A)(1).
24. Roberts, "Life Forms as Patentable Subject Matter," *supra* note 13 at p. 3.
25. See Jennings & Tomkies, "Trade Secret and IP Leaks," *supra* note 6.
26. It is common practice for those in academia to be encouraged to study with various researchers within their discipline.
27. Jennings & Tomkies, "Trade Secret and IP Leaks," *supra* note 6 at p. 243.

is required under patent law, as opposed to trade secrecy where non-disclosure is a prerequisite, intellectual property protection under the *Patent Act* will inexorably lead to more information sharing than trade secrecy.[28] Consequently, intellectual property protection through patent law contributes to dissemination of scientific knowledge to a greater extent than trade secrecy law can afford.[29] Indeed, trade secrecy has even been assigned the label of "the most troubling [form of intellectual property] from a social progress perspective."[30] Of course, this is not to suggest that intellectual property protection through patenting does not come with its own share of problems in the academic setting.[31]

2.1.2. Patent

In essence, patents represent a bargain between the inventor and society: the inventor agrees to disclose his or her invention to society in exchange for society affording the inventor a monopoly over the invention.[32] The granting of the patent allows the patentee "the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used"[33]—that is, the right to use, manufacture and sell. Under the Canadian patent regime, this monopoly is granted for a period of twenty years from the filing date.[34] This twenty-year monopoly is seen as an incentive to investment in research and development, as "[w]ithout the possibility of patent protection, many people might not take the risks or invest the time and money involved in devising and perfecting new products."[35] It is therefore not surprising that a major justification for affording intellectual property protection through patent law is that patents "foster technological and economic progress"[36] and are "[i]ntended to stimulate the creation and development of new technologies."[37] Philosophical constructs such as these are clearly consistent with a utilitarian justification for intellectual property rights, in addition to serving as mechanisms for perpetuating the notion that "without such rights, much research and creativity would not be carried on or would not be financed by capitalists."[38] Indeed, the Canadian Intellectual Property Office contends that without a patent regime, we would be "[a]t a more primitive stage of industrial development, without a doubt."[39] It is implicit from this utilitarian justification that without providing intellectual property protection there would be insufficient incentives to encourage innovation,[40] although the validity of this assertion can be called into question.[41]

28. Eileen Morin, "Of Mice and Men: The Ethics of Patenting Animals," (1997) 5 Health Law Journal 147.
29. *Ibid.* See also Roberts, "Life Forms as Patentable Subject Matter," *supra* note 13.
30. Adam D. Moore, "Intellectual Property: Theory, Privilege, and Pragmatism," (2003) 16:2 Canadian Journal of Law and Jurisprudence 191, <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=528229> at p. 205.
31. Further discussion of this topic will be found below.
32. *Free World Trust v. Électro Santé Inc.*, 2000 SCC 66, <http://scc.lexum.umontreal.ca/en/2000/2000scc66/2000scc66.html>, [2000] 2 S.C.R. 1024 at para. 13 [*Free World* cited to S.C.R.].
33. *Patent Act*, R.S.C. 1985, c. P-4, <http://laws.justice.gc.ca/en/P-4/index.html>, s. 42 [*Patent Act*].
34. *Ibid.*, s. 44. For patents filed before 1 October 1989, the monopoly extends for a period of seventeen years from when the patent is issued: *ibid.*, s. 45.
35. Canadian Intellectual Property Office, *A Guide to Patents* (Ottawa: Industry Canada, 2002), <http://strategis.ic.gc.ca/sc_mrksv/cipo/patents/pat_gd_main-e.html> at p. 1 [Canadian Intellectual Property Office, *Guide*].
36. Roberts, "Life Forms as Patentable Subject Matter," *supra* note 13 at p. 3.
37. Vaver, *Intellectual Property Law*, *supra* note 3 at c. 3(A).
38. Vaver, *Intellectual Property Law*, *supra* note 3 at c. 1(A)(2).
39. Canadian Intellectual Property Office, *Guide*, *supra* note 35 at p. 1.
40. Hettinger, "Justifying Intellectual Property," *supra* note 18 at pp. 47–48.
41. Indeed, there are advocates who suggest that ownership of patents, in the university setting or otherwise, is not required to promote technological and economic progress. See Hettinger, *supra* note 18 at p. 48.

2.1.2.1. Pre-conditions to Patentability as Relevant to University-Generated Inventions: The Novelty Requirement

To be patentable, and thus to be afforded intellectual property protection under the Canadian patent regime, an invention must be novel,[42] useful,[43] and non-obvious.[44] Notwithstanding that these requirements are equally important as pre-conditions to patentability, the novelty requirement appears to generate the most salient issues with respect to those innovations created in the university setting and, therefore, focus is directed to the law pertaining to this requirement.[45]

As previously discussed, patents are considered to be a bargain between inventor and society, whereby the inventor agrees to disclose his or her invention to society in exchange for a twenty-year monopoly over the invention.[46] Accordingly, if the invention sought to form the subject matter of a patent is not novel to society, consideration flowing from the inventor to society is lacking,[47] as is justification for providing the inventor with a monopoly over the invention. This approach is embodied in section 28.2 of the *Patent Act*.

Pursuant to section 28.2, the patent applicant, or a person who obtained knowledge from the patent applicant, must not disclose the subject matter of a patent in such a manner that the subject matter of the patent becomes "available to the public in Canada or elsewhere."[48] Such disclosure of the patent's subject matter amounts to anticipation, or lack of novelty, subsequently resulting in the novelty requirement of patentability failing to be satisfied and hence, resulting in an invalid patent.[49] An important qualification to non-disclosure is that the *Patent Act* provides a one-year grace period for such disclosure. Specifically, previous disclosure does not amount to anticipation where the subject matter of a patent was disclosed by the applicant, or someone who obtained knowledge either directly or indirectly from the applicant, which subsequently became available anywhere in the world one year, or less than one year, before the filing date by either potential party.[50] However, where the above disclosure is made within a year by anyone who is not the applicant or someone who did not obtain the knowledge directly or indirectly from the applicant, the grace period extends to disclosures made one year, or less than one year, before the claim date.[51] It is presumed that this grace period exists to aid in the expedient dissemination of scientific discovery to the public.[52] It is worthy to note that this one-year grace

42. *Patent Act*, *supra* note 33, s. 2 "invention," s. 28.2(1).
43. *Ibid.*, s. 2, "invention."
44. *Ibid.*, s. 28.3.
45. It is important to note that the utility requirement also raises important issues in the context of the commercialization of university-generated research, particularly with respect to its effect on basic long-term research. Although a thorough analysis of this pre-condition to patentability is beyond the scope of this paper, implications of the utility requirement on basic, long-term research is discussed in Part 3.2(b), below. For an examination of the utility requirement in Canada, see Vaver, *Intellectual Property Law*, *supra* note 3 at c. 3(C)(3).
46. *Free World*, *supra* note 32 at para. 13; *Patent Act*, *supra* note 33, s. 45.
47. *SmithKline Beecham Pharma Inc. v. Apotex Inc.*, 2002 FCA 216, <http://decisions.fca-caf.gc.ca/en/2002/2002fca216/2002fca216.html>, [2003] 1 F.C. 118 at para. 11.
48. *Patent Act*, *supra* note 33, s. 28.2(1)(a).
49. *Beloit v. Valmet* (1986), 8 C.P.R. (3d) 289 (FCA) at p. 297 [*Beloit*].
50. *Patent Act*, *supra* note 33, s. 28.2(1)(a).
51. *Ibid.*, s. 28.2(1)(b).
52. Roberts, "Life Forms as Patentable Subject Matter," *supra* note 13 at p. 8.

period is recognized in the United States; however, only a six-month grace period is allowed in Europe and, even then, falls within a much narrower ambit.[53]

The critical issue surrounding subsection 28.2(1) of the *Patent Act* is the meaning of "available to the public in Canada or elsewhere."[54] Being made available to the public encompasses use of the invention, sale of the invention, or publication of the invention in such a manner that it became available to the public beyond the one-year grace period.[55] The medium used to convey this information to the public is irrelevant,[56] as is whether the public has acquired actual knowledge or details of the invention.[57]

In *Xerox of Canada Ltd. et al. v. IBM Canada Ltd.*, Collier J held that the disclosure must have been made available without restriction and to a person or persons not in a special relationship with the discloser in order for a disclosure to be considered available to the public.[58] As the parties were held to be in a special relationship by virtue of their relationship in a joint venture, the Federal Court held that the document was not made available to the public within the meaning of the *Patent Act*. Therefore, disclosing information with restrictions or with confidentiality requirements, express or implied, does not constitute being made available to the public.[59]

Additionally, section 28.2(1)(a) requires that, to constitute anticipation, the quality of the disclosure surpass a requisite threshold. With respect to prior publication, the information disclosed must be as practically useful as that included in the actual patent disclosure.[60] It is not considered anticipation if the disclosure is insufficient to allow the invention to be carried out.[61] To determine whether a publication constituted anticipation, Justice Binnie in *Free World Trust v. Électro Santé Inc.* affirmed the approach adopted by Hugessen JA in *Beloit Canada Ltd. v. Valmet Oy*:

> One must, in effect, be able to look at a prior, single publication and find in it all the information which, for practical purposes, is needed to produce the claimed invention without the exercise of any inventive skill. The prior publication must contain so clear a direction that a skilled person reading and following it would in every case and without the possibility of error be led to the claimed invention.[62]

It has been held that this principle is equally applicable to anticipation via prior use or sale; however, as there are differences in the nature of the medium used to convey the information in instances of prior use or sale, slight modifications

53. Vaver, *Intellectual Property Law*, *supra* note 3 at c. 3(C)(1).
54. *Patent Act*, *supra* note 33, s. 28.2(1).
55. *Diversified Products Corp. v. Tye-Sil Corp.* (1991), 35 C.P.R. (3d) 350 at p. 360 (FCA) [*Diversified Products*].
56. Vaver, *Intellectual Property Law*, *supra* note 3 at c. 3(C)(1).
57. *Canadian Patent Scaffolding Co. Ltd. v. Delzotto Enterprises Ltd. et. al.* (1978), 42 C.P.R. (2d) 7 at para. 68 (FCTD), aff'd (1980) 47 C.P.R. (2d) 77 (FCA) [*Canadian Patent Scaffolding*].
58. *Xerox of Canada Ltd. et al. v. IBM Canada Ltd.* (1977), 33 C.P.R. (2d) 24 at para. 303 (FCTD).
59. Vaver, *Intellectual Property Law*, *supra* note 3 at c. 3(C)(1).
60. *Proctor & Gamble Co. v. Bristol-Myers Canada Ltd.* (1978), 39 C.P.R. (2d) 145 at para. 22 (FCTD), aff'd [1979] F.C.J. No. 405 (FCA).
61. *Minerals Separation North American Corp. v. Noranda Mines Ltd.* (1947), 12 C.P.R. 99, [1947] Ex. C.R. 306 at para. 59 [*Minerals Separation* cited to Ex. C.R.], rev'd on other grounds [1950] S.C.R. 36, 12 C.P.R. 99 at 182.
62. *Free World*, *supra* note 32 at para. 26, quoting *Beloit*, *supra* note 47 at p. 297.

must be made to the aforementioned discussion of the anticipation doctrine.[63] Elaborating, but without abrogating the approach adopted in *Free World* and *Beloit*,[64] Rothstein JA, with the aid of UK jurisprudence, enunciated the modern test of prior use and sale.[65] For a sale to or use by the public to constitute anticipation, it must amount to "enabling disclosure," that is, allowing the public to make or to obtain the invention.[66] A sale or use will constitute enabling disclosure where the discovery of the invention can be determined through analysis "by a person skilled in the art in accordance with known analytical techniques available at the relevant time."[67] It is irrelevant how much work or time the analysis requires from the person skilled in the art, and the analysis need not necessarily "be capable of exact reproduction."[68] In instances where reverse engineering can be used to discover the invention, the invention is considered as being made available to the public where the product containing the invention is sold to the public without restriction.[69] A sale to, or use by, just one member of the public can constitute availability to the public, and it is irrelevant whether the person or persons in the public domain actually undertake an analysis to discover the invention.[70] At issue is not whether the invention was actually made, obtained, or witnessed by the public, but rather, whether such an opportunity was available.[71]

A further exception to public disclosure carved out by the courts relates to those disclosures arising from experimentation.[72] Specifically, it is not considered anticipation where the disclosure relates to an experiment "with a view to either perfecting the invention as such or testing its merits or practical utility,"[73] regardless of whether the experimentation is conducted by the inventor or another.[74] However, if experimentation is conducted by someone other than the inventor, confidentiality and/or restricted use of the invention is necessary.[75] In order to fall within the purview of this exception, the experimentation must be *bona fide*, as well as reasonable and necessary.[76] Neither profit nor benefit derived through the course of experimentation automatically constitutes failure to qualify under this experimental exemption; however, the public use no longer falls within the umbrella of the experimental exception once the public use is no longer "principally and fundamentally for experimental purposes" or no longer "reasonable and necessary."[77]

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63. *Baker Petrolite Corp. v. Canwell Enviro-Industries Ltd.*, 2002 FCA 158, <http://decisions.fca-caf.gc.ca/en/2002/2002fca158/2002fca158.html>, 17 C.P.R. (4th) 478 at para. 35 [*Baker Petrolite* cited to C.P.R.].
64. *Ibid.* at para. 43.
65. *Ibid.* at para. 42.
66. *Ibid.* at para. 42.
67. *Ibid.* "Relevant time" is considered to be the time at which the patent application was filed.
68. *Ibid.* at para. 42.
69. *Ibid.* at para. 42.
70. *Ibid.* at para. 42.
71. *Letourneau v. Clearbrook Iron Works Ltd.*, 2004 FC 1422 <http://decisions.fct-cf.gc.ca/en/2004/2004fc1422/2004fc1422.html>, (2004), 36 C.P.R. (4th) 228 at para. 31 [*Letourneau* cited to C.P.R.].
72. *Conway v. Ottawa Electric* (1904), 8 Ex. C.R. 432 at para. 6 [*Conway*].
73. *Canadian Patent Scaffolding*, *supra* note 57 at para. 60.
74. *Conway*, *supra* note 72 at para. 6; Vaver, *Intellectual Property Law*, *supra* note 3, c. 3(C)(1).
75. *Gibney et al. (carrying on business as Progen Distributors) v. Ford Motor Co. of Canada Ltd.* (1967), 35 Fox Pat. C. 143 at paras. 58, 52 C.P.R. 140 (Ex Ct).
76. *Canadian Patent Scaffolding*, *supra* note 57 at para. 60.
77. *Ibid.* at para. 60.

Notwithstanding that patents are considered the more practical and theoretically consistent mode of intellectual property protection in the university setting as compared to trade secrecy, incompatibilities subsist between the novelty requirement and inventions generated in the university setting. This is particularly prominent with respect to academic publications related to university-generated innovation sought to be protected via the *Patent Act*.

2.1.2.1. Decreased Dissemination of Knowledge: The Novelty Requirement's Interference with Academic Publication and Communication

In addition to teaching and to the production of graduates, publication of research is viewed as a fundamental aspect of university culture.[78] Reputations in academia are largely a result of publications, which is why freedom to publish is of great significance to academic researchers.[79] It is therefore not surprising that the pursuit of truth is often ingrained into the value system of those in academia—a value system that is oriented towards disseminating research results both to academics' peer group and to the public.[80] However, because publication risks compromising the satisfaction of the novelty requirement, it is critical for those who have a financial interest in obtaining a successful patent application that researchers are aware of what can be published and when.[81] The result is that those who have financial interests in the invention often require the right to approve and delay publication until the patent application is filed.[82]

Unsurprisingly, evidence suggests that there are academics who no longer present at, nor attend, scientific conferences, and if and when they do, the full extent of their research is not disclosed.[83] This appears to be considerably more prominent in instances where researchers are under contractual obligation not to publish, as, generally speaking, there is a demonstrable increase in data withholding tendencies in those who have industry support with respect to commercialization processes as compared to those researchers who commercialize their own research.[84] In fact, there is a negative correlation between the rates of publication and the amount of industry funding where industry funding exceeds two-thirds of the total funding.[85] Furthermore, those researchers with over two-thirds of their total funding derived from industry publish less frequently in higher tiered journals than their non-industrial funded counterparts.[86] The result of research withholding is the inability to confirm results, which is an important component

78. Etzkowitz, "Future of the University," *supra* note 4 at p. 314. For recent commentary on the importance of publishing research results and the importance of ensuring open dissemination of knowledge, see Canadian Association of University Teachers, "The Freedom to Publish: CAUT Briefing to Academic Staff Associations," <http://www.caut.ca/uploads/brief_associations.pdf>.
79. Tom Reid, "Academics and Intellectual Property: Treading the Tightrope," (2004) 9:2 Deakin Law Review 759, <http://www.austlii.edu.au/au/journals/DeakinLRev/2004/32.html> at p. 764.
80. John F. Pickering *et al.*, "The University: Industry Interface in the Generation of Intellectual Property," (1999) 53:1 Higher Education Quarterly 6 at p. 15 [Pickering, "The University"].
81. Patrick Vallance, "Biotechnology and New Companies Arising from Academia," (2001) 358 Lancet 1804 at p. 1804 [Vallance, "Biotechnology and New Companies"].
82. Pickering, "The University," *supra* note 80 at p. 24.
83. Claire Polster, "The Future of the Liberal University in the Era of the Global Knowledge Grab," (2000) 39:1 Higher Education 19 at p. 24 [Polster, "Future of the Liberal University"].
84. David Blumenthal, "Conflict of Interest in Biomedical Research," (2002) 12:2 Health Matrix 366 at p. 387.
85. *Ibid.* at p. 386.
86. *Ibid.* at p. 386.

to the peer review process, in addition to increasing delays for researchers who might otherwise put a new spin on previously conducted research.[87]

It is unquestionable that "these practices have the potential to slow the pace, and possibly reduce the scope, of public knowledge production."[88] Dissemination of knowledge is critical to the evolution of science, as without such dissemination researchers "build on something less than the total accumulation of scientific knowledge, and scientific work is slowed by problems for which solutions already exist but are unavailable."[89] Substantiating this notion, a number of studies have demonstrated that academic research is a critical component to advancements made in a number of industries and industrial productivity.[90] This is not surprising considering that academic publication is a significant component to research and development ("R & D") in the Canadian industrial sector,[91] and, as the leading source of propagating scientific knowledge, it accounts for approximately 65% of Canadian scientific publications.[92]

Any potential stifling of innovation demands intervention, particularly when one considers that the promotion of technological and economic progress is a fundamental role of our patent regime.[93] And although fundamental modifications to patent law are required to rectify this problem, minor initiatives by both industry and university can aid in this process. In particular, all parties involved, including industry partners, the researcher, and the university must be cognizant of what constitutes public disclosure within the meaning of the *Patent Act*. Generally speaking, those parties must become aware of the one-year grace period allowed for public disclosure,[94] and that a patent application will not be compromised by publication, regardless of whether it falls within the one-year exception, so long as the information disclosed does not surpass the requisite threshold.[95] The complexity in deciphering whether a prospective publication could compromise the ability to obtain a valid patent is best addressed through explicit guidelines provided to the parties involved, particularly the researchers. Although it is a reality that researchers may choose, or may be under obligation, not to publish their research, well-established guidelines will allow those researchers who are willing and able to publish to do so without fear of compromising their ability to obtain a patent.

2.1.2.2. Patent Ownership

There is a presumption of ownership in patent law that an inventor who complies with the requirements under the *Patent Act*[96] owns the rights in the invention;

87. *Ibid.* at p. 388.
88. Polster, "Future of the Liberal University," *supra* note 83 at p. 24.
89. David Blumenthal *et al.*, "Withholding Research Results in Academic Science: Evidence from a National Survey of Faculty," (1997) 277:15 Journal of the American Medical Association 1224 at p. 1224.
90. Wulong Gu & Lori Whewell, "University Research and the Commercialization of Intellectual Property in Canada," (1999) Occasional Paper No. 21 Industry Canada Research Publications Program, <http://strategis.ic.gc.ca/epic/internet/ineas-aes.nsf/vwapj/op21e.pdf/$FILE/op21e.pdf> at p. 62 [Gu & Whewell, "University Research and Commercialization of IP"].
91. *Ibid.* at p. 40.
92. *Ibid.* at p. 62.
93. Roberts, "Life Forms as Patentable Subject Matter," *supra* note 13 at p. 3.
94. *Patent Act*, *supra* note 33, s. 28.2.
95. See Part 2.1.2.1, above.
96. *Patent Act*, *supra* note 33, ss. 2 "invention," 28.2, 28.3. See also Part 2.1.2.1, above.

that is, the inventor owns the patent.[97] As discussed, this encompasses the right to use, manufacture, and sell the invention[98] for a period of twenty years from the filing date.[99] Where there is more than one inventor, joint ownership is provided for under the Act.[100] Another issue is the ownership of inventions created by employees in the course of their employment, which is something that the *Patent Act* does not address.[101]

One begins from the proposition that creating an invention within the course of one's employment does not *prima facie* bar an employee-inventor from obtaining a patent for the invention.[102] As stated by Chief Justice Moss for a unanimous court in *Piper v. Piper*:

> [T]he mere existence of a contract of service does not per se disqualify a servant from patenting for his own benefit an invention made by him during his term of service, even though the invention may relate to a subject matter germane to and useful for his employers in their business, and that, even though the servant may have made use of his employer's time and servants and materials in bringing his invention to completion, and may have allowed his employers to use the invention while in their employment.[103]

Qualifications to the presumption that an inventor-employee owns his or her invention are: "(1) an express contract to the contrary, or (2) where the person was employed for the express purpose of inventing or innovating."[104] In determining whether the person was employed for the express purpose of inventing or innovating, the Federal Court in *Comstock Canada v. Electec Ltd.* held that the "nature and context of the employer-employee relationship" is to be examined, including:

a) whether the employee was hired for the express purpose of inventing;
b) whether the employee at the time he was hired had previously made inventions;
c) whether an employer had incentive plans encouraging product development;
d) whether the conduct of the employee once the invention had been created suggested ownership was held by employer;
e) whether the invention is the product of the problem the employee was instructed to solve, i.e., whether it was [his] duty to make inventions;
f) whether the employee's invention arose following his consultation through normal company channels (i.e., was help sought?);

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97. *Ibid.*, ss. 27(1), 42.
98. *Ibid.*, s. 42.
99. *Ibid.*, s. 44.
100. *Ibid.*, s. 31.
101. *TechformProducts Ltd. v. Wolda* (2000), [2000] O.J. No. 5676, (2002), 5 C.P.R. (4th) 25 (Ont Sup Ct) at para. 11 [*Techform Products* cited to C.P.R.], rev'd on other grounds (2001), 150 O.A.C. 163, <http://www.ontariocourts.on.ca/decisions/2001/october/techformC33757.htm>, (2001), 206 D.L.R. (4th) 171 (Ont CA).
102. *Ibid.* at para. 12.
103. *Piper v. Piper*, [1904] O.J. No. 609 (Ont CA) at para. 14 [*Piper*].
104. *Comstock Canada v. Electec Ltd.* (1991), 45 F.T.R. 241, 38 C.P.R. (3d) 29 (FCTD) at p. 53 [*Comstock Canada* cited to C.P.R.]; *Techform Products*, *supra* note 101 at para. 13.

g) whether the employee was dealing with highly confidential information or confidential work;
h) whether it was a term of the servant's employment that he could not use the ideas which he developed to his own advantage.[105]

The *Patent Act* provides for an inventor to assign not only any patent that has previously been issued to the inventor,[106] but also the inventor's right to obtain the patent upon successful application.[107] Accordingly, a possible mechanism to vest ownership of the patent in an entity other than the inventor is through contract.

2.1.2.2.1. Patent Ownership in Universities Generally

Universities provide for ownership polices with respect to inventions created by university researchers. As university researchers are not typically hired to generate commercial inventions,[108] the common law presumption is that a university researcher owns the rights in the invention.[109] However, as illustrated by universities in both the United States and Canada, inventors in the university setting, either under obligation or by election, abrogate their rights in the invention through contract.[110]

2.1.2.2.1.1. University Patent Ownership Policies in the United States

In 1980, two contemporaneous pieces of legislation were enacted in the United States which dramatically altered the nature of federally funded research: the *Stevenson-Wydler Technology Innovation Act*[111] and the *Bayh-Dole Act*.[112] Although the former did entrench technology transfer into federally funded research laboratories by ensuring the establishment and sustenance of technology transfer offices,[113] the *Bayh-Dole Act* deals with ownership rights pertaining to university-generated innovation and is therefore more relevant for the purposes of the present discussion.

The *Bayh-Dole Act*, which was enacted in December 1980 and took effect in July 1981, is a uniform patent policy that applies to all small businesses and non-profit organizations who receive federal funding, including universities.[114] Prior to enactment of the *Bayh-Dole Act*, ownership of intellectual property arising from

105. *Comstock Canada*, *ibid.* at pp. 53–54.
106. *Patent Act*, *supra* note 33, s. 50(1); note, this must be done in writing.
107. *Patent Act*, *ibid.*, s. 49(1); note, this must be done in writing.
108. Adrian Zahl, "University Technology Transfers Raise Thorny Issues," *The Lawyers Weekly* 23:14 (15 August 2003).
109. *Techform Products*, *supra* note 101 at paras. 11–13; *Piper*, *supra* note 103 at para. 14.; *Comstock Canada*, *supra* note 104 at pp. 53–54.
110. *Patent Act*, *supra* note 33, ss. 33, 49(1), 50(1).
111. *Stevenson-Wydler Technology Innovation Act* of 1980, 15 U.S.C. s. 3710 (2002), <http://www.access.gpo.gov/uscode/title15/chapter63_.html>.
112. *Bayh-Dole University and Small Business Patent Procedures Act of December 12*, 1980, Pub. L. No. 96-517, 94 Stat. 3015-3028 (codified as amended at 35 U.S.C. ss. 200–211, 301–307 (1994) <http://www.access.gpo.gov/uscode/title35/partiii_chapter30_.html>) [*Bayh-Dole Act*].
113. Barry Bozeman, "Technology Transfer and Public Policy: A Review of Research and Theory," (2000) 29:4–5 Research Policy 627, <http://www.cspo.org/ourlibrary/documents/Tech%20Transfer%20Pub%20Pol.pdf> at pp. 634–644.
114. *Bayh-Dole Act*, *supra* note 112, s. 202; Jennifer A. Henderson & John J. Smith, *Academia, Industry, and the Bayh-Dole Act: An Implied Duty to Commercialize* (Boston: Association of University Technology Managers, 2002), <http://www.cimit.org/coi_part3.pdf> at p. 3 [Henderson & Smith, *Academy, Industry*].

federally funded research vested with the federal government.[115] That is, neither the university nor the researcher-inventor had any ability to retain ownership rights in the invention. As a result of the *Bayh-Dole Act*, universities may elect to retain ownership of inventions that are federally funded.[116] There is no option, however, for the inventor-researcher to retain ownership of the invention. If the university elects to retain ownership in the invention, the university is thereafter obligated to commercialize the invention, which includes patenting the invention and granting licences.[117] The net revenue garnered by the university through the successful commercialization of the research is not without restriction, as the university must distribute a portion of royalties to the inventor and reinvest the remainder in research or other elements of academia.[118] Failure to comply with the regime or successfully commercialize the invention triggers the right of the government to intervene, assume ownership rights over the intellectual property, and take over the commercialization process.[119]

In essence, the *Bayh-Dole Act* imposes a duty on universities, not just to commercialize their research when federal funding has been provided,[120] but also to do so successfully. The vesting of ownership in the government when commercialization efforts by the university are unsuccessful substantiates this notion. The Act, however, is silent on the issue as to how universities are to successfully undertake the commercialization process.[121] As in Canada, American universities use technology transfer offices as the principal mechanism to commercialize their research.[122]

2.1.2.2.1.2. University Patent Ownership Policies in Canada

Unlike the United States, Canada has not adopted a uniform university ownership policy with respect to patents. In Canada, university intellectual property ownership policies typically reflect either: (i) university-ownership, which requires mandatory assignment of ownership of the invention to the university upon deciding to patent the invention; or (ii) inventor-ownership, which provides researcher-inventors with the discretion of either assigning the invention to the university or maintaining ownership of the patent. Joint-ownership policies between the university and the inventor do exist but are far less common,[123] which is likely reflective of the inherent difficulty involved in negotiating throughout the commercialization process when several competing interests might be involved.[124] Irrespective of the ownership model adopted, it is important to note that the universities' and the inventors' ability to allocate rights according to the university policy may be qualified by agreements negotiated with funding agencies, both private and

115. Henderson & Smith, *Academy, Industry*, *ibid.* at p. 2.
116. *Bayh-Dole Act*, *supra* note 112, s. 202; Henderson & Smith, *Academy, Industry*, *ibid.* at p. 3.
117. *Bayh-Dole Act*, *ibid.*, s. 202; Henderson & Smith, *Academy, Industry*, *ibid.* at p. 3.
118. *Bayh-Dole Act*, *ibid.*, s. 202; Henderson & Smith, *Academy, Industry*, *ibid.* at p. 3.
119. *Bayh-Dole Act*, *ibid.*, s. 203(a)(1); Henderson & Smith, *Academy, Industry*, *ibid.* at p. 4.
120. Henderson & Smith, *Academy, Industry*, *ibid.* at p. 4.
121. *Ibid.* at p. 5.
122. *Ibid.* Further discussion of this topic will be found at Part 3, below.
123. Bruce P. Clayman, "Technology Transfer at Canadian Universities: Fiscal Year 2002 Update—A Report for the Canada Foundation for Innovation" (2004) at p. 15 [Clayman, "Technology Transfer at Canadian Universities"].
124. It is inherent that the existence of more diffuse control would render it more difficult to reach consensus during negotiations occurring throughout the commercialization process.

public.[125] In fact, contractual agreements with funding agencies, such as industry, supersede university policy agreements.[126] Although public funding bodies such as the Natural Sciences and Engineering Research Council of Canada (NSERC), the Canadian Institutes of Health Research (CIHR) and the Social Sciences and Humanities Research Council of Canada (SSHRC) do not have intellectual property claims in the research that they fund, private funding agencies, such as pharmaceutical and biotech companies, often seek intellectual property claims in exchange for the funding revenue they provide.[127] Notwithstanding overriding third-party claims to intellectual property rights in university-generated inventions, university intellectual property ownership policies exist in the absence of such agreements. Accordingly, the two most frequently adopted university policies, the university-ownership and inventor-ownership models, are examined.

2.1.2.2.1.2.1. The University-Ownership Model[128]

Using the University of Saskatchewan as an example of a university-ownership model, the collective agreement obliges researchers to disclose inventions that they are interested in patenting to the university.[129] There is a presumption that the university has a proprietary interest with respect to an invention that was developed with the "use of [u]niversity facilities, support personnel, or services" that was not on the employee's "own time."[130] This assessment falls to be determined by a statement of opinion as to whether "[u]niversity facilities, personnel, or services [were] used in the development of the patent,"[131] which must accompany disclosure of the invention.[132] It is from this disclosure that commercialization transpires, in which case the university will be assigned all of the rights in an invention created during the course of research falling within the aforementioned definition. Undoubtedly, this will cover the majority of inventions occurring during the course of research. The agreement also provides that the university and the researcher may agree to allocate rights contrary to this presumption where the ownership of the invention *prima facie* belongs to one or the other.[133]

Notwithstanding that inventors in the university setting are obligated to assign their intellectual property rights in the invention to the university,[134] the researcher and the university will share in the net revenue procured from commercializing the invention. The amount of return shared with the inventor(s)

125. See University of Alberta, "University of Alberta Faculty Agreement (July 1998, incorporating July 2000 amendments)—Appendix C University of Alberta Patent Policy (revised 1991)" at para. 13 [University of Alberta, "Patent Policy"]; McGill University, "Policy on Intellectual Property," <http://upload.mcgill.ca/researchoffice/ipcorrectfinal.pdf> at para. 5.4.
126. See University of Alberta, "Patent Policy," *ibid.* at para. 13.
127. See University of Alberta, *Intellectual Property Guidelines for Graduate Students and Supervisors at the University of Alberta 2004* (Edmonton: University of Alberta, 2003), <http://www.uofaweb.ualberta.ca/tecedmonton//pdfs/IPGuide2004.pdf> at p. 10 [University of Alberta, *IP Guidelines*].
128. Those universities adopting the university-ownership model include, but are not necessarily limited to McMaster University, Memorial University, McGill University, l'Université de Montréal, University of British Columbia, University of Guelph, University of Ottawa, and University of Saskatchewan; see Clayman, "Technology Transfer at Canadian Universities," *supra* note 123 at p. 15.
129. University of Saskatchewan, "University of Saskatchewan Faculty Association Collective Agreement," <http://www.usaskfaculty.ca/about/agreement.php> at para. 27, [U of Saskatchewan, "Faculty Agreement"].
130. *Ibid.*, s. 27.1.
131. *Ibid.*, s. 27.2.
132. *Ibid.*, s. 27.2.
133. *Ibid.*, ss. 27.3, 27.4.
134. *Ibid.*, s. 27.1.

typically varies between 25% and 50% of the net revenue generated.[135] At the University of Saskatchewan, the inventor(s) and the university share equally in the invention's net revenue, unless it is agreed to the contrary.[136]

2.1.2.2.1.2.2. The Inventor-Ownership Model[137]

Similar to the university-ownership model, the University of Alberta requires that researchers disclose to the university inventions that they intend to patent.[138] Contrary to the university-ownership model, however, here the assignment of intellectual property rights to the university is discretionary.[139] Specifically, the inventor can elect to assign his or her interest in the invention to the university[140] or retain ownership of the invention for him- or herself.[141] If the inventor elects to assign it to the university and if accepted by the university, the university is entitled to two-thirds of the net revenue generated from the invention, while the inventor is entitled to one-third of the net revenue.[142] By adopting this route, the inventor is absolved of the costs associated with patenting, marketing, and licensing the innovation, while the university absorbs such costs.[143] Another approach available is for the inventor to retain ownership of the invention,[144] thereby entitling the inventor to two-thirds of the net revenues from the invention and the university to one-third of the revenues.[145] Adoption of such a route by the inventor renders the inventor responsible for the commercialization of the invention, which entails the patenting, marketing, and licensing of the invention.[146]

The aforementioned university policies, irrespective of whether the university-ownership or inventor-ownership model is followed, are not engaged unless the inventor has either decided, or is under obligation, to obtain a patent for an invention. Where such a decision is rendered, the commercialization of the university-generated invention proceeds.

135. Canadian University Intellectual Property Group, *A Guide to Protecting Intellectual Property*, <http://www.research.utoronto.ca/ipc/cuipg.html> [Canadian University Intellectual Property Group, *Guide*].
136. University of Saskatchewan, "Intellectual Properties Policy: Intellectual Property Rights of Graduate Students" at para. 4.4 [U of Saskatchewan, "IP Rights"].
137. Those universities adopting the inventor-ownership model include, but are not necessarily limited to Queen's University, Simon Fraser University, University of Alberta, University of Calgary, University of Manitoba, University of Toronto, University of Waterloo and University of Western Ontario; see Clayman, "Technology Transfer at Canadian Universities," *supra* note 123 at p. 15.
138. University Alberta, "Patent Policy," *supra* note 125 at para 7.2.
139. *Ibid.* at para. 7.1.
140. *Ibid.* at para. 8.1.
141. *Ibid.* at para. 7.
142. *Ibid.* at para. 8.5; just as with universities that follow a university-ownership model, the division of revenue between the university and the inventor varies.
143. *Ibid.* at para 8.2.
144. *Ibid.* at para. 7.
145. *Ibid.* at para. 9.3(c); just as with universities that follow a university-ownership model, the division of revenue between the university and the inventor varies.
146. *Ibid.* at para. 9.1.

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3. THE COMMERCIALIZATION OF UNIVERSITY RESEARCH

UPON CREATING AN INVENTION in the university setting, one of three possibilities ensues: (i) immediate publication or other form of disclosure, in which case a subsequent decision to patent the invention will be possible only if such disclosure falls within the one-year grace period, or its contents do not surpass the requisite threshold;[147] (ii) assignment of the invention to an industry partner where under contractual obligation;[148] or (iii) commercialization of the research in accordance with university policy.[149] It is the decision to commercialize the invention that invokes the commercialization process in the university setting.

Of course, a key element to this decision making process is the recognition that the research is commercially viable. With respect to the determination of the commercial viability of an invention generated from university research, "[t]he researcher is primarily responsible for recognizing the discovery and its potential, reporting it to the institution and requesting consideration for protection and commercialization" in over 70% of universities where applicable.[150]

In most universities, intellectual property management offices, also known as industrial liaison or technology transfer offices, exist to assist in protecting intellectual property by obtaining a patent and aiding in the commercialization process.[151] At the University of Saskatchewan, the process of commercializing an invention occurs through the University Office of Technology Transfer and Industrial Liaison (University of Saskatchewan Technologies, Inc.), which is the University of Saskatchewan's technology transfer agent.[152] These offices are "the university's brokers in the knowledge market," acting as the vehicle transferring "pure science" into the market.[153] As discussed, in some universities the inventor has an option of commercializing the invention through the university's technology transfer agent or commercializing it independently.[154] In other cases, the inventor is required to go through the liaison/technology transfer office to obtain a patent for the invention.[155] Where either a mandatory policy is in place, or, in cases where

147. See Part 2.1.2.1, above.
148. In such instances, the industry partner either contracted research to the institution or made it a condition of funding it provided to the university. See University of Alberta, *IP Guidelines*, *supra* note 127 at p. 10; in either case, this is consistent with the *Patent Act*, *supra* note 33 at s. 42, which allows an inventor to assign the right to patent his invention to another entity.
149. Angus Livingstone, "University-Industry Liaison Office Technology Transfer Process at University of British Columbia" (1998), cited in *Report of the Expert Panel*, *supra* note 11 at p. 13 [Livingstone, "Technology Transfer Process"].
150. Canada, Statistics Canada, *Survey of Intellectual Property Commercialization in the Higher Education Sector, 2001* (Ottawa: Science, Innovation and Electronic Information Division, 2001) at p. 16, <http://www.statcan.ca/english/research/88F0006XIE/88F0006XIE2003012.pdf> [*Statistics Canada 2001*]. Although Canada, Statistics Canada, *Survey of Intellectual Property Commercialization in the Higher Education Sector, 2003* (Ottawa: Science, Innovation and Electronic Information Division, 2003) is available, as of the time of writing, the 2003 survey, as well as those surveys conducted thereafter, have merged the statistics of research hospitals and universities, and therefore, the 2001 statistics are more appropriate for present purposes.
151. Canadian University Intellectual Property Group, *Guide*, *supra* note 135.
152. U of Saskatchewan, "IP Rights," *supra* note 136 at para. 4.2.
153. Donald Fisher & Janet Atkinson-Grosjean, "Brokers on the Boundary: Academy-industry Liaison in Canadian Universities," (2002) 44 Higher Education 449 at p. 450 [Fisher & Atkinson-Grosjean, "Brokers on the Boundary"].
154. See Part 2.1.2.2.1(b)(ii), above.
155. See Part 2.1.2.2.1(b)(i), above.

the researcher has an option and has elected to commercialize his or her invention through the university, the inventor must assign his or her intellectual property rights to the university. As discussed, assignment of the right to obtain a patent is provided for under the *Patent Act*.[156]

The technology transfer agent engages the commercialization process by first determining whether commercialization of the invention in question is in the university's interest.[157] If the particular invention is not in the university's interest, the technology can then be licensed back to the inventor. On the other hand, if the technology transfer agent accepts the invention, commercialization of the invention ensues, which includes, but is not necessarily limited to, obtaining intellectual property protection, marketing the product, and finding the appropriate means to commercialize the invention into society.[158]

The vehicles available to commercialize intellectual property include either creating a spin-off company and licensing or assigning the invention to that spin-off company, or licensing or assigning the invention to an already existing company.[159] The choice of mechanism depends on several factors, most notably the type of technology in question;[160] however, several salient commercial factors exist that dictate the most appropriate pathway. The choice of creating a spin-off company is largely dependent on the presence of support by industry and the local government for the technology, while the choice of entering into an agreement with an existing company often results from the inability to finance a new company and the desire to avoid the risk and increased effort required to deploy a successful spin-off.[161] Indeed, spin-offs are high-risk ventures and require "up to ten times more effort" in the "formation, licensing, and ongoing relationship," thereby dissuading investors.[162] Notwithstanding this, Canadian universities demonstrate a higher rate of start-ups than universities in the United States, which is most likely due to fewer companies existing in Canada that are capable of implementing university created intellectual property into their organization.[163] It should be noted, however, that the rate of spin-offs in Canada has decreased in the past few years, which is likely a result of the Canadian industry becoming more receptive to intellectual property generated in universities.[164]

In any case, net revenues generated from intellectual property are first used to extinguish those expenses incurred in the commercialization process and are thereafter disbursed according to the university policy, which, as indicated, usually guarantees the inventor anywhere between 25 and 50 per cent of this revenue stream.[165]

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156. *Patent Act*, *supra* note 33, s. 42.
157. U of Saskatchewan, "IP Rights," *supra* note 136 at para. 4.2.
158. Livingstone, "Technology Transfer Process," *supra* note 149.
159. *Ibid.*
160. Gu & Whewell, "University Research and Commercialization of IP," *supra* note 90 at p. 73.
161. *Ibid.* at p. 65.
162. *Ibid.* at p. 73.
163. Clayman, "Technology Transfer at Canadian Universities," *supra* note 123 at p. 13.
164. *Ibid.* at pp. 13–14.
165. Canadian University Intellectual Property Group, *Guide*, *supra* note 135.

3.1. The Success of Commercializing University Research in Canada

In 2001, universities received 44.4 million dollars in royalties, which was an increase of 135 percent from 1999.[166] Of course, these royalties are subject to disbursement to others who have a financial interest in the intellectual property, such as private investors. As of 2001, universities have created 655 spin-off companies, which have produced revenues of approximately 2.5 billion dollars and which employ 18,737 people.[167] Evidence of the success of such spin-offs, as dictated by their survival rate, indicates that university spin-offs have rates akin to non-university start-ups.[168] Furthermore, industry-university partnerships appear to be more established in Canada than any other G7 country.[169] Notwithstanding impressive statistics such as these, both Canada's total R & D and university R & D rank second last of G7 countries, which suggests insufficient R & D investment in Canada.[170] Nevertheless, Canadian universities provide more national R & D than any other G7 country, and Canadian industry relies more heavily on universities as a source of innovation than any other G7 country.[171] Furthermore, it has been suggested that a higher rate of return accompanies university-industry partnerships,[172] as depicted by a 21.3 percent higher rate of return associated with university-industry partnerships compared to industry alone.[173] It is therefore not surprising that the government has increased expectations of commercialization activities by universities.[174]

3.2. The Future of Commercializing University Research in Canada: Recommendations from the Expert Panel on the Commercialization of University Research

In light of the success of commercializing university research in both Canada and the United States, it is not surprising that the federal government, whose aim is to increase Canada's economic power through an increase in the commercialization of university research,[175] has recommended significant changes to intellectual property policies and the commercialization process in Canadian universities. In 1998, the Advisory Council on Science and Technology established an Expert Panel with a mandate to try to maximize Canada's federal university funding investment.[176] In 1999, this Panel compiled a document entitled "Public Investments in University Research: Reaping the Benefits," with the mandate "to present a vision and implementation strategy to maximize the economic and

166. *Statistics Canada 2001*, *supra* note 150 at p. 25.
167. *Ibid.* at p. 30.
168. Gu & Whewell, "University Research and Commercialization of IP," *supra* note 90 at p. 72.
169. *Ibid.* at p. 30.
170. *Ibid.* at pp. 30-31.
171. *Report of the Expert Panel*, *supra* note 11 at p. 8.
172. Albert N. Link & John Rees, "Firm size, university based research, and the returns to R&D," (1990) 2:1 Small Business Economics 25, cited in Gu & Whewell, "University Research and Commercialization of IP," *supra* note 90 at p. 75.
173. *Ibid.*
174. *Report of the Expert Panel*, *supra* note 11 at p. 10.
175. *Ibid.* at p. 1.
176. *Ibid.* at p. V.

social returns to Canada from public investments in university research."[177] In addition to recommending a significant increase in federal funding for university research,[178] which has been labelled as "little more than window dressing,"[179] the Panel discussed barriers preventing the full commercialization potential of universities. Those barriers that were identified as most relevant include the absence of a consistent university intellectual property ownership framework, as well as an insufficient entrenchment of commercialization processes in universities, and the absence of mandatory obligations to divulge prospective inventions to the university. According to the Panel, these factors have resulted in a loss of commercialization opportunities for universities, thereby resulting in a loss of economic benefit to Canada.[180]

3.2.1. Mandatory Implementation of a University-Ownership Model

As discussed, Canadian universities typically adopt one of two different types of intellectual property ownership regimes with respect to patents: inventor-ownership or university-ownership. The Panel contended that one of the most significant factors accounting for the loss of opportunities is the existence of university policies that do not follow a university-ownership model.[181] According to this thesis, vesting ownership in the inventor renders it difficult, if not impossible, to negotiate licensing arrangements, particularly where there are multiple inventors.[182] In addition to the licensing pitfalls associated with non-university ownership, the Panel deemed that researchers are acting more in their self-interest, and are not in all instances acting in the best interest of Canada, when commercializing their inventions.[183] The Panel cited instances where researchers have entered into contracts with US-based firms, thereby assigning their intellectual property rights to these firms instead of the university.[184] The Panel contended that this has resulted in Canada losing out on the economic potential generated from innovation funded by the federal government.[185]

Accordingly, the Panel recommended mandatory university-ownership of all inventions generated in the university setting with the aid of federal funding.[186] Adopting this model, all researchers would be obligated to assign their intellectual property rights to the university,[187] and would receive royalties only from the commercialization of the invention.[188] Under this approach, the only instance where intellectual property could be re-assigned to the researcher

177. *Ibid.* For a response to both the Expert Panel and 2002 government discussions considering the role of universities aimed at forwarding Canada's innovation strategies, see Canadian Association of University Teachers, "Canada's Innovation Agenda: CAUT's Response."
178. *Report of the Expert Panel*, *supra* note 11 at p. 28.
179. Canadian Association of University Teachers, "CAUT Commentary on The Final Report of the Expert Panel on the Commercialization of University Research" (September 1999) [CAUT, "Commentary on Report of the Expert Panel"] at p. 2.
180. *Report of the Expert Panel*, *supra* note 11 at pp. 18–20.
181. *Ibid.* at p. 19.
182. *Ibid.* at p. 19.
183. *Ibid.* at p. 19.
184. *Ibid.* at pp. 19–20.
185. *Ibid.* at p. 20.
186. *Ibid.* at p. 25.
187. *Ibid.* at p. 27.
188. Recall that this approach to invention ownership is already adopted by several Canadian Universities, including the University of Saskatchewan: see Part 2.1.2.2.1(b)(i) above.

is where the researcher is able to generate at least the same "benefits to Canada" as the university "without undue conflicts of interest."[189] The premise underlying this recommendation is lacking, particularly when one considers the complete absence of empirical data supporting the notion that university-ownership models demonstrate higher and more successful rates of commercialization than the inventor-ownership model. In fact, no significant differences in the rate of commercialization or revenue realized from intellectual property have been demonstrated between university-owned and inventor-owned intellectual property policies in Canada.[190] Rather, the key determinants of successful commercialization of university research appear to be "an active, well-supported and well-staffed technology transfer office."[191] With respect to concerns of researchers entering into contracts with US-based companies, the solution is to identify the motivations driving such transactions rather than to implement uniform intellectual property policies.

Further, and perhaps even more importantly, the mandatory implementation of uniform patent ownership policies significantly interferes with contractual freedom. The policies currently in place are the result of negotiations between university researchers and the individual universities to satisfy the particular concerns and conditions of that university.[192] Therefore, not only does this interfere with free collective bargaining,[193] it also straitjackets universities into mandatory intellectual property policies that may not address the needs or concerns of the particular university and the prospective industry partners. By ignoring factors that are essential to the commercialization process and university-industry relationships, the recommendation of a uniform intellectual property policy regime for Canadian universities might actually hinder commercialization capabilities and university-industry interaction in Canadian universities.

3.2.2. Mandatory Disclosure of Commercially Viable Research and Entrenchment of Commercialization into University Missions

The Panel recommended that innovation be entrenched in university missions and that researchers be obligated to disclose all intellectual property with commercial potential supported by federal funding to the university.[194] In the case of the latter, the Panel recommended that failure to comply with mandatory disclosure requirements should result in denial of future federal funding.[195] It is paradoxical that the Panel admits that most researchers are more interested in scientific discoveries than in commercialization activities,[196] and yet expects these same researchers to be attuned to potentially exploitable intellectual property, or face loss of future federal funding. Such a policy clearly aims at placing an even greater emphasis on researchers to adopt business expertise

189. *Report of the Expert Panel*, *supra* note 11 at p. 27.
190. Clayman, "Technology Transfer at Canadian Universities," *supra* note 123 at p. 15.
191. *Ibid.* at pp. 15–16.
192. CAUT, "Commentary on Report of the Expert Panel," *supra* note 179 at p. 3.
193. *Ibid.* at p. 3.
194. *Report of the Expert Panel*, *supra* note 11 at p. 26.
195. *Ibid.* at p. 26.
196. *Ibid.* at p. 19.

and foresight than presently exists. Substantiating this notion, the Panel also recommended that universities amend tenure and promotion policies to account for the commercialization activities of researchers.[197]

In addition to the Panel's desire for researchers to adopt entrepreneurial foresight, the Panel also recommended that research be conducted with a specific directive. By requiring universities to implement innovation into its mission,[198] this would induce researchers in all disciplines[199] to conduct research that is more likely to invoke commercialization activities. Although the Panel's recommendation did not explicitly state that research must be conducted with a view to a profit, reinforcing commercially viable research through amendments to tenure and promotion policies to account for commercialization activities[200] will undoubtedly result in this same chilling effect.[201] As "scientific-capital" shifts to a more commercial form, the ability to generate commercially viable research becomes the "status-definer," as opposed to those traditional forms such as publication.[202] Logically, as academic research becomes more focused on obtaining a marketable, patentable product, the research that academics engage in will ensure satisfaction of that end. This raises concerns that funding will become concentrated in those areas of study capable of producing commercially viable research and in short-term research that results in immediate economic gain. Accordingly, the commercialization of university research, as well as universities' and governments' increasing expectations for the commercialization of university research, risks narrowing both the scope and type of research conducted.

Undoubtedly, there is a concern that researchers may be restricted to researching specific areas of study.[203] It is without question that some areas of research are inherently incapable of generating economically viable knowledge products. In fact, some argue that only a few areas of research have the potential for profitable commercial exploitation: namely, biotechnology and computer science.[204] Accordingly, those disciplines that do not generate patentable subject matter leading to the development of marketable products do not fit within such a model. Reinforcing the commercialization of university research risks skewing research towards "commercial-friendly" disciplines[205] such as biotechnology, and away from disciplines where there is an inherent inability to provide immediate profitability,[206] such as the social sciences and humanities. As a result, incentives to engage in work that does not lead to commercialization decrease, as does the ability to freely choose to engage in such research.[207] Indeed, knowledge

197. *Ibid.* at p. 27.
198. *Ibid.* at p. 26.
199. CAUT, "Commentary on Report of the Expert Panel," *supra* note 179 at p. 3.
200. *Report of the Expert Panel*, *supra* note 11 at p. 48.
201. The Panel's recommendation that the generation and ownership of intellectual property rights form a part of university mission statements substantiates the increasing value being placed on commercialization activities.
202. Brian Rappert & Andrew Webster, "Regimes of Ordering: The Commercialization of Intellectual Property in Industrial-Academic Collaborations," (1997) 9:2 Technology Analysis and Strategic Management 115 at p. 121 [Rappert & Webster, "Regimes of Ordering"].
203. *Ibid.* at pp. 118–119.
204. John A. Armstrong, "University Research: New Goals, New Practices," (Winter 1992-1993) Issues in Science and Technology 50, <http://www.issues.org/19.4/updated/armstrong.pdf> at p. 51.
205. Polster, "Future of the Liberal University," *supra* note 83 at p. 31.
206. Kachur, "Whose Intellectual Property," *supra* note 7 at p. 399.
207. Polster, "Future of the Liberal University," *supra* note 83 at p. 32.

produced in the university sector has the potential to become severely limited,[208] and perhaps this trend might even lead to the demise of certain disciplines.[209]

In our knowledge-based economy, university-derived research is not valued on the basis of its long-term potential, but rather, on the basis of its ability to penetrate the market successfully.[210] However, as focus shifts to the generation of commercial products and away from those "speculative quests" that may result in a scientific quantum leap from long-term research in such areas, "scientific horizons" narrow.[211] And considering that the Panel recommended that research be undertaken with a commercial directive, there is a significant risk that the funding of basic research will markedly dissipate. Accordingly, there is a concern about the erosion of basic research as focus shifts to that research capable of generating a marketable end product.[212]

Notwithstanding that basic long-term research is essential to scientific advancement and leads to new discovery[213] and the emergence of novel concepts,[214] corporate entities are quite obviously more interested in short-term research that provides immediate economic gain.[215] It is inherently unlikely that industry will provide funding for basic research in areas where "societal benefit is not immediately apparent but could ultimately be realized with lengthy and continued nurturing"[216] or derived in the distant future.[217] It is also important to recognize that the biotechnology industry, a prime generator of commercially viable research,[218] relies more heavily on basic research than any other industry, and that basic research is essential for the continued advancement of this field.[219] Furthermore, it must not be forgotten that the double helix took approximately twenty years to demonstrate commercially viability.[220] Of course, in light of the utility requirement under our patent regime, ensuring the sustenance of basic long-term research is undoubtedly a difficult task to achieve. As patentability of university-generated research achieves greater significance and becomes further entrenched into university mandates, it is an inevitable consequence that basic long-term research risks being seriously compromised. As such, if the goal is to enhance the long-term commercialization capabilities of university-generated research and the ensuing benefit to the Canadian economy, policies reducing the quantity of basic research undertaken should not be adopted.

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208. *Ibid.* at pp. 33–34.
209. CAUT, "Commentary on Report of the Expert Panel," *supra* note 179 at p. 3.
210. *Ibid.* at p. 5.
211. George Monbiot, "Guard Dogs of Perception: The Corporate Takeover of Science," (2003) 9:1 Science and Engineering Ethics 49 at pp. 49–50 [Monbiot, "Guard Dogs of Perception"].
212. Luke Collins, "Richer by Degrees: Commercialising academic intellectual property is neither straightforward nor a panacea to the problem of university funding," (2004) 50:3 Institution of Electrical Engineers Review 42 at p. 44 [Collins, "Richer by Degrees"].
213. Fisher & Atkinson-Grosjean, "Brokers on the Boundary," *supra* note 153 at p. 455.
214. Nancy F. Olivieri, "Patients' Health or Company Profits? The Commercialisation of Academic Research," (2003) 9:1 Science and Engineering Ethics 29 at p. 37 [Olivieri, "Commercialisation of Academic Research"].
215. Fisher & Atkinson-Grosjean, "Brokers on the Boundary," *supra* note 153 at p. 455.
216. Anon, "The Patent Craze in Academia," (1993) 342:8885 The Lancet 1435 at p. 1436 [Anon, "Patent Craze"].
217. *Ibid.*
218. Roberts, "Life Forms as Patentable Subject Matter," *supra* note 13 at p. 1.
219. Steven G. McMillan, Francis Narin & David L. Deeds, "An analysis of the critical role of public science in innovation: the case of biotechnology," (2000) 29:1 Research Policy 1 at p. 7 [McMillan, Narin & Deeds, "Role of Public Science in Innovation"].
220. Anon, "Patent Craze," *supra* note 216 at p. 1436.

Pressure to focus on research with "short-term and predictable goals for the purposes of industrial exploitation"[221] risks disrupting the necessary equilibrium between short-term and long-term research.[222] This, as substantiated by the reliance on long-term or basic research in the biotech industry, has the potential to lead to significant barriers to scientific advancement. Undoubtedly, this problem will become more severe as basic research becomes steadily de-prioritized in government policy and the immediate commercial viability of research reaches greater significance in the university.[223] Bearing in mind that a patent regime is purportedly designed to foster economic and scientific advancement,[224] barriers to such progress that are inherent in the imbalance between short-term/applied and long-term/basic research must be addressed. Efforts must be made to ensure that a high percentage of university research remains long-term/basic research, irrespective of its immediate commercial potential. In addition to ensuring economic and innovative progress, achieving this end will also help support academics in those disciplines where the direct commercial viability of their research is lacking. Considering that industry benefits greatly by infiltrating the university sector[225] and that innovation depends on increasing public investment in basic research,[226] obligations should fall upon government and industry to fund basic research in the university setting. Only then can the indispensable aspirations of our patent regime be attained and the continued entrenchment of commercialization processes in the university sector be justified.

3.3. The Bayh-Dole Act *as a Model for Canadian University Patent Ownership Policies*

The recommendations of the Panel set forth above are quite evidently modeled after the *Bayh-Dole Act* in many respects, which is something that the Panel made no attempt to conceal.[227] As the *Bayh-Dole Act* has been touted as being the significant causative factor of the success of commercializing university research in the United States, it is not surprising that the Panel attempted to emulate this legislation. Indeed, empirical evidence substantiates a marked increase in the success of commercialization processes following enactment of the *Bayh-Dole Act*.

Prior to the *Bayh-Dole Act*, ownership of intellectual property that arose from federally funded research vested with the United States federal government.[228] Although *prima facie* appearing to be in the public interest, the commercialization process of university research was not properly carried out, which was likely due to government's inability to effectively commercialize such

221. David Weatherall, "Problems for Biomedical Research at the Academia-Industrial Interface," (2003) 9:1 Science and Engineering Ethics 43 at pp. 44–45.
222. Sean Ekins & Richard J. McGowan, "Postgraduate education and the changing interaction with the pharmaceutical industry: a cross-cultural perspective," (2002) 7:4 Foundations of Science 413 at p. 417.
223. Monbiot, "Guard Dogs of Perception," *supra* note 211 at p. 50.
224. See Roberts, "Life Forms as Patentable Subject Matter," *supra* note 13 at p. 3; Vaver, *Intellectual Property Law*, *supra* note 3 at c. 3(A).
225. Collins, "Richer by Degrees," *supra* note 212 at p. 43.
226. Michael J. Mandel, "Commentary: How to Sharpen the Innovation Edge," (11 October 2004) 3903 *Business Week* 225 at p. 225, <http://www.businessweek.com/magazine/content/04_41/b3903483.htm>.
227. *Report of the Expert Panel*, *supra* note 11 at p. 47.
228. Henderson & Smith, *Academy, Industry*, *supra* note 114 at p. 2.

research.[229] Consequently, the commercialization of university research in the pre-*Bayh-Dole* era was stagnant compared to the incidence of commercializing university research since 1980.[230]

Commentators suggest that the *Bayh-Dole Act* has been responsible for significant changes in the academic research community.[231] In general, it is suggested that the *Bayh-Dole Act* has led to a "dramatic increase in patents issued, new companies formed, licensing agreements executed, and incoming royalties and licensing fees to academic institutions," which have greatly benefited universities.[232] Specifically, the number of patents issued by universities since the Act's implementation has grown exponentially, as have the number of spin-off companies formed as a result of university innovation.[233] The Act has also been linked to an estimated 40 billion dollar addition to the US economy stemming from technology transfer in the university sector,[234] in addition to the public benefit from the marked increase in both the number of products available and efficiency in such products entering the public sphere.[235]

These remarkable statistical increases since 1980 lend credence to the notion that the *Bayh-Dole Act* has been the revolutionizing legislation that it is credited as being. Indeed, this appears to be what the Panel concluded in its recommendations. However, as university and inventor ownership were not possible prior to enactment of the *Bayh-Dole Act*,[236] statistical increases in university commercialization-related activities and subsequent success are inevitably inflated. Furthermore, it is equally as strong a contention that another catalytic event fueled these statistical triumphs: namely, the growth of the biotechnology industry over this same period.

The past twenty-five years have led to what has been termed a "revolution" in the "biological sciences."[237] The growth of biotechnology, or "the application of technology to living organisms, or to parts of products of living organisms, to make or modify products or processes useful to man,"[238] is a result of the potential commercialization of technology generated by this industry.[239] Research in this discipline is fueled by the viability of commercial exploitation.[240] Not surprisingly, of course, investors in this industry desire intellectual property protection over the technologies developed on their dollar.[241] Therefore, as the ambit of patentable subject matter increases, so too does the amount of private investment that flows into research and development of patentable technologies.

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229. *Ibid.* at p. 2.
230. See Henderson & Smith, *Academy, Industry*, *supra* note 114.
231. Henderson & Smith, *Academy, Industry*, *supra* note 114 at p. 6.
232. *Ibid.* at p. 6.
233. *Ibid.* at p. 6.
234. The Association of University Technology Managers, "Surveys—Common Questions & Answers About Technology Transfer," cited in Henderson & Smith, *Academy, Industry*, *supra* note 114 at p. 6.
235. The Association of University Technology Managers, Press Release (17 December 1998), cited in Council on Governmental Relations, "*The Bayh-Dole Act: A Guide to the Law and Implementing Regulations*," <http://www.ucop.edu/ott/faculty/bayh.html/>.
236. Recall that prior to the *Bayh-Dole Act*, ownership of intellectual property that arose from federally funded research vested with the United States federal government: see Henderson & Smith, *Academy, Industry*, *supra* note 114 at p. 2.
237. Roberts, "Life Forms as Patentable Subject Matter," *supra* note 13 at p. 1.
238. *Ibid.* at p. 1.
239. *Ibid.* at p. 1.
240. *Ibid.* at p. 1.
241. Vallance, "Biotechnology and New Companies," *supra* note 81 at p. 1804.

In 1977, the Court of Customs and Patent Appeals deemed a pure culture microorganism patentable, holding that "the fact that microorganisms . . . are alive . . . [is] without legal significance."[242] This approach was affirmed and extended in 1980 in *Diamond v. Chakrabarty*,[243] whereby live, human-made microorganisms were held to be patentable under the US patent regime. In broadening the scope of patentable subject matter,[244] Justice Burger held that, "Congress intended statutory subject matter [i.e., patentable subject matter] to 'include anything under the sun that is made by man.'"[245] In adopting this approach, the United States Supreme Court expanded the intellectual property protection afforded to technologies produced in the biotechnology industry, thereby allowing the ambit of patentable subject matter to become significantly more expansive.[246] Following the *Chakrabarty* decision, the Patent and Trademark Office Board ruled in 1985 that a genetically engineered plant was patentable,[247] and in 1987 held that a multi-cellular animal could be patentable in *Ex parte Allen*.[248] Following the latter decision, the Patent and Trademark Office released information articulating its position on what constituted patentable subject matter:

> The Board relied upon the opinion of the Supreme Court in Diamond v. Chakrabarty…as controlling authority that Congress intended statutory subject matter to include anything under the sun that is made by man. The Patent and Trademark Office now considers non-naturally occurring non-human multi-cellular living organisms, including animals, to be patentable subject matter within the scope of [the U.S. patent regime]….[249]

On 12 April, 1988, soon after issuance of this release, patent 4,736,866 was issued for a transgenic animal, the "Harvard Mouse."[250]

Arguably, the scope of patentable subject matter has largely resulted in the increase in the economic growth of the biotech industry. Further, as the biotech industry, since its inception, is heavily entwined with academic research[251] and depends more on public science than any other discipline,[252] it logically follows that the dramatic statistical increases in successful commercialization of

242. *In re Bergy*, 563 F.2d 1031, 1038 (CCPA 1977).
243. *Diamond v. Chakrabarty*, 447 U.S. 303, <http://supreme.justia.com/us/447/303/case.html>, 100 S. Ct. 2204 (1980) [*Chakrabarty* cited to U.S.].
244. *Ibid.* at p. 306.
245. US, Senate, *Report Subcommittee on Patents, Trademarks and Copyrights of the Committee of the Judiciary* (S. Rep. No. 82-1979) (Washington, DC: United States Government Printing Office, 1952), <http://ipmall.info/hosted_resources/lipa/patents/patentact/senate_report_1979.htm>; US, House of Representatives, *Report Subcommittee on Patents, Trademarks and Copyrights of the Committee of the Judiciary* (H. R. Rep. No. 82-1923), (Washington, DC: United States Government Printing Office, 1952), cited in *ibid.* at p. 309.
246. David Korn, "Industry, Academia, Investigator: Managing the Relationships," (2002) 77:11 Academic Medicine 1089 at p. 1091 [Korn, "Industry, Academia, Investigator"].
247. *Ex parte Hibberd*, 227 U.S.P.Q. 443 (Bd Pat App & Int 1985).
248. *Ex parte Allen*, 2 U.S.P.Q. 2d 1425 (Bd Pat App & Int 1987).
249. 1077 Off. Gaz. Pat. Office 24 (1987), cited in David G. Scalise & Daniel Nugent, "International intellectual property protections for living matter: biotechnology, multinational conventions and the exception for agriculture," (1995) 27 Case Western Reserve Journal of International Law 83, cited in Roberts, "Life Forms as Patentable Subject Matter," *supra* note 13 at p. 29.
250. Roberts, "Life Forms as Patentable Subject Matter," *supra* note 13 at p. 30.
251. Annetine Gelijns & Samuel Thier, "Medical Innovation and Institutional Interdependence: Rethinking University-Industry Connections," (2002) 287:1 Journal of the American Medical Association 72, <http://plaza.ufl.edu/rmelk/BestofBME/Publications/InnovateAcademia.pdf> at p. 73.
252. McMillan, Narin & Deeds, "Role of Public Science in Innovation," *supra* note 219 at p. 7.

university technologies since 1980 quite possibly reflect the exponential growth of an industry dependent on university research. Accordingly, and quite correctly, the *Bayh-Dole Act* is best labelled not as a cause but as a catalyst to the significant statistical changes reported.[253] As such, suggesting that imitation of the *Bayh-Dole Act* will result in the desired increase in university commercialization success is highly unlikely. Furthermore, notwithstanding that Canada's *Patent Act* has roots in the American regime, the jurisprudence established in Canadian and United States courts with respect to patentable subject matter are highly divergent.[254] This is even more prevalent in light of the position adopted by the Supreme Court of Canada in *Harvard College v. Canada (Commissioner of Patents)*[255] and *Monsanto Canada Inc. v. Schmeiser*.[256] How *Harvard Mouse* and *Schmeiser* will impact biotechnology in Canada has yet to be determined; however, the continued divergence from the United States' position on what constitutes patentable subject matter further supports the proposition that mere emulation of the *Bayh-Dole Act* will not necessarily lead to the desired increases in the successful commercialization of university-generated inventions.

Even more importantly, and notwithstanding the absence of *Bayh-Dole*-equivalent legislation in Canada, it has been demonstrated that:

> Canadian university researchers appear to be every bit as creative and inventive as their U.S. counterparts (citing equivalent rates of Invention Disclosures Received) and that Canadian universities are every bit as aggressive in licensing IP generated in the institutions (citing equivalent Licenses and Options Executed).[257]

This contention is validated by the comparable rates of invention disclosures and licensing options executed between Canada and the United States when assessed per one million dollars of research expenditure.[258] In fact, there is a positive correlation between the rate of technology transfer and research expenditure, suggesting that funding appears to be the determining factor in the rate and success of commercializing university-generated innovation.[259] Accordingly, Canadian universities are undoubtedly efficient in commercializing their technologies.[260] Therefore, it appears that the gap between Canada and the United States, with respect to the rate and success of technology transfer and the resultant remarkable statistics, is more likely the result of a significant difference in research expenditures[261] rather than the absence of *Bayh-Dole*-equivalent legislation. Simply put, if Canada expects universities to increase their output of commercialized technologies, more input in the form of investment and funding is required.

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253. Korn, "Industry, Academia, Investigator," *supra* note 246 at p. 1091.
254. Roberts, "Life Forms as Patentable Subject Matter," *supra* note 13 at p. 4.
255. *Harvard College v. Canada (Commissioner of Patents)*, 2002 SCC 76, <http://scc.lexum.umontreal.ca/en/2002/2002scc76/2002scc76.html>, [2002] 4 S.C.R. 45 [*Harvard Mouse*].
256. *Monsanto Canada Inc. v. Schmeiser*, 2004 SCC 34, <http://scc.lexum.umontreal.ca/en/2004/2004scc34/2004scc34.html>, [2004] 1 S.C.R. 902 [*Schmeiser*].
257. Clayman, "Technology Transfer at Canadian Universities," *supra* note 123 at p. 14.
258. *Ibid.* at p. 15.
259. *Ibid.* at p. 18.
260. Kachur, "Whose Intellectual Property," *supra* note 7 at p. 402.
261. *Ibid.* at p. 402.

3.4. The Commercialization of University-Generated Research and its Incompatibility with Traditional University Ideals

Despite the apparent success of the *Bayh-Dole Act* in the United States, that Act, and the commercialization of university research generally, has not come without criticism. In addition to criticism of those issues previously identified—namely the inherent incompatibility subsisting between academic publication and the novelty requirement and the potential to skew the type of research conducted—the commercialization of university research has also been criticized for transforming and undermining fundamental concepts of the university. Accordingly, before Canadian universities are pressured to institutionalize an even greater proportion of research commercialization into their mandate, the potential negative effects this may have on the academic institution cannot be dismissed with callous disregard.

It is quite salient that both industry and academia, at least traditionally, are premised on and are motivated by different aims and goals. It is well understood that industry has a responsibility to investors and shareholders whose motivation is financial gain.[262] In contrast, academia owes a duty to humankind generally, is motivated by "the quest for knowledge for the sake of knowledge,"[263] and is focused on "the disinterested pursuit of truth."[264] Universities and scientific journals are often viewed as "the guardians of integrity in scientific research," endorsing the quality and honesty of the same.[265] However, as commercial activity becomes more prevalent in the academy and financial interests become engrained in the institution and its researchers, those traditional motivations of the university setting are being called into question[266] and the fundamental values underlying the university are being forever transformed.[267] Furthermore, the prospect of economic gain for both researchers and the university also brings research results and the integrity of the academic institution under scrutiny.[268]

The link between selective serotonin reuptake inhibitors (SSRIs)[269] and suicide was first demonstrated in 1990;[270] it was not until recently, however, that this information reached mainstream literature[271] and has been acknowledged by the manufacturers of these products.[272] Researcher David Healy, although originally adopting the approach that SSRIs did not contribute to the increased incidence of suicide, encountered a series of events that compromised his position.[273] Specifically, David Healy conducted research demonstrating a

262. Vallance, "Biotechnology and New Companies," *supra* note 81 at p. 1805.
263. Henderson & Smith, *Academy, Industry*, *supra* note 114 at p. 6.
264. G.R. Evans & D.E. Packham, "Ethical Issues at the University-Industry Interface: A Way Forward?" (2003) 9:1 Science and Engineering Ethics 3 at p. 8 [Evans & Packham, "Ethical Issues at University-Industry Interface"].
265. *Ibid.* at p. 4.
266. Henderson & Smith, *Academy, Industry*, *supra* note 114 at p. 6.
267. Scott, "Ethics of New Research Paradigm," *supra* note 1 at p. 82; Polster, *supra* note 83 at pp. 33–34.
268. Henderson & Smith, *Academy, Industry*, *supra* note 114 at p. 6.
269. SSRIs are most commonly prescribed to treat depression and are sold under the trade name of Prozac and the like: see Carol Wade *et al.*, *Psychology: Canadian Ed.* (Toronto: Pearson Education Canada, 2004).
270. Martin H. Teicher, Carol Glod & Jonathan O. Cole, "Emergence of Intense Suicidal Preoccupation During Fluoxetine Treatment," (1990) 147:2 American Journal of Psychiatry 207.
271. See Tom Spears, "Common antidepressants increase suicide risk: study," *The StarPhoenix* (18 February 2005).
272. David Healy, "In the Grip of the Python: Conflicts at the University-Industry Interface," (2002) 9:1 Science and Engineering Ethics 59 [Healy, "Conflicts at University-Industry Interface"].
273. *Ibid.* at p. 60.

correlation between suicide and SSRIs,[274] in addition to discovering discrepancies between raw data produced from clinical trials and the data that was actually published regarding SSRI-associated suicide attempts.[275] As a result of his research, Healy's employment contract with the University of Toronto was rescinded, arguably due to the university's fear of losing significant financial contribution from pharmaceutical companies whose position was clearly adverse to the position adopted by Healy.[276]

A similar pattern is exemplified by the experience of Dr Nancy Olivieri.[277] As recounted by Olivieri, she had discovered significant negative effects during clinical drug trials, which she subsequently published in the *New England Journal of Medicine*.[278] Specifically, the sample population of children with the disease thalassaemia was experiencing increased iron concentrations in their liver, thereby increasing their risk of heart failure and death.[279] Notwithstanding the invaluable nature of such information, it was not well received by the University of Toronto where Olivieri was employed, or by the drug company who manufactured the drug in question.[280] By publishing the results of the clinical trials, Olivieri breached a non-disclosure agreement she had with the pharmaceutical company, which prohibited publication without the express consent of the company.[281] Subsequent to her publication and the ensuing aftermath associated therewith, the University of Toronto attempted to dismiss her on five separate occasions to no avail.[282] It was quite salient that prior to Olivieri's publication of the research, the University of Toronto was in the process of negotiating a twenty million dollar contribution by the pharmaceutical company in question.[283]

The public's trust and perception of integrity in academic research are fundamental to the sustenance of the academy, and are quite possibly negatively affected by universities having a significant financial interest in its research.[284] As depicted by the incidents of Olivieri and Healy, commercialization of university research not only has the potential to shape and direct the research questions asked, but also to influence the answers given.[285] Furthermore, it is not only the integrity and fundamental values of the university that are at stake when such issues arise, as the university, and perhaps even the individual researcher or research team involved, may face potential liability. Indeed, litigation in the United States found a pharmaceutical giant liable for failure to warn and test adverse psychiatric effects of its antidepressant medication that contributed to a mass-murder-suicide.[286] It therefore does not seem unreasonable to suggest that

274. David Healy, "Emergence of antidepressant induced suicidality," (2000) 6:1 Primary Care Psychiatry 23.
275. Healy, "Conflicts at University-Industry Interface," *supra* note 272 at p. 67.
276. *Ibid.* at p. 65.
277. For a recent examination of the implications of Dr Olivieri's experience, see Jon Thompson, Patricia A. Baird & Jocelyn Downie, "The Olivieri Case: Context and Significance," *Ecclectica* (December 2005), <http://www.ecclectica.ca/issues/2005/3/index.asp?Article=2>.
278. Olivieri, "Commercialisation of Academic Research," *supra* note 214 at p. 30.
279. *Ibid.* at p. 32.
280. *Ibid.* at p. 33.
281. *Ibid.* at p. 33.
282. *Ibid.* at p. 35.
283. *Ibid.* at p. 34.
284. Henderson & Smith, *Academy, Industry*, *supra* note 114 at p. 7.
285. Olivieri, "Commercialisation of Academic Research," *supra* note 214 at p. 37.
286. *Tobin v. SmithKline Beecham*, 164 F.Supp. 2d 1278 (D Wy 2001).

such liability might also befall universities and researchers involved in practices such as under-reporting statistics that might otherwise be significant. Although scientific journals can aid in this process by requiring disclosure of conflicts of interest,[287] namely requiring disclosure of direct business associations and sources of funding,[288] such measures alone are insufficient. It is therefore imperative that policy makers factor the divergent interests of universities and industry into their decision-matrix when they attempt to "enhance" university commercialization capabilities. After all, it is exceedingly difficult to justify the commercialization of university-generated research in a milieu where the commercialization of such research leads to innovation that might initiate potential liability and to a market that lacks confidence in university research and the knowledge products it generates. Accordingly, university commercialization processes should be accompanied by mandatory ethics courses, applicable to all university students and researchers, which emphasize the pertinent issues arising from university-industry interaction and the commercialization process.

3.5. The Demise of the Experimental Use Exception's Availability to University Researchers

Another potential chilling effect of the increase in commercialization activities in the University setting is the demise of the experimental use exception. Although patent ownership is generally conceptualized in terms of absolute ownership rights, the experimental use exception provides one avenue for researchers to circumvent patent infringement. In essence, the experimental use exception provides users of a patented product with an exemption from what would otherwise constitute patent infringement in the appropriate circumstances.[289] The ability to utilize this exception, without violating the Agreement on Trade-Related Aspects of Intellectual Property Rights[290] ("TRIPS") of the World Trade Organization ("WTO"), is provided for in the exception espoused by article 30 of the TRIPS agreement, which provides that:

> Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.[291]

287. Olivieri, "Commercialisation of Academic Research," *supra* note 214 at p. 39.
288. D. Packham & M. Tasker, "Industry and the Academy—a Faustian Contract?" (1997) 11:2 Industry & Higher Education 85, cited in Evans & Packham, "Ethical Issues at University-Industry Interface," *supra* note 264 at p. 12.
289. See *Smith Kline & French Inter-American Corp. v. Micro Chemicals Ltd.* (1971), [1972] S.C.R. 506 [*Micro Chemicals* cited to S.C.R.].
290. *Agreement on Trade-Related Aspects of Intellectual Property Rights*, 15 April 1994, 1869 U.N.T.S. 299 (being Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, 1867 U.N.T.S. 3) [TRIPS].
291. *Ibid.*, art. 30. It is worthy to note that the scope of article 30 of TRIPS was considered in light of section 55.2 of the *Patent Act*, which is discussed below. Specifically, in "Canada—Patent Protection for Pharmaceutical Products," it was determined that section 55.2 of the *Patent Act* was consistent with TRIPS: see World Trade Organization "Fact Sheet: TRIPS and Pharmaceutical Patents—Obligations and Exceptions," <http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm>.

3.5.1. Canada's Utilization of the Experimental Use Exception

In Canada, both the common law and *Patent Act* provide for the experimental use exception, although the scope of this exception lacks clarity.[292] Justice Hall in *Smith Kline & French Inter-American Corp. v. Micro Chemicals Ltd.* articulated Canada's position with respect to the experimental use exception:

> …no doubt if a man makes things merely by way of bona fide experiment, and not with the intention of selling and making use of the thing so made for the purpose of which a patent has been granted, but with the view of improving upon the invention the subject of the patent, or with the view of seeing whether an improvement can be made or not, that is not an invasion of the exclusive rights granted by the patent. Patent rights were never granted to prevent persons of ingenuity exercising their talents in a fair way. But if there be neither using nor vending of the invention for profit, the mere making for the purpose of experiment, and not for a fraudulent purpose, ought not to be considered within the meaning of the prohibition, and if it were, it is certainly not the subject for an injunction. [293]

At issue in *Micro Chemicals* was whether the purpose of examining the manufacturing process of a patented invention constituted patent infringement. As Micro Chemicals was not manufacturing the patented substance for profit, but rather ensuring the successful manufacture of the patented product in generic form, the court held that Micro Chemicals fell within the ambit of the experimental use exception, and was therefore not liable for patent infringement. However, as *Micro Chemicals* addressed the issue of compulsory licensing, a provision since repealed from the *Patent Act*,[294] the nature and scope of this exception is now uncertain.[295]

With respect to the statutory experimental use exception, subsection 55.2(1) of the *Patent Act* provides for an exception:

> to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.[296]

The most common circumstances where this provision applies are where generic manufacturers, prior to the expiration of a patent, are in the development and

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292. Canadian Biotechnology Advisory Committee, *Summary Report of the President/CEO Industry Hearing to CBAC* by E. Richard Gold (Ottawa: Canadian Biotechnology Advisory Committee, 2000) at para. 24, <http://cbac-cccb.ic.gc.ca/epic/internet/incbac-cccb.nsf/en/ah00370e.html> [CBAC, *Summary Report*].
293. *Micro Chemicals*, *supra* note 289 at pp. 519–520, quoting Jessel MR in *Frearson v. Loe*, (1878), 9 Ch. D. 48 at pp. 66–67.
294. Previously, the Patent Act provided for a system of compulsory licensing allowing manufacturers of generic versions of patented brand names to manufacture or import and use the generic version until expiry of the patentee's patent on the similar product in exchange for royalties. Ss. 55.2(2) and (3) were repealed in 2001. Ss. 55.2(1) and (4) now provide for the development of the generic brand and for application for regulatory approval without infringement of the patent. See *Apotex Inc. v. Canada (AG)* (1996), 71 C.P.R. (3d) 166, 123 F.T.R. 161 at paras. 6–7, 16 (FCTD) [*Apotex*].
295. *Harvard Mouse*, *supra* note 252 at para. 177.
296. *Patent Act*, *supra* note 33, s. 55.2(1).

approval stage of a generic version of a patented product.[297] Meanwhile, subsection 55.2(6), which is more relevant for the purposes of the experimental use exception generally, provides that subsection (1) does not abrogate any exception afforded by the common law with respect to:

> acts done privately and on a non-commercial scale or for a non-commercial purpose or in respect of any use, manufacture, construction or sale of the patented invention solely for the purpose of experiments that relate to the subject-matter of the patent.[298]

This appears to be a codification of the common law experimental use exception; however, due to limited judicial interpretation of this statutory exception,[299] the scope of the defence, similar to the common law position, remains unclear. This is particularly so with respect to research conducted on patented products in university laboratories that may, although perhaps not initially intended to, result in a highly profitable research-product from experimentation with the patented invention.

3.5.2. The United States' Utilization of the Experimental Use Exception

In the United States, 35 U.S.C. s. 271(e)(1) provides a safe harbour rule whereby it is not an act of infringement to:

> make, use, offer to sell, or sell within the United States or import into the United States a patented invention…solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products. [300]

As this language is somewhat similar to section 55.2 of the Canadian *Patent Act*, jurisprudence emanating from the United States pertaining to the safe harbour exception has the potential to play a significant role in the interpretation of section 55.2 by Canadian courts. Fairly recently, the United States Supreme Court was faced with determining the scope of the US provision. In finding that the alleged infringer had not infringed the patent in question, Justice Scalia in *Merck KGAA v. Integra Lifesciences I, Ltd.*[301] noted the breadth accorded to section 271(e)(1):

297. *Apotex*, *supra* note 294 at para. 16.
298. *Patent Act*, *supra* note 33 at s. 55.2(6).
299. Litigation pursuant to the *Patent Act*, *supra* note 33, s. 55.2(6) has not addressed the nature and scope of this provision.
300. 35 U.S.C. s. 271(e)(1) (1984), <http://www.law.cornell.edu/uscode/35/271.html>.
301. *Merck KGAA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, <http://supreme.justia.com/us/545/03-1237/case.html>, 125 S. Ct. 2372 (2005) [*Merck* cited to S.Ct.].

> [W]here a drugmaker has a reasonable basis for believing that a patented compound may work, through a particular biological process, to produce a particular physiological effect, and uses the compound in research that, if successful, would be appropriate to include in a submission to the FDA, that use is "reasonably related" to the "development and submission of information under . . . Federal law."[302]

Notwithstanding the apparent breadth accorded to research conducted with reasonable belief that results from experimentation with a patented compound would be appropriate for submission to the FDA, the court also noted the applicability of the statutory exception, or rather the lack thereof, to basic research:

> Basic scientific research on a particular compound, performed without the intent to develop a particular drug or a reasonable belief that the compound will cause the sort of physiological effect the researcher intends to induce, is surely not "reasonably related to the development and submission of information" to the FDA.[303]

Although the statutory exception discussed in *Merck* will undoubtedly afford researchers in the pharmaceutical industry a wide use of the exception, university researchers, particularly those conducting basic research of the kind discussed in *Merck*, are unlikely to be afforded any additional research liberties by virtue of this provision.

Also of relevance to researchers in the university setting is *Madey v. Duke University*,[304] which has significantly narrowed the scope of the common law experimental use exception in the United States. Madey, a former research professor and sole patent holder of two patents related to laboratory equipment at Duke University, brought an action against Duke for patent infringement. As alleged by Madey, the continued use of three specific components of this patented laboratory equipment without his consent constituted patent infringement of his two patents. Duke contended that its use of the equipment fell within the ambit of the experimental use exception.

The court, in finding that the district court misconstrued the breadth to be afforded to the experimental use exemption, held that the experimental use exemption is to be construed narrowly and was not available to the university in this instance. Gajarsa J stated that the experimental use exemption is restricted to those actions conducted "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry"[305] and that the exemption is inapplicable where the "slightest commercial implication is undertaken"[306] or where research with the patented technology is conducted under the "guise of scientific inquiry"[307] but

302. *Ibid.* at p. 2383.
303. *Ibid.* at p. 2382.
304. *Madey v. Duke University*, 307 F.3d 1351 (Fed Cir 2002), <http://www.ll.georgetown.edu/federal/judicial/fed/opinions/01opinions/01-1567.pdf>, certiorari denied 539 U.S. 958 (2003) [*Madey* cited to F.3d].
305. *Ibid.* at p. 1362, quoting *Embrex, Inc. v. Service Engineering Corp.*, 216 F.3d 1343 (Fed Cir 2000), <http://www.ll.georgetown.edu/federal/judicial/fed/opinions/99opinions/99-1064.pdf> at p. 1349.
306. *Madey, ibid.* at p. 1362.
307. *Ibid.*, quoting *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*, 733 F.2d 858 (Fed Cir 1984) at p. 863.

has "definite, cognizable, and not insubstantial commercial purposes."[308] Even more importantly, and of particular relevance to the university sector, the court found that a lack of direct commercial applicability from the use was not determinative of the exception's applicability:

> Our precedent clearly does not immunize use that is in any way commercial in nature. Similarly, our precedent does not immunize any conduct that is in keeping with the alleged infringer's legitimate business, regardless of commercial implications. For example, *major research universities, such as Duke, often sanction and fund research projects with arguably no commercial application whatsoever. However, these projects unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects. These projects also serve, for example, to increase the status of the institution and lure lucrative research grants, students and faculty.*
>
> In short, r*egardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense. Moreover, the profit or non-profit status of the user is not determinative.*[309]

3.5.3. Conclusions Regarding the Experimental Use Exception in Canadian Universities

As a result of the uncertain state of the experimental use exception in Canada, it is not unforeseeable that decisions from the United States may become highly relevant in defining both the nature and scope of this exception in Canada: namely, *Merck* and *Madey*. Indeed, adopting the approach in *Madey* would be consistent with the approach desired by the Canadian pharmaceutical industry—that a narrow-experimental use exception be implemented.[310] Subsequent to the adoption of a narrower scope of the exception as set forth in *Madey*, it is a reasonable contention that university institutions will be more reluctant to extend ownership status to the university researcher out of fear that subsequent use of the patented invention by the university could constitute infringement. Therefore, based on the ill-defined nature and scope afforded to the experimental use exception in Canada and based on cases such as *Madey*, which provide guidance on the use of the exception by universities in the United States, it is reasonable to conclude that the experimental use exception will provide little relief to researchers in the university setting in the years to come. Furthermore, as university mandates become more focused on commercialization processes, universities are unlikely to be afforded the experimental use exception irrespective of whether a narrow approach such as *Madey*, or a broad approach, such as *Micro Chemicals*, is adopted. Inevitably, it falls to be assessed whether

308. *Ibid.* at p. 863.
309. *Ibid.* at p. 1362 (emphasis added).
310. CBAC, *Summary Report*, *supra* note 292 at para. 25.

the commercialization of university-generated research contributes more to technological and economic progress than would the availability of the experimental use exception in the university setting. Otherwise, failure to adopt the appropriate mechanism that will achieve maximal technological and economic progress will simply result in scientific and economic inefficiency.

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4. CONCLUSION

THE COMMERCIALIZATION OF UNIVERSITY RESEARCH will inexorably subsist in the knowledge-based economy, which relies on "the development, acquisition and use of knowledge."[311] Consequently, universities will continue to face increasing pressure from both government and industry to develop commercially viable innovation to aid in the sustenance of this economy. As has been depicted, however, the haphazard entrenchment of commercialization into academic policy has the potential to interfere not only with the fundamental tenets of academia, but also with technological and economic progress. Manifestly, a patent regime purportedly designed to "foster technological and economic progress"[312] and to "stimulate the creation and development of new technologies"[313] is inconsistent with this outcome. Accordingly, if the commercialization of university-generated research is undermining the fundamental purpose of our patent regime, intervention is essential to ensure that the proliferation of economic and scientific growth ensues from commercializing university-generated research. Indeed, recent comments by Dr Arthur Carty, national science advisor to former Prime Minister Paul Martin and former head of the National Research Council, demonstrates recognition of this delicate balancing act:

> Canada is currently a world leader in [biotechnology]…and we want to ensure that we maintain our position. In order to do so, the Government is committed to ensuring that the Patent Act remains among the most modern and progressive in the world. This will further stimulate innovation, investment and trade. Given the public interest around new biotechnologies, our Patent Act must balance the need for effective patent protection to encourage the development of new products, while promoting the diffusion of information to facilitate access to these inventions, and further innovative research.[314]

Although the commercialization of university research is largely irreconcilable with the traditional university model, it is conceded that the commercialization of university-generated research is well ingrained into the structure of the modern university and will inevitably remain. Although the Panel's recommendations have not yet been implemented, the federal government in

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311. Surenda Gera, Clifton Lee-Sing & Keith Newton, "The Emerging Global Knowledge-Based Economy: Trends and Forces" in Louis A. Lefebvre, Elisabeth Lefebvre & Pierre Mohnen, eds., *Doing Business in the Knowledge-Based Economy: Facts and Policy Changes* (London: Kluwer Academic Publishers, 2001) at p. 1.
312. Roberts, "Life Forms as Patentable Subject Matter," *supra* note 13 at p. 3.
313. Vaver, *Intellectual Property Law*, *supra* note 3 at c. 3(A).
314. Interview of Dr Arthur J. Carty by Morris Berrie (May 2004) in *BioResource*, <http://www.investinbiotech.com/archive_article.php?id=254>.

2003 expressed expectations for universities to double R & D and to triple the commercialization of university-based research.[315] Identified by industry and government as generators of knowledge products,[316] universities have the ability to significantly contribute to the new wealth in this knowledge-based economy. At the same time, however, it must be brought to the forefront of consciousness that continued success in this economy depends on perpetual and efficient knowledge production. As revenues generated from the commercialization of university research are less than one per cent of university budgets in the United States,[317] beneficial contribution to this economy will not be attained from the university's generation of knowledge products with immediate market potential, but rather, from the university's ability to provide sustained foundational knowledge to this economy. To advance this aim, efforts must be made to ensure expedient knowledge dissemination, a commitment to long-term basic research, and maintenance of the integrity of academic research. Only by these means can the fundamental tenets of our patent regime be realized and the entrenchment of commercialization processes in the university sector be justified.

315. Kachur, "Whose Intellectual Property," *supra* note 7 at pp. 385–386.
316. Etzkowitz, "Future of the University," *supra* note 4 at p. 313; CAUT, "Intellectual Property Part 3," *supra* note 10 at p. 24.
317. Steven Wolf & David Zilberman, "Public Science, Biotechnology, and the Industrial Organization of Agrofood Systems," (1999) 2:1 AgBio Forum—the Journal of Agrobiotechnology Management and Economics 37 at p. 38.