AGRICULTURAL BIOTECHNOLOGY AND THE "EARLY-WORKING" EXEMPTIONS UNDER THE *PATENT ACT*

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The author explores the availability to generic manufacturers of two research exemptions under the Canadian Patent Act. *In order to expedite later market entry, processes of research and development and federal product approval are often initiated prior to patent expiry. The question arises of when these "early-working" endeavours will violate the protection offered by a patent. The "research exemption" has been interpreted narrowly, and may only be of limited use to potential manufacturers engaging in early development of protected products. However, the "regulatory approval exemption" has been given a wider interpretation, both in Canada and the United States, and it is likely that processes related to regulatory approval will not as readily be considered as patent infringing. Finally, the author also briefly explores commercial and strategic considerations as they relate to these legal issues.*

L'auteur explore la possibilité d'utiliser deux exemptions de recherche pour les fabricants génétiques en vertu de la Loi sur les brevets *du Canada. Afin d'accélérer les entrées tardives sur le marché, les procédures de recherche et développement et l'approbation du produit par le gouvernement fédéral sont souvent mises en marche avant l'expiration du brevet. Il faudrait se demander à quel moment ces démarches de « mise au point à l'avance » violent-elles la protection assurée par le brevet. L'« exemption de recherche » a été interprétée rigoureusement, et les fabricants éventuels intéressés à développer, de manière précoce, les produits protégés ne peuvent en faire qu'un usage limité. Cependant, l'« exemption d'approbation réglementaire » a été plus largement interprétée, au Canada comme aux États-Unis, et il semble que les processus relatifs à l'approbation réglementaire ne soient pas de sitôt considérés comme étant une infraction au brevet. Enfin, l'auteur survole les implications commerciales et stratégiques relatives à ces questions juridiques.*

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I. INTRODUCTION

The use of biotechnology in agricultural production is now widespread in Canada. Canola growers in particular have enthusiastically embraced herbicide tolerant (HT) varieties, most

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notably Monsanto's Roundup Ready™ product, which uses a genetically modified gene resistant to the effects of the herbicide glyphosate. As MacKay J. explained in *Monsanto Canada Inc. v. Schmeiser*:

> Glyphosate herbicides such as Roundup have been widely used in Canada for many years. Canola tolerant to glyphosate first became available commercially in Canada in 1996. It has been marketed under licensing arrangements through Monsanto Canada under Monsanto's trade-mark Roundup Ready Canola. In 1996 approximately 600 farmers in Canada planted Roundup Ready canola, on some 50,000 acres. By 2000, approximately 4.5 to 5 million acres of Roundup Ready canola were planted in Canada, by about 20,000 farmers, producing nearly 40% of canola grown in Canada.[1]

Monsanto was issued a Canadian patent on this gene in 1993,[2] and the product was first offered for sale in 1996. To grow Roundup Ready™ Canola, farmers must enter into a contract with Monsanto to purchase Monsanto seed and herbicide from approved dealers *on an annual basis* and pay an annual Technology User Fee of $15 per acre. Given the popularity of the product, Monsanto is earning significant revenue from Roundup Ready™ Canola in Canada. The lengthy litigation between Monsanto and Saskatchewan farmer Percy Schmeiser[3] is clear evidence of the importance to Monsanto of maintaining the validity (and commercial integrity) of this particular product and its associated patent.

The '830 Patent is due to expire in 2010. Given its aforementioned commercial success, it would appear highly attractive to competitors, university researchers, and/or farming groups to attempt to produce generic versions of this product. Assuming the figures cited by MacKay J.[4] are correct, at a minimum Monsanto earns $67.5 million per annum from Technology User Fees in Canada. This figure is, of course, in addition to the sales revenue generated by the seeds and herbicides. Farm revenues could be significantly enhanced if a generic version of glyphosate-resistant canola could be marketed without the additional technology user fee.

The aim of this article is to explore whether potential producers of generic glyphosate-resistant canola can avail themselves of exemptions that exist under the *Patent Act*[5] (and associated jurisprudence) to ensure a timely entrance onto the Canadian market in 2010.

II. THE UTILITY OF THE "EARLY WORKING" EXEMPTIONS

In Canada, plants that have been modified via genetic engineering are classified by federal regulators as Plants with Novel Traits (PNTs). Their commercial release must be approved by the Canadian Food Inspection Agency (CFIA), Health Canada, and Environment Canada.

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1 *Monsanto Canada Inc. v. Schmeiser*, 2001 FCT 256, 202 F.T.R. 78 at para. 17, aff'd 2002 FCA 309, [2003] 2 F.C. 165, rev'd 2004 SCC 34, [2004] 1 S.C.R. 902 [*Monsanto*].

2 "Glyphosate-Resistant Plants," Can. Patent No. 1313830 (6 August 1986, issued 23 February 1993) ['830 Patent].

3 See *supra* note 1. Much commentary also exists on this litigation. See, *e.g.*, Martin Phillipson, "Giving Away the Farm? The Rights and Obligations of Biotechnology Multinationals: Canadian Developments" (2005) 16 K.C.L.J 362 and Bruce Ziff, "Travels With My Plant: *Monsanto v. Schmeiser* Revisited" (2005) 2 U. Ottawa L. & Tech. J. 493.

4 *Monsanto* (T.D.), *supra* note 1.

5 R.S.C. 1985, c. P-4.

Each of these federal agencies has its own set of approval procedures.[6] Canada adopts a unique approach to the regulation of such crops, regulating them according to their "novelty" rather than the process by which they were produced.[7] This unique system is seen by many as time consuming:

> While regulations pertaining to plants with novel traits are increasingly frustrating crop variety researchers, the various federal departments and agencies involved in the regulatory process have given no indication that change is to be expected. Under the present system, a minimum of two years should be expected for the risk assessment process, but the reality is that it may take considerably longer.[8]

Given this situation, any potential market entrant wishing to capitalize on the expiration of Monsanto's '830 Patent in 2010 should begin research in earnest. However, any such research might risk infringing upon that patent[9] unless it can garner the protection of either of the two "early-working" exemptions that exist under s. 55 of the *Patent Act*[10] and associated jurisprudence.

III. THE EXPERIMENTAL USE OR "JUDICIAL" RESEARCH EXEMPTION[11]

The law regarding the scope and extent of any potential research exemption under the *Patent Act* is viewed as being in a highly unsatisfactory state: "[The] lack of a clear research

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6 A critique of these regulatory processes is beyond the scope and purpose of this article. For a detailed outline of the process, see Royal Society of Canada, Report to Health Canada, Canadian Food Inspection Agency, and Environment Canada, "Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada" (January 2001), online: Royal Society of Canada <www.rsc.ca//files/publications/expert_panels/foodbiotechnology/GMreportEN.pdf>. For analysis of the system and proposals for reform, see Canadian Biotechnology Advisory Committee (CBAC), Report to the Government of Canada Biotechnology Ministerial Coordinating Committee, "Improving the Regulation of Genetically Modified Foods and Other Novel Foods in Canada" (August 2002), online: CBAC <http://cbac-cceb.ca/epic/internet/incbac-cceb.nsf/vwapj/Improving_Regulation_GMFoodAug02.pdf>. For a very recent analysis of the challenges facing this regulatory system, see David Castle *et al.*, "Convergence in Biotechnology Innovation: Cases Studies and Implications for Regulation" (February 2006), online: University of Toronto <www.utoronto.ca/jcb/genomics/documents/Convergent_Biotechnology.pdf>.

7 So non-genetically engineered plants (such as those created via mutagenesis) and plants with no history of development and use in Canada are also regarded as PNTs.

8 Stuart Smyth, "Implications and Potential Impacts from the Expiry of Patents on Herbicide Tolerant Canola Varieties" (July 2006), online: Saskatchewan Canola Development Commission <www.saskcanola.com/pdfs/scdc-patent-report.pdf> at 39.

9 *Supra* note 5, s. 42, which grants the patentee the exclusive right to use, sell, construct, or manufacture the patented product for the lifetime of the patent. As the '830 Patent application was filed before 1 October 1989, s. 45(1) of the *Act* establishes a monopoly period of 17 years.

10 *Ibid.*

11 For an exhaustive, and highly impressive, analysis of this exemption and the "regulatory approval" exemption, see Stephen J. Ferance, "The Experimental Use Defence to Patent Infringement" (2003) 20 C.I.P.R. 1. For an excellent analysis of these exemptions in the context of academic research at Canadian universities, see B.M. Robinson, "Pin-Stripes, Test Tubes and Patents: Is the Commercialization of University Research Consistent with the Fundamental Tenets of the Patent Act?" U. Ottawa L. & Tech. J. [forthcoming in 2006].

exemption [has] detracted from basic research.... The ... *Patent Act* must therefore be amended to include a specific research exemption that clearly outlines the boundaries."[12]

In 2004, the Canadian Biotechnology Advisory Committee (CBAC) issued an Advisory Memorandum to the Government of Canada, recommending that a specific research exemption be included in the *Patent Act* containing the following statements:

> *It is not an infringement of a patent to use a patented process or product either:*
> *(a) privately and for non-commercial purposes, or*
> *(b) to study the subject-matter of the patented invention to investigate its properties, improve upon it, or create a new product or process.*[13]

This recommendation was based upon the CBAC's earlier finding in its 2002 report on the patenting of higher life forms[14] that the "judicial" research exemption in Canada was "vague." The source of this exemption was a 1971 decision of the Supreme Court of Canada. In *Micro Chemicals Ltd. v. Smith Kline & French Inter-American Corp.*,[15] the Court was asked to examine whether a corporation, which applied for a compulsory licence to manufacture a patented pharmaceutical product, was an infringer. In support of its application the defendant (Micro Chemicals) had prepared a small batch of the drug to be able to prove that it could manufacture the product to the requisite commercial and industry standard. Justice Hall held that an experimental user without a licence, in the course of *bona fide* experiments with a patented article, was not at law an infringer:

> The use Micro was making of the patented substance here was not for profit but to establish the fact that it could manufacture a quality product in accordance with the specifications disclosed in respondent's application for Patent No. 612204. Walsh J. found that Micro's experiments prior to January 22, 1966, constituted a technical infringement as they were not carried out for the purpose of improving the process but to enable Micro to produce it commercially as soon as the licence it had applied for could be obtained. I cannot see that this sort of experimentation and preparation is an infringement. It appears to me to be the logical result of the right to apply for a compulsory licence.[16]

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12 See Ikechi Mgbeoji & Bryon Allen, "Patent First, Litigate Later! The Scramble for Speculative and Overly Broad Genetic Patents: Implications for Access to Health Care and Biomedical Research" (2003) 2 C.J.L.T. 83 at 92.

13 CBAC, Advisory Memorandum, "Rationalizing Patent Law in the Age of Biotechnology" (September 2004), online: CBAC <http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/vwapj/Rationalizing_Patent_Law_Final_E.pdf> at 4.

14 CBAC, Report to the Government of Canada Biotechnology Ministerial Coordinating Commitee, "Patenting of Higher Life Forms and Related Issues" (June 2002), online: CBAC <http://cbac-cccb.ca/epic/site/cbac-cccb.nsf/vwapj/E980_IC_IntelProp_e.pdf/ $FILE/E980_IC_IntelProp_e.pdf>.

15 [1972] S.C.R. 506 [*Micro Chemicals*].

16 *Ibid.* at 520.

While *Micro Chemicals* has often been regarded as authority for the existence of a judicial research exemption under the *Patent Act*,[17] the decision is now over 30 years old, and the compulsory licensing provisions addressed therein have since been repealed. These factors certainly bring the contemporary value of the decision into question, and it should not be regarded as authority for the existence of a broad-based research exemption. As Ferance states: "There is ... an element of uncertainty as to whether a court may find that *Micro Chemicals* no longer applies under the present *Patent Act* and that there is no longer any basis in law to sustain an experimental use defence beyond the narrower defence for *improvement* purposes enunciated by ... Walsh J. at trial in *Micro Chemicals*."[18]

This uncertainty regarding the scope of the experimental use exemption persists in spite of s. 55.2(6) of the *Patent Act*, which states:

> For greater certainty, subsection (1) does not affect any exception to the exclusive property or privilege granted by a patent that exists at law in respect of 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.[19]

However, the CBAC notes: "While section 55.2(6) explicitly preserves the common law exception as identified in the Supreme Court of Canada decision, it does nothing to clarify either its nature or extent."[20]

A recent decision, however, may have removed some of this uncertainty and appears to confirm Ferance's position. In *Merck & Co. v. Apotex Inc.*,[21] Hughes J. clearly envisaged the exemption in its narrower, improvement-oriented form:

> The Supreme Court of Canada in [*Micro Chemicals*] dealt with whether certain exemptions existed at common law respecting patent infringement. It found that some exemptions exist ... [and] affirmed a decision of the English Court of Appeal in *Frearson v. Loe* (1878), 9 Ch. D.48 which states that there is a doctrine of "fair dealing" in respect of patent infringement:
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> > *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 prohibition and, if it were, it is certainly not the subject for an injunction.*

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17 See, *e.g.*, the decision in *Cochlear Corp. v. Cosem Neurostim Ltée.* (1995), 64 C.P.R. (3d) 10 at 44 (F.C.T.D.), where Joyal J. applies *Micro Chemicals*, noting:

> [T]he parties acknowledged that should the Court find for the plaintiff on the infringement issue, damages were not warranted and were not being claimed. This follows, of course, from the fact that the Cosem device is still in the experimental or research stage of its ultimate development.... Until Cosem, at some stage of its product development, should decide to give a fix to a particular model and take steps to manufacture, promote and sell it, its current use of a paired, bipolar and sequential mode of stimulation does not constitute an infringement of the patent-in-suit.

18 Ferance, *supra* note 11 at 23-24.

19 *Supra* note 5, s. 55.2(6).

20 *Supra* note 14 at 14.

21 2006 FC 524, [2006] F.C.J. No. 671 (QL) [*Merck*].

> The Supreme Court ... found that an experimental user, without a license, in the course of bona fide experiments with a patented article was not an infringement. The use of the product, not for profit, but to establish the fact that a person could manufacture a product in accordance with the patent, was not an infringement.
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> In this case, the evidence shows that there has been a use of lisinopril that should be considered in the circumstance of "fair dealing". That is the use of lisinopril in ongoing research and development of alternate formulae, alternate techniques for tablet making and the like.
>
> As to this research and development material, I find that it clearly falls within the "fair dealing" exemption provided by the Supreme Court of Canada in *Micro Chemicals*.[22]

In the context of producing a generic version of HT canola, potential developers would not necessarily be seeking to *improve* the subject matter of the '830 Patent, but would rather probably be simply engaged in replicating it. This could well render such work beyond the scope of *bona fide* experimentation. As such, it appears that the experimental use defence as outlined in *Micro Chemicals* (and restated in *Merck*) offers little protection from potential infringement litigation in this context.

IV. THE "REGULATORY APPROVAL" EXEMPTION

There is clear statutory authority for the existence of a "regulatory approval" exemption. Section 55.2(1) of the *Patent Act* states:

> It is not an infringement of a patent for any person 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.[23]

Despite this provision, the CBAC asserted that such language was insufficient: "[The] situation [regarding research exemptions] was not remedied through the introduction of section 55.2 into the *Patent Act*. That section sets out a specific experimental use exception applicable only to regulated inventions such as pharmaceuticals."[24]

It is submitted, however, that this criticism of the limited scope of s. 55.2(1) is simply an aspect of the CBAC's wider dissatisfaction. In its opinion, what is required is a *broad-based* research exemption providing a statutory safe-haven for researchers to engage in basic or fundamental research in fields where patents are prevalent. Indeed, their criticism of s. 55.2(1) acknowledged that the exemption only covered "regulated inventions such as pharmaceuticals."[25] Further support for an overtly pharmaceutical focus for s. 55.2(1) comes from the Supreme Court of Canada decision in *Bristol-Myers Squibb Co. v. Canada (A.G.)*.[26]

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22 *Ibid.* at paras. 159-63.
23 *Supra* note 5, s. 55.2(1).
24 *Supra* note 14 at 14.
25 *Ibid.*
26 2005 SCC 26, [2005] 1 S.C.R. 533 [*Bristol-Myers*].

The case is also useful in articulating the rationale underlying the "regulatory approval" exemption.

In *Bristol-Myers*, the Supreme Court was asked to rule in a dispute between a major pharmaceutical company and the federal government, which in 2001 had issued a Notice of Compliance (NOC) to a generic pharmaceutical manufacturer for a product similar to that of the respondents' (Bristol-Myers) patented anti-cancer drug Taxol.[27] Bristol-Myers sought to have the NOC quashed. All disputes pertaining to the issuance of a NOC are to be determined in accordance with the *Patented Medicines (Notice of Compliance) Regulations*.[28] In writing the majority decision, Binnie J. discussed the nature of the statutory exemption in s. 55.2 and the circumstances surrounding its introduction: "In a reversal of policy, Parliament in 1993 repealed the compulsory licence provisions of the *Patent Act* by what became known as Bill C-91 (S.C. 1993, c.2) and extinguished all compulsory licences issued on or after December 20, 1991."[29]

However, to offset the potential anti-competitive effects of the repeal of the compulsory licensing provisions, Binnie J. notes that,

> having agreed to respect the 20-year monopoly granted by patents, Parliament wished to facilitate the entry of competition immediately thereafter. It acted to eliminate the usual regulatory lag of two years or more after expiry of a patent for the generic manufacturer to do the work necessary to obtain a NOC. Parliament did so by introducing an exemption from the owner's patent rights under which the generic manufacturers could work the patented invention within the 20-year period ("the early working exception") to the extent necessary to obtain a NOC at the time the patent(s) expired (s. 55.2(1))... In order to prevent abuse of the "early working" ... [exception] to patent protection, the government enacted the *NOC Regulations* that are at issue in this appeal.[30]

While both the CBAC and the Supreme Court discuss s. 55.2(1) in the context of pharmaceuticals, the language of the Court confirms that the section creates an "early working" exception for potential producers of a generic version of a patented *invention*. However, the language of the section is clear in that it only provides for research to the extent necessary to facilitate an application for the requisite regulatory approval (in this case the NOC). In fact, the language used in s. 55.2 closely mirrors the so-called "regulatory review" exemption in U.S. law, which is known as the "Bolar exemption."[31]

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27 In order for a pharmaceutical product to be marketed in Canada, a Notice of Compliance (NOC) must be issued. The NOC certifies that the manufacturer's product has satisfied quality, safety, and efficacy regulations passed under the auspices of the *Food and Drugs Act*, R.S.C. 1985, c. F-27.

28 S.O.R./93-133. The *Regulations* were last amended on 5 October 2006 by the *Regulations Amending the Patented Medicines (Notice of Compliance) Regulations*, S.O.R./2006-242.

29 *Supra* note 26 at para. 10.

30 *Ibid.* at para. 11.

31 See 35 U.S.C. § 271(e). The statute was passed to reverse a Federal Court decision of *Roche Products Inc. v. Bolar Pharmaceutical Co., Inc.*, 733 F.2d 858 (Fed. Cir. 1984) [*Roche Products Inc.*]. The Court ruled that infringing conduct for the purpose of making submissions for regulatory approval was not excused by the "scientific use" exemption in U.S. patent law, and could thus be prohibited by the patent holder. However, in the United States the Bolar exemption is restricted to the pharmaceutical sector.

In *Procter & Gamble Pharmaceuticals Canada, Inc. v. Canada (Minister of Health)*, Rothstein J.A. stated:

> Subsection 55.2(1) states that it is not an infringement of a patent for a person to take steps for the development and submission of information required for a notice of compliance from the Minister of Health. If the generic restricts its activities to the development and submission of such information, it will not infringe a patent. However, paragraph 55.2(4)(e) authorizes regulations to prohibit infringement of the patent if the generic oversteps what it is authorized to do under subsection 55.2(1). Issuance of a notice of compliance that would allow a generic to make, construct, use, or sell a patented invention in competition with a patentee during the lifetime of a valid patent is precisely what the Regulations are designed to prevent.[32]

However, the courts have not explicitly stated whether s. 55.2(1) could apply to generic manufacturers in other fields where regulatory approval is required prior to marketing, such as agricultural biotechnology. Ferance is adamant that it would apply: "[I]t is clear from the references to 'a patented invention' and 'any product' that this exception is not limited to any particular type of product."[33]

Indeed, the language of the *Patent Act* makes no specific reference to pharmaceuticals, but of the 128 cases that have referred to s. 55.2 since it became law, 18 have referred to s. 55.2(1). Of these 18 cases, however, 17 have been in the context of pharmaceutical products and NOCs.

The one exception is *Visx Inc. v. Nidek Co.* in which Wetston J. noted that "[s]ection 55.2(1) applies to pharmaceutical patents and does not apply to a medical apparatus."[34] Justice Wetston also stated that he based his conclusion on the analysis of MacKay J. in *Apotex Inc. v. Canada (A.G.)*.[35] The decision of Wetston J. was reversed on appeal, with Strayer J.A. ruling that *Apotex* "involved a pharmaceutical patent and it did not purport to determine the scope of subsection 55.2(1) upon which the defendant relies here. The scope to be given subsection 55.2(1) remains in our view an arguable issue and, as applied here, potentially one of mixed law and fact."[36]

It is submitted that in *Apotex*, MacKay J. was referring to specific regulations passed pursuant to s. 55.2(4) of the *Patent Act* that were limited to pharmaceutical products, and not the more general language of s. 55.2(1). Apotex is one of Canada's leading generic drug manufacturers. In its submission to the Court they argued that "the words of section 55.2 are said to be clear that Parliament intended the regulation of patents in general, not limiting that section to pharmaceutical patents."[37]

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32 2004 FCA 393, [2005] 2 F.C.R. 269 at para. 28.

33 Ferance, *supra* note 11 at 3.

34 (1997), 77 C.P.R. (3d) 286 (F.C.T.D.) at 288. The case concerned laser equipment used in eye surgery.

35 [1997] 1 F.C. 518 (T.D.) [*Apotex*].

36 *Nidek Co. v. Visx Inc.* (1998), 82 C.P.R. (3d) 289 at para. 2 (F.C.A).

37 *Supra* note 35 at para. 52.

Justice MacKay stated that he was "prepared to accept that interpretation, but [he did] not agree with all of the implications Apotex draws from this."[38]

It is submitted that the language of s. 55.2(1) clearly encompasses the notion of a "regulatory approval" exemption extending beyond the pharmaceutical industry.

V. THE SCOPE OF THE "REGULATORY APPROVAL" EXEMPTION

While judicial confirmation of the broad scope of the s. 55.2(1) exemption has not been forthcoming, public clarifications by the federal government have, in fact, been more forthcoming. In *Canada — Patent Protection of Pharmaceutical Products*,[39] the World Trade Organization's Dispute Settlement Body (WTO DSB) received a complaint from the European Community that, *inter alia*, s. 55.2 of the *Patent Act* breached Canada's obligations under various provisions of the TRIPs Agreement:[40]

> [T]he provisions of s. 55.2(1) concerning activities related to the development and submission of information required to obtain marketing approval for pharmaceutical products carried out without the consent of the patent holder violated the provisions of Article 28.1 of the TRIPs Agreement.
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> ...
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> Canada, by treating patent holders in the field of pharmaceutical inventions by virtue of these provisions less favourably than inventions in all other fields of technology, violated its obligations under Article 27.1 of the TRIPs Agreement requiring patents to be available and patent rights enjoyable without discrimination as to the field of technology.[41]

In essence, the European Community alleged that in spite of the broad wording of the "regulatory approval" exemption in s. 55.2(1), it only applied *de facto* to the pharmaceutical industry, and such discriminatory legislation breached Canada's non-discrimination obligations under the TRIPs Agreement.

The Panel found in Canada's favour and could find no support for the European Community's contention that s. 55.2(1) applied solely to the pharmaceutical industry. Of particular significance were Canada's own statements as to the scope of the "regulatory approval" exemption:

> The Panel concluded that the European Communities had not presented sufficient evidence to raise the issue in the face of *Canada's formal declaration that the exception of Section 55.2(1) was not limited to pharmaceutical products*. Absent other evidence, the words of the statute compelled the Panel to accept *Canada's assurance that the exception was legally available to every product that was subject to marketing approval requirements*. In reaching this conclusion, the Panel took note that its legal finding of conformity

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38 *Ibid.*

39 World Trade Organization (WTO), *Report of the Panel on Canada — Patent Protection of Pharmaceutical Products*, WTO Doc. WT/DS114/R (2000), online: WTO <www.wto.org/english/tratop_e/dispu_e/7428d.pdf>.

40 WTO, *Agreement on Trade-Related Aspects of Intellectual Property Rights*, Annex 1C of the Marrakesh Declaration Agreement Establishing the World Trade Organization (15 April 1994), 33 I.L.M. 1197 [TRIPS Agreement].

41 *Supra* note 39 at 8.

on this point was based on a finding as to the meaning of the Canadian law that was in turn *based on Canada's representations as to the meaning of that law.*[42]

Given these public statements by the Government of Canada as to the scope of the "regulatory approval" exemption, it is clearly envisaged that such an extension extends beyond the pharmaceutical context. Indeed, the WTO DSB Panel noted that, "[a]pplied literally, these words apply to any of a wide range of products that require regulatory approval for marketing. The EC itself mentioned agricultural chemicals, foodstuffs, cosmetics, automobiles, vessels and aircraft as products that often require regulatory approval."[43]

Furthermore, the WTO DSB Panel noted that, "Canada denied that the *de jure* scope of Section 55.2(1) is limited to pharmaceuticals ... and has reaffirmed without qualification that the legal scope of the statute is as broad as the words indicate."[44]

While the availability and potential scope of the so-called "judicial" research exemption is questionable (given subsequent legislative amendments),[45] producers of generic versions of non-pharmaceutical patented products requiring regulatory approval may well be able to engage in work *related to that approvals process* prior to the expiry of any patent. However, as Ferance notes: "The recent WTO Report ... may provide guidance, although [it] must be treated with caution, because it lacks the precedential status of Canadian jurisprudence."[46]

Given the absence of Canadian judicial authority defining the scope of the "regulatory approval" exemption, it may be of use to examine American jurisprudence on the Bolar exemption that uses language virtually identical to that of s. 55.2(1) of the *Patent Act*.[47]

VI. THE AMERICAN POSITION

As stated above, the language used in s. 55.2(1) of the *Patent Act*[48] is modeled on that of the so-called Bolar exemption. Therefore, any American case law defining or clarifying the scope of that exemption may be of some value.

In 2005, the United States Supreme Court in *Merck KGaA v. Integra Lifesciences I, Ltd.*[49] unanimously held that the text of the Bolar exemption provides a "wide-berth" for the use of patented drugs in relation to federal regulatory processes, including pre-clinical studies. The decision is being viewed by many as a significant restriction on the rights of patent holders in the United States.[50]

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42 *Ibid.* at 172 [emphasis added].
43 *Ibid.* at 171.
44 *Ibid.* at 172 (including n. 434).
45 See, *e.g.*, Ferance, *supra* note 11.
46 *Ibid.* at 3 [footnote omitted].
47 See *Roche Products Inc.*, *supra* note 31.
48 *Supra* note 5.
49 545 U.S. 193 (2005) [*Integra Lifescience*].
50 See, *e.g.*, Janice Mueller, *Supreme Court Decision Curbs Rights Of Patent Holders* (13 June 2005), online: IP Law Bulletin <www.iplawbulletin.com>.

With regard to the "judicial" experimental use exemption, American law appears much less favourable. In *Madey v. Duke University*,[51] the Federal Court of Appeals was asked to examine the common-law or "judicial" research exemption in the United States. The origins of this exemption in the United States lie in the 1813 decision of Story J. in *Whittemore v. Cutter*, who stated: "[I]t could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects."[52]

In a highly controversial decision, the Court in *Madey* held that this exemption in United States patent law should be interpreted very narrowly. They concluded:

> In short, regardless 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.[53]

Apart from its dramatic reduction of the scope of the exemption, *Madey* is also of interest for present purposes as it involved research conducted at a university. The ultimate conclusion to be drawn from the decision is that there may no longer be any such thing as "pure research" in the university context. As universities increasingly form research partnerships with commercial third parties, it is less possible to characterize such research as "non-commercial." Previously, it had been thought that if research was conducted at a publicly funded institution, the mere fact of that status might garner the protection of the exemption. The decision in *Madey* firmly disavows such a belief. As Jennifer Miller notes: "[I]t is clear that, under the [new test in *Madey*], universities and non-profit organizations now face numerous additional obstacles to their performance of basic research, and it is this result and the fear that such a result will inevitably stifle the progress of science that has incited much outcry from the scientific community."[54]

While the restrictive approach of the Court in *Madey* is noteworthy in its own right, it is also significant if, as suggested above, university researchers or farming groups in Canada attempt to avail themselves of the "judicial" research exemption. As the available Canadian jurisprudence lacks clarity[55] and is in need of legislative refinement,[56] an analogous American decision may be highly persuasive in the absence of intervening clarification by a Canadian authority.

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51 307 F.3d 1351 (Fed. Cir. 2002) [*Madey*].

52 29 F. Cas. 1120 (C.C.D. Mass. 1813) at 1121.

53 *Supra* note 51 at 1362.

54 See Jennifer Miller, "Sealing the Coffin on the Experimental Use Exception," online: Duke L. & Tech. Rev. 12 at 19 <www.duke.edu/journals/dltr/articles/PDF/2003DLTR0012.pdf>. Duke University attempted to appeal this decision to the Supreme Court of the United States, but leave was denied. For a Canadian perspective on intellectual property law and the changing nature of University research, see Robinson, *supra* note 11.

55 See Mgbeoji & Allen, *supra* note 12.

56 See *supra* note 14.

The probative value of American intellectual property jurisprudence in Canadian courts is the subject of perennial (if not interminable) debate. Writing for the majority of the Federal Court of Appeal in the infamous *Harvard Mouse* case, Rothstein J.A. noted:

> [W]hile United States patent decisions are obviously not binding on Canadian courts, where the statutory language which is being interpreted is similar in both countries and where the reasoning underlying the United States Court's interpretation of the language is persuasive, there is no reason why Canadian courts should ignore the U.S. jurisprudence.... I am, therefore, of the view that the majority opinion of the United States Supreme Court in *Chakrabarty* provides useful guidance in interpreting the definition of "invention" in the Canadian *Patent Act*, and ... I have placed significant reliance on it.[57]

However, when faced with the same language in the same decision, Isaac J. commented in dissent: "I conclude then that our decision on this appeal should not be affected in any way by the fact that the oncomouse has been patented in the United States of America."[58]

For present purposes it is neither necessary, nor advisable, to adjudicate such disputes. However, it is undeniable that American decisions in the biotechnology field have often influenced the development of Canadian patent law and policy.[59]

Given that influence, it is arguable that notice should be taken of the decisions in *Integra Lifesciences* and *Madey*. Certain commentators[60] assert that *Integra Lifesciences* represents a step back from the overly restrictive approach adopted in *Madey* (at least in the pharmaceutical context) in that: "In this regard, the statutory exception is a revitalization of research protection for drug manufacturers who lost the common law exception in *Madey*."[61]

What the American jurisprudence may provide, therefore, is judicial confirmation that the "regulatory approval" exemption provides a safer haven for potential generics researchers than the "judicial" research exemption.

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57 *President and Fellows of Harvard College v. Canada (Commissioner of Patents)*, [2000] 4 F.C. 528 at paras. 140, 147 (C.A.) [*Harvard Mouse*]. The Supreme Court of Canada ultimately reversed Rothstein J.'s decision. See (2002), 21 C.P.R. (4th) 417. However, it is submitted that the discussion cited here is still valid evidence of a continuing debate as to the utility of American jurisprudence in Canadian biotechnology law.

58 *Ibid.* at para. 74. For a "classic" discussion of the value of American jurisprudence in Canadian Intellectual Property cases, see Harold G. Fox, *The Canadian Law and Practice Relating to Letters Patent for Invention*, 4th ed. (Toronto: Carswell, 1969).

59 As discussed in *Harvard Mouse*, *ibid.*, the landmark United States Supreme Court decision in *Diamond, Commissioner of Patents and Trademarks v. Chakrabarty*, 447 U.S. 303 (1980) [*Diamond*] is one such case. *Diamond* opened the door to life patenting in the United States and its reasoning was subsequently cited with approval in the landmark Canadian decision of *Re Application of Abitibi Co.* (1982), 62 C.P.R. (2d) 81.

60 See, *e.g.*, Samuel Rubin, "Merck KGaA v. Integra Lifesciences I, Ltd.: Greater Research Protection for Drug Manufacturers" (2006) 1 Duke J. Con. Law & Pub. Pol'y 79.

61 *Ibid.* at 85.

VII. LEGAL CONCLUSIONS

In the Canadian context, the cumulative effect of the "judicial" research and the statutory "regulatory approval" exemptions has lead one author to conclude that:

> [I]n Canada, neither the use of a patented product or process to obtain information to be used for a regulatory approval process, nor the use, manufacture or sale of a patented product or process solely for the purpose of experimental or testing activity prior to finalization of a commercial product for manufacture, promotion or sale is an infringing use. The Canadian exemption appears to extend to basic research.[62]

Such opinions (although not universally held)[63] are indicative of the existence of a fairly broad exemption for *bona fide* experimental research and work pertaining to regulatory approvals in Canada. However, it is also clear that any activity that goes beyond the scope of experimentation or an approvals process may well constitute patent infringement. In relation to the "regulatory approval" exemption, Ferance states that "[a]ctivities in relation to the invention for any collateral purpose beyond the development and submission of information required by law would likely render the defence unavailable."[64]

VIII. EXTRA-LEGAL ISSUES: COMMERCIAL AND STRATEGIC CONSIDERATIONS

While it is argued that there is no *legal* impediment to a Canadian researcher/producer conducting research on a generic HT canola product under one of the aforementioned exemptions, there may be strategic and commercial reasons that will render this possibility unlikely. Monsanto has faced challenges related to patent expiry before.

In 1983, Monsanto was granted a U.S. Patent[65] on a glyphosate based herbicide that it eventually marketed as Roundup™. By the year 2000 it had become the most successful agro-chemical product in history, and amassed annual global sales of US$2.8 billion, outselling other chemicals by a ratio of 5:1.[66] However, as Smyth notes:

> The patent for Roundup was scheduled to expire in 2000. For Monsanto, this represented [a potential] influx of generic glyphosinate products on the market that would compete with and potentially diminish Roundup's large market share. Company representatives projected that market share could potentially drop from 77% (as of 2003) to the low 60's as early as 2005. Additionally, analysts also projected that the price for Roundup would drop to as little as $14 or $15 per gallon from its 2003 price of $23 per gallon. As of 2003, the projected affects of competition by generic brands could have an estimated impact of $1.69 billion in lost revenues.[67]

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62 Sheldon Burshtein, "Experimental Use Exception To Patent Infringement In Canada," online: Blakes <www.blakes.ca/english/publications/brip/article.asp?A_ID=188&DB=blakesProperty>.

63 See, *e.g.*, *supra* notes 12, 14.

64 Ferance, *supra* note 11 at 35.

65 "Salts of N-phosphonomethylglycine," U.S. Patent No. 4405531 (8 March 1982, issued 20 September 1983).

66 David Barbosa, "The Power of Roundup; A Weed Killer Is a Block For Monsanto To Build On" *New York Times* (2 August 2001), online: New York Times <http://query.nytimes.com/gst/fullpage.html?sec=health&res=9C00EED8173CF931A3575BC0A9679C8B63>.

67 Smyth, *supra* note 8 at 34.

In an attempt to prevent such losses, Monsanto developed "[a] brilliant strategy of dropping its price years ahead of patent expiration and tying its use to the early growth of genetically modified crops — crops made to work in tandem with the herbicide."[68]

Smyth asserts that this strategy achieved two major objectives:

> First, it created new value for the product through an effective bundling strategy. Roundup was no longer viewed primarily as a standalone product. Secondly, the new pricing strategy increased the level of adoption by producers thereby expanding Monsanto's market share.[69]

However, while the strategy certainly maintained shareholder value and propped up Monsanto's market share, it did not prevent generic glyphosate producers from infiltrating the market. As Innovest Strategic Value Advisors note: "In some cases, Monsanto has been driven out of the glyphosate market altogether, as was the case in Australia, where competition from cheap Chinese imports caused the company to close its manufacturing plant there."[70]

Clearly, any potential entrant into a market for generic HT canola will face similar strategic initiatives from Monsanto attempting to ensure the continued commercial success of Roundup Ready™ Canola. One possibility is that Monsanto will reduce prices and eliminate the Technology User Fee in order to retain market share. Such an initiative could render the financial viability of a generic competitor questionable.

IX. CONCLUSION

In the next decade many of the first generation of Canadian agricultural biotechnology patents will begin to expire. Monsanto's '830 Patent is one of the first and most significant. This may present an opportunity for the development of a generics manufacturing sector as there are no *concrete* legal obstacles to the use by potential market entrants of the two "early working" exemptions contained under the *Patent Act*[71] and associated jurisprudence. At present, fiscal and commercial considerations provide more likely obstacles to the emergence of such a sector than any possible legal impediments. However, that situation may change and the uncertain nature of the scope and extent of these exemptions may once again be under scrutiny. At that stage, Parliament may have to introduce a new regulatory framework in the field of agricultural biotechnology patenting similar to the NOC regime for pharmaceutical products. Such a framework may well be necessary in order to balance the legitimate rights of patent holders with the legitimate commercial aspirations of the potential builders of a new technology sector in Canada.

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68 *Supra* note 66. Roundup Ready™ Canola being the example *par excellence* of the effectiveness of this product bundling strategy.

69 *Supra* note 8 at 34.

70 Innovest Strategic Value Advisors, "Monsanto & Genetic Engineering: Risks for Investors" (January 2005), online: Innovest Group <www.innovestgroup.com/pdfs/2005-01-01_Monsanto_Genetic Engineering.pdf> at 30.

71 *Supra* note 5.