

UPDATE ON PATENTS:
LEGISLATIVE CHANGES AND CASE LAW IN 2004

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1. INTRODUCTION

2004 was a busy year for Canadian patent law developments.

In the spring, the Supreme Court of Canada issued judgment in the *Monsanto v. Schmeiser* case¹, relating to a genetically engineered gene for canola to render it resistant to glyphosphate herbicides, which decision effects patentable subject matter, infringement, and remedies for infringement.

The decision of the Federal Court of Appeal in *Dutch Industries*² in relation to issues relating to errors in paying fees and a “small entity” has led the Patent Office to propose a retroactive remedy, but not soon enough to prevent another patent being held invalid for failure to pay the proper fees.

In *Trojan v. Suntec*³, the Federal Court of Appeal set aside a summary judgment as to patent infringement and validity and in *Realsearch v. Valone Kone Brunette*⁴ the Federal Court of Appeal set aside an order for a “*Markman*-type” pre-trial determination of the construction of a patent, in both cases determining that the issues should be determined at trial. In *Eli Lilly v. Apotex*⁵, issues concerning the interface between patent law and competition law were considered on an appeal and further hearing.

As in other recent years, decisions made under the *Patented Medicines (Notice of Compliance) Regulations* outnumbered patent decisions in all other areas. In December, the Supreme Court of Canada heard argument in the *Biolysse Pharma v. Bristol-Myers Squibb* case⁶, concerning the application of section 5(1.1) of these *NOC Regulations*..

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¹ *Schmeiser et al v. Monsanto Canada Inc. et al.* 2004 SCC 34 (2004), 31 C.P.R. (4th) 161 (S.C.C.), varying [2002] FCA 309 (F.C.A.)

² *Barton No-Till Disk Inc. v. Dutch Industries Ltd et al.* 2003 FCA 121 (F.C.A.)

³ *Trojan Technologies, Inc. v. Suntec Environmental Inc.* (2003), 26 C.P.R. (4th) 417 (F.C.T.D.), reversed (2004), 31 C.P.R. (4th) 241 (F.C.A.), leave to appeal refused (S.C.C.)

⁴ *Realsearch Inc. et al v. Valone Kone Brunette Ltd. et al* 2003 FCT 669 (F.C.T.D.), reversed (2004) 31 C.P.R. (4th) 101 (F.C.A.)

⁵ *Eli Lilly & Co. et al v. Apotex Inc.* (2003), 28 C.P.R. (4th) 37 (F.C.); (2004), 32 C.P.R. (4th) 195 (F.C.A.); (2004) F.C. 1445 (F.C.)

⁶ *Biolysse Pharma Corporation v. Bristol-Myers Squibb Company* 2003 FCA 180, 24 C.P.R. (4th) 417 (F.C.A.)

2. LEGISLATION

2.1 *Jean Chretien Pledge to Africa Act*

In May 2004, Parliament enacted the *Jean Chretien Pledge to Africa Act*⁷ to amend the *Patent Act* and the *Food and Drugs Act* to facilitate access to pharmaceutical products to address public health problems afflicting many developing and least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics. The legislation is to come into force on a date set by the Governor in Council and will come into force when the necessary regulations have been prepared.

With respect to the *Patent Act* the legislation, when in force, will add sections 21.01-21.19 and 21.2 under the heading “Use of Patents for International Humanitarian Purposes to Address Public Health Problems”. The legislation provides that Commissioner shall grant authorization, if the prescribed documentation is provided and the prescribed fee is paid, to make, construct and use a patented invention solely for purposes directly related to the manufacture of the pharmaceutical product named in an application and to sell it for export to a country listed in a schedule to the legislation and named in the application. Royalties are to be paid to the patentee or patentees, the amount of the royalty to be determined in accordance with the regulations. A right is provided to the patentee to apply to Federal Court for increased royalty, for termination of the authorization or for an order that the sale is commercial in nature.

Bill C-29, referred to below, includes a minor amendment to section 21.18(2) of the Patent Act, enacted by this Act.

2.2. Amendment of the *Patent Rules* – New Rule 3.1

Section 3.1 of the *Patent Rules*, set out below, came into force on January 1, 2004:

“3.1 (1) Subject to subsection 6(1), if, before the expiry of a time limit for paying a fee set out in Schedule II, the Commissioner receives a communication in accordance with which a clear but unsuccessful attempt is made to pay the fee, the fee shall be considered to have been paid before the expiry of the time limit if

- (a) the amount of the fee that was missing is paid before the expiry of the time limit;
- (b) if a notice is sent in accordance with subsection (2), the amount of the fee that was missing, together with the late payment fee set out in item 22.1 of Schedule II, are paid before the expiry of the two-month period after the date of the notice; or
- (c) if a notice is not sent, the amount of the fee that was missing, together with the late payment fee set out in item 22.1 of Schedule II, are paid

⁷ S.C.2004 c.23

before the expiry of the two-month period after the day on which the communication was received by the Commissioner.

- (2) Subject to subsection 6(1) and unless the person making the communication did not provide information that would allow them to be contacted, if the Commissioner has received a communication in the circumstances referred to in subsection (1), the Commissioner shall, by notice to the person who made the communication, request payment of the amount of the fee that was missing together, if applicable, with the late payment fee referred to in subsection (1).
- (3) Subsections (1) and (2) do not apply in respect of the fees set out in items 9 to 9.4 and 22.1 of Schedule II. SOR/2003-208, s. 2.”

This amendment was considered in *Johnson & Johnson v. Boston Scientific*⁸ in which, as discussed in more detail below⁹, it was found not to have application to an erroneous payment of fees as a “small entity” made before the coming into force of the amendment.

2.3 “Small Entities” Fees Problem Remedial Legislation

In December 2004, legislation¹⁰ to remedy the effects of the *Dutch Industries* decisions¹¹ and the resulting invalidity of patents for errors in paying the maintenance fees by persons who believed they were entitled to pay as a “small entity” was given first reading in Parliament as Bill C-29. This bill proposes the introduction of new section 78.6 as follows:

- “78.6 (1) If, before the day on which this section comes into force, a person has paid a prescribed fee applicable to a small entity, within the meaning of the *Patent Rules* as they read at the time of payment, but should have paid the prescribed fee applicable to an entity other than a small entity and a payment equivalent to the difference between the two amounts is submitted to the Commissioner in accordance with subsection (2) either before or no later than twelve months after that day, the payment is deemed to have been paid on the day on which the prescribed fee was paid, regardless of whether an action or other proceeding relating to the patent or patent application in respect of which the fee was payable has been commenced or decided.
- (2) Any person who submits a payment to the Commissioner in accordance with subsection (1) is required to provide information with respect to the day on which the prescribed fee was paid, the service or proceeding in respect of which the fee was paid and the patent or application in respect of which the fee was paid.

⁸ *Johnson & Johnson Inc. et al v. Boston Scientific Ltd.* 2004 FC 1672 (F.C.) at para. 98-104

⁹ *Infra* section 8

¹⁰ Bill C-29, “An Act to Amend the Patent Act”

¹¹ *Dutch Industries Ltd. v. Canada* (2001), 14 C.P.R. (4th) 499 (F.C.T.D.), varied *Barton No-Till Disk Inc. v. Dutch Industries Ltd et al.* 2003 FCA 121 (F.C.A.),

- (3) A payment submitted in accordance with subsection (1) shall not be refunded.
- (4) No action or proceeding for any compensation or damages lies against Her Majesty in right of Canada in respect of any direct or indirect consequence resulting from the application of this section.”

There will be opportunities to amend the details of the bill consistent with its objectives during the committee stage following second reading.

2.4 Proposed Amendments to the *Patented Medicines (Notice of Compliance) Regulations*

In the December 11, 2004 issue of the Canada Gazette¹², the Government published proposed amendments to the *Patented Medicines (Notice of Compliance) Regulations* accompanied by a nine page Regulatory Impact Analysis Statement (“RIA Statement”).

The RIA Statement commences:

“The proposed amendments are intended to restore the balanced policy underlying the *Patented Medicines (Notice of Compliance) Regulations* (“PM(NOC) Regulations”) by reaffirming the rules for listing patents on the register and clarifying when listed patents must be addressed.”

Linking the Patent to a Submission

A principal area of amendment is to link a patent on the register to the submission in respect of which it was filed and to prevent a patent filed in respect of a later submission impacting the grant of a NOC in respect of a product or use which was the subject of an earlier submission. Several amendments are proposed to achieve this result.

- Providing definitions for “new drug submission” (“NDS”) and “supplement to a new drug submission” (“SNDS”) – new section 3(1) – and using these terms elsewhere in the *Regulations* in place of the prior reference simply to a “submission” (e.g. in section 4(1)).
- Amending current section 3(3) as new section 3(4) to provide:

“(4) No patent on a patent list or other information that is submitted under section 4 shall be added to the register until after the Minister has issued a notice of compliance in respect of the new drug submission or supplement to a new drug submission, as the case may be, to which the patent list or information relates.”
- Amending the eligibility of patents for listing on the register by adding new section 4(2):

“(2) A patent on a patent list submitted under subsection (1) in relation to a new drug submission is eligible to be added to the register if the patent contains

¹² Canada Gazette, Vol. 138, No. 50, p. 3718, December 11, 2004

(a) a claim for the medicine itself, and

(i) if that claim is for a medicinal ingredient, that ingredient has been approved through the issuance of a notice of compliance in respect of that submission, or

(ii) if that claim is for a formulation that consists of medicinal and non-medicinal ingredients, that formulation has been approved through the issuance of a notice of compliance in respect of that submission; or

(b) a claim for the use of the medicine and that use has been approved through the issuance of a notice of compliance in respect of that submission.”

- Amending the provisions relating to a patent list to require identification of the patent with the NDS or SNDS by adding sections 4(3) and 4(4)(a)-(b) as follows:

“(3) A patent on a patent list submitted under subsection (1) in relation to a supplement to a new drug submission is eligible to be added to the register if that supplement is for a change in formulation or use and

(a) in the case of a change in formulation, the patent contains a claim for a formulation that consists of medicinal and non-medicinal ingredients and that formulation has been approved through the issuance of a notice of compliance in respect of that supplement; or

(b) in the case of a change in use, the patent contains a claim for the use of the medicine and that use has been approved through the issuance of a notice of compliance in respect of that supplement.

(4) A patent list shall contain the following:

(a) an identification of the new drug submission or the supplement to a new drug submission to which the list relates;

(b) the brand name, dosage form, strength, route of administration and use set out in the new drug submission or the supplement to a new drug submission to which the list relates;”

[Section 4 also will include sections 4(4)(c)-(f) which correspond to current subsections 4(2)(b)-(e).]

- Specifying in sections 4(5) and 4(6), which correspond to current sections 4(3) and 4(4), that the submission of a patent list or amendment of it must be in respect of the NDS or SNDS to which the patent relates.

- New section 4.1 is added to clarify that patents previously listed in respect of a NDS may be relisted for a new SNDS. The proposed section 4.1 is as follows:

“4.1 (1) In this section, "supplement to a new drug submission" means a supplement to a new drug submission as that term is used in Division 8 of Part C of the *Food and Drug Regulations*.

(2) A first person who submits a patent list in relation to a new drug submission as referred to in subsection 4(2) may, if that list is added to the register, resubmit that same list in relation to a supplement to that new drug submission but may not submit a new patent list in relation to a supplement except in accordance with subsection 4(3).”

- The addition as subsection 5(1) (b)(v) of a new ground of allegation in a NOA as follows:

“(v) in the case of a patent that was added to the register on the basis of eligibility under paragraph 4(3)(b), its submission does not seek approval for the use of the medicine that is claimed in that patent.”

- Adding new section 5(4) to qualify section 5(3) [old 5(2)]

“(4) Despite subsection (3), a second person is not required to amend its submission if

(a) the patent referred to in that subsection is added to the register in relation to a supplement to a new drug submission as set out in subsection 4(3); and

(b) the filing date of its submission precedes the filing date of the supplement referred to in paragraph (a).”

The RIA Statement refers to its reason for preventing a first person using a patent filed in respect of an SNDS for a later use to prevent sale by the generic of a product for an old use for which the patent had expired as follows:

“This would result in a real injustice: since a generic company cannot possibly control how everyone in the world uses its product, the prevention of the generic from marketing the product would further fortify and artificially extend the monopoly held by the patent holders. The patent holders would, therefore, effectively control not just the new uses for the old compound, but the compound itself, even though the compound itself is not protected by the patent in the first place. The patent holders, as a result, would obtain a benefit they were not meant to have.

Again, the Government acknowledges that there may be instances where approval of the generic drug in these circumstances may ultimately result in infringement. However, given that the alternative is a complete bar to generic competition for

the lifetime of the new use patent, it is felt that the balance weighs in favour of immediate generic entry and resolution of the issue through an ordinary infringement action.”

Amendment of the Introductory Wording of Section 5(1)

The introductory wording of section 5(1) has been somewhat simplified to read:

5. (1) If a second person files, or has filed, a submission for a notice of compliance for a drug and its submission directly or indirectly compares the drug to another drug and if that comparison forms the basis on which the issuance of a notice of compliance is sought, the second person shall, in respect of each patent on the register for that other drug,

Repeal of Section 5(1.1)

Another significant amendment is the repeal of Section 5(1.1) of the *NOC Regulations*. Section 5(1.1) and the decision in *Biolysse Pharma v. Bristol-Myers Squibb*¹³ in respect of it are discussed below in section 16.2. If this amendment is brought into force, it will make the result in the recently argued appeal to the Supreme Court of Canada in *Biolysse* of little future effect.

The RIA Statement provides the following explanation for this amendment:

“Finally, as a separate and unrelated measure, the amendments also propose to repeal subsection 5(1.1) of the PM(NOC) Regulations. This provision was introduced in 1999, when it became apparent that a generic company could avoid compliance with the PM(NOC) Regulations by making an indirect comparison to an innovator's drug with patents on the register. In the Government's view, subsection 5(1.1) was rendered redundant soon after its passage when the Federal Court of Appeal ruled that the pre-existing triggering provision, subsection 5(1), was sufficiently broad to capture avoidance strategies founded on indirect reliance.

Repeal of subsection 5(1.1) will also clarify that the PM(NOC) Regulations are not intended to apply to second-entry drug submissions where the sponsor of the submission is required by the Minister of Health to conduct independent clinical studies to establish the safety and efficacy of its product. Consequential amendments are also being proposed to subsection 5(1) to further confirm that this provision is in fact triggered by a second entrant's indirect comparison to the innovator's drug.”

Introduction of New Section 5(2)

Another amendment is the introduction of section 5(2). Apparently this is to discourage a first person cancelling its DIN to prevent a generic from making a comparison with it.

¹³ *Biolysse Pharma Corporation v. Bristol-Myers Squibb Company* 2003 FCA 180, 24 C.P.R. (4th) 417 (F.C.A.)

“(2) Subsection (1) does not apply if the assignment of the drug identification number for that other drug referred to in that subsection has been cancelled under paragraph C.01.014.6(1)(a) of the *Food and Drug Regulations*.”

Amendment of Section 6(5)(a)

Section 6(5)(a) has been simplified in view of the expanded definition of the requirements for a patent to be on the register to read:

“(a) if the court is satisfied that the patents at issue are not eligible for inclusion on the register; or”

Amendment of Section 7(2)(b)

Section 7(2)(b) has been simplified to read;

“(b) the court has found the second person's allegation to be justified.”

Other Amendments

There are other consequential amendments to reflect the changes in numbering of several of the sections.

Transition

It is proposed that the amendments will not have a retroactive effect. The operative transition provision, section 5(2) of the proposed amending regulation, provides:

“(2) Any matter that arises on or after the day on which these Regulations come into force in respect of a patent that is on the register on that day shall be dealt with and disposed of in accordance with the prior regulations, except that

(a) subsection 5(1.1) of the prior regulations does not apply;

(b) subsection 5(2) of the prior regulations, excluding the reference in that subsection to subsection 5(1.1), applies; and

(c) subsection 5(2) of the *Patented Medicines (Notice of Compliance) Regulations*, as enacted by section 2 of these Regulations, applies.”

Comments May Be Submitted

The notice in the Canada Gazette of the proposed amendments states:

“Interested persons may make representations with respect to the proposed Regulations within 75 days after the date of publication of this notice. All such representations must cite the *Canada Gazette*, Part I, and the date of publication of this notice, and be addressed to Susan Bincoletto, Acting Director General, Marketplace Framework Policy Branch, Industry Canada, 10th Floor, East Tower,

235 Queen Street, Ottawa, Ontario K1A 0H5 (tel.: (613) 952-0736; fax: (613) 948-6393); e-mail: bincoletto.susan@ic.gc.ca .”

3. PATENTABLE SUBJECT MATTER – “INVENTION”

The first requirement for patentability is that there be patentable subject matter satisfying the definition of “invention” in section 2 of the *Patent Act*, which is as follows:

“Invention’ means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter.”

3.1 Patentable Subject Matter – Plant Cells and Genes

Monsanto v. Schmeiser

In May 2004, the Supreme Court of Canada issued its decision in *Monsanto v. Schmeiser*¹⁴, concerning a patent for a plant gene and a plant cell. Following the detailed examination of the definition of “invention” in relation to higher life forms and particularly mammals in the “*Harvard Mouse*” case¹⁵, there had been some speculation that the Supreme Court might conduct a similar review with respect to plants in this case. However, the Supreme Court dealt relatively briefly with the issue of patentable subject matter.

In a 5:4 decision, McLachlin C.J. and Fish J. for the majority reviewed the patent and noted that the claims of the patent were for: (1) a chimeric gene, this is a gene that does not exist in nature and is constructed from different species; (2) an expression vector, a DNA molecule into which another DNA segment has been integrated so as to be useful as a research tool; (3) a plant transformation vector, used to permanently insert a chimeric gene into a plant's own DNA; (4) various species of plant cells into which the chimeric gene has been inserted; (5) a method of regenerating a glyphosate-resistant plant.

With regard to the issue of the validity of these claims, they continued:

“21 The appellant Schmeiser argues that the subject matter claimed in the patent is unpatentable. While acknowledging that Monsanto claims protection only over a gene and a cell, Schmeiser contends that the result of extending such protection is to restrict use of a plant and a seed. This result, the argument goes, ought to render the subject matter unpatentable, following the reasoning of the majority of this Court in *Harvard College v. Canada*¹⁶ (“*Harvard Mouse*”). In that case, plants and seeds were found to be unpatentable “higher life forms”.”

22 This case is different from *Harvard Mouse*, where the patent refused was for a mammal. The Patent Commissioner, moreover, had allowed other claims, which

¹⁴ Supra footnote 1

¹⁵ *Harvard College v. Canada (Commissioner of Patents)* [2002] 4 S.C.R. 45 (S.C.C.)

¹⁶ Supra footnote 15

were not at issue before the Court in that case, notably a plasmid and a somatic cell culture. The claims at issue in this case, for a gene and a cell, are somewhat analogous, suggesting that to find a gene and a cell to be patentable is in fact consistent with both the majority and the minority holdings in *Harvard Mouse*.

23 Further, all members of the Court in *Harvard Mouse* noted in obiter that a fertilized, genetically altered oncomouse egg would be patentable subject matter, regardless of its ultimate anticipated development into a mouse (at para. 3, per Binnie J. for the minority; at para. 162, per Bastarache J. for the majority.).

24 Whether or not patent protection for the gene and the cell extends to activities involving the plant is not relevant to the patent's validity. It relates only to the factual circumstances in which infringement will be found to have taken place, as we shall explain below. Monsanto's patent has already been issued, and the onus is thus on Schmeiser to show that the Commissioner erred in allowing the patent: *Apotex Inc. v. Wellcome Foundation Ltd.*¹⁷, at paras. 42-44. He has failed to discharge that onus. We therefore conclude that the patent is valid.”

Arbour J. for the minority, who dissented on other issues, concurred that the patent was not invalid.

The minority accepted that *Harvard* stands for the proposition that plants are not patentable.

3.2 Patentable Subject Matter - Aggregation

Sabaf SpA v. MFI Furniture (UK HL)

While this is a review of developments in Canadian patent law in 2004, brief mention will be made of a very few foreign decisions. In *Sabaf SpA v. MFI Furniture*¹⁸ the patent concerned a burner for gas cookers. The trial judge found that the two features of the burners said to constitute an invention were: (i) drawing primary air in from above the hob unit, and (ii) the use of a flow path under the flame spreader in which the Venturi effect will be present.

He noted that it was not suggested in specification, nor argued at trial that these two features interacted. The trial judge found that that each of the two features was obvious. There was no item of prior art that taught both features, but he held that, applying the law of collocation, the mere placing together of two old integers each of which performs its own function is not a patentable combination and the patent was invalid.

The Court of Appeal reversed and held that the combination was not obvious.

The House of Lords restored the trial determination of invalidity. Lord Hoffmann said:

¹⁷ *Apotex Inc. v. Wellcome Foundation Ltd.* [2002] 4 S.C.R. 153 (S.C.C.)

¹⁸ *Sabaf SpA v. MFI Furniture Centres Limited et al.* [2004] UK HL 45 (H.L.)

“24. In my opinion the approach of the Court of Appeal is contrary to well established principles both in England and in the European Patent Office, as stated in the quotation from Lord Tomlin and the EPO Guidelines to which I have referred. I quite agree that there is no law of collocation in the sense of a qualification of, or gloss upon, or exception to, the test for obviousness stated in section 3 of the Act. But before you can apply section 3 and ask whether the invention involves an inventive step, you first have to decide what the invention is. In particular, you have to decide whether you are dealing with one invention or two or more inventions. Two inventions do not become one invention because they are included in the same hardware. A compact motor car may contain many inventions, each operating independently of each other but all designed to contribute to the overall goal of having a compact car. That does not make the car a single invention.

25. Section 14(5)(d) of the Act provides (following article 82 of the EPC) that a claim shall “relate to one invention or to a group of inventions which are so linked as to form a single inventive concept”. Although this is a procedural requirement with which an application must comply, it does suggest that the references in the Act to an “invention” (as in section 3) are to the expression of a single inventive concept and not to a collocation of separate inventions.

26. The EPO guidelines say that “the invention claimed must normally be considered as a whole”. But equally, one must not try to consider as a whole what are in fact two separate inventions. What the Guidelines do is to state the principle upon which you decide whether you are dealing with a single invention or not. If the two integers interact upon each other, if there is synergy between them, they constitute a single invention having a combined effect and one applies section 3 to the idea of combining them. If each integer “performs its own proper function independently of any of the others”, then each is for the purposes of section 3 a separate invention and it has to be applied to each one separately. That, in my opinion, is what Laddie J meant by the law of collocation.”

4. OBVIOUSNESS

Procter & Gamble v. Genpharm

In *Procter & Gamble v. Genpharm*¹⁹, an appeal from the prohibition of a NOC for etridonate for the treatment of osteoporosis, counsel for Genpharm submitted that, as a result of the decisions of the Supreme Court in *Whirlpool* and *Apotex Inc. v. Wellcome Foundation*²⁰, the Supreme Court had altered the traditional test for obviousness such that it is no longer as difficult to meet as had traditionally been thought. It was submitted that obviousness and sound prediction are one and the same.

¹⁹ *Procter & Gamble Pharmaceuticals Canada Inc. et al v. Genpharm Inc. et al* (sub nom *Genpharm Inc. v. Procter & Gamble Pharmaceuticals Canada Inc. et al*) 2004 FCA 393 (F.C.A.). See also infra section 16.4.2.1.

²⁰ *Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 S.C.R. 153 (S.C.C.)

Rothstein J.A. for the Federal Court of Appeal rejected these submissions, stating:

44 ... The long-standing "difficult test to satisfy" for obviousness is that expressed by Hugessen J.A. (as he then was) in *Beloit v. Valmet*²¹ ...

45 Genpharm says *Whirlpool* changed the *Beloit* test. I do not agree. *Whirlpool* only reiterated what was already stated in *Beloit*. I see nothing in *Whirlpool* that would make the test for obviousness less difficult to satisfy than that expressed in *Beloit*.

46 In *Apotex v. Wellcome*, the doctrine of sound prediction was extensively reviewed by Binnie J. At paragraph 56, he explains that where the invention is a new use for an old product, the utility required for patentability must, as of the priority date, either be demonstrated or be a sound prediction based on the information and expertise then available. At paragraph 61, Binnie J. refers to *Monsanto v. Commissioner*²², in which the Supreme Court dealt with a patent that included claims to numerous chemical compounds to inhibit premature vulcanization of rubber, but only three of which had actually been prepared and tested before the date the application was filed. The Supreme Court applied the doctrine of sound prediction on the basis that the "architecture of chemical compounds" was no longer a mystery but was, within limits, soundly predictable.

47 As counsel for P&G has pointed out, sound prediction and obviousness are considerations with different perspectives. Sound prediction is relied upon by an inventor to justify patent claims whose utility is not actually demonstrated but can be soundly predicted from information and expertise that is available. Obviousness is relied upon by a potential competitor of the patentee, who argues that what is claimed in a patent is something that a skilled technician keeping up with the state of the art and common general knowledge would be able to come to directly and without difficulty in the absence of the solution taught by the patent. These are different concepts and they are not to be conflated. The doctrine of sound prediction has no application to the doctrine of obviousness.”

Wessel v. Energy Rentals

*Wessel v. Energy Rentals*²³ was an action for infringement of a patent for a trailer having a power swivel unit mounted on one section such that the trailer is unbalanced without additional load. Although this was a New Act patent (filed May 29, 1997), obviousness was addressed under Old Act test and no reference was made to s.28.3. Snider J. noted that the invention was simple, but its simplicity did not lead to conclusion that trailer was obvious. In finding that the claimed invention was not obvious, she referred to the following factors supporting inventiveness:

- There were no prior similar units;

²¹ *Beloit Canada Ltd. v. Valmet OY* (1986), 8 C.P.R. (3d) 289 at 294 (F.C.A.)

²² *Monsanto Co. v. Commissioner of Patents*, [1979] 2 S.C.R. 1108 (S.C.C.)

²³ *Wessel et al. v. Energy Rentals Inc.* 2004 FC 791 (F.C.), (2004) 32 C.P.R. (4th) 315 (F.C.)

- The trailer was a commercial success;
- The solution not “plain as day” or “crystal clear”; and
- “Imitation is the sincerest form of flattery”, referring to evidence that the defendant sought to “design around” the patent” and stating that that “the mere fact that the competitor took steps to copy the unit is indicative of the inventiveness of the Westmen trailer.”

Halford v. Seed Hawk

In *Halford v. Seed Hawk*²⁴, Pelletier J., on the facts of that case, concluded that the defendants had not proved that the patented seed/fertilizer placement system was obvious – he was unable to conclude that the skilled but unimaginative technician would be led directly and without difficulty to the invention by the elements of the mosaic of prior art put forward by the defendants.

Stonehouse v. Batco

In *Stonehouse v. Batco*²⁵, an allegation that the patent relating to a grain conveyor was invalid for obviousness was rejected by Shore J. He quoted the well known test for obviousness from *Beloit v. Valmet*²⁶ and also cited authority establishing that simplicity is not proof of obviousness and after the fact reconstruction is not the proper approach to obviousness. Applying the principles to this case, he said:

“[165] Mr. Hanson's analysis on obviousness was purely an *a posteriori* reconstruction. He first read and understood the patent. He then reviewed the prior art to identify those he considered to be most like the patented invention. He so identified Dussault ... and the Compton device. He then looked at the remaining prior art to see if he could find the missing pieces. It is significant that Mr. Hanson apparently overlooked the fact that Dussault was a two-belt and not a continuous belt device, although he had identified the continuous belt as an essential element of the claimed invention ...

[166] None of the art cited by the defendants has the key elements of a belt mounted on an inner surface of a sidewall so as to be formed into a cupped shape thereby so as to confine material on the belt for entry of the material onto the tube conveyor for transport along the tube.

[167] Without these elements, an ordinary skilled person in the art would not be led by the prior art, alone or in combination, directly and without difficulty to the solution taught by the '257 Patent.”

²⁴ *Halford et al. v. Seed Hawk Inc. et al.* (2004) 31 C.P.R. (4th) 569 (F.C.)

²⁵ *Stonehouse v. Batco Manufacturing Limited et al.* 2004 FC 1767 (F.C.)

²⁶ *Beloit Canada Ltd. v. Valmet Oy* (1986) 8 C.P.R. (3d) 289 (F.C.A.)

GlaxoSmithKline v. Pharmascience

*GlaxoSmithKline v. Pharmascience*²⁷, an NOC proceeding, concerned a patent relating to the use of carvediol to treat congestive heart failure (“CHF”). The allegation of obviousness was held to be justified.

In that case, the prior art taught the use of carvediol to treat CHF and there had been positive results in Phase II trials, but no conclusive results as to its effect had been obtained prior to the relevant date. Noël J. held that there is no creativity in confirmation and that the prior art led directly to the “invention” without undue experimentation.

Other NOC Cases

Other decisions concerning obviousness in NOC proceedings are discussed below²⁸.

5. ANTICIPATION

Wessel v. Energy Rentals

In *Wessel v. Energy Rentals*²⁹, although the patent was a New Act Patent, the anticipation issue (erroneously) was said to be whether the invention was known or used before the invention citing section 27(1)(a) of the Old Act. However, in applying the test, anticipation appears to have been tested at application date, perhaps because no earlier invention date was proved, but in fact apparently corresponding to the appropriate date under s. 27.2 of the New Act.

As referred to above³⁰, the patent claimed a trailer having a power swivel unit mounted on one section such that trailer is unbalanced without additional load. The prior art trailer asserted to be an anticipation had a swivel mounted slightly off to one side. Snider J. held that there were significant differences between the prior art trailer and the claimed invention – it was designed for rig assist, not to carry a complete swivel unit, and it was not necessarily unbalanced. She concluded that the prior art trailer did not give all the information needed to produce the claimed invention.

Halford v. Seed Hawk

Allegations of anticipation were rejected in *Halford v. Seed Hawk*³¹. The patent, an Old Act Patent, concerned a seed/fertilizer placement system. Anticipation under sections 27(1)(a) and 27(1)(b) were asserted based on the use of devices developed in Sweden and publications concerning such devices. Pelletier J. found that the alleged anticipating devices differed in several respects from the claimed system.

²⁷ *GlaxoSmithKline Inc. et al. v. The Minister of Health and Pharmascience et al.* 2004 FC 116 (F.C.)

²⁸ See infra section 16.4.2.1

²⁹ Supra footnote 23

³⁰ Supra section 4

³¹ *Halford et al. v. Seed Hawk Inc. et al.* (2004) 31 C.P.R. (4th) 569 (F.C.)

6. UTILITY

Stonehouse v. Batco

In *Stonehouse v. Batco*³², an allegation that the patent relating to a grain conveyor was invalid for lack of utility was rejected by Shore J. He said:

[177] The test for utility is appropriately stated as follows:

..."not useful" in patent law. It means "that the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promises that it will do".

... it is sufficient utility to support a patent that the invention gives either a new article, or a better article, or a cheaper article, or affords the public a useful choice...³³

...If when used in accordance with the directions contained in the specification the promised results are obtained, the invention is useful in the sense in which that term is used in patent law. The question to be asked is whether, if you do what the specification tells you to do, you can make or do the thing which the specification says that you can make or do.³⁴

[178] The plaintiff's invention clearly satisfies the test for utility."

7. SUFFICIENCY OF DISCLOSURE

Halford v. Seed Hawk

In *Halford v. Seed Hawk*³⁵, in which the patent concerned a seed/fertilizer placement system, it was alleged that each of the claims was invalid in that the disclosure did not teach certain elements said to be essential to the invention. Pelletier J. found no defect in the disclosure as alleged.

8. FAILURE TO PAY THE PRESCRIBED FEE

Since the decisions in the *Dutch Industries* case³⁶, there has been an increased strictness to the application of the time limits for fee payments and patents have been found to be abandoned for

³² Supra footnote 25

³³ *Consolboard*, citing Halsbury's Law of England, (3rd ed.), vol. 29, at p. 59.

³⁴ *Consolboard*, citing *Unifloc Reagents, Ltd. v. Newstead Colliery, Ltd. (1943)*, 60 R.P.C. 165, at p. 184.

³⁵ *Halford et al. v. Seed Hawk Inc. et al. (2004)* 31 C.P.R. (4th) 569 (F.C.)

³⁶ Supra footnote 11

errors in relation to fee payment. Of the cases referred to below, two relate to the “small entity” problem discussed in the *Dutch Industries* decisions, but two others related to failure to pay fees as a result of other problems.

Eiba v. Canada

*Eiba v. Canada*³⁷ was an application for judicial review of an abandonment of an application for failure to pay the required maintenance and reinstatement fees. The applicant had, within the reinstatement period, separately filed a submission paying the maintenance fee and a submission paying the examination fee, both of which requested reinstatement. The submission regarding examination was received by the Office, but the second submission was not. The Court found that it “evidently went astray somewhere in transit.” Notwithstanding the applicant’s intention to reinstate, Mosley J. held that “the Act is clear that an applicant must be held responsible for not allowing his application to become irrevocably abandoned”. An allegation that the applicant had a “legitimate expectation” that the Commissioner would inform the applicant of the deficiency was rejected. The Court also held that the maintenance fee provisions must be interpreted strictly by the Commissioner and by the Court, and that the Commissioner has no authority to extend the deadline for payments of maintenance fees beyond the reinstatement period.

P.E.Fusion v. Canada

Similarly, in *P.E.Fusion v. Canada*³⁸, Mosley J. dismissed an application to set aside the abandonment of an application for failure to pay maintenance fees. The failure arose from a clerical error in the patent agent’s office. The Court rejected a submission that there was a general inherent jurisdiction in the Commissioner to correct genuine mistakes made by patentees or their agents.

Johnson & Johnson v. Boston Scientific

On November 30, 2004, just days before the introduction of Bill C-29 to remediate the “small entity” problem as discussed above³⁹, on a motion for summary judgment in *Johnson & Johnson v. Boston Scientific*⁴⁰, three patents relating to stents were held invalid as a result of fees improperly paid as a small entity.

The motion had been argued in June 2003, but while the decision was under reserve, the government announced its intention to pass remedial legislation. In view of that announcement and since an application for leave to appeal the *Dutch Industries* decision to the Supreme Court of Canada was pending, Martineau J. allowed a motion to stay the proceedings for a period of one year. That stay was affirmed by the Federal Court of Appeal⁴¹, but that Court noted that “it is a rare circumstance where the Court will decline to proceed because of anticipated legislative

³⁷ *Eiba v. Canada (Attorney General)* (2004), 34 C.P.R. (4th) 119 (F.C.)

³⁸ *P.E. Fusion v. Canada (Attorney General and Commissioner of Patents)* 2004 FC645 (F.C.)

³⁹ Supra section 2.3

⁴⁰ *Johnson & Johnson Inc. et al. v. Boston Scientific Ltd.* 2004 FC 1672 (F.C.). A similar order was also made in *Johnson & Johnson Inc. et al. v. Arterial Vascular Engineering Canada Inc. et al* 2004 FC 1673 (F.C.), adopting the reasons in the *J&J v. Boston Scientific* case

⁴¹ *Johnson & Johnson Inc. v. Boston Scientific Ltd.* 2004 FCA 354 (F.C.A.)

changes.” Since during the one year period the application for leave to appeal in *Dutch Industries* had been refused and no remedial legislation had been introduced, Martineau J. refused to extend the stay and issued his judgment on the summary judgment motion.

He held that the defendant was entitled to raise this issue as an issue of invalidity, dismissing an argument that the defendant should have sought judicial review, and that it had adequately done so in its statement of defence and counterclaim. He also held that this was an appropriate case for summary judgment, there being sufficient evidence to make the determination of whether the patentee was a small entity at the material dates.

Although the patent applications for the patents in issue were filed on the basis that the applicant was a small entity, prior to their filing, the applicant had entered into a licence agreement with Ethicon, a subsidiary of Johnson & Johnson, pursuant to which it was entitled to receive \$3.6 million. On this basis, Martineau J found that the applicant did not qualify as a “small entity” at the filing date and that the entire filing fee for the applications was not paid at the filing date – the amount of the filing fee for a small entity was paid, but not the full fee found to be due since it was not a small entity - and accordingly, the applications were incomplete and deemed to have been abandoned 12 months after their filing date. As to the two earlier applications, the applicant sought to top up the filing fees about 7 months after their deemed abandonment, but did not petition for reinstatement nor pay the required fees. As to the later application, while some large entity fees were paid in time, others, including the completion fee, were not. The Court held that the Commissioner had no authority to waive these defects.

He considered the effect of section 3.1 of the *Patent Rules*, although it was not in force at the time the motion was argued. As discussed above⁴², this amendment allows remediation of a late fee where a “clear but unsuccessful attempt” was made to pay the fee before the expiry of the time limit for its payment, provided the conditions stated in the amendment are satisfied. Martineau J. held that this amendment to the *Patent Rules* did not affect the rights of the parties – it had no application at the material time, it did not allow avoidance of the consequences of payment of the wrong fee, it was not a remedial provision for the *Dutch Industries* problem, and, in any event, there had been no clear attempt to pay the proper fees within the time limit.

In the result, Matineau J. granted summary judgment dismissing the infringement action and declaring the patents in issue to be invalid, void and of no force and effect.

9. ONUS OF PROOF OF INVALIDITY

In modern Canadian jurisprudence, most issues relating to the validity of patents have been addressed by a consideration of whether the party challenging the validity had met the onus⁴³ of proving that the statutory requirements for patentability had been satisfied⁴⁴. The issue has not been approached as a review of the Patent Office decision and, accordingly, in most cases, the factors that led to the Patent Office decision to issue the patent have not been addressed by the

⁴² Supra section 2.2

⁴³ See: *Tye-Sil Corp. Ltd. v. Diversified Products Corp. et al* (1991), 35 C.P.R. (3d) 350 (F.C.A.)

⁴⁴ See: William L. Hayhurst, Q.C., “Grounds for Invalidating Patents”, (1975), 18 C.P.R. (2d) 222 at pp. 233-4

court as a relevant consideration⁴⁵. This is not to say that the prosecution file has never been considered relevant,⁴⁶ but the issue has not been approached by reviewing the reasoning of the Commissioner as inferred from the materials before the Commissioner or the submissions made to the examiner.

However, in *Apotex v. Wellcome Foundation*⁴⁷, the “AZT” case, an action for a declaration that a patent for the use of the known pharmaceutical AZT to treat AIDS was invalid, the Supreme Court of Canada addressed the “standard of review”, treating the issue of the validity of the patent as a review of the decision of the Commissioner granting the patent⁴⁸. In that case, which involved mixed questions of law and fact, particularly an issue as to whether the patent was invalid for failing to name as inventors persons found by the trial judge to have been inventors (a finding reversed by the Federal Court of Appeal), Binnie J. for the Supreme Court said:

“43 There is no privative clause and the statutory presumption of the patent's validity in s. 45 of the *Patent Act* is rather weakly worded. It provides that after issuance a patent "in the absence of any evidence to the contrary" is presumed to be valid. As Pratte J. (as he then was) said in *Rubbermaid (Canada) Ltd. v. Tucker Plastic Products Ltd.*:

‘...once the party attacking the patent has introduced evidence, the Court, in considering this evidence and in determining whether it establishes the invalidity of the patent, must not take the presumption into account. It cannot be said that the presumption created by [now s. 45] is, as a rule, either easy or difficult to overcome; in some cases, the circumstances may be such that the presumption will be easily rebutted, while, in other cases the same result may be very difficult or even impossible to obtain.’

In other words, the statutory “presumption” adds little to the onus already resting, in the usual way, on the attacking party. The Commissioner and his staff have considerable expertise in these matters but the trial judge heard 60 days of expert evidence and legal submissions that post-dated their review of the patent application.

44 In the circumstances, I think the appropriate standard of review of these issues, which largely raise mixed questions of law and fact, is reasonableness *simpliciter*, i.e., that the Commissioner's decision must withstand a somewhat probing examination; (*Canada (Director of Investigation and Research) v. Southam Inc.*” [citations omitted]

⁴⁵ In contrast, for example, in the U.S., whether particular art was or was not considered by the Patent Office is a very material consideration.

⁴⁶ Note the comment of Binnie J. in *Free World Trust v. Électro Santé Inc.* [2000] 25 S.C.R. 1024, 9 C.P.R. (4th) 168 (S.C.C.) at para. 67

⁴⁷ *Supra* footnote 17

⁴⁸ This decision was issued at the same date as its decision in *Harvard College v. Commissioner*, *Supra* footnote 15, which was a review of the Commissioner's decision. This issue is discussed in more detail in D.H. MacOdrum, “What's New at the Supreme Court: AZT”, *Canadian IP Rev.*, Vol. 20, p. 201 at pp. 206-208

In *Monsanto v. Schmeiser*⁴⁹, an infringement action in which the validity of the patent was challenged, the majority of the Supreme Court, in a brief discussion of the validity of the patent in that case, concluded:

“24 Monsanto's patent has already been issued, and the onus is thus on Schmeiser to show that the Commissioner erred in allowing the patent: *Apotex Inc. v. Wellcome Foundation Ltd.*⁵⁰; at paras. 42-44. He has failed to discharge that onus. We therefore conclude that the patent is valid.”

When the validity of a patent is challenged as a defence to a patent infringement action under section 59, or in an action to impeach the validity of the patent under section 60(1), the issue is not whether the decision of the Commissioner erred in the decision to allow the patent on the facts before the Patent Office, but whether the patent is shown to be invalid on the evidence before the Court.

10. CONSTRUCTION OF THE PATENT

Cases in 2004 continued to cite and to seek to apply the principles for construction of patents stated by the Supreme Court of Canada in *Free World Trust v. Électro Santé*⁵¹ and *Whirlpool v. Camco*⁵². In addition to the cases discussed below, see also for example *MacLennan v. Gilbert Tech*⁵³.

10.1 Purposive Construction - Federal Court of Appeal

Canamould v. Driangle

In February 2004, in *Canamould v. Driangle*⁵⁴, the Federal Court of Appeal dismissed an appeal from a trial judgment of Layden-Stevenson J. holding that the patent, which related to a method of manufacturing elongate decorative moulding and to a device for such manufacture, was valid but not infringed.

The claims for both the method and the apparatus required a table and specified that the table had or included “a smooth continuous planar top surface”. The trial judge concluded that it was essential that the top surface of the table be uninterrupted in the area that supported the foam core for the moulding. She found that the defendant’s table was not smooth and continuous in the area supporting the foam core and that there was no infringement.

Stone J.A. for the Federal Court of Appeal noted that, as to the standard of review, since construction of patent claims is “a matter of law”, the standard of review is that of correctness,

⁴⁹ Supra footnote 1

⁵⁰ *Apotex Inc. v. Wellcome Foundation Ltd.* [2002] 4 S.C.R. 153 (S.C.C.)

⁵¹ *Free World Trust v. Électro Santé* (2000), C.P.R. (4th) 168 (S.C.C.)

⁵² *Whirlpool Corporation v. Camco Inc. et al.* (2000), 9 C.P.R. (4th) 129 (S.C.C.)

⁵³ *MacLennan et al v. Gilbert Tech Inc.* 2004 CF 1700 (F.C.)

⁵⁴ *Canamould Extrusions Ltd. v. Driangle Inc.* (2004), 30 C.P.R. (4th) 129 (F.C.A.), affirming (2003) 25 C.P.R. (4th) 343 (F.C.)

whereas infringement of a patent is “a mixed question of fact and law” which calls for the standard of palpable and overriding error.

Stone J.A. reviewed the principles of construction as referred to in *Free World* and *Whirlpool*, including the one-step purposive construction approach enunciated in *Catnic*, and particularly the approach to determining whether an element is essential referred to in *Free World*, including the three question test from *Improver v. Remington*⁵⁵ which was quoted in *Free World*. At the end of his review of these principles he stated:

“[28] The task of a trial judge is to determine, on a purposive construction of the patent, which of the elements of the claimed invention were crucial or "essential" and which ones were not. Having properly stated the principles of claim construction at paras. 30 through 36 of her decision, it is clear that the Trial Judge appreciated the task that was before her. She was to purposively construe the Patent through the eyes of a skilled reader as of the date of publication. Assisted by the expert evidence, the context to the claims provided by the disclosure and figures, and the purposes served by the top surface of the table under the Patent, it was open to the Trial Judge to adopt a construction of the claims that was different from that put forward by the parties (*Whirlpool*, supra, at para. 61).”

He then considered in some detail the arguments concerning the construction of the claims in relation to the various point in issue in light of the language of the claims, the specification and the evidence. On the issue of the continuous table he concluded:

“[38] In summary, the Patent teaches that an essential element of the invention is a table that is "continuous" (i.e. uninterrupted) across the width of the foam core from the input portion through to and including the exit of the core from the coating containment chamber. Nothing in the context of the claims or in the expert evidence indicates that the patentee was aware of or intended to claim variants of that element. Furthermore, the essential nature of that element is supported by the purposes of the table as specified under the Patent. It may be that the patentee could have done without a ‘continuous’ table as that word was construed by the Trial Judge or that the invention would have worked just as well without having the bottom surface of the coating containment chamber ‘defined by the top surface of the table’. However, the language of the claims cannot be ignored. The care with which such language is crafted has been stressed by courts, most recently by the Supreme Court of Canada in *Free World Trust*, supra, at para. 51, where Binnie J. stated that ‘if the inventor has misspoken or otherwise created an unnecessary or troublesome limitation in the claims, it is a self-inflicted wound’. The appellants have not shown that the Trial Judge incorrectly construed claims 1 and 9 of the Patent.”

On this construction, there was no infringement in view the trial judge’s findings as to the defendant’s apparatus which were not palpably wrong.

⁵⁵ *Improver Corporation v. Remington Consumer Products Ltd.* [1990] F.S.R. 181 (Pat. Ct.)

Procter & Gamble v. Genpharm

In *Procter & Gamble v. Genpharm*⁵⁶, an appeal from the prohibition of a NOC for etridonate for the treatment of osteoporosis, the Federal Court of Appeal considered the construction of the claim in relation to an allegation of obviousness. Claim 17, which was the most general use claim, provided:

“17. Use of a bone resorption inhibiting polyphosphonate for the treatment or prevention of osteoporosis in humans or lower animals afflicted with or at risk to osteoporosis, wherein the polyphosphonate is used in two or more cycles including use for about 1 day to 90 days followed by a rest period from about 50 days to 120 days.” [emphasis added]

The claims in issue were dependant on claim 17, but limited to the use of etridonate at particular dosages and cycles.

The term “rest period” was defined in the disclosure as follows:

“By "rest period" as used herein is meant a period of time during which the patient is not given a bone resorption inhibiting polyphosphonate, nor is the patient subjected to a bone cell activating amount of a bone cell activating compound or other conditions which would result in significant activation or inhibition of new bone remodeling units...”

Snider J. interpreted the claim to require only two stages and to exclude use of an activator. In affirming this construction, Rothstein J.A. for the Federal Court of Appeal held that, in giving the claims a purposive construction, it was appropriate to have regard to the disclosure to ascertain the nature of the invention and to assist in apprehending and construing the claim⁵⁷.

10.2 Purposive Construction - Trial Decisions

Wessel v. Energy Rentals

In *Wessel v. Energy Rentals*⁵⁸, Snider J. noted that no experts were presented to assist in the task of construction. The claim related to a trailer divided into two sections for carrying a power swivel unit and a number of drill collars, and required that the trailer be unstable for highway travel if loaded only with the power swivel. The Court interpreted the word “highway” in the claims in accordance with the *Alberta Highway Traffic Act*. The Court concluded further that, on a purposive construction, in this patent “highway” should be interpreted to include all types of roadways that would be traveled by the units. The Court construed the term “unstable for highway travel” as meaning that there was a reasonable possibility that the trailer, without a

⁵⁶ *Procter & Gamble Pharmaceuticals Canada Inc. et al v. Genpharm Inc. et al* (sub nom *Genpharm Inc. v. Procter & Gamble Pharmaceuticals Canada Inc. et al*) 2004 FCA 393 (F.C.A.)

⁵⁷ Citing the comments of Binnie J. in *Whirlpool*, supra footnote 50, at para. 52.

⁵⁸ Supra footnote 23

balancing load, could overturn in certain driving situations, or that it would lead to loss of control.

Halford v. Seed Hawk

In *Halford v. Seed Hawk*⁵⁹, Pelletier J. upon his construction of the patent found that a patent relating to a seed/fertilizer placement system was valid but not infringed by the Seed Hawk seed/fertilizer apparatus. He began by considering the elements of the claim and their interpretation. Having done so, he said:

“[80] That is the construction of Claim 1, at least in the sense of defining the terms and their relationships. The task of purposive construction, that is identifying the essential elements of the claim, still remains.”

With respect to the identification of the essential elements he said:

“[81] I am now to identify those elements of the invention which are essential. Since this is to be done without regard to the issues of infringement and invalidity, there is a considerable temptation to simply characterize as essential every discrete element of the claim on the theory that the invention could not function without all of these elements. This is a kind of but-for test. But for the frame, the invention could not move over the ground, therefore the frame is an essential element. The difficulty with this approach is that it does not account for variants. It may be that an element which does not fall within the description of an element is substituted for that element. That substitution may be a mere cosmetic change or it may have a material effect upon the operation of the invention described in the patent. Treating both cases as the absence of an essential element is an unreliable guide to infringement.”

He referred to his prior decision in *Norac v. Prairie*⁶⁰ in which he had concluded that essential elements must relate to the inventiveness of the invention. He said that this approach was consistent with what the Supreme Court did in *Free World Trust* and concluded: “...essential elements must be those elements which are necessary to achieve the new and useful result, or the accomplishment of a useful result by novel means, which justified the issuance of the patent.”

He then identified the essential elements of the claims in issue – five elements in the case of claim 1.

Pelletier J. then turned to the question of infringement. Comparing the claim as construed with the Seed Hawk apparatus he identified certain “variants” – four in the case of claim 1. As to these he said:

“[139] None of these amount to the absence of an essential element. They could more accurately be described as variants of what is described in the claim. To that extent, we are not dealing with the absence of an essential element. Consequently,

⁵⁹ *Halford et al. v. Seed Hawk Inc. et al.* (2004) 31 C.P.R. (4th) 569 (F.C.)

⁶⁰ *Norac Systems International Inc. v. Prairie Systems and Equipment Ltd.* (2002), 19 C.P.R. (4th) 360

simply asking if any essential element is lacking is not a useful way of determining whether infringement has occurred. It may be that one element has been substituted for another, the substituted member doing exactly what the original member did, doing it in the same way, and leading to the same result. Such a substitution would clearly amount to infringement even if on a literal reading of the claim one of the essential elements was missing. As Willis J. pointed out in *Incandescent Gas Light Co. v. De Mare Incandescent Light System Ltd.* (1896), 13 R.P.C. 301 at page 330:

It is seldom that the infringer does the thing, the whole thing, and nothing but the thing claimed in the Specification.

Cited by Binnie J. in *Free World Trust*, *supra*, at para. 71.

[140] It is for this reason that Binnie J. incorporated into his analysis the test in *Improver Corp. v. Remington Consumer Products Ltd.*, [1990] F.S.R. 181:

(i) Does the variant have a material effect upon the way the invention works? If yes, the variant is outside the claim. If no: --

(ii) Would this (i.e.: that the variant had no material effect) have been obvious at the date of publication of the patent to a reader skilled in the art? If no, the variant is outside the claim. If yes: --

(iii) Would the reader skilled in the art nevertheless have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention? If yes, the variant is outside the claim.

Free World Trust supra at para.55

[141] The *Improver* test incorporates the elements of essentiality, timeliness and the inventor's intention.”

He then applied this test in determining whether the variants were inside or outside the claim. In the result he concluded that the Seed Hawk apparatus did not infringe any of the asserted claims.

An appeal is pending from this decision. In their notice of appeal, *inter alia*, the plaintiffs assert that this two step approach is contrary to the one step approach mandated by the Supreme Court in *Free World Trust*.

Gold v. Serratus

*Gold v. Serratus*⁶¹ concerned a patent relating to a closure mechanism for gloves, knapsacks, etc. The claims all referred to a closure mechanism where a stretchable cord within a channel extends

⁶¹ *Gold v. Serratus Mountain Products Ltd.* 2004 FC 815 (F.C.)

beyond either two closely spaced openings or at least one opening. In every case, the stretchable cord has a stretched cross-sectional area which is lesser than the opening, and an unstretched cross-sectional area which is larger than the opening. The disclosure said that one of the objects was to provide an improved closure mechanism which does not require a buckle or additional closure member.

Blais J. reviewed the evidence concerning the construction of the claims, including the expert evidence, noting that he was not obliged to accept it. He said:

“[20] The judge must thus find support in the text of the patent itself, which I intend to do. First, however, I must state that for the purposes of construing the claims of the patent, I believe the most important part of the evidence was the gloves and mittens that were presented as material evidence. ... The important feature is the closure system, which applies indifferently to gloves or mittens.”

He reviewed the principles of construction and the text of the patent. With respect to the question of the essential features of the claims he said:

“[49] The claims all refer to a single closure mechanism, whereby the unstretched cross-sectional area of a stretchable cord being larger than the openings through which it extends, or larger than the cross-sectional area of the inserts added within the channel means, provides a blocking action once the tubular opening enclosed by the channel means has been reduced by pulling on the cord. Basically, an elastic drawstring system where closure is maintained as the elastic cord fills the space through which it slid when stretched.

[50] Nowhere in the claims nor in the disclosure is there a mention of another device to effect the blocking system. The system depends on the expansion of the cord once it returns to its unstretched state. I think an important principle stated at paragraph 42 in *Whirlpool, supra*, bears repeating at this point: ‘The usual rule is that what is not claimed is considered disclaimed.’”

On the basis of this construction of claims, he found that there was no infringement.

10.3 Purposive Construction - NOC Prohibition Application Decisions

During 2004, the principles of purposive construction of a patent were referred to and applied in several NOC prohibition applications. Most are discussed in Section 16.4, but a few are noted here.

Novartis v. Rhoxalpharma

In *Novartis v. Rhoxalpharma*⁶², the patent was for a pharmaceutical preparation containing cyclosporine, such preparation comprising either a hydrosol, or the stabilized particulate phase of

⁶² *Novartis Pharmaceuticals Canada Inc. et al v. Rhoxalpharma Inc.* 2004 FC 474 , 34 C.P.R. (4th) 218 (F.C.)

a hydrosol in dry or isolated form. The preferred embodiment described in the patent used a hydrosol preparation for intravenous application. Lemieux J. held that the construction of the patent claims was not limited to the preferred embodiment and, on the evidence, construed the broadest claim to cover a hydrosol formed in a human stomach (notwithstanding a prior contrary decision⁶³ of Tremblay-Lamer J. in a proceeding between the same parties concerning the same patent, but relating to 100 mg capsules of Rhoxalpharma's product). [This application related 25mg and 50 mg capsules.]

10.4 Purposive Construction – UK House of Lords

Kirin-Amgen v. Hoechst (HL) (Oct. 2004)

In October 2004, the U.K. House of Lords re-visited the *Catnic* test in *Kirin-Amgen v. Hoechst*⁶⁴. The case related to DNA sequence claims relating to synthetic erythropoietin. Construction of patents under UK patent law is now governed by the European Patent Convention and the protocol to that convention which requires that and the law and construction is governed infringement be determined by construction of the claims in light of disclosure, but the claims are not to be strictly construed nor viewed as mere guidelines, but a position is to be taken between these extremes to give fair protection and reasonable certainty.

Lord Hoffmann reviewed the pre-protocol UK law re construction, including *Catnic* and purposive construction. He said that the *Catnic* principle of purposive construction accords with the protocol, but that the *Catnic* or *Improver* questions are not always appropriate.

Lord Hoffmann said:

“‘Purposive construction’ does not mean that one is extending or going beyond the definition of the technical matter for which the patentee seeks protection in the claims. The question is always what the person skilled in the art would have understood the patentee to be using the language of the claim to mean. And for this purpose, the language he has chosen is usually of critical importance. The conventions of word meaning and syntax enable us to express our meanings with great accuracy and subtlety and the skilled man will ordinarily assume that the patentee has chosen his language accordingly. As a number of judges have pointed out, the specification is a unilateral document in words of the patentee's own choosing. Furthermore, the words will usually have been chosen upon skilled advice. The specification is not a document *inter rusticos* for which broad allowances must be made...

I agree with the Court of Appeal that the invention should normally be taken as having been claimed at the same level of generality as that at which it is defined in the claims. It would be unusual for the person skilled in the art to understand a specification to be claiming an invention at a higher level of generality than that chosen by the patentee.”

⁶³ *Novartis Pharmaceuticals Canada Inc. et al v. Rhoxalpharma Inc* 2001 FCT 137, 11 C.P.R. (4th) 370 (F.C.T.D.)

⁶⁴ *Kirin-Amgen Inc. et al. v. Hoechst Marion Roussel Limited et al.* [2004] UK HL 46 (H.L.)

These paragraphs were quoted by Shore J. in his recent decision in *Stonehouse v. Batco*⁶⁵.

11. INFRINGEMENT

11.1 Subject Matter Infringement

Canamould v. Driangle

As noted above⁶⁶, in *Canamould v. Driangle*⁶⁷, the Federal Court of Appeal dismissed an appeal from a trial judgment of Layden-Stevenson J. holding that the patent, which related to a method of manufacturing elongate decorative moulding and to a device for such manufacture, was not infringed in view of the construction of the patent affirmed by the Court of Appeal.

Wessel v. Energy Rentals

In *Wessel v. Energy Rentals*⁶⁸, the patent claimed a trailer for servicing oil and gas wells divided in two sections and having a power swivel unit mounted on one section such that trailer is unbalanced so that unsafe for highway travel without additional load. The issue was whether the defendant's trailers were, when loaded only with the power swivel unit, sufficiently unbalanced to be unstable for highway travel.

The defendant's trailer was designed to avoid infringement, but it was not not balanced when all equipment for swivel added. Snider J. held on conflicting expert evidence that the patent was infringed. A field test conducted by the defendant was criticized as not an adequate test of stability - the unit was driven by a very experienced driver under good conditions and speeds; the Court found that the trailer would have to meet a much wider variety of operating conditions. Theoretical calculations presented were not convincing. Snider J. found that there was little difference in stability from plaintiff's trailer which had been shown to be unstable.

Halford v. Seed Hawk

As referred to above, in *Halford v. Seed Hawk*⁶⁹, Pelletier J. upon his construction of the patent found that a patent relating to a seed/fertilizer placement system was valid but not infringed by the Seed Hawk seed/fertilizer apparatus.

Lapierre v. Equipments d'Erabliere

⁶⁵ *Stonehouse v. Batco Manufacturing Limited et al* 2004 FC 1767 (F.C.)

⁶⁶ Supra section 10.1

⁶⁷ *Canamould Extrusions Ltd. v. Driangle Inc.* (2004), 30 C.P.R. (4th) 129 (F.C.A.), affirming (2003) 25 C.P.R. (4th) 343 (F.C.)

⁶⁸ Supra footnote 23

⁶⁹ *Halford et al. v. Seed Hawk Inc. et al.* (2004) 31 C.P.R. (4th) 569 (F.C.)

The patent in issue in *Lapierre v. Equipments d'Erabliere*⁷⁰ related to a method for making maple syrup using reverse osmosis to concentrate the sap. The dispute between the parties regarding the construction of the claim related to whether the following two elements of the claim are essential, namely (1) the centrifugal pump with a 360 degree radial discharge and (2) the direction of the flow of fluid in the circulation path within the pressure vessel. Blanchard J. referred to *Free World* and said that in that case Binnie J. considered the three concise questions, stated by Hoffman J. in *Improver v. Remington*⁷¹, for determining whether an element is non-essential, and therefore substitutable.

On the facts of the case, the central issue was whether or not the claimed requirement for "a centrifugal pumping mechanism" was an essential limitation of the claim. In the defendant's device, the pump was axial, not centrifugal. After reviewing the evidence, the Court found that the modification introduced by the defendant had a material effect on the way the invention works. The first *Improver* criterion was therefore not met. The Court also found that the answer to the second *Improver* question was in the negative, and further, that a person skilled in the art would have concluded that strict compliance with the meaning with the words chosen was what the inventor intended (the third *Improver* question). Blanchard J. noted that the plaintiff's expert did not address the third question at all, and in fact did not discuss the words of the claim at all. The defendant's expert did address these issues. He concluded in paragraph 60 as follows:

"[60] I cannot alter the specific and clear terms of the claim without extending the monopoly obtained by the inventor at the date of publication of Patent '781. That which the inventor failed to claim belongs to the public."

Gold v. Serratus

As referred to above⁷², in *Gold v. Serratus*⁷³. Blais J. held that on the basis of the construction of the claims of a patent relating to a closure mechanism for gloves, knapsacks, etc there was no infringement.

MacLennan v. Gilbert Tech

*MacLennan v. Gilbert Tech*⁷⁴ was an action for infringement of a patent for a saw tooth and saw tooth holder combination for a cutting saw. Beaudry J. held that the patent was not infringed by any of the five products of the defendant in issue⁷⁵. Four of the Gilbert products were saw teeth manufactured without a saw tooth holder. Beaudry J. held that since all of the claims required a combination of saw tooth and saw tooth holder, the absence of any Gilbert saw tooth holder was sufficient to declare that these teeth did not infringe the asserted claims. The plaintiffs asserted contributory infringement or inducing infringement by the sale of such teeth to customers of the

⁷⁰ *Lapierre et al v. Les Equipments d'Erabliere C.D.L. Inc.* (2004) 33 C.P.R. (4th) 402 (F.C.)

⁷¹ *Improver Corp. v. Remington Consumer Products Ltd.*, [1990] F.S.R. 181

⁷² Supra section 10.2

⁷³ Supra footnote 61

⁷⁴ *MacLennan et al v. Gilbert Tech Inc* 2004 CF 1700 (F.C.)

⁷⁵ In view of that conclusion, he found it unnecessary to deal with the allegations of invalidity.

plaintiff who could use them as such or with adapters in the plaintiffs' saws, but none resulted in an infringing combination.

One of the Gilbert products was a saw tooth and saw tooth holder combination. Initially, the plaintiffs' expert admitted that this combination did not infringe claim 2, but asserted that it did infringe claim 3 which was dependant on claim 2. A lengthy excerpt from the cross-examination on this point is reproduced in the decision. The Court accepted that a dependent claim could not be broader than the claim to which it referred. Although the plaintiffs' expert recast his opinion to assert that claim 2 must be infringed because claim 3 was infringed, the court was not convinced, finding that it did not infringe because it did not have an "abutment means", which he had found to be an essential feature of the claims.

Stonehouse v. Batco

Mr. Justice Shore commenced his decision in *Stonehouse v. Batco*⁷⁶ as follows:

"After expert evidence, it's the judgment's call, is there infringement or none at all? And, the patent does it fall, or is it valid after all."

The patent concerned a conveyor for particulate materials such as grain. The patent noted that belt conveyors were well known, but that, in farm use, they usually required that the vehicle supplying grain, etc. to the conveyor be backed to the hopper section of the conveyor accurately. The conveyor of the invention allowed a vehicle to be driven over the hopper section by providing hinged side walls which folded down. The principal claim in issue was claim 2 which provided:

2. A conveyor for particulate material comprising: a conveyor tube; a hopper section at a feed end of the duct; a continuous belt movable longitudinally of the tube and the hopper section so as to transport the particulate material deposited in the hopper section into and along the tube; the tube and belt being shaped and arranged such that the belt forms a cupped section having a channel shape for moving along the tube to transport material along the tube; the hopper section having a pair of side walls each having a bottom edge arranged longitudinally of and spaced inwardly from a respective side edge of the belt; the side walls each being mounted for pivotal movement about a longitudinal axis at the bottom edge of the respective side wall such that each side wall can fold flat downwardly to allow passage over the side wall and the hopper section of a vehicle wheel; the side walls being arranged such that each can be moved to a raised position in which the side wall is inclined upwardly and outwardly from the bottom edge; the belt being mounted on an inner surface of the side walls so as to be formed into a cupped shape thereby so as to confine material on the belt for entry of the material onto the cupped section of the belt for transport along the tube ; and means for raising the side walls into said raised position. [emphasis added]

⁷⁶ *Stonehouse v. Batco Manufacturing Ltd. et al* 2004 FC 1767 (F.C.)

The defendant's conveyor was designed with hinged side walls to allow a vehicle to drive over the hopper section, but the defendant's conveyor additionally used a gusset welded to the hopper floor and adjacent hinge.

The issue was whether there was infringement on a purposive construction of the claim.

The decision of Shore J. is in some respects curious. In paragraph 9, he outlines the structure of the decision and states that a detailed background is provided prior to a presentation of the issues. One part of this background is entitled "Non-Infringement" which contains discussion of the evidence and reference to authorities which lead him to a conclusion of non-infringement. However, this determination precedes the description of the "Issues"- the construction of the patent, infringement, and validity – and his determination of those issues. Did he determine "non-infringement" before construing the patent?

In the "Non-infringement section of the decision, Shore J. referred to the *Free World* case⁷⁷, said that determining whether a variant is non-essential and hence substitutable had been reduced to the three questions from *Improver*, which were quoted in *Free World*, and then said:

"[66] When the facts of the present case are applied to the above test, it is clear that the defendants' pivotal sidewall plus gusset cannot be construed to be the sidewall of the patent. First, the sidewall and gusset do have a material effect on the way the invention works. As noted above, the gusset does not pivot, does not fold flat, and the combination of the two do not seal the gap and confine material on the belt does not extend to the pivotal sidewall. Second, there is no evidence, other than a statement by Mr. Rogers which is contradicted by the defendants' expert, Mr. Craig Hanson, that it would have been obvious to the skilled person at the publication date that these two structures could be substituted. Third, the evidence is that the language of the claims make it clear that the patentee did intend that strict compliance with the position and structure of the sidewall – the primary meaning – was an essential element of the invention. The patentee is stuck with the narrow words of his own choosing.

[67] It is those words in the claim that give the ambit of the monopoly certainty and the claims must be taken to mean what they say.

[68] Mr. Rogers' opinion that the wording of the '257 Patent would not make a skilled person believe that strict compliance with "bottom edge" of the sidewall was essential since such a construction would contradict the words of the claims. Specifically, the configuration of the sidewalls and the respective bottom edges is essential, as it is this configuration that confines material on the belt. A sidewall that is not pivotal at its bottom edge, but instead anywhere along its surface, not only does not accomplish the function and result of the '257 Patent, but also contradicts the claim language. Furthermore, there is nothing in the '257 Patent that suggests a fixed portion as well as a pivotal portion of a sidewall. A sidewall

⁷⁷ Supra footnote 51

pivoting somewhere other than its bottom edge could not fold flat. The existence of a fixed portion means that part of the sidewall would not be pivotal.⁷⁸

[69] Regarding the specific words chosen by the patentee, the court in *Free World Trust* held that ‘...if the inventor has misspoken or otherwise created an unnecessary or troublesome limitation in the claims, it is a self-inflicted wound. The public is entitled to rely on the words used provided the words used are interpreted fairly and knowledgeably’.⁷⁹

He then referred to the recent decision of the House of Lords in *Kirin-Amgen Inc. et al. v. Hoechst*⁸⁰ quoted above. In the result he found the patent valid but not infringed.

11.2 Infringing Use

Monsanto v. Schmeiser

In *Monsanto v. Schmeiser*⁸¹, McLachlin C.J. and Fish J. for the majority of the Supreme Court of Canada commenced their reasons with these comments:

“1 This case concerns a large scale, commercial farming operation that grew canola containing a patented cell and gene without obtaining licence or permission. The main issue is whether it thereby breached the *Patent Act*, R.S.C. 1985, c. P-4. We believe that it did.

2 In reaching this conclusion, we emphasize from the outset that we are not concerned here with the innocent discovery by farmers of "blow-by" patented plants on their land or in their cultivated fields. ...”

Monsanto’s patent was for a plant gene resistant to glyphosphate herbicides such as Monsanto’s “Roundup” and also claimed plant cells containing that gene. Canola seeds containing this gene were marketed to farmers as “Roundup Ready Canola”, their advantage being that, after planting, the crop could be sprayed with Roundup which would kill the weeds but the plants with the patented gene would not be affected.

Schmeiser never purchased “Roundup Ready” canola from Monsanto, but tests revealed that, in that year, 95 to 98 percent of his 1,000 acres of canola crop was made up of “Roundup Ready” plants. The exact origin of these plants was unclear, but the trial judge found that Schmeiser knew that they were “Roundup” resistant. Schmeiser did not spray with Roundup after planting.

⁷⁸ Reply Affidavit of Expert Witness Craig A. Hanson, paras. 8-12.

⁷⁹ *Free World Trust*, at para. 51 citing *Improver Corporation v. Reminton Consumer Products Ltd. and others*, [1990] F.S.R. 181 at 182.

⁸⁰ *Kirin-Amgen Inc. et al. v. Hoechst Marion Roussel Limited et al.* [2004] U.K.H.L. 46.

⁸¹ *Supra* footnote 1

The trial judge held that this was not necessary to establish infringement, and found the patent infringed and the Federal Court of Appeal affirmed this determination⁸².

A patent grants to the patentee for the patent term the exclusive right of making, constructing, using and selling the patented invention⁸³.

McLachlin C.J. and Fish J. were “not inclined” to accept an argument that Schmeiser by cultivation the seeds made the patented gene or cell, but found it unnecessary to deal with this for they found infringement by use of the patented cell and gene. They discussed in some detail the interpretation of “use” in the context of section 42 of the *Patent Act*. They concluded their review with this summary of principles:

“58 These propositions may be seen to emerge from the foregoing discussion of ‘use’ under the *Patent Act*:

- 1 ‘Use’ or ‘exploiter’, in their ordinary dictionary meaning, denote utilization with a view to production or advantage.
- 2 The basic principle in determining whether the defendant has ‘used’ a patented invention is whether the inventor has been deprived, in whole or in part, directly or indirectly, of the full enjoyment of the monopoly conferred by the patent.
- 3 If there is a commercial benefit to be derived from the invention, it belongs to the patent holder.
- 4 It is no bar to a finding of infringement that the patented object or process is a part of or composes a broader unpatented structure or process, provided the patented invention is significant or important to the defendant's activities that involve the unpatented structure.
- 5 Possession of a patented object or an object incorporating a patented feature may constitute "use" of the object's stand-by or insurance utility and thus constitute infringement.
- 6 Possession, at least in commercial circumstances, raises a rebuttable presumption of ‘use’.
- 7 While intention is generally irrelevant to determining whether there has been ‘use’ and hence infringement, the absence of intention to employ or gain any advantage from the invention may be relevant to rebutting the presumption of use raised by possession.”

⁸² *Monsanto Canada Inc. v. Schmeiser* (2001), 12 C.P.R. (4th) 204 (F.C.T.D.), affirmed (2002), 21 C.P.R. (4th) 1 (F.C.A.)

⁸³ *Patent Act* s.42

They noted that the trial judge had found that Schmeiser had saved, planted, harvested and sold the crop from plants containing the gene and plant cell patented by Monsanto. This on a common sense view constituted utilization of the patented material for production and advantage within the meaning of s. 42. Also, cultivating a plant with the patented gene without a licence deprived Monsanto of full enjoyment – its license fee. Schmeiser used the seeds in its business or growing canola – clearly commercial use.

They rejected the defence asserted by Arbour J. for the minority in dissent that because Monsanto's claims are for genes and cells rather than for plants, infringement by use will only occur where a defendant uses the genes or cells in their isolated, laboratory form - it is no defence to say that the thing actually used was not patented, where the patent covers a significant or important component.

They also rejected the argument that Schmeiser did not use the invention because he did not spray the plants with “Roundup”. They held that he had failed to rebut the presumption of “use” arising from possession. He had the benefit of the stand-by or insurance benefit that he could do so if necessary. He might have rebutted the presumption by showing that he never intended to cultivate plants containing the patented gene, or that seed with patented gene unwelcome and he quickly took steps to remove it, but Schmeiser actively cultivated canola containing the patented gene.

They rejected a further argument (accepted by Arbour J. in dissent) that propagation of canola with the patented gene cannot be a “use” because plants are living things that grow by themselves, noting this ignored the human role in the cultivation and that many inventions make use of natural processes in order to work.

Accordingly, they affirmed the conclusion of the trial judge and the Federal Court of Appeal that Schmeiser “used” the patented invention and thereby infringed the patent.

11.3 Infringement By Officers and Directors

Halford v. Seed Hawk

In *Halford v. Seed Hawk*⁸⁴, Pelletier J. considered the allegations of personal liability of the three individual defendants notwithstanding his finding that the defendants’ apparatus did not infringe. Citing two Ontario Court of Appeal decisions⁸⁵, he concluded that : “corporate directors and officers are personally liable for conduct undertaken in the course of their corporate duties if that conduct is itself tortious or if it serves an interest other than the corporation's.” He expressed some confusion with the test as stated by Le Dain J.A. for the Federal Court of Appeal in *Mentmore v. National Merchandise*⁸⁶ as follows:

⁸⁴ *Halford et al. v. Seed Hawk Inc. et al.* (2004) 31 C.P.R. (4th) 569 (F.C.)

⁸⁵ *Scotia MacLeod Inc. et al. v. Peoples Jewellers Ltd. et al.* [1995] 26 O.R. (3d) 481 (Ont.C.A.); *Normart Management Ltd. v. West Hill Redevelopment Co.* (1998), 37 O.R. (3d) 97 (Ont.C.A.)

⁸⁶ *Mentmore Manufacturing Co. Ltd. et al. v. National Merchandise Manufacturing Co. Inc. et al.* (1978), 40 C.P.R. (2d) 164 (F.C.A.)

“What, however, is the kind of participation in the acts of the company that should give rise to personal liability? It is an elusive question. It would appear to be that degree and kind of personal involvement by which the director or officer makes the tortious act his own. It is obviously a question of fact to be decided on the circumstances of each case. ...

But in my opinion there must be circumstances from which it is reasonable to conclude that the purpose of the director or officer was not the direction of the manufacturing and selling activity of the company in the ordinary course of his relationship to it but the deliberate, wilful and knowing pursuit of a course of conduct that was likely to constitute infringement or reflected an indifference to the risk of it. The precise formulation of the appropriate test is obviously a difficult one. Room must be left for a broad appreciation of the circumstances of each case to determine whether as a matter of policy they call for personal liability.”

Pelletier J. stated that in his view liability attaches when the actions of the director or officer are either such that the director's own behaviour is tortious, or when the corporation is simply used as a cloak for the personal activities of the director. He said that he believed that some care must be taken in applying a test based on "an analysis of the conduct of the personal defendant, to determine whether or not her actions can be characterized as dishonest, "deceptive and deliberately reckless behaviour", or indifference to the obvious consequences of her actions, such that a finding of personal liability is appropriate", referring to *Society of Composers, v. 1007442 Ontario Ltd.*⁸⁷, noting that dishonesty is not commendable but it is not infringement. He also concluded that a warning of possible infringement was not enough to establish personal liability.

He rejected the suggestion that the Seed Hawk device was simply a copy and modification of the Halford invention and concluded: “All in all, I find that the case against the individual defendants, at its highest, is that they decided to take a chance that they were right about infringement and that Mr. Halford was wrong. That is a long way from embarking upon a deliberate scheme of appropriating the plaintiffs' invention.”

12. INFRINGEMENT REMEDIES

12.1 Damages - Account of Profits

Monsanto v. Schmeiser

As referred to above, *Monsanto v. Schmeiser*⁸⁸ concerned a claim by Monsanto for damages or an account of profits resulting from Schmeiser's infringement of its patent covering “Roundup” resistant canola gene. Monsanto elected to claim the infringer's profits from the sale of the seeds containing the infringing gene, which profits were assessed at approximately \$20,000. The quantum was not in issue in the Supreme Court, but the entitlement to claim these profits was

⁸⁷ *Society of Composers, Authors and Music Publishers of Canada v. 1007442 Ontario Ltd.* (2002), 20 C.P.R. (4th) 68 (F.C.T.D.)

⁸⁸ Supra footnote 1

challenged on the basis that they did not flow from the infringement – Schmeiser would have made the same profit had he sold seeds without the infringing gene. The majority of the Supreme Court of Canada accepted this argument and set aside the award, McLachlin C.J. and Fish J. stating:

“100 The *Patent Act* permits two alternative types of remedy: damages and an accounting of profits. Damages represent the inventor's loss, which may include the patent holder's lost profits from sales or lost royalty payments. An accounting of profits, by contrast, is measured by the profits made by the infringer, rather than the amount lost by the inventor. Here, damages are not available, in view of Monsanto's election to seek an accounting of profits.

101 It is settled law that the inventor is only entitled to that portion of the infringer's profit which is causally attributable to the invention: *Lubrizol Corp. v. Imperial Oil Ltd.*⁸⁹, *Celanese International Corp. v. BP Chemicals Ltd.*⁹⁰ This is consistent with the general law on awarding non-punitive remedies: “[I]t is essential that the losses made good are only those which, on a common sense view of causation, were caused by the breach” (*Canson Enterprises Ltd. v. Boughton & Co.*)⁹¹

102 The preferred means of calculating an accounting of profits is what has been termed the value-based or "differential profit" approach, where profits are allocated according to the value contributed to the defendant's wares by the patent: N. Siebrasse⁹². A comparison is to be made between the defendant's profit attributable to the invention and his profit had he used the best non-infringing option: *Collette v. Lasnier*⁹³, also referred to with approval in *Colonial Fastener Co., v. Lightning Fastener Co.*⁹⁴.

103 The difficulty with the trial judge's award is that it does not identify any causal connection between the profits the appellants were found to have earned through growing Roundup Ready Canola and the invention. On the facts found, the appellants made no profits as a result of the invention.

104 Their profits were precisely what they would have been had they planted and harvested ordinary canola. They sold the Roundup Ready Canola they grew in 1998 for feed, and thus obtained no premium for the fact that it was Roundup Ready Canola. Nor did they gain any agricultural advantage from the herbicide resistant nature of the canola, since no finding was made that they sprayed with

⁸⁹ (1996), 71 C.P.R. (3d) 26 (F.C.A.)

⁹⁰ (1999), 6 R.P.C. 203 (Pat. Ct.), at para. 37

⁹¹ (*Canson Enterprises Ltd. v. Boughton & Co.*, [1991] 3 S.C.R. 534, at p. 556, *per* McLachlin J. (as she then was) quoted with approval by Binnie J. for the Court in *Cadbury Schweppes Inc. v. FBI Foods Ltd.*, [1999] 1 S.C.R. 142, at para. 93).

⁹² N. Siebrasse, "A Remedial Benefit-Based Approach to the Innocent-User Problem in the Patenting of Higher Life Forms" (2004), 20 *C.I.P.R.* 79

⁹³ (1887), 13 S.C.R. 563, at p. 576

⁹⁴ [1937] S.C.R. 36

Roundup herbicide to reduce weeds. The appellants' profits arose solely from qualities of their crop that cannot be attributed to the invention.

105 On this evidence, the appellants earned no profit from the invention and Monsanto is entitled to nothing on their claim of account.” [emphasis in original]

In finding infringement, McLachlin C.J. and Fish J. referred to the benefit derived by Schmeiser from the stand-by or insurance benefit that he could have sprayed with “Roundup” if necessary⁹⁵, but apparently gave this benefit no value in assessing the profits made by him.

12.2 Procedure - Damages and Profits

Apotex v. Merck

*Apotex v. Merck*⁹⁶ concerned the procedure for addressing the monetary remedies following summary judgment. Merck had previously been granted summary judgment that its patent for enalapril and enalapril maleate had been infringed by Apotex. The issue of the “remedy” had been deferred to be determined at a subsequent hearing. The present motion related to the procedure for such determination. In the particular circumstances of this case, Martineau J. ordered that:

1. The question of whether Merck is entitled to elect an accounting of Apotex’s profits was to be determined before any further discovery as to quantification of damages or profits.
2. Further discovery as to such entitlement could be conducted before such determination.
3. If Merck is found to be entitled to elect an accounting of profits, Merck is entitled to complete its discovery of Apotex as to the extent of infringement and as to Apotex’s profits prior to making its election as to damages or profits.
4. Any discovery of Merck as to damages shall occur only if Merck elects to recover damages and only after such election.

13. OWNERSHIP, ASSIGNMENT LICENSING

13.1 Assignment Agreement

MacMillan v. Kaiser (BCCA) (2004)

⁹⁵ *Monsanto v. Schmeiser*, supra footnote 1, at paras. 83-84; see supra Section 11.2

⁹⁶ *Apotex Inc. v. Merck & Co.* (2004), 34 C.P.R. (4th) 514 (F.C.)

*MacMillan v. Kaiser*⁹⁷ concerned the effectiveness of an assignment of patent rights contained in an employment agreement. MacMillan's employment agreement included an assignment of all past, present and future patents of MacMillan; he was paid \$35,000 as consideration for this assignment. When his employment terminated, MacMillan alleged a collateral agreement to give him equity and that breach of it avoided patent assignment terms. The British Columbia Court of Appeal held that the entire agreement clause of the agreement precluded this argument.

13.2 Patent Assignments - Competition Law

Eli Lilly v. Apotex

In this action Eli Lilly alleged that Apotex had infringed eight patents relating to the antibiotic Cefaclor. Four of the patents had been acquired by Eli Lilly from Shionogi & Co. Ltd.

In its statement of defence and counterclaim *Apotex* claimed damages under section 36 of the *Competition Act*, referring to the acquisition of the four patents and alleging that Eli Lilly had acquired them to preserve its monopoly for Cefaclor in Canada and that the assignment was a conspiracy or agreement to prevent or lessen competition in Canada contrary to s. 45 of the *Competition Act*. The paragraphs in issue are reproduced in Appendix A hereto.

Eli Lilly brought a motion to strike out these allegations and for summary judgment in respect of them. In 2003, Hugessen J. held⁹⁸ (reversing a decision of a prothonotary) that the facts alleged did not show a cause of action and dismissed the claim. He said that the question of whether the bare allegations in the pleading raised a cause of action was "a pure question of law and suitable for resolution either on a motion to strike or on motion for summary judgment."

He said that in *Molnlycke v. Kimberly-Clark*⁹⁹, the Federal Court of Appeal had held: that, as a matter of law, it is not arguable that the impairment of competition inherent in the exercise of rights expressly provided by that Act - the obtaining of a patent or reissue of a patent, its assignment and action by the assignee to enforce its monopoly - can be undue and he said that follows that undue impairment of competition cannot be inferred from evidence of the exercise of those rights alone.

***Eli Lilly v. Apotex* - Federal Court of Appeal**

In 2004, the Federal Court of Appeal¹⁰⁰ set aside the summary judgment. Rothstein J.A. for the Federal Court of Appeal said that Hugessen J. was correct to hold that he was bound by *Molnlycke*, but went on to consider whether his interpretation of that case was correct. On this point Rothstein J.A. said:

“[14] In the case of *Molnlycke*, there was a single supplier lawfully entitled to sell the subject of the patent prior to the patent being assigned. The assignment merely

⁹⁷ *MacMillan v. Kaiser Equipment Ltd.* 2004 BCCA 270 (B.C.C.A.)

⁹⁸ *Eli Lilly & Co. et al. v. Apotex Inc.* (2003), 28 C.P.R. (4th) 37 (F.C.)

⁹⁹ *Molnlycke AB v. Kimberly-Clark of Canada Ltd.* (1991), 36 C.P.R. (3d) 493 (F.C.A.)

¹⁰⁰ *Eli Lilly & Co. et al. v. Apotex Inc.* (2004), 32 C.P.R. (4th) 195 (F.C.A.), reversing (2003), 28 C.P.R. (4th) 37 (F.C.)

transferred the patent to another company. The only effect of the assignment was that a different company could sue the defendant for infringement. There was no change in the number of patent-holders before and after the assignment. The defendant appears to have claimed that an agreement to assign a patent and thereby allow the assignee to enforce the patent monopoly, with nothing more, could itself be an agreement that unduly lessened competition under s. 45(1).

[15] *Molnlycke* held that, in order to provide scope for the statutory monopolies granted by the *Patent Act* to operate, Parliament must have intended that ‘undue impairment of competition cannot be inferred from evidence of the exercise of [patent] rights *alone*’ (emphasis added). Where, however, there is evidence of something more than the mere exercise of patent rights that may affect competition in the relevant market, *Molnlycke* does not purport to completely preclude application of the *Competition Act*.”

He referred to section 32 of the *Competition Act* and noted:

“...the express statement in s. 32 that the use of patent rights could lessen competition unduly giving rise to a remedy under s. 32 indicates that *Molnlycke* cannot reasonably be interpreted as completely precluding application of the *Competition Act* whenever patent rights are involved.”

He continued:

“[17] In the present case, Apotex does not allege that it is the mere assignment of patent rights or the enforcement of those patent rights by Lilly that gave it a cause of action. Rather, Apotex says that the assignment in this case resulted in one company, Lilly, acquiring patent rights that allow it to control all of the commercially viable processes for making cefaclor where, before the agreement, those processes were controlled by two companies, Shionogi and Lilly. Apotex argues that this consolidation was something more than the mere exercise of patent rights. Therefore, it says, the assignment agreement gave rise to an undue lessening of competition which engaged s. 45(1) of the *Competition Act*.

[18] ... in my opinion, *Molnlycke* did not preclude the motions judge from considering whether the evidence presented by Apotex of other facts and circumstances beyond the simple assignment from Shionogi to Lilly resulted in an undue lessening of competition which could engage s. 45(1).

[19] Subsection 45(1) is silent as to whether it applies to agreements involving the exercise of patent rights to lessen competition unduly. The question, therefore, of whether s. 45(1) can ever apply to an agreement involving the exercise of patent rights when there is evidence of something more than the assignment itself has never been decided. The motions judge was obliged to carry out his own analysis of whether s. 45(1) could apply and, if so, whether there was sufficient evidence to prove that Lilly and/or Shionogi engaged in conduct that was contrary to s. 45. ...”

In the result, The Federal Court of Appeal held: (1) with respect to the motion to strike the pleading, it was not plain and obvious that Apotex has no reasonable cause of action; (2) with respect to the motions for summary judgment, the appeals were allowed and they were remitted for further consideration by the motions judge. The Court of Appeal said that in considering the matter further, the motions judge will have to address:

- (1) whether s. 45(1) can ever apply to an agreement involving the exercise of patent rights;
- (2) if it can, whether the facts of this case are sufficient to prove that Lilly and/or Shionogi engaged in conduct that was contrary to s. 45;
- (3) if so, whether any of the other arguments raised by Lilly and Shionogi, which he did not originally consider, prevent Apotex from recovering damages under s. 36 of the *Competition Act*;
- (4) whether he is able to resolve one or more of these issues at the summary judgment stage or whether he should refer the matter, in whole or in part, for trial.

***Eli Lilly v. Apotex* – Decision of the Motions Judge, Hugessen J. on the Re-Hearing**

The summary judgment motions came back before Hugessen J. and his decision was issued in October 2004¹⁰¹. He again allowed the motions for summary judgment dismissing the allegations.

On the first question posed by the Court of Appeal, whether s. 45(1) can ever apply to an agreement involving the exercise of patent rights, he said:

“[9] On the first question, it appears to me to be undoubted that the *Patent Act* does not have the effect of insulating from liability under the *Competition Act* any and every agreement which may also have to do with the exercise of patent rights. However, where an agreement deals only with patent rights and is itself specifically authorized by the *Patent Act*, any lessening of competition resulting therefrom, being authorized by Parliament, is not "undue" and is not an offence under section 45. The two statutes must be read together harmoniously and that can only be done if the meaning of the key word "undue" in section 45 is limited to restrictions on competition which are not specifically authorized by the *Patent Act*.

[10] Thus, as *Molnlycke (supra)* makes clear, agreements involving the mere exercise of patent rights are exempt from subsection 45(1). The basic proposition of *Molnlycke*, which was accepted by the Court of Appeal in the present case, is that an undue impairment of competition cannot be inferred from evidence of the exercise of patent rights alone.”

¹⁰¹ *Apotex Inc. v. Eli Lilly and Company et al.* 2004 FC 1445 (F.C.)

As to the second question posed by the Court of Appeal, whether the facts of this case are sufficient to prove that Lilly and/or Shionogi engaged in conduct that was contrary to s. 45, he reviewed the evidence and said:

“[14] So, there is and never has been any doubt that the result of the assignment of Shionogi's patents to Lilly was to increase the latter's monopoly power. Where formerly it had held four process patents useful in the production of cefaclor, it now held eight and no one else held any. In a word, it had a monopoly of the known production processes. It may well have been in a position of market dominance.

[15] The agreement which constitutes the conspiracy alleged by Apotex, however, is solely and exclusively the assignment of the Shionogi patents and there is no other agreement alleged or shown by the evidence which could be the basis of a section 45 offence.

[16] But the assignment of a patent is a transaction which has been specifically authorized by Parliament. Section 50 of the *Patent Act* reads in relevant part:

50.(1) Every patent issued for an invention is assignable in law either as to the whole interest or as to any part thereof, by an instrument in writing.

[17] This is no mere formal authorization, nor is it, as Apotex argues, the simple confirmation of the normal right of any owner of property to sell or assign it to another. What Parliament is dealing with here is a patent, a monopoly. The monopolist is given specific legal warrant to deal in his monopoly by transferring it to another. The provision would not be necessary if it did not go beyond the right of every proprietor to deal with his own as he or she sees fit.”

He reviewed sections 36 and 45 of the *Competition Act* and concluded:

“[21] But as we have seen, in section 50 of the *Patent Act* Parliament specifically authorizes the agreement ("an instrument in writing") to assign a monopoly right. Assuming that the patent is for an invention that is useful and marketable, which in the present case it manifestly was, that agreement has for a necessary consequence an increase in the assignee's market power. But, since the agreement has been so authorized and deals with nothing other than the permitted assignment of patents, its effects cannot be undue and the number of patents involved or of other players in the market is irrelevant.

[22] Accordingly, my answer to the second question is that although there was an agreement between Lilly and Shionogi and although it had the effect of lessening competition, that lessening was not undue because it had been authorized by an Act of Parliament....

[23] I would add that this conclusion which flows from the very words of the relevant statutes is also in my view fully compatible with the "Intellectual Property Enforcement Guidelines" issued by the Competition Bureau.”

With regard to the third question regarding the defences raised by Eli Lilly and Shionogi - allegations that Apotex suffered no damages and that the claim was prescribed – he said that he would not have been prepared to dismiss the claim at the summary judgment stage on these grounds alone.

An appeal from this decision granting summary judgment has been filed by Apotex.

14. PATENT LITIGATION

14.1 Interlocutory Injunction

Pfizer v. Lilly

*Pfizer v. Lilly*¹⁰² was a motion for an interlocutory injunction to restrain the sale of “Cialis”, a drug to treat erectile dysfunction (“ED”) and a competitor to Pfizer ‘s ED drug “Viagra”, asserting infringement of a patent relating to the use of a cGMP PDE enzyme inhibitor to treat ED. This was a skirmish in litigation taking place in several jurisdictions around the world – in some cases between Pfizer and Eli Lilly/Lilly ICOS (“Lilly”) companies, in some cases between Pfizer and Bayer/GSK who had an ED drug “Levitra”, and in several cases, as in Canada, both groups. (No interlocutory injunction was sought in any of the other jurisdictions.)

The Canadian litigation started in 2002 with impeachment actions launched by Lilly and by Bayer. Pfizer separately sued both parties for threatened infringement – both parties had applied for approval but had not then received it. No injunction was sought at that time. Lilly successfully brought a motion to dismiss the action brought against it as premature and, as a result, Pfizer discontinued the action against Bayer.

Lilly obtained approval in Canada for its “Cialis” product in the fall of 2003. Pfizer immediately sued for infringement and sought both an interim and an interlocutory injunction. The interim injunction was heard by Kelen J. in late 2003 on the evidence pre-cross-examination and he dismissed the interim injunction on the basis that damages could be calculated and were not irreparable.

The interlocutory injunction motion was heard by Blais J. in February 2004 and it also was refused. He was not persuaded that Pfizer would suffer irreparable harm. Pfizer argued that it would suffer loss of brand equity and that there was a likelihood of a backlash against Pfizer products if “Cialis” was introduced then later enjoined. Blais J. was not convinced. He said:

¹⁰² *Pfizer Ireland Pharmaceuticals v. Lilly ICOS LLC* (2004), 30 CPR 4th 317 (FC)

“Try as I may, I cannot imagine demonstrations in the street or storming of the barricades because one impotence medicine is made unavailable, forcing customers to chose the other.”

He also found that the balance of convenience was fatal to the injunction motion, concluding that:

- If an injunction was granted and Lilly was ultimately successful, Lilly would lose all its potential revenue, development of the market once it could enter the market would be more difficult, and damages would be difficult to calculate with no baseline.
- If no injunction was granted and Pfizer was ultimately successful Pfizer would lose some revenue, its market would be temporarily modified, but would be re-established, and calculation of damages would be facilitated by the baseline from the competing sales.

Carbo Ceramics v. China Ceramics

An interlocutory injunction was granted and upheld on appeal in *Carbo Ceramics v. China Ceramics*¹⁰³. The patent concerned ceramic proppants, spherical particles used in oil and gas wells to prop open fractures in the subterranean formations to increase permeability. The plaintiff had invented the ceramic proppant which had become widely used. For the last 10 years plaintiff had no direct competitor.

Defendant is a small corporation with a sole shareholder and imports a product made in China.

Plaintiff had test evidence showing that the defendant’s product fell within the claims of its patent. While defendant challenged the test evidence and asserted invalidity of the patent, shore J. found there was a serious issue to be tried.

He found that the plaintiff would suffer irreparable harm on two bases: (i) the defendant would be unable to pay damages; and (ii) the defendant is “springboarding”, i.e. the infringer has entered the market near the end of the patent term and seeks to ramp up to take advantage of the expiry of the patent.

He found that the defendant also would suffer irreparable harm, and probably would go out of business. He concluded that the balance of convenience did not favour either side and that therefore the status quo should be preferred, i.e. that the infringer should not be allowed to continue.

In affirming the grant of the interlocutory injunction, Létourneau J.A. for the Federal Court of Appeal said:

“[6] In our view, the judge came to the right conclusion regarding the balance of convenience, but the reasons that he gave require some clarification.

¹⁰³ *Carbo Ceramics Inc. v. China Ceramics Proppant Ltd.* (2004), 34 C.P.R. (4th) 423 (F.C.), affirmed (2004), 34 C.P.R. (4th) 431 (F.C.A.)

[7] In *Garden Cottage Foods Ltd. v. Milk Marketing Bd.*, [1984] A.C. 130, at page 140, Lord Diplock defined the *status quo* as "the state of affairs existing during the period preceding the issue of the writ claiming the permanent injunction". Many cases in this jurisdiction have held that the *status quo*, where the balance of convenience is neutral, is the *status quo* at the time the application is made or heard: [citations omitted].

[8] This Court recognized in *Turbo Resources Ltd. v. Petro Canada Inc.* (1989) 24 C.P.R. (3d) 1, at pages 13 and 14, that there may be factors, such as the strength of one party's case over the other, which will tip in a party's favour a balance of convenience which otherwise appears to be neutral as a result of some factors being evenly balanced. One such factor, we believe, is the judge's finding that the appellant was "springboarding" into the market place in anticipation of expiry of the respondent's patent, thereby causing the respondent to suffer a loss of part of the market likely to endure after the expiry of the patent, as well as a disadvantage for which an award of damages would be insufficient.

[9] The judge "deemed" the appellant to be "springboarding". Although he improperly cast his conclusion in presumptive terms, it is obvious from his reasons that he made a finding of fact that the appellant was entering the market to obtain an advantage before the expiry of the patent, that it knew of the existence of the patent, that it consciously took the risk of entering the market and that it "walked into the [alleged] infringement situation with its eyes wide open": see *Lubrizol Corp. et al. v. Imperial Oil Ltd.* (1989) 22 C.P.R. (3d) 493 (F.C.T.D.), upheld (1989) 26 C.P.R. (3d) 461 (F.C.A.).

[10] There was sufficient evidence before the judge to support the serious allegation of "springboarding" made by the respondent against the appellant. That being so, we agree with the following approach taken by Martin J. in *Aluma Systems Ltd. v. J. Fitzmaurice Ltd.* (1987), 17 C.P.R. (3d) 419, at page 423:

It appears to me that Canada Scaffold, being aware of the risks of its proposed action prior to putting its system into the market-place and electing to take that risk rather than some other appropriate action to determine whether its system would infringe the plaintiffs' claims, cannot now be heard to complain that the appropriate time for the preservation of the status quo should be fixed at a time prior to which it entered the market.

To accept the appellant's contention that the *status quo* should be fixed at the time at which the injunction was sought would be to allow the appellant not only to continue the alleged infringements, but also to carry on its alleged "springboarding" with the blessings of the Court."

This springboarding together with the other factors – the inability of the defendant to financially honour an award of damages, the strength of the plaintiff's case, the strengths of the plaintiff's

undertaking with respect to the payment of damages, the time at which the appellant entered the market, in the Court's view, tipped the balance of convenience in favour of the plaintiff.

14.2 Summary Judgment

14.2.1 Summary Judgment – Construction of the Patent, Infringement and Validity

Trojan v. Suntec

In 2003, in *Trojan v Suntec*¹⁰⁴, Gibson J. granted summary judgment in an action for patent infringement notwithstanding conflicting issues of fact. The patent concerned a device which purifies fluids using ultraviolet light. The issues before the motions judge included construction and infringement of the patent and, by way of defence but not counterclaim, invalidity on the basis of anticipation and obviousness, and ownership of the patent. Despite a conflict in the evidence, all of the issues were resolved by the judge and summary judgment was granted declaring that the patent was valid and infringed.

However, on appeal¹⁰⁵, the Federal Court of Appeal allowed the appeal and set aside the summary judgment. Pelletier J.A. for the Court of Appeal said:

“[13] A fair reading of the motions judge's reasons shows that he concluded that there were no genuine issues for trial because he was able to decide all of the issues on the basis of the affidavit evidence before him. The same fair reading suggests that the motions judge proceeded as he did on the ground that he was required to take "a hard look" at the merits and to make the findings of fact and law which the evidence allowed him to make.”

He noted that there is jurisprudence which emphasizes the fact-finding role of a judge hearing a motion for summary judgment, but also noted that “However, there is also a line of cases which takes a more restrained view of the ambit of a motion for summary judgment.” He also said:

“[19] The scope of the summary judgment rules was recently reviewed by this Court in *MacNeil Estate v. Canada*¹⁰⁶. Sexton J.A. reviewed the ambiguity at the heart of subsections 216(2) and 216(3). On the one hand, a judge who finds a genuine issue for trial is to send the matter on for trial in the ordinary course. On the other hand, even where there is a genuine issue, the motions judge can decide the matter if he or she is able to find the facts necessary to decide the questions of fact and law. This ambiguity gives rise to the risk of motions for summary judgment becoming summary trials on affidavit evidence. While both are useful measures in the struggle to contain the length and cost of litigation, one ought not to be confused for the other.

¹⁰⁴ *Trojan Technologies, Inc. v. Suntec Environmental Inc.* (2003), 26 C.P.R. (4th) 417 (F.C.T.D.)

¹⁰⁵ *Suntec Environmental Inc. v. Trojan Technologies Inc.*, 2004 FCA 140 (F.C.A.)

¹⁰⁶ *MacNeil Estate v. Canada (Indian and Northern Affairs Department)*, 2004 FCA 50 (F.C.A.)

[20] It is not necessary for the purposes of this appeal to define the outer limits of the operation of the summary judgment rules since the limitation which is relevant to this appeal is already well established. The jurisprudence is clear that issues of credibility ought not to be decided on summary judgment applications. See *MacNeil, supra*, at para. 32. ...”

Pelletier J.A. noted that, in the view of the motions judge, no serious issues of credibility arose, but he disagreed with that assessment. He pointed out that there were a number of issues which raised issues of credibility. He said:

“[28] When the motions judge preferred the evidence of one expert to the evidence of the other on each of the critical issues, it is difficult to say that there was no credibility issue. The fact that the motions judge resolved that issue does not mean it did not arise. As the examples cited above show, the motions judge was repeatedly called upon to make determinations based upon his assessment of the credibility of the expert witnesses.

[29] The jurisprudence is consistent that such determinations are best left to a judge who has had the opportunity to hear all of the evidence *viva voce*.”

In the result, he concluded that that serious issues of credibility did arise and that, in keeping with the jurisprudence, the motions judge was required to send the matter on for trial and the summary judgment was set aside.

An application for leave to appeal to Supreme Court of Canada was dismissed in October 2004.

14.2.2 Summary Judgment – Improper Reissue

Grand Tank v. Brown

In *Grand Tank v. Brown*¹⁰⁷, defendant moved for summary judgment dismissing the action on the basis that the reissue of the patent clearly offended the requirements of s.47 in that the subject matter was altered, rather than merely correcting deficiencies. Gibson J. dismissed the motion noting that the weighing of conflicting evidence on this issue is a matter for trial.

14.2.3 Summary Judgment - Settlement

Hallstrom v. Trans-Isle Freightways

Summary judgment was granted in *Hallstrom v. Trans-Isle Freightways*¹⁰⁸, an action for infringement of a patent relating to a reciprocating conveyor. The parties had entered into an agreement in settlement of patent litigation in the United States, which also provided for a release of all claims under corresponding foreign patents. Hugessen J. granted summary

¹⁰⁷ *Grand Tank (International) Inc. et al v. Brown et al* 2004 FC 1355 (F.C.)

¹⁰⁸ *Hallstrom v. Trans-Isle Freightways Inc.* (2004), 35 C.P.R. (4th) 13 (F.C.)

judgment dismissing the action in view of the release. He concluded that there was no need for a trial in relation to U.S. law nor other testimony. In this case, there was a transcript of the contract negotiations so there could be no dispute as to what was said in such negotiations.

14.2.4 Summary Judgment – Invalidity for Failure to Pay Maintenance Fees

As referred to above¹⁰⁹, in *Johnson & Johnson v. Boston Scientific*¹¹⁰, the three patents in issue, all relating to stents, were held invalid as a result of fees improperly paid as a small entity on a motion for summary judgment.

14.2.5 Summary Judgment – Claim that Assignment Gave *Competition Act* Damages Claim

Also as referred to above¹¹¹, in *Eli Lilly v. Apotex*¹¹², a patent infringement action, a motion for summary judgment dismissing a counterclaim for damages under section 36 by reason of the assignment to the plaintiff of four of the patents asserted by it was granted by the motions judge, set aside by the Federal Court of Appeal and returned to the motions judge for further consideration, again granted by the motions judge, and again appealed.

14.2.6 Summary Judgment - *NOC Regulations* Damage Claim

In 2004 there were several decisions on motions for summary judgment with respect to aspects of claims made under Section 8 of the *NOC Regulations*. These are considered below¹¹³.

14.2.7 Summary Judgment – Interpretation of a Patent Agreement

Saint-Gobain. v. Diamond

*Saint-Gobain v. Diamond*¹¹⁴, a motion for summary judgment in the Ontario Superior Court of Justice, concerned a dispute over the interpretation of a product license and sales agreement which resulted from the settlement of patent infringement litigation; payment of royalties had been refused on the ground that parts were defective. The court dismissed a motion for summary judgment stating that whether the payment of royalties or purchase of goods were the essence of the contract, whether the products were defective, and whether, in the circumstances, the plaintiff had the right to give notice of termination of the agreement, created genuine issues for trial.

14.3 Separate Determination of an Issue

14.3.1 Separate Determination of the Construction of the Patent

¹⁰⁹ Supra section 8

¹¹⁰ *Johnson & Johnson Inc. et al v. Boston Scientific Ltd.* 2004 FC 1672 (F.C.). A similar order was also made in *Johnson & Johnson Inc. et al v. Arterial Vascular Engineering Canada Inc. et al* 2004 FC 1673 (F.C.), adopting the reasons in the *J&J v. Boston Scientific* case

¹¹¹ Supra section 13.2

¹¹² Supra footnotes 100, 101

¹¹³ Infra section 16.5

¹¹⁴ *Saint-Gobain Abrasives Inc. v. Diamond Systems Inc.* (2003), 30 CPR 4th 173 (Ont. S.C.J.)

Realsearch v. Valone Kone Brunette

As we noted in our presentation last year¹¹⁵, in *Realsearch v. Valone Kone Brunette*¹¹⁶, Noël J. granted a motion brought by the defendant to a patent infringement action for an order for a separate determination of the construction of the patent claims in advance of the trial of the issues of infringement or validity.. He noted that the motion was founded on the “*Markman*¹¹⁷ Proceeding”, a preliminary proceeding used in the U.S. to obtain a construction of the claims by a judge in advance of a jury determination of the facts. He said that this procedure might speed up the litigation and facilitate settlement.

The patent concerned a wood fibre debris processor, a mechanical device for removing bark from logs. Only one device of the defendant was alleged to infringe. Two terms from the claims were said by the defendant to require construction.

In January 2004, the Federal Court of Appeal set aside this order¹¹⁸. Stone J.A. for the Court of Appeal noted that Rule 107 permits separate determination of issues, but the question was whether it was appropriate in this case. He noted that Rule 3 requires that the Federal Court Rules be interpreted so as to secure “the just, most expeditious and least expensive determination of every proceeding on the merits” – not only expeditious but, as importantly, “just”.

Stone J.A continued:

“The appellants may lose the advantage of having the whole of the action tried at the same time by the same judge. Issues of claim construction and infringement are closely interwoven even though, as has been held, it is wrong to construe a patent “with an eye on the allegedly infringing device in respect of infringement”: *Whirlpool Corp., supra*, at paragraph 49. Nevertheless, the claim language must be read in an informed and purposive way: *Free World Trust, supra*, at paragraph 31(e). Again, as the appellants assert, the supporting affidavit provides no evidence specific to this particular piece of litigation with respect to how long discoveries are expected to last, or how long the trial is expected to take. Hence there is uncertainty as to the extent to which the duration of discoveries and trial will be reduced by the rule 107 order.”

He said that concerns expressed in patent cases in the past that severance of an issue of law for determination prior to trial on the merits, with the possibility of multiple appeals, would not necessarily save time and expense were worthy of serious reflection on an issue such as this. He noted: “While the present case is to be decided under our own Rules, we should not lightly ignore the caution that: ‘Preliminary points of law are too often treacherous short cuts. Their price can be . . . delay, anxiety and expense’.”

¹¹⁵ D.H. MacOdrum, A.D. Morrow, “Update on Patents: Legislative Changes and Case Law in 2003”, Law Society of Upper Canada, “Intellectual Property Law: The Year in Review”, January 2004

¹¹⁶ *Realsearch Inc. et al v. Valone Kone Brunette Ltd. et al* 2003 FCT 669 (F.C.T.D.)

¹¹⁷ Originating with the direction of the U.S. Supreme Court in *Markman v. Westview Instruments Inc.*, 52 F.3d 967; aff'd 116 S.Ct. 1384 (1996)

¹¹⁸ *Realsearch Inc. v. Valon Kone Brunette Ltd.* [2004] 2 F.C. 514, 2004 FCA 5 (F.C.A.)

In dismissing the appeal in the circumstances of this case, he stated: “It is not to suggest that a *Markman*-type order would not be available in any circumstances under the rule which, admittedly, is broadly phrased.”

The applicant had suggested that the procedure would promote settlement and this had been a reason accepted by Noel J. for making the order. On this point, Stone J.A. said: “It is not altogether clear, however, that promoting settlement is even an unstated objective of rule 107,”, noting that other Rules are provided with the express object of promoting settlement.

Finally, he said that there was substance to the plaintiff’s point that such an order on these facts would produce a novel and fundamental change in current Canadian patent law practice, and that such a change ought not to be made by the courts on an *ad hoc* basis. He said:

“A change of this kind might better be made the subject of some debate within the intellectual property bar, with a view to possibly submitting it for consideration to the Court’s rules committee. If such were done, the procedure would receive careful and thoughtful consideration before being adopted by the Court.”

14.3.2 Separate Determination of Entitlement to Account of Profits As An Alternative to Damages

Apotex v. Merck

As referred to above¹¹⁹, in *Apotex v. Merck*¹²⁰, which concerned the procedure for addressing the monetary remedies following summary judgment. determining that Merck’s patent for enalapril and enalapril maleate had been infringed by Apotex, in the particular circumstances of this case, Martineau J. ordered, *inter alia*, that the question of whether Merck is entitled to elect an accounting of Apotex’s profits was to be determined as a separate issue with discovery confined to that issue.

14.4 Examinations For Discovery – Infringement and Validity

Letourneau v. Clearbrook

*Letourneau v. Clearbrook*¹²¹ is a lengthy (74 pages) decision of Mr. Hargrave, Prothonotary, in respect of cross-motions for further answers on discovery in an action for infringement of a patent relating to rail stanchions for use with modular concrete panel walls. The defendant counterclaimed for a declaration of invalidity of the patent and in respect of alleged false statements. Among the issues addressed by the Prothonotary were the propriety of questions as to:

- the experience and background of the witness

¹¹⁹ Supra section 12.2

¹²⁰ *Apotex Inc. v. Merck & Co.* (2004), 34 C.P.R. (4th) 514 (F.C.)

¹²¹ *Letourneau et al v. Clearbrook Iron Works Ltd.* 2004 FC 1422 (FC – Proth)

- advantages of the patented stanchions
- commercial success
- the interpretation of photographs
- information from a lawyer/patent agent
- communications with one's spouse
- Canadian prosecution file
- Corresponding U.S. file wrapper

14.5 Examinations For Discovery – Examination of Non-Parties

***Grand Tank v. Brown* (FC–Gibson J.) (Oct. 2004)**

In *Grand Tank v. Brown*¹²², the validity of the reissue of the patent in issue was challenged. On discovery, the inventors' recollections were vague as to their intentions at the filing date. In view of their poor recollections, Gibson J. granted an order for the examination for discovery of the patent agents (who were solicitors) who handled original application and reissue application. He noted that some matters and documents might be the subject of a claim of privilege, but that did not immunize the patent agents/solicitors from discovery.

15. ABUSE OF PATENT RIGHTS

Sections 65 to 71 of the *Patent Act* provide that the Commissioner may grant a compulsory licence or other relief where "abuse" of the exclusive rights granted by the patent is shown to have occurred. The amendments made to implement the North American Free Trade Agreement ("NAFTA") considerably reduced the impact of these sections, removing as a ground of abuse the non-working of the invention in Canada, but there still remain grounds of abuse which, if shown, can give rise to the remedies provided by these sections.

Section 65 sets out the basis for an application for relief and the circumstances in which "abuse" will be deemed to have occurred. It provides:

"65. (1) The Attorney General of Canada or any person interested may, at any time after the expiration of three years from the date of the grant of a patent, apply to the Commissioner alleging in the case of that patent that there has been an abuse of the exclusive rights thereunder and asking for relief under this Act.

(2) The exclusive rights under a patent shall be deemed to have been abused in any of the following circumstances:

¹²² *Grand Tank (International) Inc. et al v. Brown et al* 2004 FC 1355 (F.C.)

[subsections (a) and (b) were repealed in 1993]

(c) if the demand for the patented article in Canada is not being met to an adequate extent and on reasonable terms;

(d) if, by reason of the refusal of the patentee to grant a licence or licences on reasonable terms, the trade or industry of Canada or the trade of any person or class of persons trading in Canada, or the establishment of any new trade or industry in Canada, is prejudiced, and it is in the public interest that a licence or licences should be granted;

(e) if any trade or industry in Canada, or any person or class of persons engaged therein, is unfairly prejudiced by the conditions attached by the patentee, whether before or after the passing of this Act, to the purchase, hire, licence or use of the patented article or to the using or working of the patented process; or

(f) if it is shown that the existence of the patent, being a patent for an invention relating to a process involving the use of materials not protected by the patent or for an invention relating to a substance produced by such a process, has been utilized by the patentee so as unfairly to prejudice in Canada the manufacture, use or sale of any materials.

[subsections (3) and (4) were repealed in 1993]

(5) For the purposes of this section, the expression “patented article” includes articles made by a patented process.”

Torpharm v. Canada

*Torpharm v. Canada*¹²³ was an appeal from the Commissioner's refusal to institute compulsory licence proceedings. MacKay J. held that a demand for bulk product for use in manufacturing tablets in Canada for export is a demand in Canada for the patented bulk product, and as such could constitute grounds for an application under paragraph 65(2)(c) and that the Commissioner was wrong in concluding that the evidence of the patentee's refusal to grant a licence on the terms proposed by the applicant could not give rise to a case under paragraph 65(2)(d). He concluded that the reasonableness of the terms could not be determined in the circumstances of this case without consideration of submissions directly made to the Commissioner by the appellant and the patentee.

Having found that that the Commissioner erred, MacKay J. set aside that decision and the matter was remitted to the Commissioner “for reconsideration on the basis that the application of *Torpharm* warrants a preliminary finding that a case for relief is made, and that the application be dealt with in accord with s-s. 68(2) and related provisions of the *Act*.”

¹²³ *Torpharm Inc. v. Canada* 2004 FC 673 (F.C.)

In dicta, MacKay J. commented that subsection 65(2) is a deeming provision and is not exhaustive of the kinds of circumstances that can give rise to abuse. (In this case, the appellant had not alleged facts that could give rise to an abuse other than the abuses specifically alleged under paragraphs (c) and (d).)

He also noted that section 68(2) requires an applicant to “provide enough evidence to allow the Commissioner to determine the facts that, absent persuasive objection, could result in the relief sought.” The Commissioner's decision is thus “a preliminary determination that the applicant has some merit and it should be permitted to proceed to the next stage.” He compared this decision to the decision on an application for leave to appeal or leave to proceed for judicial review.

16. NOC REGULATIONS

16.1 Eligible Patents

16.1.1 Eligible Patents – Containing a Claim for the Medicine Itself or a Claim for the Use of the Medicine

In accordance with section 4 of the *NOC Regulations*, a person who files a submission may submit a patent list of patents for inclusion on the register maintained in accordance with those regulations, which patents must contain a claim for the medicine itself or a claim for the use of the medicine.

GlaxoSmithKline v. Canada

In *GlaxoSmithKline v. Canada*¹²⁴, Von Finckenstein J. dismissed an application to challenge the refusal of the Minister to list a patent for a controlled release tablet of paroxetine hydrochloride and a patent for a system for controlled rate release of paroxetine hydrochloride.

Procter & Gamble v. Genpharm

*Procter & Gamble v. Genpharm*¹²⁵ concerned a patent, the “376 Patent” containing claims for the use of etridonate disodium for the treatment of osteoporosis and claims for a kit for use in such treatment. Snider J. held that the kit claims were not claims for the medicine itself nor for use of the medicine, rather they claimed a system for facilitating compliance with the intermittent treatment regimen. Consequently no allegation was required in respect of these claims. (However, the patent also included use claims and was properly listed on that basis).

Pfizer v. Minister of Health

¹²⁴ *GlaxoSmithKline Inc. v. Canada* 2004 FC 1725 (F.C.), affirmed 2004 FCA 393 (F.C.A.)

¹²⁵ *Procter & Gamble Pharmaceuticals Canada Inc. et al v. The Minister of Health and Genpharm Inc.* 2004 FC 204 (F.C.)

*Pfizer v. Minister of Health*¹²⁶ was an application for judicial review of the Minister's refusal to list a patent. The patent covered a dosage form for the administration of a medicine, comprising a tablet having a complex structure allowing for controlled gradual release of the drug into the system. Mosley J. referred to the definition of "medicine" in the *NOC Regulations*, meaning "a substance intended or capable of being used" for treating, diagnosing, etc. He construed the patent as being for a delivery system for any one of a number of drugs, and not for the drugs themselves. He referred to cases regarding inhalers, and cases regarding combinations of medicine with excipients, and found that this patent was not a patent for the medicine itself, and therefore did not qualify for listing.

16.1.2 Eligible Patents – Timing of The Patent List

Sections 4(3) and (4) of the *NOC Regulations* require that the patent list be submitted at the time of filing of the submission or within 30 days of issuance of a patent that has a filing date that precedes the filing of the submission.

Abbott v. Minister of Health

The issue of when a Supplemental New Drug Submission (SNDS) can support the addition of a patent was in issue in three proceedings (involving Pharmascience Inc., Ratiopharm Inc. and Apotex Inc.) which were the subject of a consolidated ruling by the Federal Court of Appeal in *Abbott v. Minister of Health*¹²⁷. At issue was a patent filed with respect to Abbott's product "Biaxin", of which the active ingredient was clarithromycin.

Following the initial *NOC* for Biaxin, *inter alia*, a SNDS had been filed in respect of the use of a triple drug therapy using the combination of Biaxin (clarithromycin), omeprazole and amoxicillin for the eradication of *H. pylori*. Also, on behalf of its partly owned subsidiary, TAP Pharmaceuticals, Abbott filed a SNDS in regard to a triple therapy combination of Biaxin (clarithromycin), amoxicillin and lansoprazole (A TAP product which could replace amoxicillin in that therapy).

Subsequently, Abbott filed an SNDS to allow Abbott to amend its product monograph to incorporate TAP's product monograph by reference and allow Abbott to sell and market Biaxin (clarithromycin) in triple therapy with amoxicillin and lansoprazole. The issue was whether this SNDS could be used to support the addition of a patent to the patent list. (It was too late to add it to patent list based on any prior SNDS). The motions judge had found that the SNDS lacked substance and could not support the listing of the patent.

Richard C.J. for the Federal Court of Appeal held that, since the motions judge had found that an SNDS was required by Health Canada for Abbott to market Biaxin (clarithromycin) in concert with amoxicillin and lansoprazole, and that the SNDS was not filed in an effort to circumvent the time limitations stipulated in section 4 of the *NOC Regulations*, and that Abbott's filing of the '732 patent in conjunction with the disputed SNDS was "*bona fide*", the motion should have been dismissed.

¹²⁶ *Pfizer Canada Inc. v. Minister of Health* 2004 FC 370 (F.C.)

¹²⁷ *Abbott Laboratories et al v. Minister of Health et al* (2004), 31 C.P.R. (4th) 321, 2004 FCA 154 (F.C.A.)

He noted that in other cases the Court had held that an SNDS will not support a patent listing where it is simply a manifest attempt to list a patent after the time limitations set out in section 4 had expired¹²⁸, but said that this case fell outside those authorities because the SNDS was in respect of a new indication.

Hoffmann-La Roche v. Minister of Health

In *Hoffmann-La Roche v. Minister of Health*¹²⁹, Harrington J. affirmed the refusal of the Minister to list two patents on the basis of a SNDS to change the manufacturing site. The court observed that the submission for a NOC which can support a patent list within the meaning of section 4 of the *NOC Regulations* need not necessarily be a new drug submission or an abbreviated new drug submission; it may be an SNDS. application supplementary to either." (paragraph 22).

An SNDS that relates to the drug or its use may support listing, but matters such as brand names and manufacturing sites that are merely incidental to the drug and its purpose do not. They could have been listed with an earlier SNDS, but not with this one. Harrington J. said: "This case brings to mind such old songs as 'Its just a Matter of Time' and 'Time Changes Everything'."

16.2 Requirement To Deliver a Notice of Allegation

Biolyse Pharma v. Bristol-Myers Squibb

As reported in our Update last year¹³⁰, *Biolyse Pharma v. Bristol-Myers Squibb*¹³¹ concerned the interpretation of section 5(1.1) of the NOC Regulations.

Section 5(1) provides that where a second person who seek a NOC for a drug and has made a comparison with or reference to another drug for which a NOC has been issued to establish bioequivalence, the second person must serve a Notice of Allegation (NOA) in respect of any patents on the Patent Register (unless the second person accepts that the ONOC will not issue until the expiry of such patent(s)).

Section 5(1.1) was added in 1999. It requires service of a NOA where subsection (1) does not apply and where a person files or has filed a submission for a notice of compliance in respect of a drug that contains a medicine found in another drug that has been marketed in Canada pursuant to a NOC issued to a first person and in respect of which a patent list has been submitted, where the drug has the same route of administration and a comparable strength and dosage form.

Biolyse received a NOC in respect of Paclitaxel for injection. Bristol-Myers Squibb ("BMS") applied to set aside the NOC on the basis that pursuant to s.5(1.1) a NOA should have been served as to the patents listed respect of its product Taxol.

¹²⁸ Referring to *Bristol -Myers Squibb Canada Inc. v. Attorney General of Canada et al.* (2002) 16 C.P.R. (4th) 425 (F.C.A.), aff'g (2001), 10 C.P.R. (4th) 318 and *Ferring Inc. v. Canada (Attorney General)* (2003), 26 C.P.R. (4th) 155 (F.C.A.)

¹²⁹ *Hoffmann-La Roche Limited v. Minister of Health et al* 2004 FC 1547 (F.C.)

¹³⁰ Supra footnote 115

¹³¹ *Biolyse Pharma Corporation v. Bristol-Myers Squibb Company* 2003 FCA 180, 24 C.P.R. (4th) 417 (F.C.A.)

Both drugs contain paclitaxel as their active ingredient, but the paclitaxel in Biolyse's drug comes from the leaves and twigs of one species of yew, while that in BMS's drug is obtained from the bark of another species of yew. Because of the different source of the paclitaxel, Biolyse was required by Health Canada to make a new drug submission ("NDS"), rather than an abbreviated new drug submission ("ANDS"). The NDS for Paclitaxel for injection contained many references to and comparisons with Taxol, but not for the purpose of establishing bioequivalence. Paclitaxel and TAXOL are identical in all material respects other than the botanical source of their active ingredient, paclitaxel.

The Federal Court of Appeal found that if subsection 5(1.1) is given its ordinary, grammatical meaning, Biolyse fell within the section and a NOA was required.

It was argued that the legislative intent required a different meaning and indeed the Attorney General submitted that section 5(1.1) was only intended to apply when a second person submitted an ANDS and compared its drug, directly or indirectly, with a first person's drug in order to demonstrate their bioequivalence, and particularly to deal with the situation dealt with in *Merck v. Nu-Pharm*¹³², citing the Regulatory Impact Statement and a government policy document in support of this interpretation. However, as noted, The Federal Court of Appeal did not accept this submission and held that the NOC granted to Biolyse in breach of Section 5(1.1) of the NOC Regulations was properly quashed by the judge hearing the application.

The Supreme Court of Canada granted leave to appeal this decision and the appeal was argued in December 2004.

16.3 Production of Documents and Samples

Section 6(7) of the *NOC Regulations* provides that the court may order a second person (the generic) to produce relevant portions of the submission for a NOC and for the Minister to verify that the portion produced corresponds to the submission.

Pfizer v. Apotex

In *Pfizer v. Apotex*¹³³, an appeal from the dismissal of a prohibition motion with respect to azithromycin tablets, the principal issues were whether an adverse inference should have been drawn from the failure of Apotex to produce tablets in its possession. Snider J. had not drawn an adverse inference because (i) Apotex had produced its process for making its tablets, (ii) it had produced a sample made by one of its employees following that process, (iii) the other samples it had were left over from its clinical trials, but Apotex led evidence that they might not have been subject to the same careful manufacture to ensure that no dihydrated product was included and their shelf life had expired, (iv) Pfizer could have made tablets using the Apotex process. Evans J.A. for the Federal Court of Appeal. In dismissing the appeal held that the decision was based on the facts and was not a palpable error.

As to a further submission, Evans J.A. said:

¹³² *Merck & Co. v. Nu-Pharm Inc.* (2000), 5 C.P.R. (4th) 138 (F.C.A.)

¹³³ *Pfizer Canada Inc. v. Apotex Inc.* 2004 FCA 398 (F.C.A.)

“[21] Second, counsel submitted that, as a matter of law, Apotex' refusal to produce the tablets in its possession was sufficient *in itself* to give rise to the adverse inference presumption since their content was the central issue in the proceeding. In my view, this proposition is not supported by the case law. The law on adverse inferences is as stated by Snider J. and applies in the context of NOC prohibition proceedings. The triggering of the inference is very dependent on the facts of the particular NOC case, just as it is in other types of litigation.

[22] Indeed, there are good reasons for not accepting counsel's argument that the law should more readily require the drawing of an adverse inference from the non-production of drugs when their content is in issue in NOC cases. They include: the summary nature of the prohibition proceeding and the absence of discovery; the absence of a duty on applicants making an ANDS to supply samples of the drug to the Minister and, hence, to provide them under subsection 6(7) to the applicant in the prohibition proceeding; and the fact that the dismissal of the application for an order of prohibition only denies the applicant the benefit of the statutory stay on the entry onto the market of a possibly infringing product, and does not preclude a subsequent action for infringement, complete with discovery.

[23] Nonetheless, the result in this case is grounded firmly in the particular evidence before the Applications Judge and in the findings of fact that she made on that evidence. It is certainly not my intention to discourage judges, on appropriate facts, from drawing an adverse inference from the non-production of medicines when their content is at issue in NOC proceedings. If non-production, and other forms of gamesmanship, are recurring problems in this kind of proceeding (and this is certainly not the first case in which the issue has arisen and been commented on), they are best remedied through an amendment to the Regulations. Meanwhile it falls to the Courts to do what they can to protect the judicial process from abuse.”

Pfizer v. Rhoxalpharma

In *Pfizer v. Rhoxalpharma*¹³⁴, the issue concerned confidential documents of a third party filed with the Minister. Rhoxalpharma proposed to have the manufacturing of the azithromycin tablets made for it by Teva. Teva had provided its drug master file to the Minister on the basis that it would not be shown to anyone including Rhoxalpharma. An order was made that Rhoxalpharma obtain the relevant portions of Teva's master file. It requested that Teva supply it under the confidentiality order, but Teva refused. The court then ordered that the Minister produce the relevant portions of the Teva file. The Minister appealed this order.

Sharlow J.A. for the Federal Court of Appeal held that there is no jurisdiction under the NOC Regulations to require production from the Minister.

¹³⁴ *Pfizer Canada Inc. et al v. Rhoxalpharma Inc.* (sub nom *The Minister of Health v. Pfizer Canada Inc. et al*) 2004 FCA 402 (F.C.A.)

She also observed: “While Teva's refusal to consent is difficult to understand given the disclosures that had already been made in the other proceedings (subject to a confidentiality order), the record provides no factual basis for concluding that Teva had any obligation to consent in this case. Teva is entitled to make such decisions in its own interest.”

The prothonotary had also concluded that Rhoxalparma hasd not made best efforts to obtain the documents. Sharlow J.A. noted that no reasons were given and she did not understand what steps Rhoxal could have taken that it failed to take in view of its numerous requests to Teva and Teva’s unwillingness to consent. She also commented on the effect of a failure to produce documents where an order is made that a party use its best efforts t o obtain them, stating:

“46 I digress at this point to observe that, if a second person fails to comply with an order to use its best efforts to obtain third party information about the manufacturing process for the second person's proposed product, the appropriate remedy is not to order the second person to do something that it cannot do. The appropriate remedy is to deny the second person any advantage it might derive from the fact that the third party information is not available.

47 This could be done, for example, by an order preventing the second person from presenting or relying on any evidence at all relating to the third party's manufacturing process. The Judge hearing the prohibition application would then have the second person's bare allegation of non-infringement based on some aspect of the manufacturing process, unsupported by evidence from the second person. The Judge might then be persuaded to find that the non-infringement allegation is not justified, either because an inference adverse to the second person should be drawn, or because of the statutory presumption that the second person's proposed product will be prepared or produced by the method or process claimed in the first person's patent (subsection 6(6) of the *Patented Medicines (Notice of Compliance) Regulations*, quoted above).

48 On the other hand, if the second person uses its best efforts to obtain the third party information and its efforts are unsuccessful, then the second person should suffer no disadvantage because of its lack of success. In that case, the second person should be free to adduce such evidence as it has in support of its non-infringement allegation. The first person will of course adduce such evidence as it may have. The Judge hearing the prohibition application will consider all the evidence in disposing of the application in the ordinary course.”

In the result, the Teva information came before the Federal Court, apparently as a result of the appeal, and all confidentiality issues were resolved to Teva's satisfaction, so that it was directed that the prohibition proceedings should be permitted to proceed in the Federal Court with the Teva information in evidence on the terms agreed to by the parties and Teva.

16.4 NOC Prohibition Application Decisions

16.4.1 NOC Prohibition Application Decisions – Onus of Proof

Procter & Gamble v. Genpharm

Section 6(20) of the NOC Regulations provides that “The court shall make an [prohibition] order pursuant to subsection (1) in respect of a patent that is the subject of one or more allegations if it finds that none of those allegations is justified.” In *Procter & Gamble v. Genpharm*¹³⁵, an appeal from the prohibition of a NOC for etridonate for the treatment of osteoporosis, Genpharm advanced an argument that the term “justified” in this section indicated that a lower standard of proof was required than that which would be applicable in a patent infringement action. It argued that the issue to be determined was whether there was a genuine issue that the patent was invalid analogous to the test on a motion for summary judgment, or whether the generic had a reasonable belief that the patent was invalid. (Invalidity was the allegation in that case.)

Rothstein J.A. for the Federal Court of Appeal rejected these allegations. He said: “Contrary to Genpharm's submission, the term “justified” does not connote a lower standard of proof than proof on a balance of probabilities.” He noted that there were no words in the *Regulations* supporting this interpretation. Counsel for Genpharm said that an implication should be drawn from the availability of a patent infringement action as a separate remedy that the burden was different. Rothstein said: “The *Regulations* constitute a self-contained procedure. There is no indication in the *Regulations* that the burden of proof on a generic alleging patent invalidity in a prohibition application is reduced or is in any way affected by the availability of a patent infringement action to a patentee.” He concluded that the standard of proof under subsection 6(2) of the *Regulations* is proof on a balance of probabilities (as had been previously held in *Bayer v. Canada*¹³⁶.)

16.4.2 NOC Prohibition Application Decisions – Decisions on the Merits

16.4.2.1 NOC Prohibition Application Decisions –Validity Issues

GlaxoSmithKline v. Pharmascience (Jan. 2004)

As noted above¹³⁷, in *GlaxoSmithKline v. Pharmascience*¹³⁸ concerned a patent relating to treat congestive heart failure was held invalid as obvious. (As to the other grounds asserted, Noël J. found no anticipation and that there was a proper use claim.)

Procter & Gamble v. Genpharm (February 2004 FC)

*Procter & Gamble v. Genpharm*¹³⁹ concerned a patent, the “376 Patent” containing claims for the use of etridonate disodium for the treatment of osteoporosis and claims for a kit for use in

¹³⁵ *Procter & Gamble Pharmaceuticals Canada Inc. et al v. Genpharm Inc. et al* (sub nom *Genpharm Inc. v. Procter & Gamble Pharmaceuticals Canada Inc. et al*) 2004 FCA 393 (F.C.A.)

¹³⁶ *Bayer v. Canada (Minister of National Health and Welfare)* (2000), 6 C.P.R. (4th) 285 (F.C.A.)

¹³⁷ *Supra* Section 4

¹³⁸ *Supra* footnote 27

¹³⁹ *Procter & Gamble Pharmaceuticals Canada Inc. et al v. The Minister of Health and Genpharm Inc.* 2004 FC 204 (F.C.)

such treatment. Genpharm asserted that the use claims were invalid as obvious and the kit claims would not be infringed by its product.

This patent had been in issue before between these parties and Snider J. looked to the construction of the claims in the prior decisions in construing the claims. The essential features of use claims from the earlier decisions were:

- a. use of etridonate at a limited effective dose (“LED”) to treat osteoporosis
- b. intermittent administration in a two stage regimen consisting of (i) use of etridonate, and (ii) a rest period during which the patient takes a placebo or a nutrient, such as calcium
- c. use on a cyclical basis.

She construed both the use claims and the kit claims to exclude the presence of other components, such as an activator¹⁴⁰.

The 376 Patent was an “Old Act Patent” and obviousness was tested at the priority date, June 1985, (no earlier date of invention having been asserted). Following a review of the evidence. Snider J. concluded:

- The use of etridonate in daily doses ranging from 0.25 x LED to 4 x LED was not obvious. To make the extrapolations or inferences from the prior art would require at least a scintilla of invention. As to one point made by one of the experts called by Genpharm she noted: “This moves Dr. Chamber’s skilled technician away from being one that applies mechanistic skill to one that innovates. Such technician falls outside the scope of the legal test of obviousness.” Another Genpharm submission was rejected because it would require the skilled technician to carry out tests to arrive at the range of etridonate dosages for rats, and then to use this data to extrapolate the dosages for humans, which she said “goes well beyond the current legal understanding of obviousness.”
- Intermittent administration of etridonate was not obvious since none of the studies tied the continuous use of etridonate to its negative side effects, and since it was not obvious from a study in which etridonate plus an activator were administered intermittently that the results were due to the intermittent use and not due to the activator.
- It was not obvious to use etridonate without an activator.
- It would be obvious to assemble a suitable kit to facilitate compliance with the particular regimen
- The combination of the various elements would not be obvious. She noted that it was not obvious to Dr. Russell, one of the experts called by P&G, who was a leading inventor at the critical date. She “readily” distinguished three recent cases in which patents had

¹⁴⁰ See Supra section 10.1

found obviousness where the alleged invention was “reasonably predictable”, or “lay in the path” or was “one of the options that a person would try”¹⁴¹.

There being no allegation of non-infringement of the use claims and those claims having been held not to be obvious, a prohibition order was issued. (The kit claims were not claims to the use of the medicine and no allegation was required in respect of them.)

Procter & Gamble v. Genpharm (November 2004 FCA)

In November 2004, the Federal Court of Appeal¹⁴² dismissed an appeal from that decision. The principal issues on the appeal were the onus of proof¹⁴³, the construction of the patent¹⁴⁴, and the test for obviousness¹⁴⁵ discussed above.

Jansen-Ortho v. Novopharm (November 2004)

In *Ortho v. Novopharm*¹⁴⁶, Mosley J. held that the patent in issue was invalid as obvious (but not on the other invalidity grounds asserted). The patent related to the antimicrobial drug levofloxacin. This was an Old Act Patent and obviousness was tested at the date of invention. Mosley J. said that the patent in issue could be described as a selection patent as a "selection patent" in that levofloxacin was selected out of its class of substances - the racemate and the two enantiomers - because of its beneficial properties. He cited two passages from Fox on Patents concerning selection patents and said:

“[51] What Fox and the jurisprudence suggest, in my view, when dealing with selection patents, is that in order to demonstrate sufficient inventive ingenuity, there must be discovered some *special* advantage or quality, previously unknown, or an advantage discovered for a new use, which constitutes a definite advance upon the knowledge already existing with regard to the original group or series. In *Pfizer v. Apotex*¹⁴⁷, Richard J. (as he then was), found a selection patent valid that claimed the pharmaceutical preparation of fluconazole, the originating patent having claimed "an enormous class of compounds".

[52] In that case, the compound described in the subsequent patent was not described in the original patent, and neither were "its superior and previously unknown efficacy" previously known. The Court there relied upon expert evidence that described the surprising features of fluconazole, and the discovery that it was soluble in water as compared to the earlier disclosed compound that was virtually insoluble. Justice Richard concluded that since fluconazole had "unexpected and valuable properties which are not possessed by the structurally

¹⁴¹ *SmithKline Beecham Pharma Inc. v. Apotex Inc.* (2001), 14 C.P.R. (4th) 76 (F.C.T.D.), affirmed (2002), 291 N.R. 168 (F.C.A.); *Novartis AG v. Apotex Inc.* (2001), 15 C.P.R. (4th) (F.C.T.D.), affirmed (2002), 22 C.P.R. (4th) 450 (F.C.A.); *Pfizer Canada Inc. v. Apotex Inc.* (2002), 22 C.P.R. (4th) 466 (F.C.T.D.)

¹⁴² Supra footnote 19

¹⁴³ Supra section 16.4.1

¹⁴⁴ Supra section 10.1

¹⁴⁵ Supra section 4

¹⁴⁶ *Pfizer Canada Inc. et al v. Novopharm Limited et al* 2004 FC 1633 (F.C.)

¹⁴⁷ *Pfizer Canada Inc. v. Apotex Inc.* (1997), 77 C.P.R. (3d) 547 (F.C.T.D.)

closest compounds disclosed" in the original, prior patent, it was not invalid on the grounds of either obviousness or anticipation.”

He said that in this case, this reasoning lead to the opposite conclusion. The beneficial properties were not unknown. He found that knowledge of the existence of and the possibility of separating the two enantiomers of ofloxacin was common to the ordinary chemist, and the determination of which enantiomer possessed a greater amount of the same benefits of the previously known racemic antibiotic was not surprising or inventive. He said that the test for obviousness did not exclude “routine testing to determine characteristics of known compounds, not undertaken for the purpose of "searching for something novel", but rather for the purpose of verifying the actual attributes of already known compounds, where the results indicate no new uses or surprising results, or properties that are clearly superior to the already known parent compound, citing *Pfizer v. Apotex*¹⁴⁸. Following a review of the evidence, he concluded:

“[85] I am satisfied that Novopharm has established on a balance of probabilities that a technician skilled in the art would have come directly and without difficulty to the solution taught by the '080 patent by simply conducting known, routine experiments with racemic ofloxacin. I conclude that the claims set out in the '080 patent are obvious; what is claimed as the "discovery" or "invention" in the '080 patent does not suggest the scintilla of inventive ingenuity to qualify for the patent monopoly, but rather was the result of "mere verification" of the attributes of already known components of a compound.

[86] Furthermore, based on the state of knowledge in 1985, I am satisfied that an average chemist would have been led directly to the conclusion, prior to such testing, that one enantiomer was likely to have more beneficial characteristics than the racemate, or the other optical isomer, in relation to the same beneficial qualities that had already been discovered, namely antimicrobial activity, solubility and toxicity. Therefore, in undertaking experimentation to verify which enantiomer possessed comparatively better qualities in these areas, no inventive step was involved.”

He reviewed the other grounds of invalidity asserted – anticipation, ambiguity, claims broader than the invention, and insufficiency of the specification but found that they had not been established in that case. He also held that the allegation of non-infringement was not justified, but having found the patent invalid for obviousness, the prohibition application was dismissed.

AB Hassle v. Apotex (November 2004 FCA)

In *AB Hassle v. Apotex, sub nom Apotex v. AB Hassle*¹⁴⁹, the Federal Court of Appeal dismissed an appeal from a determination that a patent relating to certain base addition salts of omeprazole effective in treating gastric acid disorders was not invalid Richard C.J for the Court of Appeal said:

¹⁴⁸ *Pfizer Canada Inc. v. Apotex Inc.* (2002), 22 C.P.R. (4th) 466 (F.C.T.D.)

¹⁴⁹ *Apotex Inc. v. AB Hassle et al* 2004 FCA 369 (F.C.A.), affirming *AB Hassle et al v. Apotex Inc.* 2003 FCT 771 (F.C.T.D.)

“[1] We are satisfied, having heard full argument by counsel for the appellant, that Campbell J. applied the proper legal test for anticipation and obviousness and did not make any reviewable error when he concluded on a balance of probabilities that the patent in issue was not invalid.”

***Abbott v. Pharmascience* (Oct. 2004)**

In *Abbott v. Pharmascience*¹⁵⁰, an allegation that the claims were broader than invention made and disclosed found not justified. The issue turned on the construction of the claims¹⁵¹.

16.4.2.2 NOC Prohibition Application Decisions – Infringement Issues

***AstraZeneca v. Apotex* (Jan. 2004)**

In *AstraZeneca v. Apotex*¹⁵² the patent related to magnesium omeprazole having specified degree of crystallinity. Russell J. held that the evidence did not show that the Apotex allegation that it would only use amorphous magnesium omeprazole was not justified. The prohibition motion was dismissed.

***Bayer v. Apotex* (February 2004)**

In *Bayer v. Apotex*¹⁵³, Campbell J. held that an allegation of non-infringement of the patent relating to ciprofloxacin hydrochloride was justified. The issue was whether the six-step Apotex process for producing ciprofloxacin an obvious chemical equivalent of the process claimed in the patent. The claims in suit included the language “obvious chemical equivalent”. The Court construed that term by reference to the *Free World Trust*, where the Supreme Court construed the phrase “work in the same way” as meaning that the variant would “perform substantially the same function in substantially the same way to obtain substantially the same result.” Based on the expert testimony, the Court found that “the difference matters” and that the Apotex process was not an obvious chemical equivalent of the Bayer process claimed in the patent.

***AstraZeneca v. Apotex* (Mar. 2004)**

This *AstraZeneca v. Apotex* decision¹⁵⁴ concerned a patent for the combined use of omeprazole and an antibacterial compound for the treatment of gastritis and peptic ulcer. Apotex contended that its application related solely to the sale of omeprazole, and that it was not seeking approval for the use of omeprazole in combination with an antibacterial compound, nor would its product monograph claim such use.

The applicant argued that the product monograph in fact contained statements about administration of the respondent's product with an antibiotic and that this indicated that use

¹⁵⁰ *Abbott Laboratories et al v. Minister of Health and Pharmascience Inc.* 2004 FC 1349

¹⁵¹ See *infra* in the discussion of infringement, section 16.4.2.2

¹⁵² *AstraZeneca AB et al v. Apotex Inc.* 2004 FC 44 (F.C.)

¹⁵³ *Bayer AG v. Apotex Inc. et al* (2004), 31 C.P.R. (4th) 46, 2004 FC 177 (F.C.)

¹⁵⁴ *AstraZeneca AB et al v. Apotex Inc.* (2004), 33 C.P.R. (4th) 97, 2004 FC 313 (F.C.)

would occur. The product monograph contained a reference to the increased bio-availability of an antibiotic during "concomitant administration in healthy volunteers." This was supported by a detailed disclosure of actual tests involving these substances. The material was not contained in the "Indications and Clinical Uses" section of the monograph. An expert testified that the approved uses are contained in this section and that they are the only uses that can lawfully be promoted. O'Keefe J. held that the uses sought to be approved by the respondent were limited to those contained in the "Indications and Uses" section, and the prohibition application was dismissed.

AB Hassle v. Apotex (Mar. 2004)

*AB Hassle v. Apotex*¹⁵⁵ concerned two patents relating to the use of omeprazole – the 668 Patent concerned its use against bacteria, especially H.pylori; the 762 Patent concerned the use of a combination of omeprazole and an antibiotic to treat gastritis or peptic ulcer caused by bacteria, especially H.pylori. Apotex alleged that no claim would be infringed - omeprazole was old and it was not seeking a NOC for the patented uses.

Lemieux J. reviewed the authorities, particularly *P&G v. Genpharm (FCA)* and *AB Hassle v. Apotex (FCA)* and *AB Hassle v. Rhoxalpharma (FC)*. He concluded that applicant had not proved that the patents would be infringed and the prohibition application was dismissed.

Novartis v. Rhoxalpharma (Mar. 2004)

As noted above¹⁵⁶, in *Novartis v. Rhoxalpharma*¹⁵⁷, Lemieux J., construed the patent claim to cover a hydrosol formed in a human stomach and issued a prohibition order with respect to the Rhoxalpharma 25mg and 50 mg capsules (notwithstanding a prior contrary decision of Tremblay-Lamer J. regarding its 100mg capsules).

AstraZeneca v. Apotex (April 2004)

*AstraZeneca v. Apotex*¹⁵⁸ involved a patent for a composition comprising omeprazole and a potassium, sodium or aluminum salt stabilizing agent. Gauthier J. found that Apotex's allegation that its tablets would not contain such a salt not proved wrong and the prohibition application was dismissed.

Abbott v. Pharmascience (Oct. 2004)

*Abbott v. Pharmascience*¹⁵⁹ related to a patent for a process for producing particular crystal forms of clarithromycin. Pharmascience alleged it would use a different process – the end product was the same. Gibson J. held that the Notice of allegation was insufficient, that it was not cured by disclosure much later of details of process, and that the prohibition order should be

¹⁵⁵ *AB Hassle et al. v. Apotex et al.* (2004), 34 C.P.R. (4th) 65, 2004 FC 379 (F.C.)

¹⁵⁶ Supra section 10.3

¹⁵⁷ *Novartis Pharmaceuticals Canada Inc. et al v. Rhoxalpharma Inc.* 2004 FC 474 (F.C.)

¹⁵⁸ *AstraZeneca Canada Inc. v. Apotex Inc. et al* (2004), 34 C.P.R. (4th) 450, 2004 FC 647 (F.C.)

¹⁵⁹ *Abbott Laboratories et al v. Minister of Health and Pharmascience Inc.* 2004 FC 1349

granted on this basis alone. However, he went on to consider the construction of the patent and the issues of infringement and invalidity.

In construing the patent, after very briefly summarizing the principles of construction from *Whirlpool v. Camco*, and considering conflicting expert evidence, the Gibson J. found that the word "treating" in the claim in issue should be interpreted broadly to cover any method of crystallization including slurring, as opposed to a very narrow construction urged by the respondent. On this construction, he held that the allegation of non-infringement was not made out. As noted above, an allegation that the claims were broader than invention made and disclosed was held not justified – the allegation was based on a narrow definition of “treating” which was rejected by the Court. A prohibition order was issued.

***Pfizer v. Novopharm* (November 2004)**

In *Pfizer v. Novopharm*¹⁶⁰, the patent claimed crystalline azithromycin dehydrate. Novopharm asserted that its product was formulated with azithromycin monohydrate which is stable and does not convert to crystalline azithromycin dehydrate. Gibson J. held that the Notice of Allegation was deficient because it did not address whether crystalline azithromycin dehydrate was formed in the process for making the bulk azithromycin monohydrate which Novopharm was planning to import. On this basis alone, the prohibition order was issued. With regard to the merits, he found that Pfizer had not proved that azithromycin monohydrate converted to crystalline azithromycin dehydrate.

***AB Hassle v. Genpharm* (December 2004 FCA)**

In December 2004, the Federal Court of Appeal in *AB Hassle v. Genpharm*¹⁶¹ dismissed an appeal from an order prohibiting an NOC in respect of omeprazole capsules until the expiration of two AB Hassle patents and an AstraZeneca patent. There were four principal issues – the onus, anticipation, obviousness and infringement.

Genpharm’s onus argument that the wrong standard of proof was used in respect of the “justified” test in section 6(2) of the NOC Regulations was rejected on the basis stated by the Court of Appeal in *Genpharm v. Procter & Gamble*¹⁶². The issues of anticipation and obviousness turned on the particular facts and no palpable error in the findings of Layden-Stevenson J. was shown.

The infringement issue concerned two of the patents, both for new uses of omeprazole. The 668 Patent claimed the use of omeprazole in the treatment of Campylobacter (now called *H.pylori*) infections. The 762 Patent claimed the use in combination of omeprazole and antibiotics to treat gastritis and peptic ulcers caused by *H.pylori* bacteria. Genpharm asserted that it was seeking a NOC for the old use of omeprazole – the treatment of conditions where a reduction of gastric acid secretion is required – and that its product would be labelled and marketed for the old uses

¹⁶⁰ *Pfizer Canada Inc. et al v. Novopharm Limited et al* 2004 FC 1633 (F.C.)

¹⁶¹ *AB Hassle et al v. Genpharm Inc.* (sub nom *Genpharm Inc. v. AB Hassle et al*) 2004 FCA 413 (F.C.A.), affirming 2003 FC 1443 (F.C.)

¹⁶² Supra footnote 135, see also Supra section 16.4.1

and would not be labelled or marketed for the uses claimed in the 688 and 762 Patents, and, as to the 762 Patent, the capsules would not contain an antibiotic.

The Court of Appeal noted that, having regard to Genpharm's product monograph, Layden-Stevenson J. concluded that if a NOC for its omeprazole issued to it and if Genpharm were to sell its omeprazole, patients would infringe the 688 and 762 Patents.

The "Indication and Clinical Use", section of the product monograph referred only to old uses of omeprazole. Genpharm asserted that this showed that the product monograph only referred to the old uses.

However, the Court of Appeal noted that in another section of the product monograph there was reference to studies conducted using *H.pylori* positive patients which Layden-Stevenson J. concluded was a "blatant attempt to leave the reader with the impression that Genpharm's omeprazole may be used for treating patients with *H.pylori*." The Court of Appeal interpreted this to be a finding that Genpharm would be attempting to induce others to infringe the 688 Patent. Genpharm objected that there was no evidence that the product monograph would induce infringement, but the Court of Appeal held she was entitled to draw this inference.

Similar inferences were drawn from passages in the product monograph with respect to the 762 Patent.

16.4.3 NOC Prohibition Application Decisions – Appeal

Apotex v. Bayer

*Apotex v. Bayer*¹⁶³ concerned an application to dismiss the appeal from a prohibition order on the basis that the appeal was moot, since the patent had expired and a Notice of Compliance had issued. However, the Court found that the proceeding, although technically moot, should be allowed to proceed in any event pursuant to the Court's discretion because the appeal was the only way the appellant had a possibility to present a claim for compensation under section 8 of the Rules.

16.5 Damage Claim Under NOC Regulations Section 8

16.5.1 NOC Regulations Section 8

Section 8 of the *NOC Regulations* provides, *inter alia*:

“8. (1) If an application made under subsection 6(1) is withdrawn or discontinued by the first person or is dismissed by the court hearing the application or if an order preventing the Minister from issuing a notice of compliance, made pursuant to that subsection, is reversed on appeal, the first person is liable to the second person for any loss suffered during the period

¹⁶³ *Apotex Inc. v. Bayer AG et al* 2004 FCA 242 (F.C.A.)

(a) beginning on the date, as certified by the Minister, on which a notice of compliance would have been issued in the absence of these Regulations, unless the court is satisfied on the evidence that another date is more appropriate; and

(b) ending on the date of the withdrawal, the discontinuance, the dismissal or the reversal.

(2) A second person may, by action against a first person, apply to the court for an order requiring the first person to compensate the second person for the loss referred to in subsection (1).

(3) The court may make an order under this section without regard to whether the first person has commenced an action for the infringement of a patent that is the subject matter of the application.

(4) The court may make such order for relief by way of damages or profits as the circumstances require in respect of any loss referred to in subsection (1).

(5) In assessing the amount of compensation the court shall take into account all matters that it considers relevant to the assessment of the amount, including any conduct of the first or second person which contributed to delay the disposition of the application under subsection 6(1).”

16.5.2 Motions for Summary Judgment re Claims under Section 8

In 2004 there were several decisions on motions for summary judgment with respect to aspects of claims made under Section 8.

Apotex v. Canada

In *Apotex v. Canada, sub nom Bristol-Myers Squibb v. Apotex*¹⁶⁴, the Federal Court of Appeal affirmed a decision of Russell J. dismissing a motion for summary judgment dismissing Apotex’s claim for an accounting of profits following the discontinuance of an application for the prohibition of a NOC. Strayer J.A. for the Court of Appeal noted that it was open to the judge to conclude that there was a genuine issue for trial which would require more complete argument and even evidence, and that even if it was a question of law, he had a discretion as to whether to grant summary judgment.

Apotex v. Merck (March 2004 FC; September 2004 FCA)

In *Apotex v. Merck*¹⁶⁵, Snider J. dismissed a motion brought by Merck for summary judgment dismissing an action by Apotex for damages pursuant to section 8 of the *Patented Medicines*

¹⁶⁴ *Bristol-Myers Squibb Canada Inc. v. Apotex Inc. et al* (2004), 34 C.P.R. (4th) 291, affirming (2003), 25 C.P.R. (4th) 479 (F.C.)

¹⁶⁵ *Apotex Inc. v. Merck & Co. et al* 2004 FC 314 (F.C.)

(*Notice of Compliance*) Regulations (“*NOC Regulations*”) and for disgorgement of Merck’s profits as a result of delays in the marketing of Apo-Norfloxacin caused by a prohibition application brought by Merck under the *NOC Regulations* in 1993, the resulting prohibition order issued in 1995 which ultimately was set aside by the Supreme Court of Canada in 1998.

Section 8 of the *NOC Regulations* was significantly amended in 1998¹⁶⁶. Apotex claimed under the original version of section 8 (“old s. 8”) and under the amended version (“new s.8”). It also claimed disgorgement of profits made by Merck during the period that Apotex was prevented from competing with it. On this motion, Merck asserted that neither old s. 8, nor new s. 8 applied to the facts of this case, both were *ultra vires*, and no claim of unjust enrichment was available to Apotex. Almost identical arguments had been made in *Apotex v. Canada*¹⁶⁷ and Snider J concluded that a trial was necessary for reasons similar to those in that case.

This decision was affirmed by the Federal Court of Appeal in September 2004¹⁶⁸. In the view of the Court of Appeal, the legal questions raised in the case would be best answered in their complete factual context, which can only emerge after a trial.

Apotex v. Eli Lilly (Mar. 2004 FC, October FCA)

*Apotex v. Eli Lilly*¹⁶⁹ was a motion for summary judgment brought in an action under section 8 of the *NOC Regulations* in respect of nizatidine, Apotex claimed against Lilly Canada and its parent Lilly U.S., inter alia, damages or an accounting of profits and disgorgement of the defendants’ revenues attributable to the higher prices charged for their nizatidine drug product.

The claim for an accounting and disgorgement were based on allegations that the defendants were unjustly enriched by being free to sell their product at higher prices while Apotex was kept off the market. Additionally, it was alleged that during the period in which Apotex was unjustly delayed, Lilly arranged with Pharmascience to launch Lilly’s capsules purportedly as a generic product under the Pharmascience label. And that Lilly and Pharmascience thus captured a valuable long-term position in the generic market which otherwise would have gone to Apotex.

Lilly U.S. moved for summary judgment on the basis that it was not a “first person” within the *NOC Regulations* and that that section 8 grants a cause of action for damages against only a “first person”, even though it was a party to the prohibition proceeding.

Lilly Canada and Lilly U.S. also moved for summary judgment in respect of the claim for unjust enrichment, alleging that there was no jurisdiction for such claim.

Heneghan J. held that since Apotex’s claim was based solely on section 8 of the *NOC Regulations*, it could only be asserted against a “first person”, a defined term which did not include Lilly U.S. and hence it was not a proper party. She distinguished an earlier decision¹⁷⁰ in

¹⁶⁶ SOR/98-166, s.8

¹⁶⁷ *Apotex Inc. v. Canada* (2003), 25 C.P.R. (4th) 479, (F.C.T.D.), affirmed 2004 FCA 43, 34 C.P.R. (4th) 291 (F.C.A.) [sub nom *Bristol-Myers Squibb Canada Inc. v. Apotex Inc. et al*]

¹⁶⁸ *Merck & Co. et al v. Apotex Inc. et al* 2004 FCA 298 (F.C.A.)

¹⁶⁹ *Apotex Inc. v. Eli Lilly and Company et al* (2004), 32 C.P.R. (4th) 97 (F.C.), varied 2004 FCA 358 (F.C.A.)

¹⁷⁰ *Apotex Inc. v. Eli Lilly Canada Inc. et al.* (2001), 13 C.P.R. (4th) 78 at 81-82 (F.C.T.D.), affirmed 2002 FCA 389 (F.C.A.)

this action in which the claim was sustained on a motion to strike a pleading allegation. She granted summary judgment dismissing the claim against Lilly U.S.

With respect to the claim of unjust enrichment, she noted that the Court had already decided that the meaning and scope of section 8, in particular in relation to a claim for unjust enrichment¹⁷¹, should not be decided upon a motion for summary judgment,, and dismissed this aspect of the motion.

In October, the Federal Court of Appeal allowed an appeal from the summary judgment dismissing the claim against Lilly U.S.¹⁷². The Court of Appeal held that the degree of control exercised by the parent company over Lilly Canada might be such as to make the parent company a “first person” within the meaning of s.8 of the Regulations. Therefore, the question of whether or not Lilly U.S. was a “first person” was a question of law and fact that could not be determined without a trial and summary judgment dismissing the case against Lilly U.S. should not have been granted.

¹⁷¹ Citing *Apotex Inc. v. Canada*, (2003) 25 C.P.R. (4th) 479, (aff'd) [2004] F.C.J. No. 164 (F.C.A.); *Apotex Inc. v. Merck & Co. Inc. And Merck-Frost Canada & Co.*, 2004 FC 314 (F.C.); and *Apotex Inc. v. Syntex Pharmaceuticals International Limited et al.*, 2004 FC 383 (F.C.)

¹⁷² *Apotex Inc. v. Eli Lilly and Company et al* 2004 FCA 358 (F.C.A.)

Appendix A

The paragraphs of the Apotex pleading in issue in *Eli Lilly v. Apotex* (as quoted in the decision of Hugessen J. 2003 FC 1171)

Anti-Competitive Activity

18. Each of the Shionogi Patents describes and claims processes suitable for making intermediates which can be converted to cefaclor by non-infringing processes.

19. None of the patents in this action contains a claim to the product cefaclor *per se* or a product-by-process claim for cefaclor. The basic patent for cefaclor and a process for its manufacture was disclosed and claimed in Canadian Letters Patent No. 1,016,537 which patent expired August 30, 1994.

20. With the issuance of the four Shionogi Patents, after August 30, 1994 at the latest, Shionogi was entitled to manufacture and sell within Canada cefaclor using the processes covered by its four patents as such processes would not infringe any patents owned by the Plaintiffs.

21. Prior to the issuance of the Shionogi Patents, the Plaintiffs enjoyed a monopoly in the Canadian market in respect of the manufacture and sale of cefaclor in Canada.

22. Faced with the prospect of competing with Shionogi for the Canadian cefaclor market, the Plaintiffs acquired the Shionogi Patents from Shionogi in order to prevent competition in the Canadian market. ...

26. In particular, Apotex states that the Plaintiffs knowingly conspired, combined, agreed, or arranged among themselves and with Shionogi to acquire the Canadian patents and patent rights granted to Shionogi under the Shionogi Patents for the purpose, and with the result, of preventing or impeding other manufacturers from producing or acquiring cefaclor, and so prevent or impede competition in the Canadian market for cefaclor.

Counterclaim

105. The Defendant, Plaintiff by Counterclaim, repeats and adopts the allegations contained in its Second Fresh as Amended Statement of Defence.

106. The Defendant by Counterclaim, Shionogi and Company Limited ("Shionogi"), is a manufacturer of pharmaceutical products around the world. Shionogi is a corporation incorporated and existing under the laws of Japan, with a principle place of business at 1-8, Doshomachi 3 - Chome, Chuo-ku, Osaka 541-0045, Japan.

107. As a result of the unlawful conduct of the Plaintiffs and Shionogi as described in the Second Fresh as Amended Statement of Defence, the Defendant's ability to manufacture or acquire cefaclor has been prevented, limited, or lessened, unduly.

108. The Plaintiffs' and Shionogi's knowing and wilful conduct, undertaken for the purpose of restricting trade in cefaclor, constitutes a violation of section 45 of the *Competition Act*. Accordingly, the Defendant claims damages pursuant to section 36 of the *Competition Act*, together with the full costs of its investigation of this matter, and of these proceedings.

109. Apotex states that the Defendant by Counterclaim, Shionogi, has conspired, combined, agreed or arranged to prevent, limit or lessen unduly, the manufacture or production of the medicine cefaclor, and to prevent or lessen, unduly, competition in the production, manufacture or supply of cefaclor, and to otherwise restrain or injure competition unduly, contrary to section 45 of the *Competition Act*.

110. In particular, Apotex states that Shionogi knowingly conspired, combined, agreed, or arranged with Eli Lilly and Company, Eli Lilly Canada, Inc. (collectively, "Lilly") or both, to allow Eli Lilly and Company to acquire the Canadian patents and patent rights granted to Shionogi under Canadian Letters Patent Nos. 1,095,026, 1,132,547, 1,136,132 and 1,144,924 (the Shionogi Patents) for the purpose, and with the result, of preventing or impeding other manufacturers from producing or acquiring cefaclor, and so prevent or impede competition in the Canadian market for cefaclor.

111. By reason of the foregoing, each of the Defendants by Counterclaim have:

- a) limited unduly the facilities for transporting, producing, manufacturing, supplying, storing or dealing in cefaclor;
- b) restrained or injured, unduly, trade or commerce in cefaclor; and
- c) prevented, limited, or lessened, unduly, the manufacture, purchase, barter, sale, transportation or supply of cefaclor;

Contrary to the provisions of the *Competition Act*, and so are jointly and severely [sic] liable to Apotex in respect of their violations of section 45 of the *Competition Act*.

112. The Defendant, Plaintiff by Counterclaim, therefore claims:

- (a) a declaration that Canadian Letters Patent Nos. 1,095,026, 1,132,547, 1,133,007, 1,133,468, 1,136,132, 1,144,924, 1,146,536 and 1,150,725 and each of the claims contained therein are invalid, void, unenforceable and of no force or effect;
- (b) damages pursuant to section 36 of the *Competition Act* to be paid to Apotex and/or in the alternative to be set-off against any award of damages awarded against Apotex;
- (c) costs of the counterclaim on a solicitor and client basis; and
- (d) such further and other relief as to this Honourable Court may seem just.