Date: 20080725

Docket: A-383-07

Citation: 2008 FCA 244

CORAM: **LÉTOURNEAU J.A.**
NADON J.A.
PELLETIER J.A.

BETWEEN:

ATTORNEY GENERAL OF CANADA and
THE MINISTER OF HEALTH

Appellants

and

ABBOTT LABORATORIES LIMITED,
TAP PHARMACEUTICALS INC. and
TAP PHARMACEUTICAL PRODUCTS INC.

Respondents

Heard at Ottawa, Ontario, on June 11, 2008.

Judgment delivered at Ottawa, Ontario, on July 25, 2008.

REASONS FOR JUDGMENT BY: PELLETIER J.A.

CONCURRED IN BY: LÉTOURNEAU J.A.
NADON J.A.

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REASONS FOR JUDGMENT

PELLETIER J.A.

INTRODUCTION

[1] This is an appeal from the decision of Madam Justice Simpson in *Abbott Laboratories Ltd. v. Canada (Attorney General)* reported at 2007 FC 797, 315 F.T.R. 263, in which she quashed the decision of the Minister of Health deleting Canadian Patent No. 2,269,053 (the '053 patent) from the Patent Register maintained under the *Patented Medicines (Notice of Compliance) Regulations*, S.O.R./93-133 (the Regulations). The issue in this appeal is whether the Minister properly applied

recent amendments to the Regulations relating to the listing of patents "against" supplementary new drug submissions.

FACTS

[2] The following description of the links between the three respondents is taken from Simpson J.'s Reasons for Judgment (the Reasons):

> [8] TAP Pharmaceuticals Inc. (TAP) is the party which files submissions and receives Notices of Compliance for PREVACID(R) [the drug in issue] products in Canada. However, TAP does not have a regulatory affairs department in Canada. For this reason, Abbott Laboratories Limited (Abbott Canada) acts as TAP's agent in Canada for all matters relating to TAP's submissions. In the case of PREVACID(R) Abbott Canada acted as TAP's agent for the filing of the NSAID* SNDS** and the submission of the Patent List.
>
> [9] TAP Pharmaceutical Products Inc. (TAP Products) is a holding company for TAP. TAP Products is a joint venture between Takeda Pharmaceutical Company Limited and Abbott Laboratories. The latter is the American parent of the Applicant, Abbott Canada.

* Non-Steroidal Anti-Inflammatory Drug (NSAID)

** Supplement to a New Drug Submission (SNDS)

[3] For the sake of convenience, and since their interests seem to be identical, I will simply refer to the respondents collectively as Abbott.

[4] The Regulations incorporate a scheme by which pharmaceutical products are brought to market. They are intended to address both the health and safety concerns regulated by the *Food and Drugs Act*, R.S.C. 1985, c. F-7, and its regulations, the *Food and Drug Regulations*, C.R.C., c. 870, as well as the rights of patent holders as set out in the *Patent Act*, R.S.C. 1985, c. P-4. For a

description of the broad outlines of the scheme, see paragraphs 3 to 21 of this Court's reasons in *Wyeth Canada v. Ratiopharm Inc.*, 2007 FCA 264, 60 C.P.R. (4th) 375 (*Wyeth Canada*).

[5] In this case, the issue is the applicability of certain amendments to the Regulations. To assist in following the thread of events, I shall refer to the Regulations as they existed on June 15, 2006, as the Pre-amendment Regulations. On June 16, 2006, the Minister published proposed amendments to the Regulations in the Canada Gazette (Volume 140, number 24 of Part I). These took the form of regulations amending the Regulations. I shall refer to the regulations published on June 16, 2006, as the Amending Regulations. Finally, on October 5, 2006, the Amending Regulations entered into force which resulted in the Regulations in their current form.

[6] On May 12, 1995, the Minister issued a Notice of Compliance with respect to the drug PREVACID for use in the treatment of duodenal ulcers, gastric ulcers, and reflux esophagitis. The active medicinal ingredient in PREVACID is lansoprazole. On April 2, 2000, Abbott filed an SNDS seeking approval for a new indication for PREVACID, namely "Healing of NSAID-associated gastric ulcer and reduction of risk of NSAID-associated gastric ulcer".

[7] Both the Pre-amendment Regulations and the Regulations authorized Abbott to submit a patent list in respect of a new drug submission or an SNDS (generically, a submission) either at the time of the filing of the submission, or if the patent had not yet been issued, within 30 days of the issuance of the patent but only if the application for the patent was made prior to the filing date of the submission. The application for the '053 patent was filed in the Canadian Patent Office on

November 13, 1997 and the patent itself was issued on July 18, 2006. As a result, the '053 patent was not eligible to be included on a patent list with respect to the original submission for a Notice of Compliance because the patent application date did not precede the date of filing of the original submission, i.e. prior to May 12, 1995. However, the patent application date, November 13, 1997, did precede the date of the filing of the SNDS with respect to the new indication for PREVACID, April 2, 2000, so that, from the point of view of timeliness, the '053 patent was eligible to be included on a patent list with respect to that SNDS.

[8] The patent list containing the '053 patent was filed on July 20, 2006 [July 19, 2006, according to the Abbott's Brief] within 30 days of the issuance of the patent. It is common ground that the '053 patent satisfied the other condition for the listing of a patent in that it contained "a claim for the use of the medicine" as provided in paragraph 4(2)(*b*) of the Pre-amendment Regulations. The '053 patent was included on the Patent Register on July 25, 2006, in relation to the SNDS for the new indication for PREVACID.

[9] The Amending Regulations amended the listing requirements in section 4 of the Pre-amendment Regulations and, in particular, set out the types of SNDS's against which a patent list could be submitted:

4. (3) A patent on a patent list in relation to a supplement to a new drug submission is eligible to be added to the register if the supplement is for a change in formulation, a change in dosage form or a change in use of the medicinal ingredient, and	4. (3) Est admissible à l’adjonction au registre tout brevet, inscrit sur une liste de brevets, qui se rattache au supplément à une présentation de drogue nouvelle visant une modification de la formulation, une modification de la forme posologique ou une modification de l’utilisation de l’ingrédient médicinal, s’il contient, selon

	le cas :
(*a*) in the case of a change in formulation, the patent contains a claim for the changed formulation that has been approved through the issuance of a notice of compliance in respect of the supplement;	*a*) dans le cas d'une modification de formulation, une revendication de la formulation modifiée, la formulation ayant été approuvée par la délivrance d'un avis de conformité à l'égard du supplément;
(*b*) in the case of a change in dosage form, the patent contains a claim for the changed dosage form that has been approved through the issuance of a notice of compliance in respect of the supplement; or	*b*) dans le cas d'une modification de la forme posologique, une revendication de la forme posologique modifiée, la forme posologique ayant été approuvée par la délivrance d'un avis de conformité à l'égard du supplément;
(*c*) in the case of a change in use of the medicinal ingredient, the patent contains a claim for the changed use of the medicinal ingredient that has been approved through the issuance of a notice of compliance in respect of the supplement.	*c*) dans le cas d'une modification d'utilisation de l'ingrédient médicinal, une revendication de l'utilisation modifiée de l'ingrédient médicinal, l'utilisation ayant été approuvée par la délivrance d'un avis de conformité à l'égard du supplément.

[10] The Amending Regulations contained certain transitional provisions. Section 6 of the Amending Regulations provided that the amendments to section 4, including those quoted above, did not apply to a patent on a patent list submitted prior to June 17, 2006. Section 7 of the Amending Regulations provided that they applied to submissions made prior to the coming into force of the Amending Regulations and further, that the date of filing of such submissions was deemed to be the date of the coming into force of the Amending Regulations, namely October 5, 2006. On the face of section 6 of the Amending Regulations, section 4 of the Regulations applied to the '053 patent because it was on a patent list submitted after June 17, 2006.

[11] Notwithstanding the inclusion of the '053 patent on the Patent Register, the Minister determined on March 2, 2007, that the '053 patent did not meet the requirements of section 4(3)(*c*) of the Regulations, as it did not contain a claim for the changed use of the medicinal ingredient. As a result, the Minister deleted the '053 patent from the Patent Register on March 2, 2007 [February 22 according to the Minister's Brief].

[12] In doing so, the Minister purported to exercise the power and duty conferred on him by section 3 of the Regulations, as amended, which provides as follows:

3. (2) The Minister shall maintain a register of patents and other information submitted under section 4. To maintain the register, the Minister may refuse to add or may delete any patent or other information that does not meet the requirements of that section.	3. (2) Le ministre tient un registre des brevets et des autres renseignements fournis aux termes de l'article 4. À cette fin, il peut refuser d'y ajouter ou en supprimer tout brevet ou tout autre renseignement qui n'est pas conforme aux exigences de cet article.

[13] Abbott brought an application for judicial review of the Minister's decision. It made two arguments: first, that the amendments to the Regulations did not apply to the patent list submitted on July 25, 2006, and second, that, in any event, the '053 patent did contain a claim for the changed use of the medicinal ingredient.

THE DECISION UNDER APPEAL

[14] Simpson J. noted that the parties agreed that the interpretation of the Regulations was a question of law and that the standard of review was therefore correctness.

[15] On the issue of whether the July 25, 2006 patent list was subject to the amendments introduced by the Amending Regulations, Abbott made five arguments, all of which were rejected by Simpson J.

[16] Abbott's first argument was that the plain meaning of the Regulations made it clear that they were not intended to apply to the removal of patents from the Patent Register. Paragraph 4(3)(*c*) of the Regulations deals only with the inclusion of patents to the Patent Register. Abbott argues, as a result, that paragraph 4(3)(*c*) cannot be invoked to justify deleting a patent from the Patent Register.

[17] Simpson J. found that this argument was inconsistent with subsection 3(2) of the Regulations dealing with the maintenance of the Patent Register. She found that "the words of subsection 3(2), when read in their context and in their ordinary sense, have the effect of cross referencing the requirements for adding patents in section 4 so that they also become the requirements for the deletion of patents under subsection 3(2)": see paragraph 24 of Simpson J.'s Reasons.

[18] Simpson J. also rejected Abbott's argument that the deletion of the '053 patent from the Patent Register amounted to giving retroactive effect to the amendments to the Regulations. A related argument to the effect that Parliament had not authorized the Minister to interfere with vested rights was also dismissed.

[19] In rejecting the argument as to the retroactive application of the amendments, Simpson J. relied, correctly in my view, on the decision of this Court in *Eli Lilly Canada Inc. v. Canada (Minister of Health)*, 2003 FCA 24, [2003] 3 F.C. 140 (*Eli Lilly*), in which it was held that the Minister is entitled to require that patents on the Patent Register satisfy the regulatory requirements as they exist from time to time, so that past compliance with the regulatory requirements does not, in and of itself, exempt a patent from compliance with any subsequently enacted listing requirement. *Eli Lilly* disposes as well of the argument as to vested rights.

[20] Abbott then argued that the Amending Regulations must be read in light of the transitional provisions and, in particular, section 7 which provides as follows:

7. (1) Subsection 5(1) of the ***Patented Medicines (Notice of Compliance) Regulations***, as enacted by section 2 of these Regulations, applies to a second person who has filed a submission referred to in subsection 5(1) prior to the coming into force of these Regulations and the date of filing of the submission is deemed to be the date of the coming into force of these Regulations.	7. (1) Le paragraphe 5(1) du ***Règlement sur les médicaments brevetés (avis de conformité)***, édicté par l'article 2 du présent règlement, s'applique à toute seconde personne qui a déposé une présentation visée à ce paragraphe avant l'entrée en vigueur du présent règlement, et la date de dépôt de cette présentation est réputée être la date d'entrée en vigueur du présent règlement.

[21] In Abbott's view, this disposition was intended to "freeze" the register by requiring the second person to address all patents on the Patent Register as of the coming into force of the amendments to the Regulations. Simpson J. disposed of this argument by holding that it was intended to have the second person address all patents which were properly on the Patent Register as of the material date. In her view, allowing the Minister to remove patents which did not meet the

criterion for inclusion on the Patent Register did not offend the letter or the spirit of the transitional provision.

[22] Finally, Abbott argued that since the Patent Office approved its patent application on May 12, 2006 (the date of the issuance of the Notice of Allowance), but did not actually issue the patent until July 18, 2006, it should be treated as though its rights were fixed as of the date of the Notice of Allowance. Otherwise, it said, it was being penalized for the delay in the Patent Office. Simpson J. rejected this argument on the ground that there was no basis for deeming a patent list to have been filed when no list was filed, whatever the merits of the claim of delay in the Patent Office.

[23] Having disposed of the timeliness argument, Simpson J. then dealt with Abbott's substantive argument which was that, in any event, the '053 patent did contain a claim for the changed use of lansoprazole and, therefore, should not have been deleted from the Patent Register. Abbott relies upon the opinions of two experts, one a physician, the other a chemist. Both agreed that the patent contained a claim for the treatment of ulcers and that a person skilled in the art would recognize that "ulcers" included "non steroidal anti-inflammatory drug" ulcers.

[24] Simpson J. accepted this argument, saying:

> [41] In my view, it is consistent with the expert evidence to conclude that the 053 Patent is eligible to be on the Patent Register pursuant to paragraph 4(3)(c) of the New Regulations because it includes a claim for the new use of lansoprazole to treat NSAID ulcers.

[25] Simpson J. also rejected the Minister's argument that the '053 patent was not eligible for inclusion on the Patent Register because it was a patent for a polymorphic form of lansoprazole:

> New patents claiming novel physical forms of the approved medicinal ingredient will not be eligible for listing in this manner.
>
> [Regulatory Impact Analysis Statement "Changes to the patent listing requirements."]

[26] In Simpson J.'s view, the fact that the patented invention was a polymorphic form of lansoprazole did not disqualify the patent from inclusion on the Patent Register.

[27] As a result, Simpson J. found that the Minister erred in deleting the '053 patent from the Patent Register and ordered it to be restored to the Patent Register.

ANALYSIS

[28] The issues to be decided in this appeal are the following:

1- What is the standard of review of the Minister's decision?

2- Do the 2006 amendments apply to the deletion of the '053 patent from the Patent Register?

3- If they do, is the Minister's decision to delete the '053 patent from the Patent Register reviewable?

1- What is the standard of review of the Minister's decision?

[29] Simpson J. proceeded on the basis that the parties had agreed that since the issue before the Minister was a question of law, the standard of review was correctness.

[30] The Minister says that he did not agree that the question before him was a pure question of law. His position is:

> …unlike the many patent listing cases brought under the previous versions of the *PM(NOC) Regulations*, the question of whether the '053 patent is eligible for listing on the Patent Register under the amended regulatory scheme is not wholly a question of law. Pursuant to the new requirements introduced under subsection 4(3) of the amended *PM(NOC) Regulations*, the eligibility of a patent for listing on the Patent Register in connection with a SNDS now explicitly requires an assessment of the subject-matter of the drug submission against which the patent is proposed to be listed. Such an assessment is a question of fact and is one that falls squarely within the expertise of the Minister. Therefore, it is submitted that a question of patent eligibility under subsection 4(3) of the amended *PM(NOC) Regulations* is properly characterized as a question of mixed fact and law…

[31] The standard of review applicable to questions of mixed fact and law at the time the Minister's Brief was written was, he says, patent unreasonableness: see *Ferring Inc. v. Canada (Minister of Health)*, 2007 FCA 276, 60 C.P.R. (4th) 273. Since then, the legal landscape has changed with the Supreme Court's decision in *Dunsmuir v. New Brunswick*, 2008 SCC 9, [2008] S.C.J. No. 9 (*Dunsmuir*), which redefined the range of standards of review from three (patent unreasonableness through reasonableness to correctness) to two (unreasonableness and correctness). Taking *Dunsmuir* into account, the Minister's position is that the appropriate standard of review is unreasonableness.

[32] The Minister's argument rests on the fallacy that there is a difference in kind between deciding if an SNDS contains "a claim for the medicine itself or a claim for the use of the medicine" as subsection 4(2) of the Pre-amendment Regulations required, and deciding if "in the case of a change in use of the medicinal ingredient, the patent contains a claim for the changed use of the medicinal ingredient that has been approved through the issuance of a Notice of Compliance in respect of the supplement" as subsection 4(3) of the Regulations now require. While the content of the inquiry which the Minister is required to undertake has changed, the nature of the inquiry is the same. It is whether the content of the submission satisfies the legal criteria for listing. The change in the Regulations has not made the inquiry any more fact specific than it previously was: there is no meaningful legal distinction to be drawn between deciding if the claims of a patent contain "a claim for the use of the medicine" as opposed to "a claim for the changed use of the medicinal ingredient".

[33] The jurisprudence of this Court establishes that the standard of review of a decision to list, or to refuse to list, a patent on the Patent Register is correctness: see *Eli Lilly*, at paragraph 5. *Dunsmuir* teaches that we may look to the jurisprudence for guidance as to the appropriate standard of review: see *Dunsmuir*, at paragraph 57. I see no merit in the Minister's suggestion that the amendments to the Regulations have the effect of changing the standard of review which, in my view, remains correctness.

2- Do the 2006 amendments apply to the deletion of the '053 patent from the Patent Register?

[34] The many arguments which Abbott has raised on this issue amount to one argument on statutory interpretation and a series of arguments premised on a finding that the statutory language

is ambiguous. If it is not ambiguous, then there is no need to resort to presumptions against retroactivity or interference with vested rights. For example, the presumption against retroactive legislation was expressed as follows in *Gustavson Drilling (1964) Ltd. v. Canada (Minister of National Revenue - M.N.R.*), [1977] 1 S.C.R. 271, at page 279:

> The general rule is that statutes are not to be construed as having retrospective operation unless such a construction is expressly or by necessary implication required by the language of the Act.

[35] In Sullivan, *Driedger on the Construction of Statutes* (3rd Ed.) (Butterworths, Toronto, 1994) at page 512, the author points out that the term "retrospective" in the passage cited above should be "retroactive".

[36] In other words, Parliament can indeed legislate retroactively providing that it makes its intention to do so unmistakably clear.

[37] In the present case, there is no ambiguity which leaves room for the application of any presumption. The Minister's authority to remove a patent from the Patent Register is found in section 3 of the Regulations, quoted above but reproduced here for ease of reference:

3. (2) The Minister shall maintain a register of patents and other information submitted under section 4. To maintain the register, the Minister may refuse to add or may delete any patent or other information that does not meet the requirements of that section.	3. (2) Le Ministre tient un registre des brevets et des autres renseignements fournis aux termes de l'article 4. À cette fin, il peut refuser d'y ajouter ou en supprimer tout brevet ou tout autre renseignement qui n'est pas conforme aux exigences de cet article.

[38] The power to delete patents from the Patent Register is not subject to any transitional provision. It is therefore subject to the principle embodied in section 10 of the *Interpretation Act*, R.S.C. 1985, c. I-21:

10. The law shall be considered as always speaking, and where a matter or thing is expressed in the present tense, it shall be applied to the circumstances as they arise, so that effect may be given to the enactment according to its true spirit, intent and meaning.	10. La règle de droit a vocation permanente; exprimée dans un texte au présent intemporel, elle s'applique à la situation du moment de façon que le texte produise ses effets selon son esprit, son sens et son objet.

[39] Section 3 therefore looks to the requirements of section 4 as they exist at any given point in time. Thus, when the Minister re-examined the listing of the '053 patent in light of the amendments which came into effect in October 2006, section 4 of the Regulations required the '053 patent to contain a claim for the changed use of the medicinal ingredient identified in the SNDS against which it was filed. The Minister concluded that the '053 patent did not contain such a claim and that as a consequence, it was ineligible for listing as of the date of examination, and therefore liable to be deleted from the Patent Register. None of this gives rise to the least ambiguity.

[40] Abbott invokes the transitional provisions of the Amending Regulations and, in particular, section 6 which provides as follows:

6. Section 4 of the *Patented Medicines (Notice of Compliance) Regulations*, as enacted by section 2 of these Regulations, does not apply to patents on a patent list submitted prior to the day, in 2006, on which these Regulations are published in Part I of the *Canada Gazette*.	6. L'article 4 du *Règlement sur les médicaments brevetés (avis de conformité)*, édicté par l'article 2 du présent règlement, ne s'applique pas aux brevets inscrits sur la liste de brevets présentée avant la date de publication, en 2006, du présent règlement dans la partie I de la *Gazette du Canada*.

[41] Abbott argues that there is a gap created by the operation of section 6. Patent lists submitted after June 17, 2006, but which are added to the Patent Register prior to October 6, 2006, fall in this gap. They are added to the Patent Register according to the "old" rules but are subject to being removed according to the "new" rules. Abbott says that this kind of "in and out" scenario cannot have been intended by the legislator.

[42] In fact, it is passably clear that it was intended. Section 6 of the Amending Regulations uses as its reference date the filing date of a patent list. Had it been intended to protect all patents listed on the Patent Register as of the coming into force of the amendments, it would have been simple enough to say so. Abbott's argument, if accepted, would achieve that result without the benefit of enabling legislation. It is clear, though, that by using the filing date of the patent list as the reference date for the application of section 4, the legislator specifically allowed for the kind of re-examination which occurred here.

[43] In the end result, given the clear language of section 3 of the Regulations, I am satisfied that the Minister correctly decided that the Regulations applied to the '053 patent.

3. If they do, is the Minister's decision to delete the '053 patent from the Patent Register reviewable?

[44] Abbott says that even if the amendments to the Regulations apply to the listing of the '053 patent, it meets those requirements. Simpson J. accepted this argument on the strength of expert

evidence which essentially said that a claim for the treatment of ulcers includes a claim for the treatment of NSAID ulcers.

[45] The redrafting to section 4 of the Regulations into its current form comes in response to a running debate about the "relevance" of patents in relation to the submissions against which drug manufacturers seek to list them: see for example, *Eli Lilly*, at paragraphs 30 to 39.

[46] That controversy was resolved by amendments which specified the characteristics of patents which could be listed against specific types of SNDS's. Thus, where a manufacturer submitted an SNDS with respect to a new dosage form, the Regulations now require any patent sought to be filed against that submission to contain "a claim for the changed dosage form…": see paragraph 4(3)(*b*) of the Regulations. In the present case, the SNDS in question is with respect to a new indication for an existing drug PREVACID. That drug was originally approved for use in the treatment of "duodenal ulcers, gastric ulcers, and reflux esophagitis". The SNDS relevant to these proceedings claims as a new indication for the drug "Healing of NSAID-associated gastric ulcer and reduction of risk of NSAID-associated gastric ulcer". Paragraph 4(3)(*c*) of the Regulations requires that any patent sought to be listed on the Patent Register against that submission must contain "a claim for the changed use of the medicinal ingredient".

[47] It stands to reason that if a patent must contain a claim for the changed use identified in Abbott's SNDS, that patent cannot simply claim the use which formed the basis of the original submission. Such a patent does not specifically claim the changed use, even though the changed use

may come within the claims of the patent. In other words, the Regulations envisage as a condition of listing a patent in respect of a change in the use of a medicinal ingredient that the patent specifically claims the changed use as opposed to non-specific claims which are wide enough to include the changed use.

[48] It is this distinction between specific claims and broad non-specific claims which led to the discussion in the jurisprudence about the nature of the patented invention: see *Wyeth Canada*, at paragraph 22, affirmed [2007] F.C.J. No. 1062 at paragraph 29. That discussion has now been overtaken by the amendments to the Regulations.

[49] Even if one were inclined to look to the nature of the invention, the difficulty is that the language of the Regulations speaks only of "a claim for the changed use of the medicinal ingredient". I conclude that paragraph 4(3)(*c*) of the Regulations requires, as a condition of listing a patent on the Patent Register, that the patent must specifically claim the very change in use which was approved by the issuance of a Notice of Compliance with respect to an SNDS.

[50] As a result, I am of the view that Simpson J. erred in accepting the expert opinions which were placed before her as evidence that the '053 patent contained a claim for the changed use of the medicinal ingredient in PREVACID. That evidence went no further than showing that the '053 patent would have been eligible for listing against the original submission for PREVACID, had it not been for the fact that the date of the submission preceded the date of the patent application. To allow registration of the '053 patent against the SNDS for a changed use which was not the subject

of a specific claim would be to undo the reform which the amended regulations seek to introduce.

For that reason, I would allow the appeal with costs and set aside the decision of the Federal Court.

I would dismiss with costs the respondent's application for judicial review.

"J.D. Denis Pelletier"
J.A.

"I agree.
Gilles Létourneau J.A."

"I agree.
M. Nadon J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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DATED:	July 25, 2008

APPEARANCES:

David Cowie	FOR THE APPELLANTS
Steven Mason Andrew Reddon	FOR THE RESPONDENTS

SOLICITORS OF RECORD:

John H. Sims, Q.C. Deputy Attorney General of Canada	FOR THE APPELLANTS
McCarthy Tétrault LLP Toronto, Ontario	FOR THE RESPONDENTS