**Date: 20090209**

**Docket: A-208-08**

**Citation: 2009 FCA 35**

**CORAM:** **RICHARD C.J.**
**EVANS J.A.**
**SHARLOW J.A.**

**BETWEEN:**

**G.D. SEARLE & CO. and PFIZER CANADA INC.**

**Appellant**

**and**

**THE MINISTER OF HEALTH**

**Respondent**

Heard at Toronto, Ontario, on November 24, 2008.

Judgment delivered at Ottawa, Ontario, on February 9, 2009.

REASONS FOR JUDGMENT BY: SHARLOW J.A.

CONCURRED IN BY: RICHARD C.J.
EVANS J.A.

**Date: 20090209**

**Docket: A-208-08**

**Citation: 2009 FCA 35**

**CORAM:** **RICHARD C.J.**
**EVANS J.A.**
**SHARLOW J.A.**

**BETWEEN:**

**G.D. SEARLE & CO. and PFIZER CANADA INC.**

**Appellant**

**and**

**THE MINISTER OF HEALTH**

**Respondent**

## REASONS FOR JUDGMENT

**SHARLOW J.A.**

[1] This case concerns the decision of the Minister of Health to remove a patent from the patent register maintained under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the "*NOC Regulations*") on the basis that the patent was ineligible for listing. Justice Gauthier found no error in the delisting decision (2008 FC 437) and dismissed the application of Pfizer and Searle to quash the Minister's decision. This is an appeal of Justice Gauthier's decision.

Relevant parts of the regulatory scheme

[2] There are two regulatory schemes relevant to this case, both of which are administered by the Minister. For the purposes of this appeal, it is necessary to understand only limited aspects of the two regulatory schemes.

[3] The first regulatory scheme relates to the approval of drugs. It is found in the *Food and Drugs Act*, R.S.C. 1985, c. F-27, and the *Food and Drug Regulations*, C.R.C. 1978, c. 870. A drug cannot be sold in Canada without a notice of compliance (NOC) issued by the Minister under the *Food and Drug Regulations* signifying that the drug meets the applicable standards of safety and effectiveness. The NOC states, among other things, the Minister's classification of the drug and the approved use of the drug. The issuance of a NOC is accompanied by a product monograph approved by the Minister providing the same information as the NOC, as well as more detailed information for the use of health professionals and consumers. The first step in obtaining a NOC for a new drug is to submit to the Minister a "new drug submission" (NDS).

[4] If the manufacturer of a drug that has been approved for a certain use wishes the Minister to approve a new use for the drug, the manufacturer submits a request for approval in the form of a supplementary NDS (SNDS). If the change is approved, the Minister issues a new NOC to replace the previous NOC. The new NOC states all approved uses of the drug, including the new use approved in response to the SNDS. The new approved use and related information is also reflected in an amended product monograph issued at the same time as the new NOC.

[5] The second regulatory scheme that is relevant to this appeal relates to patented inventions embodied in approved drugs. That regulatory scheme is found in the *Patent Act*, R.S.C. 1985, c. P-4, and the *NOC Regulations*. For the purposes of this appeal, the most important aspect of the *NOC Regulations* is that the holder of a patent for an invention embodied in an approved drug cannot benefit from the *NOC Regulations* unless the patent is listed against that drug on the patent register maintained by the Minister pursuant to the *NOC Regulations*.

[6] Like many cases involving the *NOC Regulations*, this case exposes a controversy about the interpretation of a provision of the *NOC Regulations*. The resolution of such a debate begins with the teaching of the Supreme Court of Canada in *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26, [2005] 1 S.C.R. 533, at paragraphs 37 to 77 (see also *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, 2006 SCC 49, [2006] 2 S.C.R. 560, at paragraphs 15 and 16).

[7] Justice Binnie, writing for the majority of the Supreme Court of Canada in *Bristol-Myers*, said that the *NOC Regulations* must be interpreted in accordance with the principles stated as follows in Elmer A. Driedger, *Construction of Statutes* 2d ed. (Toronto: Butterworth & Co. 1983) at 87:

> Today there is only one principle or approach, namely, the words of an Act are to be read in their entire context and in their grammatical and ordinary sense harmoniously with the scheme of the Act, the object of the Act, and the intention of Parliament.
>
> (Emphasis in original)

and at 247:

> It is not enough to ascertain the meaning of a regulation when read in light of its own object and the facts surrounding its making; it is also necessary to read the words conferring the power in the whole context of the authorizing statute. The intent of the statute transcends and governs the intent of the regulation.

[8] For the *NOC Regulations*, the interpretive context includes their legislative history and purpose. Those subjects are discussed in detail in *Bristol-Myers*, but for this case a summary of that discussion will suffice.

[9] In 1993 it was recognized that a drug manufacturer wishing to obtain a NOC for a generic version of an approved drug embodying a patented invention would probably infringe the patent merely by undertaking the regulatory approval process before the expiry of the patent. That could delay by some years the commencement of the approval process for the generic version.

[10] To offset that potential disadvantage to generic drug manufacturers and to consumers seeking potentially less expensive drugs, the *Patent Act* was amended to add subsection 55.2(1), the "early working exception". The early working exception redefines patent infringement to exclude, among other things, the work required to obtain regulatory approval for a generic version of a drug that embodies a patented invention.

[11] At the same time, to deter potential abuses of the early working exception, the *Patent Act* was also amended to add subsection 55.2(4), which authorizes the Governor in Council to make certain regulations relating to the early working exception. The *NOC Regulations* were enacted under that provision.

[12] The grant of the regulation-making power in subsection 55.2(4) is expressly limited to regulations aimed at preventing patent infringement by a person making use of a patented invention

in reliance on the early working exception. Therefore, when a court is considering whether an interpretation of the *NOC Regulations* proposed by a patent holder should be preferred over a competing interpretation adopted by the Minister, it is not necessarily persuasive that the patent holder's proposed interpretation would tend to deter infringement of one or more claims of the patent in issue. The more relevant question is whether the proposed interpretation would tend to deter patent infringement arising from the use of the patented invention.

[13] In this case, the interpretive debate relates to section 4 of the *NOC Regulations*. For the holder of a patent, the gateway to the advantages of the *NOC Regulations* is to list the patent against an approved drug on the patent register. Section 4 of the *NOC Regulations* states the conditions that must be met to list a patent on the patent register. Subsection 3(2) of the *NOC Regulations* gives the Minister the authority to delist any patent that does not meet the requirements of section 4.

[14] Section 4 was substantially amended by SOR/2006-242, effective October 5, 2006. According to section 6 of SOR/2006-242, the post-October 5, 2006 version of section 4 does not apply to patents on a patent list submitted for listing prior to June 17, 2006. However, the patent in issue in this case was submitted for listing after June 17, 2006. Therefore, the post-October 5, 2006 version of section 4 governs its eligibility for listing. In these reasons, references to section 4 of the *NOC Regulations* are references to the post-October 5, 2006 version, unless the context indicates otherwise.

[15] The jurisprudence relating to the eligibility of patents for listing pursuant to section 4 of the *NOC Regulations* (as they read prior to the October 5, 2006 amendments) had adopted an interpretation that the government considered so broad as to unduly delay market entry of generic drugs. The October 5, 2006 amendments were intended to restore the balance. This is fully explained in the *Regulatory Impact Analysis Statement* published with the amending regulation (SOR/2006-242).

[16] Section 4 of the *NOC Regulations* requires that an application to list a patent against a drug must be filed in relation to a particular NDS or SNDS filed for that drug. The application to list the patent in issue in this case was filed in relation to a SNDS. The specific listing requirements for such applications are set out in subsection 4(3) of the *NOC Regulations*, which reads as follows:

| | |
|---|---|
| 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. |

[17] It is clear from the opening words of subsection 4(3) that only three kinds of SNDS are capable of supporting a patent listing: a SNDS for a change in formulation, a SNDS for a change in dosage form, or a SNDS for a change in the use of the medicinal ingredient.

[18] This case involves a patent listing sought on the basis of a SNDS for a change in the use of the medicinal ingredient. Therefore, the patent is eligible for listing only if the requirements of paragraph 4(3)(*c*) are met. That is, the changed use sought in the SNDS must be approved by the Minister, as evidenced by the issuance of a NOC in response to the SNDS, and the patent sought to be listed must contain a claim for the new approved use of the medicinal ingredient.

[19] Paragraph 4(3)(*c*) of the *NOC Regulations* was recently considered by this Court in *Abbott Laboratories Ltd. v. Canada (Attorney General)*, 2008 FCA 244 (leave to appeal dismissed December 18, 2008) ("*Abbott 244*"). In that case Pelletier J.A., speaking for the Court, said this about paragraph 4(3)(*c*), at paragraph 47 (my emphasis):

> […] 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 <u>specifically</u> claims the changed use as opposed to non-specific claims which are wide enough to include the changed use.

Justice Pelletier went on to say, at paragraph 49 (my emphasis):

> 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.

Facts

[20] The appellant Pfizer Canada Inc. manufactures and markets a drug named Celebrex pursuant to a NOC issued on April 14, 1999 in response to NDS 057660, which was filed in 1998. Celebrex was initially approved "for acute and chronic use in the relief of the signs and symptoms of osteoarthritis and rheumatoid arthritis in adults" (Appeal Book, Volume 6, page 1593 (original product monograph, page 8)).

[21] The medicinal ingredient in Celebrex is celecoxib, a cyclooxygenase-2 inhibitor or cox-2 inhibitor. A cox-2 inhibitor is said to interfere with the production of prostaglandins. When prostaglandins are released as the result of an injury or a condition such as osteoarthritis or rheumatoid arthritis, they initiate a process that causes pain and inflammation. Thus, the NOC for Celebrex classifies it as an anti-inflammatory analgesic agent.

[22] In 2001, Pfizer filed a supplementary new drug submission (SNDS 072375) that resulted in the issuance, on September 7, 2004, of a NOC approving a new use of Celebrex. The new use is "short term (≤ 7 days) management of moderate to severe acute pain in adults in conditions such as: musculoskeletal and/or soft-tissue trauma including sprains, postoperative orthopedic, and

pain following dental extraction" (Appeal Book, Volume 6, page 1628 (product monograph revised September 7, 2004, page 10)).

[23] Meanwhile, the appellant G.D. Searle & Co. filed an application for a patent entitled "Celecoxib Compositions". That application resulted, on July 11, 2006, in the issuance of Canadian Patent No. 2,319,201, the patent in issue in this case. The Canadian filing application date for the 201 patent is November 30, 1999.

[24] The disclosure of the 201 patent describes the invention of a number of new formulations of celecoxib said to alleviate various problems encountered with the known formulations. The 201 patent contains 16 claims. The first 10 claims refer to compositions of celecoxib that vary by reference to certain physical characteristics (for example, the size and dimension of celecoxib particulates, bioavailability characteristics, dosage forms, diluents, disintegrates, binding agents or lubricants). Claims 11, 12 and 13 refer to certain methods of administration of each of the compositions in claims 1 to 10.

[25] Claim 14 claims the use of any of the claimed compositions for "the preparation of a medicament for the treatment and/or prophylaxis of a medical condition or disorder in a subject where treatment with a cyclooxygenase-2 inhibitor is indicated". Claim 15 claims the use of any of the claimed compositions according to claim 14 where "the condition or disorder is rheumatoid arthritis, osteoarthritis or pain". Claim 16 refers to a method of commercial packaging of each of the compositions in claims 1 to 10.

[26] The Minister has agreed with Pfizer and Searle that the compositions of celecoxib claimed in the 201 patent include Celebrex, the composition of celecoxib for which the Minister issued a NOC on the basis of NDS 057660. Therefore, I will assume for the purposes of this appeal that Celebrex is a substance that is within at least one of the composition claims of the 201 patent (claims 1 to 10). Thus, any reference in claims 11 to 16 to the compositions in claims 1 to 10 must be understood to include Celebrex.

[27] But for the time limitations in the *NOC Regulations*, the 201 patent could have been listed against Celebrex on the basis of the claims for the composition of celecoxib named Celebrex. The timing problem arose because the Canadian filing application date for the 201 patent fell after the date in 1998 when NDS 057660 was filed (see subsection 4(6) of the *NOC Regulations*). However, the deadline for applying to list the 201 patent against Celebrex in relation to SNDS 072375 could be met by filing the listing application within 30 days after the issuance of the 201 patent. Accordingly, in July of 2006, Pfizer applied with Searle's consent to list the 201 patent against Celebrex in relation to SNDS 072375.

[28] The Minister accepted the application for the listing of the 201 patent on the basis of the *NOC Regulations* in force at that time. However, the Minister reexamined the listing when the amendments to the *NOC Regulations* came into force on October 5, 2006. As mentioned above, the eligibility of the 201 patent for listing turned on paragraph 4(3)(*c*) of the *NOC Regulations*. After considering a number of arguments made by Pfizer and Searle, the Minister concluded that the 201 patent was not eligible for listing against Celebrex, and removed it from the patent register.

[29] The memorandum of fact and law of Pfizer and Searle in this appeal summarizes the history of their discussions with the Minister on the question of the eligibility of the 201 patent for listing. It is the position of Pfizer and Searle that the Minister's reasoning changed over time. I am not persuaded that the Minister's position changed substantially but even if it did, the judicial review of the Minister's decision should be based on the reasons expressed by the Minister in the final decision letter dated April 24, 2007. The key part of that letter reads as follows (Appeal Book, Volume 6, page 1707):

> We accept Pfizer's representations that the indication for which S/NDS 072375 was issued is different from the indication for which the NOC was issued for NDS 057660, namely acute and chronic use in the relief of signs and symptoms of osteoarthritis and rheumatoid arthritis in adults. We also accept that the composition claimed in the '201 patent covers the composition of Celebrex that was approved through the NDS. However, the [Minister] remains of the view that listing the '201 patent on the Patent Register on the basis of claim 15, which includes a mention of "pain", would undermine the intended link between the subject matter of a patent on a patent list and the content of the underlying submission for the NOC in relation to which it is submitted [i.e., S/NDS 072375].
>
> As such, the '201 patent is not eligible for listing in respect of S/NDS 072375. Therefore, pursuant to the authority in the Minister of Health by subsection 3(2) of the *PM (NOC) Regulations*, the '201 patent will be removed from the Patent Register for the above-noted submission, one week from the date of this letter.

[30] It is common ground that the eligibility of the 201 patent for listing against Celebrex must be established on the basis of claim 15 of the 201 patent. The Minister's conclusion, as I understand it, is that claim 15 of the 201 patent is not a claim for the change in the use of Celebrex that was approved through the issuance of the NOC in respect of SNDS 072375.

[31] Pfizer and Searle applied for judicial review of the Minister's decision to delist the 201 patent. That application was dismissed by Justice Gauthier, hence this appeal.

Standard of Review

[32] Justice Gauthier did not have the benefit of the decision of this Court in *Abbott Laboratories Ltd. v. Canada (Attorney General)*, 2008 FCA 354, but the parties were aware of it prior to the hearing of this appeal. That case adopted an analytical framework developed by Justice Hughes for the determination of the eligibility of a patent for listing on the basis of a NDS, and dealt with the standard of review in light of that framework. I will use Justice Hughes' framework in this case, adapted for the slightly different factual context (i.e., the fact that this case deals with an application to list a patent on the basis of a SNDS).

[33] The analytical framework consists of three questions. In the context of this case, the first question is: "What use is claimed by claim 15 of the 201 patent?" That is a question of patent construction, which is a question of law to be reviewed on the standard of correctness.

[34] The second question is: "What use is approved by the NOC issued in response to SNDS 072375?" That question is to be reviewed on the standard of reasonableness.

[35] The third question is: "Is the use claimed by claim 15 that which is approved by the NOC?" That is a question of mixed fact and law because it requires an application of the law to the facts. The factual component must be reviewed on the standard of reasonableness. The legal component, which in this case is the meaning of paragraph 4(3)(*c*) of the *NOC Regulations*, must be reviewed on the standard of correctness.

[36] The Minister's decision to delist the 201 patent must stand unless it is based on an incorrect construction of claim 15, an incorrect interpretation of paragraph 4(3)(*c*) of the *NOC Regulations*, an unreasonable conclusion as to the approved use of Celebrex, or an unreasonable conclusion as to whether the use of Celebrex claimed in claim 15 is the new approved use of Celebrex.

[37] Justice Gauthier reviewed the Minister's decision on the standard of correctness on the basis of the submission of all parties that the decision turned entirely on the construction of the patent and the interpretation of the relevant regulation. I am not persuaded that there is any real dispute about the construction of the 201 patent. As I understand this case, the essential dispute between the parties relates to the correct interpretation of paragraph 4(3)(*c*) of the *NOC Regulations*. For that reason I agree with the decision of Justice Gauthier to apply the standard of correctness to the resolution of that dispute.

Analysis

[38] I will consider each of the three framework questions in turn.

(1) Construction of claim 15 of the 201 patent

[39] As explained above, Pfizer's application to list the 201 patent against Celebrex is based on claim 15 of the 201 patent. Claim 15 refers to and must be read with claim 14. Claim 14 claims the use of any of the compositions in claims 1 to 10 (which, as explained above, must be understood as a use of Celebrex) for the preparation of a medicament for "the treatment and/or prophylaxis of a medical condition or disorder in a subject where treatment with a cyclooxygenase-2 inhibitor is

indicated". Claim 15 claims the use according to claim 14, where "the condition or disorder is rheumatoid arthritis, osteoarthritis or pain".

[40] It appears from the record that all parties have construed claim 15 literally. The record discloses no disagreement between the parties as to its construction. Therefore, for the purposes of this appeal, I will assume without deciding that claim 15 should be read literally. On that basis, it must be understood to claim the use of Celebrex for treating pain if the nature of the pain is such that the use of a cox-2 inhibitor is indicated for its treatment.

[41] A complete review of the 201 patent indicates that the patented invention consists of the celecoxib compositions described in claims 1 to 10, including Celebrex. It was not and could not be argued that the inventor of those compositions discovered a new medicinal use of celecoxib. The Minister understood correctly that the use claimed in claim 15 is a known use of the new composition or compositions.

(2) New approved use of Celebrex

[42] There is no dispute on this point. The new approved use of Celebrex is "short term (≤ 7 days) management of moderate to severe acute pain in adults in conditions such as: musculoskeletal and/or soft-tissue trauma including sprains, post-operative orthopedic, and pain following dental extraction".

(3) Comparing the claimed use and the new approved use of Celebrex

[43] I summarize as follows the position of Pfizer and Searle on the third framework question. Celebrex is a cox-2 inhibitor. The fact that the Minister has approved the use of Celebrex to control moderate to severe acute pain in adults in "musculoskeletal and/or soft-tissue trauma including sprains, post-operative orthopedic, and pain following dental extraction" means that the nature of the pain associated with those conditions is such that the use of a cox-2 inhibitor is indicated to treat the pain. It must follow that the use of Celebrex "for pain", as claimed in claim 15 of the 201 patent includes the new approved use of Celebrex.

[44] The problem with the analysis presented by Pfizer and Searle is that a claim for the use of Celebrex "for pain" is so broad as to cover most of the known uses of Celebrex (including its use for the treatment of the pain of arthritis and osteoarthritis in adults, which was a use of Celebrex that was approved by the Minister when the initial NOC for Celebrex was issued). In my view, to accept the interpretation of paragraph 4(3)(*c*) proposed by Pfizer and Searle would be inconsistent with the decision of this Court *Abbott 244*. More importantly, it would give paragraph 4(3)(*c*) a meaning so broad as to defeat the purpose for which it was enacted.

[45] Bearing in mind the fact that the composition claims in the 201 patent include Celebrex, and considering also the principles established in *Abbott 244*, I would express the third framework question this way: Does claim 15 of the 201 patent claim the very use that was approved by the issuance of the NOC in response to SNDS 072375 (i.e., the "short term (≤ 7 days) management of moderate to severe acute pain in adults in conditions such as: musculoskeletal and/or soft-tissue

trauma including sprains, post-operative orthopedic, and pain following dental extraction")? As I read *Abbott 244*, this question must be answered in the negative because the use claimed in claim 15 ("for pain") is simply too general.

[46] That conclusion is confirmed by considering the purpose of the *NOC Regulations*, as explained above. A generic drug manufacturer who undertakes the work required to seek approval for a generic version of Celebrex would undoubtedly make use of the patented invention disclosed in the 201 patent and (but for the early working exception) would probably infringe claims 1 to 10. If, prior to the expiry of the 201 patent, the generic drug were to be approved for the same uses as Celebrex, the manufacture and sale of the generic drug would infringe claims 1 to 10. However, that potential infringement cannot be the target of the *NOC Regulations* because the deadline relevant to those claims was missed.

[47] The manufacture and sale of a generic version of Celebrex could also infringe claim 15. Nevertheless, the only part of claim 15 that reflects the patented invention is the part that refers to the new compositions of celecoxib. The "use" element of claim 15 reflects the known medicinal uses of celecoxib. To permit the *NOC Regulations* to be used to target the potential infringement of claim 15 based on those known uses would extend the scope of the *NOC Regulations* beyond their intended purpose.

[48] In my view, the Minister's decision to delist the 201 patent is consistent with the intended purpose of the *NOC Regulations*. The Minister's decision letter says that "listing the 201 patent on

the Patent Register on the basis of claim 15, which includes a mention of 'pain', would undermine the intended link between the subject matter of a patent on a patent list and the content of the underlying submission for the NOC in relation to which it is submitted." As I read the decision letter, the Minister's reasons express substantially the same rationale as *Abbott 244*.

Conclusion

[49] For these reasons, I conclude that Justice Gauthier made no error in deciding not to quash the Minister's decision to delist the 201 patent. I would dismiss this appeal with costs.

"K. Sharlow"

J.A.

"I. agree.
J. Richard C.J."

"I agree.
John M. Evans J.A."

**FEDERAL COURT OF APPEAL**

**NAMES OF COUNSEL AND SOLICITORS OF RECORD**

| | |
|---|---|
| **DOCKET:** | A-208-08 |
| **STYLE OF CAUSE:** | G.D. Searle & Co. & Pfizer Canada Inc. v. The Minister of Health |
| **PLACE OF HEARING:** | Toronto, Ontario |
| **DATE OF HEARING:** | November 24, 2008 |
| **REASONS FOR JUDGMENT BY:** | SHARLOW J.A. |
| **CONCURRED IN BY:** | RICHARD C.J.<br>EVANS J.A. |
| **DATED:** | February 9, 2009 |

**APPEARANCES:**

| | |
|---|---|
| Michael A. Penny<br>W. Grant Worden | FOR THE APPELLANT |
| David Cowie | FOR THE RESPONDENT |

**SOLICITORS OF RECORD:**

| | |
|---|---|
| Torys LLP<br>Toronto, Ontario | FOR THE APPELLANT |
| John H. Sims, Q.C.<br>Deputy Attorney General of Canada | FOR THE RESPONDENT |