Date: 20070731

Docket: T-513-07

Citation: 2007 FC 797

Ottawa, Ontario, July 31, 2007

PRESENT: The Honourable Madam Justice Simpson

BETWEEN:

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

Applicants

and

ATTORNEY GENERAL OF CANADA and
THE MINISTER OF HEALTH

Respondents

REASONS FOR JUDGMENT AND JUDGMENT

[1] In a decision dated February 22, 2007, the Minister of Health (the Minister) concluded (i) that the amendments to the *Patented Medicines (Notice of Compliance) Regulations*, S.O.R./93-133 (the New Regulations) changed the eligibility requirements for patents listed on the Patent Register and (ii) that the Applicants' patent did not meet those requirements. Accordingly, further to his obligation to maintain the Patent Register, the Minister de-listed the Applicants' patent (the Decision) even though it had been validly listed before the New Regulations came into force on October 5, 2006.

[2] In this application for judicial review, the Applicants seek an order quashing the Decision and restoring their patent to the Patent Register.

PREVACID

[3] PREVACID® is a drug used to reduce gastric acid secretions in the stomach and prevent infectious diseases caused by *Helicobacter Pylori*. The active medicinal ingredient in PREVACID® is lansoprazole. It is a compound used to treat gastric ulcers.

THE PATENT

[4] Canadian Patent No. 2,269,053 (the 053 Patent) was filed in the Canadian Patent Office (the Patent Office) on November 13, 1997. On May 12, 2006, a Notice of Allowance was issued which meant that all the requirements for the issuance of the 053 Patent had been met. As well, by that date, the required fee had been paid. However, the 053 Patent did not actually issue until July 18, 2006.

[5] The 053 Patent claims various methods for producing solvent-free lansoprazole crystals and the crystals themselves. There are also three claims related to the crystals' use in the treatment of ulcers. These use claims are the ones which are relevant in this case and are as follows: claim 10 claims a medicine comprising the solvent-free crystal for use as an anti-ulcer agent, claim 12 is for

use of the solvent-free crystal for manufacturing a medicine for use as a anti-ulcer agent and claim 13 is for the use of the solvent-free crystal for treating or preventing ulcers.

[6] On July 20, 2006, the Applicants submitted a patent list (the Patent List) for the purpose of listing the 053 Patent on the Patent Register in relation to a Supplementary New Drug Submission for PREVACID®. The 053 Patent was added to the Patent Register on July 25, 2006. All parties agree that the 053 Patent was properly listed under the *Patented Medicines (Notice of Compliance) Regulations* which then applied (the Old Regulations).

THE SUPPLEMENTARY NEW DRUG SUBMISSION

[7] The Patent List was submitted in relation to Supplementary New Drug Submission (SNDS) number 066102 dated March 31, 2000. It was for a new use of lansoprazole in the treatment of ulcers caused by non-steroidal anti-inflammatory drugs (NSAID). For this reason, SNDS 066102 will hereafter be described as the NSAID SNDS. The NSAID SNDS was entitled "New Indications: Healing of NSAID-Associated Gastric Ulcer and Reduction of Risk of NSAID-Associated Gastric Ulcer."

THE APPLICANTS

[8] TAP Pharmaceuticals Inc. (TAP) is the party which files submissions and receives Notices of Compliance for PREVACID® 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®, 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.

THE DECISION

[10] By letter dated February 22, 2007, the Minister informed the Applicants that notwithstanding their representations to the contrary, the 053 Patent would be removed from the Patent Register pursuant to the Minister's authority to maintain the Patent Register under subsection 3(2) of the New Regulations. Several reasons were given for the Decision but only two were argued on this application.

[11] First, the Minister said that the 053 Patent does not contain a claim to a changed use as required by paragraph 4(3)(c) of the New Regulations. The Minister's view is that, to be listed on the Patent Register against the NSAID SNDS, the 053 Patent must specifically mention the treatment of NSAID ulcers. Since the 053 Patent only refers to the treatment of ulcers generally it fails to meet the Minister's criterion.

[12] Second, the 053 Patent was de-listed because it claims a polymorphic form of lansoprazole and, according to the *Regulatory Impact Analysis Statement* for the New Regulations SOR/DORS/2006-242 (the RIAS), patents claiming polymorphic forms are not eligible for listing on the Patent Register in relation to an SNDS. For this reason, the Minister says that patents which also claim uses of such forms are ineligible.

THE OLD AND NEW REGULATIONS

[13] Attached as Schedule "A" to these reasons, is a chart which was used during the hearing to compare the Old and New Regulations. The following points of comparison are noteworthy:

(i) Subsection 3(1) in the Old Regulations and subsection 3(2) in the New Regulations deal with the Minister's obligation to maintain the Patent Register. The parties agreed that, for the purposes of this case, there are no material differences between the provisions.

(ii) The language used to describe the listing of the patents on the Patent Register has changed. The Old Regulations in subsection 3(3), and paragraphs 4(2)(b) and 4(7)(b) generally spoke of "including" patents on the Patent Register. In contrast, the New Regulations in subsections 3(5), (7), and 4(1), (2), (3) and 4.1(2) generally speak of "adding" patents to the Patent Register.

However, this usage is not entirely consistent because the sections dealing with maintaining the Patent Register in both the Old and New Regulations 3(1) and 3(2) both refer to “adding” and “deleting” patents.

(iii) Subsection 4(3) in the New Regulations is entirely new. It provides only three situations in which a patent is eligible to be added to the Patent Register in relation to an SNDS. These provisions are referred to in paragraph 4(4)(f) of the New Regulations as the “eligibility requirements”. It is paragraph 4(3)(c) that is relevant in this case.

STANDARD OF REVIEW

The parties agree that questions of interpretation of the Old and New Regulations are questions of law and that the Standard of Review is correctness. In this regard, see *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, [2006] 2 S.C.R. 560 at paragraph 25.

THE ISSUES

[14] Against this background, there are two broad issues. The first is whether the Minister had authority under the New Regulations to delete the 053 Patent in the course of maintaining the Patent Register. The second issue is whether the 053 Patent meets the eligibility requirements in paragraph 4(3)(c) of the New Regulations.

Issue 1 – Maintaining the Patent Register

[15] This issue involves the proper interpretation of the New Regulations. In *AstraZeneca*, the Supreme Court reiterated the modern approach to statutory interpretation in the context of the Notice of Compliance Regulations. At paragraph 26 the court wrote:

> It is now trite law that the words of an Act and regulations 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. Further, the scope of a regulation such as the provisions of the *NOC Regulations* is constrained by its enabling legislation, in this case s. 55.2(4) of *Patent Act* (*Biolyse*, at para. 38).

[16] The provisions at issue are subsection 3(2) and paragraph 4(3)(c) of the New Regulations and section 6 of the *Regulations Amending the Patented Medicines (Notice of Compliance) Regulations*, SOR/2006-242 (the Amending Regulations).

[17] Subsection 3(2) obliges the Minister to maintain the Patent Register. It states:

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.

[18] Paragraph 4(3)(c) provides the eligibility requirements for adding a patent to the Patent Register in relation to an SNDS for a changed use. It says:

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

…

(*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.

contient, selon le cas :

[…]

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.

[19] Section 6 of the Amending Regulations is a transitional provision. It sets a cutoff date of June 17, 2006. Patent Lists submitted on or after that date are subject to the New Regulations. The section reads:

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 June 17, 2006.

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 le 17 juin 2006.

[20] The Applicants' submissions on this issue were made under five headings. I will deal with each in turn.

The "Plain Meaning" Submission

[21] The Applicants take the position that since section 4 of the New Regulations deals only with the eligibility requirements for adding patents to the Patent Register, it cannot be that the requirements in paragraph 4(3)(c) can be used in conjunction with the requirement to maintain the

Patent Register in subsection 3(2) of the New Regulations when the Minister is considering deleting patents.

[22] However, in my view, if this approach is taken, subsection 3(2) has no meaning when applied to the deletion of patents because there would be no requirements in section 4 that relate to deletions. In other words, the Applicants' interpretation does not fit within the scheme of the New Regulations which apparently intends subsection 3(2) and section 4 to interrelate on two subjects – both the addition and the deletion of patents.

[23] At the hearing the Applicants emphasized that their interpretation did not eviscerate the Minister's power to maintain the Patent Register because the Minister could, for example, remove patents from the Register if a Drug Identification Number were cancelled, or if a patent expired or had been added in error, or if delisting had been ordered by a Court. However, the problem with this submission is that these situations are not referred to in section 4.

[24] As *AstraZeneca* states at paragraph 26, provisions should, if possible, be construed to fit with the scheme of the Regulations. With that in mind, it is my view 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).

The "Retroactivity" Submission

[25] The Applicants say that the eligibility requirements for listing a patent on the Patent Register in relation to an SNDS in paragraph 4(3)(c) of the New Regulations cannot justify de-listing the 053 Patent because this involves a retroactive application of the New Regulations which is not authorized by section 55.2 of the *Patent Act*, R.S.C. 1985, c. P-4. For this proposition, see *Apotex Inc. v. Canada (Attorney General)* (C.A.), [1994] 1 F.C. 742, at paragraph 126.

[26] I acknowledge that the New Regulations cannot have retroactive effect but I have also concluded that they have no such effect. In my view, the Federal Court of Appeal's decision in *Eli Lilly Canada Inc. v. Canada (Minister of Health)* (2003), 23 C.P.R. (4th) 289 (F.C.A.) is directly on point. There Justice Sharlow, for the majority said this:

> [15] The 1998 amendments also made some changes to section 4 which narrowed the scope of information that is eligible for inclusion on the patent register. Counsel for Eli Lilly argued that the eligibility of any patent lists it submitted prior to the 1998 amendments should not be assessed under the narrower rules. I do not agree. In my view, the 1998 amendments entitle the Minister to delete from the patent register any information that does not meet the requirements of the PMNOC Regulations, as they are established from time to time by the Governor in Council. Thus, a patent that qualified for inclusion on a patent list in 1993, but does not qualify under the 1998 amendments, may be removed at any time after March 11, 1998.
>
> [16] I see no merit in the submission of counsel for Eli Lilly that this offends any right or presumptive right on the part of Eli Lilly not to be subject to retroactive legislation. The 1998 amendments are not retroactive. The 1998 amendments speak only from March 11, 1998. The fact that they properly may apply to cause the removal from the patent list of a patent that was accepted for listing in 1993 does not make the 1998 amendments retroactive...

[27] The Applicants say that I should not accept *Lilly* as a binding precedent because under paragraph 4(7)(b) of the Old Regulations, the Minister was considering whether patents qualified for "inclusion", i.e. both whether they could be added to and deleted from the Patent Register, while under subsection 4(3) of the New Regulations the Minister considers only whether patents can be "added" to the Register.

[28] In my view, this submission is not persuasive. I am not satisfied that the words "include" and "add" are materially different. In the sections relied on by the Applicants both words involve the idea that a patent will be placed on the Patent Register. Paragraph 4(7)(b) of the Old Regulations deals with the contents of a patent list which is being prepared for submission and subsection 4(3) of the New Regulations deals with adding patents to the Register. Given these contexts, there is no basis for concluding that "include" has anything to do with removing patents from the Patent Register.

The "Vested Rights" Submission

[29] The Applicants say that the Minister erred when he interpreted section 6 of the Amending Regulations to mean that paragraph 4(3)(c) of the New Regulations applied to all patents lists submitted after June 17, 2006 whether or not the patents had been listed on the Patent Register before the New Regulations came into force on October 5, 2006. The Applicants base this submission on the presumption against interference with vested rights. They say that they have a

vested right to have the 053 Patent remain on the Patent Register so that it must be addressed by generic companies. As well, they submit they have a vested right to continue the prohibition action they commenced on November 23, 2006 in response to Apotex's filing a Notice of Allegation on September 27, 2006 with respect to the 053 Patent.

[30] However, these submissions depend on the Applicants' alleged right to have the 053 Patent remain on the Patent Register and I have concluded that they have no such right in view of the Minister's obligation to maintain the Register under subsection 3(2) of the New Regulations.

The "Addressability" Submission

[31] The Applicants suggest that the Minister's interpretation of subsection 3(2) of the New Regulations which allows him to delete patents which do not meet the eligibility requirements in section 4 is incorrect because it is inconsistent with the provisions of section 7 of the Amending Regulations. It is another transitional provision and it reads 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 la 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.
(2) Subsection 5(2) 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 supplement to a submission referred to in subsection 5(2) prior to	(2) Le paragraphe 5(2) 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

the coming into force of these Regulations and the date of filing of the supplement is deemed to be the date of the coming into force of these Regulations.	déposé le supplément à une présentation visé à ce paragraphe avant l'entrée en vigueur du présent règlement, et la date de dépôt de ce supplément est réputée être la date d'entrée en vigueur du présent règlement.

[32] Essentially this provision means that, if before October 5, 2006 a generic company filed an abbreviated new drug submission, it would be deemed to be filed on October 5, 2006, thus requiring the generic to address all the patents on the Patent Register at that date. The Applicants say that this provision is meaningless if the 053 Patent is deleted.

[33] I am not persuaded by this submission. In my view, section 7 is only sensibly read if it requires a generic to address all patents properly on the Register at October 5, 2006. The fact that the Minister may delete some patents listed before that date does not render the provision meaningless.

The "Delay" Submission

[34] The Applicants are frustrated because, although they received a Notice of Allowance from the Patent Office dated May 12, 2006, the 053 Patent did not issue until July 18**,** 2006. This meant that they did not have the 053 Patent on June 17, 2006 which was the cut off date for submitting patent lists under the Old Regulations. In spite of this, they say that, based on the Notice of Allowance they had an accrued right to the 053 Patent before June 17, 2006 and the Patent List should therefore be treated as if it had been submitted on or before June 17, 2006.

[35] I was not referred to any case law indicating that a Notice of Allowance creates any rights. Further, the Applicants' frustration is based on the conduct of the Patent Office. It has nothing to do with the Minister who is the respondent in this case. In these circumstances, I am not prepared to conclude that the Minister should deem the 053 Patent List to have been submitted before June 17, 2006 when the 053 Patent was not issued until July 18, 2006.

Issue 2 - Does the 053 Patent meet the requirements of paragraph 4(3)(c) of the New Regulations?

[36] The Minister concedes that the NSAID SNDS was for a new use and that a Notice of Compliance had issued for that new use. However, the Minister says that the 053 Patent which includes three claims for the use of lansoprazole in the treatment of ulcers is not eligible for listing under paragraph 4(3)(c) of the New Regulations because it does not expressly claim the treatment of NSAID ulcers.

[37] However, paragraph 4(3)(c) says that the 053 Patent is eligible to be listed on the Patent Register if it "contains" a claim for the new use, i.e. the treatment of NSAID ulcers. To address the question of whether the 053 Patent claims uses to treat NSAID ulcers, the Applicants adduced the evidence of two experts who they describe as informed and skilled readers of the 053 Patent. The Minister took no issue with their qualifications.

[38] Dr. David Armstrong is a specialist in gastroenterology. He is a professor at McMaster University and Chief of Clinical Service in the Division of Gastroenterology for the Hamilton Health Sciences group of academic hospitals. He is familiar with the use of PREVACID® in the treatment of NSAID-associated gastric ulcers.

[39] Dr. Armstrong reviewed the 053 Patent and at paragraphs 20 and 21 of his affidavit sworn on April 20, 2007, said the following:

> 20. In my opinion, a skilled physician, on May 22, 1998, would have clearly understood the word "ulcer", in claims 10, 12 and 13 to include and refer to NSAID ulcers and would certainly have known that the claims cover the use of the solvent-free crystal for healing NSAID-associated ulcers and reduction of the risk of NSAID associated ulcers. NSAID ulcers are a well-known type of ulcer. As of the relevant date, a skilled physician would readily know that an NSAID ulcer is a type of "ulcer" included within the scope of claims 10, 12 and 13. There is no scientific reason nor is there anything the '053 patent to suggest to the skilled physician any meaning for the claims that would exclude NSAID ulcers, and no such meaning would be given.
>
> 21. Indeed, the disclosure of the '053 Patent discusses the use of the solvent-free crystal as a medicine, as an anti-ulcer agent for treating or preventing ulcers (see page 14 lines 3-11). From this and the claims, a skilled physician would clearly understand that this patent is claiming a medicine and a new use for that medicine; namely, the use of that medicine as an anti-ulcer agent. A skilled physician would have no hesitation in concluding that this description includes NSAID ulcers. Similarly, from reading the claims in light of this disclosure, a skilled physician would understand that claims 10, 12 and 13 claim the use of the medicine (the solvent-free crystal of lansoprazole) for the treatment or prevention of NSAID ulcers.

[40] Dr. Jerry Atwood is the Curators' Professor of Chemistry and Chair of the Department of Chemistry at the University of Missouri-Columbia. At paragraphs 23 and 24 of his affidavit sworn on April 23, 2007, he said:

> 23. A skilled chemist would understand from reading the '053 patent that the term "ulcer" as it is used in claims 10, 12, and 13 is not limited to any particular type of gastric ulcer. Instead, the term "ulcer" would be read and understood by a skilled chemist as referring to all stomach ulcers.
>
> 24. Thus, it is my opinion that a skilled chemist would interpret claim 13 as covering the healing and reducing the risk of stomach ulcers however caused. Similarly, it is my opinion that a skilled chemist would interpret claim 13 as covering any stomach ulcer, however caused.

[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 to the new use of lansoprazole to treat NSAID ulcers.

[42] However, the Minister had a second problem with the 053 Patent. He also considered it to be ineligible to be listed on the Patent Register in relation to the NSAID SNDS because the RIAS says that polymorphic forms cannot be listed against SNDSs.

[43] The relevant passage at page 1518 of the RIAS reads as follows:

> The amendments to section 4 also formally confirm the right to list new patents on the basis of SNDS filings and introduce listing requirements governing that right. Under these requirements, a patent which had been applied for prior to the filing of an SNDS may be submitted in relation to that SNDS provided the purpose of the latter is to obtain approval for a change in use of the medicinal ingredient (i.e. new method of use or new indication), a change in formulation

> or a change in dosage form and the patent contains a claim to the formulation, dosage form or use so changed. This will protect and encourage legitimate and substantive incremental innovation of direct therapeutic application. New patents claiming novel physical forms of the approved medicinal ingredient will not be eligible for listing in this manner.
>
> [my emphasis]

[44] While it is true that the 053 Patent includes claims for the polymorphic form of lansoprazole, it is my view that this fact does not disqualify it for listing under paragraph 4(3)(c) of the Regulations. All that provision requires is that the 053 Patent "contain" a claim for the changed use. As described in paragraph 5 above and as confirmed by the Applicants' experts there are three such claims in the 053 Patent. In my view, it is therefore eligible in spite of the fact that it also contains claims to polymorphic forms.

[45] For these reasons, I have concluded that the 053 Patent meets the eligibility requirements in paragraph 4(3)(c) of the New Regulations and should not have been removed from the Patent Register.

JUDGMENT

THIS COURT ORDERS AND ADJUDGES that

- This application is allowed with costs.
- The 053 Patent is to be listed on the Patent Register under the New Regulations in relation to the NSAID SNDS. The listing is to be as of March 1, 2007 which was the effective date of its de-listing.

"Sandra J. Simpson"
JUDG

SCHEDULE “A”

COMPARISON OF PM(NOC) REGULATIONS

owing SOR/99-379 ne into force on October 1, 1999)	Following SOR/2006-242 (Came into force on Oct. 5, 2006) (includes Erratum of Nov. 15, 2006)	
REGISTER	3.	REGISTER AND PATENT LIST
		(1) The following definitions apply in this section and in section 4. "identification number" means a number, preceded by the letters "DIN", that is assigned for a drug in accordance with subsection C.01.014.2(1) of the *Food and Drug Regulations*. (*identification numérique*) "new drug submission" means a new drug submission as that term is used in Division 8 of Part C of the *Food and Drug Regulations*, but excludes a new drug submission that is based solely on the change of name of the manufacturer. (*présentation de drogue nouvelle*) "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*, but excludes a supplement to a new drug submission that is based solely on one or more of the matters mentioned in any of paragraphs C.08.003(2)(*b*) and (*d*) to (*g*) and subparagraphs C.08.003(2)(*h*)(iv) and (v) of those Regulations. (*supplément à une présentation de drogue nouvelle*)
(1) The Minister shall maintain a register of any information submitted under section 4. To maintain it, the Minister may refuse to add or may delete any information that does not meet the requirements of that section.		(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) If a patent is listed on the register in respect of a new drug submission or supplement to a new drug submission for a drug for which the identification number has been cancelled under paragraph C.01.014.6(1)(*a*) of the *Food and Drug Regulations*, the Minister shall delete the patent from the register 90 days after the date of cancellation.
		(4) Subsection (3) does not apply if the identification number is cancelled under paragraph C.01.014.6(1)(*a*) of the *Food and Drug Regulations* because of a change in manufacturer.
		(5) If, after an identification number is cancelled under paragraph C.01.014.6(1)(*a*) of the *Food and Drug Regulations*, an identification number is assigned for the same drug, the Minister shall add to the register the patent that was deleted under subsection (3) when the Minister receives the document required by section C.01.014.3 of the *Food and Drug Regulations* in respect of the drug.
(2) The register shall be open to public inspection during business hours.		(6) The register shall be open to public inspection during business hours.

owing SOR/99-379 ne into force on October 1, 1999)	Following SOR/2006-242 (Came into force on Oct. 5, 2006) (includes Erratum of Nov. 15, 2006)	
(3) No information submitted pursuant to section 4 shall be included on the register until after the issuance of the notice of compliance in respect of which the information was submitted.		(7) No patent on a patent list or other information 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 the supplement to a new drug submission, as the case may be, to which the patent or information relates.
(4) For the purpose of deciding whether information submitted under section 4 should be added to or deleted from the register, the Minister may consult with officers or employees of the Patent Office.		(8) For the purpose of deciding whether a patent, patent list or other information will be added to or deleted from the register, the Minister may consult with officers or employees of the Patent Office.
PATENT LIST	4.	[heading repealed]
(1) A person who files or has filed a submission for, or has been issued, a notice of compliance in respect of a drug that contains a medicine may submit to the Minister a patent list certified in accordance with subsection (7) in respect of the drug.		(1) A first person who files or who has filed a new drug submission or a supplement to a new drug submission may submit to the Minister a patent list in relation to the submission or supplement for addition to the register.
		(2) A patent on a patent list in relation to a new drug submission is eligible to be added to the register if the patent contains
		(*a*) a claim for the medicinal ingredient and the medicinal ingredient has been approved through the issuance of a notice of compliance in respect of the submission;
		(*b*) a claim for the formulation that contains the medicinal ingredient and the formulation has been approved through the issuance of a notice of compliance in respect of the submission;
		(*c*) a claim for the dosage form and the dosage form has been approved through the issuance of a notice of compliance in respect of the submission; or
		(*d*) a claim for the use of the medicinal ingredient, and the use has been approved through the issuance of a notice of compliance in respect of the submission.
		(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
		(*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;
		(*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
		(*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.

owing SOR/99-379 ne into force on October 1, 1999)		Following SOR/2006-242 (Came into force on Oct. 5, 2006) (includes Erratum of Nov. 15, 2006)	
(2) A patent list submitted in respect of a drug must		(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;	
(*a*) indicate the dosage form, strength and route of administration of the drug;		(*b*) the medicinal ingredient, 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;	
(*b*) set out any Canadian patent that is owned by the person, or in respect of which the person has an exclusive licence or has obtained the consent of the owner of the patent for the inclusion of the patent on the patent list, that contains a claim for the medicine itself or a claim for the use of the medicine and that the person wishes to have included on the register;			
		(*c*) for each patent on the list, the patent number, the filing date of the patent application in Canada, the date of grant of the patent and the date on which the term limited for the duration of the patent will expire under section 44 or 45 of the *Patent Act*;	
(*c*) contain a statement that, in respect of each patent, the person applying for a notice of compliance is the owner, has an exclusive licence or has obtained the consent of the owner of the patent for the inclusion of the patent on the patent list;		(*d*) for each patent on the list, a statement that the first person who filed the new drug submission or the supplement to a new drug submission to which the list relates is the owner of the patent or has an exclusive licence to the patent, or has obtained the consent of the owner of the patent to its inclusion on the list;	
(*d*) set out the date on which the term limited for the duration of each patent will expire pursuant to section 44 or 45 of the *Patent Act*; and			S
(*e*) set out the address in Canada for service on the person of any notice of an allegation referred to in paragraph 5(3)(*b*) or (*c*), or the name and address in Canada of another person on whom service may be made, with the same effect as if service had been made on the person.		(*e*) the address in Canada for service, on the first person, of a notice of allegation referred to in paragraph 5(3)(*a*) or the name and address in Canada of another person on whom service may be made with the same effect as if service were made on the first person; and	
		(*f*) a certification by the first person that the information submitted under this subsection is accurate and that each patent on the list meets the eligibility requirements of subsection (2) or (3).	S
(3) Subject to subsection (4), a person who submits a patent list must do so at the time the person files a submission for a notice of compliance.		(5) Subject to subsection (6), a first person who submits a patent list must do so at the time the person files the new drug submission or the supplement to a new drug submission to which the patent list relates.	

owing SOR/99-379 ne into force on October 1, 1999)	Following SOR/2006-242 (Came into force on Oct. 5, 2006) (includes Erratum of Nov. 15, 2006)		
(4) A first person may, after the date of filing of a submission for a notice of compliance and within 30 days after the issuance of a patent that was issued on the basis of an application that has a filing date that precedes the date of filing of the submission, submit a patent list, or an amendment to an existing patent list, that includes the information referred to in subsection (2).		(6) A first person may, after the date of filing of a new drug submission or a supplement to a new drug submission, and within 30 days after the issuance of a patent that was issued on the basis of an application that has a filing date in Canada that precedes the date of filing of the submission or supplement, submit a patent list, including the information referred to in subsection (4), in relation to the submission or supplement.	
(5) When a first person submits a patent list or an amendment to an existing patent list in accordance with subsection (4), the first person must identify the submission to which the patent list or the amendment relates, including the date on which the submission was filed.			S
(6) A person who submits a patent list must keep the list up to date but may not add a patent to an existing patent list except in accordance with subsection (4).		(7) A first person who has submitted a patent list must keep the information on the list up to date but, in so doing, may not add a patent to the list.	
(7) A person who submits a patent list or an amendment to an existing patent list under subsection (1) or (4) must certify that			S
(*a*) the information submitted is accurate; and			
(*b*) the patents set out on the patent list or in the amendment are eligible for inclusion on the register and are relevant to the dosage form, strength and route of administration of the drug in respect of which the submission for a notice of compliance has been filed.			
		(8) The Minister shall insert on the patent list the date of filing and submission number of the new drug submission or the supplement to a new drug submission in relation to which the list was submitted.	S
	4.1	(1) In this section, "supplement to the 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 referred to in subsection 4(2) may, if the list is added to the register, resubmit the same list in relation to a supplement to the new drug submission, but may not submit a new patent list in relation to a supplement except in accordance with subsection 4(3).	

FEDERAL COURT

NAME OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	T-513-07
STYLE OF CAUSE:	**ABBOTT LABORATORIES LTD. ET AL**
	-and-
	ATTORNEY GENERAL OF CANADA ET AL
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	TUESDAY, JUNE 26, 2007
REASONS FOR JUDGEMENT:	Simpson J.
DATED:	July 31, 2007

APPEARANCES:

Steve Mason Caroline Zayid	FOR APPLICANTS
David Cowie	FOR RESPONDENT

SOLICITORS OF RECORD:

McCarty Tetrault LLP Toronto, Ontario	FOR APPLICANTS
John H. Sims, Q.C. Deputy Attorney General of Canada	FOR RESPONDENT