Date: 20081117

Docket: A-350-08

Citation: 2008 FCA 354

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

BETWEEN:

ABBOTT LABORATORIES LIMITED

Appellant

and

ATTORNEY GENERAL OF CANADA and
THE MINISTER OF HEALTH

Respondents

Heard at Toronto, Ontario, on October 16, 2008.

Judgment delivered at Ottawa, Ontario, on November 17, 2008.

REASONS FOR JUDGMENT BY: SHARLOW J.A.

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

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REASONS FOR JUDGMENT

SHARLOW J.A.

[1] Abbott Laboratories Limited submitted to the Minister of Health an application to list Canadian Patent No. 2,182,620 against the drug Meridia on the patent register maintained by the Minister pursuant to the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the *NOC Regulations*). The Minister refused the request because he concluded that the 620 patent was not eligible for listing against Meridia. Abbott's application for judicial review of the Minister's decision was dismissed by Justice Hughes (2008 FC 700). The main issue on appeal is whether Justice Hughes erred in declining to intervene.

Statutory Framework

[2] The mandate of the Minister includes the administration of the *Food and Drug Regulations*, C.R.C., c. 870. Those regulations are intended to ensure, among other things, that all drugs sold in Canada meet certain standards of safety and efficacy. A drug cannot be sold in Canada without a notice of compliance issued by the Minister under the *Food and Drug Regulations* signifying that the Minister is satisfied that the drug meets those standards. In addition to issuing the notice of compliance, the Minister approves the packaging for the drug and a product monograph that states the approved use of the drug and provides technical information for medical professionals.

[3] The application for a notice of compliance for a new drug (an "innovator" drug) is called a "new drug submission". The task of satisfying the Minister as to its safety and efficacy may require the submission of extensive scientific information, including the results of clinical trials. If a notice of compliance is sought for a drug (a "generic" drug) that is similar in specified respects to an innovator drug for which a notice of compliance has been issued, the approval process may be shortened because the generic drug producer may rely on specified comparisons to the innovator drug. An application for a notice of compliance using the shortened procedure is called an "abbreviated new drug submission".

[4] If an innovator drug embodies the invention described in a patent, the patent must be respected by a generic drug producer wishing to market a generic version of the drug. However, by virtue of section 55.2 of the *Patent Act*, R.S.C. 1985, c. P-4, it is not an infringement for the generic drug producer to do the work reasonably required to prepare an abbreviated new drug submission

for its generic version based on permitted comparisons to the innovator drug. Section 55.2 is called the “early working exception”.

[5] Subsection 55.2(4) of the *Patent Act* empowers the Governor in Council to make regulations intended to deter abuses of the early working exception. The Governor in Council exercised that power in enacting the *NOC Regulations*.

[6] Pursuant to the *NOC Regulations*, the Minister is required to maintain a “patent register”. The holder of a notice of compliance for an innovator drug that embodies the invention described in a patent may, subject to a number of conditions, list the patent against the drug. Generally, a generic drug producer seeking a notice of compliance for a generic version of the innovator drug on the basis of an abbreviated new drug submission must “address” the patents listed against the innovator drug. That may be done in a number of ways. One is by alleging that the generic drug will not infringe the listed patent. Another is by alleging that the listed patent is invalid.

[7] If an allegation of non-infringement or invalidity is made, the innovator has the right to commence an application in the Federal Court to challenge the allegation. Commencing the application automatically prevents the Minister from issuing a notice of compliance for the generic drug for a period of time, generally 24 months (shorter if the application is dismissed before the end of that period, longer if the Federal Court extends the time). That delay in the market entry of the generic drug may represent a significant economic advantage to the innovator and a corresponding economic detriment to the generic drug producer. From the point of view of generic drug producers,

the automatic delay has been characterized as “draconian” because it operates regardless of the merits of any patent dispute that might arise between the innovator and the generic drug producer (see *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)*, [1998] 2 S.C.R. 193, at paragraph 33, per Justice Iacobucci, writing for the Court).

[8] The disposition of a prohibition application turns on the determination of the Federal Court as to whether the allegation of non-infringement or invalidity is justified. If the allegation is not justified, the Federal Court prohibits the Minister from issuing a notice of compliance for the generic drug until after the expiry of the patent. If it is justified, the Federal Court dismisses the application and the Minister is free to issue a notice of compliance for the generic drug once the requirements of the *Food and Drug Regulations* are satisfied.

[9] The producer of an innovator drug that embodies the invention described in a patent obtains the advantages of the *NOC Regulations* only if the patent is listed against the drug. There is a large and growing body of jurisprudence resolving disputes about the eligibility of a patent for listing. Some of that litigation has resulted in amendments to the *NOC Regulations*. The eligibility of a patent for listing is now determined by subsection 4(2) of the *NOC Regulations*, which reads in relevant part as follows:

4. (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	4. (2) Est admissible à l’adjonction au registre tout brevet, inscrit sur une liste de brevets, qui se rattache à la présentation de drogue nouvelle, s’il contient, selon le cas :
[…]	[…]
(*d*) a claim for the use of the medicinal ingredient, and the use has been approved	*d*) une revendication de l’utilisation de l’ingrédient médicinal, l’utilisation ayant

through the issuance of a notice of compliance in respect of the submission.	été approuvée par la délivrance d'un avis de conformité à l'égard de la présentation.

Facts

[10] Abbott is permitted to market Meridia in Canada pursuant to a notice of compliance issued on December 28, 2000 in response to new drug submission number 048598. The medicinal ingredient in Meridia is sibutramine hydrochloride monohydrate, also known as sibutramine.

[11] The product monograph for Meridia, as approved by the Minister, categorizes Meridia as an "anorexiant/antiobesity agent". It states that Meridia is approved for use "as adjunctive therapy within a weight management program" for obese patients with a body mass index of 30 kg/m^2 or higher, or obese patients with a body mass index of 27 kg/m^2 or higher in the presence of "other risk factors (e.g. controlled hypertension, type 2 diabetes, dyslipidemia, visceral fat)".

[12] The product monograph also states the following in bold type under the heading "Dosage and Administration" (at page 20):

> Treatment with MERIDIA® (sibutramine hydrochloride monohydrate) should only be given as part of an integrated therapeutic approach for weight reduction and weight maintenance under the care of a physician with experience in the treatment of obesity.

[13] There is one patent listed against Meridia, Canadian Patent No. 2,003,524. It has a filing date of November 21, 1989 and has a twenty year term. It apparently claims the use of sibutramine in the treatment of obesity.

[14] The application for the 620 patent was filed on February 3, 1995 and the 620 patent was issued on January 16, 2007. It is entitled “improving glucose tolerance”. The parties agree that the issues in this appeal are to be determined on the basis of claim 6 only. Claim 6 reads as follows:

> *6. The use of N,N-dimethyl-1-[1-(4-chlorophenyl)-cyclobutyl]- 3-methylbutylamine hydrochloride monohydrate for improving the glucose tolerance of humans having Impaired Glucose Tolerance or Non-Insulin Dependent Diabetes Mellitus.*

[15] On February 15, 2007, Abbott submitted an application requesting the Minister to list the 620 patent on the patent register against Meridia. By letter dated February 23, 2007, the Minister informed Abbott of his preliminary determination that the 620 patent is not eligible for listing because the use described in the claims of the 620 patent is not the approved use of Meridia.

[16] Representatives of Abbott and the Minister met on May 7, 2007. The representatives of Abbott were accompanied by Dr. Richard Lewanczuk, an endocrinologist claiming expertise in a number of subjects, including obesity, diabetes and insulin resistance. For the purposes of this appeal, I assume without deciding that Dr. Lewanczuk’s expertise qualifies him to opine on matters relating to the construction of claim 6 of the 620 patent. The record does not suggest that the Minister or Justice Hughes concluded otherwise.

[17] At the meeting of May 7, 2007, Dr. Lewanczuk made a presentation to the Minister’s representatives. That meeting was followed by a letter dated June 7, 2007, in which Abbott explained that it takes the position the 620 patent is eligible for listing because of the analysis presented by Dr. Lewanczuk at the meeting. I summarize that analysis as follows:

The 620 patent

1. A person skilled in the art would understand the following:
    a) The phrase “impaired glucose tolerance” as used in claim 6 of the 620 patent means pre-diabetes or pre-type 2 diabetes.
    b) The phrase “non-insulin dependent diabetes mellitus” as used in claim 6 means type 2 diabetes.
    c) Pre-type 2 diabetes and type 2 diabetes are conditions characterized by a deviation from normal glucose tolerance, with type 2 diabetes representing a more severe deviation than pre-type 2 diabetes.
2. A person skilled in the art would conclude that claim 6 refers to the use of sibutramine for improving the glucose tolerance of humans having pre-type 2 diabetes or type 2 diabetes.

The approved use of Meridia

3. A physician reading the product monograph for Meridia would understand that the use of sibutramine as adjunctive therapy within a weight management program would lead to improved glucose tolerance along with weight loss.
4. It follows that a physician would conclude that the approved use of Meridia would include its use for the purpose of improving glucose tolerance in persons with pre-type 2 diabetes or type 2 diabetes.

[18] Abbott has argued in this appeal that the letter of June 7, 2007 was not intended to suggest that Meridia was approved for the treatment of type 2 diabetes itself, or for the treatment of non-obese diabetic patients. The letter is somewhat ambiguous on that point. However, it is fair to say that the letter is intended to persuade the Minister at least that the use of Meridia to treat obesity should be understood to include the use of Meridia to improve glucose tolerance.

[19] In addition to summarizing Dr. Lewanczuk's oral presentation, Abbott's June 7, 2007 letter to the Minister points out that the efficacy of sibutramine in improving glucose tolerance formed part of the basis for the issuance of the notice of compliance for Meridia. In support of that proposition, Abbott referred to studies described in the product monograph, and also to the portion of the product monograph entitled "Mechanism of Action", which states among other things that sibutramine enhances satiety (reducing appetite) and also increases energy expenditure by induction of thermogenesis. The latter involves metabolic changes that improve glucose tolerance, which in turn discourages the production of fat in the abdomen and promotes weight loss.

[20] In summary, Abbott submitted to the Minister that, because the use of Meridia to treat obesity results in improved glucose tolerance, and because improving glucose tolerance is the objective of treating persons with pre-type 2 diabetes or type 2 diabetes, Meridia is approved for the use of improving glucose tolerance in persons with pre-type 2 diabetes or type 2 diabetes.

[21] By letter dated July 25, 2007, the Minister informed Abbott of his decision not to list the 620 patent. The basis of his conclusion appears in this excerpt from that letter:

> … MERIDIA is approved as an antiobesity agent/anorexiant for the use in adjunctive therapy within a weight management program to treat obese patients. It is not indicated for the treatment of hypertension, type 2 diabetes (Non-Insulin Dependent Diabetes Mellitus), dyslipidemia, and visceral fat.
>
> In contrast, the '620 patent contains claims for the use of sibutramine hydrochloride monohydrate for improving the glucose tolerance of humans having Impaired Glucose Tolerance (pre-type 2 diabetes) or Non-Insulin Dependent Diabetes Mellitus (type 2 diabetes). The claims are not directed towards the treatment of obesity. As such, the OPML [the Minister] is of the position that the uses claimed in the '620 patent have not been approved through the issuance of the notice of compliance for the drug product MERIDIA and as such, the '620 patent is not eligible to be added to the Patent Register in respect of new drug submission 048598.

[22] As I read the Minister's reasons, he accepted the argument of Abbott that claim 6 of the 620 patent refers to the use of sibutramine for improving the glucose tolerance of humans having pre-type 2 diabetes or type 2 diabetes, but he concluded that the 620 patent is not eligible for listing because Meridia is not approved for that purpose.

[23] Abbott applied to the Federal Court for judicial review of the Minister's decision not to list the 620 patent. In support of its application, it submitted the affidavit of Loretta Del Bosco, an employee of Abbott, that attests to procedural facts and authenticates the main documents considered by the Minister in reaching his decision, including the product monograph for Meridia, the 620 patent, the application for the patent listing, the Minister's letter dated February 23, 2007,

stating his preliminary conclusion, the Abbott letter to the Minister dated June 7, 2007, and the Minister's letter dated July 25, 2007 stating his decision.

[24] Abbott also submitted the affidavit of Dr. Lewanczuk sworn October 9, 2008. That affidavit was not before the Minister when he made the decision sought to be reviewed. Justice Hughes concluded that most of the affidavit was inadmissible. He took into account only paragraphs 44 to 51 of that affidavit, which are the paragraphs in which Dr. Lewanczuk presents his expert opinion in relation to the construction of the claims of the 620 patent. Justice Hughes dismissed Abbott's application for judicial review of the Minister's decision.

[25] For the purposes of this appeal, the parties agree on the following facts. "N,N-dimethyl-1-[1-(4-chlorophenyl)-cyclobutyl]- 3-methylbutylamine hydrochloride monohydrate", the substance named in claim 6 of the 620 patent, means sibutramine. The terms "impaired glucose tolerance" and "pre-type 2 diabetes" are synonymous. The terms "non-insulin dependent diabetes mellitus" and "type 2 diabetes" are also synonymous. The medical treatment of either condition is aimed at improving glucose tolerance. Some but not all persons with pre-type 2 diabetes or type 2 diabetes are obese. Some but not all obese persons have pre-type 2 diabetes or type 2 diabetes.

Standard of review

[26] The parties agree that Justice Hughes' review of the Minister's decision applied the standard of reasonableness, following *Dunsmuir v. New Brunswick*, [2008] 1 S.C.R. 190, 2008 SCC 9, which

is now the leading case on the determination of the standard of review in matters of administrative law. The Minister argues that Justice Hughes was correct to apply that standard of review.

[27] Abbott argues that Justice Hughes should have applied the standard of correctness. Abbott's argument relies on *Abbott Laboratories Ltd. v. Canada (Attorney General)*, 2008 FCA 244, at paragraphs 32 and 33, citing *Eli Lilly Canada Inc. v. Canada (Minister of Health) (F.C.A.)*, [2003] 3 F.C. 140, at paragraph 5. Each of those cases involved a challenge to the decision of the Minister to list a patent, but the only debate was the interpretation of the *NOC Regulations*. In this case, the Minister's decision also required him to determine the approved use of Meridia.

[28] Justice Hughes analyzed the Minister's decision as comprising three questions. Both parties accept that he was correct to ask himself those three questions. In determining the standard of review, Justice Hughes considered the applicable standard of review separately for each of the three questions (see paragraphs 24 to 28 of his reasons). I will discuss each of the questions in turn.

[29] The first question is: "What use does the patent claim?" Justice Hughes concluded that this is a matter of construction of the patent claim, which is a question of law to be reviewed on the standard of correctness. I agree. No one argues that any other standard of review should apply to this question.

[30] The second question is: “What is the use approved by the existing notice of compliance?” Justice Hughes concluded that this is a question of fact to be reviewed on the standard of reasonableness. I agree that the standard is reasonableness, but based on different reasoning.

[31] The determination of the approved use of a drug requires an interpretation of the notice of compliance and the product monograph. Generally, the interpretation of a document that defines legal rights and obligations is a question of law, and on that basis it is arguable that the interpretation of a product monograph is a question of law, rather than a question of fact as Justice Hughes found. Even so, it is an interpretative exercise that must necessarily be informed by a particular expertise in matters of the safety and efficacy of drugs. Those are matters on which the Minister is more expert than the Court. Further, it results in a determination that relates to a single case, rather than a principle of general application. Based on those considerations, I conclude that in a judicial review of the Minister’s decision to accept or reject a patent for listing, the Minister’s determination of the approved use of a drug should be reviewed on the standard of reasonableness, even if it is a question of law.

[32] The third question is: “Is the use claimed by the patent that which is approved by the existing notice of compliance?” Justice Hughes characterized this as a question of mixed fact and law, and concluded that “considerable deference” should be given to the Minister’s decision. I take that to mean that in reviewing the Minister’s determination of this question, Justice Hughes applied the standard of reasonableness.

[33] In my view, Justice Hughes' analysis of the standard of review to be applied to the third question is incomplete. I agree that the third question is a question of mixed fact and law because it requires an application of the law to the facts. I also agree that the factual component must be reviewed on a standard of reasonableness. However, the legal component of that question, which in this case is the meaning of paragraph 4(2)(*d*) of the *NOC Regulations*, must be reviewed on a correctness standard: see *Ferring Inc. v. Canada (Minister of Health)*, 2007 FCA 276, as altered by the abolition of patent unreasonableness as a permitted standard of review (*Dunsmuir*, cited above); see also *Eli Lilly* and *Abbott Laboratories* (cited above).

[34] In summary, the Minister's decision not to list the 620 patent must stand unless it is based on an incorrect construction of claim 6 of the 620 patent, an incorrect interpretation of paragraph 4(2)(*d*) of the *NOC Regulations*, an unreasonable conclusion as to the approved use of Meridia, or an unreasonable conclusion as to whether the use of the sibutramine claimed in the 620 patent is an approved use of Meridia.

Evidence on judicial review

[35] Justice Hughes on his own motion questioned whether Abbott was entitled to adduce evidence in the form of the affidavit of Dr. Lewanczuk. He concluded that the affidavit should be disregarded except for paragraphs 44 to 51 which, in his view, represented relevant and admissible expert evidence as to how a person skilled in the art would understand the claims of the 620 patent. The Minister did not object to that limited use of the affidavit, and does not object now.

[36] Abbott argues that Justice Hughes was wrong to raise the question of the admissibility of the affidavit at the hearing, without advance notice, in the absence of an objection from the Minister. It is not clear whether Abbott requested an adjournment to deal with this issue, but there is no reason to believe that could not have been done. In any event, the admissibility of the affidavit was a question for Justice Hughes alone. He was not bound by the consent of the parties or the absence of an objection, although he could have taken those factors into account. In my view, Abbott's argument on this point is based on a misunderstanding of the judicial review procedure.

[37] The general rule in an application for judicial review is that the record before the Federal Court should not include any documentary evidence that was not before the maker of the decision sought to be reviewed. The rationale for this rule is judicial efficiency. In an application for judicial review, unlike an originating application (such as an application for prohibition under the *NOC Regulations*), the Federal Court is not the decision maker of first instance, but rather is reviewing the decision of someone else, in this case the Minister. Judicial resources would be wasted if the parties to an application for judicial review of the Minister's decision, having failed to put their best foot forward before the Minister, could hope to provide additional evidence in the Federal Court to impugn the Minister's decision.

[38] Exceptions to the general rule are recognized for facts that are relevant to an allegation of a breach of natural justice or an allegation of bias, but those exceptions are not relevant here. I see no reason in principle to recognize a blanket exception for an application to the Federal Court for judicial review of a decision of the Minister not to list a patent on the patent register.

[39] However, where an application for judicial review requires a determination on a point of patent construction, it may well be helpful to the Federal Court judge to have the benefit of a formal expert opinion on patent construction, in the form of an affidavit. For that reason, the judge should have the discretion to admit such an affidavit or, as in this case, the portions of an affidavit containing the expert opinion on patent construction. In exercising that discretion, the judge should consider whether or not the construction of the patent proposed in the affidavit is one that was put to the Minister for consideration.

[40] In this case, the expert opinion of Dr. Lewanczuk on patent construction was presented to the Minister orally at the meeting of May 7, 2007, as documented in the letter dated June 7, 2007 to the Minister from Abbott's counsel. Justice Hughes properly exercised his discretion to consider paragraphs 44 to 51 of the affidavit of Dr. Lewanczuk dealing with his expert opinion, and to refuse to consider the other paragraphs of Dr. Lewanczuk's affidavit dealing with other matters.

[41] Even if I had concluded that Justice Hughes was wrong to consider paragraphs 44 to 51 of Dr. Lewanczuk's affidavit, I would disregard that error in determining this appeal. There are three reasons for that. First, the Minister has never objected and still does not object to consideration of those paragraphs by Justice Hughes. Second, the substance of the paragraphs considered by Justice Hughes was set out in the letter dated June 7, 2007 from Abbott's counsel to the Minister. Third, there is no real controversy on the construction of claim 6 of the 620 patent.

[42] I emphasize that an applicant for a patent listing who engages in a debate with the Minister about the construction of a patent claim is not required as a matter of law to provide the Minister with an expert opinion in the form of an affidavit (although it may do so). Nor is the Minister required to support his construction of a patent claim with an expert opinion in the form of an affidavit (although he may do so). The Minister is entitled to determine what evidence he considers relevant, in any form that he considers acceptable, and is not obliged to follow the laws of evidence in considering questions of patent listing. However, it may be difficult or impossible to establish what evidence was before the Minister, if the evidence is not documented at all.

[43] I will now discuss the three questions considered by Justice Hughes.

Construction of claim 6 of the 620 patent

[44] Counsel for Abbott agreed at the hearing that, for the purposes of this appeal, the following construction of claim 6, as stated at paragraph 33 in the reasons of Justice Hughes, may be taken as correct:

> 6. The use of sibutramine for improving the glucose tolerance of humans, obese and otherwise, having pre-type 2 diabetes or type 2 diabetes.

[45] The inclusion of the phrase “obese and otherwise” in Justice Hughes’ construction of claim 6 does not reflect any express statements in the 620 patent. Rather, it is intended to emphasize that claim 6, properly construed, is not limited to the treatment of persons who are obese. As stated above, a person with pre-type 2 diabetes or type 2 diabetes may or may not be obese.

[46] As I read the Minister's decision, the construction of claim 6 of the 620 patent that he implicitly adopted is substantially the same as the construction of that claim by Justice Hughes. For that reason, I conclude that for the purposes of this appeal, there is no dispute about the construction of claim 6.

Approved use of Meridia

[47] Abbott argued in its submissions to the Minister that, because the use of sibutramine to treat obesity leads to improved glucose tolerance along with weight loss, physicians would believe that they are permitted to use sibutramine for the purpose contemplated by claim 6 (that is, improving glucose tolerance in persons with pre-type 2 diabetes or type 2 diabetes). The Minister rejected that argument because obesity is not the same as a condition such as type 2 diabetes that may or may not be associated with obesity. More specifically, the Minister determined that Meridia is approved for use in the treatment of obese persons with a certain initial body mass index, but it is not approved for the treatment of other conditions, such as type 2 diabetes, even if they may be associated with obesity. Justice Hughes found the Minister's determination to be reasonable. I agree. In this regard, I emphasize that the Minister's understanding of the uses he has approved for a drug is entitled to considerable deference.

[48] Abbott argued in the appeal that, although the Minister concluded that Meridia is not approved for the treatment of persons with type 2 diabetes, he did not say whether Meridia is approved for the use of improving glucose tolerance in persons with pre-type 2 diabetes. There is no merit in this argument. A fair reading of the Minister's letters leaves no doubt that he did not

consider Meridia to be approved for anything except the treatment of obesity in persons who meet the specific criteria set out in the product monograph.

Comparing the claimed use of sibutramine and the approved use of Meridia

[49] The Minister concluded that the claimed use of sibutramine is not the approved use of Meridia. Justice Hughes found that conclusion to be reasonable. I agree, in relation to the factual elements of the conclusion. It remains only to consider whether this conclusion is based on an incorrect interpretation of paragraph 4(2)(*d*) of the *NOC Regulations*.

[50] It appears to me that the principal dispute about the meaning of paragraph 4(2)(*d*) of the *NOC Regulations* is based on Abbott's argument that, because claim 6 would necessarily be infringed by the use of sibutramine for improving the glucose tolerance of an obese person with pre-type 2 diabetes or type 2 diabetes, the patent should be listed against Meridia.

[51] As stated above, it is now agreed that for the purposes of this appeal, claim 6 of the 620 patent should be construed as follows (my emphasis):

> 6. The use of sibutramine for improving the glucose tolerance of humans, obese and otherwise, having pre-type 2 diabetes or type 2 diabetes.

[52] If claim 6 is valid (and there is no challenge in this case to the validity of claim 6), Abbott may well be correct to say that claim 6 would be infringed by the use of sibutramine for improving the glucose tolerance of an obese person with pre-type 2 diabetes or type 2 diabetes. However, I need not express an opinion on that point. Abbott's argument is based on the premise that paragraph

4(2)(*d*) of the *NOC Regulations* asks whether the use of Meridia for the purpose approved by the Minister would or might infringe claim 6 of the 620 patent. In my view, that is not the question asked by paragraph 4(2)(*d*).

[53] As explained above, the eligibility of a patent for listing against an approved drug is governed by paragraph 4(2)(*d*) of the *NOC Regulations*, reproduced here for ease of reference:

4. (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	4. (2) Est admissible à l'adjonction au registre tout brevet, inscrit sur une liste de brevets, qui se rattache à la présentation de drogue nouvelle, s'il contient, selon le cas :
[…]	[…]
(*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.	*d*) une revendication de l'utilisation de l'ingrédient médicinal, l'utilisation ayant été approuvée par la délivrance d'un avis de conformité à l'égard de la présentation.

[54] As I read paragraph 4(2)(*d*), it asks whether claim 6 of the 620 patent claims a use of the sibutramine that is an approved use of Meridia. That question was deliberately chosen for the current version of paragraph 4(2)(*d*) of the *NOC Regulations* to avoid the broad interpretation given to the more general provision it replaced (compare, *Eli Lilly* (cited above) at paragraphs 34 and 35, and the *Regulatory Impact Analysis Statement*, Canada Gazette Part II, Vol. 140, No. 21 (October 18, 2006), at page 1514). To accept the broader infringement question posed by Abbott as a permissible means of interpreting paragraph 4(2)(*d*) would not be consistent with its current language, or the purpose for which it was enacted.

[55] I have not ignored the argument of Abbott that, according to paragraph 4(2)(*d*) of the *NOC Regulations*, the 620 patent is eligible for listing if only one of the uses it claims for sibutramine is an approved use of Meridia. It seems to me that the Minister does not disagree with that proposition. However, the Minister concluded, reasonably in my view, that Meridia is not approved for improving glucose tolerance in anyone.

[56] I conclude that the Minister's decision not to list the 620 patent was based on a correct interpretation of paragraph 4(2)(*d*) of the *NOC Regulations*.

Conclusion

[57] I summarize as follows the three questions the Minister was required to consider in determining whether the 620 patent was eligible for listing against Meridia, and the Minister's answers to those questions:

1. What use of sibutramine is claimed by the 620 patent? Answer: It claims the use of sibutramine for improving the glucose tolerance of humans, obese and otherwise, having pre-type 2 diabetes or type 2 diabetes.

2. What is the approved use of Meridia? Answer: Meridia is approved for use as adjunctive therapy within a weight management program for obese patients with a body mass index of 30 kg/m^2 or higher, or obese patients with a body mass index of

27 kg/m^2 or higher in the presence of other risk factors (e.g. controlled hypertension, type 2 diabetes, dyslipidemia, visceral fat).

3. Is the use of sibutramine claimed by the 620 patent an approved use of Meridia?

Answer: No.

[58] Justice Hughes dismissed the application for judicial review because the Minister's decision not to list the 620 patent against Meridia was correct in law and reasonable in fact. I agree. I would dismiss this appeal with costs.

"K. Sharlow"

J.A.

"I agree.
Gilles Létourneau J.A."

"I agree.
J.D. Denis Pelletier J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-350-08

AN APPEAL FROM THE JUDGMENT OF THE HONOURABLE MR. JUSTICE HUGHES, DATED JUNE 4, 2008, IN DOCKET NO. T-1564-07

STYLE OF CAUSE:	*ABBOTT LABORATORIES LIMITED v. ATTORNEY GENERAL OF CANADA and THE MINISTER OF HEALTH*
PLACE OF HEARING:	Toronto, Ontario
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REASONS FOR JUDGMENT BY:	SHARLOW J.A.
CONCURRED IN BY:	LÉTOURNEAU J.A. PELLETIER J.A.
DATED:	November 17, 2008

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