Date: 20080604

Docket: T-1564-07

Citation: 2008 FC 700

Toronto, Ontario, June 4, 2008

PRESENT: The Honourable Mr. Justice Hughes

BETWEEN:

ABBOTT LABORATORIES LIMITED

Applicant

and

ATTORNEY GENERAL OF CANADA
and MINISTER OF HEALTH

Respondents

REASONS FOR JUDGMENT AND JUDGMENT

[1] The Applicant, Abbott Laboratories Limited is seeking judicial review of a decision of the Minister of Health not to list Canadian Letters Patent No. 2,182,620 (the '620 patent) on the Patent Register pursuant to the *Patented Medicines (Notice of Compliance) Regulations),* SOR/93-133 as amended, October 5, 2006, (*NOC Regulations*) in respect of a certain Notice of Compliance (NOC) issued to the Applicant in respect of a drug known as MERIDA. For the reasons that follow, I find that the application is dismissed with costs.

[2] The *NOC Regulations* were first put in place in 1993. Several amendments have been made to those Regulations. Of importance here are the *NOC Regulations* as amended on October 5, 2006

in respect of listing- adding to the register- a patent in respect of the use of a medicine. Sections 4(1) and 4(2)(d) of the *NOC Regulations*, as so amended, read:

4. *(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.*	***4.*** *(1) La première personne qui dépose ou a déposé la présentation de drogue nouvelle ou le supplément à une présentation de drogue nouvelle peut présenter au ministre, pour adjonction au registre, une liste de brevets qui se rattache à la présentation ou au supplément.*
(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	*(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.*

[3] In this case, the Applicant already has an NOC relating to the medicine, sibutramine, number 048598 and it seeks to add the '620 patent to the list of patents kept in respect thereof. The Minister refused to do so.

[4] To determine whether a patent should be added to an existing NOC under the provisions of paragraph 4(2)(d) of the amended *NOC Regulations*, the Minister is required to make a three step determination:

1. What use does the patent claim?

2. What is the use approved by the existing NOC?

3. Is the use claimed by the patent that which is approved by the existing NOC?

[5] The Minister in the present case determined that the use claimed in the ’620 patent was not the use approved by NOC 048598 thus the Minister would not accept that patent for listing as against that NOC.

[6] The Minister’s decision was set out in a letter dated July 25, 2007, from David Lee who was at the time the Director of the relevant department. That letter states, in part:

> *As per paragraph 4(2)(d) of the PM(NOC) Regulations, a patent on a patent list in relation to a new drug submission is eligible to be added to the Patent Register if the patent contains 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 new drug submission****. In the view of the OPML, the ’620 patent does not contain a claim for the use of the medicinal ingredient which has been approved through the issuance of a notice of compliance in respect of new drug submission 048598 for the drug product MERIDIA.*
>
> *The approved use of MERIDIA as indicated in the Product Monograph is for adjunctive therapy within a weight management program for: obese patients with an initial body mass index of 30kg/m^2 or higher, or obese patients with an initial body mass index of 27kg/m^2 or higher in the presence of other risk factors (eg. controlled hypertension, type 2 diabetes, dyslipidemia, and visceral fat). As such, 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 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.*
>
> *As discussed in the Regulatory Impact Analysis Statement accompanying the October 5, 2006 amendments to the PM (NOC) Regulations, product specificity is the key consideration required of the Minister in applying the listing requirements under section 4 of the PM(NOC) Regulations. The amended language of section 4 more precisely reflects the intended link between the subject matter of a patent on a patent list and the content of the underlying submission for the notice of compliance in relation to which it is submitted. In the view of the OPML, listing of the '620 patent on the Patent Register would undermine the intent of the PM(NOC) Regulations in this respect.*
>
> *Therefore, pursuant to the authority vested in the Minister of Health by subsection 3(2) of the PM(NOC) Regulations, the '620 patent will not be added to the Patent Register for the above-noted drug submission.*

[7] The Applicant says that the Minister's decision was wrong and that the uses claimed in the patent and the NOC are sufficiently related so as to permit listing. The Respondents say that the Minister's decision was right.

ISSUES

[8] The issue, put simply, is whether the Minister's decision was correct or reasonable as the case may be, and if not, should the Court simply send the matter back for redetermination or should the Court direct that the Minister list the patent and, if so, as of the date the request to list was made or as of the date of Judgment.

[9] In determining the fundamental issue, I am required to consider a number of matters, namely:

1. Should the Court receive new evidence in the way of Dr. Lewanczuk's affidavit in whole or in part and if so, for what purpose or purposes?
2. What is the proper standard of review of the Minister's decision?
3. Having regard to the proper standard of review:
    - What is the proper construction of the claims of the '620 patent?
    - What is the proper determination of the uses already approved in the existing NOC?
    - What is a proper comparison of the claim and NOC approved uses?

NEW EVIDENCE OF DR. LEWANCZUK

[10] This proceeding is a judicial review. As such, the Court should only be looking at the record that the Minister had before him or her in arriving at the decision under review. The Courts have, therefore, received into evidence the record before the decision-maker whether as a certified record or under affidavit of an appropriate person. The affidavit of Anne Bowes filed by the Respondents and that of Loretta del Bosco filed by the Applicant serve this purpose as well as certain certified documents.

[11] The affidavit of Dr. Lewanczuk falls into a different category. He purports to give expert evidence as to the treatment of obesity, obesity and impaired glucose tolerance, MERIDIA and its approved uses, sibutramine use in a weight management program, improved glucose tolerance as a

secondary endpoint, his experience prescribing sibutramine, how the person skilled in the art would read the ’620 patent and certain conclusions as to whether the use claimed by the ’620 patent is within the use approved by the NOC.

[12] Dr. Lewanczuk apparently attended a meeting between representatives of the Applicant and of the Minister. There is no contemporaneous record as to what was said at that meeting. There is no evidence of any written submission made by Dr. Lewanczuk. The only evidence as to what he said at the meeting is found in the submissions made by the Applicant’s lawyer in a letter dated June 7, 2006 to the Minister’s representatives. That letter says, in part:

> ***SUMMARY OF ABBOTT’S POSITION***
>
> *In Abbot’s view, the 620 Patent contains claims for the approved use of sibutramine, the medicinal ingredient in Meridia®. A physician practising today would understand the approved use of Meridia® to include the use of “improving the glucose tolerance of humans having Impaired Glucose Tolerance or Non-Insulin Dependent Diabetes Mellitus”, as recited in the claims of the 620 Patent.*
>
> *Abbott’s position in this respect is strongly supported by the opinion of Dr. Richard Lewanczuk, a leading expert on obesity and diabetes.*
>
> ***SUBMISSIONS***
>
> ***620 Patent Contains Claims for the Approved Use***
>
> *On May 7, 2007, Dr. Lewanczuk and representatives of Abbott attended a meeting with Anne Bowes, Michelle Ciesielski, Waleed Jubran and other representatives of OPML to discuss issues relating to the listability of the 620 Patent. During that meeting, Dr. Lewanczuk gave his opinion that a physician would understand the approved use of sibutramine to include “improving the glucose tolerance of humans having Impaired Glucose Tolerance or Non-*

> *Insulin Dependent Diabetes Mellitus", as recited in the claims of the 620 Patent.*

[13] The nature of Dr. Lewanczuk's submissions can be gathered from page 7 of the letter of June 7, 2007 which says in part:

> <u>*Sibutramine Currently Used for Improving Glucose Tolerance*</u>
>
> *In fact, physicians currently use sibutramine as an approved therapeutic option for "improving the glucose tolerance of humans having Impaired Glucose Tolerance [i.e., pre-type 2 diabetes] or Non-Insulin Dependent Diabetes Mellitus [i.e., type 2 diabetes]".*
>
> *As Dr. Lewanczuk pointed out, it is now well-known that improving glucose tolerance improves both Impaired Glucose Tolerance (i.e. pre-type 2 diabetes) and Non-Insulin Dependent Diabetes Mellitus (i.e., type 2 diabetes) and that a weight management program improves glucose tolerance.*[8]
>
> *However, weight management programs involving dietary and lifestyle changes alone are only partially effective due to many patients' inability to adapt to and maintain such changes. It is now well known that the low success rate of non-pharmacologic weight management programs is greatly increased by adjunctive pharmacologic therapy using drugs such as sibutramine.*[9]
>
> *As Dr. Lewanczuk emphasised, there would be no doubt in the mind of a physician practising today that the use of sibutramine as adjunctive therapy, within a weight management program, would lead to improved glucose tolerance along with weight loss. The physician would prescribe sibutramine for such a use. In doing so, the physician would be guided by the Product Monograph for MERIDIA®: …*

[14] Care must be taken when referring to Dr. Lewanczuk's affidavit filed with the Court in these proceedings. This is a judicial review of the Minister's decision thus regard is to be had only to the record before the Minister. Additional evidence filed with the Court that may endeavour to add to, correct, and supplement the evidence before the Minister is not permissible on a judicial review.

Additional evidence can only be filed with the Court where it describes the proceedings and the evidence before the tribunal whose decision is under review, or where jurisdiction or lack of procedural fairness or bias is in issue (see e.g. *Kante v. Canada (Minister of Public Safety and Emergency Preparedness)*, 2007 FC 109 at paras. 9 and 10).

[15] Applicant's counsel points to decisions such as that of the Federal Court of Appeal in *GlaxoSmithKline Inc. v. Canada (Attorney General)*, 2005 FCA 197 where Justice Pelletier in concurring reasons refers to expert evidence filed in a judicial review proceeding similar to this one at paragraphs 20 to 25 of his Reasons. Counsel also says that the question of listing a patent is a critical part of the NOC process and, where no particular process for considering that question or reviewing a decision is provided for in the *NOC Regulations*, the Court should be more lenient in accepting such affidavit evidence.

[16] It appears from a review of authorities such as *GlaxoSmithKline* that the Court's attention had not been drawn to the admissibility of new evidence. In any event, the point taken by that Court in referring to that evidence is with respect to patent construction. The parties agree that patent construction is a matter of law, to be done by the Court, assisted by experts if necessary to explain the meaning of words, terms, science and background. However, this is not to be construed as an invitation to present masses of expert evidence or shift the focus of construction to a battle of experts. As I said in *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2008 FC 11 at paragraph 47:

> ***47*** *Construction of the disclosure of the patent, as well as construction of the claims, is the task of the Court, not experts or the inventor(s). The Court may be informed by experts as to the*

> *meaning of words, terms and the science and background that are pertinent, but the Court must be careful not to let the experts supplant the role of the Court. Construction does not become a battle of experts; it is a duty of the Court. As I said in Eli Lilly Canada v. Novopharm Ltd., [2007] F.C.J. No. 800, 2007 FC 596 (appeal dismissed as moot, [2007] F.C.J. No. 1498, 2007 FCA 359) at paragraphs 103 and 104:*
>
> > *[103] A patent decision should, begin with a construction of the patent (Whirlpool Inc. v. Camco Inc. [2000] 2 S.C.R. 1067 at para. 43). This applies not only to the claims but to the whole of the patent as well when required (Burton Parsons Chemicals Inc. v. Hewlett-Packard (Canada) Inc. [1976] 1 S.C.R. 555 at page 563; Western Electric Co. v. Baldwin International Radio of Canada, [1934] S.C.R. 570 at page 572).*
> >
> > *[104] Construction is a task for the Court alone (Whirlpool supra; Burton Parsons supra.) the role of an expert, if required, is limited to assisting the Court in putting the Court in the position of a person skilled in the art of the relevant time (Halford v. Seed Hawk Inc., [2006] F.C.J. No. 1205, 2006 FCA 275 at para 11). In Dableh v. Ontario Hydro [1996] 3 F.C. 751 at paragraph 33 the Federal Court of Appeal stated what the role of the expert is:*
> >
> > > *It is a matter of accepted law that the task of constructing a patent's claim lies within the exclusive domain of the trial judge. In strict legal theory it is the role of expert witnesses that is those skilled in the art, to provide the judge with the technical knowledge necessary to construe a patent as though he or she were so skilled. Where the experts disagree, it is incumbent on the trial judge to make a binding determination.*

[17] Dr. Lewanczuk's evidence as far as claim construction is concerned is set out at paragraphs 44 to 51 of his affidavit. I repeat paragraphs 47 to 51. I put no weight on paragraphs other than 44 to 51 of his affidavit as they are not directed to claim construction despite argument of Applicant's

counsel to make them somehow relevant. Dr. Lewanczuk's affidavit clearly points to paragraphs 44 to 51 as being those directed to claim construction:

> *47. As of August 1995, a skilled person would understand that claim 6 specifically claims the use of sibutramine for improving the glucose tolerance of humans having impaired glucose tolerance or non-insulin dependent diabetes mellitus ("NIDDM"). A person skilled in the art would understand NIDDM to mean type 2 diabetes.*
>
> *48. As of August 1995, a skilled person reading the '620 Patent would understand that improving the glucose tolerance of humans having impaired glucose tolerance includes any clinically significant improvement in glucose tolerance.*
>
> *49. As of August 1995, a skilled person would likewise understand that improved glucose tolerance in a patent with impaired glucose tolerance would be expected to promote weight loss and be useful in a weight management program.*
>
> *50. As of August 1995, a skilled person would therefore understand the claims of the '620 Patent, and specifically claim 6, to include the use of sibutramine in an obese patent with impaired glucose tolerance to improve glucose tolerance and therefore promote weight loss.*
>
> *51. Although the claims of the patent do not specifically refer to obese patients, a person skilled in the art would find nothing in the claim of the '620 patent or its disclosure that would limit the claimed use such that sibutramine could not be used as adjunctive therapy within a weight management program for obese patients. To the contrary, as of August 1995, a person skilled in the art would understand and expect that the claimed use would be valuable in obese patents who have impaired glucose tolerance, as adjunctive therapy within a weight management program.*

[18] Paragraph 51 in particular is very carefully worded and contains the essence of the Applicant's position in this proceeding. I will return to this matter later.

STANDARD OF REVIEW

1) Standard of Review

[19] Since *Dunsmuir v. New Brunswick*, 2008 SCC 9, there has been a necessity to take a fresh approach to the issue as to what standard of review is applicable to any particular decision under review. The decision of the majority of the Supreme Court at paragraph 45 states that there are now only two standards of review, reasonableness and correctness:

> ***45*** *We therefore conclude that the two variants of reasonableness review should be collapsed into a single form of "reasonableness" review. The result is a system of judicial review comprising two standards correctness and reasonableness. But the revised system cannot be expected to be simpler and more workable unless the concepts it employs are clearly defined.*

[20] As to "*reasonableness*" the majority in *Dunsmuir* at paragraph 47 said that it is a deferential standard and that tribunals must be afforded a range of acceptable and rational solutions:

> ***47*** *Reasonableness is a deferential standard animated by the principle that underlies the development of the two previous standards of reasonableness: certain questions that come before administrative tribunals do not lend themselves to one specific, particular result. Instead, they may give rise to a number of possible, reasonable conclusions. Tribunals have a margin of appreciation within the range of acceptable and rational solutions. A court conducting a review for reasonableness inquires into the qualities that make a decision reasonable, referring both to the process of articulating the reasons and to outcomes. In judicial review, reasonableness is concerned mostly with the existence of justification, transparency and intelligibility within the decision-making process. But it is also concerned with whether the decision falls within a range of possible, acceptable outcomes which are defensible in respect of the facts and law.*

[21] Further light as to "*reasonableness*" can be derived from the more recent decision of the Supreme Court in *Lake v. Canada (Minister of Justice)*, 2008 SCC 23. The unanimous decision of

the Court was delivered by LeBel J. At paragraph 41 he says that a Court must determine if the decision falls within a range of reasonable outcomes:

> ***41*** *Reasonableness does not require blind submission to the Minister's assessment; however, the standard does entail more than one possible conclusion. The reviewing court's role is not to re-assess the relevant factors and substitute its own view. Rather, the court must determine whether the Minister's decision falls within a range of reasonable outcomes. To apply this standard in the extradition context, a court must ask whether the Minister considered the relevant facts and reached a defensible conclusion based on those facts. I agree with Laskin J.A. that the Minister must, in reaching his decision, apply the correct legal test. The Minister's conclusion will not be rational or defensible if he has failed to carry out the proper analysis. If, however, the Minister has identified the proper test, the conclusion he has reached in applying that test should be upheld by a reviewing court unless it is unreasonable. This approach does not minimize the protection afforded by the* Charter. *It merely reflects the fact that in the extradition context, the proper assessments under ss. 6(1) and 7 involve primarily fact-based balancing tests. Given the Minister's expertise and his obligation to ensure that Canada complies with its international commitments, he is in the best position to determine whether the factors weigh in favour of or against extradition.*

[22] As to "*correctness*", the majority in *Dunsmuir* at paragraph 50 stated that this standard must be maintained in respect of jurisdictional questions and some other questions of law:

> ***50*** *As important as it is that courts have a proper understanding of reasonableness review as a deferential standard, it is also without question that the standard of correctness must be maintained in respect of jurisdictional and some other questions of law. This promotes just decisions and avoids inconsistent and unauthorized application of law. When applying the correctness standard, a reviewing court will not show deference to the decision maker's reasoning process; it will rather undertake its own analysis of the question. The analysis will bring the court to decide whether it agrees with the determination of the decision maker; if not, the court will substitute its own view and provide the correct*

> *answer. From the outset, the court must ask whether the tribunal's decision was correct.*

[23] In determining the appropriate standard of review, the majority in *Dunsmuir* at paragraphs 51 to 65 gave guidance which is best summarized at paragraphs 53 to 56 and 62 to 64:

> ***53*** *Where the question is one of fact, discretion or policy, deference will usually apply automatically (Canada (Attorney General) v. Mossop, [1993] 1 S.C.R. 554, at pp. 599-600; Dr. Q, at para. 29; Suresh, at paras. 29-30). We believe that the same standard must apply to the review of questions where the legal and factual issues are intertwined with and cannot be readily separated.*
>
> ***54*** *Guidance with regard to the questions that will be reviewed on a reasonableness standard can be found in the existing case law. Deference will usually result where a tribunal is interpreting its own statute or statutes closely connected to its function, with which it will have particular familiarity: Canadian Broadcasting Corp. v. Canada (Labour Relations Board), [1995] 1 S.C.R. 157, at para. 48; Toronto (City) Board of Education v. O.S.S.T.F., District 15, [1997] 1 S.C.R. 487, at para. 39. Deference may also be warranted where an administrative tribunal has developed particular expertise in the application of a general common law or civil law rule in relation to a specific statutory context: Toronto (City) v. C.U.P.E., at para. 72. Adjudication in labour law remains a good example of the relevance of this approach. The case law has moved away considerably from the strict position evidenced in McLeod v. Egan, [1975] 1 S.C.R. 517, where it was held that an administrative decision maker will always risk having its interpretation of an external statute set aside upon judicial review.*
>
> ***55*** *A consideration of the following factors will lead to the conclusion that the decision maker should be given deference and a reasonableness test applied:*
>
> > *A privative clause: this is a statutory direction from Parliament or a legislature indicating the need for deference.*

> *A discrete and special administrative regime in which the decision maker has special expertise (labour relations for instance).*
>
> *The nature of the question of law. A question of law that is of "central importance to the legal system ... and outside the ... specialized area of expertise" of the administrative decision maker will always attract a correctness standard (Toronto (City) v. C.U.P.E., at para. 62). On the other hand, a question of law that does not rise to this level may be compatible with a reasonableness standard where the two above factors so indicate.*

56 *If these factors, considered together, point to a standard of reasonableness, the decision maker's decision must be approached with deference in the sense of respect discussed earlier in these reasons. There is nothing unprincipled in the fact that some questions of law will be decided on the basis of reasonableness. It simply means giving the adjudicator's decision appropriate deference in deciding whether a decision should be upheld, bearing in mind the factors indicated.*

…

62 *In summary, the process of judicial review involves two steps. First, courts ascertain whether the jurisprudence has already determined in a satisfactory manner the degree of deference to be accorded with regard to a particular category of question. Second, where the first inquiry proves unfruitful, courts must proceed to an analysis of the factors making it possible to identify the proper standard of review.*

63 *The existing approach to determining the appropriate standard of review has commonly been referred to as "pragmatic and functional". That name is unimportant. Reviewing courts must not get fixated on the label at the expense of a proper understanding of what the inquiry actually entails. Because the phrase "pragmatic and functional approach" may have misguided courts in the past, we prefer to refer simply to the "standard of review analysis" in the future.*

> ***64*** *The analysis must be contextual. As mentioned above, it is dependent on the application of a number of relevant factors, including: (1) the presence or absence of a privative clause; (2) the purpose of the tribunal as determined by interpretation of enabling legislation; (3) the nature of the question at issue, and; (4) the expertise of the tribunal. In many cases, it will not be necessary to consider all of the factors, as some of them may be determinative in the application of the reasonableness standard in a specific case.*

[24] In the present case, the Minister was called upon to answer those questions as posed previously:

1. What use does the patent claim?

2. What is the use approved by the existing NOC?

3. Is the use claimed by the patent that which is approved by the existing NOC?

[25] The parties are agreed that where the issue is a question of law, the standard of review is correctness, and where the issue is one of fact, the standard is reasonableness and where the issue is one of mixed fact and law that cannot be separated, the standard is reasonableness. Justice Gauthier of this Court in *GD Searle & Co. v. Canada (Minister of Health)*, 2008 FC 437 held that construction of the *NOC Regulations* and patent claim construction were questions of law and must be reviewed on a standard of correctness. I agree. She said at paragraphs 17 and 18:

> ***17*** *Because the Minister conceded that the relevant SNDS was for a change in the use of the medicinal ingredient that was approved through the issuance of an NOC[4], the parties agree that the '201 patent's eligibility for listing depends entirely on the construction of claims 14 and 15 as well as the construction of subsection 4 (3) of the NOC Regulations. Both issues are pure questions of law.*

> ***18*** *The Court is satisfied that in this particular case, the two questions of law are extricable from the question of fact (which was conceded) and that therefore, the decision of the Minister in respect of those two questions will be reviewed on the basis of correctness.*

[26] In a decision made before *Dunsmuir, supra* the Federal Court of Appeal in *Ferring Inc. v. Canada (Minister of Health)*, 2007 FCA 276 held in similar circumstances that where the question is one of mixed fact and law, the Minister's decision respecting listing is to be determined on a standard of patent unreasonableness. Chief Justice Richard said at paragraph 8:

> ***8*** *I would add that where there is a mixed question of law and fact then the standard of review is patent unreasonableness unless the question of law is extricable from the question of fact in which case the question of law is determined on the basis of correctness.*

[27] Given that we are in post-*Dunsmuir* environment, a standard of patent unreasonableness no longer can apply. However, on the standard of reasonableness, considerable deference still should be given to decisions of the Minister where the questions are those of mixed fact and law as well as those of fact alone.

[28] In summary:

1. Patent claim construction is a matter of law to be reviewed on a standard of correctness.
2. The uses approved by the existing NOC are questions of fact and are to be reviewed on this basis of reasonableness with considerable deference given to the Minister's decision.

3. The consideration as to how the uses claimed in the patent compare with those approved by the NOC for purposes of section 4(2)(d) of the *NOC Regulations* involves mixed fact and law and considerable deference should be given to the Minister's decision.

PATENT CLAIM CONSTRUCTION

[29] Claim 6 of the '620 patent has been referred to by all parties as a good representative of the claims of that patent for purposes of what is at issue in these proceedings. It reads:

> *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.*

[30] This claim can be simplified both as to the chemistry and uses (see Abbott's lawyers letter of June 7, 2007 to the Office of Patented Medicines, page 4) to read as follows:

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

[31] Dr. Lewanczuk's opinion at paragraph 51 of his affidavit previously set out is very carefully worded and, as worded, is not apparently contradicted by the Respondents. That paragraphs says in brief:

- Nothing limits the claimed use such that it could not be used in adjunctive therapy within a weight management program for obese patients (a double negative).

- The claimed use is understood and expected to be valuable to obese patients who have impaired glucose tolerance, as an adjunctive therapy within a weight management program.

[32] Applicant's counsel concedes that the word "*obese*" does not appear in any of the claims of the '620 patent but points out that in the description there are two examples given each of which deal with the treatment of obese patients. Claims however which are unambiguous should not be limited to the examples given in the description (*Dableh v. Ontario Hydro,* [1996] 3 F.C. 751 at 755 (C.A.)). Here the claims are not limited to or specifically directed to obese persons, they include obese as well as any other persons to be treated for pre-type 2 or type 2 diabetes related glucose tolerance problems. In effect, Dr. Lewanczuk is saying that the claimed use in useful in treating obese persons with glucose tolerance problems of this type, but, what he is not saying is that the claimed uses are limited only to treating obese persons.

[33] Thus, with respect to the issues here, a correct claim construction of claim 6 is:

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

WHAT IS THE USE APPROVED BY THE NOC?

[34] The parties are agreed that the use of sibutramine, as approved by the Minister in NOC 048598 is that as set out in the approved monograph as follows:

INDICATIONS AND CLINICAL USE

MERIDIA® (sibutramine hydrochloride monohydrate) indicated as adjunctive therapy within a weight management program for:

- Obese patients with an initial body mass index (BMI) of 30kg/m^2 or higher
- Obese patients with an initial BMI of 27kg/m^2 or higher in the presence of other risk factors (e.g., controlled hypertension, type 2 diabetes, dyslipidemia, visceral fat)

Distribution restrictions: Sibutramine hydrochloride monohydrate should only be prescribed to patients who have not adequately responded to an appropriate weight reducing diet alone.

[35] The product monograph, as approved, has changed from time to time but this statement of the approved use has not changed.

[36] Sometimes the approved use is cryptically referred to as: "*Anorexiant / Antiobesity Agent*", but this is simply a shorthand and not the approved use as such.

[37] The interpretation of the NOC approved use by the Minister is set out in David Lee's letter of July 25, 2007 previously referred to. To repeat from the last paragraph at page 2:

> *The approved use of MERIDIA as indicated in the Product Monograph is for adjunctive therapy within a weight management program for: obese patients with an initial body mass index of 30kg/m^2 or higher; or obese patients with an initial body max index of 27kg/m^2 or higher in the presence of other risk factors (eg. controlled hypertension, type 2 diabetes, dyslipidemia, and visceral fat). As such, 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.*

[38] Thus the Minister's interpretation of the use of sibutramine approved by the NOC is "*use within a weight management program to treat obese patients*" and it is not "*for the treatment of hypertension, type 2 diabetes, dyslipidemia, and visceral fat*".

[39] This interpretation is reasonable and is entitled to considerable deference. It is the duty of the Minister and the Officials assigned to the task to administer the Notice of Compliance regime. The Minister committed no reviewable error in making such interpretation.

IS THE USE CLAIMED IN THE '620 PATENT THAT AS APPROVED BY THE NOC

[40] To re-iterate, the use claimed in the '620 patent as exemplified by claim 6 properly construed is:

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

[41] The use approved by the Minister in NOC 048598 is for the use of sibutramine "*within a weight management program to treat obese patients*" and not for "*the treatment of hypertension, type 2 diabetes, dyslipidemia, and visceral fat*".

[42] Paragraph 4(2)(d) of the *NOC Regulations* states:

> *(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:*
>
> > *(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.*

[43] Thus what paragraph 4(2)(d) of the *NOC Regulations* requires is a determination as to whether the use of the medicine as claimed in the patent, is the use as approved by an NOC.

[44] The Minister's determination as set out in David Lee's letter of July 25, 2007 as to this matter, was, to repeat:

> *The approved use of MERIDIA as indicated in the Product Monograph is for adjunctive therapy within a weight management program for: obese patients with an initial body mass index of 30kg/m^2 or higher, or obese patients with an initial body mass index of 27kg/m^2 or higher in the presence of other risk factors (eg. controlled hypertension, type 2 diabetes, dyslipidemia, and visceral fat). As such, MERIDIA is approved as an antiobesity agent/anorexiant for 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 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.*

[45] As discussed previously in these Reasons, the Minister's interpretation of the claims of the patent is correct and interpretation of the NOC is reasonable. Further, in law, the Minister is correct that paragraph 4(2)(d) of the *NOC Regulations* requires that one be compared to the other.

[46] The manner in which this comparison is to be made is disputed by the Applicant Abbott whose position in this regard was set out it its letter to the Minister of June 7, 2007 at page 3:

> *In Abbott's view, the 620 Patent contains claims for the approved use of sibutramine, the medicinal ingredient in Meridia®. A physician practising today would understand the approved use of Meridia® to include the use of "improving the glucose tolerance of humans having Impaired Glucose Tolerance or Non-Insulin Dependent Diabetes Mellitus", as recited in the claims of the 620 Patent.*

[47] Thus the Applicant's position is that if the "*approved use*" can be said "*to include*" the claimed use, then the patent should be added to the register. The Minister found, in brief, that the approved use was "*treatment of obesity*" whereas the claimed use was "*improving glucose tolerance*".

[48] In its submissions, the Minister agrees that treatment of obese people who also suffer from glucose intolerance with this medicine may result in treatment for glucose intolerance of those people; however that is not what the NOC was directed to, it was directed toward treatment of obesity.

[49] Dr. Lewanczuk's carefully worded paragraph 51 of his affidavit says that a person skilled in the art would understand and expect that the claimed use would be valuable in obese patients who have impaired glucose tolerance, as adjunctive therapy within a weight management program.

[50] Applicant's counsel refers to three decisions of this Court which have considered similar problems. Each of those decisions however, dealt with a use approved in an NOC that was clearly wholly within a more broadly defined use claimed in the patent at issue.

[51] In *Abbott Laboratories Ltd. v. Canada (Attorney General)*, 2007 FC 797 (currently under appeal to be heard shortly), Justice Simpson found the NOC approved use to be a subset of the broader use claimed in the patent with respect to the treatment of ulcers.

[52] In *GD Searle & Co. v. Canada (Minister of Health)*, 2008 FC 437 at paragraphs 64 to 67, Justice Gauthier in *obiter* determined that a patent claim for treatment of pain generally included the treatment of more specific pain approved in the NOC.

[53] In *Abbott Laboratories v. Canada (Minister of Health)*, 2008 FC 352, Justice Barnes on a subsection 6(5) motion under the *NOC Regulations* held certain patents eligible for listing on the basis as set out in paragraphs 24 to 26 that they may be relevant to potential infringement. This decision has limited instructional value in the present case.

[54] At present, the Minister was aware that obese people who also have glucose intolerance may, in taking the medicine, be treating their glucose tolerance problems, if any. As was pointed out in argument, no party is asserting that all obese people are glucose intolerant nor are all glucose intolerant people obese. I find the Minster's decision that the NOC approved use is different from

the claimed use in the ’620 patent to be reasonable such that adding the patent to the register under paragraph 4(2)(d) of the *NOC Regulations* cannot be allowed.

CONCLUSION

[55] In conclusion, I find that the application is to be dismissed with costs to the Respondents at the level that has become rather usual in the proceedings of this type, the middle of Column IV.

JUDGMENT

For the Reasons provided herein:

THE COURT ADJUDGES that:

1. The application is dismissed;

2. The Respondents are entitled to costs to be taxed at the middle of Column IV.

"Roger T. Hughes"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1564-07
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PLACE OF HEARING:	Toronto, Ontario
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