Date: 20081229

Docket: T-1755-07

Citation: 2008 FC 1415

Ottawa, Ontario, December 29, 2008

PRESENT: The Honourable Madam Justice Snider

BETWEEN:

GLAXOSMITHKLINE INC.

Applicant

and

ATTORNEY GENERAL OF CANADA
and MINISTER OF HEALTH

Respondent

REASONS FOR JUDGMENT AND JUDGMENT

I. Introduction

[1] The Applicant, GlaxoSmithKline Inc. (GSK), holds Canadian Patent No. 2,447,517 (the '517 Patent). The '517 Patent is entitled "Metered Dose Inhaler for Fluticasone Propionate". To obtain the benefits of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/98-166; SOR/93-133 as amended (*NOC Regulations*), GSK applied to have the '517 Patent added to the Patent Register for ADVAIR salmeterol xinafoate/fluticasone propionate (ADVAIR) and FLOVENT HFA fluticasone propionate (FLOVENT HFA). In a decision dated August 31, 2007,

the Minister of Health (the Minister), by his delegate, refused to add the patent to the Patent Register. GSK seeks judicial review of that decision.

II. Issues

[2] The overarching issue in this application is whether the Minister's decision was correct or reasonable as the case may be.

[3] In determining this fundamental issue, I must address a number of questions, namely:

1 Should the Court receive new evidence in the way of expert affidavits 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:

a. What is the construction of the claims of the '517 patent?

b. What is the dosage form already approved in the existing Notices of Compliance (NOC)?

c. What is a proper comparison of the claim and the NOC approved dosage form?

III. Further Written Submissions

[4] After the hearing of this matter, the Federal Court of Appeal released its decision in *Abbott Laboratories Limited v. Canada (Attorney General)*, 2008 FCA 354 (*Abbott-CA*), which decision affirmed the decision of Justice Hughes in *Abbot Laboratories Limited v. Canada (Attorney General)*, 2008 FC 700, 67 C.P.R. (4th) 51 (*Abbott-Trial*). The Court of Appeal addressed two issues that are before me in this application; those are: (a) the standard of review; and (b) use of expert affidavit evidence. I asked the parties to make further written submissions on these two issues. These Reasons have been completed taking into account the decision in *Abbott-CA* and the further written submissions of the parties.

IV. Statutory Framework

[5] The *NOC Regulations*, first put in place in 1993, incorporates a scheme by which pharmaceutical products are brought to market. In addition to health and safety concerns, the *NOC Regulations* also address the rights of patent holders. A "register" of patents (the Patent Register) is maintained by the Minister. Pursuant to s. 3(2) of the NOC Regulations, "the Minister may refuse to add or may delete any patent . . . that does not meet the requirements of [s. 4]".

[6] The Patent Register is an important element of the Regulations. Listing on the Patent Register provides a patent holder with various benefits. Rather than detailing those benefits, I refer the reader to the decision of the Court of Appeal in *Hoffmann-La Roche Ltd. v. Canada (Minister of Health)*, 2005 FCA 140, [2006] 1 F.C.R. 141, where Justice Sharlow, at paragraph 7, outlined the advantages of listing. In short, a decision of the Minister not to list a patent has serious negative consequences to the patent holder. While the holder of a non-listed patent will always be able to enforce its rights under the *Patent Act*, R.S.C. 1985, c. P-4, such holder is not afforded the extra benefits of the *NOC Regulations*.

[7] Not every patent pertaining to an approved drug qualifies for inclusion on the Patent Register. As stated in the Regulatory Impact Analysis Statement (RIAS) which accompanied the latest amendments (2006 Amendments) to the *NOC Regulations* (*Regulations Amending the Patented Medicines (Notice of Compliance) Regulations*, SOR/2006-242):

. . . not every patent pertaining to an approved drug qualifies for enforcement under the scheme. Only those patents which meet the current timing, subject matter and relevance requirements set out in section 4 of the regulations are entitled to be added to Health Canada's patent register . . .	Il s'ensuit que ce ne sont pas tous les brevets protégeant une drogue approuvée qui peuvent se prévaloir du mécanisme d'application prévu par le règlement de liaison. Seuls les brevets respectant les exigences énoncées à l'article 4 du règlement relatives au délai, à l'objet et à la pertinence, peuvent être inscrits au registre des brevets de Santé Canada . . .

[8] Of importance in this case are certain of the 2006 Amendments that relate to "dosage form patents". Subsequent to the 2006 Amendments, s. 2 of the *NOC Regulations* defines the term "claim for the dosage form":

"claim for the dosage form" means a claim for a delivery system for administering a medicinal ingredient in a drug or a formulation of a drug that includes within its scope that medicinal ingredient or formulation;	«revendication de la forme posologique» Revendication à l'égard d'un mécanisme de libération permettant d'administrer l'ingrédient médicinal d'une drogue ou la formulation de celle-ci, dont la portée comprend cet ingrédient médicinal ou cette formulation.

[9] The provisions of the amended *NOC Regulations* of primary relevance to this application are ss. 4(2)(c) and 4(3)(b), which set out when such a claim is eligible for listing. The underlined provisions are those of particular interest:

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 :
. . .	. . .
(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	*c*) une revendication de la forme posologique, la forme posologique ayant été approuvée par la délivrance d'un avis de conformité à l'égard de la présentation;
(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	(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

form or a change in use of the medicinal ingredient, and	modification de la formulation, une modification de la forme posologique ou une modification de l'utilisation de l'ingrédient médicinal, s'il contient, selon le cas :
. . .	. . .
(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;	*b*) dans le cas d'une modification de la forme posologique, une revendication de la forme posologique modifiée, la forme posologique ayant été approuvée par la délivrance d'un avis de conformité à l'égard du supplément;

[10] The objective of the amendments that address this matter is described in the RIAS as follows at pages 1517-1518:

. . . the scope of eligible subject matter is being broadened to include patents for approved dosage forms.	. . . la portée de l'objet admissible à la protection du règlement est élargie de façon à inclure les brevets relatifs aux formes posologiques approuvées.
When seized of the question, courts have consistently held that the current language "claim for the medicine itself" in section 4 is insufficient to support the listing of dosage form patents. However, in light of representations from the innovative industry regarding the significant therapeutic advantages afforded by novel dosage forms, the Government has come to the view that inventions in this area merit special protection of the	Les tribunaux, lorsque saisis de la question, s'entendent pour dire que le libellé actuel de l'article 4, à savoir « revendication du médicament en soi » est insuffisant pour permettre l'inscription des brevets relatifs à des formes posologiques. Toutefois, à la lumière des observations reçues de l'industrie innovatrice au sujet des avantages thérapeutiques considérables qu'offrent de nouvelles formes

PM(NOC) Regulations. This is particularly true where biologic drugs are concerned, as effective administration of the medicinal ingredient is often dependent on the development of new and innovative delivery mechanisms. Amended section 4 thus contains new language necessary to implement this change, and a new definition for the phrase “claim for the dosage form” has been added to section 2 in order to clarify the scope of protection this change is intended to effect.

posologiques, le gouvernement est d'avis que les inventions à ce titre méritent la protection spéciale prévue par le règlement de liaison. Ceci est d'autant plus vrai dans le cas des médicaments biologiques dont l'administration efficace de l'ingrédient médicinal est souvent tributaire du développement de mécanismes d'administration nouveaux et novateurs. L'article 4 modifié offre ainsi un nouveau libellé nécessaire à la mise en œuvre de ce changement, et une nouvelle définition du terme « revendication de la forme posologique » a été ajoutée à l'article 2 afin de préciser la portée de la protection que ce changement est censé conférer.

Although amended section 2 defines the phrase "claim for the dosage form" in very general terms, in order to accommodate future advancements in this field, the intent is to provide protection for the novel delivery system by which the approved medicinal ingredient, or a formulation containing that ingredient, is administered to the patient. Examples include controlled-release tablets and capsules, implants and transdermal patches. As with other eligible subject matter, a dosage form patent must include a claim to the specific dosage form described in the NDS (typically as identified in the notification issued by the Minister pursuant to paragraph C08.004(1)(a)). In

Bien que l'article 2 modifié définisse le terme « revendication de la forme posologique » en termes très généraux pour tenir compte des progrès qui seront réalisés dans ce domaine, l'objectif consiste à conférer une protection au nouveau système par lequel l'ingrédient médicinal approuvé ou une formulation contenant cet ingrédient est administré au patient. Parmi ces modes, mentionnons les comprimés et les capsules à libération contrôlée, les implants et les timbres transdermiques. Comme dans le cas d'autres contenus, un brevet relatif à une forme posologique doit contenir une revendication pour la forme posologique précise décrite dans la PDN [(généralement

addition, it must contain a claim that includes within its scope the approved medicinal ingredient. This latter requirement is meant to ensure that a patent directed solely to a device, such as an intravenous stand or a syringe, does not meet the definition of "dosage form" and remains ineligible for listing. [Emphasis added]	telle qu'identifiée dans l'avis émis par le ministre, conformément à l'alinéa C08.004(1)*a*)]. En outre, le brevet doit également contenir une revendication incluant dans sa portée l'ingrédient médicinal approuvé. Cette dernière exigence vise à faire en sorte qu'un brevet portant uniquement sur du matériel médical, par exemple un pied à perfusion ou une seringue, ne corresponde pas à la définition du terme « revendication de la forme posologique » et demeure inadmissible à l'inscription au registre. [Non souligné dans l'original].

[11] As the parties have suggested, the RIAS may be helpful in interpreting the scope of "claim for the dosage form." The Supreme Court of Canada has relied on the RIAS to ascertain Parliament's intentions with respect to the *NOC Regulations* (See, for example, *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26, [2005] 1 S.C.R. 533 at para. 46 and paras. 155-159).

V. Analysis

A. *Should the affidavits be admitted?*

[12] As part of its record in this judicial review, GSK presented three affidavits that were not before the Minister. In oral submissions, GSK relied on only one of those affidavits, that of

Dr. Louis Cartilier. Dr. Louis Cartilier was asked by GSK to provide his opinion on whether the '517 Patent contains a claim for the dosage form of products, referred to as ADVAIR and FLOVENT HFA. The Respondent has raised the issue of whether I should have regard to this affidavit.

[13] In *Abbott-CA*, above, at paragraph 37, the Court of Appeal confirmed the general rule that, in judicial review proceedings, the record put before the Court should not include any material that was not put before the maker of the decision under review. The Court of Appeal went on to recognize an exception to the general rule where an application for judicial review requires a determination on a point of patent construction. In such cases, the Court of Appeal noted that an affidavit providing an expert opinion on patent construction can be of benefit to the Court, and confirmed that a judge should have the discretion to admit such an affidavit. However, the Court of Appeal observed that, in deciding whether to exercise such 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 at the time of his decision making (*Abbott-CA*, above, at para. 39).

[14] In this case, GSK could have produced expert evidence in its reply to the Minister's notification of December 21, 2006 that the '517 Patent was not eligible for listing; it did not do so. The evidence on patent construction provided to this Court in the affidavit of Dr. Cartilier was not provided to the Minister. Further, Dr. Cartilier was asked to provide his opinion on a matter that went beyond the construction of the patent. In his affidavit, for example, Dr. Cartilier provides his opinion on the interpretation of "claim for the dosage form" in the *NOC Regulations*. This question involves statutory interpretation, an area that is not within his expertise.

[15] As a result, and on these facts, I decline to exercise my discretion to admit Dr. Cartilier's affidavit evidence.

B. *Process of Analysis under s. 4(2)(c)*

[16] In the decision, the Minister's delegate described the requirements for eligibility as follows:

> . . . to determine the eligibility of a patent for listing on the Patent Register in relation to a new drug submission, the OPML [Office of Patented Medicines and Liaison] must, pursuant to subsection 4(2) of the *PM(NOC) Regulations*, assess whether a patent contains a claim for the medicinal ingredient which has been approved through the issuance of a notice of compliance in respect of the new drug submission. Further, to determine the eligibility of a patent for listing on the Patent Register in relation to a supplement to the new drug ingredient, the OPML must, pursuant to subsection 4(3) of the *PM (NOC) Regulations*, assess whether a patent contains a claim for the changed formulation, a claim for the changed dosage form, or a claim for the changed use of the medicinal ingredient respectively, which has been approved through the issuance of a notice of compliance.

[17] In my view, the Minister's delegate correctly described his task. I would restate the process in terms of the steps set out by Justice Hughes in *Abbott–Trial*, above. Although Justice Hughes discussed the steps in determining whether a claim for the use of a medicinal ingredient met the listing requirements of s. 4(2)(d) of the *NOC Regulations* (*Abbott-Trial*, above, at paras. 4, 24), adapting his reasoning to s. 4(2)(c) of the *NOC Regulations* and the decision before me, the decision to list involves a three-step determination:

1 What does the '517 Patent claim?

2 What is the approved dosage form?

3 Do the claims of the '517 Patent correspond to the approved dosage form?

C. *What is the Standard of Review?*

[18] GSK submits that the issue turns on the Minister's interpretation of the *NOC Regulations*, thus meriting a correctness standard. (*Apotex Inc. v. AstraZeneca Canada Inc. et. al.*, 2006 SCC 49, [2006] 2 S.C.R. 560 at para. 25).

[19] The Respondent submits that the present case turns on a question of mixed fact and law, which requires the Minister to make factual determinations about the patent in determining whether it meets the s.4 requirements of the *NOC Regulations*. As such, the appropriate standard of review is reasonableness (*Ferring Inc. v. Canada (Minister of Health)*, 2007 FCA 276, 370 N.R. 63; *Dunsmuir v. New Brunswick*, 2008 SCC 9, [2008] 1 S.C.R. 190). The Respondent also relies on the analysis and conclusion of Justice Hughes in *Abbott-Trial*, above.

[20] In my view, the decision of the Court of Appeal in *Abbott-CA*, above, is dispositive of the issue of standard of review. The Court acknowledged Justice Hughes' three-question analysis of a decision of the Minister and then proceeded to examine the applicable standard of review for each question. In conclusion, Justice Sharlow found as follows at paragraph 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.

[21] I see no reason why a decision of the Minister under s. 4(2)(c) should attract any different standard of review. Nevertheless, as can be seen from the following analysis, I conclude that, even on the higher standard of correctness, the Minister's decision not to list should be upheld.

D. *What does the '517 Patent claim?*

[22] The first step in the analysis is to construe the claims of the '517 Patent. In his decision, the Minister's delegate states that "the '517 patent contains claims directed towards an aluminium can with coated internal surfaces, in the form of a metered dose inhaler".

[23] Claim 1 of the '517 patent refers to:

> A metered dose inhaler comprising a can said metered dose inhaler having part of all of its internal surfaces coated with a polymer blend comprising one or more fluorocarbon polymers in combination with one or more non-fluorocarbon polymers, and wherein said can is made of strengthened aluminium and comprises a substantially ellipsoidal base, for dispensing an inhalation drug formulation comprising fluticasone propionate or a physiologically acceptable solvate thereof and a fluorocarbon propellant.

[24] Claims 2 to 25 are related to the metered dose inhaler and make reference to claim 1.

[25] As set out Claim 1 of the '517 Patent, the metered dose inhaler (MDI) is to be used "for dispensing an inhalation drug formulation comprising fluticasone propionate or a physiologically acceptable solvate thereof and a fluorocarbon propellant".

[26] The '517 Patent is clearly directed at an MDI that was developed to improve the efficacy of delivery of fluticasone propionate to a patient. This construction of the claims is consistent with the description set out in the patent. In the section entitled “Background of the Invention”, the inventors state as follows:

> Some aerosol drugs tend to adhere to the inner surfaces, i.e. walls of the can, valves, and caps of the MDI. This can lead to the patient getting significantly less than the prescribed amount of the drug upon each activation of the MDI. The problem is particularly acute with hydrofluoroalkane (also known as simply “fluorocarbon”) propellant systems . . .
>
> We have found that coating the interior can surfaces of MDI’s with a fluorocarbon polymer significantly reduces or essentially eliminates the problem of adhesion or deposition of fluticasone propionate on the can walls and thus ensures consistent delivery of medication in aerosol from the MDI.

[27] While the claims are directed to the new and improved MDI, the inventors claim only one use for the MDI; that is, claims 2 to 25 include the MDI described in the '517 Patent only when used for dispensing fluticasone propionate or a physiologically acceptable solvate thereof and a fluorocarbon propellant.

[28] Claim 26 is for the use of the MDI for the treatment of respiratory disorders.

[29] As acknowledged by GSK, in oral submissions, there may be other ways to administer fluticasone propionate. The '517 Patent covers one way only of administering this useful drug.

[30] In sum, on the question of patent construction, I conclude that the claims of the '517 Patent are properly construed as claims directed to an improvement to a device. In other words, I agree

with the conclusion of the Minister that “the '517 patent contains claims directed towards an aluminium can with coated internal surfaces, in the form of a metered dose inhaler”.

E. *What is the “approved dosage form”?*

[31] A Notice of Compliance (NOC) is required for a company to market a drug. The amended language of s. 4 of the *NOC Regulations* reflects a link between the subject matter of a patent on a patent list and the content of the underlying submissions for the NOC related to the drug. The question to be addressed is this: What is the content of the underlying NOCs?

[32] In this case, between December 18, 2000 and November 11, 2006, GSK had made a number of submissions for ADVAIR and, between April 10, 2000 and May 3, 2005 for FLOVENT HFA. An NOC was issued to GSK on July 18, 2001 in respect of FLOVENT HFA and on September 3, 1999 in respect of ADVAIR, based on new drug submissions (NDS) by GSK. Since those NOCs were issued, there have been a number of supplements to the new drug submission (SNDS) submitted. The Minister’s delegate reviewed these submission and NOCs. He concluded as follows:

> The approved dosage form as indicated on the notices of compliance issued for the above-mentioned submissions [for ADVAIR and FLOVENT HFA] that support the listing of a patent . . . is not for a device, namely a “metered dose inhaler” as specified in Claim 1 of the 517 patent, but for an aerosol for metered dose inhalation . . .

[33] Having reviewed the drug submissions of GSK, as well as the product monographs, for ADVAIR and FLOVENT HFA, I agree with the Minister's finding that the approved dosage form, as reflected in the submissions is an aerosol. There are numerous references in the NOCs that support this conclusion. For example:

- The NOC issued July 18, 2001, is an approval for "FLOVENT HFA metered-dose (aerosol) for inhalation 50mcg, 125mcg and 250mcg/act".

- In the SUMMARY PRODUCT INFORMATION in the product monograph for FLOVENT HFA, the Dosage Form/ Strength is listed as "Inhalation Aerosol/50. 125, and 250 mcg/metered dose".

- The NOC in respect of ADVAIR, dated December 21, 2001, specifically states "New Dosage Form: Inhalation Aerosol".

- The product monograph for ADVAIR, in the section entitled "DOSAGE FORMS, COMPOSITION AND PACKAGING" [AR 485] describes ADVAIR as an "inhalation aerosol".

[34] GSK points to some instances in this documentation where there is reference to the metered dose inhaler. For example, GSK refers to the Certified Product Information Document-Chemical Entities (CPID-CE) submitted as an SNDS in respect of ADVAIR. At page 1 of that document, GSK lists the dosage form as a "Metered dose inhaler". While I acknowledge this description, I note

that, elsewhere in the CPID-CE, GSK separately describes the container system. At best, the CPID-CE is unclear, in spite of the reference to the "Metered dose inhaler" as the dosage form.

[35] In sum on this question, I conclude that the better view is that the "approved dosage form" is for an inhalation aerosol. The Minister's conclusion on this question is not unreasonable.

F. *Do the claims of the '517 Patent correspond to the "approved dosage form?*

[36] As noted above, s. 4 of the *NOC Regulations* sets out the eligibility requirements for a patent to be added to the patent register. Pursuant to the October 5, 2006 amendments, the *Regulations* now allow patents containing a claim for a "dosage form" to be listed on the register, but only if the claimed dosage form corresponds with the dosage form of the approved drug submission with which the patent is to be listed.

[37] I have concluded above the '517 Patent is directed to a device – that being an MDI with the properties described in the claims of the patent. Secondly, I have concluded that the "approved dosage form" for ADVAIR and FLOVENT HFA is that of an inhalation aerosol. There being no correspondence, the requirements of s. 4(2)(c) for listing are not met. The decision of the Minister to refuse the listing of the '517 Patent was correct.

[38] Justice Russell dealt with a very similar issue in *Bayer Inc. v. Canada (Minister of Health)*, 2008 FC 857, 68 C.P.R. (4th) 1, a case related to the eligibility of the alleged dosage form of a package system used to prevent problems associated with the exposure of a particular drug to moisture. In rejecting the drug company's claim, he wrote, at paragraph 56:

> In other words, the invention contained in the '970 Patent is directed at improving what is administered to the patient and not the dosage form. It seems clear from the evidence that the exposure of *estradiol* to moisture can result in hydrate forms and this can lead to changes in the drug release rate. But preventing the formation of hydrate forms is still aimed at improving what is administered to the patient through a transdermal patch and not the dosage form itself.

[39] In effect, the same issue arises in the present case. The metered dose inhaler is designed to ensure consistent delivery of the medicinal ingredient. It is essentially an improved way of administering the aerosol drug. It is not the dosage form approved in the NOCs issued for FLOVENT HFA and ADVAIR. As such, the MDI, as claimed in the '517 Patent, is more closely akin to a device than to a novel delivery system. Therefore, the Minister was correct in refusing to add the '517 patent to the Patent Register on the grounds that it did not contain a claim for a dosage form which had been approved through the issuance of a NOC in respect of the new drug submissions for FLOVENT HFA and ADVAIR.

VI. Conclusion

[40] For these reasons, the application for judicial review will be dismissed with costs to the Respondent.

JUDGMENT

THIS COURT ORDERS AND ADJUDGES that

1. The application for judicial review is dismissed; and

2. Costs are awarded to the Respondent.

"Judith A. Snider"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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APPEARANCES:

Ms. Beverley Moore Mr. James E. Mills	FOR THE APPLICANT
Mr. David Cowie	FOR THE RESPONDENTS

SOLICITORS OF RECORD:

Gowling Lafleur Henderson LLP Barristers and Solicitors Ottawa, Ontario	FOR THE APPLICANT
John H. Sims, Q.C. Deputy Attorney General of Canada	FOR THE RESPONDENTS