Date: 20090130

Docket: T-1934-07

Citation: 2009 FC 102

Ottawa, Ontario, January 30, 2009

PRESENT: The Honourable Mr. Justice Lemieux

BETWEEN:

SOLVAY PHARMA INC.

Applicant

and

ATTORNEY GENERAL OF CANADA
and THE MINISTER OF HEALTH

Respondents

REASONS FOR JUDGMENT AND JUDGMENT

I. Introduction

[1] This judicial review application is a challenge by Solvay Pharma Inc. (Solvay or the innovator) to the October 10, 2007 decision by the Minister of Health (the Minister) who refused Solvay's application to list its Canadian Patent No. 2,240,895 (the '895 patent) on the Patent Register (the Register) maintained by the Minister pursuant to the *Patented Medicines (Notice of Compliance) Regulations* (the *NOC Regulations*).

[2] The Minister was of the view Solvay's '895 patent did not meet the eligibility requirements for the listing of a patent on the Register set out in paragraph 4(3)(c) of the *Regulations*. Subsection 4(3) of the *Regulation*s dealing with the eligibility requirements for listing of a patent on the Register had been substantially amended on October 5, 2006. Subsection 4(3) of the *Regulations*, incorporating the October 5, 2006 amendments, reads:

Patented Medicines (Notice of Compliance) Regulations, SOR/93-133	*Règlement sur les médicaments brevetés (avis de conformité)*, DORS/93-133
4.(3) A patent on a patent list in relation to a supplement to a new drug submission is eligible to be added to the register if the supplement is for a change in formulation, a change in dosage form or a change in use of the medicinal ingredient, and	**4.(3)** Est admissible à l'adjonction au registre tout brevet, inscrit sur une liste de brevets, qui se rattache au supplément à une présentation de drogue nouvelle visant une modification de la formulation, une modification de la forme posologique ou une modification de l'utilisation de l'ingrédient médicinal, s'il contient, selon le cas :
(a) in the case of a change in formulation, the patent contains a claim for the changed formulation that has been approved through the issuance of a notice of compliance in respect of the supplement;	a) dans le cas d'une modification de formulation, une revendication de la formulation modifiée, la formulation ayant été approuvée par la délivrance d'un avis de conformité à l'égard du supplément;
(b) in the case of a change in dosage form, the patent contains a claim for the changed dosage form that has been approved through the issuance of a notice of compliance in respect of the supplement; or	b) dans le cas d'une modification de la forme posologique, une revendication de la forme posologique modifiée, la forme posologique ayant été approuvée par la délivrance d'un avis de conformité à l'égard du supplément;
(c) in the case of a change in use of the medicinal ingredient, the patent contains a claim for the changed use of the medicinal ingredient that has been approved through the issuance of a notice of compliance in respect of the supplement. [Emphasis	c) dans le cas d'une modification d'utilisation de l'ingrédient médicinal, une revendication de l'utilisation modifiée de l'ingrédient médicinal, l'utilisation ayant été approuvée par la délivrance d'un avis de conformité à l'égard du supplément.

mine.] [Non souligné dans l'original.]

[3] As a matter of convenience at this point, I also set out the definition of "claim for the use of the medicinal ingredient" added to section 2 of the *NOC Regulations* by the October 5, 2006 amendments:

"claim for the use of the medicinal ingredient" means a claim for the use of the medicinal ingredient for the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms; [Emphasis mine.]	«revendication de l'utilisation de l'ingrédient médicinal» Revendication de l'utilisation de l'ingrédient médicinal aux fins du diagnostic, du traitement, de l'atténuation ou de la prévention d'une maladie, d'un désordre, d'un état physique anormal, ou de leurs symptômes. [Non souligné dans l'original.]

[4] Specifically, the Minister's refusal was based on two grounds. First, Solvay's Supplementary New Drug Submission (SNDS) dated March 11, 2005 to which the '895 patent was connected or related for listing on the Register was not a submission for a change in use of the medicinal ingredient – testosterone – (in the form of topical gel) as set out in the product monograph approved by Health Canada for ANDROGEL, namely, hormone replacement therapy in males suffering from conditions associated with a testosterone deficiency. According to Health Canada, all that Solvay's SNDS did was to update the product monograph to reflect its safety and efficacy for treatment beyond 180 days as a result of recent clinical studies on long term usage of ANDROGEL. Second, according to the Minister, the '895 patent does not contain a claim for the changed use introduced in the monograph by Solvay's relevant SNDS of March 11, 2005 for which an NOC issued.

[5] Two regulatory schemes provide the framework for the Minister's decision. First, there is the regulatory scheme set out in the relevant provisions of Part C, Division 8 of the *Food and Drug Regulations* (the *F&D Regulations*) which state that no drug shall be marketed in Canada unless the manufacturer has obtained from the Minister a Notice of Compliance (NOC) for that drug, by filing a drug submission. The *F&D Regulations* provide for different types of drug submissions appropriate to different circumstances. Typically, a drug innovator such as Solvay, seeking its first approval to market a new drug in Canada, files with Health Canada a new drug submission (NDS) which normally contains a vast amount of data by way of clinical trials and other studies which enables the Minister to be satisfied as to the safety and efficacy of the new drug before authorizing its sale in Canada. After a drug has been approved for sale, a wide range of changes may be made in respect of the drug or its backup document such as to the approved product monograph or label for that drug which requires the filing of an SNDS or another type of submission depending on the nature of the change.

[6] The second regulatory prong underpinning the Minister's decision are the *NOC Regulations* first enacted by the Governor-in-Council in 1993, pursuant to the provisions of section 55 of the *Patent Act*. These regulations call for the maintenance of a Patent Register listing Canadian patents held by innovator drug manufacturers. If a generic drug manufacturer wishes to market a generic drug in Canada, it must obtain an NOC from the Minister by the filing of an Abbreviated New Drug Submission (ANDS) which typically compares the generic's drug with the equivalent drug of an innovator who is already on the market via an NOC issued by the Minister. This ANDS by a generic drug manufacturer triggers the procedure set out in the *NOC Regulations* if an innovator's drug is listed on the Patent Register. In such a case, the generic drug manufacture must notify the innovator

through a Notice of Allegation (NOA) stating the marketing of its drug would not infringe the listed patent or that the listed patent is invalid. Once an NOA has been served, the innovator drug company may launch prohibition proceedings to determine whether the NOA is justified. Generally, until those proceedings are determined, the Minister cannot for a certain period of time issue an NOC to the generic under the *F&D Regulations*. However, if the patent for that drug is not listed on the Register, no NOA needs to be served and filed and the process under the *NOC Regulations* is closed to the innovator drug manufacturer albeit an action for patent infringement is not. In other words, the Minister's action to issue an NOC to the generic manufacturer is not constrained if the Minister is otherwise satisfied under the *F&D Regulations*.

II. Facts and context

[7] On August 6, 2000, Solvay filed with the Minister, pursuant to the *F&D Regulations*, a NDS for the purpose of obtaining a NOC which would authorize it to market its ANDROGEL product on the Canadian market. Solvay was issued that NOC on February 6, 2002. That NOC also approved the product monograph for ANDROGEL dated January 28, 2002. The Indications and Clinical Use section of that product monograph reads:

> AndroGel™ (testosterone gel) is indicated for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone:
>
> 1. Primary hypogonadism (congenital or acquired) – testicular failure including cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone levels but have high gonadotropins (FSH, LH) above the normal range.
>
> 2. Hypogonadotropic hypogonadism (congenital or acquired) – idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum levels but have gonadotropins in the normal or low range.

> 3. In sexual dysfunction or for male climacteric symptoms when the conditions are due to a measured or documented testosterone deficiency.

[8] On August 29, 2001, Solvay filed its application for the ‘895 patent which was laid open for public inspection on March 9, 2002. This patent issued six years later on March 13, 2007. Pursuant to subsection 4(6) of the *NOC Regulations*, Solvay had 30 days from the grant of the ‘895 patent to submit the patent for listing against an eligible drug submission. Solvay made that application on March 13, 2007 which was refused by the Minister on October 10, 2007 for the reasons previously stated herein.

[9] After it obtained its NOC in February 2002 to sell ANDROGEL, Solvay sought in March 2000, by way of a notifiable change submission, approval for certain updates to its ANDROGEL product monograph in order to reflect the most current medical terminology. That update was accepted with the product monograph revised as of July 16, 2002.

[10] In late 2004, Solvay obtained the results of a long term extension study entitled “A Long-term Study of the Safety and Effectiveness of Testosterone Gel for hormonal replacement in hypogonadal men”. Solvay’s NDS had been based on an initial six month pivotal study which contained the clinical results for the treatment of males with ANDROGEL for a treatment period of up to 180 days. The extension study continued the patient treatment with ANDROGEL for periods of up to 42 months. Solvay wanted to reflect the extension study results in its product monograph for ANDROGEL and, for this purpose, its Regulatory Affairs Associate contacted Health and Welfare Canada to determine what kind of submission was required: could the changes to the product monograph be made by way of a notifiable change submission or was an SNDS required?

Her inquiry enclosed draft changes to the product monograph. Her e-mail identified its subject as "Product Monograph Revisions".

[11] On December 31, 2004, Solvay's Regulatory Affairs Associate was advised by Adam Gibson, the A/Senior Regulatory Project Manager for the Bureau of Metabolism, Oncology and Reproductive Sciences (BMORS) in the Therapeutics Products Directorate (TPD) of Health Canada as follows:

> In response to your inquiry below, the proposed changes and inclusion of results from your extended study would be considered an SNDS.
>
> The primary reasons for this classification are as follows:
>
> - A change has occurred to the Dosage and Administration Section.
>
> - References to the long term study results in other sections, such as "Adverse Reactions" and "Action and Clinical Pharmacology" imply a long-term usage of Androgel beyond the timeframes outlined in the original clinical data. Although this is not an explicit change to the indication section of the Androgel Product Monograph, the Reproduction and Urology Division (RUD) considers the inclusion of long-term study results to directly influence the implied use of the product. You may wish to note that the latter consideration is applicable to all sponsors of steroid products making similar changes.
>
> For the reasons above and in accordance with our Changes to Marketed New Drug Products Policy, this submission will be considered an SNDS. [Emphasis mine.]

[12] The Applicant's record contains a copy of Health and Welfare Canada's Policy on Changes to Marketed New Drug Products dated April 1994 which suggested that an SNDS was required for a change:

> 5. in the labelling including package inserts, product brochures, file cards, and product monographs of the drug product respecting, either explicitly or implicitly:
>
> i) the recommended route of administration of the drug product,

ii) the dosage of the drug product, and

iii) the claims, including indications, made for the drug product.

[13] Solvay's SNDS for ANDROGEL was submitted on March 10, 2005. In a covering letter, the Regulatory Affairs Associate explained the SNDS had two purposes, the first being "to update the Product Monograph based on the results of the open-label, long-term extension study".

[14] The NOC which was issued in connection with the SNDS is dated January 25, 2006 and indicated the reason for the SNDS to be "Update PM with long term extension study results".

[15] The Applicant's record (Volume I, at page 69) contains the ANDROGEL Product Monograph (ANDROGEL PM) updated in accordance with the SNDS. Its indications and clinical use section is substantially the same in wording to the ANDROGEL PM dated January 2002; taking into account the wording update as a result of the notifiable change which occurred in March 2002. As counsel for Solvay demonstrated ANDROGEL PM contained some wording changes to the contra-indications, the warnings and precautions, adverse reactions, administration, pharmacokinetics and clinical trial sections of the product monograph. The Applicant's record also contains the affidavit of Dr. Alvaro Morales sworn December 7, 2007. Solvay relies on it to support its argument the 2006 NOC represents a change in the use of ANDROGEL. The Minister objected to its receipt because it was not before the Minister and cites jurisprudence as settled law. I will deal with this objection later.

[16] The Respondents' record contains several documents introduced through the affidavit of Waleed Jubran who is a Patent Officer – Science in the Office of the Patented Medicines and Liaison (OPML) in the TPD. His duties include the administration of the *NOC Regulations* which primarily involves ensuring that notices of compliance are issued in accordance with the *NOC Regulations* which requires knowledge of the drug submission and the *NOC Regulations*. According to him, Solvay's SNDS "was approved for an update to the safety information in the product monograph for ANDROGEL and not for a change in the formulation, a change in dosage form or a change in the use of the medicinal ingredient as required by subsection 4(3) of the *NOC Regulations*" concluding "the '895 patent … is not eligible for listing on the Patent Register in respect of the SNDS 097485." He was cross-examined on his affidavit.

[17] He states at paragraph 9 of his affidavit "the indications (the approved uses), are described in the "Indications and Clinical Use Section …" He adds: "Only those indications approved by Health Canada can be included."

[18] Paragraph 12 of his affidavit reads:

> 12. The rationale underlying the listing of "use patents" on the Patent Register is described at page 1517 of the Regulatory Impact Analysis Statement ("RIAS") accompanying the October 5th amendments to the *NOC Regulations*, attached as Exhibit "C". In respect of an NDS, the *NOC Regulations* seek to "limit the eligibility of use patents to those which contain a claim to an approved method of using the medicinal ingredient, for an approved indication. This link should be apparent from a comparison of the claims in the patent with the relevant portions of the product monograph and labelling for the approved drug." In respect of an SNDS, as described at page 1518 of the RIAS, the purpose of the SNDS must be a change in use of the medicinal ingredient (i.e. a new method of use or new indication) and the patent must contain a claim to the use so changed.

[19] At paragraph 19 of his affidavit, he describes the update of the language in the ANGROGEL PM which was authorized by the Notifiable Change submission in March 2002.

[20] At paragraph 21 of his affidavit, he analyses all of the changes proposed by Solvay through its March 10, 2005 SNDS as noted in the TD's Pharmaceutical Safety and Efficacy Assessment Template (PSEAT) which was prepared by the BMORS responsible for reviewing and approving drugs such as ANDROGEL. In that process, BMORS recommend a number of other revisions to the ANDROGEL PM.

[21] Mr. Jubran asserts that overall BMORS concluded SNDS 097485 "sought an update to the safety information of the product monograph" as reflected in the PSEAT but also in the Executive Summary for Submission Review dated December 9, 2005 which was considered by the Director General of the TPD for decision as to whether an NOC should be issued for SNDS 907485.

[22] On March 13, 2007, as noted, Solvay submitted to the OPML a form IV patent list for the '895 patent in respect of its ANDROGEL product which indicated the uses of the medicinal ingredient (testosterone) were:

1. Primary hypogonadism;
2. Secondary hypogonadism;
3. Sexual dysfunction or andropause.

[23] The record indicates that on March 20, 2007, Mr. Jubran consulted Mr. Randall, the Regulatory Project Manager, Oncology Division of BMORS who advised him: "It does not appear that the indications changed under this submission."

[24] On March 26, 2007, the Associate Director, OPML, wrote to Solvay's Vice President, Medical and Regulatory Affairs to advise the SNDS of March 10, 2005 was submitted "for approval of a Product Monograph update based on the results of a long term extension study" and was therefore not eligible because the SNDS contained no change in formulation, dosage or in the use of testosterone, the medicinal ingredient in ANDROGEL.

[25] The Associate Director, OPML, asked for Solvay's written representations, which were provided by letter dated April 25, 2007 from Solvay's outside legal counsel, Anita Nador from McCarthy Tétrault, who submitted that the changes identified in the product monograph were not simply an update but reflected a change in the use of testosterone, the medicinal ingredient based on the results of the long range safety and efficacy study "that examined the use of the drug well beyond the six month studies performed to support the original NDS". The crux of Ms. Nador's submissions are contained in the following two paragraphs:

> On the basis of these data, the SNDS amends the Product Monograph by extending the period in which the safety and efficacy of the drug has been demonstrated from 6 months to three years. Solvay regards this as a change to the use described in the Product Monograph.
>
> Fundamentally, the supplement pertains to a change in the length of the demonstrated period of time during which the drug can be used safely and effectively. The changes include reference to safety in the extended period of use and to benefits, or efficacy in that period of use. As such, the SNDS does relate to a change in the *use* of the medicinal ingredient, namely the use of the drug to achieve

> such desired effects as “hormonal steady state levels of testosterone”, safely, over a longer time frame for treatment.

[26] She then identified the numerous changes in the ANDROGEL PM and provided the following examples about safety in longer term use:

- Under the “Warning and Precaution” section which described the prolonged use of methyltestosterone may cause peliosis hepatis, the following statement was inserted: “ANDROGEL is not known to produce these adverse effects”. Ms. Nador argued this phrase was a key addition to the product monograph and is an assertion that in the long term study conducted over 36 months, ANDROGEL does not produce the adverse effects associated with “prolonged use” and that it was a claim about the relative safety of using ANDROGEL in a longer duration than had been approved by the original NOC;

- The addition of the sentence: “Similar trends were observed in patients followed up to 3 years” in a section of the product monograph dealing with the maintenance of serum testosterone concentration in follow up measurements 30, 90 and 180 days. Ms. Nador submitted the added sentence in the SNDS demonstrated “that concentrations may be maintained for longer periods than originally stated which again indicates the extended use of the product”;

- Under the “Clinical Trials” section, the added reference in the SNDS “to the implied duration of safe and effective use which had previously been based on a 6 month

study and is now based on 42 months of data". Ms. Nador submitted "this change shows that the implied duration of safe and effective use is now based on a much longer period than originally stated";

- Under the "Action and Clinical Pharmacology section", the reference to additional symptoms of hypogonadism; Ms. Nador argued: "the addition of those to the Product Monograph based on the data presented in the longer term study is clearly related to the implied use of the drug to address such symptoms".

[27] Solvay's counsel concluded:

> It is clear that the SNDS seeks approval of changes to the Product Monograph that relate directly to a change in "use" of the drug. The safe and effective duration of use is extended and important changes to the implied use of the product, as authorized to be described in the Product Monograph, are clearly the essential subject of the SNDS. [Emphasis mine.]

[28] She also pointed out that Health Canada "clearly shares Solvay's view of the nature and import of the changes to the use of ANDROGEL, as effected by the SNDS pointing to and quoting the December 31, 2004 e-mail from Adam Gibson".

[29] By letter dated June 11, 2007, from its Director David Lee, the OPML commented on Ms. Nador submissions of April 25, 2007. Mr. Lee pointed out the amended *NOC Regulations* as at October 5, 2006 applied because Solvay's patent list for the '895 patent was received by OPML on March 13, 2007. He characterized Solvay's submissions in these terms:

> In your representations, you indicate that supplemental new drug submission ("SNDS") 097485 seeks a notice of compliance for a change in use of the medicinal ingredient. You take the position that SNDS 097485 pertains to a change in the period of time during which ANDROGEL can be used safely and effectively. More specifically, you indicate that the period in which the safety and efficacy of the drug has been demonstrated has been extended from six months to three years.
>
> Even if the OPML were to accept your position that SNDS 097485 seeks a notice of compliance for a change in use of the medicinal ingredient, the fact remains that there is no claim within the '895 patent for the specific changes that have been approved through the issuance of a notice of compliance in respect of the above-noted supplement. More specifically, the '895 patent does not contain a claim for the change in duration of use, or a claim for the relative safety of using ANDROGEL for a longer duration. As indicated in paragraph 4(3)(c) of the *NOC Regulations*, a patent on patent list in relation to a SNDS is eligible to be added to the Patent Register if the supplement is for a change in use of the medicinal ingredient and **the patent contains a claim for the changed use of the medicinal ingredient** that has been approved through the issuance of a notice of compliance in respect of the supplement.

[30] Mr. Lee then referred to the Regulatory Impact Analysis Statement (RIAS) which accompanied the October 5, 2006 amendments. He indicated that "product specificity is the key consideration required of the Minister in applying the listing requirements under section 4 of the *NOC Regulations*". He wrote: "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".

[31] Ms. Nador wrote to Mr. Lee on June 15, 2007 pointing out that OPML had advanced a new ground for not listing the '895 patent on the Register. She asked for additional time to address this new ground. Those additional submissions are contained in her letter of July 20, 2007 to Mr. Lee which she submitted the '895 patent contained claims that are specific to the changes that form the basis of the SNDS; that is the '895 patent contains a claim for the changed use of the medicinal ingredient.

[32] She referred Mr. Lee to her letter of April 25, 2007 and noted one of these changes was the addition of the symptom "erectile dysfunction" to the "Action and Clinical Pharmacology" section. She noted the addition of this symptom to the Product Monograph, based on data from the longer term study, is clearly a change in the use of the drug to address this symptom. She referred to claims 25, 63, 87, 91 and 95 in the '895 patent as directed to the treatment of this function.

[33] She also observed: "Additionally, the long term efficacy data included in the Product Monograph indicates that serum testosterone concentrations are generally maintained within the eugonadal range, and can be maintained for at least a period of three years." She stated the '895 patent had claims for this changed use mentioning claims 30, 59 and 91 which in her view "contemplate maintenance of testosterone levels for extended periods as they are directed to the use of testosterone to achieve hormonal steady state levels of testosterone", adding "claims for the daily use without an upper limitation on duration of use are also claims for the changed use of ANDROGEL for instance claims 27, 56 and 88".

[34] She advanced an additional point stating "further claims for use in the treatment of conditions that are chronic conditions in which change in duration in use and change in the safety of using ANDROGEL for a longer period is beneficial, including, but not limited to hypogonadism (claims 23, 24, 53, 54, 85 and 86) are inherently claims for the changed use which was approved through the issuance of the NOC for the SNDS. These are directly related to the subject of the SNDS and the longer term duration of use and safety of ANDROGEL".

[35] Finally, she concluded by submitting the addition of data relating "to duration of use and a change in safety are a change in the use of the product ANDROGEL for the spectrum of indications/conditions outlined in the product monograph", stating "the '895 patent had claims for the use of the medicinal ingredient for the treatment of said indications/conditions. As such, those changed uses are claimed in the '895 patent (e.g. claims 1 – 95)". She concluded:

> Because the SNDS relates to a change in the use of ANDROGEL in the treatment of said indications/conditions, and because the claims in the '895 patent are claims for a changed "use" of ANDROGEL in the treatment of these indications/conditions, they are all claims that render the '895 patent listable on the Patent Register with respect to said SNDS.

[36] She closed off the issue by drawing Mr. Lee's attention, by letter dated August 3, 2007 to the Federal Court's recent decision in *Abbott Laboratories Ltd. et al v. the Attorney General of Canada*, 2007 FC 797 (*Abbott/PREVACID*) which Ms. Nador submitted supported Solvay's position.

[37] On October 10, 2007, the OPML conveyed its views to Ms. Nador that she and Solvay's solicitors had not persuaded it the relevant SNDS was for a change in the use of the medicinal ingredient for ANDROGEL – testosterone.

[38] Anne Bowes, the Associate Director of OPML reviewed the submissions made by Ms. Nador and legal counsel. She expressed the view that OPML's June 11, 2007 response did not raise a new ground for rejection – lack of a claim in the '895 patent for the alleged changed use. OPML did, however, respond to Solvay's submissions that the '895 patent did claim the changed use

namely (a) the use of testosterone to treat erectile dysfunction and (b) the long term use of testosterone as related to the submission for the new use for the treatment of erectile dysfunction.

[39] Anne Bowes then wrote:

> After reviewing your representations of July 20, 2007 and August 3, 2007, the OPML remains of the view that the '895 patent does not reflect the intended link between S/NDS 097485 and the '895 patent. As outlined further below, the '895 patent does not include a claim for the changed use of the medicinal ingredient, for the long term use and relative safety of ANDROGEL, as required in subsection 4(3)(c) of the *PM(NOC) Regulations*. [Emphasis mine.]

[40] She proceeded to analyse Solvay's submissions under the heading treatment for erectile dysfunction and she confirmed OPML's view the relevant SNDS "relates to an update to the product monograph for ANDROGEL with long term extension study results" stating "the approved use of ANDROGEL remains unchanged as a result of S/NDS 097485". She referred to relevant extracts at page 3 what was the medical indication for ANDROGEL and at page 13 of that same product monograph indicating which symptoms were associated with male hypogonadism which included erectile dysfunction. She then concluded:

> The above change in description of the symptoms of male hypogonadism are not changed uses of ANDROGEL. The uses of ANDROGEL are the same uses that were approved in the NDS 068080 for which an NOC issued on February 6, 2002. Since the '895 patent application was filed on August 29, 2001 and NDS 068080 was filed on August 28, 2000, the '895 patent is ineligible for listing on the Patent Register in accordance with section 4(6) of the *PM(NOC) Regulations*. The changes introduced in S/NDS 097485 were not changes to the use of the medicinal ingredient as contemplated by subsection 4(3) of *PM(NOC) Regulations*. Instead, the NOC is an update to the product monograph for treatment of symptoms of known uses of testosterone. [Emphasis mine.]

[41] Anne Bowes then discussed the subject matter of "long term use and chronic use treatments". She referred to Solvay's letter of July 20, 2007 which pointed to several claims in the '895 patent "that you state relate to the safe and long term use of testosterone" and to the addition to the ANDROGEL product monograph of the statement: "Similar trends were observed in patients followed up to 3 years." Anne Bowes then wrote:

> The addition of this sentence does not constitute a new use of ANDROGEL. Further, if the addition could be considered as a new use, the OPML is unable to conclude that the '895 patent contains a claim for that changed use of the medicinal ingredient that has been approved through the issuance of an NOC in respect of S/NDS 097485. Claims within the '895 patent pertaining to achieving a "hormonal steady state", for use "without an upper limit" and "chronic use treatment" must be read in light of the disclosure of the '895 patent. The disclosure does not provide for a duration of three years since the studies in the disclosure are limited to 180 days. [Emphasis mine.]

[42] She concluded her letter by referring to the Federal Court's decision in *Abbott/PREVACID*. She noted in that case the SNDS was for a new use unlike the case at hand and that moreover it was an appeal on the issue whether the patent in *Abbott/PREVACID* contained a claim for the changed use.

[43] As will be seen, the Federal Court of Appeal issued its decision in *Abbott/PREVACID* on July 25, 2008. Justice Pelletier, writing for that Court, ruled the patent reference to "ulcers" was not sufficient to support an argument that it covered the approved new use of "NSAID ulcers".

Analysis

(a) The Standard of Review

[44] In *Dunsmuir v. New Brunswick*, 2008 SCC 9, the Supreme Court of Canada reformed the standard of review analysis which had prevailed up to that time by, in particular, reducing from three to two the standards of review, namely correctness and reasonableness.

[45] The Supreme Court also said at paragraphs 57 and 62 "an exhaustive review is not required in every case to determine the proper standard of review" which will be the case where "the jurisprudence has already determined in a satisfactory manner the degree of deference to be accorded with regard to a particular category of question".

[46] The most recent case dealing with the standard of review of the Minister's decision on the listing requirements found in section 4 of the *NOC Regulations* as amended on October 5, 2006 is the Federal Court of Appeal's decision in *Abbott Laboratories v. Attorney General of Canada and the Minister of Health* (*Abbott/MERIDIA*), delivered on November 17, 2008, cited 2008 FCA 354, reasons for judgment written by Justice Sharlow who dismissed an appeal from the decision of my colleague Justice Hughes, reported at 2008 FC 700, who had determined Abbott's drug MERIDIA was not eligible for listing on the Register not having met the eligibility requirements of subsection 4(1) and paragraph 4(2)(d) of the *NOC Regulations* which stipulate a patent on a patent list in relation to a NDS 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. [Emphasis mine.]	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. [Non souligné dans l'original.]

[47] Justice Hughes had stated at paragraph 4 of his reasons to determine whether a patent should be added to an existing NOC under the provisions of paragraph 4(2)(d) of the *NOC Regulations* required the Minister to make a three step determination:

1. What use does the patent claim?
2. What is the use approved by the NOC?
3. Is the use claimed by the patent that which is approved by the existing NOC?

[48] In the case before him, the Minister had decided the use claimed in the patent was not the use approved by the NOC and, as a consequence, the patent could not be listed as against the NOC. Specifically, the Minister determined the approved use of MERIDIA as indicated in the drug's product monograph is an antiobesity agent/anorexiant for the use in adjunctive therapy within a weight management program to treat obese patients. MERIDIA was not indicated for the treatment of hypertension, type 2 diabetes, dyslipidemia, and visceral fat. In contrast, the relevant patent claimed the use of the medicinal ingredient (sibutramine) for improving the glucose tolerance of humans having pre-type 2 diabetes or for type 2 diabetes. The Minister found that the claims in the relevant patent were not directed towards the treatment of obesity. The conclusion of OPML in that case was that the uses claimed in the patent had not been approved by the NOC for MERIDIA.

[49] On the standard of review, Justice Hughes, citing Justice Gauthier in *GD Searle & Co. v. Canada (Minister of Health)*, 2008 FC 437 ruled:

1. The construction of the *NOC Regulations* and patent claim construction are questions 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 the basis of reasonableness with considerable deference given to the Minister's decision; and

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

[50] Justice Sharlow's analysis on the standard of review is contained at paragraphs 26 to 34 of her reasons. She agreed the answer to the question: "What use does the patent claim?" is a question of law to be reviewed on the standard of correctness.

[51] She also agreed reasonableness was the proper standard to apply to the question: "What is the use approved by the existing notice of compliance?" but she arrived at this determination for different reasons. She wrote at paragraph 31:

> **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. [Emphasis mine.]

[52] She also confirmed the standard of reasonableness applied to the answer to the question: "Is the use claimed by the patent that which is approved by the existing notice of compliance?" Justice Sharlow found that this question posed one of mixed fact and law because “it requires an application of the law to the facts”. She was of the view the factual component to this question must be reviewed on a standard of reasonableness but the legal component on a standard of correctness because the component to that question was the meaning of paragraph 4(2)(d) of the *NOC Regulations*.

[53] She summarized her views at paragraph 34 of her reasons:

> **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.

[54] Applying *Abbott/MERIDIA* to the application in this case of paragraph 4(3) of the *NOC Regulations*, I conclude:

1) The construction of the *NOC Regulations* and the construction of the ‘895 patent are questions of law to be reviewed on a standard of correctness.

2) The uses of the medicinal ingredient claimed by Solvay’s SNDS and subsequent approval in the NOC are questions of fact and are to be reviewed on the basis of

reasonableness with considerable deference given to the Minister's decision on the question.

3) The question is the use claimed in the '895 patent, the changed use contained in the SNDS and approved by the NOC is one of mixed fact and law where the factual component is reviewed on the standard of reasonableness but the legal component on a standard of correctness.

(b) Discussion

(1) The Federal Court of Appeal's decision in *Abbott/PREVACID*

[55] Counsel for the Minister drew the Court's attention to another *Abbott* case recently decided by the Federal Court of Appeal in *Abbott Laboratories Ltd. v. Canada (Attorney General)*, dated July 25, 2008 and cited 2008 FCA 244 (*Abbott/PREVACID*). He argued this case was dispositive of the case before me because it involved the very subsection and paragraph which are before me, namely, paragraph 4(3)(c) of the *NOC Regulations*.

[56] The Appeal Court's reasons were penned by Justice Pelletier who overturned the Federal Court's decision reported at 2007 FC 797, the case relied upon by Solvay in its letter of August 3, 2007 to Mr. Lee. It is important to note that in *Abbott/PREVACID*, the Minister and Abbott agreed, before the applications judge, Abbott had satisfied the first element of eligibility under paragraph 4(3)(c) of the *NOC Regulations*, namely Abbott had shown that in its SNDS there had been a change in the use of the medicinal ingredient because it contained a new indication for PREVACID, i.e. healing of NSAID-associated gastric ulcer and reduction of risk.

[57] As a result, the focus of the Federal Court of Appeal's decision in *Abbott/PREVACID* was on the second element required for determination under the paragraph, that is, whether the patent at issue contained a claim for the changed use of the medicinal ingredient. The Minister had ruled the patent did not contain such a claim and, as a result, he deleted the patent from the Register. The applications judge found the Minister had erred in deleting the patent from the Register but, as noted, that decision was reversed by the Federal Court of Appeal.

[58] In the *Abbott/PREVACID* case, just as in the situation before me, the NDS upon which the NOC issued authorizing the marketing of the drug PREVACID preceded the filing of the relevant patent: (1) on May 12, 1995, the Minister issued the NOC for PREVACID for use in the treatment of duodenal ulcers, gastric ulcers, and reflux esophagitis; (2) on November 13, 1997, an application was filed in the Canadian Patent Office for the relevant patent, the '053 patent, which issued only on July 18, 2006; and (3) on April 2, 2000, Abbott filed its SNDS seeking approval for the new indication for PREVACID relating to the healing of non steroidal anti-inflammatory drug (NSAID) associated gastric ulcer and its reduction.

[59] The Federal Court of Appeal's decision in *Abbott/PREVACID* was its first consideration of the amendments which came into force on October 5, 2006. Justice Pelletier made two observations as to why those amendments had been made.

[60] First, he said the redrafting to section 4 of the *NOC Regulations* into its current form came in response to "a running debate about the relevance of patents in relation to the submissions against

which drug manufacturers seek to list them", referring to the Federal Court of Appeal's decision in *Eli Lilly Canada Inc. v. Canada (Minister of Health)*, 2003 FCA 24, in which that Court quashed a decision by the Minister to remove the '969 patent from the Register. Justice Pelletier wrote the following at paragraphs 46 and 47 of his reasons:

> **46** That controversy was resolved by amendments which specified the characteristics of patents which could be listed against specific types of SNDS's. Thus, where a manufacturer submitted an SNDS with respect to a new dosage form, the *Regulations* now require any patent sought to be filed against that submission to contain "a claim for the changed dosage form...": see paragraph 4(3)(b) of the *Regulations*. In the present case, the SNDS in question is with respect to a new indication for an existing drug PREVACID. That drug was originally approved for use in the treatment of "duodenal ulcers, gastric ulcers, and reflux esophagitis". The SNDS relevant to these proceedings claims as a new indication for the drug "Healing of NSAID-associated gastric ulcer and reduction of risk of NSAID-associated gastric ulcer". Paragraph 4(3)(c) of the *Regulations* requires that any patent sought to be listed on the Patent Register against that submission must contain "a claim for the changed use of the medicinal ingredient".
>
> **47** It stands to reason that if a patent must contain a claim for the changed use identified in Abbott's SNDS, that patent cannot simply claim the use which formed the basis of the original submission. Such a patent does not specifically claim the changed use, even though the changed use may come within the claims of the patent. In other words, the *Regulations* envisage as a condition of listing a patent in respect of a change in the use of a medicinal ingredient that the patent specifically claims the changed use as opposed to non-specific claims which are wide enough to include the changed use. [Emphasis mine.]

[61] Second, he was of the view that "it was the distinction between specific claims and broad non-specific claims which led to the discussion in the jurisprudence about the nature of the patented invention", citing *Wyeth Canada v. Ratiopharm Inc.*, 2007 FCA 264 *(Wyeth)*, at paragraph 29. He continued by writing: "That discussion has now been overtaken by the amendments to the *Regulations*." For convenience, I reproduce paragraphs 29 and 30 of Justice Sharlow's reasons in *Wyeth*:

> **29** This appeal deals with the propriety of a patent listing. The part of *AstraZeneca* that is most relevant to that issue is the part explaining that the listing of a patent on the basis of a SNDS requires a certain link between the change reflected in the SNDS, the NOC issued in response to that SNDS, and the patent sought to be listed. On this point I agree with the Judge (see paragraph 22 of his reasons).
>
> **30** I also agree with the Judge that *AstraZeneca* reverses part of the reasoning for the decision of this Court *in Eli Lilly Canada Inc. v. Canada (Minister of Health)* (C.A.), [2003] 3 F.C. 140. The part of the *Eli Lilly* reasoning that cannot stand with AstraZeneca is the proposition that a patent containing a claim for the medicine in a drug is listed generally against the drug, rather than against a specific NOC issued in response to the NDS or SNDS upon which the patent listing is based.

[62] The applications judge in *Wyeth* was Justice Hughes and the paragraph she approved was his paragraph 22 reported at 2007 FC 340, which I also reproduce for completeness:

> **22** Given *AstraZeneca* and *Biolyse* it can be seen that what the Minister must do under section 3(1) of the pre-October 5, 2006 *NOC Regulations* for purposes of determining whether a patent is to be listed as against a particular NOC is to look at the "patented invention" and determine if there is a "relationship" between that "patented invention" so as to make it "relevant" to the particular NOC against which it is sought to be listed or, if listed, to be de-listed.

[63] Justice Pelletier expressed his conclusions at paragraphs 49 and 50 of his reasons:

> **49** Even if one were inclined to look to the nature of the invention, the difficulty is that the language of the *Regulations* speaks only of "a claim for the changed use of the medicinal ingredient". I conclude that paragraph 4(3)(c) of the *Regulations* requires, as a condition of listing a patent on the Patent Register, that the patent must specifically claim the very change in use which was approved by the issuance of a Notice of Compliance with respect to an SNDS.
>
> **50** As a result, I am of the view that Simpson J. erred in accepting the expert opinions which were placed before her as evidence that the '053 patent contained a claim for the changed use of the medicinal ingredient in PREVACID. That evidence went no further than showing that the '053 patent would have been eligible for listing against the original submission for PREVACID, had it not been for the fact that the date of the submission preceded the date of the patent application. To allow registration of the '053 patent against the SNDS for a changed use which was not the subject of a specific claim would be to undo the reform which the amended regulations seek to introduce. For that reason, I would allow the appeal with costs

> and set aside the decision of the Federal Court. I would dismiss with costs the respondent's application for judicial review.

(2) Statutory Interpretation Principles

[64] The Supreme Court of Canada in *Rizzo &Rizzo Shoes Ltd. (Re)*, [1998] 1 S.C.R. 27 settled the issue of the proper approach to be taken in matters of statutory interpretation – in essence it is the search for the intention of the law-maker or regulation-maker. Justice Iacobucci, writing on behalf of the Court, stated as follows at paragraph 21 of his reasons:

> **21** Although much has been written about the interpretation of legislation (see, e.g., Ruth Sullivan, Statutory Interpretation (1997); Ruth Sullivan, Driedger on the Construction of Statutes (3rd ed. 1994) (hereinafter "Construction of Statutes"); Pierre-André Côté, The Interpretation of Legislation in Canada (2nd ed. 1991)), Elmer Driedger in Construction of Statutes (2nd ed. 1983) best encapsulates the approach upon which I prefer to rely. He recognizes that statutory interpretation cannot be founded on the wording of the legislation alone. At p. 87 he states:
>
> > Today there is only one principle or approach, namely, the words of an Act are to be read in their entire context and in their grammatical and ordinary sense harmoniously with the scheme of the Act, the object of the Act, and the intention of Parliament.
>
> …

[65] In the case at hand, there are three relevant aids to the intention behind the changes to the *NOC Regulations* made on October 5, 2006: (1) A discussion in the jurisprudence what was the mischief sought to be cured in making the regulatory changes. Justice Pelletier's decision in *Abbott/PREVACID* discusses, as has already been noted, what the effect of the previous jurisprudence was and what problems were sought to be cured by making the regulatory changes; (2) A comparison between the scheme provided under the old provision with those set out under the new provisions; and, (3) The light shed on the issue as outlined in the Regulatory Impact Analysis

Statement (RIAS), which in this case is quite extensive, addresses the previous jurisprudence and points to the intent behind the October 5, 2006 changes.

[66] It becomes apparent how profound the October 5, 2006 amendments were in terms of eligibility to list patents on the Register when a comparison is made between the patent listing regime now in place and the scheme under the old regime which existed since 1999 under SOR/99-379. I set out in the Annex to these reasons the old and new regimes as set out in section 4 of each applicable regulation. It is obvious that the current regime is much more precise in spelling out the eligibility criteria for the listing of patents on the *NOC Regulations* Register.

[67] In terms of the RIAS, Justice Sharlow, in *Abbott/MERIDIA*, referred to the RIAS to provide an understanding of the October 5, 2006 amendments of the *NOC Regulations* in these terms at paragraph 54:

> **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. [Emphasis mine.]

[68] She appears to endorse the principle found in the jurisprudence that a RIAS indicates the Government's purpose and intention in promulgating regulations including the *NOC Regulations* (see paragraphs 68 to 74 of Chief Justice's reasons in *Eli Lilly* cited above).

[69] Turning to the relevant RIAS, its very first paragraph states: "These amendments are intended to restore the balanced policy underlying the *NOC Regulations* by reaffirming the rules for listing patents on the Register and clarifying when listed patents must be addressed." Under the heading "*Patent Listing Requirements"*, the RIAS states, at page 1511, that the *NOC Regulations* "are intended to operate as a very potent patent enforcement mechanism", citing the 24 month automatic stay when an innovator launches a prohibition application, adding that "it is this very potency which calls for moderation in the application" with the result that "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 … the Register and to the concurrent protection of the 24-month stay".

[70] Throughout the RIAS, examples are given of the problems caused as the government perceived them arising from the jurisprudence on the interpretation of the *NOC Regulations*. I cite a few examples:

- The impression in the previous wording in the regulations that the patent filing date precede the date of the submission for a notice of compliance without specifying if this meant and NDS or a subsequent SNDS coupled with a Court decision (*Apotex v. Minister of Health,* 11 C.P.R. (4th) 538 (F.C.A.)) that a subsequently filed SNDS could revive patents which were out of time in relation to an NDS noting that SNDSs could be filed "virtually any time for any number of reasons, ranging from the mundane, such as a change in drug name, to the substantive, such as a change in its indications or formulation".

- That same decision also expressly sanctioned the listing of new formulation patents that "do not claim the specific product the innovator is approved to sell", citing the *Eli Lilly* case, reported at 2003 FCA 24, as a decision where the Federal Court of Appeal rendered "a precedent-setting decision … which reaffirmed the right of innovator companies to list formulation patents that do not claim the formulation approved for sale".

[71] The RIAS at page 1514 expressed the Government concern "that the combined effect of the above described in the jurisprudence is a weakening of the listing requirements to the point of redundancy", citing with approval two Federal Court of Appeal decisions in *Ferring Inc. v. Canada (Attorney General)*, 2003 FCA 274 and *Hoffmann-La Roche Ltd. v. Canada (Minister of Health)*, 2005 FCA 140, where the Court refused to list a patent in relation to SNDSs involving a change to a drug's name or one in relation to a change in the manufacturer's site, its reasoning being that such changes could not possibly be relevant to any potential claim for infringement of a patent and were therefore outside the scope of section 4.

[72] The RIAS expressed the Government's view that regulatory change was a better mechanism to redress the situation rather than proceeding through the Courts on a case by case basis. In its view stated at the bottom of page 1514:

> To date, these unintended consequences include the possibility that an innovator company may delay generic market entry by listing new and sometimes irrelevant patents on the basis of minor product revisions. The result is a blurring of the lines between the original product, as approved via the NDS, and the "changed" version, as approved via the SNDS, such that generic manufacturers may be prevented from entering the market with a competing version of the original

> innovator product even when the original patents have long since expired or been addressed.

[73] The RIAS contained at page 1515 the following description of the purpose of the amendments:

> The primary purpose of these amendments is to pre-empt further such behaviour by restoring the original policy intent of the *NOC Regulations*. This entails reaffirming the requirements innovators must meet to list patents on the register and clarifying when these patents must be addressed by their generic competitors. In addition, a number of ancillary amendments are being made with a view to reducing unnecessary litigation and improving the overall effectiveness of the regime. These were developed in response to specific concerns expressed by stakeholders following pre-publication of an earlier round of proposed amendments in the *Canada Gazette*, Part I, on December 11, 2004.

[74] According to the RIAS, in order to qualify for protection under the regulations, a patent must be "relevant to the drug product the innovator is approved to sell". [Emphasis mine.] and "in making that determination the Minister can only be called upon to assess the relationship between the patent and the drug described in the innovator's submission for a NOC." The RIAS goes on to say "the amendments reflect this by further entrenching the concept of product specificity as the key consideration required of the Minister in applying the listing requirements under section 4 … They do so through more precise language respecting the intended link between the subject matter of the patent and the content of the underlying submission for a NOC in relation to which it is submitted. In addition, only certain clearly defined submission types will provide an opportunity to submit a new patent list." [Emphasis mine.]

[75] The document went on to explain that according to the amendment only a patent filed prior to an NDS which contains one of four claims may be listed; one of those claims is "a claim for an approved use of the medicinal ingredient."

[76] The document went on to elaborate on some of the new definitions in the amended regulation and stated as follows at page 1517 with respect to the definition of "claim for the use of the medicinal ingredient":

> Although the definition for "claim for the use of the medicinal ingredient" in these amendments is unchanged from the current definition for "claim for the use of the medicine", a point of clarification regarding the intention underlying this aspect of the *NOC Regulations* is in order. It is acknowledged that the regulatory language employed in the health and safety context to describe the use for which a medicinal ingredient in a drug is sometimes at odds with the manner in which claims are drafted in the many different kinds of so-called "use patents" which exist in the pharmaceutical realm. Examples of the latter include kit claims, "Swiss-type" claims and claims for dosing regimens. However, the combined effect of the definition under this part and the requirement that the claimed use be one described in the underlying NDS should be to limit the eligibility of use patents to those which contain a claim to an approved method of using the medicinal ingredient, for an approved indication. This link should be apparent from a comparison of the claims in the patent with the relevant portions of the product monograph and labelling for the approved drug.

[77] The RIAS concluded on the issue of the linkage between the patent to be listed and the underlying submission for an NOC by stating the "amendments formally confirm the right to list new patents on the basis of SNDS filings and introduce listing requirements governing that right". In this connection, it stated:

> Under these requirements, a patent which had been applied for prior to the filing of an SNDS may be submitted in relation to that SNDS provided the purpose of the latter is to obtain approval for a change in use of the medicinal ingredient (i.e. a new method of use or new indication), a change in formulation or a change in dosage form and the patent contains a claim to the formulation, dosage form or

> use so changed. This will protect and encourage legitimate and substantive incremental innovation of direct therapeutic application. New patents claiming novel physical forms of the approved medicinal ingredient will not be eligible for listing in this manner.

(c) Conclusions

[78] This judicial review application must be dismissed. The evidence before me supports the Minister's conclusions that Solvay did not meet the relevant requirements of the *Regulations* for the listing of the '895 on the Register both in terms of: (1) that the SNDS represents a change in use of the medicinal ingredient in ANDROGEL, namely testosterone; and, (2) the '895 patent claims a limitation as to duration in the use of ANDROGEL which was the principal basis upon which the SNDS to which the 2006 NOC relates was advanced.

[79] The evidence in the record satisfies me the SNDS, filed on March 11, 2005, did not represent a change in use of the medicinal ingredient of ANDROGEL – testosterone in the form of topical gel. The jurisprudence supports the proposition that "change in use" as that term is used in subsection 4(3) of the *Regulations* is measured by the approved use in ANGROGEL's product monograph, as approved by Health Canada, which is described in the Indications and Clinical Use Section of that document. ANDROGEL is indicated for hormone replacement therapy in men suffering from conditions associated with a testosterone deficiency. No change of indication and use was made to Solvay's ANDROGEL product monograph as a result of the 2006 NOC.

[80] Counsel for Solvay referred to Mr. Gibson's advice the proposed changes to its ANDROGEL product monograph would have to be by way of an SNDS as an indicator of

change in use which met the requirements of section 4(3). This argument fails on two points. First, that advice was given in 2004 before the amendment to section 4(3) was in place in October of 2006. Second, the advice was only as to the form by which approval to the product monograph updates would take place. It did not purport to rule on the nature of those changes.

[81] I deal with a second argument put forward by counsel for Solvay that there was a clash between the experts in Health Canada in the BMORS section with those in the OPML section. I cannot accept this submission. OPML has expertise in the administration of the *Regulations* and coordinates the views of Health Canada in specific cases. In 2007, when the ANDROGEL issue was on the table, OPML sought the advice of BMORS experts who indicated "it did not appear the indications changed under this submission".

[82] It is evident Solvay fails on the second requirement that the '895 patent claims the changed use. I am prepared to accept Dr. Morales' affidavit because, taken as a whole, it does not represent substantial new evidence not before the Minister. On the other hand, it provides clear evidence that the '895 patent claims contain no limitation as to duration of use. As put by the Minister's counsel, the '895 patent does not address the issue of the duration of testosterone therapy.

[83] For these reasons, this judicial review application is dismissed with costs taxed at the middle of column IV.

JUDGMENT

THIS COURT ORDERS AND ADJUDGES that this application for judicial review is dismissed with costs to be taxed at the middle of column IV.

"François Lemieux"

_____

Judge

SCHEDULE “A”

COMPARISON OF PM(NOC) REGULATIONS

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

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

Following SOR/99-379 (Came into force on October 1, 1999)		Following SOR/2006-242 (Came into force on Oct. 5, 2006) (includes Erratum of Nov. 15, 2006)		Notes
			(*a*) an identification of the new drug submission or the supplement to a new drug submission to which the list relates;	See old s.4(5)
	(*a*) indicate the dosage form, strength and route of administration of the drug;		(*b*) the medicinal ingredient, brand name, dosage form, strength, route of administration and use set out in the new drug submission or the supplement to a new drug submission to which the list relates;	
	(*b*) set out any Canadian patent that is owned by the person, or in respect of which the person has an exclusive licence or has obtained the consent of the owner of the patent for the inclusion of the patent on the patent list, that contains a claim for the medicine itself or a claim for the use of the medicine and that the person wishes to have included on the register;			
			(*c*) for each patent on the list, the patent number, the filing date of the patent application in Canada, the date of grant of the patent and the date on which the term limited for the duration of the patent will expire under section 44 or 45 of the *Patent Act*;	See old s.4(2)(d)
	(*c*) contain a statement that, in respect of each patent, the person applying for a notice of compliance is the owner, has an exclusive licence or has obtained the consent of the owner of the patent for the inclusion of the patent on the patent list;		(*d*) for each patent on the list, a statement that the first person who filed the new drug submission or the supplement to a new drug submission to which the list relates is the owner of the patent or has an exclusive licence to the patent, or has obtained the consent of the owner of the patent to its inclusion on the list;	
	(*d*) set out the date on which the term limited for the duration of each patent will expire pursuant to section 44 or 45 of the *Patent Act*; and			See new s. 4(4)(c)
	(*e*) set out the address in Canada for service on the person of any notice of an allegation referred to in paragraph 5(3)(*b*) or (*c*), or the name and address in Canada of another person on whom service may be made, with the same effect as if service had been made on the person.		(*e*) the address in Canada for service, on the first person, of a notice of allegation referred to in paragraph 5(3)(*a*) or the name and address in Canada of another person on whom service may be made with the same effect as if service were made on the first person; and	
			(*f*) a certification by the first person that the information submitted under this subsection is accurate and that each patent on the list meets the eligibility requirements of subsection (2) or (3).	See old s.4(7)
	(3) Subject to subsection (4), a person who submits a patent list must do so at the time the person files a submission for a notice of compliance.		(5) Subject to subsection (6), a first person who submits a patent list must do so at the time the person files the new drug submission or the supplement to a new drug submission to which the patent list relates.	
	(4) A first person may, after the date of filing of a submission for a notice of compliance and within 30 days after the issuance of a patent that was issued on the basis of an application that has a filing date that precedes the date of filing of the submission, submit a patent list, or an amendment to an existing patent list, that includes the information referred to in subsection (2).		(6) A first person may, after the date of filing of a new drug submission or a supplement to a new drug submission, and within 30 days after the issuance of a patent that was issued on the basis of an application that has a filing date in Canada that precedes the date of filing of the submission or supplement, submit a patent list, including the information referred to in subsection (4), in relation to the submission or supplement.	

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

FEDERAL COURT

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	T-1934-07
STYLE OF CAUSE:	SOLVAY PHARMA INC. v. ATTORNEY GENERAL OF CANADA et al
PLACE OF HEARING:	Toronto, Ontario
DATE OF HEARING:	November 13, 2008
REASONS FOR JUDGMENT AND JUDGMENT:	Lemieux J.
DATED:	January 30, 2009

APPEARANCES:

Ms. Caroline Zayid Mr. David Tait	FOR THE APPLICANT
Mr. David Cowie	FOR THE RESPONDENTS

SOLICITORS OF RECORD:

McCarthy Tétrault LLP Barristers & Solicitors Toronto, Ontario	FOR THE APPLICANT
John H. Sims, Q.C. Deputy Attorney General of Canada	FOR THE RESPONDENTS