Date: 20080710

Docket: T-1517-07/T-1518-07

Citation: 2008 FC 857

Winnipeg, Manitoba, July 10, 2008

PRESENT: The Honourable Mr. Justice Russell

BETWEEN:

BAYER INC.

Applicant

and

THE MINISTER OF HEALTH
and THE ATTORNEY GENERAL OF CANADA

Respondents

REASONS FOR JUDGMENT AND JUDGMENT

OVERVIEW

[1] Bayer Inc. (Applicant) brings these applications for judicial review of a decision of the Minister of Health (Minister) made by letter dated July 17, 2007 (Decision), wherein the Minister held that Canadian Patent No. 2,167,970 ('970 Patent) was ineligible for listing on the Patent Register.

[2] The Minister concluded that the '970 Patent did not meet the requirements set out in the October 5, 2006 amendments to the *Patented Medicines Notice of Compliance Regulations* (*NOC*

Regulations). With respect to the first application (T-1517-07) regarding the drug CLIMARA, the Minister decided that the ‘970 Patent was ineligible for listing on the Patent Register for Supplemental New Drug Submission (SNDS) numbers 065262 (SNDS 262) and 102243 (SNDS 243), pursuant to subsections 4(3) and 4.1(2), respectively, of the *NOC Regulations*. The Minister concluded that the ‘970 Patent did not contain a claim for a changed formulation or changed use of the medicinal ingredient. The Minister also found that SNDS 262 did not contain a claim for a changed dosage form, since the dosage form approved in the original new drug submission (NDS 041280) is the same dosage form referred to in SNDS 262. Following this, the Minister found that the ‘970 Patent also did not contain a claim for a changed dosage form.

[3] The second application, T-1518-07, involves the Minister’s decision that the ‘970 Patent was ineligible for listing on the Patent Register with respect to New Drug Submission (NDS) numbers 090778 (NDS 778) and 112524 (NDS 524), pursuant to paragraphs 4(2) and 4.1(2) of the *NOC Regulations*, on the basis that it “does not contain a claim for the approved dosage form of the drug MENOSTAR, namely a transdermal patch.”

[4] Because of the similarities in both applications, and the fact that the Decision under judicial review in both applications is the same decision, these applications can be considered and disposed of together.

CLIMARA and MENOSTAR

[5] The drugs CLIMARA and MENOSTAR are marketed in Canada by the Applicant. CLIMARA is indicated for the relief of menopausal and postmenopausal symptoms occurring in naturally or surgically induced estrogen deficiency states. MENOSTAR is indicated for the prevention of postmenopausal osteoporosis in women who are at least five years post-menopause and are presenting with osteopenia (BMD T scores between -1 and -2.5). The medicinal ingredient in both CLIMARA and MENOSTAR is *estradiol hemihydrate* and both are sold in Canada in a "patch" dosage form.

[6] A transdermal patch is designed to be applied directly on the skin. Upon application to the skin, the patch provides continuous systemic delivery of estrogen by releasing *estradiol*-17ß, the major estrogenic hormone secreted by the human ovary. Transdermal patches are either of the "membrane" or "matrix" type. The CLIMARA and MENOSTAR patches are of the matrix type. The matrix layer is sandwiched between an external backing layer and an adhesive layer with a release liner. In newer designs, the matrix and the adhesive layer have been integrated into one single layer.

[7] CLIMARA and MENOSTAR are sold in boxes containing four patches. Each patch is individually sealed in a protective wrapper referred to as a "pouch" in the product monographs (PM). Attached to the inside of this protective wrapper is a moisture protectant, or "desiccant."

When using CLIMARA or MENOSTAR, the patient tears open the pouch, removes the patch, and then applies the patch to the skin as directed. The pouch wrapper and the attached desiccant are discarded prior to application of the patch.

[8] The original NDS for CLIMARA was filed on December 27, 1995, by the drug manufacturer, Berlex Canada Inc. A NOC was subsequently issued to Berlex on June 16, 1997. At this time, CLIMARA was approved in two strengths: 3.9 mg (CLIMARA 50) and 7.8 mg (CLIMARA 100). On January 3, 2007, Berlex and the Applicant merged their pharmaceutical operations.

[9] Since CLIMARA was first approved, a number of SNDSs have been filed to approve changes to the original submissions. Of relevance to the T-1517-07 application are the following two SNDSs, filed February 1, 2000 and October 31, 2005, respectively:

a) SNDS 065262 was filed by Berlex for approval of two new strengths of CLIMARA, i.e. 2.0 mg (CLIMARA 25) and 5.85 mg (CLIMARA 75) and approval for a new indication, the prevention of postmenopausal osteoporosis for CLIMARA. This SNDS was approved in part with the issuance of a NOC on March 9, 2004. Approval was not granted for CLIMARA 25;

b) SNDS 102243 was filed by Berlex for approval for a revised product monograph (PM). A NOC was issued on September 11, 2006.

[10] The original NDS for MENOSTAR was filed on April 2, 2004, by the drug manufacturer, Berlex Canada Inc. A NOC was subsequently issued to Berlex on August 8, 2005. On March 5, 2007 an administrative NDS was filed to change the name of the manufacturer of MENOSTAR from Berlex to the Applicant. This change was approved with the issuance of a NOC on March 20, 2007.

THE ‘970 PATENT

[11] The ‘970 Patent, entitled “Transdermal Drug Delivery Device Containing a Desiccant” was filed on January 24, 1996 and issued on April 10, 2007. The ‘970 Patent is owned by Minnesota Mining and Manufacturing Company (3M). The Applicant has the permission of 3M to include the ‘970 Patent on patent lists with respect to CLIMARA and MENOSTAR.

[12] Pursuant to subsection 4(6) of the *NOC Regulations*, the Applicant had 30 days from the issuance of the ‘970 Patent to submit the patent for listing on the Patent Register, which is maintained by the Minister, in connection with any eligible drug submissions. Since the filing date of the ‘970 Patent precedes that of the above-mentioned SNDSs, the Applicant was able, by letter dated May 9, 2007, to file the ‘970 Patent for listing against the CLIMARA SNDS approving the two new product strengths, namely CLIMARA 25 and 75 and against the original MENOSTAR NDS and the subsequent change in manufacturer name submission.

[13] The ‘970 Patent contains 15 claims. Claims 1 to 8, 10 and 11 are directed towards a “transdermal drug delivery device” comprising a non-aqueous carrier, a desiccant, and a water vapour impermeable product package, wherein the carrier and the desiccant package are contained within the product package. Claim 9 and claims 12 to 15 of the ‘970 Patent describe a method of inhibiting drug precipitation using the transdermal drug delivery device.

[14] The transdermal route of drug administration offers several advantages over the oral route, especially for drugs that cause gastrointestinal irritation or undergo a substantial first-pass inactivation by the liver so that little of the drug is available for systemic circulation when taken orally. In addition, transdermal drug delivery can enhance the duration of activity of drugs with short half-lives, that is, drugs that lose their pharmacological activity quickly by achieving a steady level of drug absorption over several days, thus avoiding fluctuations in the concentration of the drug in the blood produced by oral dosing.

[15] For transdermal drug delivery, the drug contained within the device needs to be absorbed through the skin before reaching the systemic circulation. The major barrier to such transdermal drug absorption is the top layer of the epidermis, the *stratum corneum*. In general, transdermal drug absorption occurs through the relatively slow process of diffusion, which is driven by the drug concentration gradient across the *stratum corneum*. The drug travels from areas having a higher concentration of the drug to areas having a lower concentration (the under side of the *stratum corneum*).

[16] The ‘970 Patent describes a potential problem with transdermal devices. Unexpected precipitation of the drug in the carrier can occur through the formation of insoluble hydrates upon exposure to water vapor, and this can cause the rate of drug delivery from the carrier to decrease as the hydrate precipitates. The formation of solid hydrates can occur because the several components of a transdermal drug delivery device generally contain at least a small amount of water. The ‘970 Patent describes one possible solution to inhibit precipitation, namely, the use of a desiccant to absorb ambient moisture.

[17] The Applicant claims that the desiccant package as described in the ‘970 Patent is an integral part of the transdermal drug delivery device of Claim 1 in that it ensures the stability of the product. Claim 1 of the ‘970 Patent reads as follows:

> A transdermal drug delivery device comprising: a non-aqueous carrier comprising a dissolved drug that forms a solid hydrate when exposed to water vapour; a desiccant package permeable to water vapour and defining a desiccant compartment containing a desiccant; and a water vapour impermeable product package, wherein the carrier and the desiccant package are contained within the product package.

[18] According to the Applicant, if the desiccant package is separated from the rest of the device there would be no stable *estradiol* product based on the integrated matrix design of the transdermal drug delivery system.

THE MINISTER'S DECISION

[19] By letter dated May 30, 2007, the Minister informed the Applicant that the '970 Patent did not meet the requirements of the *NOC Regulations*. The letter provided the Applicant with thirty days within which to file written representations regarding the eligibility of the '970 Patent which would then be taken into account by the Minister in making his final decision as to the patent's eligibility. On June 29, 2007, the Applicant provided a set of representations outlining its view that the '970 Patent was eligible for listing on the Patent Register.

[20] The Minister rendered a final decision on the eligibility of the '970 Patent by letter dated July 17, 2007. With respect to CLIMARA, the Minister held that SNDS 262 was submitted for the approval of a change in formulation to provide for two new strengths of 2 mg and 5.7 mg, and for the approval of a change in use of the medicinal ingredient, namely the prevention of postmenopausal osteoporosis. The Minister found that the '970 Patent did not contain a claim for the changed formulation or a claim for the changed use of the medicinal ingredient approved through the issuance of an NOC in respect of SNDS 262. The Minister also found that the '970 Patent did not contain a claim for a change in dosage form and that there was no change contemplated by SNDS 262:

> Further, as per paragraph 4(3)(b) of the *PM(NOC) Regulations*, a patent on a patent list in relation to a supplement to a new drug submission is eligible to be added to the Patent Register if the **supplement is for a change in dosage form, and 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. The dosage form approved in the original new drug submission (Submission No. 041280) for the above product is a

> transdermal patch, the same dosage form referred to in supplemental new drug submission 065262….Therefore, no change to the dosage form is contemplated by supplemental new drug submission 065262. In addition, the '970 Patent does not contain a claim for a changed dosage form. [emphasis in original]

[21] The Minister therefore concluded that the '970 Patent was ineligible for listing in relation to SNDSs 262 and 243 since it did not meet the requirements of subsection 4(3) of the *NOC Regulations*.

[22] Regarding MENOSTAR, the Minister held that the '970 Patent did not meet the requirements of subsection 4(2)(c) of the *NOC Regulations* since the '970 Patent did not contain a claim for the approved MENOSTAR patch dosage form. In the Minister's view, the claims of the '970 Patent were directed to a novel type of packaging. Thus, the '970 Patent was also ineligible for listing in relation to NDSs 778 and 524.

ISSUES

[23] The sole issue in these applications is as follows:

1. **Does the '970 Patent meet the requirements of subsections 4(3), 4(2) and 4.1(2) of the *NOC Regulations* and is therefore eligible for listing on the Patent Register?**

RELEVANT STATUTORY PROVISIONS

[24] The following sections of the *NOC Regulations* are relevant to the applications at bar:

2. In these Regulations, "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)	**2.** Les définitions qui suivent s'appliquent au présent règlement. « 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. (claim for the dosage form)
"claim for the formulation" means a claim for a substance that is a mixture of medicinal and non-medicinal ingredients in a drug and that is administered to a patient in a particular dosage form; (revendication de la formulation)	« revendication de la formulation » Revendication à l'égard d'une substance qui est un mélange des ingrédients médicinaux et non médicinaux d'une drogue et qui est administrée à un patient sous une forme posologique donnée. (claim for the formulation)
4. (1) A first person who files or who has filed a new drug submission or a supplement to a new drug submission may submit to the Minister a patent list in relation to the submission or supplement for addition to the register.	**4.** (1) La première personne qui dépose ou a déposé la présentation de drogue nouvelle ou le supplément à une présentation de drogue nouvelle peut présenter au ministre, pour adjonction au registre, une liste de brevets qui se rattache à la présentation ou au supplément.

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 :

(*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;

a) une revendication de l'ingrédient médicinal, l'ingrédient ayant été approuvé par la délivrance d'un avis de conformité à l'égard de la présentation;

(*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;

b) une revendication de la formulation contenant l'ingrédient médicinal, la formulation ayant été approuvée par la délivrance d'un avis de conformité à l'égard de la présentation;

(*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;

(*d*) a claim for the use of the medicinal ingredient, and the use has been approved through the issuance of a notice of compliance in respect of the submission.

d) une revendication de l'utilisation de l'ingrédient médicinal, l'utilisation ayant été approuvée par la délivrance d'un avis de conformité à l'égard de la présentation.

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

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,

medicinal ingredient, and

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.

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.

4.1 (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

4.1 (2) La première personne qui présente une liste de brevets se rattachant à la présentation de drogue nouvelle visée au paragraphe 4(2) peut, si cette liste est ajoutée au registre, la présenter de nouveau à l'égard de tout supplément à cette présentation de drogue

list in relation to a supplement except in accordance with subsection 4(3).	nouvelle; elle ne peut toutefois présenter de nouvelle liste se rattachant à un supplément donné qu'en conformité avec le paragraphe 4(3).

EXPERT WITNESSES

[25] The Applicant served and filed the evidence of two witnesses, namely Mr. Eric Owston and Dr. Ping I. Lee. Mr. Owston, a Regulatory Affairs Advisor with the Applicant and previously the Director of Regulatory Affairs and Quality Assurance for Berlex, provided evidence regarding the factual underpinnings of the CLIMARA regulatory submissions and the correspondence between the Applicant and the Minister. Dr. Lee is a tenured Professor and the GlaxoSmithKline Chair in Pharmaceutics and Drug Delivery, Leslie Dan Faculty of Pharmacy at the University of Toronto. He has a Ph.D. in Physical Chemistry from Michigan State University and a B.S. in Chemical Engineering from National Taiwan University. He also has experience in academia and industry related to transdermal drug delivery. Dr. Lee provided evidence regarding transdermal drug delivery and how the person of ordinary skill in the art would understand the '970 Patent. Neither Mr. Owston nor Mr. Lee was cross-examined.

[26] The Minister of Health filed the evidence of Mr. Waleed Jubran, a patent officer with the Office of Patented Medicines and Liaison (OPML). Mr. Jubran has a B.Sc. in Chemistry from the University of Ottawa and has worked fort the OPML since he graduated in 2002. Mr. Jubran was cross-examined.

[27] The Applicant notes that Mr. Jubran has never formulated a drug product and has never served as a Health Canada new drug submission reviewer. With respect to the affiants put forward by the Applicant, the Respondents submit that neither of them has any special expertise or experience in matters relating to the *NOC Regulations* and, as such, their evidence should not be afforded any significant weight by this Court in considering whether the ‘970 Patent is eligible for listing on the Patent Register.

STANDARD OF REVIEW

[28] The Applicant submits that the standard of review for a decision of the Minister of Health regarding whether a patent meets the requirements of section 4 of the *NOC Regulations* is a question of regulatory interpretation reviewable on a standard of correctness. The Applicant also notes that the construction of a patent is also question of law, although the Court may have regard to the understanding of the patent by the person of the ordinary skill in the art. Thus, the Applicant argues that no deference is owed to the Minister of Health in his construction of the claims.

[29] The Respondents submit that, unlike the many patent listing cases brought under the former *NOC Regulations*, the question of whether the ‘970 Patent is eligible for listing on the Patent Register under the amended regulatory scheme is not wholly a question of law. The Respondents suggest that, pursuant to the new requirements introduced under subsections 4(2) and 4(3) of the amended *NOC Regulations*, the eligibility of a patent for listing on the Patent Register now explicitly requires an assessment of the subject-matter of the drug submission against which the

patent is proposed to be listed. Such an assessment, the Respondents suggest, is a question of fact and is one the falls squarely within the expertise of the Minister.

[30] Thus, according to the Respondents, a question of patent eligibility under subsections 4(2) and 4(3) of the amended *NOC Regulations* is properly characterized as a question of mixed fact and law and is reviewable on a standard of patent unreasonableness. The Respondents cite Chief Justice Richard's decision in *Ferring Inc. v. Canada (Minister of Health)*, 2007 FCA 276 (F.C.A.), to support their position:

> **7.** […] In our view, the standard of review is correctness for questions of law, and patent unreasonableness for questions of fact (*AstraZeneca Canada Inc. v. Canada (Minister of Health)*, [2004] F.C.J. No. 1545, 2004 FC 1277, per Justice Kelen at paragraph 33).
>
> **8.** I would add that where there is a mixed question of law and fact then the standard of review is patent unreasonableness unless the question of law is extricable from the question of fact in which case the question of law is determined on the basis of correctness.

[31] In my view the '970 Patent's eligibility for listing depends on the construction of the claims as well as the construction of subsections 4(2) and 4(3) of the *NOC Regulations*. As Justice Gauthier held in *GD Searle & Co. v. Canada (Minister of Health)*, 2008 FC 437 (F.C.T.D.) at paragraphs 17-18, these are questions of pure law extricable from the questions of fact and, therefore, following *Ferring*, she found that the applicable standard of review was correctness. I also conclude that the applicable standard of review of the Minister's Decision in both applications is correctness.

THE CLIMARA APPLICATION (T-1517-07)

The Applicant's Arguments

[32] The *NOC Regulations* seek to preserve the patent rights of innovators by requiring a generic to address patents on the Patent Register before the issuance of a NOC. The generic is only required to address those patents listed on the Patent Register. Thus, the listing of a patent on the Patent Register is the first and critical step in ensuring that the issuance of a NOC to the generic will not result in patent infringement.

[33] Subsection 4(3) of the *NOC Regulations* sets out the requirements which a patent, submitted in relation to a SNDS, must satisfy in order to be eligible for listing:

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	**a)** dans le cas d'une modification de formulation, une revendication de la formulation modifiée, la formulation ayant été

of a notice of compliance in respect of the supplement;	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.	**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.

[34] The Applicant does not contend that the '970 Patent contains a claim for a change in formulation or a change in use of the medicinal ingredient. Rather, the Applicant submits that SNDS 262 ought to be considered a submission for a change in dosage form and, further, that the '970 Patent contains a claim for the changed dosage form and is thus eligible for listing on the Patent Register.

[35] Patents containing a claim to a dosage form first became eligible for listing on the Patent Register with the October 2006 amendments to the *NOC Regulations*. A "claim for a dosage form"

is defined in section 2 of the *NOC Regulations* to mean "a claim for a delivery system that includes within its scope that medicinal ingredient or formulation."

[36] The Regulatory Impact Analysis Statement (RIAS) accompanying the October 6, 2006 amendments to the *NOC Regulations* explains the rationale of the amendment to section 2:

> 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, 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 addition, it must contain a claim that includes within its scope the approved medicinal ingredient.

[37] Thus, the RIAS contemplates three characteristics of an eligible dosage form patent: (1) the patent must contain a claim for a novel delivery system for administering the medicinal ingredient; (2) the claimed dosage form must be approved via a NOC; and (3) the patent must contain a claim that includes within its scope the approved medicinal ingredient. The Applicant submits that the '970 Patent meets all three requirements for listing.

[38] The parties agree that the claimed dosage form has been approved via a NOC, but are at odds with respect to whether the '970 Patent contains a claim for a novel delivery system.

[39] The Applicant submits that the '970 Patent contains a claim for a novel delivery system because: (a) the dosage form is not limited to the patch; (b) the patent claims are not limited to the

package/desiccant, but include the patch; and (c) protection of such patents is consistent with the wording of the definition of “dosage form” and the purpose of the amendment.

[40] The Applicant submits that the Minister erred in interpreting the definition of “dosage form” too narrowly when he concluded that the patent claims “a product package comprising a transdermal drug delivery device and a desiccant compartment containing a desiccant” rather than a dosage form. The Applicant argues that the Minister relied on a reference to “patch” in the relevant NOCs to decide that the approved dosage form for the purpose of subsection 4(3) can only be the transdermal patch and nothing more.

[41] The Applicant says that the Minister should have considered whether the entire delivery device properly fell within the definition, despite the references in the NOCs. That one aspect of the transdermal patch was listed on the NOCs, the Applicant argues, is not dispositive of the question because the description of the dosage form on the NOC is not necessarily co-extensive with the definition of a dosage form in the *NOC Regulations*. The Applicant suggests that the RIAS contemplates the possibility that the dosage form is not fully described in the NOC, since it provides that the description of the dosage form is “typically as identified in the notification issued by the Minister pursuant to paragraph C08.004(1)(a)” [emphasis added]. Thus, the Applicant admits that the patch is an integral component of the transdermal delivery device, but argues that the delivery device is not limited to the patch.

[42] The Applicant further argues that, by focusing on the product package, the Minister effectively attempted to read out an essential element of claim 1 of the ‘970 Patent, namely the patch itself. In support of this argument, the Applicant notes that, at paragraph 32 of his Affidavit, Mr. Jubran stated as follows:

> …it is the view of the OPML that the subject matter of the ‘970 Patent is directed to a product package that contains a desiccant compartment containing a desiccant, in order to lessen or prevent precipitation in a transdermal patch (a non-aqueous carrier comprising a dissolved drug) included in the package. As such, the ‘970 Patent is not directed to a dosage form.

[43] The Applicant cites the principle enunciated in *Lister v. Norton Brothers and Co.* (1886), 3 R.P.C. 199 (Ch. D.) that a patent “must be read by a mind willing to understand not by a mind desirous of misunderstanding.” The Applicant also submits that the claims must be construed in a purposive manner, which requires that they be interpreted in light of the whole of the disclosure, using the specifications. The Applicant relies on the evidence submitted by Dr. Lee, which states that the transdermal delivery device claimed in the ‘970 Patent has three components: a transdermal patch; a desiccant; and a product package. Dr. Lee was of the opinion that all three components of the transdermal drug delivery device of claim 1 are required for a useful commercial product. Thus, each element is important for a well-functioning device. In addition, the Applicant submits that if the desiccant package as described is separated from the rest of the device, there would not be a stable *estradiol* product based on the integrated matrix design of the transdermal drug delivery device.

[44] The Applicant also argues that the definition of “dosage form” should properly include the claimed subject matter of the ‘970 Patent, having regard to the ordinary wording of the definition and the purpose of the amendment to extend protection to dosage form patents. The Applicant notes that the desiccant forms an important part of the “delivery system” for administering the medicinal ingredient because it is used to prevent the drug from forming a solid hydrate and precipitation from the transdermal patch. Thus, the desiccant improves the performance of the patch by preventing the rate of drug delivery from decreasing as a result of drug crystallization and so provides a transdermal patch more suitable for commercial use. The Applicant further submits that the subject matter of the claims of the ‘970 Patent properly falls within the definition of a “dosage form” as it complies with the purpose of the amendments to permit the listing of novel dosage forms. The Applicant suggests that the entire delivery device is what permits the optimal administration of medication to the patient and, therefore, is worthy of protection under the *NOC Regulations*.

[45] With respect to whether or not SNDS 262 contains a change in dosage form, the Applicant submits that, although the Minister does not consider the change effected by SNDS 262 to be a change in dosage form, the dosage form is necessarily changed by a change in strength. Therefore, the SNDS is an eligible submission.

The Respondents' Arguments

[46] The Respondents submit that SNDS 262 does not represent a change in dosage form in the sense intended by subsection 4(3) of the *NOC Regulations* and notes that CLIMARA was first approved as a transdermal patch and remains approved as a transdermal patch.

[47] The Respondents also submit that the mere fact that the claims of the '970 Patent make general reference to transdermal patches does not lead to the conclusion that the '970 Patent contains a claim for a dosage form. In support of this argument, the Respondents rely analogously on the Federal Court of Appeal's judgment in *Biovail Corp. v. Canada (Minister of Health)*, 2006 FCA 105, wherein Justice Evans noted that the mere fact that a single claim within a patent makes reference to the medicine at issue does not warrant a finding that the patent contains a "claim to the medicine" for the purposes of the *NOC Regulations*.

[48] The Respondents note that, in coming to this conclusion, Justice Evans followed a long line of cases that recognized that where the essential elements of a patent relate to novel formulations or dosage forms, rather than to the medicines capable of being delivered by the novel formulation or dosage form, the patent cannot be said to "contain a claim to the medicine itself," despite claims with explicit references to the medicines at issue (see *Glaxo Group Ltd. v. Novopharm Ltd*. (1998), 144 F.T.R. 252 (F.C.T.D.); *Eli Lilly Canada Inc. v. Canada (Minister of Health)* (2002), 225 F.T.R. 110, 2002 FCT 1248 (F.C.T.D.), *Novartis Pharmaceuticals Canada Inc. v. Canada (Minister of Health)* (2003), 243 F.T.R. 160, 2003 FCA 299 (F.C.A.) [hereinafter *Novartis*], aff'g 2002 FCT

1042; *Eli Lilly Canada Inc. v. Canada (Attorney General)* (2003), 235 F.T.R. 134, 2003 FCT 676 (F.C.T.D.), *Pfizer Canada Inc. v. Canada (Attorney General)* (2004), 251 F.T.R. 195, 2004 FC 370 (F.C.T.D.), *GlaxoSmith Kline Inc. v. Canada (Attorney General)* (2005), 40 C.P.R. (4th) 193, 2005 FCA 197 (F.C.A.), aff'g 2004 FC 1725, *Janssen-Ortho Inc. v. Canada (Minister of Health)* (2003), 229 F.T.R. 268, 2003 FCT 286, aff'd [2004] F.C.J. No. 242 (F.C.A.), *Abbott Laboratories Limited v. Canada (Minister of Health)*, 2007 FC 865).

[49] The Respondents argue that the '970 Patent makes reference to the transdermal patch but does not claim a dosage form, in the same way as the references to specific medicinal ingredients in the claims of the patents in the cases referred to above were found not to amount to a "claim for the medicinal ingredient itself."

ANALYSIS

Does the '970 Patent Contain a Claim to a Dosage Form?

[50] In relation to CLIMARA the Minister decided, among other things, that the '970 Patent is not directed to a dosage form.

[51] The Applicant sees the '970 Patent as a unique way to overcome problems that occur when *estradiol* is exposed to water and forms insoluble hydrates. The permeation of moisture through packaging material can lead during product storage to formation of an insoluble hydrate and a

drastic change in the drug release rate. The Applicant says that the device referred to in the ‘970 Patent provides a unique way to overcome this stability problem by combining the transdermal drug delivery system with a desiccant package that eliminates any moisture in the device and maintains the physical stability of the transdermal system. In short, the Applicant sees the desiccant package as described in the ‘970 Patent as an integral part of the transdermal delivery device in Claim 1 of the patent. If the desiccant package as described in the rest of the device is separated, then the *estradiol* product based upon the integrated matrix design of transdermal drug delivery systems would not be stable.

[52] Hence, it is the Applicant’s position that the ‘970 Patent contains claims to a “dosage form” as that term is used in the Regulations, that the ‘970 Patent was submitted in connection with a SNDS for a change in dosage form, and that the claims include within their scope a changed dosage form approved via a NOC, so that the ‘970 Patent is eligible for listing on the Patent Register with respect to the Applicant’s CLIMARA products.

[53] The OPML was of the view that “the ‘970 Patent covers a product package that contains a desiccant compartment which lessens or prevents precipitation in the transdermal drug delivery system (a non-aqueous carrier comprising a dissolved drug).” In other words, the Respondents say that the invention taught by the ‘970 Patent is as described in lines 18-19 on page 2 of the Disclosure which states that the “invention provides a method of inhibiting precipitation of a drug in the carrier of a transdermal drug delivery device.” This is reiterated in lines 1-6 on page 3 of the Disclosure which say that “through the use of a desiccant [the] invention lessens or avoids

precipitation (e.g. crystallization) in transdermal drug delivery devices containing drugs that form hydrate forms upon exposure to water."

[54] Any analysis of whether the '970 Patent is eligible for listing requires a consideration and construction of the patent as a whole, and of the intent and purpose of the regulatory framework at issue. I am guided in this regard by the words of Justice Hugessen in *Abbott Laboratories Ltd. v. Canada (Minister of Health)* 2007 FC 865:

> 20. In my respectful view the Prothonotary has in this passage displayed a thorough grasp of the proper principles of patent claim construction. He has read the entire patent, including the disclosure. He has looked at all the claims together, reading each one in the light of the others, and has neither failed to distinguish between them nor gone outside their terms or had recourse to some ephemeral notion of the "nature of the invention". He has informed his analysis by reference to the disclosure and the expert evidence before him without allowing himself to be held prisoner by the latter.

[55] If I apply these principles of construction to the '970 Patent, it seems clear to me that the package system referred to in the patent is designed to prevent problems associated with the exposure of the drug to moisture, which problems can lead to changes in the drug release rate when the drug is administered to the patient.

[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. The function of the patented invention is to protect carriers such as the non-aqueous carrier.

[57] In my view, this interpretation is evident from reading the '970 Patent as a whole. It is also specifically referred to in the Disclosure at page 185, lines 9-18:

> The several components of a transdermal drug delivery device generally contain at least small amounts of water, which might not be intentionally incorporated but could be incidentally present e.g., as a result of method of manufacture or exposure to ambient moisture during manufacture or storage. Certain drugs tend to interact with this water and form relatively insoluble forms (e.g., solid hydrates). Consequently certain transdermal delivery devices involving dissolved drugs have shown a tendency to exhibit precipitation of the drug during storage. This problem is at least in part attributable to formation hydrate forms of the drug. Accordingly this invention provides a method of inhibiting precipitation of a drug in the carrier of a transdermal drug delivery device…
>
> [emphasis added]

[58] Such an interpretation is also supported at page 186, lines 1-6 of the Disclosure:

> Through the use of a desiccant, this invention lessens or avoids precipitation (e.g., crystallization) in transdermal drug delivery devices containing drugs that form hydrate forms upon exposure to water. The desiccant system can be made small, thin, and flexible, allowing incorporation into a flexible unit-dose transdermal drug delivery system product package without adversely affecting the appearance or shape of the product package.

[59] In other words, the invention in the '970 Patent lessens or avoids precipitation. This in turn prevents the rate of drug delivery from decreasing as a result of crystallization when the drug is administered to the patient. But that fact does not, in my view, render the invention a part of the dosage form.

[60] Page 186, lines 15-26 of the Disclosure make it clear, in my view, that references in the '970 Patent to a transdermal patch ("non-aqueous carrier") are intended to be general and are present in the claims to illustrate that the function of the invention is to protect such carriers:

> As used herein the term "non-aqueous carrier" refers to a substantially water free carrier that contains only small amounts of water, for example less than about one to five percent by weight of water as may be incidentally present in materials of construction that have not been dried prior to use. Examples of suitable carriers include pressure sensitive skin adhesives (e.g., those disclosed in U.S. Pat. Nos. RE 24,906 (Ulrich), 4,732,808 (Krampe), and 5,232,702 (Pfister)), non adhesive polymeric matrices (e.g., those disclosed in U.S. Pat Nos. 4,814,173 (Song)), and other reservoir systems (e.g., those disclosed in US Pat. Nos. 4,834,979 (Gale), 4,820,525 (Leonard), and 5,310,559 (Shaah)). A particularly preferred carrier is an acrylate pressure sensitive adhesive such as that disclosed, eg., in U.S. Pat. No. 5,223,261 (Nelson et al.) and commonly assigned copending application 08/305,883.

[61] Claim 1 of the '970 Patent refers to a "transdermal drug delivery device" which comprises the following:

> …a non-aqueous carrier comprising a dissolved drug that forms a solid hydrate when exposed to water vapour; a desiccant package permeable to water vapour and defining a desiccant compartment containing a desiccant; and a water vapour impermeable product package, wherein the carrier and the desiccant package are contained within the product package.

[62] However, by analogy to the Federal Court of Appeal pointed out in *Biovail Corp. v. Canada (Minister of Health)* 2006 FCA 105, the fact that the '970 Patent claims make reference to transdermal patches does not mean that, when read in its entirety, the patent contains a claim for a dosage form. It is important to read and assess the patent in its entirety in order to determine what the claimed invention is. I take Justice Evan's words in *Biovail* regarding what constitutes a "claim

to the medicine" for purposes of the *PM(NOC) Regulations* to be instructive in the present case where I must read the '970 Patent as a whole in order to determine whether it contains a claim to a dosage form:

> 7. I do not agree. Whether a patent claims a composition, which can be "the medicine itself", or a delivery system for medicine, is a question of construing the patent. While each claim of the patent must be considered individually, they must not be construed in isolation from the other claims and the rest of the patent. In my view, when considered in the context of the '684 patent as a whole, claim 30 should be construed as a claim for the use of the polymers to achieve the slow release of six of the 40 or so active ingredients mentioned in the patent. The claimed invention is thus not the medicine itself.

[63] By analogy, in the present case, I must construe the '970 Patent as a whole to determine whether it claims a dosage form or whether it merely references a dosage form that is not part of the invention claimed. When considering the context of the '970 Patent as a whole, in my view the references to transdermal patches are general and do not constitute the invention claimed by the patent. Consequently, I cannot say that the '970 Patent can be understood to contain a "claim to a dosage form," and I believe the Minister was correct in his interpretation.

[64] As the Applicant says, the invention of the '970 Patent provides a unique way to overcome the stability problem associated with the exposure of the drug to ambient moisture. It does this by storing the transdermal system in a package containing a desiccant. The Applicant says that this "maintains the physical stability of the transdermal system." My understanding of Dr. Lee's advice in his affidavit is that the desiccant absorbs "all the moisture initially present and all moisture that may subsequently enter the product package over the shelf-life of the product" (para. 44) and the

product package isolates the carrier and the desiccant package from the ambient environment (para. 37) in matrix type systems that can occur in such systems that do not use such protective packaging. Hence, I think the invention would be understood to maintain the stability of the drug that is administered by way of a matrix type system.

[65] "Inhibiting precipitation" will impact how the drug performs when it is administered to the patient through a matrix system, but that does not mean that the invention includes all of the components that go to make up this product, including the dosage form.

[66] The Applicant says that the three principal components of the product delivery system (the carrier, the desiccant package containing the desiccant and the water vapour impermeable product package) are all "an integral part of the drug delivery device of Claim 1" and that "If one separates the dessicant package as described from the rest of the device, one would not have a stable *estradiol* product based on the integrated matrix design of transdermal drug delivery system."

[67] It seems to me, however, that all "integral" can mean in this context is that the desiccant package maintains the stability of the drug, which is then rendered more effective when administered to the patient by way of the patch. It does not mean that the dessicant package is an integral part of a dosage form that thereby becomes inseparable from the invention claimed in the '970 Patent. The function of the patented invention claimed in the '970 Patent is to protect carriers such as non-aqueous carriers.

The Evidence

[68] In coming to the conclusion that the '970 Patent does not claim a dosage form, I have, in accordance with Justice Hugessen's words in *Abbott Laboratories*, also taken into account the expert evidence before me.

[69] In particular, in his affidavit at paragraph 37, Dr. Lee describes the general problem with transdermal drug delivery devices comprising matrix type systems (the carrier), and says that the '970 Patent

> …describes a potential problem with these devices; namely that unexpected precipitation of the drug in the carrier by forming insoluble hydrates upon exposure to water vapour can cause the rate of drug delivery from the carrier to decrease as the hydrate precipates.

[70] He advises that the problem occurs "because the several components of a transdermal drug delivery device generally contain at least a small amount of water" (paragraph 38) and the '970 Patent describes a possible solution "to inhibit precipitation of a drug which forms insoluble hydrates upon exposure to water vapour, such as estradiol, in the carrier of a transdermal drug delivery device …" (paragraph 39). The solution is "the use of a desiccant to absorb ambient moisture."

[71] He further advises that the "'970 Patent describes each component of a transdermal drug delivery device that will solve the problem in detail. Claim 1 contains each of these components." (paragraph 40)

[72] Dr. Lee then discusses each of the components that go to make up the "transdermal drug delivery device" that will "solve the problem in detail." He points out that the carrier is also one of the components of the device, but he also says that the '970 Patent "discusses possible carrier matrices, such as acrylate pressure sensitive adhesive" (paragraph 41).

[73] His summary at paragraph 47 of his affidavit is as follows:

> In my opinion, a person of average skill in the art would understand from the patent that useful commercial transdermal drug delivery devices can be successfully created for estradiol if the device contains several integral components including a carrier, a desiccant and a product package. In other words, the device containing estradiol provided to a patient has all of these components, including the desiccant package.

[74] I take it from what Dr. Lee says that a "carrier" is an integral part of a "useful commercial transdermal drug delivery device" for *estradiol*, but I do not take him to be saying that the invention taught by the '970 Patent is the "non-aqueous carrier" component of the device. The problem that the delivery device was intended to solve, according to Dr. Lee, was not solved by the "non-aqueous carrier" component of the device, which was already known. The problem of the drug forming insoluble hydrates because of ambient moisture was solved by the desiccant package and the water vapour impermeable product package wherein the carrier and the desiccant package are contained within the product package, and this is born out by a reading of the Patent in its entirety, including the Disclosure.

[75] The device provided to the patient has all of the components described by Dr. Lee, but this cannot mean that, because the patient receives the non-aqueous carrier as well as the other two

components, the ‘970 Patent, for that reason, would be understood to contain an invention whose components are all an inseparable part of a dosage form. In his affidavit, Dr. Lee fails, in my view, to consider the extent to which references to the “non-aqueous carrier” are there to make it clear that the function of the invention is to protect such carriers as opposed to being an integral part of a “dosage form” for the administration of the drug. In this regard, then, I believe I have to go beyond the advice in his affidavit and consider the implications of Justice Evan’s words in *Biovail* for the ‘970 Patent as a whole.

[76] The product that reaches the patient combines a patch with a desiccant and packaging which eliminates any moisture in the device and maintains the physical stability of the drug that is administered through the transdermal patch. The ‘970 Patent is directed at ensuring that the drug delivered through the patch is free of the moisture that can cause insoluble hydrates to form, which insoluble hydrates can change the drug release rate. In my view, the invention in the patent is directed at maintaining the stability of the drug; it does not include the dosage form, which is the patch. The plastic wrapping and the desiccant strip are not part of the transdermal administration of the medical ingredient. Hence, I agree with the Respondents that the Minister’s finding that the dosage form is the patch itself, which is not claimed in the ‘970 Patent, is also supported by the CLIMARA NOCS and the PM.

THE REGULATIONS

[77] Section 4(3) of the *Regulations* reads as follows:

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.

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.

[78] The *Regulatory Impact Analysis Statement* (RIAS) which accompanied the amendment to the Regulations describes the scope of the new "dosage form" provisions in the following terms:

> 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 C.08.004(1)(*a*). [emphasis added]

[79] The RIAS makes it clear that the intent of the Regulations 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." By "delivery system" the RIAS also makes it clear that the intention is to encompass such things as "controlled-release tablets and capsules, implants and transdermal patches."

[80] In my view, the '970 Patent does not claim a "novel delivery system by which the approved medicinal ingredient … is administered to the patient" in the sense intended by the RIAS.

[81] The '970 Patent is directed at, and claims, a product package that enhances the stability of the medicinal ingredient until such time as the medicinal ingredient is administered to the patient, at which point the invention is discarded and the drug is administered to the patient through the transdermal patch.

[82] The invention is product packaging that enhances the stability and performance of the drug; it is not, in my view, a “dosage form” or a “novel delivery system” in the sense intended by the *NOC Regulations* and as explained in the RIAS.

[83] I agree with the Respondents that the references to a “non-aqueous carrier” in the claims of the ‘970 Patent are incidental to the invention claimed in the ‘970 Patent as a whole and are not “a claim for the dosage form” in the sense intended by the *NOC Regulations*.

[84] In my view, the SNDS at issue does not represent a change in dosage form in the sense intended by subsection 4(3) of the *PM (NOC) Regulations*. Because I have already found that the ‘970 Patent is ineligible for listing with respect to SNDS 262, I need not address SNDS 243.

THE MENOSTAR APPLICATION (T-1518-07)

[85] The Applicant’s submissions in the MENOSTAR application, T-1518-07, are identical to those put forward relating to a change in dosage form in the CLIMARA application. I have already concluded that the ‘970 Patent does not contain a claim for a change in dosage form. Thus, the MENOSTAR application must also be refused.

JUDGMENT

THIS COURT ORDERS AND ADJUDGES that

1. **The applications for judicial review are dismissed with costs awarded to the Respondents for both applications.**

Judge

FEDERAL COURT

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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