Federal Court  Cour fédérale

Date: 20100708

Docket: T-248-10

Citation: 2010 FC 738

Ottawa, Ontario, July 8, 2010

PRESENT: The Honourable Mr. Justice Crampton

BETWEEN:

PURDUE PHARMA

Applicant

and

ATTORNEY GENERAL OF CANADA and THE MINISTER OF HEALTH

Respondents

REASONS FOR JUDGMENT AND JUDGMENT

[1] The Applicant, Purdue Pharma, seeks judicial review of a decision of the Office of Patented Medicines and Liaison (OPML) in which the OPML determined that one of the Applicant's patents is not eligible for listing on the Patent Register.

[2] The Applicant claims that the OPML erred by misinterpreting paragraph 4(2)(c) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (Regulations).

[3] For the reasons discussed below, this application is dismissed.

I. Background

[4] In May 2009 the Applicant, an innovator drug company, filed a New Drug Submission (NDS) as part of its application for a Notice of Compliance (NOC) to market and sell the drug TARGIN in Canada. The Applicant received that NOC in December 2009.

[5] TARGIN is a controlled-release drug in tablet form that contains two medicinal ingredients: oxycodone hydrochloride (oxycodone), a painkiller, and naloxone hydrochloride (naloxone), which counteracts certain side effects of oxycodone, such as constipation.

[6] Along with its NDS, the Applicant applied to list Canadian Patent No. 2,098,738 (the "'738 Patent") pursuant to section 4 of the Regulations in relation to TARGIN. The '738 Patent, filed on November 25, 1992, contemplates a controlled-release technology for delivering oxycodone. It contains 28 claims, none of which mention naloxone. For the purposes of this proceeding, Purdue confined its submissions to Claim 3 and Claim 5.

[7] Claim 3 contains the following formulation claim:

> A controlled release oxycodone formulation for oral administration to human patients, comprising from, about 10 to about 40 mg oxycodone or a salt thereof in a matrix, said formulation providing a mean maximum plasma concentration of oxycodone from about 6 to about 60 ng/ml from a mean of about 2 to about 4.5 hours after administration, and a mean minimum plasma concentration from about 3 to about 30 ng/ml from a mean of about 10 to about 14 hours

> after repeated administration every 12 hours through steady-state conditions.

[8] Claim 5 contains the following dosage form claim:

> A solid controlled release oral dosage form, comprising
>
> oxycodone or a salt thereof in an amount from about 10 to about 160 mg said oxycodone or salt thereof being dispensed in a matrix which includes;
>
> an effective amount of a controlled release matrix selected from the group consisting of hydrophilic polymers, hydrophobic polymers, digestible substituted or unsubstituted hydrocarbons having from about 8 to about 50 carbon atoms, polyalkylene glycols, and mixtures of any of the foregoing;
>
> a suitable amount of a suitable pharmaceutical diluent, wherein said composition provides a mean maximum plasma concentration of oxycodone from about 6 to about 240 ng/ml from a mean of about 2 to about 4.5 hours after administration, and a mean minimum plasma concentration from about 3 to about 120 ng/ml from a mean of about 10 to about 14 hours after repeated administration every 12 hours through steady-state conditions.

[9] In June 2009, the OPML advised the Applicant of its preliminary decision that the ‘738 Patent is not eligible for listing in the Patent Register in relation to TARGIN, on the grounds that the requirements set forth in paragraphs 4(2)(b) and (c) of the Regulations were not met. Those paragraphs establish the eligibility requirements for listing patents that make a claim to a formulation containing a medicinal ingredient or a dosage form of a drug or drug formulation containing a medicinal ingredient, respectively, as more specifically set forth in Part II below. In recognition of the preliminary nature of its decision, the OPML invited further submissions from the Applicant.

[10] The Applicant made further submissions to the OPML in August 2009. Those submissions included affidavits of Dr. Louis Cartilier and Dr. Kris Krishnamurthy. Dr. Krishnamurthy provided some factual information regarding TARGIN and the history of the ‘738 Patent, while Dr. Cartilier construed the ‘738 Patent and compared its claims to the formulation and dosage form of TARGIN. Dr. Cartilier concluded that “the presence of additional ingredients like undisclosed excipients or another active ingredient in Purdue’s TARGIN™ product will not cause the formulation or dosage form to fall outside the scope of Claims 3, 4 and 5.” In essence, Dr. Cartilier found “that since the term ‘comprising’ has been used, a dosage form can also include in addition to oxycodone or a salt thereof, excipient(s) and active ingredient(s) undisclosed in the claim.”

[11] Approximately two weeks later, on August 17, 2009, the Applicant sent a further letter attaching a copy of a decision released on July 16, 2009 by Justice Harrington, concerning another drug (OXYCONTIN) in respect of which the Applicant had sought to list the ‘738 Patent (*Purdue Pharma v. Pharmascience Inc. et al.*, 2009 FC 726).

[12] In October 2009, the OPML advised the Applicant that it remained of the view that the ‘738 Patent is not eligible for listing. However, the OPML noted that a similar issue regarding the interpretation of subsection 4(2)(b) was then before this Court in *Bayer Inc. v. Canada (Minister of Health)*, 2009 FC 1171 [*Bayer* (2009)]. The OPML offered the Applicant 30 days from the date of the judgment in *Bayer* to make any further submissions.

[13] This Court’s judgment in *Bayer* was rendered by Justice Russell on November 17, 2009. The Applicant made its further submissions to the OPML on December 17, 2009.

[14] After the OPML issued its final decision, the Federal Court of Appeal dismissed, in reasons given from the Bench on June 15, 2010, an appeal from Justice Russell's decision for "substantially for the reasons he gave" (*Bayer Inc. v. Canada (Minister of Health)*, 2010 FCA 161).

II. The Relevant Legislation

[15] Subsection 4(2) of the Regulations states:

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.

[16] Section 2 states, among other things:

2. In these Regulations,	2. Les définitions qui suivent s'appliquent au présent règlement.
"claim for the dosage form" means a claim for a delivery system for administering a medicinal ingredient in a drug or a formulation of a drug that includes within its scope that medicinal ingredient or formulation;	[…] « revendication de la forme posologique » Revendication à l'égard d'un mécanisme de libération permettant d'administrer l'ingrédient médicinal d'une drogue ou la formulation de celle-ci, dont la portée comprend cet ingrédient médicinal ou cette formulation.
"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 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.

[17] Additional legislation relevant to this decision is set forth in Annex "A" below.

III. The Decision under Review

[18] On February 5, 2010, the OPML issued its final decision stating that the '738 Patent is not eligible to be listed on the Patent Register in relation to TARGIN.

[19] With respect to the Applicant's formulation claim, the OPML noted that the Applicant had not made any new representations subsequent to the OPML's preliminary decision in October 2009. Accordingly, the OPML simply referred the Applicant to the reasoning in that preliminary decision. There, the OPML stated its view "that in order to be eligible for listing on the Patent Register under paragraph 4(2)(b), a patent must contain a claim to the formulation that contains all the medicinal ingredients" that are included in the formulation that was approved through the issuance of a NOC.

Given that Claim 3 of the ‘738 Patent does not mention naloxone as a medicinal ingredient, it was not eligible to be listed in respect of TARGIN.

[20] Similarly, with respect to the Applicant’s dosage form claim, the OPML observed that “Claim 5 … appears to be limited to delivering a formulation containing only oxycodone as the medicinal ingredient”. However, in the OPML’s view:

> … in order to be eligible for listing in respect of a combination drug (a drug containing multiple medicinal ingredients) under paragraph 4(2)(c), a patent must contain a claim for a delivery system for administering all the medicinal ingredients in a drug or a formulation of a drug that includes within its scope the medicinal ingredients, or formulation.

[21] Elaborating, the OPML stated:

> … a formulation containing a single medicinal ingredient must be a different formulation from one which contains multiple medicinal ingredients. A patent containing claims for a dosage form for delivering a particular formulation cannot “match” the approved dosage form unless both formulations explicitly contain the same medicinal ingredients.

[22] The OPML then specifically rejected the Applicant’s submission that the word “comprising” in the ‘738 Patent is non-limiting, such that naloxone can be considered to be within the scope of the patent. The OPML stated that “the conclusion that an unlimited number of other medicinal ingredients are within the scope of the ‘738 patent supports the view that it does not meet the requirement of product specificity under section 4.”

[23] In this latter regard, the OPML observed that in *Bayer* (2009), above, Justice Russell recognized that in the absence of product specificity, the patent at issue could be listed against any drug that contained ethinyl estradiol, contrary to the intent of section 4 of the Regulations.

[24] The OPML further observed that Justice Russell drew a distinction between the requirement for product specificity contemplated by the Regulations and the prevention of patent infringement. The OPML noted that at paragraph 89 of his decision, Justice Russell stated:

> In my view, the Applicant is inviting the Court to equate specificity under the Regulations with patent infringement. My reading of the RIAS [*Regulatory Impact Analysis Statement*] is that this is not what specificity means and it is fully recognized that not all patents will be protected and that some patents may be infringed.

IV. Issues

[25] In its correspondence with the OPML, the Applicant maintained that the ‘738 Patent contains claims to the formulations and dosage forms of TARGIN, as contemplated by the Regulations.

[26] However, as a result of the decision in *Bayer* (2009), above, the Applicant is no longer contesting the OPML’s rejection of its position that Claim 3 of the ‘738 Patent contains a claim to the formulation of TARGIN that was approved through the issuance of an NOC.

[27] Accordingly, the sole substantive issue is whether the OPML erred in finding that the ‘738 Patent is ineligible for listing in relation to the dosage forms of TARGIN that are contemplated by the NOC.

[28] The Respondent has also raised a procedural issue regarding two pieces of evidence submitted by the Applicant in this proceeding, namely, (i) an affidavit of Dr. Roland Bodmeier (the “Bodmeier Affidavit”), and (ii) an exhibit to the cross-examination of Elsa Maria Thompson (the “Maillé Transcript”).

V. The Standard of Review

[29] In *Abbott Laboratories Ltd. v. Canada (Attorney General)*, 2008 FCA 354 at paras. 29 – 32, the Court endorsed the view that the Minister’s determination of whether a patent is eligible for listing comprises three questions. In the context of paragraph 4(2)(c) of the Regulations, those questions can be restated as follows:

i. What dosage form does the patent claim?

ii. What is the dosage form approved by the existing NOC?

iii. Does the dosage form approved by the NOC fall within the scope of the ‘738 Patent?

[30] The Court held that (i) the first question is a question of law that is reviewable on a standard of correctness, (ii) the second question is a question of law that is reviewable on a standard of

reasonableness, and (iii) the third question is a question of mixed fact and law, the factual component of which is reviewable on a standard of reasonableness and the legal component of which is reviewable on a standard of correctness. In this case, the legal component of the latter question concerns the appropriate interpretation of paragraph 4(2)(c) of the Regulations.

[31] The approach described above is the approach that will be applied in my review of the issues raised in this application. In short, the OPML's decision will stand unless it is based on an incorrect construction of Claim 5, an incorrect interpretation of paragraph 4(2)(c) of the Regulations, an unreasonable conclusion as to the approved dosage form of TARGIN, or an unreasonable conclusion as to whether the approved dosage form of TARGIN falls within the scope of the '738 Patent (*G.D. Searle & Co. v. Canada (Minister of Health)*, 2009 FCA 35 at para. 36).

VI. Analysis

A. *The Bodmeier Affidavit and Maillé Transcript*

[32] These pieces of evidence were not before the OPML. Accordingly, they would not ordinarily be admissible in an application for judicial review before this Court. However, where an application for judicial review requires a determination on a point of patent construction, this Court has the discretion to admit evidence which may be helpful in that regard (*Abbott Laboratories*, above, at para. 39).

[33] I do not find either of the two documents to be particularly helpful.

[34] The Bodmeier Affidavit consists of twelve introductory paragraphs followed by a single paragraph in which Dr. Bodmeier simply states that he has reviewed and completely agrees with the opinions, comments and observations in Dr. Cartilier's Affidavit.

[35] As to the Maillé Transcript, it was an Exhibit to the cross-examination of Elsa Maria Thompson, a paralegal with clerical duties in the OPML. That Exhibit was attached to an affidavit filed in another proceeding, which in turn attached the Notice of Application and Maillé Transcript from a third proceeding. In the brief discussion regarding the Maillé Transcript that took place during the hearing before me, it was apparent to me that there was little, if anything, in that document which would be of assistance in addressing the questions identified above.

[36] Accordingly, I agree with the Respondent that the Bodmeier Affidavit and the Maillé Transcript ought not to be admitted as evidence in this proceeding.

B. *What dosage form is claimed by the '738 Patent?*

[37] The '738 Patent specifically makes a claim to "oxycodone or a salt thereof " in the dosage form claim that is made in Claim 5.

[38] The Applicant maintains that the word "comprising" in Claim 5 contemplates that medicinal and non-medicinal ingredients that are not specifically mentioned can also be included within the scope of that claim, except to the extent that they have been specifically excluded. Dr. Cartilier, a person skilled in the art, agreed with this interpretation. The Respondent did not adduce evidence in this regard from anyone skilled in the art.

[39] Patent construction is a task for the Court, "assisted by experts if necessary to explain the meaning of words, terms, science and background" (*Abbott Laboratories Ltd. v. Canada (Attorney General)*, 2008 FC 700 at para. 16).

[40] In performing this task, it is necessary and appropriate to adopt a "purposive construction," to identify "what the inventor considered to be the 'essential' elements of his invention" (*Whirlpool Corp. v. Camco Inc.*, [2000] 2 S.C.R. 1067 at para 45). In this regard, a purposive construction can "cut either way," in the sense that it can either expand or limit a literal text (*Whirlpool*, above, at subparagraph 49(h)).

[41] The Applicant submits that the presence of naloxone, which is not excluded by Claim 5, in TARGIN does not change the fact that the dosage form of TARGIN is within the scope of Claim 5. More generally, the Applicant submits that "a product containing all of the ingredients in the dosage form as described in the claim and one or more active ingredients would still be included within claim 5, so long as one of those active ingredients is oxycodone or a salt thereof."

[42] The Applicant further submits that to construe Claim 5 in a manner that does not encompass a dosage form that includes naloxone would require Claim 5 to be construed in a manner different to how it would be construed for the purpose of considering infringement or validity. (See, for example, *Pfizer Canada Inc. et al. v. Ratiopharm Inc. et al.*, 2010 FC 612 at para. 75.) The Applicant states that this would be contrary to the Supreme Court of Canada's observation that "it has always been a fundamental rule of claims construction that the claims receive one and the same interpretation for all purposes" (*Whirlpool*, above, at subparagraph 49(b)).

[43] The latter observation must be viewed in the context within which it was made. That context was the Court's reluctance to embrace a view that could result in a different claims construction for the purpose of validity than for the purpose of infringement. In my view, the purpose for which patent construction is conducted in the context of section 4 of the Regulation is sufficiently unique and different from the other purposes for which patents are constructed that it is unlikely that the Court intended its observation to apply in the former context.

[44] In short, requiring patents to be construed under section 4 in the same manner in which they are construed for all other purposes could seriously undermine a key objective of the 2006 amendments to the Regulation. As described in the *Regulatory Impact Analysis Statement* (RIAS) published with the 2006 amendments to the Regulations, that objective was to entrench "the concept of product specificity as the key consideration required of the Minister in applying the listing requirements under section 4 of the [Regulations]." This was considered necessary in order "to restore the balanced policy underlying" the Regulations (RIAS, at p. 1510), which was perceived to have been distorted by jurisprudence which appeared to be "predicated on the court's view that the sole purpose of the [Regulation] is the prevention of patent infringement" (RIAS, at p. 1513; see also *G.D. Searle*, above, at para. 15). The RIAS specifically recognized (at p. 1512) that:

> … there may be instances where a patent which does not qualify for the protection of the [Regulation] is ultimately infringed by the fact of generic market entry. However, the Government's view is that where the patent fails to meet the listing requirements described above, policy considerations tip the balance in favour of immediate approval of the generic drug and the matter is better left to the alternative judicial recourse of an infringement action.

[45] In my view, the foregoing passage makes it clear that the fact that an innovator has invested time and money to test an invention and have it approved for sale is secondary to the goals sought to be achieved by entrenching product specificity in the Regulation.

[46] In its letter to the Applicant dated October 26, 2009, the OPML provided the following support for its conclusion that the dosage form contemplated by Claim 5 relates to a formulation containing oxycodone as the sole medicinal ingredient:

> The OPML's position appears to be supported by numerous references in the patent. For example, the disclosure states the following at page 5, line 29, under the heading "Detailed Description":
>
> > It has now been surprisingly discovered that the presently claimed controlled release oxycodone formulations acceptably control pain over a substantially narrower, approximately four-fold (10 to 40 mg every 12 hours – around-the-clock dosing) in approximately 90% of patients. This is in sharp contrast to the approximately eight-fold range required for approximately 90% of patients for opioid analgesics in general.
>
> In addition, page 9 states the following at line 20:
>
> > The present oral dosage form preferably contains between 1 and 500 mg, most especially between 10 and 160 mg, of oxycodone hydrocholoride. Alternatively, the dosage form may contain molar equivalent amounts of other oxycodone salts or of the oxycodone base.

[47] I agree that these passages in the '738 Patent support the view that the dosage form contemplated by Claim 5 relates to a formulation (mixture of medicinal and non-medicinal ingredients) containing oxycodone as the sole medicinal ingredient. In my view, a purposive interpretation of both Claim 5 and the '738 Patent in its entirety supports this view.

[48] As the OPML noted, further support for this view is provided in Justice Harrington's decision concerning another application brought by the Applicant in respect of the '738 Patent, in relation to its OXYCONTIN drug (*Purdue Pharma*, above). At paragraph 4 of that decision, Justice Harrington noted:

> Suffice it to say that Purdue's Canadian patent 2,098,738 ('738), which claims a novel 12-hour controlled release formulation of oxycodone having a specific pharmacokinetic profile, is on the list maintained by the Minister pursuant to s. 4 of the Regulations. […]

In addition, Justice Harrington noted the following at paragraph 29:

> The specification describes various solid oral dosage forms containing about 10 to about 160 mg of oxycodone, or a salt thereof, in which release after ingestion is spread out either by a retardant coating or by a matrix. A matrix system consists of an active ingredient, in this case oxycodone, being dispersed homogeneously throughout a matrix of inert, erodible or swelling-controlled material, generally a polymer. It calls for certain dissolution ranges *in vitro* and blood plasma levels over time, "substantially independent of pH".

It is also noteworthy that the Applicant's position was described by Justice Harrington at paragraph 24, as follows:

> According to Purdue, the patent specification discloses an invention with three primary elements: 1) the choice of oxycodone as the active ingredient for a product to be used in the treatment of moderate to severe pain; 2) the choice of a particular pharmacokinetic profile; and 3) the development of formulations which would result in the type of profile being sought (12-hour controlled release). […]

[49] In conclusion, I find that the OPML correctly determined that the dosage form contemplated by Claim 5 relates to a formulation containing oxycodone as the sole medicinal ingredient, and that naloxone is not within the scope of Claim 5 for the purposes of the Regulation. A construction of Claim 5 that would recognize a potentially unlimited number of unnamed other medicinal

ingredients to be within the scope of that claim would be inconsistent with the requirement of product specificity that was enshrined in section 4 of the Regulations by the 2006 amendments thereto. Such a construction would also "[invite] the Court to equate specificity under the Regulations with patent infringement" (*Bayer* (2009), above, at para. 89). Such a construction must therefore be rejected (*Abbott Laboratories Ltd. v. Canada (Attorney General)*, 2008 FCA 244 at paras. 47-50; *G.D. Searle*, above, at para. 48).

C. *What is the dosage form approved by the NOC?*

[50] The Applicant submits that the dosage form approved through the NOC issued in December 2009 in respect of TARGIN is "controlled release tablets." This begs the question regarding the content of the controlled release tablets that were approved.

[51] As will be discussed further in the next section of these reasons, a "claim for the dosage form" is defined in Section 2 of the Regulations to mean "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." In my view, this clearly contemplates that a dosage form cannot merely be a delivery system, such as a controlled release tablet. It must be a delivery system for either a drug or a formulation of a drug. In the case of TARGIN, the dosage form that was approved is a controlled release tablet for the delivery of specific strengths of a formulation containing both oxycodone and naloxone.

[52] This interpretation is consistent with the description that appears in the table entitled "Summary Product Information", at page 3 of the TARGIN Product Monograph dated May 19, 2009. Under the heading "Dosage Form / Strength," the following is stated:

> Controlled Release Tablets
>
> 10 mg. oxycodone hydrochloride/
> 5 mg naloxone hydrochloride
>
> 20 mg. oxycodone hydrochloride/
> 10 mg. naloxone hydrochloride
>
> 40 mg. oxycodone hydrochloride/
> 20 mg. naloxone hydrochloride

[53] In my view, it was entirely correct, and in any event was not unreasonable, for the OPML to implicitly conclude that the dosage form of TARGIN that was approved is a controlled release tablet for the delivery of specific strengths of a formulation containing both oxycodone and naloxone.

D. *Does the dosage form approved by the NOC fall within the scope of the '738 Patent?*

[54] As noted at paragraph 30 above, this question is one of mixed fact and law. The question of law concerns the appropriate interpretation of paragraph 4(2)(c) of the Regulations. The question of fact is whether, having regard to that interpretation, the approved dosage form of TARGIN can be said to fall within the scope of the '738 Patent.

[55] In its final decision determining that the '738 Patent is not eligible for listing in respect of TARGIN, the OPML held that "the eligibility for listing a patent on the basis of a claim for the

dosage form under paragraph 4(2)(c) must take into consideration the requirement for product specificity." Proceeding from that premise, the OPML concluded:

> [I]n order to be eligible for listing in respect of a combination drug (a drug containing multiple medicinal ingredients) under paragraph 4(2)(c), a patent must contain a claim for a delivery system for administering all the medicinal ingredients in a drug or a formulation of a drug that includes within its scope the medicinal ingredients, or formulation.

[56] In reaching its conclusion, the OPML followed Justice Russell's reasoning in *Bayer* (2009), above. In that case, Justice Russell rejected the argument that the words "contains the medicinal ingredient" in paragraph 4(2)(b) of the Regulations simply requires that the patent claim contain (a) the medicinal ingredient, without necessarily explicitly referring to that ingredient, and (b) one, but not necessarily all, of the medicinal ingredients in the approved formulation. In this regard, he observed, at para. 71, that subsection 33(2) of the *Interpretation Act* provides that "words in the singular include the plural, and words in the plural include the singular," so there is nothing incorrect about reading "the medicinal ingredient" in subsection 4(2)(b) of the *Regulations* to include "the medicinal ingredients". With this in mind, he concluded, at para. 71:

> […] it would distort the plain and ordinary meaning of 'the medicinal ingredient' if the phrase were to read to mean 'one of the medicinal ingredients' that has been approved, because it is the formulation that must have been approved, and the formulation in this case contains a mixture of two medicinal ingredients."

[57] The Applicant notes that *Bayer* (2009), above, concerned paragraph 4(2)(b), as opposed to paragraph 4(2)(c), and submits that the OPML erred by ignoring the differences in language

between those paragraphs as well as between the definitions of “claim for the dosage form” and “claim for the formulation” in section 2 of the Regulations. Relying on the principle of statutory construction that different words should be interpreted to have different meanings, the Applicant submits that the Governor in Council did not intend paragraph 4(2)(c) to have the same meaning as paragraph 4(2)(b). In the Applicant’s view, it was improper for the OPML to require its claim to the dosage form to contain both of the medicinal ingredients in TARGIN.

[58] Instead, the Applicant submits that for claims for the dosage form under paragraph 4(2)(c), all that is required is that the dosage form has been approved. In support of this position, the Applicant suggests that the text of paragraph 4(2)(c) is devoid of any requirement relating to the medicinal ingredient.

[59] I am unable to agree with the Applicant’s interpretation of paragraph 4(2)(c).

[60] Section 2 defines the words “claim for the dosage form” to mean “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.” Accordingly, on a plain reading of these words, paragraph 4(2)(c) is not “devoid of any requirement relating to the medicinal ingredient”, as suggested by the Applicant.

[61] In my view, when read together while keeping in mind the principle of specificity that permeated the 2006 amendments to the Regulations, paragraph 4(2)(c) and section 2 require more than simply that the dosage form in question have been approved.

[62] It is implicit that the two dosage forms referred to in paragraph 4(2)(c) are dosage forms of something. With respect to the first of those dosage forms, namely, the "claim for the dosage form," section 2 makes it clear that that something is "a delivery system for administering a medicinal ingredient in a drug or a formulation of a drug." It can be inferred that the other reference to "dosage form" in paragraph 4(2)(c) also refers to "a delivery system for administering a medicinal ingredient in a drug or a formulation of a drug." This inference is consistent with the basic principle of statutory interpretation that the same words in a statute should be given the same meaning (Ruth Sullivan, *Sullivan on the Construction of Statutes*, 5th ed. (Markham: LexisNexis, 2008) at 215).

[63] In section 2, the words "that includes within its scope that medicinal ingredient or formulation" require that the medicinal ingredient in a drug or formulation of a drug to be administered by the claimed delivery system be included within the scope of the dosage form claim in question. Pursuant to subsection 33(2) of the *Interpretation Act*, the words "a medicinal ingredient" and "that medicinal ingredient" may be interpreted to mean "medicinal ingredients" and "those medicinal ingredients", respectively. Keeping in mind the principle of product specificity, it follows that where a claim has been made for a delivery system for administering multiple medicinal ingredients in a drug or a formulation of a drug, the claim in question must include within its scope each of those medicinal ingredients.

[64] As discussed in Section VI.B of these reasons, the dosage form claimed by Claim 5 of the '738 Patent is a delivery system for administering a formulation containing oxycodone as the sole medicinal ingredient. For the purposes of the Regulation, the medicinal ingredient naloxone is not within the scope of that claim.

[65] However, the approved dosage form of TARGIN is a delivery system for administering a formulation containing two medicinal ingredients, namely, oxycodone and naloxone.

[66] In short, the dosage form claimed by Claim 5 and the dosage form that was approved by the NOC issued in respect of TARGIN are delivery systems for administering two different formulations (*Bayer* (2009), above, at para. 64).

[67] In my view, for the purposes of the Regulation, the two dosage forms are therefore different. This is fatal for the Applicant's attempt to list the '738 Patent in relation to TARGIN, because paragraph 4(2)(c) plainly requires the claimed dosage form and the approved dosage form to be the same. This is clear from the use of the definite article "the" in the phrase "and the dosage form has been approved".

[68] To be eligible for listing under paragraph 4(2)(c) in relation to TARGIN, the dosage form claimed in Claim 5 must include within its scope both of the medicinal ingredients included in the approved dosage form of TARGIN.

[69] Accordingly, I conclude that the OPML correctly interpreted paragraph 4(2)(c) and section 2 of the Regulations as requiring a match between the dosage form claimed in Claim 5 and the dosage form that was approved through the issuance of a NOC in respect of TARGIN.

[70] I also conclude that it was not unreasonable for the OPML to conclude that there is in fact no match between the dosage form claimed in Claim 5 and the dosage form that was approved

through the issuance of a NOC in respect of TARGIN. Indeed, I believe that the OPML's conclusion in this regard is correct.

VII. Conclusion

[71] This application is dismissed with costs.

JUDGMENT

THIS COURT ORDERS AND ADJUDGES THAT this application for judicial review is dismissed with costs.

"Paul S. Crampton"

_____

Judge

ANNEX "A"

Patented Medicines (Notice of Compliance) Regulations, SOR/93-133	*Règlement sur les médicaments brevetés (avis de conformité)*, DORS/93-133
2. In these Regulations,	**2.** Les définitions qui suivent s'appliquent au présent règlement.
"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;	[…]
	« liste de brevets » Liste présentée aux termes du paragraphe 4(1).
	[…]
"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;	« ministre » Le ministre de la Santé.
	« première personne » La personne visée au paragraphe 4(1).
[…]	« registre » Le registre des brevets et des autres renseignements tenu par le ministre conformément au paragraphe 3(2).
"first person" means the person referred to in subsection 4(1);	« 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.
[…]	
"Minister" means the Minister of Health;	« 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.
[…]	
"patent list" means a list submitted under subsection 4(1);	
"register" means the register of patents and other information maintained by the Minister in accordance with subsection 3(2);	
3.(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	**3.** (2) Le ministre tient un registre des brevets et des autres renseignements fournis aux termes de l'article 4. À cette fin, il peut refuser d'y ajouter, ou en

delete any patent or other information that does not meet the requirements of that section.

supprimer, tout brevet ou tout autre renseignement qui n’est pas conforme aux exigences de cet article.

[…]

[…]

4. (1) A first person who files or who has filed a new drug submission or a supplement to a new drug submission may submit to the Minister a patent list in relation to the submission or supplement for addition to the register.

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

(2) A patent on a patent list in relation to a new drug submission is eligible to be added to the register if the patent contains

(2) Est admissible à l’adjonction au registre tout brevet, inscrit sur une liste de brevets, qui se rattache à la présentation de drogue nouvelle, s’il contient, selon le cas :

(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.

Interpretation Act, R.S.C. 1985, c. I-21

Number

33. (2) Words in the singular include the plural, and words in the plural include the singular.

Loi d'interprétation, L.R.C. 1985, c. I-21

Nombre grammatical

33. (2) Le pluriel ou le singulier s’appliquent, le cas échéant, à l’unité et à la pluralité.

FEDERAL COURT

SOLICITORS OF RECORD

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