Federal Court of Appeal | Cour d'appel fédérale

Date: 20110414

Docket: A-288-10

Citation: 2011 FCA 132

CORAM: **BLAIS C.J.**
LAYDEN-STEVENSON J.A.
STRATAS J.A.

BETWEEN:

PURDUE PHARMA

Appellant

and

ATTORNEY GENERAL OF CANADA and MINISTER OF HEALTH

Respondents

Heard at Ottawa, Ontario, on March 29, 2011.

Judgment delivered at Ottawa, Ontario, on April 14, 2011.

REASONS FOR JUDGMENT BY: LAYDEN-STEVENSON J.A.

CONCURRED IN BY: BLAIS C.J.
STRATAS J.A.

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REASONS FOR JUDGMENT

LAYDEN-STEVENSON J.A.

[1] The Minister of Health (the Minister) determined that Canadian Patent No. 2,098,738 (the '738 Patent) was ineligible for listing on the patent register maintained under the *Patented Medicines* (*Notice of Compliance*) *Regulations*, SOR/93-133 (the Regulations). The appellant, Purdue Pharma (Purdue), applied to the Federal Court for judicial review of the Minister's decision.

Justice Crampton (the judge) dismissed its application. Purdue now appeals from the Federal Court judgment. For the reasons that follow, I would dismiss the appeal.

Background

[2] The statutory framework and legislative history underlying the Regulations is well-known and fully described in the decisions of this Court and need not be repeated here. See: *Wyeth Canada v. ratiopharm inc.*, 2007 FCA 264, [2008] 1 F.C.R. 447; *Abbott Laboratories Ltd. v. Canada* (*Attorney General*), 2008 FCA 354, [2009] 3 F.C.R. 547 (*Abbott Meridia*); and *G.D. Searle & Co. v. Canada* (*Minister of Health*), 2009 FCA 35, 71 C.P.R. (4th) 389 (*G.D. Searle*).

[3] The factual context may be summarily stated. Purdue, an innovator, filed a new drug submission (NDS) in relation to the drug TARGIN in May, 2009 and received a notice of compliance (NOC) for TARGIN in December, 2009. TARGIN is a combination controlled release tablet that contains oxycodone hydrochloride (oxycodone) and naloxone hydrochloride (naloxone). Oxycodone is an opioid analgesic used for continuous relief of moderate to severe pain over several days or more. Naloxone is for the treatment of opioid-induced constipation.

[4] At the time of filing its TARGIN NDS, Purdue also filed a Form IV Patent List for its '738 Patent. The Minister is required, under the Regulations, to maintain a patent register. Subject to meeting the eligibility requirements of the Regulations, an innovator (owner or licensee) holding a NOC that embodies the invention described in a patent can list the patent against its NOC. If a patent is listed on the patent register, the innovator may benefit from the advantages of the

Regulations, in addition to any rights under the *Patent Act*, R.S.C. 1985, c. P-4. Purdue's '738 Patent is listed on the register with respect to its OXYCONTIN drug, which contains oxycodone as the only medicinal ingredient.

The '738 Patent

[5] Oxycodone is not new. The '738 Patent is titled "Controlled Release Oxycodone Compositions" and addresses controlled release formulations and dosage forms of oxycodone or a salt thereof. The invention relates to methods and formulations which are said to improve the efficiency and quality of pain management and substantially reduce variability, daily dosages, and the time and resources required for titration. There are 28 claims. Claims 1 and 2 are use claims; Claims 3 and 4 are formulation claims; Claims 5-24 are dosage form claims; Claims 25-28 are process claims for the preparation of a dosage form. There are both independent and dependent claims. We are concerned only with Claim 5, a dosage form claim, which reads as follows:

> 5. 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; and
>
> 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.

TARGIN

[6] As stated earlier, TARGIN is a controlled release drug in tablet form that contains the medicinal ingredients oxycodone and naloxone. The Product Monograph's "Consumer Information" section, under the heading "What the medication is used for", states:

> Targin is an oral controlled release tablet that slowly releases oxycodone (an opioid analgesic) and naloxone (an opioid antagonist) over a 12 hour period, and requires a dose every 12 hours to control your pain and lessen the effect of constipation.

Under the heading "What it does" the following appears:

> As its active substances, Targin contains oxycodone and naloxone. Oxycodone is a medicine used to treat moderate to severe pain requiring the continuous use of an opioid analgesic preparation for several days or more… Naloxone is a medicine used to prevent opioid medications from binding to receptors in the gastrointestinal tract, to help reduce constipation.

The Relevant Legislative Provisions

[7] The current eligibility requirements for listing a patent, subject to transitional provisions that are not in issue here, have been in effect since October 5, 2006. The rationale underlying the 2006 amendments was explained in detail in the *Regulatory Impact Analysis Statement* (RIAS) published with the amending regulation (SOR/2006-242). The conditions of eligibility for listing are found in subsection 4(2) of the Regulations. These provisions are reproduced below. Since we are dealing here with a dosage form claim, paragraph 4(2)(*c*) is the pertinent provision. The definition of "claim for the dosage form" in section 2 is also relevant.

Patented Medicines (*Notice of Compliance*) *Regulations* (SOR/93-133)	*Règlement sur les médicaments brevetés (avis de conformité)* (DORS/93-133)
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.
2. "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.	2. « 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.
“claim for the medicinal ingredient” includes a claim in the patent for the medicinal ingredient, whether chemical or biological in nature, when prepared or produced by the methods or processes of manufacture particularly described and claimed in the patent, or by their obvious chemical equivalents, and also includes a claim for different polymorphs of the medicinal ingredient, but does not include different chemical forms of the medicinal ingredient.	« revendication de l’ingrédient médicinal » S’entend, d’une part, d’une revendication, dans le brevet, de l’ingrédient médicinal — chimique ou biologique — préparé ou produit selon les modes ou procédés de fabrication décrits en détail et revendiqués dans le brevet ou selon leurs équivalents chimiques manifestes, et, d’autre part, d’une revendication pour différents polymorphes de celui-ci, à l’exclusion de ses différentes formes chimiques.
“claim for the use of the medicinal ingredient” means a claim for the use of the medicinal ingredient for the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms.	« revendication de l’utilisation de l’ingrédient médicinal » Revendication de l’utilisation de l’ingrédient médicinal aux fins du diagnostic, du traitement, de l’atténuation ou de la prévention d’une maladie, d’un désordre, d’un état physique anormal, ou de leurs symptômes.

The Decision

[8] The judge concluded the Minister’s determination 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” was correct. With respect to the NOC issued to Purdue in relation to TARGIN, he agreed with the Minister’s

conclusion that the approved dosage form was a controlled release mechanism for delivering a formulation containing both oxycodone and naloxone.

[9] Relying on the definition of a “claim for the dosage form” in section 2 of the Regulations, the judge rejected Purdue’s argument that paragraph 4(2)(*c*) of the Regulations was devoid of any requirement relating to a medicinal ingredient and that the only relevant consideration was whether the dosage form in question had been approved. The judge determined that it is implicit that the two dosage forms referred to in paragraph 4(2)(*c*) are dosage forms of something. Section 2 is clear that the something is a delivery system for administering a medicinal ingredient in a drug or a formulation of a drug. Adopting *Bayer Inc. v. Canada* (*Minister of Health*), 2009 FC 1171, 358 F.T.R. 20, aff’d 2010 FCA 161, 86 C.P.R. (4th) 81 (*Bayer*) the judge concluded, in accordance with subsection 33(2) of the *Interpretation Act*, R.S.C. 1985, c. I-21, the words “medicinal ingredient” should be interpreted as including their plural forms.

[10] The judge held, for the '738 Patent to be listed 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. Relying on his previous finding that naloxone was not within the scope of the dosage form claimed under Claim 5 and noting that the NOC issued for TARGIN approved a dosage form for a formulation containing both oxycodone and naloxone, the judge found that the Minister correctly determined that the '738 Patent could not be listed on the patent register in respect of TARGIN.

The Analytical Framework

[11] In *Abbott Meridia* and *G.D. Searle*, this Court adopted the analytical framework developed by Justice Hughes for the determination of the eligibility of a patent for listing on the basis of a NDS. The applicable standards of review have also been determined. The parties agree that the framework applies and that the appropriate standards of review are settled.

[12] The framework consists of three questions and can be adapted or reformulated in accordance with the particular nature of the claim. In the case of a dosage form claim, the questions are:

1. What dosage form does the patent claim?
2. What is the dosage form approved by the existing notice of compliance?
3. Is the dosage form claimed by the patent that which is approved by the existing notice of compliance?

[13] The standards of review are: correctness for the first question; reasonableness for the second question; and reasonableness for the third question except for its legal component (the interpretation of the Regulations), which is to be reviewed on a standard of correctness.

[14] It is the product specificity requirement of paragraph 4(2)(*c*) of the Regulations that underlies the analysis of question three. That is primarily what this case is about.

Question One – What dosage form does the patent claim?

[15] Purdue contends the judge, in addressing the first question, erred in three respects. Its first and second allegations amount to only one – the judge conflated claims construction with interpretation of the Regulations and thereby failed to adhere to the teachings of the Supreme Court in *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, [2000] 2 S.C.R. 1067 (*Whirlpool*). Next, Purdue asserts the judge, having accepted its expert as a person skilled in the art, erred in favouring the Minister's interpretation over that of Purdue since Purdue's evidence "is the only evidence before the Court relating to construction." I will deal first with the expert evidence issue.

[16] First, although there was no evidence that the Minister consulted a person skilled in the art, neither was there evidence that she did not. In the context of patent listing, expert evidence regarding the construction of a patent claim is permissive, but not obligatory: *Abbott Meridia* at para. 42. Second, it is not accurate to say the judge ignored the evidence of Purdue's expert. He clearly considered it (reasons for judgment at paras. 10, 38, 41, 42). Third, the judge was entitled to adopt a construction that differed from that put forth by the parties, or either of them: *Whirlpool* at para. 61; *Novartis Pharmaceuticals Canada Inc. v. RhoxalPharma Inc.*, 2005 FCA 11, [2005] 3 F.C.R. 261 at para. 59. Fourth, although the judge did not explicitly reject Purdue's expert's opinion, he did so implicitly when he concluded that a purposive interpretation of both Claim 5 and the '738 Patent in its entirety supports 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 (reasons for judgment at para. 47). Fifth, for reasons that will

become apparent, the evidence of Purdue's expert was not without difficulty. There is no error warranting the Court's intervention in relation to this allegation.

[17] That said, I agree with Purdue that the judge impermissibly imported the legislative requirements of paragraph 4(2)(*c*) into his construction of the patent (reasons for judgment at paras. 43-45 and 49 (excluding only the first sentence)). The legislative requirements are to be considered in the context of question three. Question one is concerned solely with the construction of the patent and its relevant claims. That is, the patent is to be construed in accordance with the principles articulated in *Whirlpool*.

[18] The comments in the latter portion of paragraph 49 of the judge's reasons indicate that the provisions of the Regulations factored heavily into his conclusion. Since that approach does not accord with *Whirlpool*, the judge erred when he defined and applied the product specificity concept of the Regulations at the claims construction stage of the framework.

[19] Purdue submits that its expert's construction should be accepted. I indicated earlier that the evidence of Purdue's expert was not without difficulty. I made that observation for a variety of reasons.

[20] First, paragraphs 128 through 145 of the expert's affidavit do not relate directly to claims construction. Rather, they constitute what may be described as an infringement analysis albeit in

relation to the TARGIN product. The claims construction portion of the affidavit begins at paragraph 44 and ends at paragraph 127.

[21] Second, prior to construing the patent's claims, Purdue's expert received a document titled "Legal Principles of Patent Claim Construction" from Purdue's counsel. The content of the document is largely non-contentious. However, there is one paragraph that constitutes legal argument rather than legal principle (appeal book, vol. 3, tab 19, p. 474, para. 4). Notably, the Minister does not agree with the stated proposition. This presents a problem because the expert's opinion may have been coloured by this comment, particularly in view of his statement that he had "applied these principles to my interpretation or construction of the claim language" (appeal book, vol. 4, tab 38, para. 44).

[22] Third, his construction of the pertinent claim turns on an interpretation of the word "comprising". Purdue's expert interprets the word "comprising" as not excluding other ingredients, active or inactive. I do not disagree that the word "comprising" may be regarded as open-ended. That is abundantly clear. However, the inclusion of an additional element requires some justification. There must be a basis for it within the confines of the patent. No such basis has been shown here.

[23] Reliance on other cases (two were cited) where "comprising" was construed to include a particular feature does not transform the result in those cases to a principle of general application. Cases are rarely identical and frequently are not even similar. Each will turn on its facts. The

interpretation accorded “comprising” in the two authorities cited by Purdue was based on the particular patents in suit and the evidence in relation to them. They are not helpful in this matter.

[24] Fourth, Purdue’s expert states that the disclosure does not teach away from including additional active ingredients. That statement does not resolve the debate with respect to naloxone. Purdue produced the affidavit of its Executive Director, Research and Development for the purpose of providing information regarding Purdue’s TARGIN product and the history of the invention of the '738 Patent. Although the deponent holds a PhD in Organic Chemistry, he was a factual witness. Nonetheless, I think it is safe to assume that the statement at paragraph 6 of his affidavit is accurate. That paragraph reads:

> TARGIN is a combination product, containing two medicinal ingredients: oxycodone hydrochloride and naloxone hydrocholoride. Each of these medicinal ingredients performs a specific function in the human body when TARGIN is administered.

[25] Keeping in mind that naloxone is held out to be a treatment for opioid-induced constipation, I note that in the disclosure, specifically the portion titled “Summary of the Invention”(p. 3, lines 10-14), the following statement appears:

> The present invention can also provide controlled release opioid formulations which have substantially less inter-individual variation with regard to the dose of opioid analgesic required to control pain without unacceptable side effects.

In the “Detailed Description” (p. 9, lines 11-15) the following statement appears:

> A further advantage of the present composition, which releases oxycodone at a rate that is substantially independent of pH, is that it avoids dose dumping upon oral

> administration. In other words, the oxycodone is released evenly throughout the gastrointestinal tract.

In the "Clinical Studies", Example 17 (p. 29, lines 20-22 and lines 32-34) the following statements appear:

> Before remedication, a total of 104 (57%) of patients reported 120 adverse experiences. The most common were somnolence, fever, dizziness and headache.
>
> …
>
> Side effects are expected and easily managed. Headache may be related to dose. Dizziness and somnolence were reported.

It seems that these excerpts, on their face, provide some indication that the patent does teach away from naloxone. In other words, it does not appear to contemplate the side effects naloxone is intended to address. Purdue's expert's evidence does not discuss these excerpts. Although Purdue's counsel provided an explanation regarding "inter-individual variation" at the hearing, that is precisely the sort of technical information one would expect the expert to have addressed.

[26] In the circumstances, I would attach little weight to Purdue's expert's opinion. Essentially, it is an assertion based on the word "comprising" without more. This was not the situation in the two cases referred to by Purdue. I agree with the judge that, taken to its limits, the expert's opinion would recognize a potentially unlimited number of unnamed other medicinal ingredients to be within the scope of that claim.

[27] However, I need not dwell on this question because, even if I were to assume that Purdue's construction of the claim is correct, the product specificity requirement discussed later in these reasons is not met. Therefore, although the judge erred in importing the legislative requirements of paragraph 4(2)(*c*) of the Regulations into his construction of the patent, he did not err in dismissing Purdue's application for judicial review.

Question Two – What is the dosage form approved by the existing notice of compliance?

[28] The judge concluded the Minister's determination that the approved dosage form of TARGIN is a "controlled release tablet for the delivery of specific strengths of a formulation containing both oxycodone and naloxone" was reasonable. No issue is taken with the judge's conclusion in relation to question two.

Question Three – Is the dosage form claimed by the patent that which is approved by the existing notice of compliance?

[29] Prior to the 2006 amendments to the Regulations, a patent for a delivery system was not eligible for listing on the patent register. In response to representations from the innovative industry regarding the significant therapeutic advantages afforded by novel dosage forms, the Governor in Council determined that inventions in this area merit the special protection of the Regulations (RIAS at p.1517). Although this is the first time that paragraph 4(2)(*c*) has been considered by this Court, guidance can be gleaned from the jurisprudence that addressed paragraphs 4(2)(*b*) and 4(3)(*c*) of the Regulations.

[30] In *Canada* (*A.G.*) *v. Abbott Laboratories Limited*, 2008 FCA 244, 68 C.P.R. (4th) 445, leave to appeal refused, [2008] 3 S.C.R. v (*Abbott Prevacid*), Justice Pelletier commented on the level of specificity required under paragraph 4(3)(*c*) of the Regulations. The debate there concerned the eligibility for listing of a patent in relation to a NOC issued pursuant to a supplementary new drug submission (SNDS) approving a new use. The Federal Court concluded that the patent was eligible for listing because the patent could be construed as including the new approved use notwithstanding that it was not explicitly claimed in the patent. This Court disagreed. Paragraphs 47 and 49 of the Court's reasons for judgment read:

> [T]he Regulations envisage as a condition of listing a patent in respect of a change in the use of a medicinal ingredient that the patent specifically claims the changed use as opposed to non-specific claims which are wide enough to include the changed use.
>
> …
>
> I conclude that paragraph 4(3)(*c*) of the Regulations requires, as a condition of listing a patent on the Patent Register, that the patent must specifically claim the very change in use which was approved by the issuance of a Notice of Compliance with respect to an SNDS. (my emphasis)

[31] In *G.D. Searle*, Justice Sharlow, writing for the Court, formulated the test required under paragraph 4(3)(*c*) as, "Does claim 15 of the 201 patent claim the very use that was approved by the issuance of the NOC in response to SNDS 072375…"

[32] In *Bayer*, the product specificity requirement under paragraph 4(2)(*b*) of the Regulations (a formulation claim) was interpreted. The Court determined that the patent did not claim the approved formulation because it claimed a formulation containing only one of the approved medicinal ingredients. The approved drug was a formulation containing two medicinal ingredients. The

argument that the "product specificity" intended in paragraph 4(2)(*b*) can be achieved without the strict matching required by the Minister was rejected. In respect of formulation claims, regard must be had to the particular components of the approved mixture that are responsible for the drug's effects in the body.

[33] For ease of reference, the definition of "claim for the dosage form" in section 2 and paragraph 4(2)(*c*) of the Regulations are again reproduced.

Patented Medicines (*Notice of Compliance*) *Regulations* (SOR/93-133)	*Règlement sur les médicaments brevetés (avis de conformité)* (DORS/93-133)
2. "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.	2. « 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.
4(2) A patent on a patent list in relation to a new drug submission is eligible to be added to the register if the patent contains	4(2) Est admissible à l'adjonction au registre tout brevet, inscrit sur une liste de brevets, qui se rattache à la présentation de drogue nouvelle, s'il contient, selon le cas
(*c*) a claim for the dosage form and the dosage form has been approved through the issuance of a notice of compliance in respect of the submission;	*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;

[34] The judge reasoned that a plain reading of paragraph 4(2)(*c*) supports the view that a similarly strict or explicit "matching" between the dosage form claimed under Claim 5 and the dosage form approved in respect of TARGIN was required for the Minister to grant Purdue's listing application. This reasoning is consistent with the statements in the RIAS, which serves as an interpretive tool. The following appears at pages 1517 and 1518:

> Although amended section 2 defines the phrase "claim for the dosage form" in very general terms, in order to accommodate future advancements in this field, the intent is to provide protection for the novel delivery system by which the approved medicinal ingredient, or a formulation containing that ingredient, is administered to the patient. Examples include controlled-release tablets and capsules, implants and transdermal patches. As with other eligible subject matter, a dosage form patent must include a claim to the specific dosage form described in the NDS (typically as identified in the notification issued by the Minister pursuant to paragraph C08.004(1)(a)). In addition, it must contain a claim that includes within its scope the approved medicinal ingredient. This latter requirement is meant to ensure that a patent directed solely to a device, such as an intravenous stand or a syringe, does not meet the definition of "dosage form" and remains ineligible for listing. (my emphasis)

[35] Purdue disagrees with the judge's interpretation of paragraph 4(2)(*c*) of the Regulations. It contends the judge failed to recognize the statutory interpretation principle that "different language should be given different effects."

[36] In *AstraZeneca Canada Inc. v. Canada* (*Minister of Health*), 2006 SCC 49, [2006] 2 S.C.R. 560 at paragraph 26, Justice Binnie set out in general terms the principles that govern the interpretive exercise in this case. The starting point is that "the words of an Act and regulations are to be read in their entire context and in their grammatical and ordinary sense harmoniously with the scheme of the Act, the object of the Act and the intention of Parliament." He added that "the scope

of a regulation such as the provisions of the *NOC Regulations* is constrained by its enabling legislation, in this case s. 55.2(4) of [the] *Patent Act*" (citations omitted).

[37] Purdue's first argument is: "for claims for the dosage form under [paragraph] 4(2)(*c*), all that is required is that the dosage form has been approved." Purdue draws a distinction between the wording of paragraph 4(2)(*b)* which refers to a claim for the formulation that contains the medicinal ingredient and paragraph 4(2)(*c*) which makes no reference to a medicinal ingredient. According to Purdue, since there is no requirement for a medicinal ingredient in paragraph 4(2)(*c*), it had to establish only that the delivery system approved under the TARGIN NOC (the controlled release tablet) was the same as that claimed under Claim 5.

[38] The judge made short shrift of this argument by referring to the definition of "claim for a dosage form" in section 2. By virtue of the definition, paragraph 4(2)(*c*) necessarily requires a claim for a dosage form for administering a medicinal ingredient in a drug. I completely agree with the judge's reasoning.

[39] Purdue's second argument is that there is a further distinction in relation to the definition of "claim for the dosage form" and "claim for the formulation." A claim for the dosage form "requires that the medicinal ingredient be within the scope of the claim, while a claim for the formulation refers only to the mixture of medicinal and non-medicinal ingredients" (emphasis in original). In Purdue's view, the language in the definition of a claim to the dosage form indicates that the medicinal ingredient is not required to be a part of a claim for the dosage form.

[40] To the extent that this submission adds anything to its first argument, it hinges on Purdue's proposed construction of Claim 5 of the '738 Patent, specifically that it is broad enough to include naloxone although it is not expressly named in that claim. Yet that is precisely the problem. The claim is so broad that, as noted earlier, it could cover an unlimited number of unnamed other medical ingredients. That is not what the patent eligibility requirements are about.

[41] The product specificity requirement of paragraph 4(2)(*c)* of the Regulations requires a matching between: (1) the claim for the dosage form; and (2) the dosage form that has been approved through the issuance of a notice of compliance.

[42] The claim for the dosage form is defined by the construction of the patent, that is, the question one inquiry. This equates to the definition of "claim for the dosage form" in section 2. However, the fact that naloxone may come within the scope of Claim 5 does not end the matter because even if it is within the patent's scope, it nonetheless may not match the dosage form approved by the NOC.

[43] Claim 5 relates to oxycodone and, at best, does not exclude naloxone from within its scope. That is not the same as the dosage form of the NOC, which explicitly includes both oxycodone and naloxone. Purposive claims construction under question one contemplates a different inquiry than the legislated test under paragraph 4(2)(*c*), which asks specifically whether the claimed dosage form and the approved dosage form are the very same. Absent precise and specific matching, the patent is

not eligible for listing on the patent register under the Regulations. Thus, Purdue's OXYCONTIN drug met the matching requirement; its TARGIN drug did not.

[44] In my view, the requirement for this level of specificity is consistent with the text, the object and the purpose of the Regulations. It is also consistent with the interpretation of the other classes of claims in section 4 of the Regulations as determined by the jurisprudence of this Court.

[45] I do not disagree with Purdue that the purpose of the Regulations is to prevent patent infringement by a person making use of a patented invention in reliance on the early working exception. However, there is no obligation to provide the advantages of the Regulations in every case. The fact that the Governor in Council establishes eligibility criteria for the listing of patents does not detract from the legitimate purpose.

[46] I have not overlooked Purdue's submission that the judge erred in not admitting into evidence the exhibit to the cross-examination of Ms. Thompson. As I understand it, Purdue obtained a certified copy of an affidavit filed in another proceeding that, in turn, exhibited (with respect to a third proceeding), the notice of application and the transcript of the cross-examination of another deponent. The judge refused to admit the document noting that it had not formed part of the record before the Minister and was of little probative value to the issues raised in the application before him.

[47] Purdue maintains that the impugned affidavit was that of an employee of the Office of Patented Medicines and Liaison (OPML) at the time the decision was rendered regarding the eligibility for listing of the '738 Patent and that the testimony was thus before the OPML.

[48] The judge did not err in refusing to admit the exhibit. He considered its admissibility and concluded that the deponent's testimony was not before the Minister. That is a factual determination. Purdue has not established palpable or overriding error in this respect. Moreover, if Purdue's purpose was to establish that the Minister's reasoning changed over time, as noted in *G.D. Searle*, the judicial review of the Minister's decision "should be based on the reasons expressed by the Minister in the final decision letter" (at para. 29).

[49] For the foregoing reasons, I conclude that the judge did not err in dismissing the application for judicial review. I would dismiss the appeal with costs.

"Carolyn Layden-Stevenson"
J.A.

"I agree.
Pierre Blais C.J."

"I agree
David Stratas"

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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CONCURRED IN BY:	BLAIS C.J. STRATAS J.A.
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APPEARANCES:

James E. Mills Beverley Moore	FOR THE APPELLANT
F. B. Woyiwada	FOR THE RESPONDENTS

SOLICITORS OF RECORD:

Borden Ladner Gervais LLP Ottawa, Ontario	FOR THE APPELLANT
Myles J. Kirvan Deputy Attorney General of Canada	FOR THE RESPONDENTS