Federal Court  Cour fédérale

Date: 20120629

Docket: T-1679-11

Citation: 2012 FC 836

Ottawa, Ontario, June 29, 2012

PRESENT: The Honourable Mr. Justice Martineau

BETWEEN:

NOVARTIS PHARMACEUTICALS CANADA INC.

Applicant

and

ATTORNEY GENERAL OF CANADA AND MINISTER OF HEALTH

Respondents

REASONS FOR JUDGMENT AND JUDGMENT

[1] The applicant, Novartis Pharmaceuticals Canada [Novartis], is seeking judicial review of a decision of the Office of Patented Medicines and Liaison [OPML] of the Minister of Health [Minister], issued on September 14, 2011, in which the latter held that Canadian Patent No. 2,304,819 ['819 patent] was ineligible for listing on the Patent Register pursuant to subsection 4(2) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, as amended [*Regulations*].

[2] In this application for judicial review, Novartis takes issue with both the OPML's interpretation of the listing requirements as prescribed by paragraphs 4(2)(b) and (c) of the *Regulations*, and with the OPML's "literal" construction of the '819 patent claims. At the hearing before this Court, Novartis abandoned its written representations regarding paragraph 4(2)(d) of the *Regulations*.

[3] After having carefully considered the parties' submissions with respect to the current state of the jurisprudence on the key matter at issue in this case, the impugned decision of the OPML, the '819 patent's sixty eight claims and the corresponding Notice of Compliance [NOC], as well as the expert evidence submitted by Novartis, I have reached the conclusion that this application for judicial review should be dismissed. These are my reasons for concluding so.

I. BACKGROUND

Tobi Podhaler®

[4] Novartis filed a New Drug Submission [NDS] with the Minister on March 22, 2010 with respect to a pharmaceutical product used for the management of cystic fibrosis caused by chronic pulmonary infections, and a NOC was accordingly issued for a drug product called Tobi Podhaler (Tobramycin Inhalation Powder) on April 1, 2011. The said NOC is for a respiratory antibiotic, the sole medicinal ingredient of which is tobramycin, to be delivered via inhalation of a dry powder contained in a 28 mg capsule.

[5] Tobi Podhaler consists of a medicinal and a non medicinal component: the medicinal component consists of a capsule dosage form providing a dry powder formulation which contains

the active ingredient tobramycin (an amino-glycoside antibiotic), intended for oral inhalation with the help of the Podhaler inhalation device (the non medicinal component).

The '819 patent

[6] Along with the NDS, Novartis filed a patent list application with the OPML in order to have its '819 patent in respect of the Tobi Podhaler® product listed on the Patent Register, as maintained by the Minister pursuant to subsection 3(2) of the *Regulations*. As several decisions of this Court and the Federal Court of Appeal explain in greater detail, the underlying rationale of this regulatory mechanism, established under subsection 55.2(4) of the *Patent Act*, RSC 1985, c P-4, is to provide relative protection against infringement to patent-owners whose patents would be subject to "early working" by a generic, an exception to the prohibition of infringement set out under subsection 55.2(1) which permits a generic drug manufacturer to work a patented invention prior to the expiry of the patent.

[7] The '819 patent is entitled "Perforated Microparticles and Methods of Use" and was issued on April 8, 2008. It essentially relates to formulations and methods for the production of perforated microstructures which comprise an active agent which, in preferred embodiments, will also comprise a bioactive agent. It is also specified that the perforated microstructures will preferably be used in conjunction with inhalation devices such as a metered dose inhaler, a dry powder inhaler, or a nebulizer.

[8] Of importance to the matter at bar, the '819 patent includes claims for the use of a bioactive agent in the manufacture of a medicament for pulmonary delivery, comprising a plurality of

perforated microstructures and administered by an inhalation device (claims 1 to 11) and claims for a perforated microstructure powder comprising a bioactive agent (claims 41 to 50 and 59 to 68), as well as claims of an inhalation system for pulmonary administration of a bioactive agent to the patient (claims 51 to 58).

[9] Novartis sought listing of the '819 patent on the Patent Register in respect of its Tobi Podhaler product on the basis that it purportedly contained claims for "the formulation that contains the medicinal ingredient" (paragraph 4(2)(b) of the *Regulations*), a claim for "the dosage form" (paragraph 4(2)(c) of the *Regulations*), and a claim for "the use of the medicinal ingredient" (paragraph 4(2)(d) of the *Regulations*), for which approval was sought in the March 22, 2010 NDS.

OPML's Preliminary Analysis of the Patent List

[10] By letter dated April 12, 2010, the OPML advised Novartis that it had formed the preliminary view that the '819 patent was not eligible for listing since nowhere in the said patent was the medicinal ingredient tobramycin specified as a potential active agent, as required by subsection 4(2) of the *Regulations*. The OPML thus invited Noartis to submit written representations with respect to this concern within 30 days.

[11] Novartis filed written representations supported by an expert affidavit by Dr. Robert O Williams – Professor and Division Head of Pharmaceutics at the College of Pharmacy at the University of Texas –, taking the position that the OPML incorrectly construed the claims of the '819 patent in reaching the conclusion that it did not contain a claim for the use of the formulation containing the medicinal ingredient, a claim for the dosage form, or a claim for the use of the

medicinal ingredient for which approval was being sought. Novartis essentially argued that in the eyes of the person skilled in the art, tobramycin is encompassed in the '819 patent, in particular in claims referring to antibiotics as a potential bioactive agent, because, as a matter of scientific fact, antibiotics do include tobramycin.

[12] Novartis added that as Dr. Williams indicated in his affidavit, the '819 patent specification having identified two related antibiotics by name (gentamicin and streptomycin), it would be well understood by a person of skill in the art as also specifying the use of tobramycin. It should be made clear at this junction that the respondents are not taking issue with the expert evidence submitted by Novartis with respect to the class of "antibiotics" as spelled out in the '819 patent counting tobramycin within its meaning. The respondents' position is rather focused on a matter of statutory interpretation regarding the scope of the listing requirements of subsection 4(2) of the *Regulations*.

[13] In fact, Novartis raised the issue in its submissions before the OPML that for the purposes of patent listing pursuant to paragraphs 4(2)(b), (c) and (d) of the *Regulations*, the specific reference made in the '819 patent to a class of medicinal ingredients, namely antibiotics, as well as the inclusion of other examples of the subclass of amino-glycoside antibiotics in the description of the patent, was sufficient to cover tobramycin.

II. RELEVANT REGULATORY PROVISIONS

[14] The proper interpretation of the patent listing requirements found in subsection 4(2) of the *Regulations*, and more specifically its paragraphs 4(2)(b) and (c), is at the heart of this judicial review. As mentioned earlier, the *Regulations* were intended to restore the balance by providing

more significant protection to patent holders, in order to prevent abuses of the early working exception mechanism. The October 2006 amendments to the *Regulations* did away with the concepts of "claim for the medicine itself" and "claim for the use of the medicine", in order to extend patent protection to the "dosage form" and the "use" claimed by a patent. As a result, since 2006, in order to qualify for listing, a patent should contain a claim for "the medicinal ingredient", "the formulation that contains the medicinal ingredient", "the dosage form" or "the use of the medicinal ingredient" as approved through the issuance of a NOC in respect of the relevant NDS:

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	*d*) une revendication de l'utilisation de l'ingrédient

the issuance of a notice of compliance in respect of the submission.	médicinal, l'utilisation ayant été approuvée par la délivrance d'un avis de conformité à l'égard de la présentation.

[Emphasis added]

[15] Definitions of "claim for the medicinal ingredient", "claim for the formulation", "claim for the dosage form" and "claim for the use of the medicinal ingredient" are provided in section 2 of the *Regulations*:

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 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*)
"claim for the medicinal ingredient" includes a claim in the patent for the medicinal ingredient, whether chemical	« revendication de l'ingrédient médicinal » S'entend, d'une part, d'une revendication, dans le brevet, de l'ingrédient

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*)	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 medicinal ingredient*)
[…]	
"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 » 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. (*claim for the use of the medicinal ingredient*)

[Emphasis added]

III. DECISION UNDER REVIEW

[16] In its final decision, the OPML reaffirmed its preliminary view. In fact, the OPML refused to list the '819 patent on the sole basis that the approved formulation of Tobi Podhaler, containing tobramycin as its only medicinal ingredient, was not "contained" in any of the '819 patent claims within the meaning of paragraph 4(2)(b) of the *Regulations* because it was not explicitly named therein. In the absence of an approved formulation containing the medicinal ingredient, the OPML

concluded that the product specificity requirements under paragraphs 4(2)(c) and (d) of the *Regulations* were also not satisfied.

[17] The OPML took the position that the requirement for an explicit mention of the medicinal ingredient for the purposes of listing is consistent with the principles of product specificity that underline the *Regulations*, as can be found in the Regulatory Impact Analysis Statement of the October 5, 2006 amendments [RIAS]:

> To the extent that the efficient functioning of the regime depends upon a threshold determination of what patents can be listed, in making that determination the Minister can only be called upon to assess the relationship between the patent and the drug described in the innovator's submission for a NOC. A broader inquiry into the relationship between the patent and any potentially equivalent generic drug is not relevant to the listing question.
>
> The proposed amendments reflect this by further entrenching the concept of product specificity as the key consideration required of the Minister in applying the listing requirements under section 4 of the PM(NOC) Regulations. They do so through more precise language respecting the intended link between the subject matter of a patent on a patent list and the content of the underlying submission for a NOC in relation to which it is submitted. In addition, under the amendments, only certain clearly defined submission types would provide an opportunity to submit a new patent list.

[18] The OPML also relied on this Court's decision in *Bayer Inc v Canada (Minister of Health)*, 2009 FC 1171, aff'd 2010 FCA 161 [*Bayer*], in which the Court confirmed the Minister's decision that a patent directed to a formulation containing one medicinal ingredient was not eligible to be listed in respect of a combination drug containing two medicinal ingredients.

[19] With regard to paragraph 4(2)(c) of the *Regulations*, the OPML did not discuss the dosage form claimed by '819 patent versus the approved dosage form of Tobi Podhaler. The OPML concluded rather that since the '819 patent did not contain a claim relating to a dosage form that includes within its scope the approved medicinal ingredient (tobramycin) or the approved formulation containing the medicinal ingredient, it followed that the product specificity requirement with respect to the dosage form was not met. The OPML stated that in light of this Court's decision in *Purdue Inc v Canada (Minister of Health)*, 2010 FC 378, aff'd 2011 FCA 132 [*Purdue*], an eligible dosage form must contain a claim that includes within its scope the approved medicinal ingredient or formulation containing the approved medicinal ingredient. In that case, both this Court and the Federal Court of Appeal ruled that an oral dosage form containing a single medicinal ingredient is not eligible for listing in respect of an approved dosage form containing a combination of that medicinal ingredient and another medicinal ingredient which falls outside the scope of the patent.

[20] The OPML further stated that the '819 patent was not eligible under paragraph 4(2)(d) of the *Regulations* since it contains general claims for the use of a bioactive agent in the manufacture of medicaments for pulmonary delivery, but includes no claims for the approved use of Tobi Podhaler's main medicinal ingredient tobramycin, namely the management of cystic fibrosis patients with chronic pulmonary infections, as per the Product Monograph.

[21] As noted above, the final decision neither takes issue, nor mentions, the expert opinion submitted by Novartis. However, the OPML considered the fact that the patent specification discloses examples of other antibiotics (namely gentamicin and streptomycin) that belong to the

same subclass of antibiotics (known as amino-glycosides) as tobramycin, and that this would be understood by a person of skill in the art. The OPML found than this was insufficient to meet the product specificity requirement of subsection 4(2) of the *Regulations*.

IV. THE PRESENT JUDICIAL REVIEW

[22] The parties are in agreement that the question before this Court is whether the OPML erred in law by applying an interpretation of subsection 4(2) of the *Regulations* that requires patent claims to "explicitly mention" the medicinal ingredient(s) of the related drug product in order to be eligible for listing on the Patent Register.

[23] Novartis also raises the fact that this question should be answered with the Court bearing in mind that the medicinal ingredient tobramycin is undisputedly included, as a matter of scientific fact, in a class of antibiotics that fall within the scope of the claims. The respondents do not consider this latter issue to be relevant in this judicial review and conceded at the hearing that tobramycin, as an antibiotic, is encompassed by the '819 patent.

Applicant's position

[24] As noted earlier, Novartis does not question the fact that the claims to the '819 patent do not specify tobramycin, nor does the '819 patent description in the patent. The latter provides a list of possible bioactive agents, including antibiotics as well as examples of antibiotics (streptomycin and gentamicin) that belong to the narrower subclass of amino-glycoside antibiotics to which tobramycin also belongs. However, nowhere in the '819 patent is tobramycin itself made explicit as a possible bioactive agent.

[25] Nevertheless, Novartis argues that a matter of patent construction arises in this case as to whether a person skilled in the art, based upon a purposive construction, would read the '819 patent claims as specifically claiming or covering formulations or dosage forms comprising tobramycin. Novartis thus maintains that the OPML erred in law by failing to apply a purposive construction with a person skilled in the art having been involved or consulted before the making of the impugned decision. It is submitted that OPML's statement in the impugned decision that "given that there is no explicit mention of tobramycin in the '819 patent, it follows that tobramycin is not within the scope of the '819 patent" is incorrect because the OPML should have construed the '819 patent with reference to the "common knowledge of the ordinary skilled worker in the art".

[26] In this respect, Novartis relies on Dr. Williams' expert opinion to argue that claim 41, 49 and 50 of the '819 patent (the formulation claims) specifically refer to a bioactive agent to be selected from a group consisting of, *inter alia*, antibiotics and that a person skilled in the art knows that the term antibiotic includes tobramycin as another example of the amino-glycoside type; streptomycin and gentamicin being explicitly referred to in the patent. Essentially, Novartis contends that through the inclusion of antibiotics, and by the overall description of the patent which assists in the understanding of this term, tobramycin is included in a number of claims as a medicinal ingredient by virtue of the reference to "antibiotic" and that such inclusion is sufficient for the '819 patent to qualify under paragraph 4(2)(b) of the *Regulations*.

[27] Novartis also submits that claims 51, 52 and 58 of the '819 patent (dosage form claims) claim other aspects of the Tobi Podhaler product, i.e. the dry powder formulation, which could serve

to satisfy the product specificity requirement. Novartis asserts that the respondents' witness, Mr. DiFranco, stated at cross-examination that the *capsule* dosage form that is approved in the NOC is found nowhere in the '819 patent claims. Novartis contends that the respondents should not be allowed to supplement the reasons for its refusal to list the '819 patent as the OPML's reasons are exclusively based on the '819 patent formulation claims not containing the word tobramycin. Furthermore, Novartis submits that the dry powder contained in the capsule itself is the innovative element of Tobi Podhaler and there are claims to this novel delivery mechanism in the '819 patent. In fact, Novartis argues that the capsule is only a reservoir that contains the powder and is not part of the delivery system.

[28] Novartis' second argument is that the OPML erred in its interpretation of subsection 4(2) of the *Regulations* by equating the product specificity requirement to a requirement of explicit designation of the approved medicinal ingredient in the language of patent.

[29] As will be discussed in more detail below, Novartis also takes issue with the OPML's reading of the *Purdue* and *Bayer* cases, arguing that in those cases there were medicinal ingredient(s) in the approved drug that the formulation and dosage form claims of the patent sought to be listed did not comprise, while in this case the formulation claims of the '819 patent do encompass the single medicinal ingredient found in the approved product, tobramycin.

[30] In their written representations, Novartis qualified the '819 patent's formulation claims as genus claims and argued that where a claim incorporates a number of species within the genus, there is a claim to each of the species within the genus. At the hearing, counsel for the applicant admitted

that the ‘819 patent contains no genus claims. However, counsel argued that in the specific context of this case, nothing in the language of subsection 4(2) of the *Regulations* requires that the claims relate explicitly to the single medicinal ingredients of the product, because patents can still include permissibly broad claims.

[31] Novartis further submits that the “explicit mention” requirement is inconsistent with the objective of preventing abuse of the early working exception as an infringement analysis does not impose any explicit mention requirement, but simply looks to whether the infringing device falls within the scope of the claim. Essentially, Novartis maintains that the higher the risk of being subject to infringement through early working, the greater the need to protect the patent under the *Regulations* regime.

[32] In addition, Novartis submits that the 2006 RIAS is a policy statement of the Minister and cannot be used to broaden the scope of the *Regulations*, nor does it impose a binding way as to how administrative discretion is to be exercised. Alternatively, Novartis argues that the purpose of the 2006 RIAS was not to set out any requirements subject to which patents can be listed, and that the stated intention of “product specificity” does not equate to a “claim specificity” requirement or an “explicit mention” requirement arising from the 2006 amendments.

Respondents’ position

[33] As mentioned earlier, the respondents do not specifically take issue with Dr. Williams’ expert opinion. The respondents rather argue that even if the Court would assume that tobramycin is

encompassed within the '819 patent, the mere inclusion of a particular approved ingredient in a patent is not sufficient to bring the patent within the *Regulations*.

[34] First, the respondents submit that the OPML correctly construed the '819 patent as protecting a delivery system, rather than a delivery system for the delivery of a particular medication containing the medicinal ingredient tobramycin (*GlaxoSmithKline Inc v Canada (Attorney General)*, 2005 FCA 197). The respondents refers to *Janssen-Ortho Inc v Canada (Attorney General)*, 2007 FC 729 at paras 7-16 and *Biovail Corp (cob Biovail Pharmaceuticals Canada) v Canada (Minister of National Health and Welfare)*, 2005 FC 1135 at paras 15-22, in which cases the Court held that where the "main thrust" of the patent is an innovative delivery system, even where the approved medicinal ingredient is explicitly mentioned in the patent, the eligibility requirements are not satisfied if the patent protects the delivery system without claiming the medicine itself or the use of the medicine. In both cases, the Court construed the approved active ingredients as being only incidental to the patent's main thrust, which consisted of a "tablet that possesses the means of delivering an active ingredient according to a particular release profile, and the use of such tablet for the treatment of ADD" in the first case, and a "controlled-release tablet made up of an active ingredient plus two intelligent polymers" in the second.

[35] Moreover, the respondents refer to *Purdue* (FCA), above, at para 42, to argue that even if the '819 patent's extremely broad formulation claims are construed so as to include all antibiotics, that is not dispositive of the patent's eligibility. In fact, the respondents contend that the Podhaler device, per se, is not an eligible device since other medicinal ingredients can be administered in association with the same device.

[36] Regarding paragraph 4(2)(b) of the *Regulations*, the respondents argue that "product specificity" is a mandatory requirement of the *Regulations* towards patent listing and is consistently supported by the jurisprudence. They asserts that in *Bayer* (FC), above, at paras 66-71, this Court ruled that where a formulation contains a mixture of two or more medicinal ingredients, it would distort the plain and ordinary meaning of the "medicinal ingredient" as intended in paragraph 4(2)(b) of the *Regulations* if the phrase was read to mean only "one of the medicinal ingredients" that have been approved.

[37] In addition, the respondents submit that another recent decision of this Court in *Gilead Sciences Canada, Inc v Canada (Minister of Health)*, 2012 FC 2 [*Gilead*], confirms the requirement of precise matching between the claimed formulation in the patent and the approved formulation in the NOC. In *Gilead*, the Court found ineligible a patent that referred to two of the three approved medicinal ingredients explicitly and also referenced a class of chemicals, namely the non-nucleoside reverse transcriptase inhibitors [NNRTIs], to which the third unnamed medicinal ingredient belonged. Therefore, the respondents submit that the fact that the '819 patent refers to various classes of agents, including antibiotics and anti-infective, is insufficient to meet the specificity requirements under paragraph 4(2)(b) of the *Regulations*.

[38] With regard to eligibility of the '819 patent under paragraph 4(2)(c) of the *Regulations*, the respondents submit that the principle of product specificity reaches across paragraphs 4(2)(a) to (c), so that it is irrelevant whether tobramycin is or is not encompassed by the '819 patent. Essentially, the respondents contend that there is no precise matching between the "dosage form" claimed in the

‘819 patent and the NOC issued in respect to Tobi Podhaler, because as per *Purdue* (FCA), above, at para 34, such matching requires sufficient matching of the patent claims with the approved medical ingredient or the formulation containing the approved medical ingredients.

V. ANALYSIS

[39] As will be explained below, I am of the view that the present application for judicial review must fail; the OPML’s construction of the relevant claims of the ‘819 patent and the relevant provisions of the *Regulations* being both correct in law.

Analytic Framework and Appropriate Standards of Review

[40] The three part analytical framework developed by Justice Hughes and adopted by the Federal Court of Appeal in *Abbott Laboratories Ltd v Canada* (*AttorneyGeneral*), 2008 FCA 354 [*Abbott Laboratories*]; *GD Searle & Co v Canada* (*Minister of Health*), 2009 FCA 35; and *Purdue* (FCA), above, is now trite law: when reviewing the Minister’s determination of the eligibility of a patent for listing on the basis of a NDS, the Court should consider the three following questions, to be reformulated in accordance with the particular nature of the claim(s) at issue:

(a) What formulation/dosage form does the patent claim?

(b) What is the formulation/dosage form approved by the existing notice of compliance? and,

(c) Is the formulation/dosage form claimed by the patent that which is approved by the existing notice of compliance?

[41] It is also trite law that the first question is a matter of construction of the patent claim, which is a question of law (*Whirlpool Corp v Camco Inc*, 2000 SCC 67 at para 76 [*Whirlpool*]), to be reviewed on the standard of correctness. The second question is a question of fact to be reviewed on the standard of reasonableness. The third question is one of mixed fact and law. In light of the above-cited Post-*Dunsmuir* jurisprudence of the Federal Court of Appeal, it attracts a reasonableness standard for its factual component, entailing "considerable deference" by the Court, and a correct standard for the legal component pertaining to the interpretation of the relevant provisions of the *Regulations* (*Abbott Laboratories*, above, at paras 29-33; *Purdue* (FCA), above, at paras 13-14), notwithstanding the fact that the Minister's interpretation of its home statute should, in theory, be reviewed against the standard of reasonableness and that there is ample authority that "[d]eference will usually result where a tribunal is interpreting its own statute or statutes closely connected to its function, with which it will have particular familiarity" (*Dunsmuir v New Brunswick*, 2008 SCC 9 at para. 54, [2008] 1 SCR 190 [*Dunsmuir*]; *Smith v Alliance Pipeline Ltd*, 2011 SCC 7, [2011] 1 SCR 160, at para. 28; *Alberta (Information and Privacy Commissioner) v Alberta Teachers' Association*, 2011 SCC 61, at paras 34-41, [2011] 3 SCR 654.

[42] In *Dunsmuir*, above at para 57, the Supreme Court also observed that where prior jurisprudence has established the standard of review that should apply in a particular case, that standard can be followed. Thus, as I apply the Federal Court of Appeal's reasoning in *Abbott Laboratories*, above, at para 34 to the matter at bar, the Minister's decision not to list a patent must stand unless it is based on (1) an incorrect construction of the patent's claims, (2) an incorrect interpretation of the *Regulations*, (3) an unreasonable conclusion as to the approved

formulation/dosage form/use of Tobi Podhaler, or (4) an unreasonable conclusion as to the fact whether any of the claims of the '819 patent "contains" the approved medicinal ingredient, tobramycin, within the meaning of subsection 4(2) of the *Regulations*. In view of the parties' submissions, the first two options are at issue in this case. I will thus review each of the above-stated question under paragraphs 4(2)(b) and (c) of the *Regulations*.

(a) What formulation/dosage form does the patent claim?

[43] It is well established that claim construction is a question of law for the Court to decide, with, if needed, the assistance of experts to explain technical terms and the scientific background: *Hoffmann-LaRoche Ltd. v Mayne Pharma (Canada) Inc.*, 2005 FC 814 at para 16. That said, it is also well established that expert evidence, although essential to the construction of a claim, does not govern the construction of a claim. Claims construction is a question of law, for the judge, who is even entitled to adopt a construction of the claims that differs from that put forward by the parties: *Pfizer Canada Inc v Canada (Minister of Health)*, 2007 FC 446 at para 35; *Whirlpool***,** above, at para 61. Furthermore, the Federal Court of Appeal has determined that expert evidence is permissive but not obligatory for the purposes of patent listing: *Purdue* (FCA), above, at para 16; *Abbott Laboratories*, above, at para 42. On the basis of this jurisprudence, I reject the applicant's argument that the OPML should have sought expert opinion, or that its failure to do so must be presumed in any way as having affected the correctness of its construction of the patent claims in this case.

[44] Claims must be construed with a purposive approach and a mind willing to understand, in a manner that best ensure the attainment of the patent's objects, taking into account the context

of the specifications and seeking a reasonable and fair construction: *Whirlpool*, above, at para 49. Also, in *Free World Trust v Électro Santé Inc*, 2000 SCC 66 at para 31, the Supreme Court of Canada stated established, as a matter of interpretation principle, that:

> The claims language will, on a purposive construction, show that some elements of the claimed invention are essential while others are non-essential. The identification of elements as essential or non-essential is made:
>
> > (i) on the basis of the common knowledge of the worker skilled in the art to which the patent relates; […]
> >
> > [Emphasis added]

[45] In the matter at bar, the general language of '819 patent, entitled "Perforated Microparticles and Methods of Use", relates to formulations and uses of perforated microparticles for the delivery of a bioactive agent, in the form of a dry powder, to the respiratory tract of the patient, the object of the invention being to ensure more effective absorption of the bioactive agent than when it is taken orally.

Formulations claims 41, 49 and 50

[46] The patent refers to a large variety of bioactive agents with broad claims, such as claims 1, 11, 41, 49, 50 and 58, more specifically referring to antibiotics as a possible bioactive agent. However, a careful reading of the patent shows that those antibiotics are not amongst the most preferred bioactive agents for inhalation therapy. As the patent descriptions read, at page 14:

> In particularly preferred embodiments, the selected bioactive agent may be administered in the form of an aerosolized medicament. Accordingly, particularly compatible bioactive agents comprise any drug that may be formulated as a flowable dry powder or which is relatively insoluble in selected dispersion media. In addition, it is preferred that the formulated agents are subject to pulmonary or

> nasal uptake in physiologically effective amounts. Compatible bioactive agents comprise hydrophilic and lipophilic respiratory agents, pulmonary surfactants, bronchodilators, antibiotics, antivirals, anti-inflamatories, steroids, antihistaminics, leukotriene, inhibitors or antagonists, antineoplastics, anesthetics, enzymes, cardiovascular agents genetic material including DNA and RNA, viral vectors, immunoactive agents, imaging agents, vaccines, immuno-suppressives agents, peptides, protein and combinations thereof. Particularly preferred bioactive agents for inhalation therapy comprise mast cell inhibitors (anti-allergics), bronchodilators, and anti-inflammatory steroids such as, for example, cromoglycate (e.g. the sodium salt), and albuterol (e.g. the sulphate salt).

[47] Be that as it may, in view of the respondents' recognition of the fact that tobramycin falls within the very large ambit of the bioactive agents encompassed by the '819 patent, I need not to discuss the issue further. However, the problem I have with Dr. Williams' affidavit is that it is an *ex post facto* recognition of the fact that tobramycin is one of the many possible antibiotics envisaged in the '819 patent. The mere reference to antibiotics or to other types of amino-glycoside antibiotics does not support the expert's opinion that a person skilled in the art would have been able to assume that tobramycin is included within the antibiotics. Such reading of the patent would result in innumerable medicinal ingredients being encompassed in the '819 patent and I consider such construction to be unreasonable. As a result, I am of the view that the OPML correctly construed the '819 patent's formulation claims.

[48] Another problem I have with the expert opinion submitted by Novartis is that, in my view, it should only be used to assist the Court in answering the first and/or the second step of the analysis and not the third, which requires no more than an assessment of whether the formulation/dosage form claimed by the patent is identical to that of the approved drug product.

Dosage form claims 51, 52 and 58

[49] Of importance to this case, the patent also contains other claims towards a powder of increased dispersibility and comprising the said bioactive agent (claims 51, 52 and 58) as well as claims for an inhalation device comprising a reservoir and a powder comprising the said bioactive agent (claims 51 through 58). In view of the object of the '819 patent, I am thus ready to admit that the main thrust of the '819 patent consists of the improved method of delivery, which in turn includes a flowable dry powder contained in a capsule or a reservoir, and administered by an inhalation device.

[50] In sum, on the question of patent construction, I conclude that the dosage form claims of the '819 patent are correctly construed as claims generally directed to an improved delivery system, as described at page 2 of the impugned decision:

> Claims 41 through 50 are directed towards a powder having increased dispersibility comprising a plurality of perforated microstructures having a bulk density of less than 0.5 g/cm³ wherein said perforated microstructure powder comprises an active agent. Claims 51 through 58 are directed towards an inhalation system for the pulmonary administration of a bioactive agent to a patient comprising: an inhalation device comprising a reservoir; and a powder in said reservoir wherein said powder comprises a plurality of perforated microstructures having a bulk density of less than 0.5 g/cm³ wherein said perforated microstructure powder comprises an active agent whereby said inhalation device provides for the aerosolized administration of the said powder to at least a portion of the nasal or pulmonary air passage of a patient in need thereof.
>
> [Emphasis added]

[51] As a final note on this issue, I disagree with the applicant that the OPML's construction of the '819 patent discounts the principle of purposive construction. Claim construction is informed by

the context in which it is conducted; this also seems to me to be the reason why, according to the Federal Court of Appeal, expert evidence is permissive but not obligatory for the purposes of patent listing. As Justice Crampton stated in *Purdue* (FC), above, at para 44:

> [R]equiring 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).

(b) What is the formulation/dosage form approved by the existing notice of compliance?

[52] The formulation/dosage form approved in the NOC is clear and not a matter of much disagreement between the parties. However, the applicant contends that the inhalation device, as well as the capsule or the reservoir, are only components of the approved delivery system and should be distinguished from the dry powder containing tobramycin.

[53] In view of the drug submissions for Tobi Podhaler, the NOC, as well as the product monographs, the better view is that the "approved dosage form" is for the inhalation delivery system as a whole and cannot be disintegrated into its different components when it comes to determining what the approved dosage form is. I conclude that Tobi Podhaler is a respiratory

antibiotic (the sole medicinal ingredient of which is tobramycin) in the form of a dry-powder formulation, to be delivered with the help of the inhalation device.

(c) Is the formulation/dosage form claimed by the patent that which is approved by the existing notice of compliance?

[54] The parties agree that the purpose of the *Regulations* is to prevent abuse by generic drug manufacturers of the early working exception to patent infringement in relation to pharmaceutical patents. However, as a preliminary note, the Court does not share the applicant's concern that the OPML's interpretation of the *Regulations* and the claims of the '819 patent might upset the early working exception principle. As stated by Justice Layden-Stevenson in *Purdue* (FCA), above, at para 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.

The applicant's argument on the early working exception cannot stand simply because establishing eligibility criteria for the listing of patents does not detract from this principle. It is a further purpose of the *Regulations*. In fact, the rationale of the 2006 amendments is, amongst other things, to prevent "hypothetical innovations" from impeding the generic market entry and to encourage innovator drug companies to bring their latest innovations to the market.

[55] The principal issue in this case is the proper interpretation to be given to paragraph 4(2)(b) of the *Regulations*. There is no dispute that the '819 patent is not eligible as a compound patent under paragraph 4(2)(a), and the applicant abandoned its arguments under paragraph 4(2)(d) of the

Regulations. Furthermore, eligibility by reason of a claim for the approved "dosage form" under paragraph 4(2)(c) of the *Regulations* does not provide a stand-alone basis for eligibility, unless the said dosage form relates specifically to the approved formulation or the approved medical ingredient. In *Purdue* (FCA), above, at para 34, the Federal Court of Appeal approved this Court's view 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:
>
> > 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.

Correct Interpretation of paragraph 4(2)(b) of the Regulations

[56] That being said, in view of the leading jurisprudence cited by the parties, it is clear to me that a rather high threshold of specificity in the formulation claims is required for a patent to be eligible for listing under paragraph 4(2)(b) of the *Regulations*.

[57] In *Bayer*, above, a NOC was issued with respect to YAZ, a "combination oral contraceptive", which contains a low dose of two medicinal ingredients: progestin drospirenone and estrogen ethinylestradiol. The patent that the applicant sought to list contained a claim

regarding a pharmaceutical composition containing ethinylestradiol, but not the other medicinal ingredient. The applicant argued that product specificity was achieved through the requirement that the formulation must have been approved, rather than through explicit designation of each and every medicinal ingredient contained in the approved drug. Considering the policies behind the new regulations, the Court in Bayer (FC), above, at paras 88-89, held however that a strict matching with the approved formulation of the drug was required for the patent to be eligible for listing under paragraph 4(2)(b) of the *Regulations*:

> [T]he mixture contains two medicinal ingredients which are responsible for YAZ's desired effect upon the body. The '979 Patent does not match because it only encompasses one of the medicinal ingredients. In other words, it is not the same mixture that is responsible for YAZ's desired effect upon the body.
>
> In my view, the Applicant is inviting the Court to equate specificity under the *Regulations* with patent infringement. My reading of the RIAS 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.

[58] I agree with the applicant that the facts in this case are different with the facts in *Bayer*, above. Nonetheless, the ratio in *Bayer* (FC), above, readily applies. Essentially, the applicant is asking the Court to do exactly what the Federal Court of Appeal refused to do in *Bayer*; that is, to find that the inclusion of antibiotics as a class, without specifying tobramycin, is sufficient to constitute a claim for the formulation containing the medicinal ingredient. This type of inclusion had been rejected in *Bayer*, and more strictly in *Gilead*, with regard to the interpretation of paragraph 4(2)(b) of the *Regulations*.

[59] The applicant argues that this case should be distinguished from *Bayer* and *Purdue* in that in those cases there were medicinal ingredient(s) in the approved drug that did not fall within the claims of the patent sought to be listed, while the '819 patent contains formulation claims that encompass the one medicinal ingredient of the approved product, tobramycin. However, this is only part of the principles established in *Bayer* and *Purdue*. In light of *Gilead*, it is not sufficient that the approved medicinal ingredient be, as a matter of scientific fact, within a more or less large class of active agents that the patent claims. In that case, Gilead had obtained approval of tablets formulated with three antiviral agents as the drug's medicinal ingredients: tenofovir, emtricitabine and rilpivirine. Although rilpivirine comes within the rather limited class of agents known as NNRTIs that the patent explicitly referenced, no reference to the medicinal ingredient rilpivirine itself was found in the patent. The Court found that in order to be eligible for listing, the relevant claim for the formulation must be identical to the formulation in the NDS, so that the non inclusion of rilpivirine alone in the patent rendered it ineligible.

[60] Therefore, in light of *Gilead*, even if the '819 patent at issue gave priority to amino-glycoside antibiotics as being a preferred embodiment and went on to name gentamicin and streptomycin and other examples of amino-glycoside antibiotics, the applicant would not have a greater chance of success.

[61] The applicant argues that in *Gilead*, Justice Mosley erred in reading down the product specificity requirement under paragraph 4(2)(b) of the *Regulations* and in supporting his decision with reference to Federal Court of Appeal's decision in *Purdue*, which relates more specifically to eligibility under paragraph 4(2)(c) of the *Regulations*. However, I believe that Justice Mosley's

finding in *Gilead*, is perfectly consistent with the prior jurisprudence of this Court and that of the Federal Court of Appeal and that given the purpose and the scheme of the patent listing provisions of the *Regulations*, nothing prevents the Court from seeking insights on the product specificity requirement as defined by the jurisprudence under paragraph 4(2)(b) or (c) of the *Regulations*.

Correct Interpretation of paragraph 4(2)(c) of the Regulations

[62] As mentioned earlier in these reasons, I do not believe that the OPML erred in law in not proceeding with a detailed assessment of the patent claims for dosage form in view of the approved dosage form, because the non product specificity of the formulation claims was, in this case, determinative of the eligibility issue. This is made clear in the following excerpt from the 2006 RIAS, quoted in *Purdue* (FCA), above, at para 34:

> […] 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.

[63] In *Purdue*, above, Purdue had obtained a NOC for Targin; a controlled release tablet containing oxycodone and naloxone. Purdue also had a 1992 patent for Oxycontin, which contemplated a controlled-release technology for delivering oxycodone: its only medicinal ingredient. The OPML refused to list the patent in relation to Targin. The Federal Court of Appeal addressed the product specificity requirement in the context of claims for dosage form under paragraph 4(2)(c) of the *Regulations*, and found that the relevant claim for dosage form

referred to oxycodone but, at best, did not exclude naloxone from within its scope, while the NOC explicitly included both. The Court stated:

> 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. 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.

[64] There is no doubt that the approved dosage form of Tobi Podhaler is more complex and more nuanced than an intravenous stand or a syringe. However, the rationale remains the same because the delivery system on the grounds of which the applicant seeks to list the '819 patent, including its different components, is one that can be used in association with a broad range of medicinal ingredients and is therefore insufficient to help the '819 patent qualify under paragraph 4(2)(c) of the *Regulations*.

[65] I therefore conclude that the OPML correctly construed the relevant claims of the '819 patent, correctly interpreted the *Regulations*, and reached a reasonable conclusion that, in fact, none of the claims of the '819 patent contains the approved medicinal ingredient tobramycin and this issue is determinative of the case.

VI. CONCLUSION

[66] As a result, this application for judicial review shall be dismissed with costs in favour of the respondents.

JUDGMENT

THIS COURT'S JUDGMENT is that this application for judicial review is dismissed, with costs in favour of the respondents.

"Luc Martineau"

Judge

FEDERAL COURT

SOLICITORS OF RECORD

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