Federal Court  Cour fédérale

Date: 20091117

Docket: T-582-09

Citation: 2009 FC 1171

Ottawa, Ontario, November 17, 2009

PRESENT: The Honourable Mr. Justice Russell

BETWEEN:

BAYER INC.

Applicant

and

THE MINISTER OF HEALTH and
THE ATTORNEY GENERAL OF CANADA

Respondents

REASONS FOR JUDGMENT AND JUDGMENT

OVERVIEW

[1] Bayer Inc. (Applicant) brings this application for judicial review of a March 11, 2009 decision (Decision) of the Minister of Health, which held that Canadian Patent No. 2,194,979 ('979 Patent) was ineligible for listing on the Patent Registry.

[2] The Minister found that the '979 Patent in respect of NDS 119387 did not meet the requirements set out in the October 5, 2006 amendments to the *Patented Medicines Notice of Compliance Regulations* (*NOC Regulations*) because the '979 Patent did not contain a claim for a formulation containing the medicinal ingredient drospirenone/ethinyl estradiol, as required by subsection 4(2) of the *NOC Regulations*. The Minister determined that the patent contained a claim for a pharmaceutical composition containing only 17α –ethinylestradiol, which was not a formulation that contained the medicinal ingredient approved in the NOC.

YAZ

[3] YAZ is used for conception control and the treatment of moderate acne in women 14 and older. It is available to patients in a package of 24 tablets that contain a combination of two sex hormones (0.020 mg ethinyl estradiol and 3.0 mg drospirenone) and four reminder tablets which contain no active ingredients.

[4] Bayer filed new drug submission (NDS) No. 119387 in January of 2008 to seek approval for YAZ. Bayer was issued a notice of compliance (NOC) on December 23, 2008.

[5] The YAZ product monograph (PM) indicates that YAZ is a "combination oral contraceptive," which contains a low dose of the progestin drospirenone and a low dose of the estrogen ethinyl estradiol. In YAZ, the ethinyl estradiol is stabilized by β-cyclodextrin as a clathrate.

THE ‘979 PATENT

[6] The ‘979 Patent, entitled “Solid Drug Forms Containing Clathrates of Steroid Sex Hormones,” was filed on July 10, 1995 and was issued on January 6, 2009. The ‘979 Patent relates to solid drug forms that contain low doses of steroidal sex hormones.

[7] The ‘979 Patent claims inventorship of a composition combining 17α-ethinylestradiol with β-cyclodextrin to form a clathrate. This clathrate reduces oxidative degradation by making it more difficult for oxygen to react with the sex hormone.

[8] The ‘979 Patent contains 15 claims. Claims 1 through 5 involve the combination of β-cyclodextrin and 17α-ethinylestradiol in solid form to reduce oxidative degradation of the 17α-ethinylestradiol. Claims 6 through 11 are concerned with the combination of 17α-ethinylestradiol and β-cyclodextrin to form a clathrate. Claims 12 through14 are process claims. Claim 15 is directed towards the use of a combination of 17α-ethinylestradiol and β-cyclodextrin in a solid dosage form to achieve an estrogenic effect.

THE MINISTER’S DECISION

[9] The Minister informed the Applicant by letter dated January 16, 2009 that the '979 Patent did not meet the requirements of the *NOC Regulations*. The Applicant was given thirty days within which to file representations regarding the eligibility of the '979 Patent. The Applicant provided the Minister with written representations supporting the eligibility of the '979 Patent for listing on the patent register.

[10] The Minister rendered a final decision by letter dated March 11, 2009 and found that the claims in the '979 Patent were concerned with pharmaceutical compositions including 17α-ethinylestradiol, which did not specify drospirenone/ ethinyl estradiol as the medicinal ingredient.

[11] Specifically, the Minister held that:

> …While we agree that drospirenone is a gestagenically active compound…OPML takes the position that the inclusion of gestagens as a class, without specifying drospirenone, is not sufficient to constitute a claim for the formulation containing the medicinal ingredient, as required by subsection 4(2) of the *PM(NOC) Regulations*.

[12] Accordingly, the Minister was of the view that the '979 Patent was not eligible for listing on the Patent Register with regard to NDS 119387 since it did not contain a claim for the formulation containing the medicinal ingredient which was approved through the issuance of a NOC as required by paragraph 4(2)(*b*) of the *NOC Regulations*.

ISSUE

[13] The Applicant submits the following issue on this application:

1. Whether the Minister erred in her interpretation of s. 4(2)(*b*) of the *NOC Regulations* and therefore erred in finding that the '979 Patent was ineligible for listing in relation to the NDS for YAZ?

RELEVANT STATUTORY PROVISIONS

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

2. In these Regulations,	**2.** Les définitions qui suivent s'appliquent au présent règlement.
"claim for the formulation" means a claim for a substance that is a mixture of medicinal and non-medicinal ingredients in a drug and that is administered to a patient in a particular dosage form; (revendication de la formulation)	« revendication de la formulation » Revendication à l'égard d'une substance qui est un mélange des ingrédients médicinaux et non médicinaux d'une drogue et qui est administrée à un patient sous une forme posologique donnée. (claim for the formulation)
4. (2) A patent on a patent list in relation to a new drug submission is eligible to be added to the register if the patent contains	**4. (2)** Est admissible à l'adjonction au registre tout brevet, inscrit sur une liste de brevets, qui se rattache à la présentation de drogue nouvelle, s'il contient, selon le cas :
(*a*) a claim for the medicinal ingredient and the medicinal ingredient has been approved through the issuance of a notice of compliance in respect of the submission;	*a*) une revendication de l'ingrédient médicinal, l'ingrédient ayant été approuvé par la délivrance d'un avis de conformité à l'égard de la présentation;

(*b*) a claim for the formulation that contains the medicinal ingredient and the formulation has been approved through the issuance of a notice of compliance in respect of the submission;

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

(*c*) a claim for the dosage form and the dosage form has been approved through the issuance of a notice of compliance in respect of the submission; or

c) une revendication de la forme posologique, la forme posologique ayant été approuvée par la délivrance d'un avis de conformité à l'égard de la présentation;

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

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

4. (3) A patent on a patent list in relation to a supplement to a new drug submission is eligible to be added to the register if the supplement is for a change in formulation, a change in dosage form or a change in use of the medicinal ingredient, and

4. (3) Est admissible à l'adjonction au registre tout brevet, inscrit sur une liste de brevets, qui se rattache au supplément à une présentation de drogue nouvelle visant une modification de la formulation, une modification de la forme posologique ou une modification de l'utilisation de l'ingrédient médicinal, s'il contient, selon le cas :

(a) in the case of a change in formulation, the patent contains a claim for the changed formulation that has been approved through the issuance of a notice of compliance in respect of the supplement;

a) dans le cas d'une modification de formulation, une revendication de la formulation modifiée, la formulation ayant été approuvée par la délivrance d'un avis de conformité à l'égard du supplément;

(b) in the case of a change in dosage form, the patent contains a claim for the changed dosage form that has been approved through the issuance of a notice of compliance in respect of the supplement; or	**b)** dans le cas d'une modification de la forme posologique, une revendication de la forme posologique modifiée, la forme posologique ayant été approuvée par la délivrance d'un avis de conformité à l'égard du supplément;
(c) in the case of a change in use of the medicinal ingredient, the patent contains a claim for the changed use of the medicinal ingredient that has been approved through the issuance of a notice of compliance in respect of the supplement.	**c)** dans le cas d'une modification d'utilisation de l'ingrédient médicinal, une revendication de l'utilisation modifiée de l'ingrédient médicinal, l'utilisation ayant été approuvée par la délivrance d'un avis de conformité à l'égard du supplément.

EXPERT WITNESSES

[15] The Applicant served and filed the evidence of two witnesses, namely Dr. Manoj Saxena and Dr. Xiao Yu Wu. Dr. Saxena is the Director and Head of Regulatory affairs at Bayer. Dr. Saxena provided evidence with regard to the factual underpinnings of the YAZ NDS and the correspondence with the OPML. Dr. Wu is a Professor of Pharmaceutics and Controlled Drug Delivery at the Faculty of Pharmacy at the University of Toronto. Dr. Wu provided evidence with regard to some of the terms used in the '979 Patent, explained certain claims of the Patent, and provided her opinion that YAZ contains a pharmaceutical composition that falls within the scope of the patent claims.

[16] The Minister of Health filed the evidence of Ms. Marie Lisa Maille, a patent officer with the Office of Patented Medicines and Liaison (*OPML*). Ms. Maille's evidence helps to provide some context for the Minister's decision.

STANDARD OF REVIEW

[17] The Applicant and the Respondents agree that the appropriate standard of review for a decision regarding whether a patent meets the requirements of s. 4 of the *NOC Regulations* is a question of regulatory interpretation reviewable on a standard of correctness. See *Abbott Laboratories Limited c. Canada (Attorney General)*, 2008 FCA 354, 70 C.P.R. (4th) 161 (*Abbott*). Accordingly, the Minister's decision will stand unless it is found that the Minister incorrectly interpreted the *NOC Regulations*: See *Abbott* at paragraph 34.

THE APPLICATION

The Applicant's Arguments

Principles of Interpretation

[18] The Applicant submits that a statute and its regulations should be read in their entire context and in their grammatical and ordinary sense, harmoniously with the statute's scheme, object, and the intention of Parliament.

[19] The *NOC Regulations* attempt to preserve the patent rights of inventors by requiring a generic to respect patents listed on the Patent Register. A listing on the Register is the first step to ensuring that the issuance of a NOC to the generic will not result in patent infringement. See *Hoffman-La Roche Ltd. v. Canada (Minister of Health)*, 2005 FC 1415, 45 C.P.R. (4th) 439 and *Hoffman-La Roche Ltd. v. Canada (Minister of Health)*, 2005 FCA 140, 40 C.P.R. (4th) 108.

Interpretation of section 4(2)(*b*)

[20] The Applicant submits that according to the plain meaning of s. 4(2)(b), a patent is eligible for listing if it contains:

1. A claim for the formulation;
2. That contains the medicinal ingredient; and
3. The formulation has been approved through the issuance of a NOC in respect of the submission.

[21] The 2006 amendments to the *NOC Regulations* were accompanied by a Regulatory Impact Analysis Statement (RIAS). The RIAS described the new term "formulation":

> [t]he term "formulation"…refers to the physical mixture of medicinal and non-medicinal ingredients administered to the patient by means of the approved drug. The term "medicinal ingredient", according to the RIAS, refers to the substance in the formulation which, once administered, is responsible for the drug's desired effect in the body.

[22] The Minister's decision does not dispute that the '979 Patent contains formulation claims as defined in section 2 of the *NOC Regulations*. Rather, the Decision was based on the fact that:

a) the claims did not specifically refer to one of the medicinal ingredients in the approved product; and

b) OPML believes that when the approved product contains two medicinal ingredients, the claims must specifically refer to them both.

[23] The Applicant submits that the effect of the Minister's decision was to find that:

a) "contains" means an explicit reference to; and

b) "the medicinal ingredient," in the case of a product containing more than one medicinal ingredient, means all medicinal ingredients.

[24] Accordingly, the Minister found that for the purpose of paragraphs 4(2)(*b*) and 4(2)(*a*) the medicinal ingredient was drospirenone/ethinyl estradiol, as opposed to just ethinyl estradiol, which is the medicinal ingredient referred to in the '979 Patent claims.

[25] The Applicant submits that the plain meaning of the words "contains the medicinal ingredient" does not require an explicit reference to the medicinal ingredients. Rather, containing the medicinal ingredient is enough to satisfy the plain meaning interpretation.

[26] Moreover, the Minister's interpretation is contradictory to the Canada Health Guidance Document: *Patented Medicines (Notice of Compliance) NOC Regulations*. Pursuant to section 4(2)(*a*) a compound patent claiming one medicinal ingredient can be listed against a drug that contains the medicinal ingredient in combination with other medicinal ingredients. By this definition, the Minister has recognized that whether the claims specifically refer to any other medicinal ingredients does not affect whether the product falls within the scope of the claims.

[27] The Applicant suggests that this same reasoning applies to the case of formulation claims; simply because the claims do not specifically refer to the other medicinal ingredient does not automatically mean that the product falls outside of the scope of the claims.

[28] The Guidance Note relied on by the Minister to address this point does not have the force of law. Nor does the Guidance Note expressly address the issue at hand. The Guidance Note simply states that the claimed formulation must "include, as an element, the medicinal ingredient of the drug." However, the Guidance Note also recognizes that the inclusion of an additional ingredient (an excipient) to a formulation does not remove relevance "if patent A claims a formulation that includes excipients X and Y and the drug against which the patent is requested to be listed includes X,Y, and Z."

[29] The Applicant suggests that it can be presumed that the legislature chooses its language carefully and consistently in a statute or legislative instrument. Accordingly, the same words should be presumed to have the same meaning throughout a piece of legislation. The Applicant contends that this is especially so where the repeated words are close together or related. See Ruth Sullivan, *Sullivan on the Construction of Statutes*, 5th ed. (2008) at pp. 214-215 and *Thompson v. Canada (Deputy Minister of Agriculture)*, [1992] 1 S.C.R. 385, [1992] S.C.J. No. 13. Consequently, "the medicinal ingredient" in section 4(2)(*b*) should be interpreted as it was interpreted in section 4(2)(*a*) to mean one of the approved medicinal ingredients.

[30] The Applicant submits that the Minister's interpretation does not help ensure product specificity, although this is her intention. Rather, product specificity is achieved by the requirement that the formulation must be approved. A specific reference to one medicinal ingredient makes the nexus between the approved and claimed formulation closer. However, there is no reason to require the specific naming of the second medicinal ingredient in order to meet the product specificity requirement.

[31] Moreover, the Applicant submits that its interpretation is consistent with the prevention of patent infringement, which is a fundamental objective of the *NOC Regulations*. In interpreting the *NOC Regulations*, the Court must consider whether "the proposed interpretation would tend to deter patent infringement arising from the use of the patented invention": *G.D. Searle & Co. v. Canada (Minister of Health)*, 2009 FCA 35, 386 N.R. 262 at paragraph 12 (*G.D. Searle*).

[32] The Applicant contends that a reasonable likelihood exists that its patent may be infringed by a manufacturer seeking approval for a generic version of YAZ. The Applicant's interpretation of the *NOC Regulations* would help to prevent patent infringement. On the other hand, the Minister's interpretation would not grant protection to the Applicant's patent.

[33] The Applicant submits that both the interpretation of section 4(2)(*b*) and the facts of the case support the Applicant's belief that the Minister erred in her decision. Dr. Wu has provided evidence that the addition of a second active ingredient after the formation of the clathrate would not interfere with the cyclodextrin clathrate of ethinyl estradiol. Accordingly, the stability of the clathrate would

not be affected by the addition of this ingredient. This demonstrates the irrelevancy of the second medicinal ingredient to the patented invention. The Applicant believes that this demonstrates that the '979 Patent would encompass formulations that include additional active and/or non-medicinal ingredients.

[34] The Applicant submits that Dr. Wu's evidence explains why the pharmaceutical composition of YAZ falls within the scope of Claims 1, 3 through 6, and 8 through 10 of the '979 Patent.

[35] The OPML considered irrelevant and prejudicial factors in making its assessment of eligibility of the '979 Patent for listing on the Register. For example, the OPML's consideration of other patents currently listed on the Patent Register with regard to NDS No. 119387 was irrelevant. This factor should not have been considered during the assessment.

[36] Furthermore, the Minister's assessment was not done in the uniform manner envisaged in the *NOC Regulations*. Instead, evidence shows that the OPML "noticed that there was already a formulation patent listed on the register" and the OPML "took note of it because it was of some interest that there was this formulation patent containing both medicinal ingredients." The Applicant contends that the OPML erred in considering a patent on the Patent Register as a factor in its Decision, even if both patents were listed on the Patent Register with regard to the same submission.

The Respondents' Arguments

[37] The Respondents point out that the Applicant is claiming a formulation containing one specified medicinal ingredient; however, the Applicant's approved drug contains two medicinal ingredients. Accordingly, the subject matter of the '979 Patent does not match that of the drug submission.

[38] Three patents are listed on the Register with regard to NDS 119387, including Canadian patent 2,382,426 entitled "Pharmaceutical Combination of Ethinylestradiol and Drospirenone For Use as a Contraceptive." This patent is properly listed as containing a claim for the formulation that includes both medicinal ingredients in YAZ.

[39] The '979 Patent contains a claim regarding a pharmaceutical composition containing 17α – ethinylestradiol. However, this is only one of the two medicinal ingredients approved in NDS 119387. Because YAZ contains two medicinal ingredients and the '979 Patent contains a claim regarding a formulation that contains only one, the '979 Patent is not eligible for listing on the Patent Registry.

Interpretive Principles

[40] The Respondents submit that the Court has adopted a "words-in-total-context" approach with regard to legislative interpretation. Accordingly, words must be considered in their entire

context in such a way that their ordinary meaning is harmonized with the scheme, object and intention of the legislation. See *Merck & Co. v. Nu-Pharm Inc.*, 254 N.R. 68, [2000] F.C.J. No. 380 (QL) (*Merck*).

[41] The Supreme Court of Canada clarified in *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, 2006 SCC 49, [2006] 2 S.C.R. 560 that the object of the regulatory scheme is limited to preventing infringement by a person who is taking advantage of the "early working" exception in s. 55.2(1) of the Act.

[42] The Respondents contend that the interpretation of singular and plural nouns is relevant to this case. As found in the *Interpretation Act*, R.S.C. 1985, c. I-23 s. 33(2), "words in the singular include the plural, and words in the plural include the singular." This interchangeablility exists where it is necessary: a) in the context and facts of the case; and b) to best fulfill the purpose of the provision.

[43] The *NOC Regulations* are part of a government policy that seeks to balance effective patent enforcement with the timely market entry of lower-priced generic competition. The "early working" exception provided in paragraph 55.2(1) of the Act allows a drug manufacturer to use a patented, innovative drug to seek approval to market a competing version of the drug. This exception provides generic companies with the opportunity to complete Health Canada's regulatory approval process while the first drug is still under patent so that the generic company can enter the market

shortly after the patent expires. The *NOC Regulations* attempt to ensure that the early-working exception is not abused.

[44] The Respondents submit that the 24-month stay period provided by the *NOC Regulations* is a potent and extraordinary remedy. According to the RIAS, "it is this very potency which calls for moderation in the application of the *NOC Regulations,* lest their effect dominate that of early-working and defeat the overall purpose of the policy."

[45] Under the previous legislation, a patent was generally eligible for listing on the Register (thus eligible for protection under the *NOC Regulations*) if it contained a claim for the medicine in the drug being copied. However, the 2006 amendments made the eligibility requirements more specific in order to entrench product specificity as the primary consideration. Under the current Act, a patent is only eligible for listing if the subject matter of the patent matches the subject matter of the approved drug submission.

Statutory Interpretation

[46] The Respondents apply the statutory interpretation principles to the specification requirement in subsection 4(2)(*b*) and find that the second part of the sentence ("that contains the medicinal ingredient") is intended to modify the first part ("a claim for the formulation that contains the medicinal ingredient"). Accordingly, the question can be asked: "which formulation must the patent claim to be eligible?" The Respondents submit that the correct response is: "the formulation

that contains the medicinal ingredient." Moreover, the Respondents note that the legislation's intent is made clear by use of the article "the" rather than "a" before the terms "formulation" and "medicinal ingredient."

[47] The Respondents also note the amended definition of a "claim for formulation" in s. 2 of the *NOC Regulations* which establishes that a formulation patent must claim the mixture of ingredients as administered to the patient:

> "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.

[48] The Respondents submit that the detailed product-specificity (or relevance) requirements exist to limit the application of the *NOC Regulations* to "that which the innovator has invested time and money to test and have approved for sale." The Federal Court of Appeal has noted that the interpretation in the previous act was so broad that it unduly delayed market entry of generic drugs. As such, the amendments were intended to restore the desired balance. See *G.D. Searle*.

[49] Furthermore, the Respondents submit that some patent infringement may fall outside of the protection provided by the *NOC Regulations*, and that this was considered in their development. See pp. 1511-12 of RIAS.

[50] There is no dispute that the approved formulation contains two medicinal ingredients and the claimed formation includes only one. When asking which formulation must the patent claim to be eligible, the answer is YAZ, which is the formulation containing the medicinal ingredient. The

‘979 Patent, however, does not claim that formulation, since YAZ contains two medicinal ingredients. Therefore, the claimed formulation does not match the approved formulation as required by subsection 4(2)(b). The Respondents submit that this conclusion is supported by the cases of *Abbott* and *G.D. Searle*.

[51] The Respondents also note the amended definition of a “claim for formulation” in section 2 of the Act. This definition can be distinguished from a compound patent because it must claim the mixture of ingredients as they are actually administered to the patient. The Respondents submit that the purpose of this is to limit the protection provided by the *NOC Regulations* to “that which the innovator has invested time and money to test and have approved for sale,” in order to prevent “hypothetical innovation” from impeding generic entry into the market.

[52] The Respondents dispute the interpretive discrepancy alleged by the Applicant and explain the distinction between compound and formulation patents. A compound patent claims the key active portion of the drug formulation. As such, it is relevant to every formulation which contains that compound. For the purposes of the product-specificity requirement, there will generally be a match between the compound patent and any formulation containing the compound (no matter what other excipients or medicinal ingredients it contains). A formulation patent, on the other hand, contains a claim for the particular approved mixture of medicinal and non-medicinal ingredients administered to patients. Accordingly, the formulation claimed will not “match” the approved formulation unless they both contain the same medicinal ingredients.

[53] Pursuant to the *Interpretation Act*, the fact that "medicinal ingredient" was referred to in the Act as being singular is not determinative of the interpretation issue. The Respondents suggest that, in this instance, the "words-in-context" approach requires that the singular include the plural.

Additional Arguments

[54] The Applicant had argued that the '979 Patent could be listed against any formulation containing ethinyl estradiol, whether or not it contained the second medicinal ingredient. The Respondents dispute this assertion; this would mean treating the formulation patent as a compound patent. This is incorrect, and it would defeat the purpose of the "product specificity" in section 4.

[55] The Respondents also dispute the Applicant's allegation that the relevance requirement has been met. The relevance requirement is narrower than the Applicant suggests. Contrary to what the Applicant contends, the *NOC Regulations* recognize that not all drug patents will be protected. Moreover, an interpretation should not be preferred simply because it would prevent patent infringement. See *G.D. Searle*, at paragraphs 47 and 48.

[56] The Respondents submit that the listing of the '426 patent did not influence the decision. While the Minister's deponent mentioned that the '426 patent was "of some interest," she also indicated that it did not influence the Minister's decision.

[57] In the alternative, the Respondents contend that if the Court decides that the '979 Patent is eligible for inclusion in the Register that it should not be retroactive to January 8, 2009 as demanded by the Applicant. If the Court decides that the patent is eligible for inclusion on the Register, then the Minister will add it immediately. The inclusion of the patent on the Register should take effect the day it is added. This practice is consistent with the *NOC Regulations* and public policy concerns. Furthermore, this approach has recently been approved by the Federal Court in *Eli Lilly Canada Inc. v. Canada*, 2009 FC 474, [2009] F.C.J. No. 587.

ANALYSIS

[58] This application is focussed upon a question of interpretation of the *NOC Regulations*.

[59] The Applicant says that, under section 4(2)(*b*) of the *NOC Regulations*, it is sufficient for listing requirements if the patent claims refer to one of the medical ingredients in the approved drug submission.

[60] The Respondents say this is not enough and that, in the case of a formulation patent, the subject matter of the patent must match the subject matter of the approved drug submission.

[61] This issue is important in the present case because the OPML decided that the '979 Patent did not satisfy the requirements for eligibility specified in subsection 4(2) of the *NOC Regulations*

because the YAZ tablet comprises a formulation with two medical ingredients (drospirenone and ethinyl estradiol), while the '979 Patent contains claims that contain only one (ethinyl estradiol).

[62] Both parties agree that the Court should review the decision of the OPML using a standard of correctness and I concur with them. See *Abbott* at paragraphs 27-34.

[63] The parties also agree that the approach to interpretation of the *NOC Regulations* in this case is the "words-in-total-context" approach. See *Merck*.

[64] Ms. Maille confirmed on cross-examination that OPML's decision refusing to list the '979 Patent was based on the fact that the claims did not specifically refer to one of the medicinal ingredients in the approved product. As the Respondents point out in argument, a formulation is a mixture of medicinal ingredients, so a formulation that contains more than one medicinal ingredient is different from one that contains a single medicinal ingredient. The Applicant has raised a variety of reasons as to why the Decision is incorrect.

Plain Meaning of Words

[65] The Applicant says that the plain meaning of the words "contains the medical ingredient" in subsection 4(2)(*b*) of the *NOC Regulations* simply requires that the claim contains the medical ingredient (i.e. there need not be explicit reference to the medicinal ingredient(s)) and that "the medicinal ingredient" does not refer to all medicinal ingredients.

[66] In my view, the Applicant is dissecting the words "a claim for the formulation that contains the medicinal agreement," in order to play down the significance of "the formulation." However, we must examine the plain and ordinary meaning of the full phrase: "a claim for the formulation that contains the medicinal ingredient."

[67] There is no dispute about the meaning of "medicinal agreement," and "claim for the formulation" is defined in section 2 to mean "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."

[68] The '979 Patent contains claims directed to a pharmaceutical composition containing ethinyl estradiol. But ethinyl estradiol is only one of the medicinal ingredients approved in NDS 119387 for YAZ.

[69] Hence, in my view, and on a plain and ordinary reading of subsection 4(2)(*b*), the '979 Patent does not claim the formulation that has been approved. It claims, rather, a formulation that contains one of the medical agreements that has been approved. The formulation that has been approved, that is YAZ, contains two medicinal ingredients. It seems to me that a mixture containing two medicinal ingredients is different from a mixture that contains only one medicinal agreement. Medicinal agreements are combined to achieve an optimal effect when the drug is delivered to the patient. Generally speaking, then, a drug with one medicinal ingredient will have a different effect from a drug where two medicinal ingredients are combined to achieve the desired affect.

[70] In my view, the Applicant is seeking to avoid the plain and obvious meaning of subsection 4(2)(*b*) by isolating "the medicinal ingredient" from "the formulation." The subsection says "the formulation" and "the medical ingredient"; it does not say "a formulation" or "a medical ingredient." The NDS 119387 approval for YAZ involves two medicinal ingredients, only one of which (ethinyl estradiol) is involved in the '979 patent claims.

[71] As the Respondents point out, 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 medical ingredient" in subsection 4(2)(*b*) of the *Regulations* to include "the medical ingredients." In my view, then, it would distort the plain and ordinary meaning of "the medicinal ingredient" if the phrase were 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.

Inconsistency

[72] The Applicant argues further that the Minister's interpretation of subsection 4(2)(*b*) is inconsistent with the Minister's reading of subsection 4(2)(*a*), and with subsection 4(3).

[73] In particular, as regards 4(2)(*a*), the Minister agrees that a patent containing a claim that refers to only one medicinal ingredient may be listed against a combination product under subsection 4(2)(*a*).

[74] The Applicant says that this shows the Minister has recognized that the fact that the relevant claims do not explicitly refer to the other medicinal ingredient(s) is irrelevant to the question of whether the product falls within the scope of the claims. The Applicant then argues that, similarly, in the case of formulation claims, unless the claims are construed to be a formulation containing a single medicinal ingredient, or to not include within their scope formulations containing the specific other medicinal ingredient(s) at issue (neither of which is the case before me), the fact that the claims do not explicitly refer to the other medicinal ingredient(s) is irrelevant.

[75] In other words, the Applicant says that the Minister has offered no principled basis for making the distinction between a compound patent and a formulation patent that has been made in this case.

[76] Added to this is the fact that it must be presumed that the legislature uses language carefully and consistently so that within a statute or other legislative instrument the same words should have the same meaning. Thus the "medicinal ingredient" in subsection 4(2)(*b*), according to the Applicant, should be interpreted by the Minister in subsection 4(2)(*a*), in the context of a combination product, to mean one of the approved medicinal ingredients.

[77] The principled distinction, it seems to me, is found in the fundamental difference between a compound patent and a formulation patent. A compound patent is eligible for listing on the Register under 4(2)(*a*) because it contains a claim for the approved medicinal ingredient which is the key

active part of the drug formulation. This means that, in the context of early working, a generic copy of the drug containing the compound has early-worked the compound patent.

[78] On the other hand, as the Respondents point out, a formulation patent such as '979 does not contain a claim for the medicinal ingredient itself. It is rather a claim for the approved mixture of medicinal and non-medicinal ingredients that are actually administered to the patient.

[79] In my view, there is nothing unprincipled or inconsistent in the Minister's interpretation, because a formulation that is a mixture of more than one compound is different from a composition containing only one compound.

[80] The essence of a compound patent is the medicinal ingredient; the essence of a formulation patent is the mixture of ingredients. This distinction requires a different approach when matching and specificity are being considered under subsections 4(2)(*a*) and 4(2)(*b*). In my view, there is nothing inconsistent or unprincipled about the Minister's approach to this distinction.

[81] In essence, the Applicant is saying that matching and specificity are present under subsection 4(2)(*b*) whenever the patent claims refer to at least one of the medicinal agreements in the approved drug submission. This would mean, for instance, that if the drug submission encompassed a mixture of, for example, five medicinal ingredients, the required degree of matching would still be present even if the patent refers to only one of them. In my view, this equates listing

on the Register with patent infringement under the Act. I do not believe that either the wording of subsection 2 or the policies behind the new regulations support such a position.

Product Specificity

[82] The Applicant also argues that the Minister's interpretation of subsection 4(2)(*b*) of the *NOC Regulations* does not ensure product specificity. In the Applicant's view, product specificity is achieved by the requirement that the formulation must have been approved, i.e. the innovator has invested time and money to test the invention and have it approved for sale.

[83] The argument that there is no rationale for requiring the second medicinal ingredient to be specifically named to meet the product specificity requirement would mean that the '979 Patent could be listed against any formulation that contains ethinyl estradiol.

[84] Once again, in my view, the Applicant is inviting the Court to ignore the nature of a formulation patent insofar as it relates to specificity. In effect, the Applicant is urging the Court to interpret the *NOC Regulations* in such a way that a formulation patent is treated in the same way as a compound patent so that specificity is equated with infringement.

[85] It seems to me, however, that the RIAS makes it clear that this is not the proper approach to specificity and listing. The RIAS provides that "not every patent pertaining to an approved drug qualifies for enforcement under the scheme" and that "it is recognized that there may be instances

where a patent which does not qualify for the protection of the PM(NOC) *Regulations* 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. It follows that the continued viability of the regime greatly depends upon the fair and proper application of these listing requirements.

[86] In relation to the greater specificity which the amendments were intended to bring to the listing process, the RIAS provides the following guidance on "formulation" and "medicinal ingredient":

> For the purposes of amended section 4, the terms "formulation" and "medicinal ingredient" are intended to bear their established meaning under the extensive body of case law interpreting "a claim for the medicine itself." The term "formulation" thus refers to the physical mixture of medicinal and non-medicinal ingredients administered to the patient by means of the approved drug. The term "medicinal ingredient," in turn, refers to the substance in the formulation which, once administered, is responsible for the drug's desired effect in the body.

[87] It seems to me that, for purposes of specificity, the RIAS directs us to look at the "mixture" in question and at the "substance in the formulation" that "is responsible for the drug's desired effect in the body."

[88] In the present case, the 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.

[89] 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.

Patent '426

[90] There is some suggestion in the materials that the Minister's decision with regards to the '979 patent was improperly based upon a consideration of the listing of the '426 patent. In my view, however, although the '426 patent may have been of some interest, the record is clear that the audit of the '979 Patent stands by itself.

Other Arguments

[91] The Applicant has raised other, more peripheral arguments which I have reviewed. However, I believe that the heart of the matter lies with the issues addressed above. Essentially, I believe the Minister was correct in his interpretation of the *Regulations* and I accept the Respondents' arguments in favour of supporting the decision.

JUDGMENT

THIS COURT ORDERS AND ADJUDGES that

1. The application is dismissed with costs to the Respondents.

"James Russell"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-582-09
STYLE OF CAUSE:	BAYER INC. v. MINISTER OF HEALTH and THE ATTORNEY GENERAL OF CANADA
PLACE OF HEARING:	Ottawa, Ontario
DATE OF HEARING:	October 6, 2009
REASONS FOR Judgment and Judgment:	RUSSELL J.
DATED:	November 17, 2009

APPEARANCES:

Gunars A. Gaikis Nancy P. Pei	FOR THE APPLICANT
Frederick B. Woyiwada	FOR THE RESPONDENTS

SOLICITORS OF RECORD:

Smart & Biggar LLP Barristers and Solicitors Toronto, ON	FOR THE APPLICANT
John H. Sims, Q.C. Deputy Attorney General of Canada	FOR THE RESPONDENTS