Federal Court of Appeal  Cour d'appel fédérale

Date: 20121009

Docket: A-44-12

Citation: 2012 FCA 254

CORAM: **SHARLOW J.A.**
TRUDEL J.A.
MAINVILLE J.A.

BETWEEN:

GILEAD SCIENCES CANADA INC.

Appellant

and

THE MINISTER OF HEALTH and
THE ATTORNEY GENERAL OF CANADA

Respondents

Heard at Toronto, Ontario, on September 12, 2012.

Judgment delivered at Ottawa, Ontario, on October 9, 2012.

REASONS FOR JUDGMENT BY: TRUDEL J.A.

CONCURRED IN BY: SHARLOW J.A.
MAINVILLE J.A.

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REASONS FOR JUDGMENT

TRUDEL J.A.

Introduction

[1] The main issue in this appeal is whether Canadian Patent No. 2,512,475 (the '475 Patent) is eligible for listing on the patent register in respect of new drug submission 140115 (the NDS) where the medicinal ingredients claimed in the '475 Patent do not match up with those in the NDS.

[2] The Minister of Health (the Minister) refused to list the '475 Patent on the patent register as, in his view, it did not meet the requirements of paragraph 4(2)(*b*) of the *Patented Medicines (Notice*

of Compliance) Regulations (SOR/93-133) (the PM (NOC) Regulations). A Judge of the Federal Court accepted the Minister's position and dismissed Gilead Sciences Canada Inc.'s (Gilead or the appellant) application for judicial review. This is an appeal from the Federal Court's decision reported at 2012 FC 2.

[3] I propose to dismiss Gilead's appeal, but for reasons different than those expressed by the Judge in dismissing the application for judicial review. Contrary to what he found, I conclude that the claims at issue in the '475 Patent are for a new combination of medicinal ingredients so that eligibility of the '475 Patent for listing depends upon the requirements of paragraph 4(2)(*a*) of the PM (NOC) Regulations, not paragraph 4(2)(*b*). This said, the relevant claims in the '475 Patent do not meet the requirements of paragraphs 4(2)(*a*) as they lack strict product specificity with regards to the three medicinal ingredients listed in the NDS.

[4] Paragraphs 4(2)(*a*) and 4(2)(*b*) of the PM (NOC) Regulations read:

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

compliance in respect of the Submission;	l'égard de la presentation;

The relevant facts

[5] The relevant facts are uncontested. On October 4, 2010, Gilead filed an NDS with the Minister seeking approval of a drug for the treatment of human immunodeficiency virus (HIV) infection. The NDS states that the drug, known as Complera, contained the following medicinal ingredients: 1) tenofovir disoproxil fumarate (tenofovir), 2) emtricitabine, and 3) rilpivirine (Judge's reasons at paragraph 3). Rilpivirine is one of a class of agents known as non-nucleoside reverse transcriptase inhibitors (NNRTIs). On October 20, 2011, after the evidence was filed in the application below but before issuance of the decision under appeal, a Notice of Compliance (NOC) was issued for Complera. From this point on, I shall refer to NDS or NOC depending on the context.

[6] At the same time Gilead filed its NDS, it also submitted eight patents for listing on the patent register in relation to Complera, including Patent '475. By letter of October 26, 2010, the Office of Patented Medicines and Liaison advised Gilead of the Minister's preliminary view that Patent '475 was not eligible for listing because it did not contain a claim for all of the medicinal ingredients contained in the NDS, that is, tenofovir, emtricitabine and rilpivirine, as required by the PM (NOC) Regulations. Rather, the '475 Patent contains claims combining the medicinal ingredients tenofovir and emtricitabine, together with a third unnamed antiviral agent selected from, amongst other classes of agents, NNRTIs. It is admitted that rilpivirine is not mentioned in any of the'475 Patent claims. Gilead was provided 30 days to respond to the Minister.

[7] It did so on November 26, 2010, and submitted that the claims in the '475 Patent were directed to chemically stable combinations of ingredients and thus fell within paragraph 4(2)(*a*) of the PM (NOC) Regulations (emphasis added). Alternatively, Gilead submitted that the '475 Patent did make formulation claims which provided for sufficient product specificity because rilpivirine was a drug within one of the specified classes of drugs, i.e., NNRTIs (emphasis added). Therefore, the '475 Patent also met the requirements of paragraph 4(2)(*b*) of the PM (NOC) Regulations.

[8] The Minister issued a final decision letter on January 13, 2011 confirming that the '475 Patent was not eligible for listing. The Minister found that "a patent containing claims for a formulation cannot "match" the approved formulation [in the NDS or NOC] unless both formulations explicitly contain all of the same medicinal ingredients" (Minister's final decision letter, appeal book, volume I, tab 4E). Consequently, reference only to classes of ingredients in the '475 Patent did not meet the "matching requirement" for lack of product specificity.

The standard of review

[9] The role of this Court in the case at bar is to determine whether the reviewing Judge has chosen and applied the correct standard of review and, if not, to assess the Minister's decision in light of the correct standard of review (*Dr. Q. v. College of Physicians and Surgeons of British Columbia*, 2003 SCC 19, [2003] 1 S.C.R. 226 at paragraphs 43-44).

[10] In this instance, the standard of review is tied to the three part analytical framework for analyzing questions relating to section 4 of the PM (NOC) Regulations, which was adopted by this Court in *Abbott Laboratories Ltd. v. Canada (Attorney General)*, 2008 FCA 354, [2009] 3 F.C.R.

547 at paragraphs 29-33, and cited most recently in *Purdue Pharma v. Canada (Attorney General)*, 2011 FCA 132 at paragraphs 11-13 [*Purdue*].

[11] At paragraph 12 of his reasons, the Judge adopted this framework, which consists of the following questions:

a. What is the correct construction of the '475 Patent? This question is reviewed on a standard of correctness;

b. What is the nature of the drug approved in the NDS or in the NOC? This question is reviewed on a standard of correctness;

c. Is the subject matter claimed in the patent that for which approval is sought under the NDS or NOC?

[12] The first step in answering the third question requires interpreting the PM (NOC) Regulations. This is a question of law reviewable on a standard of correctness. The second step consists of applying the law to the facts, an exercise reviewed on a standard of reasonableness.

[13] The Judge correctly noted that question 2 of the analytical framework was not at issue, as the parties agreed that the NDS referred to a drug containing tenofovir, emtricitabine and rilpivirine.

Issues

[14] The Judge therefore framed the remaining issues as follows:

a. What is the correct construction of the '475 Patent?

b. What is the correct interpretation of paragraphs 4(2)(*a*) and (*b*) of the PM (NOC) Regulations; and,

c. Was the Minister's decision to exclude the '475 Patent from the Register reasonable? (reasons for judgment at paragraph 14).

[15] I will deal with the Judge's reasons on each of these questions in the course of my analysis.

Analysis

Issue 1) The construction of the '475 Patent

[16] The '475 Patent is entitled "Compositions and Methods for Combination Antiviral Therapy". It contains 53 claims consisting of claims for ingredients and claims for formulations, as well as claims for dosages and uses, the latter of which are not relevant to the within appeal. Of relevance are claims 15, 31, 32 and 34, as well as claims 42, 45, 46 and 48 which are reproduced in annex to these reasons.

[17] At the hearing of this appeal, Gilead focused on claims 42, 45, 46 and 48, arguing that these are claims to the medicinal ingredients in Complera. In Gilead's view, once considered separate and apart from the formulation claims, those claims are eligible for listing pursuant to paragraph 4(2)(*a*) of the PM (NOC) Regulations (appellant's memorandum of fact and law at paragraphs 79-80).

[18] Having reviewed the approach to patent construction set out in the case law, the Judge first held that the object of the invention was to take advantage of the chemically stable characteristics of tenofovir and emtricitabine in combination and sometimes with a third medicinal ingredient

(reasons at paragraph 25). He had previously found that claims 42, 45, 46 and 48 refer to the combination of two or more anti-viral agents while claims 15, 31, 32 and 34 refer to a formulation containing two or more anti-viral agents.

[19] Ultimately, at paragraph 26 of his reasons, the Judge construed the relevant claims as

> … combinations and formulations of two medicinal ingredients plus a third one of the NNRTI class that could possibly include but is not specifically rilpivirine.

[20] The parties do not take issue with the Judge's construction of the relevant claims *per se*. As a result, the crux of this dispute is over the Judge's conclusions on the second and third issues, more specifically the Minister and the Judge's interpretation of paragraphs 4(2)(*a*) and (*b*) of the PM (NOC) Regulations, and their application of these to the facts.

Issue 2: The interpretation of paragraphs 4(2)(*a*) and 4(2)(*b*) of the PM (NOC) Regulations

The Regulatory framework

[21] Drug manufacturers wishing to sell a new drug in Canada must submit a new drug submission to the Minister and obtain a notice of compliance. These documents set out basic information regarding the drug in question. Although most new drugs are covered by patents which protect them from being copied, generic drug producers may work patents without infringing them in order to seek the necessary approvals from the Minister to release generic equivalents of drugs as soon as the patents expire. This is known as the "early working exception" of the *Patent Act* (R.S.C., 1985, c. P-4) [*Patent Act*].

[22] To ensure that this exception is not abused, the *Patent Act* also provides for the PM (NOC) Regulations to manage this exception. To benefit from the protections of the PM (NOC) Regulations, drug companies must apply to the Minister to have the patents related to their drugs listed on a patent register.

[23] Thus the *Patent Act* and the PM (NOC) Regulations seek to balance "effective patent enforcement" over new and innovative drugs with the "timely market entry" of lower priced generic versions once the patents have expired (*Regulatory Impact Analysis Statement*, (2006) Canada Gazette Part II., Vol. 140, 1510-1525) [RIAS].

[24] According to the Minister, deficiencies in the language of the PM (NOC) Regulations led to court decisions which made it too easy to list patents on the register and thus tilted the balance too far in favour of patent protection. To correct this, the Minister introduced revisions to the PM (NOC) Regulations in 2006. Among the key features of these revisions is the concept of "product specificity," whereby the subject matter of the patent must reflect the subject matter of the approved drug submission to qualify for listing on the patent register (respondent's memorandum of fact and law at paragraph 7).

The meaning of paragraphs 4(2)(*a*) and (*b*)

[25] After construing the relevant claims, the Judge went on to describe these claims in comparison with the three ingredients contained in Complera (reasons at paragraph 28). In my respectful view, this is where the Judge erred in law in applying the three part framework. He moved directly from the question of claims construction to the question of whether the claims

matched the description of Complera as set out in the NDS, without interpreting paragraphs 4(2)(*a*) and (*b*) to assess whether the claims fell more appropriately under (*a*) or (*b*). In the end, the Judge adopted the Minister's position without much explanation as to why he did so.

[26] As mentioned above, paragraphs 4(2)(*a*) and (*b*) refer to claims "for the medicinal ingredient" and "for the formulations". Section 2 of the PM (NOC) Regulations defines these expressions:

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*)
"claim for the medicinal ingredient" includes a claim in the patent for the medicinal ingredient, whether chemical or biological in nature, when prepared or produced by the methods or processes of manufacture particularly described and claimed in the patent, or by their obvious chemical equivalents, and also includes a claim for different polymorphs of the medicinal ingredient, but does not include different chemical forms of the medicinal ingredient; (*revendication de l'ingrédient médicinal*)	« revendication de l'ingrédient médicinal » S'entend, d'une part, d'une revendication, dans le brevet, de l'ingrédient médicinal — chimique ou biologique — préparé ou produit selon les modes ou procédés de fabrication décrits en détail et revendiqués dans le brevet ou selon leurs équivalents chimiques manifestes, et, d'autre part, d'une revendication pour différents polymorphes de celui-ci, à l'exclusion de ses différentes formes chimiques. (*claim for the medicinal ingredient*)

[27] In my view, both the Minister and the Judge failed to give sufficient weight to the requirement that formulations contain non-medicinal ingredients and set out a particular dosage form, which is administered to the patient. At the hearing of this appeal, counsel for the respondent readily conceded that on a plain reading of section 2, the relevant claims do not meet the definition of formulation, because they do not contain non-medicinal ingredients. Yet, the respondent argues that the inventive step here is the "formulation of the separate medicinal ingredients into the new combination product" (respondent's memorandum of fact and law at paragraph 35).

[28] I conclude that these arguments have no basis in law. The first rule in interpreting statutes is that words "must be read in their entire context and in their grammatical and ordinary sense, harmoniously with the scheme of the PM (NOC) Regulations, their object, and the intention of Parliament. Where regulations are concerned, the purpose of the enabling statute must also be considered" *Apotex v. Merck & Co. Inc.*, 2009 FCA 187 at paragraph 83.

[29] As mentioned above, the definition of formulation in the PM (NOC) Regulations is clear. It must contain both medicinal and non-medicinal ingredients.

[30] In addition, the PM (NOC) Regulations are subject to the *Interpretation Act*, R.S.C. 1985, c. I-21 [*Interpretation Act*]. The term medicinal ingredient is to be read in both the singular and the plural, and thus allows for more than one medicinal ingredient in an eligible claim under paragraph 4(2)(*a*) (*Interpretation Act* at section 33(2)).

[31] Finally, the overall inventive step of the ‘475 Patent, as found by the Judge, is the combination of chemically stable medicinal ingredients. The ‘475 Patent emphasizes the beneficial effects of combining chemically stable combinations of medicinal ingredients.

[32] Thus, I conclude that the ‘475 Patent falls under paragraph 4(2)(*a*), as the relevant claims consist of chemically stable combinations of medicinal ingredients.

The product specificity requirement

[33] As stated previously, the current version of the PM (NOC) Regulations makes product specificity between the patent claims and the NOC for the approved drug a key requirement for a patent to be considered eligible for listing on the register. The parties agree on this point.

[34] However, Gilead argues for a low threshold of connection between the wording of the NDS and the patent claim. It cites the case of *Nowegijick v. The Queen*, [1983] 1 S.C.R. 29, at page 39 [*Nowegijick*] for the proposal that the words “in relation to” found in section 4 of the PM (NOC) Regulations are to be given wide scope in conveying a connection between two related subject matters. As well, it argues that the PM (NOC) Regulations must be given a broad interpretation, consistent with the interpretation given by this Court to subsection 55.2(1) of the *Patent Act*, which sets out the exemption from patent protection which gives rise to the PM (NOC) Regulations , in *Merck & Co., Inc. v. Apotex Inc.*, 2006 FCA 323 at paragraphs 100-104.

[35] Finally, Gilead points to the Minister’s *Health Canada Guidance Document: Patented Medicines (Notice of Compliance) Regulations* [Guidance Document], and the commentary it sets

out regarding section 4 of the PM (NOC) Regulations. The Guidance Document states that under paragraph 4(2)(*a*), a claim to one medicinal ingredient is eligible for listing in respect of a product which contains the said medicinal ingredient in combination with other medicinal ingredients (Guidance Document, appeal book, volume II, tab 6C, page 343).

[36] These arguments cannot succeed. First, the case of *Nowegijick* concerned whether tax imposed upon the income of Mr. Nowegijick, a registered Indian, could be said to be "in respect of" personal property situated upon a reserve. The case is of little value to resolve the issue in the within appeal. I prefer to rely on the case of *Purdue* where the current version of the PM (NOC) Regulations was at play.

[37] In *Purdue*, this Court considered whether a patent, whose relevant claim for a dosage form contained only one medicinal ingredient, was eligible for listing on the patent register under paragraph 4(2)(*c*) of the PM (NOC) Regulations when the approved dosage form consisted of two medicinal ingredients. This Court held that absent precise and specific matching between the patent claims and the approved NOC, the patent was not eligible for listing. Writing for the Court, Layden-Stevenson J.A., stated:

> 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 (at paragraph 44).

[38] I adopt here Layden-Stevenson J.A.'s comments and apply them to the within appeal, with the result that her reasoning extends to paragraph 4(2)(*a*).

[39] There is no sound reason to adopt different legislative requirements for the paragraphs set out in subsection 4(2). Each paragraph uses the definitive form in referring to both the substance of the claim and the substance in the notice of compliance: "*the* medicinal ingredient", "*the* formulation", "*the* dosage" and "*the* use" (in French, "*l'*ingrédient," "*la* formulation", "*la* forme posologique", "*l'*utilisation"). The content of each paragraph is otherwise completely consistent.

[40] The wording of the PM (NOC) Regulations, as well as their object and purpose, suggest that the product specificity requirement sets a high threshold of consistency. Thus, in the case at bar, "the" medicinal ingredients, i.e., tenofovir, emtricitabine, and rilpirivine, must be set out in the patent claims and the NOC for the patent to be eligible on the register.

[41] Second, the 2006 revisions to the PM (NOC) Regulations clearly establish that not all patents relating to an NDS will necessarily be listed on the patent register. Under the 1993 version of the Regulations, section 4 provided that persons could submit a list of patents that they wished to have included on the patent list provided the patents met certain general criteria. Section 4 now states that patents are "eligible" for listing if they meet a more specific and detailed set of criteria. The revised section 3 provides new powers to the Minister to manage the patent register, including the ability to refuse to list patents, to remove patents from the register, and to consult with the Patent Office to determine whether to accept or remove a patent.

[42] Further, according to the RIAS, the government's view was that where the patent failed to meet the requirements, policy considerations tip the balance in favour of the generic manufacturer,

and the matter is better left to the alternative (and traditional) judicial recourse of an infringement action.

[43] The 2006 revisions also clearly introduced the requirement for product specificity. A plain reading of the version in force prior to the 2006 revisions establishes that if the patent claims were shown to be "relevant to" the approved drug, the submitted patents were generally accepted for listing. In contrast, the revised version introduces a requirement for more detailed information on the product against which the patent is to be listed, including the medicinal ingredient, the brand name, the dosage form, the strength, the route of administration and the use as set out in the NDS. In addition, the categories set out in section 4 are now more detailed and precisely defined. These changes, combined with the greater emphasis on meeting eligibility criteria and being subject to the Minister's determination as noted above, lead to a clear rejection of Gilead's argument for a wide scope of connection between the patent claims and the NOC.

[44] Finally, the Guidance Document cited by the appellant is useful to clarify the roles of the different actors in the patented medicine system, notably innovators, generic manufacturers, and the Minister. However, it is not a legally binding document. More significantly, where the Guidance Document is inconsistent with, or in conflict with, the PM (NOC) Regulations, the latter takes precedence over the former (Guidance Document, section 1.2, appeal book, volume II, tab 6C). At the hearing, the Minister conceded that only the PM (NOC) Regulations are a binding statement of law.

[45] I note also that the PM (NOC) Regulations provide no support for the interpretation suggested in the Guidance Document. As noted above, the wording of section 4 is consistent across the four subsections and requires a high degree of specificity between the wording of the claim and the NOC. It would be necessary to read an interpretation into paragraph 4(2)(*a*) to allow the paragraph to support claims which contain only some of the medicinal ingredients. Such an interpretation goes against the ordinary meaning of the words, the purpose and object of the PM (NOC) Regulations, and the government's position that product specificity is the key consideration in interpreting section 4. As a result, I would not attribute this interpretation to the PM (NOC) Regulations.

Issue 3: The decision to exclude the '475 Patent from the Register

[46] The Judge was tasked with assessing the reasonableness of the Minister's decision to exclude the '475 Patent under paragraph 4(2)(*b*) of the PM (NOC) Regulations. As I find that both the Minister and the Judge erred in applying this paragraph to the claims at issue, the Minister's decision cannot stand.

[47] As set out above, the claims should have been considered under paragraph 4(2)(*a*). That said, the Judge did not err in his reasoning under the product specificity analysis. He adopted the comments set out by Layden-Stevenson J.A. in *Purdue* and determined that, as set out in paragraph 48 of his reasons, "the claimed formulation and the approved formulation do not match precisely and the requirement of product specificity is not met".

[48] I agree with the Judge and conclude that his reasoning regarding product specificity is equally applicable under paragraph 4(2)(*a*) of the PM (NOC) Regulations.

Conclusion

[49] I would therefore uphold the Judge's conclusion that the patent claims fail the requirement for product specificity because they do not make specific reference to the medicinal ingredient rilpirivine, but only the broad class of compounds. However, as set out above, I would do so under paragraph 4(2)(*a*) rather than 4(2)(*b*).

[50] As success was divided, and the interests of both parties are served by clarifying the interpretation of paragraphs 4(2)(*a*) and (*b*), as well as by setting out a consistent approach to product specificity under subsection 4(2), I propose that both parties bear their own costs in the present appeal.

"Johanne Trudel"

J.A.

"I agree,
K. Sharlow J.A."

"I agree
Robert M. Mainville J.A."

ANNEX

The '475 Patent's claims 15, 31, 32, 34, 42, 45, 46 and 48

15. A pharmaceutical formulation comprising [2-(6-amino-purin-9-yl)-1-methyl-ethoxymethyl]-phosphonic acid diisopropoxycarbonyloxymethyl ester fumarate, hereafter called tenofovir disoproxil fumarate, and (2R, 5S, cis)-4-amino-5-fluoro-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)pyrimidin-2-one, hereinafter called emtricitabine.

31. The pharmaceutical formulation of any one of claims 15 or 29, which further comprises a third antiviral agent.

32. The formulation of claim 31, wherein the third agent is selected from an HIV protease inhibitor (PI), an HIV nucleoside reverse transcriptase inhibitor (NRTI), an HIV non-nucleoside reverse transcriptase inhibitor (NNRTI), and an HIV integrase inhibitor.

34. The formulation of claim 32, wherein the third antiviral agent is an NNRTI.

42. A chemically stable combination of tenofovir disoproxil fumarate and emtricitabine.

45. The chemically stable combination of any one of claims 42 to 44 which further comprises a third antiviral agent.

46. The chemically stable combination of claim 45 wherein the third antiviral agent is an NNRTI or PI.

48. The chemically stable combination of claim 46 wherein the third antiviral agent is an NNRTI.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-44-12
APPEAL FROM A JUDGMENT OF THE HONOURABLE MR JUSTICE MOSLEY DATED JANUARY 3, 2012, DOCKET NUMBER T-235-11.	
STYLE OF CAUSE:	GILEAD SCIENCES CANADA INC. and THE MINISTER OF HEALTH and THE ATTORNEY GENERAL OF CANADA
PLACE OF HEARING:	Toronto, Ontario
DATE OF HEARING:	September 12, 2012
REASONS FOR JUDGMENT BY:	Trudel J.A.
CONCURRED IN BY:	Sharlow J.A. Mainville J.A.
DATED:	October 9, 2012

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