Federal Court  Cour fédérale

Date: 20120103

Docket: T-235-11

Citation: 2012 FC 2

Ottawa, Ontario, January 3, 2012

PRESENT: The Honourable Mr. Justice Mosley

BETWEEN:

GILEAD SCIENCES CANADA, INC

Applicant

and

THE MINISTER OF HEALTH
AND
THE ATTORNEY GENERAL OF CANADA

Respondents

REASONS FOR JUDGMENT AND JUDGMENT

[1] This is an application for judicial review under s.18.1 of the *Federal Courts Act*, RSC, 1985, c F-7 of a decision of the Minister of Health made on January 13, 2011 refusing to list Canadian Patent 2,512,475 on the Patent Register in relation to a new drug submission.

[2] For the reasons that follow the application is dismissed.

BACKGROUND

[3] The applicant (“Gilead”) filed a New Drug Submission ("NDS") with the Minister of Health on October 4, 2010 with respect to a pharmaceutical product for the treatment of human immunodeficiency virus (HIV) infection. The submission was for the approval of tablets formulated with three medicinal ingredients: (1) tenofovir disoproxil fumarate (“tenofovir”); (2) emtricitabine; and (3) rilpivirine. These medicinal ingredients are antiviral agents.

[4] Rilpivirine comes within the class of agents known as non-nucleoside reverse transcriptase inhibitors (“NNRTIs”). The term refers to compounds which bind to the reverse transcriptase enzyme found in the HIV virus and inhibits its ability to integrate the viral DNA into the host cell's DNA.

[5] While the drug is referred to as “the Gilead Product” in the record, counsel advised that a Notice of Compliance was issued by the Minister prior to the hearing and the tablets are now marketed under the name “Complera” which is the term I will use in these reasons.

[6] In relation to the NDS, Gilead submitted eight patents for registration on the Patent Register maintained by the Minister pursuant to section 3 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, as amended, (“*PM (NOC) Regulations*”) including Patent 2,512,475 (“the ‘475 Patent”). The Minister agreed that seven of the patents were eligible for listing subject to a final review when the NOC issued.

[7] By letter dated October 26, 2010, officials on behalf of the Minister advised Gilead of their preliminary view that the ‘475 Patent was not eligible for listing in respect of the NDS. The letter stated that the ‘475 Patent was not eligible for listing because it does not contain a claim for the medicinal ingredients - tenofovir, emtricitabine and rilpivirine - the formulation in the NDS, as required by s.4(2) of the *PM (NOC) Regulations*. The Minister invited Gilead to file responding submissions within 30 days.

[8] Gilead filed representations dated November 24, 2010. The applicant took the position that the claims in the ‘475 Patent are *directed* to chemically stable combinations, rather than formulations, and as such are claims for medicinal ingredients within the scope of paragraph 4(2)(a) of the *PM (NOC) Regulations*. Alternatively, Gilead submitted that the ‘475 Patent does make formulation claims and that those claims provide for sufficient product specificity by virtue of rilpivirine being a drug within one of the specified classes of drugs in the claims, namely, NNRTIs.

[9] In the final decision letter dated January 13, 2011 the officials confirmed the Minister’s view that the ‘475 Patent was not eligible for listing. The ground provided was that the patent referenced NNRTIs as a class without specifying rilpivirine. The letter stated that the product requirements for listing a patent on the register were not met by reference to classes of medicinal ingredients.

[10] In this application, the parties agreed that Complera contains the medicinal ingredients tenofovir, emtricitabine and rilpivirine. They also agree that rilpivirine is within the class of NNRTIs referenced in the claims of the ‘475 Patent. The controversy arises because the claims do

not specifically reference rilpivirine as a medicinal ingredient in the formulations to treat infection which the patent addresses.

ISSUES:

[11] The applicant characterizes the issues as (i) whether the ‘475 Patent contains eligible "claims for the medicinal ingredient" in its product, Complera, pursuant to paragraph 4(2)(a) of the *PM (NOC) Regulations*, and; (ii) whether the ‘475 Patent contains eligible "claims for the formulation" of Complera pursuant to paragraph 4(2)(b) of the *PM (NOC) Regulations*.

[12] The respondent refers to the questions posed in the three part analytical framework approved by the Federal Court of Appeal in *Abbott Laboratories Ltd. v Canada (Attorney General)*, 2008 FCA 354 at paragraphs 29-33; *GD Searle & Co. v Canada (Minister of Health)*, 2009 FCA 35 at paragraphs 33-35; and *Purdue Pharma v Canada (Attorney General)*, 2011 FCA 132 at paragraphs 11-13. The questions may be adapted or restated in accordance with the particular nature of the claim. Here they read as follows:

1. What medicinal ingredient or formulation does the patent claim?
2. What is the medicinal ingredient or formulation in the drug submission for which approval is sought?
3. Is the medicinal ingredient or formulation claimed by the patent that which is approved by the existing notice of compliance?

[13] The second question respecting the nature of the medicinal ingredient or formulation in the drug submission is not in dispute in these proceedings. As noted above, a notice of compliance had not been issued as of the date of the Minister’s decision but was issued prior to the hearing.

[14] I will discuss the issues raised by the application in considering the following questions:

1. What is the correct construction of the ‘475 Patent?
2. What is the correct interpretation of paragraphs 4(2)(a) and (b) of the *Patented Medicines (Notice of Compliance) Regulations*?
3. Was the Minister’s decision to exclude the ‘475 Patent from the Register reasonable?

RELEVANT LEGISLATION:

[15] Section 2 and paragraphs 4 (2) (a) and (b) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, as amended, are relevant to this application and read as follows:

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 » 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.

(*revendication de l'ingrédient médicinal*)	(*claim for the medicinal ingredient*)
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;
[…]	[…]

ARGUMENT AND ANALYSIS:

Standard of Review

[16] The standards of review are settled by the jurisprudence. When reviewing a decision of the Minister on patent listing, the Court must first construe the claims. The Minister's understanding of the patent is reviewed for correctness.

[17] With respect to the third question set out above, whether the medicinal ingredient or formulation approved by the notice of compliance is that claimed by the patent, the Minister's understanding of the legal principles including the interpretation of the *PM (NOC) Regulations* is reviewed for correctness. The Minister's application of those principles to the facts of the NDS is reviewed for reasonableness: *Purdue*, above, para. 13.

What is the correct construction of the '475 Patent?

[18] The '475 patent was filed on January 13, 2004 and was issued on June 2, 2009.

[19] Claims must be construed purposively, with a mind willing to understand and in a manner that ensures the attainment of the objects of the patent, taking into account the context of the specification seeking a construction which is reasonable and fair: *Whirlpool Corp. v Camco Inc.*, 2000 SCC 67 at para 49.

[20] The words of the claims must be read in the sense the inventor is presumed to have intended. When plain words are used, they should be given their plain and ordinary meaning unless the words are defined otherwise in the specification (*Free World Trust v Électro Santé Inc.*, 2000 SCC 66 at para 51; *Procter & Gamble Co. v Beecham Canada Ltd.*, [1982] FCJ No 10 (CA), 40 NR 313, 61 CPR (2d) 1 at para 48; and *Reliance Electric Industrial Co. v Northern Telecom Ltd.*, 47 CPR (3d) 55, 60 FTR 208). Different claims should be construed as having different meanings: *Hoffmann-La Roche Ltd. v Mayne Pharma (Canada) Inc.*, 2005 FC 814 at para 43.

[21] The ‘475 Patent is entitled "Compositions and Methods for Combination Antiviral Therapy" and contains 53 claims. The language of the claims refers to combinations of antiviral agents, pharmaceutical formulations of antiviral agents, claims for methods of preparing the claimed formulations, claims for dosage forms and claims for uses.

[22] Claims 42, 45, 46 and 48 refer to the combination of two or more anti-viral agents. Claims 15, 31, 32 and 34 refer to a formulation containing two or more anti-viral agents.

[23] The background section of the ‘475 Patent describes it as addressing a need for new combinations of orally active drugs for the treatment of patients infected with certain viruses that provide enhanced therapeutic safety and efficacy, impart lower resistance, and predict higher patient compliance.

[24] The summary of the invention describes it, in part, as follows:

> The present invention provides combinations of antiviral compounds, in particular compositions and methods for in addition of HIV. In an exemplary aspect, the invention includes a composition including tenofovir disoproxil fumarate and emtricitabine which has anti-HIV activity. The composition of tenofovir DF and emtricitabine is both chemically stable and either synergistic and/or reduces the side effects of one or both of tenofovir DF and emtricitabine. Increased patient compliance is likely in view of the lower pill burden and simplified dosing schedule.
>
> … The present invention is also concerned with pharmaceutical compositions and formulations of said combinations of tenofovir disoproxil fumarate and emtricitabine.
>
> … Another aspect of the invention is directed to chemically stable combination antiviral compositions comprising tenofovir disoproxil fumarate and emtricitabine. In a further aspect of the invention, the chemically stable combinations of tenofovir disoproxil fumarate and

> emtricitabine further comprise a third antiviral agent. In this three component mixture, the unique chemical stability of tenofovir disoproxil fumarate and emtricitabine is taken advantage of in order to enable the combination with the third antiviral agent… Preferably, a third component is an agent approved for antiviral use in humans, more preferably, it is an NNRTI or a protease inhibitor (PI), more preferably yet, it is an NNRTI.

[25] The object of the invention, as I understand it, was to take advantage of the chemically stable characteristics of tenofovir and emtricitabine, both known for their effectiveness as anti-virals, in combination and sometimes with a third medicinal ingredient.

[26] I construe the relevant claims of the ‘475 Patent 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.

[27] The applicant submits that claims 42, 45, 46 and 48 of the ‘475 Patent are “claims for the medicinal ingredient” in Complera and claims 31, 32 and 34 of the patent are “claims for the formulation” found in Complera.

[28] Claim 42 refers only to tenofovir and emtricitabine and, therefore, does not encompass the three medicinal ingredients in Complera. Claims 31 and 45 refer to a third agent but say nothing more than that it is an “anti-viral”. That could cover a very large number of unnamed other ingredients. Claims 32 and 46 say that the third active anti-viral agent is to be selected from a menu of an NNRTI, an NRTI (nucleoside reverse transcriptase inhibitor), an integrase inhibitor or a PI (protease inhibitor). Claims 34 and 48 say that the third antiviral agent is an NNRTI. Rilpivirine is

not expressly referenced in any of the claims and can be included only by deductive reasoning because it falls within a named class.

What is the correct interpretation of s.4(2)(a) and (b) of the Patented Medicines (Notice of Compliance) Regulations?

[29] The parties agree that the purpose of the *PM (NOC) Regulations* is to prevent abuse by generic drug manufacturers of the early working exception to patent infringement in relation to pharmaceutical patents: *AstraZeneca Canada Inc. v Canada (Minister of Health)*, 2006 SCC 49, 2 SCR 560 at para 15. They also agree that a key consideration in interpreting the listing requirements under the *PM (NOC) Regulations* is the concept of product specificity, introduced by amendments to the *PM (NOC) Regulations* in 2006: *Regulatory Impact Analysis Statement* (2006), Canada Gazette Part II, Vol. 140, pages 1510-1525 at 1516.

[30] Justice Sharlow of the Federal Court of Appeal commented on the intent of the 2006 amendments in *GD Searle & Co.*, above**.** At paragraph 15 she stated:

> The jurisprudence relating to the eligibility of patents for listing pursuant to section 4 of the *NOC Regulations* (as they read prior to the October 5, 2006 amendments) had adopted an interpretation that the government considered so broad as to unduly delay market entry of generic drugs. The October 5, 2006 amendments were intended to restore the balance. This is fully explained in the *Regulatory Impact Analysis Statement* published with the amending regulation (SOR/2006-242).

[31] The applicant submits that the decision not to list the ‘475 Patent does not accord with a correct interpretation of the *PM (NOC) Regulations*. It is sufficient, the applicant submits, if there is

a “link” between the subject matter of the patent considered for listing and the content of the underlying NDS.

[32] The applicant also contends that the decision was not consistent with the Minister’s policy and past practice.

[33] The applicant acknowledges that rilpivirine, the third medicinal ingredient in Complera, had not been disclosed when the ‘475 Patent application was filed but argues that the class of compounds to which it belongs is described and claimed in the ‘475 Patent. The applicant contends that the Minister erroneously: (i) construed the relevant "combination" claims of the ‘475 Patent as relating to formulations; and (ii) improperly considered the patent list eligibility of the ‘475 Patent only in relation to paragraph 4(2)(b) of the *PM (NOC) Regulations*

[34] The parties agree that the class of compounds to which rilpivirine belongs, NNRTIs, is described and claimed in the ‘475 Patent. They disagree on whether that is sufficient to make the patent eligible for listing.

[35] The applicant contends that on a purposive interpretation, the ‘475 Patent is eligible for listing on the Patent Register under subsection 4(2) of the *PM (NOC) Regulations*. The applicant argues that the ‘475 Patent contains claims for the combination of the medicinal ingredients in the NDS and should therefore qualify under paragraph 4(2)(a) of the *PM (NOC) Regulations*.

[36] In the alternative, the applicant submits that the formulation claims in the‘475 Patent provide for sufficient product specificity because rilpivirine is a drug within one of the specified classes of drugs, namely NNRTI's.

[37] The respondent submits that the relevant claims must be considered for eligibility under paragraph 4(2)(b) as formulations rather than as combinations under paragraph 4(2)(a) because the NDS was for approval of a formulation of three active medicinal ingredients in a tablet.

[38] With regard to the Minister’s policy, the applicant cites the *Guidance Document: Patented Medicines (Notice of Compliance) Regulations* (the “Guidance Document”) issued under the authority of the Minister to provide assistance with respect to the application of the *PM (NOC) Regulations*. The following paragraphs are found at pages 8-9 of that document:

> Patents claiming a combination of medicinal ingredients are not eligible for listing in respect of a drug that contains only one of the claimed medicinal ingredients. However a patent claiming, as a compound, a single medicinal ingredient will be eligible for listing with respect to a drug that contains a set of medicinal ingredients in combination with other medicinal ingredients, notwithstanding that the medicinal ingredient on the NOC is a combination of medicinal ingredients.
>
> …
>
> In the case of formulation patents, the *PM (NOC) Regulations* further specify that the claimed formulation must include, as an element, the medicinal ingredient of the drug. This requirement was added to ensure that a patent directed solely to a formulation with no claim to or inclusion of the approved medicinal ingredient is not eligible for listing on the Patent Register.
>
> [emphasis added]

[39] Under the logic of the Minister's Guidance Document, the applicant contends, a patent containing a claim to a single medicinal ingredient is eligible for listing in respect of a product which contains that ingredient together with one or more other medicinal ingredients. In this context, the applicant submits, the ‘475 Patent was eligible for listing as it claimed the combination of tenofovir and emtricitabine (claim 42), two of the medicinal ingredients in Complera, as well as the combination of tenofovir and emtricitabine with a NNRTI (claims 45, 46 and 48).

[40] The *Manual of Patent Office Practice* (Ottawa-Gatineau: Canadian Intellectual Property Office, 2009) (the “Manual”) at Chapter 11, §11.07, recognizes combination claims as a valid type of claim. The term combination is described in the Manual at § 11.07:

> A combination is a union of elements or process steps co-operating to produce a unitary and practical result that is not the sum of the known characteristics of the elements or steps.
>
> A patentable combination is one in which the elements or steps cooperate in an unexpected manner or cooperate in a known way to give an unobvious result or effect. If all the requirements of the *Patent Act* and Rules are met, a claim to such a combination can be allowed.

[41] Justice Russel discussed the distinction between a compound patent and a formulation patent in *Bayer Inc. v Canada (Minister of Health),* 2009 FC 1171, aff’d 2010 FCA 161, at paragraphs 77 to 80. He noted that under paragraph 4(2)(a)of the *PM (NOC) Regulations*, a compound patent may be eligible for listing on the Register because it contains a claim for the approved medicinal ingredient which is the key active part of the drug. A formulation patent does not contain a claim for the medicinal ingredient itself. It is rather a claim for the approved mixture of medicinal and nonmedicinal ingredients that are actually administered to the patient. At paragraph 80, Justice Russel concluded:

> 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)…

[42] There is no dispute that "medicinal ingredient" refers to the substance in the formulation which, when administered to a patient, is responsible for the drug's desired effect in the body. The term, while expressed in the singular, encompasses the plural: subsection 33(2) of *Interpretation Act*, RSC, 1985, c I-21.

[43] With respect to past practice, the applicant relies on the fact that the Minister listed Canadian Patent No. 2,068 790 (the '790 Patent) in 2005. The '790 Patent claims combinations of two medicinal ingredients to treat HIV infection. The related NDS claimed those ingredients in combination with a third ingredient. Accordingly, the applicant argues, the Minister has already listed a patent on analogous facts. The respondent submits that the listing of the '790 Patent occurred prior to the 2006 amendments to the *PM (NOC) Regulations* which changed the rules for listing patents under paragraph 4(2)(b).

[44] I agree with the respondent that the example of the '790 Patent is not helpful to the applicant as a result of those changes.

Was the Minister's decision to exclude the '475 Patent from the Register reasonable?

[45] In *Bayer*, the Court found that the patent was not eligible for listing because it claimed a formulation containing only one of the two approved medicinal ingredients. Here, the NDS

submitted for approval was not based on the two medicinal ingredients claimed in the ‘475 Patent, with an uncertain third ingredient, but on tablets with three specific medicinal ingredients.

[46] There is nothing in the ‘475 Patent that points specifically to rilpivirine as the third ingredient in the class of NNRTIs. As the evidence of Dr. Miller on behalf of the applicant states, several other NNRTI’s had been studied for their efficacy in treating HIV prior to the grant of the patent. References to an NNRTI in the patent are not to a specific medicinal ingredient but rather to the class of compounds, one or more of which may have been found to be suitable to be included in a formulation with tenofovir and emtricitabine. The claims that specify such a formulation are not specific to the drug in the Complera NDS.

[47] I agree with the respondent that the patent was properly considered for listing under paragraph 4(2)(b) rather than 4(2)(a) as containing formulation rather than combination claims. The listing application failed the specificity requirement for eligibility under 4(2)(b). On a plain and ordinary reading of paragraph 4(2)(b), all of the ingredients in the NDS have to be found in the formulation in the claim.

[48] This interpretation is supported by *Purdue*, above, a recent decision of the Federal Court of Appeal which dealt with a claim for a dosage. Strict interpretation of the product specificity concept, as discussed at paragraphs 42 and 43 of *Purdue*, applied in this case to s.4(2)(b) of the *PM (NOC) Regulations*, leads me to the conclusion that a formulation of the claim in the patent sought to be listed must match the formulation in the NDS. Here, the claimed formulation and the approved formulation do not match precisely and the requirement of product specificity is not met.

[49] I conclude that the Minister correctly construed the relevant ‘475 Patent claims as formulations. The Minister correctly interpreted s.4(2)(b) of the *PM (NOC) Regulations* as requiring strict product specificity with regards to the formulation. The ‘475 Patent did not meet the specifics of the NDS. Therefore the Minister reasonably concluded that the ‘475 Patent was not eligible for listing. The requirements of paragraph 4(2)(b) were not met and the Minister’s decision that the ‘475 Patent is not eligible for listing is reasonable and must be upheld.

[50] The application is dismissed with costs to the respondent.

JUDGMENT

THIS COURT'S JUDGMENT is that the application is dismissed with costs to the respondent in the normal scale.

"Richard G. Mosley"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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