Federal Court  Cour fédérale

Date: 20160308

Docket: T-1693-14

Citation: 2016 FC 231

Ottawa, Ontario, March 8, 2016

PRESENT: The Honourable Madam Justice Heneghan

BETWEEN:

GILEAD SCIENCES, INC. AND GILEAD SCIENCES CANADA, INC.

Applicants

and

THE MINISTER OF HEALTH AND APOTEX INC.

Respondents

REASONS
(Confidential Reasons issued February 19, 2016)

I. INTRODUCTION

[1] By Notice of Motion dated, March 6, 2015, Apotex Inc. ("Apotex") seeks an order dismissing the within application on the basis that the Canadian Patents 2,261, 619 (the " '619 Patent") and 2, 298,059 (the " '059 Patent") are ineligible for inclusion on the Patent Register in respect of the drug TRUVADA®.

[1] By Order dated May 8, 2015, Justice Barnes struck out the application insofar as it concerned the validity of the ‘059 Patent. In light of this Order, this motion only deals with the ‘619 Patent.

II. CONTEXT

[2] This motion arises in the context of an application for an order pursuant to the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the “Regulations” or “Unamended Regulations”), prohibiting the Minister of Health (the “Minister”) from issuing a Notice of Compliance (“NOC”) until the expiry of the ‘619 Patent, the ‘059 Patent and Canadian Patent 2, 512, 475 (the “ ‘475 Patent”).

A. *The Parties*

[3] Gilead Sciences, Inc. is a research based biopharmaceutical company, incorporated in the United States**,** which distributes and sells TRUVADA®. Gilead Sciences Canada, Inc. is a subsidiary of Gilead Sciences and licensee of intellectual property rights pertaining to Gilead owned drug products. Gilead Sciences, Canada Inc. distributes and sells TRUVADA® in Canada. These parties shall be referred to, collectively, as “Gilead”.

[4] Apotex is a Canadian corporation that manufactures generic pharmaceuticals.

[5] The Minister, although a party to this proceeding, is not actively participating in it.

[6] The within proceeding was in response to the service of a Notice of Allegation ("NOA") dated June 19, 2014 on Gilead Sciences Canada, Inc. by Apotex. The NOA sets out the following allegations:

> With respect to the 619 Patent, Apotex alleges that:
>
> (a) Claims 1 to 32 of the 619 Patent are not relevant under the Regulations.
>
> (b) Claims 6 to 8, 10, 14, 16 to 20 and 22 to 24 of the 619 Patent and their dependent claims will not be infringed by the making, constructing, using or selling of the Apotex Product, by Apotex, in Canada.
>
> (c) The 619 Patent and all its claims are and have been invalid, void, unenforceable and of no force and effect.
>
> With respect to the 059 Patent, Apotex alleges that:
>
> Claims 1 to 14 are not relevant under the Regulations.
>
> (a) Claims 1 to 14 of the 059 Patent will not be infringed by the making, constructing, using or selling of the Apotex Product, by Apotex, in Canada.
>
> (b) Gilead is estopped from asserting the validity of the 059 Patent for reasons of and abuse of process
>
> (c) The 059 Patent and all its claims are and have been invalid, void, unenforceable and of no force and effect.
>
> With respect to the 475 Patent, Apotex alleges that:
>
> (a) Claims 1 to 14, 27, 31 to 38, 41, 45 to 49 and 51 to 53 and claims dependent on them are irrelevant under the Regulations.
>
> (b) Claims 7 to 11, 13, 19 to 21, 27, 31 to 39, 41, 45 to 49 and 51 to 53 of the 475 Patent and their dependent claims will not be infringed by the making, constructing, using or selling of the Apotex Product, by Apotex, in Canada.
>
> (c) The 475 Patent and all its claims are and have been invalid, void, unenforceable and of no force and effect.

B. *Nature of This Proceeding*

[7] This proceeding seeks to prohibit the issuance of a NOC to Apotex for its product. In this motion, Apotex challenges the Applicants' '619 Patent on the ground that it is ineligible for inclusion on the Patent Register.

[8] A NOC grants marketing approval for drugs in Canada. It is issued by the Federal Government, indicating that all requirements have been met pursuant to the *Food and Drug Regulations*, C.R.C., c. 870 for the protection of public health and safety.

[9] The Regulations authorize owners of existing patents for pharmaceutical products to file a "patent list" relative to those products for which they hold a NOC. The Regulations refer to the person filing such a list as the "first person". In this case, the Applicants are the "first person". Often, the first person is an innovator drug manufacturer.

[10] The framework of the Regulations allows generic drug manufacturers to rely on prior approval of related pharmaceutical products in seeking for marketing approval of their generic form of the products. Manufacturers who produce the same drug may file an application for a NOC that refers to and relies on the fact that prior approval has been granted for the brand-name version of the drug. Such a manufacturer is known as the "second person" and that is the status of Apotex.

[11] The Regulations prohibit the Minister from issuing a NOC until all relevant product and use patents in the earlier approved medicine, as described in the patent list, have expired. This means that a second person must either wait until patent expiry before receiving a NOC or submit a NOA to the Minister with its new drug submission.

[12] Following service of the NOA, the Minister may issue a NOC to the second person, unless the first person exercises its right, pursuant to subsection 6(1) of the Regulations, to seek an order from this Court prohibiting the Minister from issuing the NOC. Such step must be taken within 45 days of receipt of the NOA and once such a proceeding is commenced, the issuance of a NOC to the second person is stayed for a maximum period of 24 months.

[13] The Regulations provide that a patent can be added to the Patent Register in respect of a drug that has received a NOC where it meets the requirements set out in the Regulations. Section 4 provides as follows:

4 (1) A first person who files or who has filed a new drug submission or a supplement to a new drug submission may submit to the Minister a patent list in relation to the submission or supplement for addition to the register.	4 (1) La première personne qui dépose ou a déposé la présentation de drogue nouvelle ou le supplément à une présentation de drogue nouvelle peut présenter au ministre, pour adjonction au registre, une liste de brevets qui se rattache à la présentation ou au supplément.

(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	(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 médicinal 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.

[14] A failure to list patents on the Patent Register may result in the Minister granting a NOC to the second person notwithstanding the existence of a valid patent.

[15] Paragraph 6(5)(a) of the Regulations allows the second person to move for dismissal of an application in the Federal Court in respect of patents that are not eligible for inclusion in the Register. Paragraph 6(5)(a) provides as follows:

(5) Subject to subsection (5.1), in a proceeding in respect of an application under subsection (1), the court may, on the motion of a second person, dismiss the application in whole or in part	5) Sous réserve du paragraphe (5.1), lors de l'instance relative à la demande visée au paragraphe (1), le tribunal peut, sur requête de la seconde personne, rejeter tout ou partie de la demande si, selon le cas :
(a) in respect of those patents that are not eligible for inclusion on the register; or	a) les brevets en cause ne sont pas admissibles à l'inscription au registre;

C. *The Amended Regulations*

[16] On November 3, 2014, Industry Canada announced its intention to amend the Regulations. On May 2, 2015, the proposed amendments were pre-published in the Canada Gazette, Part 1.

[17] The amended Regulations came into force on June 19, 2015; see *Regulations Amending the Patented Medicines (Notice of Compliance) Regulations*, SOR/2015-169 (the "2015 Amendments").

[18] Subsection 4(2) of the 2015 Amendments provides as follows:

4. (2) Section 4 of the Regulations is amended by adding the following after subsection (2):	(2) L'article 4 du même règlement est modifié par adjonction, après le paragraphe (2), de ce qui suit :

(2.1) The following rules apply when determining the eligibility of a patent to be added to the register under subsection (2):	(2.1) Les règles ci-après s'appliquent au moment de la détermination de l'admissibilité des brevets pour leur adjonction au registre aux termes du paragraphe (2) :
(a) for the purposes of paragraph (2)(a), a patent that contains a claim for the medicinal ingredient is eligible even if the submission includes, in addition to the medicinal ingredient claimed in the patent, other medicinal ingredients;	a) pour l'application de l'alinéa (2)a), un brevet qui contient la revendication de l'ingrédient médicinal est admissible même si la présentation comprend, en plus de l'ingrédient médicinal revendiqué dans le brevet, d'autres ingrédients médicinaux;

[19] Section 5 of the 2015 Amendments provides as follows:

5. The court shall consider any ongoing application made under subsection 6(1) or any ongoing motion made under paragraph 6(5)(a) of the Patented Medicines (Notice of Compliance) Regulations that are initiated during the period that begins on May 2, 2015 and ends on the day on which this section comes into force, having regard to sections 2 and 4 of the Patented Medicines (Notice of Compliance) Regulations, as amended on the coming into force of this section.	5. Le tribunal traite toute demande en cours faite aux termes du paragraphe 6(1) du Règlement sur les médicaments brevetés (avis de conformité) au cours de la période commençant le 2 mai 2015 et se terminant à la date de l'entrée en vigueur du présent article, ainsi que toute requête en cours faite aux termes de l'alinéa 6(5)a) du même règlement au cours de cette période, en tenant compte des articles 2 et 4 du même règlement tels qu'ils sont modifiés à la date d'entrée en vigueur du présent article.

D. *This Motion*

[20] Apotex filed this Notice of Motion on March 6, 2015. The motion was scheduled to be heard on June 23, 2015.

[21] Following the June 23 hearing, Gilead submitted a letter dated June 24, 2015 advising the Court that the proposed amendments to the Regulations came into force on June 19, 2015. Gilead requested the opportunity to make further submissions. Apotex responded to the letter from Gilead by letter dated June 25, 2015, providing further submissions on the applicability of the Amended Regulations.

[22] By Order dated June 26, 2015, the Court ordered that the hearing of this motion be resumed on August 18, 2015. Further submissions from Gilead were filed on July 15, 2015.

[23] On July 23, 2015, parties were invited to address the decision of the Federal Court of Appeal, *Eli Lilly Canada v. Attorney General of Canada and the Minister of Health*, (2015) 475 N.R. 299 ("*Eli Lilly*") at the August 18 hearing.

[24] Apotex submitted supplemental written representations on July 31, 2015. Apotex filed additional further written representations on August 14, 2015.

III. THE EVIDENCE

[25] Apotex filed the following affidavits in support of its motion:

- Lisa Edon sworn March 2015, law clerk at Goodmans LLP

- Dr. Paul A. Grieco sworn March 6, 2015, Professor of Chemistry at Montana State University-Bozeman

[26] Gilead filed the following affidavits:

- Edward Gudaitis sworn May 14, 2014, General Manager, Gilead Sciences Canada, Inc.

- Catherine Ma sworn May 15, 2015, law clerk, Norton Rose Fulbright

- Dr. Ian M. Cockburn sworn May 15, 2015, Richard C. Shipley Professor of Management, Boston University School of Management

- Mark A. Wainberg sworn May 13, 2015, Professor of Medicine and Microbiology at McGill University

- Dr. Gary Blick sworn May 15, 2015, Dr. Blick sworn a supplementary affidavit dated June 12, 2015, Medical and Research Director, CIRCLE C.A.R.E Centre

- Dr. Mark Lautens sworn May 14, 2015, University Professor of Chemistry, University of Toronto

- Immacula Bien-Aimé sworn June 12, 2015, paralegal, Norton Rose Fulbright

[27] Neither party cross-examined on these affidavits for the purposes of this motion.

IV. THE ISSUES

[28] The following issues are addressed by the parties:

1. Is this motion governed by the Amended Regulations?
2. Is the '619 Patent eligible for inclusion on the Patent Register with respect of TRUVADA®

V. SUBMISSIONS

A. *Apotex's Submissions*

(1) *Is this motion governed by the Amended Regulations?*

[29] Apotex argues that the Regulations existing at the time its motion was filed should not be read in view of the subsequent amendments. Subsection 45(3) of the *Interpretation Act*, R.S.C. 1985, c. I-21 (the "Interpretation Act"), provides that amendment of an enactment shall not be deemed to be a declaration on the previous state of the law.

[30] Apotex, relying on the decision in *United States of America v. Dynar*, [1997] 2 S.C.R. 462, submits that there is a presumption against retrospective and retroactive application of the Regulations. The transitional provision, found in section 5 of the 2015 Amendments, creates an exception to this presumption. The provision expressly states that ongoing motions under paragraph 6(5)(a) initiated on or after May 2, 2015 are governed by the Amended Regulations.

[31] As this motion was initiated prior to May 2, 2015, Apotex argues that the Unamended Regulations apply.

[32] In reply to Gilead's submission that the French and English versions of the transitional provision are different, Apotex says that this argument is without merit. Both versions contemplate that the Amended Regulations will apply only to motions initiated on or after May 2, 2015.

[33] Gilead focuses on the fact that the words "that are initiated" appear in the English version of the transitional provision, but not in the French version. Apotex says that, while the sentence structure of the French version is different, the meaning of the provision is the same. Gilead ignores the words "au cours de la période commençant le 2 mai 2015" which appear in the transitional provision.

[34] In the alternative, should the Court find that the words of the transitional provision are not the same, Apotex relies upon the equal authenticity rule, which provides that both versions of

a provision are equally authoritative and neither can be read out of the law; see *Canadian Pacific Railway Co. v. Robinson* (1891), 19 S.C.R. 292 at 325.

[35] Apotex further argues that the proper interpretation would be to recognize that the verb "faite" means initiate. This approach would harmonize the two versions.

[36] Apotex then submits that Gilead ignores the purpose of the transitional provision, as set out in the 2015 Regulatory Impact Analysis Statement (the "2015 RIAS"); see 2015 Regulatory Impact Analysis Statement, C. Gaz. 2015, II, 2210. The 2015 RIAS says the purpose of the transitional provision was to "prevent applications seeking benefit from the old rules after the amendments were published in the Canada Gazette, Part 1". The 2015 RIAS is clear: the purpose of the transitional provision was to make the Amended Regulations apply only to motions commenced after the prepublication, that is May 2, 2015.

[37] As well, Apotex responds to Gilead's assertion, that the transitional provision does not identify which regulations apply to motions that were pending on May 2, 2015, by stating that that assertion offends the maxim *express unius est exclusion alterius*e. By reference only to ongoing applications initiated on or after May 2, 2015, it should be presumed that the Governor-in-Council intended to exclude ongoing motions made before that date; see Ruth Sullivan, *Sullivan on the Construction of Statutes*, 6th ed (LexisNexis Canada) at para. 8.92.

[38] In response to Gilead's submissions on section 10 of the Interpretation Act, Apotex argues that Gilead has misinterpreted the meaning of "circumstances" in that provision. The

circumstances referred to are the facts upon which the Court has to make a decision, not the motion itself. It submits that the Amended Regulations were in force on the date the Court became seized the motion does not mean that those Regulations apply to the motion.

[39] Apotex then submits that there is a presumption that the legislature does not intend to delegate a power to legislate retroactively or retrospectively or to interfere with vested rights; see *Sullivan on the Construction of Statutes, supra* at para. 25.176. It relies on the decision in *Apotex Inc.v. Merck Frosst Canada & Co. et al.*(2011), 425 N.R. 279 ("*Merck Frosst*") at paras. 56 and 65-68 where the Federal Court of Appeal distinguished between amendments which have retroactive or retrospective effect**,** and those which merely clarified an obscure law.

[40] Apotex contends that the 2015 Amendments fall in the first category, that the purpose was to change the meaning given by the courts to paragraph 4(2)(a) of the Regulations. Apotex claims that the law was clear when this motion was filed, with respect to the ineligibility of the '619 Patent to be listed on the Patent Register.

[41] As well, in *Merck Frosst, supra* at para. 31, the Federal Court of Appeal held that the *Patent Act*, R.S.C. 1985, c. P-4 (the "Patent Act") does not authorize the making of retroactive or retrospective regulations.

[42] Apotex submits that it would be unfair to compel it to operate within a different legal context, which would be the result if the Amended Regulations were held to apply. There is no

reason why Gilead should be permitted to have its past actions, that is the improper listing of the '619 Patent, undone by legislative change.

(2) *Is the '619 Patent eligible for inclusion on the Patent Register?*

[43] Apotex has not made submissions on whether the '619 Patent is eligible for inclusion on the Patent Register under the Amended Regulations.

[44] Apotex says that subsection 4(2) of the Regulations sets out the eligibility requirements of listing a patent on the Patent Register. Product specificity, which was introduced through amendments in 2006, is a key requirement. Prior to the 2006 amendments patent claims needed be "relevant to" the approved drug.

[45] Apotex submits that the 2006 amendments require that the patent contain a claim for the medicinal ingredient, formulation, dosage and use which matches the drug issued the NOC. A patent claim will fail to meet the requirement of product specificity if it does not make specific reference to each of the medicinal ingredients in the combination drug.

[46] Apotex acknowledges that the Federal Court and Court of Appeal have considered the 2006 amendments in five cases involving combination drugs. In each of these cases, the Courts held that patents which do not claim all the medicinal ingredients in the combination drug are not eligible for listing; see *Bayer Inc. v. Canada (Minister of Health) et al.* ,(2009) 358 F.T.R. 20 at paras. 88-89, aff'd (2010) 86 C.P.R. (4th) 81; *Purdue Pharma v. Canada (Attorney General) et*

al. (2011) 417 N.R. 223 at para. 43; *Gilead Sciences Canada Inc. v. Canada (Minister of Health) et al.* (2012) 435 N.R. 188 at para. 49 ("*Gilead Sciences*"); *Eli Lilly, supra* and *ViiV Healthcare ULC et al. v. Teva Canada Ltd.* (2015), 474 N.R. 235 ("*Viiv*").

[47] Apotex argues that the '619 Patent does not claim a combination of tenofovir disoproxil fumarate and emtricitabine, the two medicinal ingredients in TRUVADA®. The claims of the '619 Patent are directed to a group of nucleotide compounds which has a phosphonate group attached to a base. According to the affidavit of Dr. Grieco, filed on behalf of Apotex in support of its motion, emtricitabine, a nucleoside compound, does not contain a phosphonate group in its structure or an adenine base.

[48] In *Gilead Sciences Inc. et al. v. Canada (Minister of Health)* (2013), 445 F.T.R. 1 at para. 22, the Court construed Claim 32 of the '619 Patent and held it claimed tenofovir disoproxil and its salts.

[49] Apotex submits that it is plain and obvious that the claims of the '619 Patent do not strictly match the medicinal ingredients found in the approved drug TRUVADA®.

[50] Gilead asserts that *Eli Lilly, supra* eliminates the matching principle for patent listing under subsection 4(2) of the Regulations. Apotex submits that this argument misinterprets the decision.

[51] Apotex argues that the issue in *Eli Lilly, supra* was the eligibility of the '329 Patent to be listed against the fixed dose combination drug ("FDC") Trifexis® pursuant to paragraph 4(2)(b) of the Regulations.

[52] Trifexis® contains two medicinal ingredients, spinosad and milbemycin. To determine that patent's eligibility the Federal Court of Appeal considered the three part test set out in *Abbott Laboratories Ltd. v. Canada (Attorney General) et al.* (2008), 329 F.T.R. 190 as follows:

> 1. What formulation does the patent claim?
>
> 2. What is the formulation of the NOC issued for the drug in question?
>
> 3. Is the formulation claimed by the patent that which was authorized in the NOC?

[53] The Federal Court of Appeal found that the '329 Patent was eligible because it claimed both medicinal ingredients and said at para. 71:

> … the claimed formulation in the '329 Patent must include the two medicinal ingredients found in Trifexis. This view finds support in all the leading cases on the question and is in accordance with paragraph 4(2)(b) of the Regulations.

[54] Apotex submits that the Court of Appeal did not depart from the *Gilead Sciences, supra* and *ViiV, supra* decisions.

[55] According to Apotex, the Federal Court of Appeal in *Eli Lilly*, *supra* distinguished *Gilead Sciences*, *supra* on its facts. Apotex submits that the conclusions of the Court of Appeal in *Eli Lilly* are consistent with both *Gilead Sciences*, *supra* and *ViiV*, *supra*.

[56] Finally, Apotex argues it will suffer prejudice if this motion is dismissed, since it has been barred from marketing its generic version of TRUVADA® on the basis of an improperly listed patent.

B. *Gilead's Submissions*

(1) *Is this motion governed by the Amended Regulations?*

[57] Gilead argues that the English version of transitional provision does not say which version of the Regulations apply to subsection 6(5)(a) motions that were initiated before May 2, 2015. In the absence of explicit language addressing motions initiated prior to May 2, 2015, it submits that the ordinary principle, that the law is continually speaking, should apply.

[58] As well, Gilead argues that the French version of the transitional provision does not contain the same conditions for its application as the English version.

[59] The English version requires that the motion be initiated between May 2, 2015 and June 19, 2015, the date the Amended Regulations came into force. The words "that are initiated" have no equivalent in the French version.

[60] The French version does not impose the requirement that the motion be initiated between May 2, 2015 and June 19, 2015. The French version only imposes two conditions for the application of the Amended Regulations: first, that a motion is made pursuant to paragraph 6(5)(a) and second, the motion is ongoing when the Amended Regulations come into force.

[61] Gilead submits that where there is discord between the two versions, the common meaning which is consistent with Parliament's intention will govern; see *R. v. Daoust*, [2004] 1 S.C.R. 217 at paras 27-30. Where one version is ambiguous and the other is plain and unequivocal, the shared meaning is that of the version that is plain and unambiguous; see *R. v. SAC*, [2008] 2 S.C.R. 675 at para. 15. In this case, the English version of the transitional provision is ambiguous. The French version is not ambiguous and should govern.

[62] Gilead argues that the Court should interpret the transitional provision in light of its objective; see *Takeda Canada Inc. v. Canada (Minister of Health) et al.* (2013), 440 N.R. 346 at para. 123.

[63] The 2015 RIAS confirms the Regulator's intent that the Amended Regulations apply to the present motion. The 2015 RIAS states, in part, at page 2208:

> [i]n any legal proceeding commenced under section 6 of the PM(NOC) Regulations … following the prepublication of these regulatory amendments in the *Canada Gazette*, Part 1, the Court will be required to apply the PM(NOC) Regulations as amended…

[64] The expression "any motion brought" corresponds with the French "une requête présentée". Gilead suggests that "présentée" refers to adjudication of the motion by the Court.

[65] Gilead submits that section 10 of the Interpretation Act codifies the principle that regulations in force be applied whenever a matter is being adjudicated before the Court.

[66] Gilead argues that a Notice of Motion gives notice of an intention to make a motion at a future date. The Amended Regulations were in force at the time when the Court became seized of this motion. Apotex bears the burden of establishing an exception that would allow the Court to apply the Unamended Regulations.

[67] Gilead submits that the 2015 Amendments are retrospective since they attach new consequences to past events. There is no prohibition against retrospective legislation as long as there is no interference with a vested right. Vested rights are found where the individual's legal situation is tangible and concrete and this legal situation is sufficiently constituted at the time the new statute came into force; see *Dikranian v. Quebec (Attorney General)*, [2005] 3 S.C.R. 530 at para. 37.

[68] Gilead argues that Apotex had no vested rights in the issuance of a NOC or in the adjudication of its motion pursuant to the Unamended Regulations. The mere possibility of availing oneself of a specific statute is not enough to establish a vested right; see *Dikranian*, *supra* at para. 39.

[69] There is no vested right in prior judicial interpretations of a provision; see *Merck Frosst*, *supra* at paras. 65-67. Apotex knew at the time of filing this motion that the legal environment was fundamentally uncertain.

[70] Further, Gilead submits that Apotex would suffer no prejudice if its motion is denied because this motion is not dispositive of the within application, and Apotex does not deny that its proposed product would infringe the '619 Patent.

(2) *Is the '619 Patent eligible for inclusion on the Patent Register?*

[71] Gilead argues that subsection 4(2.1) provides that when determining the eligibility of a patent to be added to the Patent Register, a claim for a medicinal ingredient is eligible even if the submission includes additional medicinal ingredients.

[72] In short, Gilead submits that the '619 Patent claims a medicinal ingredient in TRUVADA® and was eligible for listing.

[73] If the Amended Regulations do not govern this motion, Gilead submits that a plain reading of paragraph 4(2)(a) shows a medicinal ingredient claimed in the patent must be the same as a medicinal ingredient approved in the NOC. There is no requirement that all medicinal ingredients approved in the NOC be claimed.

[74] Gilead argues that in the interpretation and application of paragraph 4(2)(a), courts must read the words in their entire context and in their grammatical and ordinary sense harmoniously with the scheme, and object of the statute and the intention of Parliament; see *Astrazeneca Canada Inc. v. Canada (Minister of Health)*, [2006] 2 S.C.R. 560 at para. 26.

[75] Gilead refers to the early-working exception which allows generic manufacturers to make use of an innovator's patented inventions, in order to prepare drug submissions to Heath Canada without infringing those patents; see subsection 55.2(1) of the Patent Act. It argues that the purpose of section 4 of the Regulations is to prevent abuse of the early-working exception by requiring generic manufacturers to address relevant patents of the innovator which have been listed in respect of the drug. Paragraph 4(2)(a) must be interpreted with this aim in mind.

[76] Gilead submits that the listing of patents for a single medicinal ingredient against FDCs is consistent with the purpose of section 4.

[77] Gilead then argues that *Eli Lilly, supra* reversed the previous jurisprudence relied upon by Apotex. It submits that this recent decision was made under the Unamended Regulations. In *Eli Lilly, supra* the Federal Court of Appeal affirmed the test set out in *Abbott Laboratories Ltd., supra* at para. 54, for the listing of patents under subsection 4(2) and the specific match requirement. The majority of the Court read down and distinguished *Gilead Sciences, supra*.

[78] Gilead notes that in a concurring judgment, Justice Dawson concluded *Gilead Sciences, supra* was wrongly decided. It submits that this Court should adopt the reasoning of Justice Dawson, as it reflects the policy intention of the Regulations.

[79] Gilead argues that in light of the Federal Court of Appeal's judgment in *Eli Lilly, supra*, this Court should conclude that the '619 Patent is eligible for listing on the Patent Register.

[80] In the alternative, Gilead submits the Federal Court of Appeal was "manifestly wrong" in its interpretation of paragraph 4(2)(a) in *Gilead Sciences, supra* and *ViiV, supra*, in failing to give proper consideration to the aim of promoting innovation. Those two decisions create a disincentive to create FDCs when single medicinal ingredient drugs are better protected.

[81] Finally, Gilead argues that the *Patented Medicines (Notice of Compliance) Guidance Document* and the 2015 RIAS confirm the error of the Federal Court of Appeal in *Gilead Sciences, supra*. The 2015 RIAS specifically says that the decisions in *Gilead Sciences, supra* and *ViiV, supra* conflict with the intention of the Governor in Council in making the Regulations. Furthermore, the 2015 RIAS states that the 2015 Amendments clarify the existing listing eligibility requirements.

VI. DISCUSSION

A. *Is this motion governed by the Amended Regulations?*

[82] This motion principally involves a question of statutory interpretation.

[83] The statutory provision in question is section 5 of the 2015 Amendments, that is the transitional provision. On the one hand, Apotex argues, as outlined above, that this provision means that its Notice of Motion, challenging the inclusion of the '619 Patent on the Patent Register, is governed by the Regulations as they stood on the date the motion was filed.

[84] On the other hand, Gilead submits that the motion is subject to the Amended Regulations that came into force on June 19, 2015.

[85] The transitional provision in issue is section 5 of the 2015 Amendments and reads as follows:

5. The court shall consider any ongoing application made under subsection 6(1) or any ongoing motion made under paragraph 6(5)(a) of the Patented Medicines (Notice of Compliance) Regulations that are initiated during the period that begins on May 2, 2015 and ends on the day on which this section comes into force, having regard to sections 2 and 4 of the Patented Medicines (Notice of Compliance) Regulations, as amended on the coming into force of this section.	5. Le tribunal traite toute demande en cours faite aux termes du paragraphe 6(1) du Règlement sur les médicaments brevetés (avis de conformité) au cours de la période commençant le 2 mai 2015 et se terminant à la date de l'entrée en vigueur du présent article, ainsi que toute requête en cours faite aux termes de l'alinéa 6(5)a) du même règlement au cours de cette période, en tenant compte des articles 2 et 4 du même règlement tels qu'ils sont modifiés à la date d'entrée en vigueur du présent article.

[86] According to the decision in *Rizzo & Rizzo Shoes Ltd. (Re)*, [1998] 1 S.C.R. 27, the modern approach to statutory interpretation, including the interpretation of subordinate legislation such as regulations, is to discern Parliament's intent by reading the words of the

provisions at issue according to a textual, contextual and purposive analysis to find a meaning that is harmonious with the Act as a whole.

[87] In *AstraZeneca Canada Inc.*, *supra*, Justice Binnie writing for the Supreme Court of Canada said the following at paragraph 26:

> It is now trite law that the words of an Act and regulations are to be read in their entire context and in their grammatical and ordinary sense harmoniously with the scheme of the Act, the object of the Act and the intention of Parliament. Further, the scope of a regulation such as the provisions of the *NOC Regulations* is constrained by its enabling legislation, in this case s. 55.2(4) of *Patent Act* (*Biolsye*, at para. 38).

[88] In my opinion, considering the first factor, that is the textual analysis, I find that this element requires consideration of the words used, in their plain and ordinary meaning.

[89] Further, I find that the "plain and ordinary meaning" of the words "any ongoing motion made under paragraph 6(5)(a) of the [Regulations] that are initiated during the period that begins on May 2, 2015 and ends on the day on which this section comes into force" is that the Unamended Regulations apply in respect of any motion that was filed before May 2, 2015.

[90] The filing date of the motion is apparent from the record.

[91] The context of the transitional provision, found in the 2015 Amendments, is the amendment of the Regulations. The Regulations provide a balance to the early working exception by providing effective patent protection.

[92] In determining the purpose of the 2015 Amendments, it is useful to consider the 2015 RIAS; see *Merck Frosst*, *supra* at para. 45.

[93] The 2015 RIAS states that the purpose of the 2015 Amendments is to restore the policy intent behind the Regulations, in the wake of *Gilead Sciences*, *supra* and *ViiV*, *supra*.

[94] In my opinion, the 2015 Amendments do more than simply clarify paragraph 4(2)(a) of Unamended Regulations. They introduce a new scheme, and the issue in this motion is whether the new regime, as manifested in the 2015 Amendments, apply to the motion brought by Apotex.

[95] Considering the three elements identified in *Rizzo*, *supra*, I am satisfied that the correct interpretation of the transitional provision is that the motion of Apotex, challenging the inclusion of the '619 patent on the Patent Register, is governed by the Unamended Regulations, and not by the Amended Regulations that came into force on June 19, 2015.

[96] In my opinion, this is the correct interpretation of the transitional provision, whether the words are considered in the English or French language. Section 13 of the *Official Languages Act*, R.S.C. 1985, c. 31 (4th Supp.) reads as follows:

13. Any journal, record, Act of Parliament, instrument, document, rule, order, regulation, treaty, convention, agreement, notice, advertisement or other matter referred to in this Part that is made, enacted, printed, published or tabled in both official languages shall be	13. Tous les textes qui sont établis, imprimés, publiés ou déposés sous le régime de la présente partie dans les deux langues officielles le sont simultanément, les deux versions ayant également force de loi ou même valeur.

> made, enacted, printed, published or tabled simultaneously in both languages, and both language versions are equally authoritative.

[97] This provision requires a court to consider both the French and English versions when interpreting legislation.

[98] In *R v. Daoust*, *supra* at paragraph 28, the Supreme Court of Canada said the following about the interpretation of bilingual legislation:

> … If there is an ambiguity in one version but not the other, the two versions must be reconciled, that is, we must look for the meaning that is common to both versions. Côté, *supra*, at p. 327. The common meaning is the version that is plain and not ambiguous: Côté, *supra*, at p. 327; see *Goodyear Tire and Rubber Co. of Canada v. T. Eaton Co.*, [1956] S.C.R. 610, at p. 614; *Kwiatkowsky v. Minister of Employment and Immigration*, [1982] 2 S.C.R. 856, at p. 863.

[99] There is no ambiguity here but the submissions of Gilead require a search for the common meaning between the two versions of the provision.

[100] The English version of the transitional provision clearly provides that the Amended Regulations governs ongoing motions made after May 2, 2015.

[101] The word "faite" translates to the verb "make"; see Marianne Durand *et al.*, 8th ed., *Le Robert & Collins Dictionnaire*, (Glasgow: HarperCollins, 2006). The term "en cours" means "in

progress"; see *Le Robert & Collins, supra*. The phrase "requête en cours faite aux termes de l'alinéa 6(5)a)" can be interpreted as "claim in progress made pursuant to paragraph 6(5)(a)".

[102] The French version then refers to the time period of "la période commençant le 2 mai 2015 et se terminant à la date de l'entrée en vigueur du présent article". In my opinion, the French language version shares a common meaning with the English version.

[103] Although this motion was pending on June 19, 2015, it was filed on March 6, 2015. It was not "initiated" after May 2, 2015. Accordingly, in my opinion the motion is not subject to the Amended Regulations.

[104] Legislation should not be construed as having retrospective or retroactive effect unless it is expressly or by necessary implication required by the language of the legislation; see *Sullivan on Construction of Statutes, supra* at para. 25.51. Even where legislation is intended to have retroactive effect it should be construed narrowly; see *Sullivan on Construction of Statutes, supra* at para. 25.51.

[105] Declaratory or clarifying legislation, which corrects defects in earlier legislation, does not meet the threshold of retrospective, retroactive or interferes with vested rights, *Merck Frosst, supra* at para. 50.

[106] The 2015 Regulations are retrospective as they attach new consequences in respect of a past event; see *Epiciers Unis Metro-Richelieu Inc., division "Econogros" v. Collin*, [2004] 3

S.C.R. 257 at para. 46. It follows that the transitional provision operates as an exemption from the general presumption that legislation does not operate retroactively or retrospectively. However, the transitional provision limits the retrospective effect to motions initiated after May 2, 2015 but which have not yet been decided.

[107] Gilead offers a very broad interpretation of the transitional provision which maximizes the retrospective effect. This is not consistent with common principles of statutory interpretation.

[108] There is no express language in the transitional provision, as found in the 2015 Amendments, to rebut the presumption against retrospective application as it relates to motions brought pursuant to paragraph 6(5)(a) of the Regulations before May 2, 2015. In my opinion, the Regulations as they existed on March 6, 2015 govern this motion.

B. *Is the '619 Patent Eligible for inclusion on the Patent Register with respect of TRUVADA®?*

[109] In light of my conclusion on the first issue, that is the interpretation of the transitional provision, the next issue requires consideration of the relevant jurisprudence. What is the authoritative jurisprudence: is it *Gilead Sciences*, *supra* or *Eli Lilly*, *supra*?

[110] According to Apotex, the decisions of the Federal Court of Appeal in *Gilead Sciences*, *supra* and *Viiv*, *supra* apply to its motion. Following these decisions, the '619 Patent is not eligible to be listed on the Patent Register.

[111] Gilead, on the other hand, submits that the recent decision of the Federal Court of Appeal *Eli Lilly*, *supra* has reversed the jurisprudence relied on by Apotex.

[112] Having considered the submissions of the parties, I do not agree with Gilead that *Eli Lilly*, *supra* has reversed the prior decisions of *Gilead Sciences*, *supra* and *Viiv*, *supra*. I agree with Apotex that the three decisions can be read consistently, and that in *Eli Lilly*, *supra*, the Federal Court of Appeal made a distinction on the facts.

[113] On a motion pursuant to paragraph 6(5)(a) of the Regulations, the moving party carries the burden to establish on a balance of probabilities that the patent is not eligible for listing on the Patent Register; see *Nycomed Gmbh v. Canada (Health)* (2008), 64 C.P.R. (4th) 388.

[114] In the present motion, there is no factual dispute between the parties that the '619 Patent does not claim both active ingredients in the approved drug TRUVADA®, 300 mg of tenofovir disoproxial fumarate and 200 mg of emtricitabine. The parties agree that the '619 Patent claims only tenofovir disoproxil and its salts. Disposition of this motion does not require construction of the '619 Patent.

[115] I have already determined that the interpretation of the transitional provision, that is section 5 of the 2015 Amendments, means that the motion to strike the '619 Patent from the Patent Register is subject to paragraph 4(2)(a) of the Unamended Regulations. The interpretation of that paragraph was addressed by the Court of Appeal in *ViiV*, *supra* at paragraphs 15-16:

> In *Gilead*, this Court found that paragraph 4(2)(*a*) of the Regulations sets an exacting threshold of specificity between what is claimed in the patent and what has been approved in the NOC—a patent that does not explicitly claim all of the medicinal ingredients contained in the drug for which the NOC was issued cannot be listed against that drug.
>
> In *Gilead*, the Court considered the policy arguments put forward by the appellants and the Minister in this matter with respect to the interpretation of paragraph 4(2)(*a*) and did not accept them. …

[116] As stated recently by the Federal Court of Appeal in *Allergan Inc. et al. v. Canada (Minister of Health) et al.* (2012), 440 N.R. 269 at para. 43, "Stare decisis requires judges to follow binding legal precedents from higher courts."

[117] There is no basis, in my opinion, to depart from the Court of Appeal's interpretation of paragraph 4(2)(a) of the Unamended Regulations that, in order to be eligible, the patent must claim all medicinal ingredients contained in the NOC approved drug. Since the '619 Patent does not claim emtricitabine, which is a medicinal ingredient in TRUVADA®, it is not eligible to be listed on the Patent Register.

[118] I acknowledge that Justice Dawson, in concurring reasons, determined that *Gilead Sciences, supra* was wrongly decided. However, the basis of her conclusion was that paragraph 4(2)(a) had been interpreted too narrowly in the factual circumstances of that case.

[119] In the result, I conclude that the '619 Patent is ineligible to be listed on the Patent Register pursuant to paragraph 4(2)(a) of the Regulations**.** This is the basis upon which the motion was granted.

[120] Apotex seeks costs on an elevated basis. By Judgment issued on February 18, 2016 Apotex was awarded costs and the parties are at liberty to resolve costs; if unable to agree, they are invited to make brief submissions on costs within two weeks from the date of that judgment.

[121] These Reasons are issued as confidential in light of the Protective Order and Confidentiality Order in place in this file.

[122] The parties shall advise the Court within fourteen days as to what redactions, if any, are required before Public Reasons are released.

"E. Heneghan"

Judge

FEDERAL COURT

SOLICITORS OF RECORD

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