Federal Court  Cour fédérale

Date: 20140918

Dockets: T-1517-13
T-333-14
T-335-14

Citation: 2014 FC 893

Docket: T-1517-13

BETWEEN:

VIIV HEALTHCARE ULC,
VIIV HEALTHCARE UK LIMITED AND
GLAXO GROUP LIMITED

Applicants

and

TEVA CANADA LIMITED AND
THE MINISTER OF HEALTH

Respondents

Docket: T-333-14

AND BETWEEN:

VIIV HEALTHCARE ULC,
VIIV HEALTHCARE UK LIMITED AND
GLAXO GROUP LIMITED

Applicants

and

**APOTEX INC. AND
THE MINISTER OF HEALTH**

Respondents

Docket: T-335-14

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Applicants

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**APOTEX INC. AND
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JUDGMENT AND REASONS

HUGHES J.

[1] The issue is arcane. Can a patent claiming but one medicinal ingredient be listed by the Minister of Health under the provisions of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, as amended SOR/2006-242, where the underlying Notice of Compliance is directed to a fixed-dose combination of two or more medicines?

[2] This is an appeal from two decisions for three proceedings of Prothonotary Milczynski, in which she determined that such a patent could not be listed. I have determined that those decisions were correct for the Reasons that follow.

[3] Also before me was another claim of the same patent directed to a formulation containing one named medicinal ingredient, and another medicinal ingredient to be selected from a group of medicinal ingredients. Counsel for the Appellant did not pursue that claim in oral argument. I have determined, based on the written material which the Appellant did not withdraw, that this claim also does not support a listing.

I. THE THREE PROCEEDINGS

[4] There are three proceedings under consideration. The Applicants ViiV, et al, are common Applicants in all three. Under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, as amended SOR/2006-242 ["*NOC Regulations*"], ViiV, et al, are referred to as the "first person" (s 2, 4(1)).

[5] The Minister of Health (the "Minister"), who is charged with administering the provisions of the *NOC Regulations*, including maintaining the Patent Register, is a common Respondent in all three proceedings.

[6] In the first proceeding, T-1517-13 (the "Teva Proceedings"), Teva Canada Limited, a "second person" under the *NOC Regulations*, is a Respondent (s 2, 5(1)-(2)). In the other two proceedings, T-333-14 and T-335-14, Apotex Inc., also a "second person', is a Respondent.

[7] The Teva proceedings T-1517-13 were the first in time to be filed. Teva brought a motion under subsection 6(5) of the *NOC Regulations* for an Order that Canadian Patent No. 2,289,753 (the '753 patent) be struck from the Patent Register kept by the Minister under those *NOC Regulations*. Prothonotary Milczynski heard that motion and, for Reasons cited as 2014 FC 328, gave an Order on April 3, 2014 that the '753 patent was not eligible for inclusion on the Patent Register (the "Teva Order").

[8] It should be noted that the Teva Order did not terminate the Teva proceedings, since ViiV has also asserted another patent in those proceedings. Canadian Patent No. 2,216,634 (the '634 patent) which was not challenged by Teva on a subsection 6(5) motion.

[9] In two later proceedings against Apotex (T-333-14 and T-335-14) ViiV asserted only one patent; the '753 patent. Apotex brought a subsection 6(5) motion on the same basis as Teva; namely, that the '753 patent was ineligible for inclusion on the Patent Register. It was agreed by ViiV and Apotex that the evidence on the Teva motion would be evidence in the Apotex motion. Prothonotary Milczynski gave the same Order that she did on the Teva motion; namely, that the '753 patent was ineligible for listing (the "Apotex Order"). That Apotex Order would have terminated the two Apotex proceedings since there was only one patent involved; therefore, her Apotex Order also provided for a stay permitting this appeal.

[10] The parties agreed that the evidence presented on the Teva motion is common to all three appeals. Teva's motion and the Apotex motion in T-333-14 are closely related, as the "reference" drug of ViiV in each case is a Fixed-Dose Dual Combination drug, called

KIVEXA, which contains two medicinal ingredients. In the second Apotex proceedings, T-335-14, the ViiV reference drug contains three medicinal ingredients, and is called TRIZIVIR. I will discuss these two drugs in respect of the Notice of Compliance ("NOC") listings.

II. NOC LISTINGS

[11] Pursuant to the regulatory scheme under the *Food and Drugs Act*, RSC 1985, c F-27 and the *Food and Drug Regulations*, CRC 1978, c 870: in order that a drug may legitimately be distributed for sale in Canada, the Minister must approve it for that purpose (see *Bristol-Myers Squibb Co v Canada (Attorney General)*, 2005 SCC 26 at paras 13-17, [2005] 1 SCR 533 ["*Bristol-Myers*"] and *GD Searle & Co and Pfizer Canada Inc*, 2009 FCA 35 at paras 2-4, 71 CPR (4th) 389 ["*GD Searle*"] for a description of this regulatory scheme). In brief, the Minister must be satisfied that the drug is safe and effective for the stated use. This usually involves lengthy and expensive trials. Once approved, the Minister provides the party seeking to distribute that drug with an NOC and a Drug Identification Number (DIN) in respect off the particular drug.

[12] ViiV has two such drugs. One is KIVEXA, which is a Fixed-Dose Combination ("FDC") (sometimes referred to in the evidence as Fixed-Dosed Combination) tablet containing as the active ingredients, 600 mg of abacavir sulphate and 300 mg of lamivudine. To use acronyms, KIVEXA is an FDC containing A and L.

[13] The second such drug for which ViiV has received approval is TRIZIVIR, which is a FDC tablet containing 300 mg of abacavir sulphate, 150 mg lamivudine, and 300 mg zidovudine. Again, to use acronyms, TRIZIVIR is an FDC containing A, L and Z.

[14] Pursuant to the *NOC Regulations*, the Minister listed the '753 patent on the Patent Register in respect of each of KIVEXA and TRIZIVIR.

[15] Teva, known as a second person under the *NOC Regulations* - often called a "generic" - wishes to market in Canada a generic copy of KIVEXA.

[16] Apotex, a second person or generic, wishes to market generic copies of each of KIVEXA (proceeding T-333-14) and TRIZIVIR (proceeding T-335-14).

[17] As is required by the *NOC Regulations*, each of Teva and Apotex served on ViiV Notices of Allegations, which prompted ViiV to institute the three proceedings now before the Court.

III. THE '753 PATENT

[18] Canadian Patent No. 2,289,753 (the '753 patent) was issued and granted to Glaxo Group Limited, one of the ViiV Applicants, on January 23, 2007. The application for that patent has an effective filing date of May 14, 1998, which means that the term of that patent will expire twenty years from that date; namely, May 14, 2018.

[19] The description of the '753 patent begins at page 1. I repeat the first paragraph without the complex chemical terms:

> *The present invention relates to a novel salt of [abacavir] or a solvate thereof, pharmaceutical formulations containing such a compound and their use in medicine, specifically in the treatment of human immunodeficiency virus (HIV) and hepatitis B viris (HPV) infection.*

[20] In the second paragraph, it is acknowledged that [abacavir] has already been described in a European Patent Specification. In the third paragraph, it is acknowledged that [abacavir] is currently under clinical investigation as an anti-HIV agent.

[21] At page 2 of the '753 patent, it states that the invention lies in the discovery of advantages of the hemisulfate salt of abacavir over the previously known hydrochloride salt.

[22] Two claims of the '753 patent are at issue here - claim 2 and claim 32 – although ViiV's Counsel expressly refrained from addressing claim 32 in oral argument. Claim 2 is a claim simply to abacavir hemisulfate. Claim 32 claims a pharmaceutical formulation of abacavir hemisulfate and another medicinal ingredient selected from a defined group. There is no claim directed to the specific combination of abacavir and lamivudine, although the description of the '753 patent at page 4 says that lamivudine is a member of one of the groups defined in claim 32.

[23] There is no claim in the '753 patent specifically directed to a three-medicinal ingredient combination such as found in TRIZIVIR.

[24] ViiV, in its Written Submissions at paragraph 33, said that it accepted the factual findings of Prothonotary Milczynski. At paragraphs 15 to 17 of her Reasons, she states that there was no dispute between the parties as to the proper construction of the '753 patent. I set out, and agree with, what she wrote:

> *15 There is no dispute between the parties regarding the proper construction of the 753 Patent. The 753 Patent relates to the hemisulfate salt of abacavir. Claim 1 is a claim to abacavir hemisulfate and solvates thereof. Claim 2 depends on Claim 1, and expressly and exclusively claims abacavir hemisulfate, one of the medicinal ingredients in KIVEXA(R). There is no claim of the 753 Patent that specifically claims the combination of abacavir and lamivudine, the two medicinal ingredients in KIVEXA(R). Claim 32 of the 753 Patent, however, claims abacavir in combination with another or other medicinal ingredient(s), as follows:*
>
> > *32. A pharmaceutical formulation as claimed in any one of claims 25 to 31, additionally comprising one or more therapeutic agents selected from the group consisting of [1] nucleoside reverse transcriptase inhibitors, [2] non-nucleoside reverse transcriptase inhibitors, [3] protease inhibitors, [4] immune modulators and [5] interferons.*
>
> *16 The 753 Patent elaborates at page four, that abacavir may be used alone or in combination with a number of these therapeutic agents suitable in the treatment of HIV and HBV infections:*
>
> > *The compounds of the invention may be administered alone or in combination with other therapeutic agents suitable in the treatment of HIV infections, such as Nucleoside Reverse Transcriptase Inhibitors (NRTIs) for example zidovudine, zalcitabine, lamivudine, didanosine, stavudine, 5-chloro-2',3'-dideoxy-3'-fluorouridine, adefovir and (2R,5S)-5fluoro-1-[2-(hydroxymethyl)-1,3-oxathiolan-5yl]cytosine, lovaride, non-NRTIs for example nevirapine, delavuridine, [alpha]-APA, HBY-1293 and efavirenz HIV protease inhibitors for example saquinavir, indinavir, nelfinavir, ritonavir and VX-478, other anti-HIV agents for example soluble CD4, immune modulators for example interleukin II, erthyropoetin, tucaresol, and interferons for example [alpha]-interferon. In addition the compound of the invention may be administered in combination with other therapeutic agents suitable in the treatment of HBV*

> *infections for example lamivudine, (2R,5S)-5-fluoro-1-[2-(hydroxymethyl)-1,3-oxathiolan-5yl]cytosine, immune modulators, and interferons as described above. Such combinations may be administered together or sequentially providing that any duration between the administration of each therapeutic agent does not diminish their additive effect.*
>
> *17 Claim 32 thus claims a fixed dose combination of abacavir hemisulfate and one or more of the therapeutic agents selected from the above-noted five defined classes, one of which is the class of nucleoside reverse transcriptase inhibitors, or NRTIs. There are nine specific NRTIs identified, one of which is lamivudine and some twenty-one therapeutic agents in all identified across the five classes (NRTIs, non-NRTIs, protease inhibitors, immune modulators and interferons) that may be selected in combination with abacavir. In other words, claim 32 of the 753 Patent is not limited to a two drug combination with a pharmaceutical formulation comprising abacavir hemisulfate and lamivudine. Claim 32 only includes or encompasses within its scope, a formulation that contains abacavir and another (unspecified) NRTI. Claim 32 contemplates any one or more classes of therapeutic agents that may be combined with abacavir, only one of which is lamivudine.*

IV. THE PROTHONOTARY'S DETERMINATION

[25] Prothonotary Milczynski determined that the '753 patent was not eligible for listing as against KIVEXA. She concluded, at paragraph 31 of her Reasons:

> *31 The 753 Patent is not eligible to be listed on the Patent Register against KIVEXA(R) as it does not claim the medicinal ingredient as required by section 4(2)(a) of the PMNOC Regulations or the formulation of abacavir sulfate and lamivudine as required by section 4(2)(b) of the Regulations, as approved through the issuance of the NOC in respect of the drug submission for abacavir sulfate (600 mg) and lamivudine (300 mg) KIVEXA(R) tablets.*

[26] In the Apotex proceedings T-335-14, her Order was directed to ViiV's TRIVIZIR listing, in respect of which it can be reasonably concluded, her reasoning respecting KIVEXA would equally apply.

[27] The Prothonotary, in her Reasons of the Teva Order, set out the positions of the parties and reviewed, in particular, the decision of the Federal Court of Appeal in *Gilead Sciences Canada v The Minister of Health*, 2012 FCA 254 [*"Gilead"*]. The basis for her decision is set out at paragraphs 28 to 30 of her Reasons:

> *28 Similarly, in the case of KIVEXA(R), no claim of the 753 Patent specifically claims the combination of the two medicinal ingredients that are the subject of the NOC for KIVEXA(R), namely abacavir sulfate and lamivudine. There is nothing in the 753 Patent that requires lamivudine. The 753 Patent claims only abacavir in combination with another unnamed medicinal ingredient. Section 4(2)(a) of the PMNOC Regulations, as held in Gilead, requires all of the medicinal ingredients identified in the submission that results in the issuance of the NOC to be claimed in the patent for that patent to be listed on the Patent Register. In the same manner, the specific formulation identified in the submission that led to the issuance of the NOC must be claimed in the patent. In the case of the 753 Patent, it is not enough that it encompasses the medicinal ingredient lamivudine (among others) in combination with abacavir for the purposes of section 4(2)(b) of the Regulations.*
>
> *29 The requisite degree of product specificity is the same for section 4(2)(a) of the PMNOC Regulations as it is for each of sections 4(2)(b), (c) and (d). The medicinal ingredient, formulation, dosage form or use of the medicinal ingredient claimed in the patent sought to be listed must match that in the drug submission that was approved through the issuance of the NOC. Different listing requirements in the case of section 4(2)(a) would not be consistent with the purpose and object of the PMNOC Regulations to require product specificity, and also contrary to the Federal Court of Appeal's reasons for judgment in Gilead (see also: Purdue Pharma v. The Minister of Health, 2011 FCA 132, and in the case of subsection 4(2)(b), Bayer Inc. v. The Minister of Health, 2010 FCA 161 and Eli Lilly Canada Inc. v.*

A.G. of Canada and Minister of Health, 2014 FC 152). The Court in Gilead states at para.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.*

30 *Applied to the 753 Patent, it is clear that it does not contain:*

> *(i) a claim for the medicinal ingredient, which medicinal ingredient has been approved through the issuance of a notice of compliance in respect of the submission;*
>
> *(ii) 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;*
>
> *(iii) 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*
>
> *(iv) 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.*

V. ISSUES

[28] The overall issue before me is whether the Prothonotary erred in finding that the '753 patent was not eligible for listing under the *NOC Regulations* in respect of ViiV's KIVEXA or TRIZIVIR products.

[29] The question dealt with by the Prothonotary is, as stated by ViiV in setting out the issues at paragraph 30 of its Written Representations, whether subsections 4(2)(a) and/or 4(2)(b) of the *NOC Regulations* allow a person to list on the Patent Register kept under the *NOC Regulations* in respect of a FDC product, a patent containing:

a) a claim to a compound (A) that corresponds to one of two medicinal ingredients of an FDC (A + B); in particular, claim 2 of the '753 patent; and/or

b) a claim to a formulation of an FDC that specifically names one of two medicinal ingredients and incorporates the second by reference to a class of therapeutic agents, wherein the second medicinal ingredient is a member of the class referenced, and is specifically identified in the description of the patent; in particular, claim 32 of the '753 patent. This can be described as a claim to A, plus a medicinal ingredient selected from Group B, Group C, Group D or Group E.

[30] ViiV's Counsel's oral representations were directed only to subsection 4(2)(a) of the *NOC Regulations* and only claim 2 as set out in (a) above.

VI. STANDARD OF REVIEW

[31] This is an appeal; not a judicial review. As to matters of law, the Court must address them on the basis of correctness. As to findings of fact, they are to be dealt with on the basis of palpable and overriding error (*Housen v Nikolaisen*, 2002 SCC 33 at paras 8, 10, 22-23, [2002] 2 SCR 235).

VII. A BRIEF HISTORY OF DRUG PATENTS IN CANADA

[32] For quite some time, Canada simply did not permit patents that claimed a food or medicine. Many other countries did the same.

[33] Matters evolved; Canada permitted patents directed to a medicine, provided that the medicine was claimed as produced by a particular process (*Parke, Davis & Co v Fine Chemicals of Canada Ltd*, [1959] SCR 219 at paras 11, 15, 17 DLR (2d) 153). Thus, if a person made the same medicine by a different process, there would be no infringement.

[34] Subsequently, Canada permitted patents to claim medicines alone, however produced. However, any person wishing to make or sell such a medicine in Canada could apply to the Commissioner of Patents and, almost always, receive a "compulsory licence" under the patent upon payment of a royalty; usually 15% for the bulk product, and 4% to 5% for a finished product (*Bristol-Myers Squibb Co v Canada (Attorney General)*, 2005 SCC 26 at para 8, [2005] 1 SCR 533 ["*Bristol-Myers*"]).

[35] Canada was put under pressure by its trading partners to abandon the compulsory licence scheme, and did so in 1993 (*Bristol-Myers*, at para 10). In its stead came the *NOC Regulations*, imperfectly modelled after the United States *Hatch Waxman Act*, colloquially called the "Orange Book" proceedings because of the colour of the cover of the booklet containing the United States Act and Regulations (*Pfizer Canada Inc v Canada (Minister of Health)*, 2009 FC 1165 at para 40, 78 CPR (4th) 428.

[36] There is no dispute that the Canadian *NOC Regulations* are not perfect. Several amendments have been made over the years. The interested parties, the so-called "brand" and "generic" drug companies, compete vigorously in the political sphere to secure or prevent changes being made to the legislation. It is not for the Court to decide whether particular facets of the legislation, or changes made, provide a perfect "balance" between the interests of the parties.

[37] As the late Justice Layden-Stevenson wrote in *Purdue Pharma v Canada (Attorney General)*, 2011 FCA 132, 93 CPR (4th) 186 ["*Purdue*"], in respect of listing a patent under the *NOC Regulations* at paragraph 45:

> *45 I do not disagree with Purdue that the purpose of the Regulations is to prevent patent infringement by a person making use of a patented invention in reliance on the early working exception. However, there is no obligation to provide the advantages of the Regulations in every case. The fact that the Governor in Council establishes eligibility criteria for the listing of patents does not detract from the legitimate purpose.*

VIII. SCHEME OF THE NOC REGULATIONS – LISTING A PATENT

[38] The *NOC Regulations* provide a scheme whereby a "first person", usually called a "brand" or "innovator" who has secured from the Minister permission to market a drug in Canada - the mechanism being the issuance of the Minister to that person of a NOC - may "list" on a Register kept by the Minister under those *NOC Regulations*, a patent or patents that they own or are licensed (s 4(1)). Those patents are placed on a Patent Register (a computer database) kept by the Minister (s 3(2)).

[39] A "second person", usually called a "generic" who wishes to market a similar drug in Canada, and who does not wish to submit all the clinical and other data required to obtain a NOC, may apply under an "abbreviated" process whereby it would submit a limited amount of data and "reference" the data already provided by the first person (s 5(1)). Considerable time, money, and effort would be saved.

[40] However, the second person must come to grips with the patents listed by the first person by serving on the first person a Notice of Allegation setting out the legal and factual basis for alleging, usually, that the patents will not be infringed and/or are invalid (s 5(1)).

[41] The first person may do nothing and, after forty-five days have passed, the second person usually receives a Notice of Compliance from the Minister opening the door for it to market its generic product Canada (s 7(1)(d)). However, if the first person chooses, it may institute proceedings to prohibit the Minister from issuing an NOC to the second person (s 6(1)). Those

proceedings must be completed within two years (s 7(1)(e)). The usual issues are whether the allegations as to non-infringement or invalidity are justified. If they are not justified, the Minister is prohibited from issuing an NOC to the second person until all relevant patents expire (s 7(1)(f)). Until the matter is decided, the first person has, in effect, an injunction preventing the second person – the generic – from entering the marketplace with its generic copy.

[42] Thus, critical to the process is the listing of a patent. There are certain somewhat complex timing requirements, which are not at issue here. The subject-matter requirements are at issue here.

[43] The subject matter listing requirements pertinent to the patent at issue here are set out in subsections 4(2)(a) and 4(2)(b) of the *NOC Regulations*, as amended by SOR/2006-242, effective October 5, 2006. They 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*

compliance in respect of the submission;	*formulation ayant été approuvée par la délivrance d'un avis de conformité à l'égard de la présentation;*

[44] The terms "*claim for the medicinal ingredient*", as found in subsection 4(2)(a) of the *NOC Regulations*; and "*claim for the formulation*", as found in subsection 4(2)(b) of the *NOC Regulations*, are defined in section 2 of those *NOC Regulations*, as follows:

2. "claim for the medicinal ingredient"	*2. « revendication de l'ingrédient médicinal »*
"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)*
"claim for the formulation"	*« revendication de la formulation »*
"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)

[45] The *NOC Regulations* prior to the 2006 amendments respecting listing stated:

4. (2) A patent list submitted in respect of a drug must	*4. (2) La liste de brevets au sujet de la drogue doit contenir les renseignements suivants :*
(a) indicate the dosage form, strength and route of administration of the drug;	*a) la forme posologique, la concentration et la voie d'administration de la drogue;*
(b) set out any Canadian patent that is owned by the person, or in respect of which the person has an exclusive licence or has obtained the consent of the owner of the patent for the inclusion of the patent on the patent list, that contains a claim for the medicine itself or a claim for the use of the medicine and that the person wishes to have included on the register;	*b) tout brevet canadien dont la personne est propriétaire ou à l'égard duquel elle détient une licence exclusive ou a obtenu le consentement du propriétaire pour l'inclure dans la liste, qui comporte une revendication pour le médicament en soi ou une revendication pour l'utilisation du médicament, et qu'elle souhaite voir inscrit au registre;*

[46] Sharlow JA, in *GD Searle & Co v Canada (Minister of Health)*, 2009 FCA 35, 71 CPR (4th) 389, explained the change to the *NOC Regulations* at paragraphs 13 to 15:

> *13 In this case, the interpretive debate relates to section 4 of the NOC Regulations. For the holder of a patent, the gateway to the advantages of the NOC Regulations is to list the patent against an approved drug on the patent register. Section 4 of the NOC Regulations states the conditions that must be met to list a patent on the patent register. Subsection 3(2) of the NOC Regulations gives the Minister the authority to delist any patent that does not meet the requirements of section 4.*
>
> *14 Section 4 was substantially amended by SOR/2006-242, effective October 5, 2006. According to section 6 of SOR/2006-242, the post-October 5, 2006 version of section 4 does not apply to patents on a patent list submitted for listing prior to June 17,*

2006. However, the patent in issue in this case was submitted for listing after June 17, 2006. Therefore, the post-October 5, 2006 version of section 4 governs its eligibility for listing. In these reasons, references to section 4 of the NOC Regulations are references to the post-October 5, 2006 version, unless the context indicates otherwise.

15 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).

The Regulatory Impact Statement that Sharlow JA referred to said, in part:

Patent Listing Requirements

. . .

Consistent with this understanding of the PM(NOC) Regulations is the fact that not every patent pertaining to an approved drug qualifies for enforcement under the scheme. Only those patents which meet the current timing, subject matter and relevance requirements set out in section 4 of the regulations are entitled to be added to Health Canada's patent register and to the concurrent protection of the 24-month stay. Embodied in each of these requirements are certain fundamental principles which must be respected if the PM(NOC) Regulations are to operate in balance with early-working. While the operation of some of these requirements is described in more detail below, a brief discussion of the principles they represent is warranted.

By stipulating that the application filing date of the patent precede the date of the corresponding drug submission, the timing requirement promotes a temporal connection between the invention sought to be protected and the product sought to be approved. This ensures that patents for inventions discovered after the existence of a product do not pre-empt generic competition

Les exigences relatives à l'inscription des brevets

. . .

Il s'ensuit que ce ne sont pas tous les brevets protégeant une drogue approuvée qui peuvent se prévaloir du mécanisme d'application prévu par le règlement de liaison. Seuls les brevets respectant les exigences énoncées à l'article 4 du règlement relatives au délai, à l'objet et à la pertinence, peuvent être inscrits au registre des brevets de Santé Canada et bénéficier de la protection correspondante de la suspension de 24 mois. Ces exigences reposent sur certains principes fondamentaux devant être respectés afin que le règlement de liaison fonctionne de manière équilibrée avec l'exception relative à la fabrication anticipée. Avant de passer à l'explication du fonctionnement de quelques-unes de ces exigences, les principes qui les sous-tendent seront d'abord décrits.

En stipulant que la date de dépôt de la demande de brevet doit précéder celle de la demande d'avis de conformité correspondante, l'exigence relative au délai procure un lien temporel entre l'invention que l'on cherche à protéger et le produit visé par la demande d'approbation. Ceci permet de faire en sorte que les brevets

on that product Similarly, the relevance requirement limits the protection of the PM(NOC) Regulations to that which the innovator has invested time and money to test and have approved for sale. This prevents hypothetical innovation from impeding generic market entry and encourages innovators to bring their latest inventions to market. Finally, in only allowing patents to be listed which contain claims for the medicine or its use, the subject matter requirement makes it clear that innovations without direct therapeutic application, such as processes or intermediates, do not merit the special enforcement protection of the PM(NOC) Regulations.

It is recognized that there may be instances where a patent which does not qualify for the protection of the PM(NOC) Regulations is ultimately infringed by the fact of generic market entry. However, the Government's view is that where the patent fails to meet the listing requirements described above, policy considerations tip the balance in favour of immediate approval of the generic drug, and the matter is better left to the alternative judicial recourse of an infringement action. It follows that the continued viability of the regime greatly depends upon the fair and proper application of these listing requirements.

protégeant des inventions dont la découverte est postérieure à l'existence d'une drogue n'empêchent pas l'arrivée sur le marché de versions génériques de cette même drogue. De la même façon, l'exigence relative à la pertinence vise à faire en sorte que le règlement de liaison protège uniquement ce pourquoi l'innovateur a investi temps et argent afin d'effectuer les études et l'approbation nécessaires en vue de l'entrée sur le marché. Ceci fait en sorte que l'innovation hypothétique n'entrave pas la mise en marché du produit générique et encourage les innovateurs à commercialiser leurs inventions les plus récentes. Enfin, en permettant uniquement l'inscription des brevets contenant des revendications à l'égard du médicament ou de son utilisation, l'exigence relative à l'objet signale clairement que les innovations ne comportant aucune application thérapeutique directe, comme les procédés ou les intermédiaires, ne méritent pas la protection spéciale prévue au règlement de liaison.

Bien entendu, il peut y avoir des cas où un brevet n'étant pas admissible à la protection conférée par le règlement de liaison soit finalement contrefait suite à l'arrivée d'un produit générique sur le marché. Toutefois, le gouvernement estime que dans

It has come to the Government's attention that an increasing number of court decisions interpreting the PM(NOC) Regulations have given rise to the need to clarify the patent listing requirements. These decisions, which turn on timing and relevance issues, are not the product of judicial error but rather of deficiency in the language of the PM(NOC) Regulations themselves. Of particular concern is the failure of the language to fully account for the range of submission types possible under the Food and Drug Regulations, .the various pharmaceutical patent claims available under the Patent Act and, most importantly, the breadth of scenarios which can arise from the linkage between the two established by the PM(NOC) Regulations.

le cas où le brevet ne respecterait pas les exigences susmentionnées, les intérêts de la politique sous jacente font pencher la balance en faveur de l'approbation immédiate du produit générique et qu'il est préférable que la question soit tranchée au moyen d'une action en contrefaçon ordinaire. Il s'ensuit que la viabilité du régime dépend en grande partie de l'application juste et équitable de ces exigences.

Le gouvernement a constaté qu'un nombre accru de décisions judiciaires portant sur l'interprétation du règlement de liaison ont donné lieu à la nécessité d'apporter des précisions quant aux exigences relatives à l'inscription des brevets décrites ci-dessus. Ces décisions, concernant les exigences relatives au délai et à la pertinence, ne sont pas le résultat d'erreurs de la part des tribunaux, mais plutôt d'une lacune dans le libellé du règlement lui-même. Plus précisément, le libellé du règlement de liaison ne tient pas pleinement compte de l'éventail de types de demandes d'avis de conformité possibles en vertu du Règlement sur les aliments et drogues, des différentes revendications relatives aux brevets pharmaceutiques pouvant être formulées en vertu de la Loi sur les brevets et, surtout, de la foule de scénarios pouvant

découler du lien entre les deux lois résultant du règlement de liaison.

IX. THE CURRENT JURISPRUDENCE

[47] There have been a number of decisions of this Court and the Federal Court of Appeal dealing with the propriety of the listing of certain patents under the *NOC Regulations* as amended in 2006. They include:

- *Abbott Laboratories Ltd v Canada (Attorney General)*, 2008 FCA 244, 68 CPR (4th) 445 [*"Abbott"*] dealt with a decision of the Minister to de-list a patent directed to the use of a medicinal ingredient. The Federal Court of Appeal considered the meaning of "claim for the dosage form", as found in subsections 4(3)(b) and 4(2)(c) as well as the "change in the use" requirement under subsections 4(3)(c) and 4(2)(d) of the *NOC Regulations*. That Court held that while the patent included a general claim that may cover the use identified in the listing party's amended NOC, it did not cover the *specific* use found in the amended NOC; thus, it was not properly listed. Pelletier JA, for the Court, at paragraphs 46 to 49, addressed the need for the patent claims to match specifically the dosage form in respect of which the amended NOC was granted:

  > *46 That controversy was resolved by amendments which specified the characteristics of patents which could be listed against specific types of SNDS's. Thus, where a manufacturer submitted an SNDS with respect to a new dosage form, the Regulations now require any patent sought to be filed against that submission to contain "a claim for the changed dosage form...": see paragraph 4(3)(b) of the Regulations. In the present case, the SNDS in*

> *question is with respect to a new indication for an existing drug PREVACID. That drug was originally approved for use in the treatment of "duodenal ulcers, gastric ulcers, and reflux esophagitis". The SNDS relevant to these proceedings claims as a new indication for the drug "Healing of NSAID-associated gastric ulcer and reduction of risk of NSAID-associated gastric ulcer". Paragraph 4(3)(c) of the Regulations requires that any patent sought to be listed on the Patent Register against that submission must contain "a claim for the changed use of the medicinal ingredient".*
>
> *47 It stands to reason that if a patent must contain a claim for the changed use identified in Abbott's SNDS, that patent cannot simply claim the use which formed the basis of the original submission. Such a patent does not specifically claim the changed use, even though the changed use may come within the claims of the patent. In other words, the Regulations envisage as a condition of listing a patent in respect of a change in the use of a medicinal ingredient that the patent specifically claims the changed use as opposed to non-specific claims which are wide enough to include the changed use.*
>
> *48 It is this distinction between specific claims and broad non-specific claims which led to the discussion in the jurisprudence about the nature of the patented invention: see Wyeth Canada, at paragraph 22, affirmed [2007] F.C.J. No. 1062 at paragraph 29. That discussion has now been overtaken by the amendments to the Regulations.*
>
> *49 Even if one were inclined to look to the nature of the invention, the difficulty is that the language of the Regulations speaks only of "a claim for the changed use of the medicinal ingredient". I conclude that paragraph 4(3)(c) of the Regulations requires, as a condition of listing a patent on the Patent Register, that the patent must specifically claim the very change in use which was approved by the issuance of a Notice of Compliance with respect to an SNDS.*

- *GD Searle & Co v Canada (Minister of Health)*, 2009 FCA 35, 71 CPR (4th) 389 [*"Searle"*] dealt with the decision of the Minister to de-list a patent directed to the use of a medicine. The Federal Court of Appeal addressed

subsection 4(2)(d) of the *NOC Regulations*, and a claim to use. Sharlow JA, for the Court, made it clear that a general claim for use (here a claim for treatment of pain) was insufficient to support a listing where the use was specific to treatment of short-term pain. She wrote at paragraphs 44 to 47:

> *44 The problem with the analysis presented by Pfizer and Searle is that a claim for the use of Celebrex "for pain" is so broad as to cover most of the known uses of Celebrex (including its use for the treatment of the pain of arthritis and osteoarthritis in adults, which was a use of Celebrex that was approved by the Minister when the initial NOC for Celebrex was issued). In my view, to accept the interpretation of paragraph 4(3)(c) proposed by Pfizer and Searle would be inconsistent with the decision of this Court Abbott 244. More importantly, it would give paragraph 4(3)(c) a meaning so broad as to defeat the purpose for which it was enacted.*
>
> *45 Bearing in mind the fact that the composition claims in the 201 patent include Celebrex, and considering also the principles established in Abbott 244, I would express the third framework question this way: Does claim 15 of the 201 patent claim the very use that was approved by the issuance of the NOC in response to SNDS 072375 (i.e., the "short term (= 7 days) management of moderate to severe acute pain in adults in conditions such as: musculoskeletal and/or soft-tissue trauma including sprains, post-operative orthopedic, and pain following dental extraction")? As I read Abbott 244, this question must be answered in the negative because the use claimed in claim 15 ("for pain") is simply too general.*
>
> *46 That conclusion is confirmed by considering the purpose of the NOC Regulations, as explained above. A generic drug manufacturer who undertakes the work required to seek approval for a generic version of Celebrex would undoubtedly make use of the patented invention disclosed in the 201 patent and (but for the early working exception) would probably infringe claims 1 to 10. If, prior to the expiry of the 201 patent, the generic drug were to be approved for the same uses as Celebrex, the manufacture and sale of the generic drug would infringe claims 1 to 10. However, that potential infringement cannot be the target*

> *of the NOC Regulations because the deadline relevant to those claims was missed.*
>
> *47 The manufacture and sale of a generic version of Celebrex could also infringe claim 15. Nevertheless, the only part of claim 15 that reflects the patented invention is the part that refers to the new compositions of celecoxib. The "use" element of claim 15 reflects the known medicinal uses of celecoxib. To permit the NOC Regulations to be used to target the potential infringement of claim 15 based on those known uses would extend the scope of the NOC Regulations beyond their intended purpose.*

- *Bayer Inc v Canada (Minister of Health)*, 2009 FC 1171, 79 CPR (4th) 1, aff'd-2010 FCA 161, 86 CPR (4th) 81 [*"Bayer"*], is relied upon heavily by ViiV in the appeal before me. It dealt with a refusal by the Minister to list a patent directed to non-degrading composition of a known drug. The decision of the Federal Court Judge, Russell J, is important because the Federal Court of Appeal, in brief Reasons delivered from the bench by Sharlow JA, dismissed the appeal, stating that they agreed with the Trial Judge's conclusion that the Minister's interpretation of *subsection 4(2)(b)* was correct "*substantially for the reasons he gave.*" It is to be noted that the Court of Appeal made no mention of subsection 4(2)(a).

At issue was the interpretation of subsection 4(2)(b) of the *NOC Regulations*. The drug for which the party listing the patent had obtained its NOC contained two medicinal ingredients, whereas the listed patent contained only one of those medicinal ingredients. Russell J held that the listing was improper. He wrote at paragraphs 67 to 69:

> *67 There is no dispute about the meaning of "medicinal agreement," and "claim for the formulation" is defined in section 2 to mean "a claim for a substance that is a mixture*

> *of medicinal and non-medicinal ingredients in a drug and that is administered to a patient in a particular dosage form."*
>
> *68 The '979 Patent contains claims directed to a pharmaceutical composition containing ethinyl estradiol. But ethinyl estradiol is only one of the medicinal ingredients approved in NDS 119387 for YAZ.*
>
> *69 Hence, in my view, and on a plain and ordinary reading of subsection 4(2)(b), the '979 Patent does not claim the formulation that has been approved. It claims, rather, a formulation that contains one of the medical agreements that has been approved. The formulation that has been approved, that is YAZ, contains two medicinal ingredients. It seems to me that a mixture containing two medicinal ingredients is different from a mixture that contains only one medicinal agreement (sic). Medicinal agreements (sic) are combined to achieve an optimal effect when the drug is delivered to the patient. Generally speaking, then, a drug with one medicinal ingredient will have a different effect from a drug where two medicinal ingredients are combined to achieve the desired effect.*

- *Purdue Pharma Canada v Canada (Attorney General)*, 2011 FCA 132, 93 CPR (4th) 186 [*"Purdue"*], dealt with the refusal of the Minister to list a patent directed to a dosage form of a medicine having regard to subsection 4(2)(c) of the *NOC Regulations*. The Federal Court of Appeal dealt with subsection 4(2)(c) of the *NOC Regulations*; a "claim for the dosage form." The dosage form for which the listing party received its NOC contained two medicinal ingredients, whereas the listed patent claimed only one of those ingredients. Layden-Stevenson JA, for the Court, found the listing to be improper because it did not precisely and specifically match the drug for which NOC approval had been given. She wrote at paragraphs 41 to 44:

> *41 The product specificity requirement of paragraph 4(2)(c) of the Regulations requires a matching between: (1) the claim for the dosage form; and (2) the dosage form that*

> *has been approved through the issuance of a notice of compliance.*
>
> *42 The claim for the dosage form is defined by the construction of the patent, that is, the question one inquiry. This equates to the definition of "claim for the dosage form" in section 2. However, the fact that naloxone may come within the scope of Claim 5 does not end the matter because even if it is within the patent's scope, it nonetheless may not match the dosage form approved by the NOC.*
>
> *43 Claim 5 relates to oxycodone and, at best, does not exclude naloxone from within its scope. That is not the same as the dosage form of the NOC, which explicitly includes both oxycodone and naloxone. Purposive claims construction under question one contemplates a different inquiry than the legislated test under paragraph 4(2)(c), which asks specifically whether the claimed dosage form and the approved dosage form are the very same. Absent precise and specific matching, the patent is not eligible for listing on the patent register under the Regulations. Thus, Purdue's OXYCONTIN drug met the matching requirement; its TARGIN drug did not.*
>
> *44 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.*

- *Gilead Sciences Canada Inc v Canada (Minister of Health)*, 2012 FCA 254, 105 CPR (4th) 1 [*"Gilead"*] dealt with the refusal of the Minister to list a patent directed to a chemically stable combination of two or more medicinal ingredients. It is the leading Federal Court of Appeal case on the proper interpretation of section 4(2). The meaning and applicability of this decision is a core area of dispute in this appeal. The Federal Court of Appeal considered both subsections 4(2)(a) and 4(2)(b) of the *NOC Regulations*. On appeal, the listing party focused on subsection 4(2)(a). The party seeking to list a patent

had received an NOC for a drug containing three specific medicinal ingredients, tenofovir, emtricitabine and rilpivrine. The patent sought to be listed claimed a drug containing tenofovir and emtricitabine, plus a third unnamed medicinal ingredient selected from a certain class of non-nucleoside reverse transcriptase inhibitors (NNRTIs). Rilpivirine is known as an NNRTI but was not mentioned in the patent's claims.

Trudel JA wrote the decision of the Court. At paragraphs 27 to 32, she explained why subsection 4(2)(a) was relevant; not subsection 4(2)(b):

> *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.*

At paragraph 39, she stated that there was no sound reason to adapt different legislative requirements for each of the subsections of section 4(2) of the *NOC Regulations*:

> *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.*

At paragraph 43, she emphasized that the 2006 amendments to the *NOC Regulations* required product specificity:

> *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.*

At paragraphs 44 and 45, she refused to adopt the Minister's *Guidance Document* for the purpose of her interpretation of subsection 4(2)(a):

> *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.*

The Guidance Document referred to by Trudel JA was published by the Minister in 2007 and said, *inter alia*:

> *[A] patent claiming, as a compound, a single medicinal ingredient, will be eligible for listing with respect to a drug which contains the said medicinal ingredient in combination with other medicinal ingredients,*

> *notwithstanding that the medicinal ingredient on the NOC is a combination of medicinal ingredients.*

Trudel JA concluded at paragraph 49 that the patent could not be listed:

> *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).*

- *Novartis Pharmaceuticals Canada Inc v Canada (Attorney General)*, 2012 FC 836, 104 CPR (4th) 107 [*"Novartis"*] dealt with the refusal of the Minister to list a patent formulation of perforated microstructure comprising of a "bioactive agent" to be used with metered dose inhalers and the like. Martineau J found the patent ineligible for listing against tobramycin under subsection 4(2)(b). The patent at issue claimed an inhalation device comprising a bioactive agent, and included in the description:

> *24 [a] list of possible bioactive agents, including antibiotics as well as examples of antibiotics (streptomycin and gentamicin) that belong to the narrower subclass of amino-glycoside antibiotics to which tobramycin also belongs. However, nowhere in the '819 patent is tobramycin itself made explicit as a possible bioactive agent.*

Following Trudel JA's reasons in *Gilead*, Martineau J rejected Applicant's attempt to distinguish its case from *Bayer* and *Purdue* at paragraphs 58 to 60:

> *58 I agree with the applicant that the facts in this case are different with the facts in Bayer, above. Nonetheless, the ratio in Bayer (FC), above, readily applies. Essentially, the applicant is asking the Court to do exactly what the Federal Court of Appeal refused to do in Bayer; that is, to find that the inclusion of antibiotics as a class, without*

> *specifying tobramycin, is sufficient to constitute a claim for the formulation containing the medicinal ingredient. This type of inclusion had been rejected in Bayer, and more strictly in Gilead, with regard to the interpretation of paragraph 4(2)(b) of the Regulations.*
>
> *59 The applicant argues that this case should be distinguished from Bayer and Purdue in that in those cases there were medicinal ingredient(s) in the approved drug that did not fall within the claims of the patent sought to be listed, while the '819 patent contains formulation claims that encompass the one medicinal ingredient of the approved product, tobramycin. However, this is only part of the principles established in Bayer and Purdue. In light of Gilead, it is not sufficient that the approved medicinal ingredient be, as a matter of scientific fact, within a more or less large class of active agents that the patent claims. In that case, Gilead had obtained approval of tablets formulated with three antiviral agents as the drug's medicinal ingredients: tenofovir, emtricitabine and rilpivirine. Although rilpivirine comes within the rather limited class of agents known as NNRTIs that the patent explicitly referenced, no reference to the medicinal ingredient rilpivirine itself was found in the patent. The Court found that in order to be eligible for listing, the relevant claim for the formulation must be identical to the formulation in the NDS, so that the non inclusion of rilpivirine alone in the patent rendered it ineligible.*
>
> *60 Therefore, in light of Gilead, even if the '819 patent at issue gave priority to amino-glycoside antibiotics as being a preferred embodiment and went on to name gentamicin and streptomycin and other examples of amino-glycoside antibiotics, the applicant would not have a greater chance of success.*

- *Eli Lilly Canada Inc v Canada (Attorney General)*, 2014 FC 152, 238 ACWS (3d) 446 [*"Eli Lilly"*], and is currently under appeal, A-146-14. The Court dealt with a patent claiming one medicinal ingredient. Bédard J of the Federal Court held that under subsection 4(2)(b) of the *NOC Regulations* a patent claiming one medicinal ingredient could not be listed in respect of an NOC

granted for two medicinal ingredients. As with *Novartis*, Bédard J followed and applied Trudel JA's holding in *Gilead* to her reasoning. At paragraphs 73, 80 to 85, she wrote:

> *73 The jurisprudence has been consistent that the current version of subsection 4(2) of the Regulations, as amended in 2006, has introduced a product specificity requirement and that there must be a perfect match between what is claimed and what has been authorized. In the case of a claim for a formulation, all of the medicinal ingredients included in the drug product as authorized must be included in the patent claims. Despite counsel for the applicant's very able submissions, I am bound by the judgments rendered by the Federal Court of Appeal and I cannot depart from the interpretation of subsection 4(2) of the Regulations adopted by the Federal Court of Appeal in a series of judgments and more recently in Gilead. Furthermore and with respect, I do not understand Gilead as having enhanced the product specificity requirement as interpreted in the previous judgments of the Federal Court of Appeal. I see it as the application of the recognized principles to the specific set of facts of that case...*
>
> . . .
>
> *80 As indicated earlier, my interpretation of the '329 Patent claims is somewhat broader than that of the Minister. I concluded, in the first tier of the analysis, that the claims are directed not only to a formulation including spinosad alone as the active ingredient, but also to formulations that include other active ingredients such as, but not restricted to, milbemycin oxime. In other words, I concluded that the '329 Patent could extend to a formulation containing both spinosad and milbemycin oxime.*
>
> *81 The question now is whether the fact that the claims can be read as covering a formulation that could, but that does not necessarily, comprise the specific ingredient, milbemycin oxime, is sufficient to meet the strict matching requirement with Trifexis' NOC which clearly comprise this specific ingredient.*
>
> *82 The situation in Gilead was somewhat similar to that in this case. In Gilead, the Federal Court of Appeal found*

that the Federal Court (Mosley J.) did not err in its reasoning under the product specificity requirement (Gilead, at para 47). It is useful to reproduce the following excerpt from the Federal Court's judgment in that regard:

> *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.*
>
> *Gilead Sciences Canada Inc v. Canada (Minister of Health), 2012 FC 2, [2012] F.C.J. No. 495*

83 The applicant distinguishes the facts in Gilead from those in this case. He asserts that the medicinal ingredient that was not specifically mentioned in the patent claims in Gilead (the patent referred to the general class of non-nucleoside transcriptase inhibitors (NNRTIs) to which the specified medicinal ingredient mentioned in the approved drug belongs), but was specified in the NDS, was invented and disclosed only after Gilead's invention and as such, a person of ordinary skill in the art could not have known of its existence at the relevant time. This distinction is a valid one as it is clear in this case that, at the relevant time, milbemycin oxime existed and was part of the family of milbemycins.

84 However, the Federal Court of Appeal endorsed the Federal Court's reasoning pertaining to the product specificity requirement. It is worth noting that Justice Mosley's finding was that it was insufficient for a patent to meet the product specificity requirement by referring to a class of compound rather than to a specific medicinal ingredient. He found that the claim was not specific enough to match the medicinal ingredients in Complera. That

> *conclusion was based on the principle above, not on the fact that the third medicinal ingredient could not have been claimed in the patent because it had not been discovered at the date of the patent's publication.*
>
> *85 I feel bound by this reasoning and, therefore, I conclude that it should equally apply to the case at bar. Referring to the general family of milbemycins in the definition of oral formulation is not specific enough to conclude that the claims match the formulation contained in Trifexis. In my respectful view, this conclusion is not altered by the possibility that the '329 Patent could extend to a formulation containing milbemycin oxime.*

- Lastly, we have the decision of Prothonotary Milczynski, under appeal here.

[48] I draw the following principles respecting the interpretation of the various subsections of 4(2) of the *NOC Regulations* having regard particularly to the Federal Court of Appeal decisions and the Reasons of Justice Russell in *Bayer*, as affirmed by the Federal Court of Appeal:

- There is no sound reason to adopt different legislative requirements of product specificity for the various subparagraphs of subsection 4(2) of the *NOC Regulations* (*Gilead,* paragraph 39);

- absent precise and specific matching between what the patent claims and the product/use/dosage forms for which the NOC has been granted to the first person, the Minister cannot properly list the patent (*Purdue*, paragraphs 43; *Abbott*, paragraph 49; *Gilead*, paragraphs 37-38);

- a claim for a formulation means a claim that includes both medicinal and non-medicinal ingredients. A claim directed to medicinal ingredients, without

claiming also non-medicinal ingredients, does not qualify for listing as a formulation under subsection 4(2)(b) of the *NOC Regulations* (*Gilead*, paragraphs 27 to 32, 49; *Bayer*, paragraphs 67 to 69).

- where a patent claims only one medicinal ingredient, it cannot be listed as against an NOC obtained for two (or more) medicinal ingredients; at least where, to use the words of Russell J, at paragraph 69 of *Bayer*, where "*...a drug with one medicinal ingredient will have a different effect from a drug where two medicinal ingredients are combined* ***"to achieve the desired effect*** *[emphasis added]*." This same distinction appears in *Gilead*, where Trudel JA wrote at paragraphs 31 and 32:

> *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.*

[49] Thus, in *Bayer* and *Gilead* a patent claiming only one medicinal ingredient could not be listed where the relevant NOC was directed to a combination of that one medicinal ingredient and other medicinal ingredients, arguably, to produce *a different effect* than if the drugs were administered separately. I will address this matter later in these Reasons.

X. POLICY REASONS FOR INCLUDING FDC'S LIKE THE '753 PATENT

[50] ViiV argues that the question of whether under subsection 4(2)(a) of the *NOC Regulations* a patent claiming a compound that corresponds to one of the two medicinal ingredients in an FDC would be eligible for listing on the Patent Register is a matter of first impression, i.e., no jurisprudence expressly dealt with this question. Therefore, according to ViiV, the Court is free to construe subsection 4(2)(a) of the *NOC Regulations* in light of policy considerations. Needless to say, ViiV argues that policy considerations favour listing patents claiming a single medicinal ingredient where the drug in question contains that medicinal ingredient, plus at least one more; the so-called fixed-dose combination (FDC).

[51] ViiV's argument respecting policy begins with the basis for the *NOC Regulations.* Section 55.2(1) of the *Patent Act*, provides, as an exception to the monopoly granted by the patent, that others may work the patented invention in limited circumstances related to the development and submission of information required by any law of Canada. ViiV argues that the Court should limit the meaning of this exception, so as not to discourage innovation; which is the purpose of the *Patent Act.* ViiV argues, as does the Minister, that, in the course of drug development, the innovators usually develop one medicinal ingredient first; and later follows on with combinations of that medicinal ingredient with others; such development should not be hindered.

[52] I pause here to remark upon the basis for this statement as to drug development. It comes from the Affidavit of Karen Feltmate, who characterizes herself as an expert in drug regulatory strategy. She says, at paragraph 69 of her Affidavit:

> *Generally, fixed-dose combination drugs are developed by combining medicinal ingredients where one or more are already marketed as separate products, whether by the same or different companies. I have no doubt that companies will continue to develop and commercialize individual medicinal ingredients.*

[53] Such a statement is clearly hearsay, and is not within the scope of her expertise. Drug development and incentivizing such development, is beyond the scope of expertise of one dealing with drug regulatory affairs.

[54] ViiV relies heavily on the decision of the Supreme Court of Canada in *Bristol-Meyers Squibb Co v Canada (Attorney General)*, 2005 SCC 26, [2005] 1 SCR 533 ["*Bristol-Myers*"]. The reasons for the majority of that Court were given by Binnie J. That case dealt with an interpretation of the *NOC Regulations* as they stood prior to the *NOC Regulations* at issue in the case before me. The Federal Court of Appeal ([2003] 4 FC 505, 24 CPR (4th) 417) had held that the wording of the *NOC Regulations* at that time captured the application of an innovator – not a generic – who had come to the market with a similar, but not identical, product to the first innovator. In other words, innovators, and not just generics, were caught by the wording of the *NOC Regulations* as they stood.

[55] Binnie J, for the majority, found that such an interpretation was wrong. He explained the basis for the arguments at paragraphs 3 and 4:

> *3 The drug in dispute contains a cancer-fighting medicine called paclitaxel. Paclitaxel was discovered by the National Cancer Institute in the United States, not the respondents Bristol-Myers Squibb Company and Bristol-Myers Squibb Canada Inc. (collectively "BMS"), but BMS has three subsisting patents related to its formulation and administration. The appellant, Biolyse Pharma Corporation ("Biolyse"), argues that the Patented Medicines (Notice of Compliance) Regulations, SOR/93-133 ("NOC Regulations"), must be taken to refer to patented medicines, and points out that BMS can have no patent on paclitaxel itself. There is an unchallenged finding of fact by the motions judge that approval of the Biolyse product was not based on bioequivalence with the BMS product, but on its own clinical studies and "what was known to scientists in the public realm about paclitaxel" ((2002), 224 F.T.R. 236, 2002 FCT 1205, at para. 40 (emphasis added)).*
>
> *4 Nevertheless, BMS says that a literal application of the words in s. 5(1.1) of the NOC Regulations entitles it to the statutory injunction under s. 7 to keep a Biolyse product containing paclitaxel off the market despite the clear indication that an application of s. 5(1.1) would put the NOC Regulations in conflict with the terms of the regulation-making power under which they were issued. BMS contends that under the NOC Regulations the mere presence of the public domain medicine paclitaxel in the [page544] Biolyse formulation is enough. (Although there are other similarities between the Biolyse product and the BMS product, the only common component relevant to the NOC Regulations is the medicine paclitaxel.) The Federal Court of Appeal accepted this argument but in my opinion, with respect, it erred in doing so ([2003] 4 F.C. 505, 2003 FCA 180). An interpretation of the NOC Regulations that confers on BMS a monopoly merely by demonstrating the presence of a public domain medicine like paclitaxel in its product provides no value to the public in exchange for the monopoly BMS seeks. When the NOC Regulations are considered in their proper context, and in particular in light of the wording of s. 55.2(4) of the Patent Act, R.S.C. 1985, c. P-4, that authorized them, the NOC Regulations do not have the sweeping effect contended for by BMS. I would therefore allow the appeal.*

[56] Binnie J began his analysis by emphasizing that facts are important. He wrote at paragraph 34:

> *34 As always, the facts are important. BMS sought to quash the NOC issued to Biolyse on the basis that its issuance depended on the Minister's [page556] finding that the Biolyse product was "bioequivalent" to the BMS product. It was therefore a "copy-cat" drug which s. 5(1) of the NOC Regulations required the Minister to put into the statutory freeze. The BMS position was rejected both by the Minister and by the motions judge. It is useful to quote the language of the motions judge:*
>
> > *Biolyse did not compare its drug or make reference to another drug for the purpose of demonstrating bioequivalence. Biolyse did not apply for a declaration of equivalence nor was one granted.*
> >
> > *On the evidence, the Biolyse submission contains clinical studies on sick patients; specifically those with advanced breast cancer unresponsive to usual treatments and those with locally advanced non-small-cell lung cancer. The safety and efficacy of the Biolyse product assessment was based on those studies and on what was known to scientists in the public realm about paclitaxel. This is consistent with the usual procedure for a NDS. [Emphasis added; paras. 39-40.]*
>
> *This finding was not challenged by BMS*

[57] The argument of the party caught by the *NOC Regulations,* Bristol-Myers Squibb (BMS), was set out at paragraph 42 of Binnie J's Reasons:

> *42 Biolyse contends that not all "submissions" to the Minister are caught by s. 5(1.1), and on this point it is supported by the intervener Pfizer Canada Inc., itself an innovator drug company. Pfizer argues that s. 5(1.1) does not apply to certain types of submissions (in its case Supplementary New Drug Submissions ("SNDS")) which are outside the policy objective s. 5(1.1) was intended to implement. Biolyse agrees that s. 5(1.1) should be construed by reference to the policy objective, and in particular that it should not apply to an innovator drug NDS (as the motions judge found its [page560] product had correctly been classified by the Minister) but only to submissions for generic "copy-cat" drugs which use a "Canadian reference product" and are applied for under an ANDS.*

[58] Binnie J followed with a substantial analysis, which I will not repeat here, reading the *NOC Regulations* in the broader context of the *Patent Act* and reciting portions of the *Regulatory Impact Analysis Statement* ("*RIAS*"). At paragraphs 52 and 53 of his Reasons, Binnie J pointed out that *"...it is not every use of the patented invention that will trigger the NOC Regulations..."*

> *52 Firstly, the regulations are to be directed to persons who are making use of the "patented invention". As pointed out by this Court in Monsanto Canada Inc. v. Schmeiser, [2004] 1 S.C.R. 902, 2004 SCC 34, the patented invention is not necessarily co-extensive with the patent claims. The distinction was critical in that case to the issue of remedy. While farmer Schmeiser had used the patented product (Roundup Ready Canola seed), he had not taken advantage of the patented invention (its herbicide resistant property) because he had not sprayed his crop with Roundup. The Court thus rejected Monsanto's claim to Schmeiser's profits from his canola crop.*
>
> > *The difficulty with the trial judge's award is that it does not identify any causal connection between the profits the appellants were found to have earned through growing Roundup Ready Canola and the invention. On the facts found, the appellants made no profits as a result of the invention. [Emphasis in original; para. 103.]*
>
> *[page565]*
>
> *The use of the expression "patented invention" in s. 55.2 is therefore an important clue to the scope of the regulations it authorizes to be made. BMS did not invent or discover paclitaxel.*
>
> *53 Secondly, it is not every use of the patented invention that will trigger the NOC Regulations. Section 55.2(4) is specifically directed to preventing infringement by persons who use "the patented invention" for the "early working" exception and the "stockpiling" exception set out earlier in ss. 55.2(1) and 55.2(2). That is all the Governor in Council is authorized to regulate. (The stockpiling exception was repealed by S.C. 2001, c. 10, s. 2(1); assented to June 14, 2001.)*

[59] Binnie J concluded that the interpretation given by the Federal Court of Appeal and argued before him by BMS, would lead to an absurd result and stifle innovation. He wrote at paragraph 66:

> *66 The broad interpretation urged by BMS would lead to an absurd result. The "medicine" in the drug to which the patent list relates need not itself be patented, or indeed owe anything to the ingenuity of the "first" person. It could be a "medicine" whose usefulness was discovered by somebody else (as in the case of paclitaxel) or something in the public domain as common as penicillin. So long as such "medicine" shows up as a component, however minor, in the chemical composition of the drug to which the patent list relates, the "second person" (including an innovator who is seeking to manufacture a new and useful drug) is barred from proceeding to market by the automatic statutory freeze, and this "bar" will continue for so long as the patent list [page569] holder can evergreen its product by resort to patentable improvements to other components or additions, be they ever so minor. This would stifle competition and innovation in the pharmaceutical industry and produce a result at odds with what the regulator was trying to achieve.*

[60] In the case before me, ViiV argues that to exclude patents like the '753 patent from listing under the *NOC Regulations* would deter innovation. ViiV argued that the rebalancing made by the 2006 amendments to the *NOC Regulations* should not be interpreted so as to exclude FDC products.

[61] I reject ViiV's arguments. First, Justice Marshall Rothstein of the Supreme Court of Canada in his Comment entitled "Advocacy in Intellectual Property Litigation in the Supreme Court of Canada" (2014) 26:2 Intellectual Property Journal at 145, wrote at page 146:

> *...we're not an error-correcting court, but a jurisprudential court.*

[62] Thus, at the highest level, the Supreme Court of Canada may, as it did in *Bristol-Myers*, engage in a jurisprudential exercise, including consideration, if needed, of policy. However, at this Lower Court level, it is for a Court such as this one to follow the jurisprudence where it has been established; even if established in *obiter* by a Higher Court. Trial Courts should be loathe to embark on "policy" interpretations of legislation without a clear and substantial reason to do so.

[63] Second, I reject ViiV's arguments because the 2006 amendments to the *NOC Regulations* have endeavoured to strike a balance between the interests of the various parties. It may be imperfect, but it did endeavour to strike a balance. As I quoted earlier from the late Justice Layden-Stevenson in *Purdue*, at paragraph 45:

> *I do not disagree with Purdue that the purpose of the Regulations is to prevent patent infringement by a person making use of a patented invention in reliance on the early working exception. However, there is no obligation to provide the advantages of the Regulations in every case. The fact that the Governor in Council establishes eligibility criteria for the listing of patents does not detract from the legitimate purpose.*

[64] I have earlier quoted substantially from the RIAS respecting the 2006 amendments to the *NOC Regulations*. That statement made it clear that in enacting those amendments:

> *[N]ot every patent pertaining to an approved drug qualifies for enforcement under the scheme.*
>
> ...
>
> ***It is recognized that there may be instances where a patent which does not qualify for the protection of the PM(NOC) Regulations is ultimately infringed by the fact of generic market entry****[emphasis added]. However, the Government's view is that where the patent fails to meet the listing requirements described above, policy considerations tip the balance in favour of immediate*

> *approval of the generic drug, and the matter is better left to the alternative judicial recourse of an infringement action.*

[65] Therefore, unlike *Bristol-Myers* where the Supreme Court of Canada held that the effect of BMS's interpretation of the *NOC Regulations* would lead to an absurd result, the Federal Court of Appeal in *Purdue* already found that the effects of the *NOC Regulations'* product specificity requirement, as described in the *RIAS* above, is not inconsistent with the purpose of section 55.2(4) of the *Patent Act* to prevent patent infringement.

[66] In light of the foregoing, I agree with Teva that adopting ViiV's interpretation of the *NOC Regulations* would constitute an effective rewriting of those *NOC Regulations* in order to create what ViiV perceives as a fair and proper balance between the interests of brand and generic manufacturers. As I indicated before, such an act of supplanting the government's attempt to maintain this balance for a balance preferred by the Court would be a political decision, not a judicial decision and would constitute an unjustified overstepping of this Court's bounds outside the jurisprudential sphere and into the political sphere of policy-making (*Ontario v Criminal Lawyers' Association of Ontario*, 2013 SCC 43 at paras 27-30, [2013] 3 SCR 3).

[67] Finally, I reject ViiV's arguments respecting policy, because I find that the Federal Court of Appeal has already interpreted subsection 4(2)(a) and (b) of the *NOC Regulations* and, given that interpretation, the '753 patent does not qualify for listing. I address this elsewhere in the Reasons. "I address this in the next part of my reasons."

[68] On this point it is worth noting that the '753 patent's ineligibility for listing on the Patent Register does not prevent ViiV from bringing an infringement action (*Gilead*, at paragraph 42).

[69] If a party such as ViiV is unhappy with the *NOC Regulations* as they stand, the better course of action is to approach Parliament and its law makers, rather than the Courts.

XI. DID GILEAD DEAL WITH SUBSECTION 4(2)(a)?

[70] ViiV argues that the Federal Court of Appeal dealt with subsection 4(2)(a) of the *NOC Regulations* only in *obiter*, and that I should follow the decision of Russell J in *Bayer* in determining the meaning and effect of that subsection. I disagree.

[71] There is no doubt that Russell J dealt with subsection 4(2)(b) in his Reasons in *Bayer*, and that the Federal Court of Appeal, in its brief oral reasons, adopted that reasoning *in respect of subsection 4(2)(b).*

[72] Russell J, in his Reasons at paragraphs 72 to 81, dealt with an argument raised by Bayer, based largely on the Minister's Guidelines, reproduced earlier in my Reasons. Russell J found that a different approach to compound patents from formulation patents was required when matching and specificity are being considered under subsections 4(2)(a) and 4(2)(b). At paragraphs 77 to 81, he wrote:

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

> *drug formulation. This means that, in the context of early working, a generic copy of the drug containing the compound has early-worked the compound patent.*
>
> *78 On the other hand, as the Respondents point out, a formulation patent such as '979 does not contain a claim for the medicinal ingredient itself. It is rather a claim for the approved mixture of medicinal and non-medicinal ingredients that are actually administered to the patient.*
>
> *79 In my view, there is nothing unprincipled or inconsistent in the Minister's interpretation, because a formulation that is a mixture of more than one compound is different from a composition containing only one compound.*
>
> *80 The essence of a compound patent is the medicinal ingredient; the essence of a formulation patent is the mixture of ingredients. This distinction requires a different approach when matching and specificity are being considered under subsections 4(2)(a) and 4(2)(b). In my view, there is nothing inconsistent or unprincipled about the Minister's approach to this distinction.*
>
> *81 In essence, the Applicant is saying that matching and specificity are present under subsection 4(2)(b) whenever the patent claims refer to at least one of the medicinal agreements in the approved drug submission. This would mean, for instance, that if the drug submission encompassed a mixture of, for example, five medicinal ingredients, the required degree of matching would still be present even if the patent refers to only one of them. In my view, this equates listing on the Register with patent infringement under the Act. I do not believe that either the wording of subsection 2 or the policies behind the new regulations support such a position.*

[73] This distinction with respect to subsections 4(2)(a) and (b) by Russell J was not endorsed by the Federal Court of Appeal in their brief reasons in *Bayer*. Thus Russell J's discussion of subsection 4(2)(a) in *Bayer* is not binding on me.

[74] In *Gilead*, the Federal Court of Appeal expressly considered subsection 4(2)(a) of the *NOC Regulations*. Trudel JA, in her reasons for the Court drew an analogy to the reasoning of

Layden-Stevenson JA in *Purdue* in dealing with subsection 4(2)(c), and applied them equally to subsection 4(2)(a), stating that there is no sound reason to adopt different requirements for each of the subsections of 4(2). I repeat what she wrote at paragraphs 37 to 40:

> *37 Purdue's first argument is: "for claims for the dosage form under [paragraph] 4(2)(c), all that is required is that the dosage form has been approved." Purdue draws a distinction between the wording of paragraph 4(2)(b) which refers to a claim for the formulation that contains the medicinal ingredient and paragraph 4(2)(c) which makes no reference to a medicinal ingredient. According to Purdue, since there is no requirement for a medicinal ingredient in paragraph 4(2)(c), it had to establish only that the delivery system approved under the TARGIN NOC (the controlled release tablet) was the same as that claimed under Claim 5.*
>
> *38 The judge made short shrift of this argument by referring to the definition of "claim for a dosage form" in section 2. By virtue of the definition, paragraph 4(2)(c) necessarily requires a claim for a dosage form for administering a medicinal ingredient in a drug. I completely agree with the judge's reasoning.*
>
> *39 Purdue's second argument is that there is a further distinction in relation to the definition of "claim for the dosage form" and "claim for the formulation." A claim for the dosage form "requires that the medicinal ingredient be within the scope of the claim, while a claim for the formulation refers only to the mixture of medicinal and non-medicinal ingredients" (emphasis in original). In Purdue's view, the language in the definition of a claim to the dosage form indicates that the medicinal ingredient is not required to be a part of a claim for the dosage form.*
>
> *40 To the extent that this submission adds anything to its first argument, it hinges on Purdue's proposed construction of Claim 5 of the '738 Patent, specifically that it is broad enough to include naloxone although it is not expressly named in that claim. Yet that is precisely the problem. The claim is so broad that, as noted earlier, it could cover an unlimited number of unnamed other medical ingredients. That is not what the patent eligibility requirements are about.*

[75] ViiV's Counsel calls this *obiter*. It is not; and, even if it were it was so integral to Trudel JA's analysis that determined the outcome of *Gilead* that, this Court should be bound to follow

it (*R v Henry*, 2005 SCC 76 at paras 54-57, [2005] 3 SCR 609; *R v Prokofiew*, 2010 ONCA 423 at paras 18-20, 100 OR (3d) 401, aff'd 2012 SCC 49, [2012] 2 SCR 639).

[76] ViiV's Counsel argues that if the Federal Court of Appeal meant to distinguish *Bayer*, it would (or should) have done so in its reasons. In my view, there is no reason to distinguish *Bayer*. While, in a perfect world, the reasons of a Court would deal with every possible criticism and future challenges – anticipated and unanticipated – there was no need to explicitly deal with *Bayer*; as the latter dealt with subsection 4(2)(b) in its result. In *Gilead*, the Federal Court of Appeal clearly states at paragraph 49, in its Conclusion, that it was dealing with subsection 4(2)(a).

[77] *Gilead* is amply clear; a high threshold of specificity between what is claimed in the patent and the NOC is required. A patent claiming only one medicinal ingredient cannot be listed in respect of an NOC containing two or more medicinal ingredients.

XII. ARE FIXED-DOSE COMPOSITIONS UNIQUE SO AS TO BE ABLE TO BE LISTED UNDER 4(2)(a)?

[78] I raised this issue with Counsel at the hearing, invited an adjournment if requested, but Counsel were content to address the matter at the hearing.

[79] Logic would dictate that, if two separate tablets, each containing a single medicinal ingredient, were to be placed in a single envelope suitable for swallowing, then, while the

envelope contained two medicines, each remained discrete. Thus, it could be argued, the envelope still contained a discrete – or single – medicinal ingredient.

[80] Having considered the matter further, I find that this argument cannot prevail. First, in law, *Gilead* is amply clear. There is a "high threshold" of consistency; every medicine in the envelope must be claimed. I repeat paragraph 40:

> *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.*

[81] Second, the evidence in the record is ambiguous as to whether we have two separate medicines functioning independently, or whether they somehow interact and are synergistic.

[82] In *Bayer*, Russell J seemed to be under the impression that when two medicines are combined, they have a different effect than two separate medicines. I repeat paragraph 69 of his Reasons:

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

[83] In *Gilead*, at paragraph 31, the Court of Appeal speaks of "beneficial effects" of combining the medicinal ingredients:

> *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.*

[84] With the consent of all Counsel before me, I looked at the patent that the Court was dealing with in *Gilead*; Canadian Patent No. 2,512,475 (the '475 patent). At page 3, that '475 patent states in the "Summary of Invention":

> *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 emricitabine.*

[85] However, at page 19, under the title "Administrator of the Formulations" the '475 patent states:

> *While it is possible for the active ingredients of the combination to be administered alone and separately as monotherapies, it is preferable to administer them as a pharmaceutical co-formulation.*

[86] In the case before me, the Affidavit of ViiV's expert, Dr. Wainberg, states that the two medicinal ingredients "retain their independent identities" He stated at paragraph 81 of his affidavit:

> *81 As KIVEXA®, abacavir hemisulfate and lamivudine are presented together in a fixed-dose combination, which provides a common delivery vehicle for patient convenience and adherence. The fact that KIVEXA® contains a combination of two medicinal ingredients does not alter their separate and distinct identity. Rather, they operate as, and are understood to be, two different medicinal ingredients delivered together in a single pill. They*

> *retain their independent identities and characteristics after the single pill is ingested. Assuming perfect adherence, taking one KIVEXA® pill results in the same therapeutic effect as simultaneously taking two 300 mg ZIAGEN® pills and one 300 mg 3TC® pill.*

[87] However, ViiV has asserted another patent against Teva; Canadian Patent No. 2,216,634, which is not the subject of a listing challenge. (The Teva evidence, including this patent is, by agreement, part of the record in the Apotex appeals; however, this patent has not been asserted against Apotex). That patent claims the combination of the same two medicines as found in the ViiV NOC at issue against Teva. At page 6 of the '634 patent, it speaks of the synergistic effects of combining the two medicinal ingredients:

> *It will be appreciated that the compounds of the combination may be administered simultaneously, either in the same or different pharmaceutical formulation or sequentially. If there is sequential administration, the delay in administering the second and third active ingredient should not be such as to lose the benefit of a synergistic therapeutic effect of the combination of the active ingredients. It will also be understood that 1592U89, zidovudine and 3TC (or, alternatively to 3TC, FTC), or the physiologically functional derivatives of any thereof, whether presented simultaneously or sequentially, may be administered individually or in multiples or in any combination thereof. 1592U89, zidovudine and 3TC [or, alternatively to 3TC, FTC), are preferably administered simultaneously or sequentially in separate pharmaceutical formulations, most preferably simultaneously.*
>
> . . .
>
> *The synergistic effects of the combination of 1592U89, zidovudine and 3TC (or, alternatively to 3TC, FTC), or a physiologically functional derivative of any thereof are seen over a ratio, for example, of 1 to 20: 1 to 20:1 to 10 (by weight) preferably 1 to 10: to 10: 1 to 5 (by weight), particularly 1 to 3: 1 to 3: 1 to 2 (by weight)*

[88] Counsel for the Minister advised the Court that the Minister's officials do not look into the description of a patent claiming several medicines to determine if a synergistic effect is described. Nor should they; this would lead to evidence and more evidence as to yes or no as to synergy. The matter should simply be decided on the claims.

[89] In my view, it is not productive when considering the listing requirements of subsection 4(2) of the *NOC Regulations* to consider synergy or not. The decision of the Federal Court of Appeal in *Gilead* is sufficiently clear. A patent claim for only one medicinal ingredient cannot support a listing under the *NOC Regulations* where the underlying NOC is for a combination (synergistic or otherwise) of two or more medicinal ingredients.

XIII. CLAIM 32 AND SUBSECTION 4(2)(b)

[90] ViiV in its oral submissions relied solely only claim 2 to submit the 753 Patent's eligibility under subsection 4(2)(a) of the *NOC Regulations*, and made no submissions on the issue of claim 32 of the 753 Patent and subsection 4(2)(b) of the *NOC Regulations*. However, ViiV did not disclaim its written submissions relating to the question of whether claim 32 of the 753 Patent met the product specificity requirements under subsection 4(2)(b) of the *NOC Regulations*. I will therefore briefly address this issue based on the parties' written submissions.

[91] Trudel JA held in *Gilead* that the level of product specificity required under subsection 4(2)(a) equally applies to subsection 4(2)(b) of the *NOC Regulations* (Paragraphs 27-39, 45). This was the basis of Prothonotary Milcznyski's conclusion regarding product specificity for

the purpose of subsection 4(2)(b) and its application to claim 32 of the 753 Patent, which I adopt:

> *[5] Although the 753 Patent may encompass lamivudine as a medicinal ingredient, this does not satisfy the requirements for listing under either section 4(2)(a) or section 4(2)(b) of the PMNOC Regulations. It is not sufficient for the purposes of listing that a patent identify only one of the two (or more) medicinal ingredients identified in the drug submission in respect of which the NOC was issued. As held by the Federal Court of Appeal in Gilead Sciences Canada v. Minister of Health, 2012 FCA 254 (CanLII), 2012 FCA 254 ("Gilead"), the medicinal ingredient or formulation approved in the NOC must "match up" and be claimed in the patent sought to be listed. A high degree of specificity is required between the patent and the NOC. However, as noted, the NOC for KIVEXA® is for an abacavir sulfate/lamivudine tablet, and the 753 Patent claims only the medicinal ingredient, abacavir sulfate.*
>
> ...
>
> *[28] [i]n the case of KIVEXA®, no claim of the 753 Patent specifically claims the combination of the two medicinal ingredients that are the subject of the NOC for KIVEXA®, namely abacavir sulfate and lamivudine. There is nothing in the 753 Patent that requires lamivudine. The 753 Patent claims only abacavir in combination with another unnamed medicinal ingredient. Section 4(2)(a) of the PMNOC Regulations, as held in Gilead, requires all of the medicinal ingredients identified in the submission that results in the issuance of the NOC to be claimed in the patent for that patent to be listed on the Patent Register.* ***In the same manner, the specific formulation identified in the submission that led to the issuance of the NOC must be claimed in the patent. In the case of the 753 Patent, it is not enough that it encompasses the medicinal ingredient lamivudine (among others) in combination with abacavir for the purposes of section 4(2)(b) of the Regulations*** *[emphasis added].*
>
> *[29] The requisite degree of product specificity is the same for section 4(2)(a) of the PMNOC Regulations as it is for each of sections 4(2)(b), (c) and (d). The medicinal ingredient, formulation, dosage form or use of the medicinal ingredient claimed in the patent sought to be listed must match that in the drug submission that was approved through the issuance of the NOC.*

[92] Regarding the last two sentences of paragraph 28 of Prothonotary Milcznyski's Reasons, ViiV attempted to distinguish this case from *Novartis* and *Eli Lilly*. As cited above, the Court in *Novartis* and *Eli Lilly*, found the 2,304,819 Patent and the 2,379,329 Patent ineligible for listing under subsection 4(2)(b) of the *NOC Regulations* because they failed to claim tobramycin and milbemycin oxime, respectively. These patents did not explicitly include those ingredients in the description but made reference to a narrower sub-class in *Novartis*, and a general family in *Eli Lilly*, to which those ingredients belong.

[93] ViiV submits that those cases did not foreclose the possibility of a patent's eligibility under subsection 4(2)(b) of the *NOC Regulations* when said patent, such as the 753 Patent, claims one medicinal ingredient, abacavir sulphate, in combination with one or more therapeutic agents selected from a group, and specifically names one such therapeutic agents in the description, lamivudine. On this reasoning, ViiV submits that claim 32 of the 753 Patent is distinguishable from the facts of *Novartis* and *Eli Lilly* and would meet the requisite degree of product specificity under subsection 4(2)(b) of the *NOC Regulations*.

[94] I prefer Teva and Apotex's interpretation of the meaning of those cases in relation to claim 32 of the 753 Patent. In each case the Court found itself bound by *Gilead* to hold the patents ineligible for listing because said patents failed to include in their claim all of the medicinal ingredients contained in the approved New Drug Submission for which the first person sought the patent to be listed against: "the relevant **claim** for the formulation must be identical to the formulation in the NDS" [emphasis added] (*Novartis*, paragraph 59; and *Eli Lilly*, paragraphs 73, 84-85).

[95] It is worth noting that in oral argument before Prothonotary Milcznyski and in his written submissions for this appeal, Counsel for the Minister took the position that subsection 4(2)(b) of the *NOC Regulations* requires a patent to claim all of the medicinal ingredients in the approved drug. While I do not agree with Counsel's submissions on subsection 4(2)(a) of the *NOC Regulations*, I agree with Counsel's written submission that "a patent for a formulation that does not explicitly claim a composition containing abacavir sulfate and lamivudine would not "match" the KIVEXA formulation" (Paragraph 28); such being the case here.

[96] Therefore, while the 753 Patent explicitly includes lamivudine and zidovudine in its description, its failure to specifically claim those ingredients in combination with abacavir sulphate against KIVEXA® and TRIZIVIR® constitutes a failure to meet the product specificity requirements under subsection 4(2)(b) of the *NOC Regulations*. For the purpose of subsection 4(2)(b) of the *NOC Regulations*, product specificity requires listing in the claim all of the medicinal ingredients included in the formulation contained in the approved FDC, and not just in the patent description.

XIV. CONCLUSION AND COSTS

[97] In conclusion, I find that Prothonotary Milczynski's Orders that Canadian Patent No. 2,289,753 was ineligible for listing on the Patent Register is correct. The motions, by way of an appeal, will be dismissed.

[98] Since my Order will, at least in the Apotex proceedings, effectively terminate the matter, I will stay my Order in each proceeding for thirty days to permit ViiV to file an appeal, if so advised.

[99] As to costs, Teva and Apotex were successful. Teva asked for costs fixed at $10,000.00. I find that sum to be reasonable and will fix costs in that amount. Apotex's appeals largely followed Teva. Apotex will get half the costs allowed to Teva, split between the two Apotex appeals; that is, $2,500.00 in each appeal.

"Roger T. Hughes"
Judge

Toronto, Ontario
September 18, 2014

I HEREBY CERTIFY that the above document is a true copy of the original issued out of / filed in the Court on the SEP 18 2014 day of _____ A.D. 20 ____

Dated this SEP 18 2014 day of _____ 20 ____

ALICE PRODAN (A)
REGISTRY OFFICER
AGENT DU GREFFE

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1517-13
STYLE OF CAUSE:	VIIV HEALTHCARE ULC, VIIV HEALTHCARE UK LIMITED AND GLAXO GROUP LIMITED v TEVA CANADA LIMITED AND THE MINISTER OF HEALTH
DOCKET:	T-333-14
STYLE OF CAUSE:	VIIV HEALTHCARE ULC, VIIV HEALTHCARE UK LIMITED AND GLAXO GROUP LIMITED v APOTEX INC. AND THE MINISTER OF HEALTH
DOCKET:	T-335-14
STYLE OF CAUSE:	VIIV HEALTHCARE ULC, VIIV HEALTHCARE UK LIMITED AND GLAXO GROUP LIMITED v APOTEX INC. AND THE MINISTER OF HEALTH
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	SEPTEMBER 4, 2014
REASONS FOR JUDGMENT:	HUGHES J.
DATED:	SEPTEMBER 18, 2014

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