Federal Court  Cour fédérale

Date: 20140217

Docket: T-1071-11

Citation: 2014 FC 152

Ottawa, Ontario, February 17, 2014

PRESENT: The Honourable Madam Justice Bédard

BETWEEN:

ELI LILLY CANADA INC.

Applicant

and

ATTORNEY GENERAL OF CANADA AND MINISTER OF HEALTH

Respondents

REASONS FOR JUDGMENT AND JUDGMENT

[1] The applicant, Eli Lilly Canada Inc. [Eli Lilly] brings this application for a judicial review, under section 18.1 of the *Federal Courts Act*, RSC 1985, c F-7, of a decision made by the Minister of Health [Minister], dated May 30, 2011. In that decision, the Minister refused to list Canadian Patent No. 2,379,329 ['329 Patent] on the patent register maintained under the *Patented Medicines (Notice of Compliance) Regulations* (SOR/93-133, as amended by SOR/98-166, SOR/99-379, SOR/2006-242) [Regulations] against Eli Lilly's product Trifexis [New Drug Submission [NDS] No. 141 509].

[2] The Minister found that the ‘329 Patent did not meet the product specificity requirement set out in paragraph 4(2)(*b*) of the Regulations.

[3] The Minister considered that the ‘329 Patent did not contain claims for the formulation combining both medicinal ingredients (spinosad and milbemycin oxime). Rather, the Minister was of the view that the patent claimed a formulation comprising only one of the two medicinal ingredients present in Trifexis, namely spinosad, and that, referencing the general family of milbemycins in the definition of oral formulation provided in the disclosure of the patent was insufficient to meet the product specificity requirement.

[4] For the reasons that follow, the application is dismissed.

I. Background

[5] The ‘329 Patent application was filed on August 2, 2000, and the patent was issued on October 20, 2009. It is entitled “Oral Treatment of Companion Animals with Ectoparasiticidal Spinosyns”.

[6] On September 16, 2010, Eli Lilly filed the NDS 141 509 regarding Trifexis, and the Notice of Compliance [NOC] was issued on November 1, 2011. Trifexis is a veterinary drug product indicated for the prevention of heartworm, the prevention and treatment of flea infestations, and the treatment and control of adult hookworm, adult roundworm and adult whipworm infections in dogs and cats. It is not disputed that Trifexis is authorized as an oral dosage form of a drug that contains two active medicinal ingredients: spinosad and milbemycin oxime.

[7] On September 16, 2010, Elanco, a division of Eli Lilly, submitted the '329 Patent to the Minister for listing on the patent register.

[8] The '329 Patent contains seven claims but it is sufficient, for the purpose of these proceedings, to reproduce the two independent claims 1 and 5:

> 1. A single-dose oral formulation for controlling an ectoparasite infestation on a dog or cat comprising an ectoparasiticidal amount of spinosad, or a physiologically acceptable N-demethyl derivative or salt thereof, and a physiologically acceptable carrier in a dosage form selected from tablet, capsule or liquid suitable for administration once every at least 7 days at a dose of 10 to 100mg of spinosad per kg of body weight.
>
> […]
>
> 5. A single-dose oral formulation for controlling an ectoparasite infestation on a dog or cat comprising an ectoparasiticidal amount of spinosad, or a physiologically acceptable N-demethyl derivative or salt thereof, and a physiologically acceptable carrier in a chewable treat oral dosage form suitable for administration once every at least 7 days at a dose of 10 to 100mg of spinosad per kg of body weight.

[9] The term "oral formulation" is defined in the disclosure portion of the patent:

> (p.8; lines 6-13) The formulations of this invention may further include, in combination with the spinosyn component, one or more other compounds that have activity against the specific ectoparasite or endoparasite to be controlled, such as, for example, synthetic pyrethroids, natural pyrethins, organophosphates, organochlorines, carbamates, foramidines, […].milbemycins, […] [emphasis added]
>
> […]
>
> (p. 8; lines 16-19) The term "oral formulation" means that the spinosyn component or components, either alone or in combination with one or more of the other types of compounds listed supra, is formulated into a product or formulation suitable for administering to the animal by mouth. […]

II. The Minister's decision

[10] The '329 Patent was assessed for eligibility by the Office of the Patented Medicines and Liaison [OPML] of the Therapeutic Products Directorate of Health Canada. On November 8, 2010, Mr. Waleed Jubran, Senior Patent Officer at the OPML, issued a preliminary decision stating that the OPML was of the view that the '329 Patent did not contain a claim for both spinosad and milbemycin oxime, but was limited to claims directed to a formulation comprising spinosad only.

[11] In reply to the preliminary decision, Eli Lilly filed additional submissions along with two affidavits of expert witnesses, Dr. Manon Paradis and Mr. Michel Sofia, and maintained that the claims cover both medicinal ingredients. Eli Lilly argued that while each claim specifically referenced spinosad, it also referenced milbemycin oxime indirectly. More precisely, each claim referenced an "oral formulation" which formulation is defined in the patent to include spinosyn alone or in combination with certain other active ingredients, the list of which includes milbemycins. Further, Eli Lilly submitted that a person skilled in the art would understand that the term "oral formulation" could include spinosyn and milbemycin oxime which is in the family of milbemycins.

[12] On May 30, 2011, the Minister issued a final decision in which she refused to list the '329 Patent on the register. In her decision, the Minister clearly indicated that she disagreed with Eli Lilly's position that the reference to milbemycins in the definition of oral formulation was sufficient to conclude that the patent claimed a formulation containing both spinosad and milbemycin oxime. The Minister's reasoning appears in the following excerpt of her decision:

> In the case of formulation patents, as noted in the above paragraph, the *PM(NOC) Regulations* specify that the claimed formulation must

> include, as an element, the medicinal ingredient(s) contained in the approved drug. […]
>
> While we agree that the '329 patent contains claims for a formulation containing the medicinal ingredient spinosad, there are no claims in the '329 patent specifying milbemycin oxime as the second medicinal ingredient present in the formulation of the invention. The mere mention of milbemycins in the disclosure as one of many groups of compounds that may be combined with spinosad in the formulation of the invention is not sufficient to constitute a claim for the formulation containing the medicinal ingredient(s), as required by section 2 and paragraph 4(2)(b) of the *PM(NOC) Regulations*. […]
>
> […]
>
> Milbemycins are characterized as a family of macrolide antibiotics with insecticidal and acaricidal activity and include not only milbemycin oxime but milbemectin, nemadectin and moxidectin as well. (…)
>
> Therefore, even if the OPML accepts your position that the *PM(NOC) Regulations* do not require that all of the medicinal ingredients be present in the approved drug be specified in the claim for the formulation, a close examination of the above-noted passage of the disclosure reveals that the specific medicinal ingredient milbemycin oxime, which is not explicitly mentioned in the claims, is <u>also</u> not explicitly mentioned in the disclosure. Rather, as indicated above, milbemycins are mentioned as one of many groups of compounds that may be combined with spinosad in the formulation of the invention.

III. The Regulatory framework

[13] The applicable regulatory framework, and its history, has been outlined in several judgments. In *Gilead Sciences Canada Inc v Canada (Ministry of Health)*, 2012 FCA 254, [2012] FCJ No 1259 [*Gilead*], Justice Trudel provided the following useful summary:

> **The Regulatory framework**
>
> 21. Drug manufacturers wishing to sell a new drug in Canada must submit a new drug submission to the Minister and obtain a notice of compliance. These documents set out basic information

> regarding the drug in question. Although most new drugs are covered by patents which protect them from being copied, generic drug producers may work patents without infringing them in order to seek the necessary approvals from the Minister to release generic equivalents of drugs as soon as the patents expire. This is known as the "early working exception" of the *Patent Act* (R.S.C., 1985, c. P-4) [*Patent Act*].
>
> 22. To ensure that this exception is not abused, the *Patent Act* also provides for the PM (NOC) Regulations to manage this exception. To benefit from the protections of the PM (NOC) Regulations, drug companies must apply to the Minister to have the patents related to their drugs listed on a patent register.
>
> 23. Thus the *Patent Act* and the PM (NOC) Regulations seek to balance "effective patent enforcement" over new and innovative drugs with the "timely market entry" of lower priced generic versions once the patents have expired (*Regulatory Impact Analysis Statement*, (2006) Canada Gazette Part II., Vol. 140, 1510-1525) [RIAS].
>
> 24. According to the Minister, deficiencies in the language of the PM (NOC) Regulations led to court decisions which made it too easy to list patents on the register and thus tilted the balance too far in favour of patent protection. To correct this, the Minister introduced revisions to the PM (NOC) Regulations in 2006. Among the key features of these revisions is the concept of "product specificity," whereby the subject matter of the patent must reflect the subject matter of the approved drug submission to qualify for listing on the patent register (respondent's memorandum of fact and law at paragraph 7).

[14] The eligibility requirements for patent listing on the register are set out in subsection 4(2) of the Regulations. In this case, we are concerned with paragraph 4(2)(*b*) of the Regulations pertaining to a claim for a formulation. The current versions of the relevant provisions read as follows:

2. “claim for the formulation” “claim for the formulation” means a claim for a substance that is a mixture of medicinal and non-medicinal ingredients	2. « revendication de la formulation » « revendication de la formulation » Revendication à l’égard d’une substance qui est

in a drug and that is administered to a patient in a particular dosage form; (*revendication de la formulation*)

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*)

[…]

[…]

3. (2) The Minister shall maintain a register of patents and other information submitted under section 4. To maintain the register, the Minister may refuse to add or may delete any patent or other information that does not meet the requirements of that section.

3. (2) Le ministre tient un registre des brevets et des autres renseignements fournis aux termes de l'article 4. À cette fin, il peut refuser d'y ajouter, ou en supprimer, tout brevet ou tout autre renseignement qui n'est pas conforme aux exigences de cet article.

[…]

[…]

4. (1) A first person who files or who has filed a new drug submission or a supplement to a new drug submission may submit to the Minister a patent list in relation to the submission or supplement for addition to the register.

4. (1) La première personne qui dépose ou a déposé la présentation de drogue nouvelle ou le supplément à une présentation de drogue nouvelle peut présenter au ministre, pour adjonction au registre, une liste de brevets qui se rattache à la présentation ou au supplément.

(2) A patent on a patent list in relation to a new drug submission is eligible to be added to the register if the patent contains

(2) Est admissible à l'adjonction au registre tout brevet, inscrit sur une liste de brevets, qui se rattache à la présentation de drogue nouvelle, s'il contient, selon le cas **:**

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

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

of the submission;	présentation;
(*b*) a claim for the formulation that contains the medicinal ingredient and the formulation has been approved through the issuance of a notice of compliance in respect of the submission**;**	*b*) une revendication de la formulation contenant l'ingrédient médicinal, la formulation ayant été approuvée par la délivrance d'un avis de conformité à l'égard de la présentation**;**
(*c*) a claim for the dosage form and the dosage form has been approved through the issuance of a notice of compliance in respect of the submission; or	*c*) une revendication de la forme posologique, la forme posologique ayant été approuvée par la délivrance d'un avis de conformité à l'égard de la présentation;
(*d*) a claim for the use of the medicinal ingredient, and the use has been approved through the issuance of a notice of compliance in respect of the submission.	*d*) une revendication de l'utilisation de l'ingrédient médicinal, l'utilisation ayant été approuvée par la délivrance d'un avis de conformité à l'égard de la présentation.
[…]	[…]

IV. Issues and standards of review

[15] When assessing the eligibility of a patent to be listed on the patent register, the Minister must apply a three-prong analytical framework that is well established. This framework was enunciated by Justice Hughes in *Abbott Laboratories and Canada (Attorney General)*, 2008 FC 700 [*Abbott Laboratories*], and it has since been approved on several occasions by the Federal Court of Appeal (*Abbott Laboratories Ltd v Canada (Attorney General)*, 2008 FCA 354, [2009] FCJ No 1580 at paras 29-33, [*Abbott*]; *G.D. Searle & Co v Canada (Minister of Health)*, 2009 FCA 35, [2009] FCJ No 145 at paras 33-35 [*Searle*]; *Purdue Pharma v Canada (Attorney General)*, 2011

FCA 132, [2011] FCJ No 578 at paras 11-13 [*Purdue*] and more recently in *Gilead* at paras 11-12. This framework must be adapted to the specific type of patent that is at issue.

[16] In this case, paragraph 4(2)(*b*) of the Regulations which relates to a claim for a formulation is involved. The Minister was required to answer the following questions:

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

[17] In this application, the Court is asked to determine whether the Minister erred in answering the above-noted questions.

[18] The standards of review applicable to the Minister's assessment of these three questions have been well established by the Federal Court of Appeal in *Abbott* at paras 29-34, and these were reiterated on several occasions, including in *Searle*, *Purdue* and *Gilead*.

[19] The first question the Minister was asked to answer involves the construction of the patent claims which is a question of law that is reviewable under the correctness standard of review. The second question is reviewable under the reasonableness standard of review, but the parties agree that this question is not at issue in this case. The third question involves two sub-questions. First, it requires the Minister to interpret paragraph 4(2)(*b*) of the Regulations, and that exercise is reviewable under the correctness standard of review. Second, it requires the Minister to apply

paragraph 4(2)(*b*) of the Regulations to the specific facts of the case, and this involves a question of mixed fact and law that is to be reviewed under the reasonableness standard of review.

[20] Therefore, this Court must answer the following questions:

(1) Did the Minister correctly construe the '329 Patent?

(2) Did the Minister correctly interpret the requirements set out in paragraph 4(2)(*b*) of the Regulations?

(3) Was the Minister's decision to exclude the '329 Patent from the patent register reasonable?

V. Arguments of the parties

A. *The Applicant*

[21] The applicant argues that each of the three steps of the analytical framework must be applied independently. Accordingly, at the first stage of the analysis, the patent must be construed on a stand-alone basis, based on the principles elaborated by the Supreme Court of Canada in *Free World Trust v Électro Santé Inc*, 2000 SCC 66 [*Free World*] and *Whirlpool Corp v Camco Inc*, 2000 SCC 67 [*Whirlpool*], without regard to the language of subsection 4(2) of the Regulations. The applicant argues that the comparison exercise between the patent claims and the drug submission, with consideration to the requirements of the Regulations, must be undertaken at the last stage of the analysis, once the patent has been properly construed.

[22] The applicant contends that the Minister erred in the interpretation of the '329 Patent. In requiring that the specific words "milbemycin oxime" be recited in the patent to conclude that it covers a formulation containing both spinosad and milbemycin oxime, the Minister construed the

‘329 Patent in light of her interpretation of the Regulations instead of construing it first, in an independent and purposive manner. In the applicant’s view, the Minister conflated claim construction with the interpretation of paragraph 4(2)(*b*) of the Regulations, and in doing so, she introduced additional requirements for specificity to the claims. The applicant relies on this passage of *Purdue* and insists that the Minister erred in the same manner that the judge did in that case:

> 17. That said, I agree with Purdue that the judge impermissibly imported the legislative requirements of paragraph 4(2)(*c*) into his construction of the patent (reasons for judgment at paras. 43-45 and 49 (excluding only the first sentence)). The legislative requirements are to be considered in the context of question three. Question one is concerned solely with the construction of the patent and its relevant claims. That is, the patent is to be construed in accordance with the principles articulated in *Whirlpool*.
>
> 18. The comments in the latter portion of paragraph 49 of the judge's reasons indicate that the provisions of the Regulations factored heavily into his conclusion. Since that approach does not accord with *Whirlpool*, the judge erred when he defined and applied the product specificity concept of the Regulations at the claims construction stage of the framework.

[23] The applicant insists on the following principles applicable to claim constructions: the patent must be read as of the date of its publication, as a whole, in a purposive manner through the eyes of the person skilled in the art with one meaning and one interpretation, for all purposes. Further, the applicant insists that claim construction involves identifying where the fences around the monopoly are instead of limiting the analysis to identifying the inventive step. It adds that the patent must be read by a mind willing to understand, not a mind willing to misunderstand.

[24] For the applicant, at the first stage of the analysis, the only question to be answered is: What does the ‘329 Patent cover? The applicant argues that, properly construed, the ‘329 Patent covers

different oral formulations, comprising the spinosyn component alone or in combination with different compounds, of which a formulation comprising both spinosad and milbemycin oxime.

[25] The applicant's proposition is essentially the same as formulated before the Minister. The applicant argues that the patent claims expressly mention spinosad and they also reference milbemycin oxime indirectly through the defined term "oral formulation". The definition of "oral formulation" includes a formulation containing both spinosad and milbemycins. Since milbemycin oxime was known at the time of the publication of the patent to be one of the compounds in the family of milbemycins, the '329 Patent clearly claims a formulation containing spinosad and milbemycin oxime. The applicant further argues that the '329 Patent is addressed to veterinarians. The person skilled in the art would be one holding a degree in veterinarian medicine and would understand that the patent can cover a formulation containing spinosad alone or in combination with milbemycins. Further, that person skilled in the art would also understand that when referring to milbemycins, the patent could include milbemycin oxime which is part of the family of milbemycins.

[26] In support of its position, the applicant relied on the affidavit of Dr. Paradis.

[27] Dr. Paradis is a veterinarian and professor at the Department of Clinical Sciences, Faculty of Veterinary Medicine of the University of Montreal and she specializes in dermatology.

[28] Dr. Paradis expressed the view that the '329 Patent is addressed to veterinarians and that the person skilled in the art "would have a Diploma in Veterinary Medicine and would have worked in

the field for at least a couple of years". Further, she added, at paragraph 20, that the "person skilled in the art would be familiar with the use of the drugs mentioned in the patent for the treatment of various diseases in animals like fleas, heartworms and intestinal worms".

[29] In addition, Dr. Paradis discussed the composition of Trifexis and explained what spinosad and milbemycin oxime are, along with their respective and combined actions in Trifexis. With respect to milbemycin oxime, Dr. Paradis explained, in paragraphs 24 and 25 of her affidavit, that milbemycin oxime is part of the family of macrocyclic lactones which are broad potent antiparasitic agents that include two closely related chemical groups: avermectins (e.g., ivermectin, abamectin, eprinomectin, doramectin and selamectin) and milbemycins (e.g., milbemycin oxime and moxidectin).

[30] In the summary of her analysis, Dr. Paradis explained her understanding that both spinosad and milbemycin oxime are covered by the '329 Patent as follows:

> 17. The '329 Patent is for the use of spinosad, a new compound for the treatment of fleas and other ectoparasites, either alone or in combination with one or more compounds. Each claim contains reference to both spinosad and milbemycin oxime. Spisonad is specifically mentioned within the claims, and the term "oral formulation" is defined to include milbemycin oxime in the specification. Also, the inventors use the term "comprising" within the claims to indicate they contemplated spinosad could be formulated with one or more additional ingredients.

[31] Dr. Paradis holds the view that Trifexis falls within the scope of the '329 Patent and that this would be understood by veterinarians (paragraph 42 of her affidavit). Further, she explained in

paragraphs 44 and 47 of her affidavit why she is of the view that milbemycin oxime is also mentioned in the claims:

> 44. […] First, the patent defines "oral formulation" to include milbemicyn oxime, and second, the use of the term "comprising" means that the inventors contemplated spinosad could be formulated with one or more additional ingredients. [emphasis added]
>
> […]
>
> 47. The inventors go on to state at page 8, lines 7-13, that "the formulations of this invention may further include, in combination with the spinosyn component, one or more other compounds that have activity against the specific ectoparasite or endoparasite to be controlled, such as, for example, synthetic pyrethroids, natural pyrethins, organophosphates, organochlorines, carbamates, formanidines, avermectins, milbemycins, insect growth regulators […], nitromethylenes, pyredines and pyrazoles." The investors specifically contemplated the use of spinosad with milbemycin oxime. [emphasis in original]

[32] The applicant also relied on the affidavit of Mr. Sofia, a patent agent with Bereskin & Parr LLP who has over 23 years of experience in the field of intellectual property. He was past President of the Intellectual Property Institute of Canada and of the Canadian Group of the International Association for the Protection of Industrial Property.

[33] At paragraph 16 of his affidavit, Mr. Sofia expressed the view that when read in a purposive manner, with one interpretation for all purposes, each claim of the '329 Patent covers spinosad, including when combined with milbemycin oxime.

[34] He further opined, at paragraph 53 of his affidavit, that "the term "milbemycins" is used in a broad manner, and a person skilled in the art would understand this term to mean "a family of novel

macrolide antibiotics with insecticidal and acaricidal activity" of which "milbemycin oxime" is a member". He then referenced the *Merck Index* entries that define milbemycins and milbemycin oxime.

[35] The applicant contends that the Minister would have reached a different conclusion if she had properly construed the patent without regard to the Regulations. In the applicant's view, it is only when the OPML applied paragraph 4(2)(*b*) of the Regulations that they found there were no claims to the specific formulation because the claims, or the definition of "oral formulation", in the patent do not expressly enumerate milbemycin oxime. To support this argument, the applicant relied on the Minister's decision and on the cross-examination of Mr. Jubran. The applicant argues that Mr. Jubran conceded that when construed without regard to the Regulations, the '329 Patent covers the specific formulation comprising spinosad and milbemycin oxime.

[36] In answering a question from counsel for the applicant, Mr. Jubran acknowledged that the patent, when read by itself, without applying the requirements of subsection 4(2) of the Regulations, could extend to a combination of spinosad and milbemycin oxime: The relevant excerpt from the transcription of the cross-examination reads as follows:

> Q. You would be able to appreciate that spinosad and milbemycin oxime are within the scope of spinosad as claimed and milbemycin as described at page 8 of the patent?
>
> A. Well spinosad is claimed, milbemycin oxime is, again a part of the family of milbemycins referred to in the disclosure.
>
> […]
>
> Q. We certainly can figure it out if we have to, that oral formulation would extend to a combination of spinosad and milbemycin oxime?

> A. If you are just reading the patent by itself, yes.
>
> Q. Yes. I am setting aside the second tier of analysis. I will get to it, but you are ahead of me.
>
> I am setting aside the second tier of analysis under the Regulations, I am just looking at the patent claims and the patent disclosure right now.
>
> A. Okay
>
> Q. I think you and I are essentially in agreement that if we set aside the regulatory analysis that OPML does, but look only at the patent claims and disclosure and the product monograph, we can see that the claims cover Trifexis generally, without the regulatory analysis.
>
> Are we agreed?
>
> A. I can't agree that the claim covers Trifexis.
>
> I can agree that somebody reading this patent could read in an extra compound or family of compounds, one of which could be something else.
>
> But for me, when we do our analysis, it's always after that step; there is something else that we have to apply.
>
> So I can't say that is covers the product.

[37] Turning to the third step of the analysis, the applicant contends that the '329 Patent was refused for listing only because it did not contain a specific recitation of the term milbemycin oxime. On that issue, the applicant referred the Court to the Minister's decision and the following excerpt from Mr. Jubran's cross-examination:

> Q. … What did the OPML look for in that second tier of analysis that was missing from the claim?
>
> Was it the specific wording, "milbemycin oxime", had to be there? It had to say "an oral formulation comprising spinosad and milbemycin oxime?"

> A. Yes.
>
> Q. That's it?
>
> A. Yes.
>
> Q. That is the technical requirement that we did not meet. That is the sole requirement that we did not meet.
>
> A. The claim for the formulation in the patent contains spinosad. There is no mention of milbemycin oxime in the claim as required by the 4(2)(b).
>
> If you look at the definition, even if you look at the definition of oral formulation and you take into account milbemycins, "milbemycin" is referring to a broad family of compounds. There is still no specificity there for milbemycin oxime.
>
> So the milbemycin oxime component is missing from the claim.

[38] The applicant argues that in requiring a specific recitation of milbemycin oxime, the Minister erred. Its position turns on two arguments. First, the applicant insists that subsection 4(2) of the Regulations, when properly interpreted, should not require a recitation of every specific word contained in the product's monograph. Second, the applicant argues that even if a perfect match is required between the product's monograph and what is claimed in the patent, the '329 Patent, when properly construed, is directed to a formulation that contains the specific ingredients spinosad and milbemycin oxime.

[39] The applicant argues that a proper interpretation of the Regulations, and more specifically of paragraph 4(2)(*b*) of the Regulations, should require that a patent "covers" the innovator's approved drug, akin to the assessment made in the context of an infringement allegation, and that the product

specificity requirement should not go as far as requiring that the patent claims "recite" every medicinal ingredient contained in the approved drug.

[40] The applicant insists that prior to the 2006 amendments to the Regulations, ancillary patents were recognized to be eligible for listing on the patent register, and that specifically in *Eli Lilly Canada Inc v Canada (Minister of Health)*, 2003 FCA 24, [2003] 3 FC 140, the Federal Court of Appeal allowed the listing of a patent on the mere possibility of infringement by a second entrant, but where the approved product made no use of the invention disclosed in the patent. The applicant submits that the Governor in Council found this interpretation too broad and sought to re-align the Regulations with the policy intent of the Regulations. Relying on *Merck Frosst Canada v Canada (Minister of National Health and Welfare)*, [1998] 2 SCR 193, the applicant states the original intent of the Regulations, at paragraph 15, of its Supplemental Submissions:

> 15. According to the Supreme Court of Canada in *Merck Frosst Canada v. Canada*, [1998] 2 S.C.R. 193, the original policy intent of the *Regulations* is to **"prevent patent infringement"**. The *Regulations* ensured that the exception to patent infringement (s. 55.2) was not abused by generic drug applicants seeking to sell their product in Canada during the term of the patent while nonetheless allowing generic competitors to undertake their regulatory approval work necessary to ensure they are in a position to market their products immediately after the expiry of any relevant patents.

[41] The applicant acknowledges that to restore that balance, the Regulations introduced the product specificity requirement, the purpose of which "is to only allow patents to be listed where direct infringement results from unauthorized use of the approved drug product" (para 13 of the applicant's Supplemental Submission). However, in the applicant's view, those amendments were not meant to require a reciting of the exact medicinal ingredients in both the patent and the NDS but

rather to "restrict listing of patents to those where the claims covered the **subject matter** of the approved drug" (para 16 of the applicant's Supplemental Submissions). The applicant insists that in order to respect Parliament's intent, the Minister must follow the law of patent construction and determine whether a patent covers a specific formulation. In this case, the applicant contends that it is clear that the '329 Patent covers the subject matter of Trifexis.

[42] The applicant is of the view that in *Gilead*, the Federal Court of Appeal created an enhanced requirement for listing by requiring that the patent recites every medicinal ingredient of the approved drug. The applicant submits that this does not accord with the intent and purpose of the 2006 amendments. The applicant invites the Court to depart from the reasoning adopted in *Gilead*.

[43] Further, the applicant contends that in *Gilead*, the parties did not sufficiently explore the purpose of the Regulations as explained in the RIAS. The applicant insists that the purpose of the Regulations was to prevent generic drug manufacturers from taking an undue advantage of the early working exception until the patent is addressed. In the applicant's view, the requirement set out in subsection 4(2) of the Regulations is one of relevance that is not limited to a mere word to word matching exercise.

[44] The applicant further contends that in *Gilead* the provisions of the Regulations were not interpreted in light of the Agreement on Trade-Related Aspects of Intellectual Property Rights [TRIPS] and the North American Free Trade Agreement [NAFTA]. The applicant submits that Article 31 of TRIPS and Article 1709 of NAFTA require that where the law of a country member allows for the use of a patented subject matter without the authorization from the patent owner (like

s. 55.2 of the *Patent Act*, RSC 1985, c P-4), the country member must ensure that certain conditions are met. More precisely, any incursion on the exclusive rights of the patentee must be justified on its own individual merit. The applicant contends that such an exercise is restricted by the interpretation of the Regulations adopted by the Federal Court of Appeal in *Gilead*. The applicant states the following at paragraphs 26 to 28 of its Supplemental Submissions:

> 26. Subsection 55.2(4) and the *Regulations* provide the mechanism by which such authorization may be justified. While not applicable to all situations of patent infringement, the *Regulations* do provide that, based upon a review of the innovator drug product and the patents listed on the Patent Register, a generic must address those patents before market approval will be granted. Where the patents listed on the Patent Register have claims that contain the innovator's product, the second entry manufacturer will, by definition, infringe those patent claims when comparing the second entry manufacturer's product to the product of the innovator, whether the comparison is direct or indirect. Using the innovator's product for commercial purpose, by definition, is an act of infringement.
>
> 27. Therefore, any patent covering the innovator's product is to be addressed in accordance with the *Regulations*. By circumscribing the patents that are eligible for listing on the Patent Register, the Minister is restricting the opportunities available to the patentee to prevent infringement of its patent that will follow the early working of the invention.
>
> 28. Where listing of the patent is refused, the second entry manufacturer does not need to address, seek authorization, or justify its infringement of the innovator's patent, contrary to NAFTA and TRIPS.

[45] As a second argument, the applicant contends that even if the enhanced test adopted in *Gilead* is the correct one, the '329 Patent, properly construed, meets the product specificity requirement as its claims disclose both spinosad and milbemycin oxime. The applicant referred the Court to the construction of the patent in the first portion of his arguments. The applicant insists that

since the patent claims a formulation containing spinosad and milbemycin oxime, the matching requirement is met even with the test adopted in *Gilead*.

[46] The applicant also argues that because of its similarity to the Canadian framework, the United States [US] regulatory framework should assist the Court in its interpretation of the Regulations. Based on the affidavit of Mr. Aaron F. Barkoff, who is a registered patent attorney in the US, the applicant contends that in the US, the Food and Drug Administration's role (that is played by the Minister in Canada) is limited to an administrative exercise, and that the Courts do not require a perfect matching, word for word, between the patent and the products' monograph. The applicant insists that given the similarity between the two regimes, where doubts exist, the Minister should resolve it in favour of listing the patent.

B. *The Respondents*

[47] The respondents argue that the Minister did not err in determining that the '329 Patent was not eligible for listing on the patent register as it fails to meet the product specificity requirements set out in paragraph 4(2)(*b*) of the Regulations. The respondents submit that the Minister's decision is consistent with the principles adopted on several occasions by the Federal Court and the Federal Court of Appeal in relation to the application of subsection 4(2) of the Regulations.

[48] Further, the respondents argue that the Minister proceeded to the three steps of the analytical framework and did not conflate the first and third steps.

[49] The respondents insist that there is a difference between the conclusions that a court could reach in an infringement action and the exercise that the Minister is called upon to do in assessing whether a patent is eligible for listing. The respondents concede that milbemycin oxime would not necessarily be excluded from the boundaries of the '329 Patent, given the reference to its class in the definition of "oral formulation", but that would be a question of patent law. For the respondents, the fact that milbemycin oxime would not necessarily be excluded from the patent in an infringement action is not conclusive because, in addition to construing the patent, the Minister must determine if the patent meets the product specificity requirements set out in paragraph 4(2)(*b*) of the Regulations.

[50] In the respondents' view, the language used in subsection 4(2) of the Regulations and the case law that has interpreted its paragraphs is clear and requires a strict test for product specificity: in order to be eligible for listing on the patent register, the formulation defined in a patent must precisely and specifically match the formulation described in the product monograph as authorized in the NOC.

[51] The respondents assert that in order to meet the eligibility requirements of paragraph (4)(2)(*b*) of the Regulations, a patent must contain claims to a formulation comprising all the medicinal ingredients found in the referenced NDS. The respondents insist that the 2006 amendments to the Regulations entrenched the concept of product specificity as the key consideration when assessing the eligibility of a patent and that the Minister's role in maintaining the patent register is an active one.

[52] The respondents argue that the '329 Patent does not meet the product specificity requirement. First, no claims in the '329 Patent specify milbemycin oxime as another medicinal ingredient in the formulation of the invention. Second, milbemycin oxime is not referenced in the patent's disclosure section. Since Trifexis was approved for a precise formulation containing two specific medicinal ingredients (spinosad and milbemycin oxime), it is not sufficient for the patent claims to merely refer to the possibility that spinosad may be combined with other ingredients, such as, in this case, milbemycins, without further specificity.

[53] In the respondents' view, it is clear that the '329 Patent does not claim the specific formulation that Trifexis described in its NDS. The respondents contend that Eli Lilly's construction of the '329 Patent requires an exercise of deduction that does not meet the product specificity requirement. The respondents added that "[u]sing the same deductive reasoning, it is equally possible to construe the '329 Patent as "covering" an oral formulation containing *an unlimited number of other compounds*" (para 1 of the respondents submissions).

[54] Answering a question from the Court, counsel for the respondents acknowledged that the Minister's decision may have been different if the specific compound "milbemycin oxime" had been included in the definition of "oral formulation" instead of the broader family of "milbemycins" to which milbemycin oxime belongs.

[55] The respondents also argue that the Court should disregard Eli Lilly's reference to the US law and practice first, because it was not raised with the Minister before the decision was made and

second, because it is irrelevant to the interpretation of the Regulations which are different than the framework applicable in the US.

VI. Analysis

(1) *Did the Minister correctly construe the '329 Patent?*

[56] The first question that the Minister was required to answer is: Does the '329 Patent claim a formulation that contains spinosad along with milbemycin oxime? Put differently, the issue is whether the reference to the family of milbemycins in the definition of oral formulation provided in the disclosure section of the patent is sufficient to conclude that the specific formulation comprising spinosad and milbemycin oxime is claimed by the '329 Patent. The Minister found it was not. With all due respect, I disagree in part.

[57] The principles to claim construction are well established and they are not in issue in this case but it is worth mentioning some key principles.

[58] In *Free World*, the Court made it clear that patents must be construed through the eyes of the person skilled in the art that has a mind willing to understand:

> 44. The courts have traditionally protected a patentee from the effects of excessive literalism. The patent is not addressed to an ordinary member of the public, but to a worker skilled in the art described by Dr. Fox as
>
> > a hypothetical person possessing the ordinary skill and knowledge of the particular art to which the invention relates, and a mind willing to understand a specification that is addressed to him. This hypothetical person has sometimes been equated with the "reasonable man" used as a standard in negligence cases. He is assumed to be a man who is going to try to achieve success and not one who is looking for difficulties or seeking failure.

(*Fox*, supra, at p. 184)

[59] In *Whirlpool*, the Court endorsed the purposive approach to claim construction and outlined that a patent must receive one meaning and must be construed with regard to the entirety of the patent:

> 45. The key to purposive construction is therefore the identification by the court, with the assistance of the skilled reader, of the particular words or phrases in the claims that describe what the inventor considered to be the "essential" elements of his invention.
>
> […]
>
> 48. […] In *Catnic*, as in the earlier case law, the scope of the monopoly remains a function of the written claims but, as before, flexibility and fairness is achieved by differentiating the essential features ("the pith and marrow") from the unessential, based on a knowledgeable reading of the whole specification through the eyes of the skilled addressee rather than on the basis of "the kind of meticulous verbal analysis in which lawyers are too often tempted by their training to indulge" (*Catnic*, *supra*, p. 243).
>
> […]
>
> 53. A second difficulty with the appellants' dictionary approach is that it urges the Court to look at the words through the eyes of a grammarian or etymologist rather than through the eyes and with the common knowledge of a worker of ordinary skill in the field to which the patent relates. An etymologist or grammarian might agree with the appellants that a vane of any type is still a vane. However, the patent specification is not addressed to grammarians, etymologists or to the public generally, but to skilled individuals sufficiently versed in the art to which the patent relates to enable them on a technical level to appreciate the nature and description of the invention: H. G. Fox, *The Canadian Law and Practice Relating to Letters Patent for Inventions* (4th ed. 1969), at p. 185.
>
> […]

[60] In *Bell Helicopter Textron Canada Limitée v Eurocopter, société par action simplifiée*, 2013 FCA 219, at para 74, the Federal Court of Appeal reiterated that it is the Court's task to construe the patent claims and that expert witnesses can be of assistance but they cannot overstep the Court's role:

> As noted in *Whirlpool* at para. 53, the words used in a patent must be looked at and understood "through the eyes and with the common knowledge of a worker of ordinary skill in the field to which the patent relates." This enables the reader to appreciate the nature and description of the invention on a technical level. Consequently, in construing the claims, a judge may be assisted by expert witnesses. However, a judge is not bound by the opinion of any expert. A judge's assessment of the expert evidence will not be reversed on appeal absent palpable and overriding error: *Halford v. Seed Hawk Inc.* 2006 FCA 275, 54 C.P.R. (4th) 130 at para. 11; *Weatherford* at para. 24.

[61] In *Purdue*, at para 17, the Federal Court of Appeal clearly stated that a patent construed in the context of an eligibility assessment under the Regulations must be construed in accordance with the principles articulated in *Whirlpool*.

[62] In this case, the question to be asked is whether a person skilled in the art would have understood that the formulations encompassed in the '329 Patent claims, in light of the definition provided for the term "oral formulation", could include a formulation containing the specific medicinal ingredients spinosad and milbemycin oxime.

[63] It is common ground that milbemycin oxime is part of the family of milbemycins. That was explained by Dr. Paradis and recognized by the Minister in the refusal decision. It was also readily admitted by Mr. Jubran. What is in contention is whether a definition in the descriptive portion of

the patent of "oral formulation" would be understood by a person skilled in the art to include a formulation comprising both spinosad and milbemycin oxime.

[64] In her affidavit, Dr. Paradis states that that the '329 patent claims specifically references the compound milbemycin oxime. She expresses her opinion as follows:

> 44. As mentioned, Trifexis® contains both spinosad and milbemycin oxime. Spinosad is specifically mentioned within all the claims. However, milbemycin oxime is also mentioned within the claims for two reasons. First, the patent defines "oral formulation" to include milbemycin oxime, and second, the use of the term "comprising" means that the inventors contemplated spinosad could be formulated with one or more additional ingredients.

[65] Dr. Paradis' assertion involves a deduction. Her affidavit, in referring to the definition of oral formulation in the description of the patent, uses the words milbemycins and milbemycin oxime as if they were interchangeable. In fact, the uncontested evidence is that while milbemycin oxime is a member of the class of milbemycins compounds, it is not specifically mentioned in the descriptive portion of the patent.

[66] Dr. Paradis explains that milbemycin oxime is a macrocyclic lactone and that macrocyclic lactones are a broad spectrum potent antiparasitic agents that are derived from soil organisms and that they include two closely related chemical groups, one of which is milbemycins (e.g., milbemycin oxime and moxidectin). Dr. Paradis does not state specifically in her affidavit that a person skilled in the art would understand that a reference to milbemycins encompasses a reference to the precise compound milbemycin oxime.

[67] In his affidavit, Mr. Sofia asserts that a person skilled in the art would understand that a reference to milbemycins could include the specific compound milbemycin oxime. Mr. Sofia is a very knowledgeable patent agent, but he is not the person skilled in the art, i.e. a veterinarian.

[68] However, both parties agree, and the evidence is unequivocal on that point, that milbemycin oxime is a compound that is included in the class of compounds described as milbemycins. I conclude that a person skilled in the art would have had that understanding as of the publication of the '329 Patent.

[69] With this in mind, I construe the claims in the '329 Patent to be directed not only to a formulation including spinosad as the only active ingredient, but also to formulations that include other active ingredients such as, but not restricted to, milbemycin oxime.

[70] This interpretation is somewhat broader than that adopted by the Minister. The Minister's decision is focussed on the requirements of paragraph 4(2)(b) of the Regulations, but her reasoning makes it clear that she understands the patent as not claiming a formulation containing both spinosad and milbemycin oxime. The Minister's reasoning appears from this excerpt of the decision at page 3:

> While we agree that the '329 Patent contains claims for a formulation containing the medicinal ingredient spinosad, there are no claims in the '329 patent specifying milbemycin oxime as the second medicinal ingredient present in the formulation of the invention. The mere mention of milbemycins in the disclosure as one of many groups of compounds that may be combined with spinosad in the formulation of the invention is not sufficient to constitute a claim for the formulation containing the medicinal ingredient(s), as required by section 2 and paragraph 4(2)(b) of the *PM(NOC) Regulations*. […]

> […]
>
> Therefore, even if the OPML accepts your position that the *PM(NOC) Regulations* do not require that all of the medicinal ingredients be present in the approved drug be specified in the claim for the formulation, a close examination of the above-noted passage of the disclosure reveals that the specific medicinal ingredient milbemycin oxime, which is not explicitly mentioned in the claims, is also not explicitly mentioned in the disclosure. Rather, as indicated above, milbemycins are mentioned as one of many groups of compounds that may be combined with spinosad in the formulation of the invention.

[71] Applying the correctness standard of review, I therefore conclude that the Minister erred in interpreting the patent in a manner that was too restrictive. However, this finding is not conclusive of the eligibility of the patent to be listed since the matching exercise under paragraph 4(2)(*b*) of the Regulations has yet to be done.

(2) *Did the Minister correctly interpret the requirements set out in paragraph 4(2)(b) of the Regulations?*

[72] In her decision, the Minister expressed the view that under paragraph 4(2)(*b*) of the Regulations, the claimed formulation in the '329 Patent must include the two medicinal ingredients contained in Trifexis. This, in my view, is consistent with the principles developed in the jurisprudence (see for example *Abbott*, *Searle*, *Bayer*, *Purdue* and *Gilead*).

[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.

[74] In *Purdue*, the Federal Court of Appeal reiterated the requirement for a perfect match between the medicinal ingredients for which a specific use is claimed in the patent and those approved in the NOC:

> 32. In *Bayer*, the product specificity requirement under paragraph 4(2)(*b*) of the Regulations (a formulation claim) was interpreted. The Court determined that the patent did not claim the approved formulation because it claimed a formulation containing only one of the approved medicinal ingredients. The approved drug was a formulation containing two medicinal ingredients. The argument that the "product specificity" intended in paragraph 4(2)(*b*) can be achieved without the strict matching required by the Minister was rejected. In respect of formulation claims, regard must be had to the particular components of the approved mixture that are responsible for the drug's effects in the body.[…]
>
> […]
>
> 34. The judge reasoned that a plain reading of paragraph 4(2)(*c*) supports the view that a similarly strict or explicit "matching" between the dosage form claimed under Claim 5 and the dosage form approved in respect of TARGIN was required for the Minister to grant Purdue's listing application. This reasoning is consistent with the statements in the RIAS, which serves as an interpretive tool. The following appears at pages 1517 and 1518:
>
> > Although amended section 2 defines the phrase "claim for the dosage form" in very general terms, in order to accommodate

> future advancements in this field, the intent is to provide protection for the novel delivery system by which the approved medicinal ingredient, or a formulation containing that ingredient, is administered to the patient. Examples include controlled-release tablets and capsules, implants and transdermal patches. As with other eligible subject matter, a dosage form patent must include a claim to the specific dosage form described in the NDS (typically as identified in the notification issued by the Minister pursuant to paragraph C08.004(1)(a)). In addition, it must contain a claim that includes within its scope the approved medicinal ingredient. This latter requirement is meant to ensure that a patent directed solely to a device, such as an intravenous stand or a syringe, does not meet the definition of "dosage form" and remains ineligible for listing. (my emphasis)

> 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.
>
> 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.

[75] In *Gilead*, speaking to the product specificity requirement, Justice Trudel expressed the following:

> 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.
>
> Second, the 2006 revisions to the PM (NOC) Regulations clearly establish that not all patents relating to an NDS will necessarily be listed on the patent register. Under the 1993 version of the

> Regulations, section 4 provided that persons could submit a list of patents that they wished to have included on the patent list provided the patents met certain general criteria. Section 4 now states that patents are "eligible" for listing if they meet a more specific and detailed set of criteria. The revised section 3 provides new powers to the Minister to manage the patent register, including the ability to refuse to list patents, to remove patents from the register, and to consult with the Patent Office to determine whether to accept or remove a patent.
>
> […]
>
> 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.
>
> […]

[76] In *Searle*, Justice Sharlow made it clear that the fact that the patent at issue could be infringed should not be the target in interpreting the Regulations:

> 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.
>
> 48. In my view, the Minister's decision to delist the 201 patent is consistent with the intended purpose of the *NOC Regulations*. The Minister's decision letter says that "listing the 201 patent on the Patent Register on the basis of claim 15, which includes a mention of 'pain', would undermine the intended link between the subject matter of a patent on a patent list and the content of the underlying submission for the NOC in relation to which it is submitted." As I read the decision letter, the Minister's reasons express substantially the same rationale as *Abbott 244*.

[77] That principle was reiterated in *Purdue*. The Court was dealing with a patent directed to dosages and made it clear that even if a patent claim could be construed so as to include a certain dosage that did not mean that the claim would satisfy the requirements of the Regulations:

> 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.

[78] Having concluded that the Minister adopted the correct interpretation of paragraph 4(2)(*b*) of the Regulations, I still need to determine if her finding that the '329 Patent does not meet the product specificity requirement was reasonable.

(3) *Was the Minister's decision to exclude the '329 Patent from the patent register reasonable?*

[79] It is clear that the Minister's finding that the '329 Patent claims did not match the authorized formulation in Trifexis was based on her preliminary finding that the '329 Patent did not claim a formulation containing both spinosad and milbemycin oxime.

[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] FCJ 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.

[86] For all of these reasons, I conclude that the Minister's decision to refuse to list the '329 Patent on the patent register was reasonable despite the fact that the Minister erred in her construction of the patent claims.

JUDGMENT

THIS COURT'S JUDGMENT is that the application for judicial review is dismissed with costs in favour of the respondents. In accordance with the parties' agreement, costs will be assessed at the middle of column II plus disbursements.

"Marie-Josée Bédard"

Judge

FEDERAL COURT

SOLICITORS OF RECORD

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